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A J S M U

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EDITORIAL

Professionalism in Medical, Dental, and Allied Health Professions Students

Lubna Ansari Baig

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This editorial will focus on the importance of Professionalism for students of Medical, Dental and Allied Health professions. I would make a case for including teaching of Professionalism in health sciences institutions and conclude with some guidelines for professional behaviour in Medical, Dental, and Allied Health students. I dedicate this editorial to my teachers who exhibited Professionalism while I was a student at Sindh Medical College and contributed to my development from an amateur to a professional.

"There was a moment when I changed from an amateur to a professional. I assumed the burden of a profession, which is to write even when you don't want to, don't much like what you're writing, and aren't writing particularly well." Agatha Christie[1]. The message is that one has to accept the burden of one's profession irrespective of one's preferences or willingness to continue in one's field of training.

According to the Merriam-Webster Dictionary, Professionalism is 'the, aims, or qualities that characterize or mark a profession or a person.' The conduct here is defined as the standard of personal behaviour on moral principles. As a trait, Professionalism is not clearly defined for the society or for any profession. Medical Professionalism is commonly described to include characteristics of professional excellence, integrity, and altruism.[4] The Accreditation Council for Graduate Medical Education, USA, defines Professionalism in medicine as a "commitment to carrying out professional responsibilities, adherence to ethical principles and sensitivity to a diverse patient population".[2]

A Latin systematic review defined medical Professionalism based on respect for life and human dignity and identified the virtues of benevolence, compassion, prudence, and justice.[3] In medical practice, it is the basis of medicine's **contract with society.** Medical Professionalism demands

- placing the interests of the patients above the physician,
- setting and maintaining standards of competence and integrity,
- providing expert advice to society on matters of health, and
- exhibiting noble behaviour befitting the profession of medicine.

Education, and more so, medical education is a complex endeavour. It should instill Professionalism into the students by default. However, the traits of Professionalism do not develop automatically in the students. When students enter institutions of higher education for Medical/Dental/ Allied Health training, they come with the zest and the zeal to become high profile practitioners. They may not have realized the importance and seriousness of the medical profession. The students may not be aware of their responsibilities and may not exhibit professional behaviour due to this lack of knowledge. Studies have shown that students have a vague idea of Professionalism particularly in colleges where it is not included in the curriculum.[8] The institution responsible for the professional development of future healthcare providers, also bears the duty of inculcating Professionalism in its students through direct or indirect methods built into the curriculum.

Ahmadi et al[5] suggests that the traits of Professionalism should be viewed as contextual values for the society. He recommends these values to be built into the health professionals' education and be measured to ensure that they have been internalized before graduation. These values may be inculcated in the future health professionals through active communication and contemporary methods during their professional development years.[5]

Eraky in 2015, suggested twelve tips for teaching Professionalism in medical schools, though none of the medical curricula have been evaluated since then.[6] The nursing curricula have been found to be geared towards building professional values in the students,

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particularly in the areas of responsibility, security, and autonomy.[7] Other health professions curricula have also not been assessed for the presence of the traits of Professionalism. The situation is bleaker in most institutions of higher education in Pakistan and the students and eventually graduates unknowingly exhibit unprofessional behaviour.

Earlier studies have suggested that preceptors, teachers, and professors of medical colleges should be role-modeling behaviours that are considered professional.[10] The teachers help students acquire a huge amount of knowledge to ensure that they are graduating competent healthcare providers. Their duty is also to not only teach the values of Professionalism but to display these as role models.[10] This discussion draws attention to the earliest stages of the selection and the training of teachers; which is when we need to ensure that the candidates selected to teach at our institutions have internalized the core values of Professionalism.

If a physician teacher is not showing traits of an empathetic caregiver, the students will not internalize this concept no matter what is taught and assessed in the courses. If a teacher is not regular, is late for lectures and meetings, and does not dress appropriately, the students receive the message that this is acceptable conduct. As teachers of future healthcare providers, we should be prudent and ensure that we display behaviour befitting a professional healthcare provider.

Nevertheless, the burden of internalizing traits of Professionalism lies on the students as well. The students should be exhibiting Professionalism not only within but outside the institutions as well. In most Medical, Dental, and Allied Health curricula in Pakistan, Professionalism is not actively included and hence, neither taught nor assessed. Students of healthcare professions are generally given rules and guidelines for managing their learning, while professional traits, values, and guidelines are usually omitted. Students should be given guidelines on professional behaviour during their orientation and then should be observed and monitored for their demeanour.

Following are some guidelines for students' professional and ethical behaviours during their education at the medical, dental, and allied health institutions. These guidelines have been adapted from the University of Chicago's handbook on students' rights and responsibilities.

Guidelines for Students' Professional and Ethical Practices[11]

- Dress appropriately in accordance with the norms of the society.
- Seek and accept feedback and constructive instruction from teachers, peers, and seniors to continually improve educational experience, knowledge, and clinical skills.
- Meet the expectations for class participation, assignments, and timeliness.
- Commit to the highest standards of competence and seek help when needed.
- Recognize the importance of life-long learning and commit to enhancing competence.
- Admit to and assume responsibility for mistakes in a mature and honest manner.
- Identify, develop, and implement a plan to achieve the educational goals.
- Be mindful of demeanour, language, and appearance in the classroom, with patients, and in healthcare settings.
- Be accountable to all members of the medical/dental/allied health community, including students, faculty, and support staff.
- Refrain from using *paan, gutka*, cigarettes, alcohol, and illicit drugs.
- Be considerate and respectful of others' (teachers, peers, staff, and faculty) time, rights, values, religious and socioeconomic backgrounds, lifestyles, opinions, and choices, even when they are different.
- Take an active role in caring for the diverse patient population served by the institution.

Generally, the people in Pakistan do not have a favourable view of healthcare providers. "My doctor is nice; every time I see him, I'm ashamed of what I think of doctors in general."[9] As teachers and professionals, we need to ensure that the future generations of healthcare professionals improve that image. We would like our graduates to be praised by the communities they go out to serve, changing the negative impressions about physicians.

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Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Conflict of interest exists when an author (or the author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his or her actions (such relationships are also known as dual commitments, competing interests, or competing loyalties). These relationships vary from those with negligible potential to those with great potential to influence judgment, and not all relationships represent true conflict of interest. The potential for conflict of interest can exist whether or not an individual believes that the relationship affects his or her scientific judgment. Financial relationships (such as employment, consultancies, stock ownership, honoraria, paid expert testimony) are the most easily identifiable conflicts of interest and the most likely to undermine the credibility of the journal, the authors, and of science itself. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

All participants in the peer review and publication process must disclose all relationships that could be viewed as presenting a potential conflict of interest. Disclosure of these relationships is also important in connection with editorials and review articles, because it is can be more difficult to detect bias in these types of publications than in reports of original research. Editors may use information disclosed in conflict of interest and financial interest statements as a basis for editorial decisions.

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ORIGINAL ARTICLE

Relative Therapeutic Efficacy of Laser Acupuncture Applied at Different Acupuncture Points in Symptomatic Management of Knee Osteoarthritis: A Randomized Controlled Trial

Bashir Abdulhakim[1], Shmaila Hanif [2], and Aishat Shittu[2]

ABSTRACT

Objectives: To determine the therapeutic efficacy of laser acupuncture applied at the basic acupuncture points in the symptomatic management (pain, Range of Motion (ROM), and physical function) of knee Osteoarthritis (OA); To determine the difference in relative therapeutic efficacy of laser acupuncture applied at the distal acupuncture points in the symptomatic management (pain, ROM and physical function) of knee OA; and to determine the relative therapeutic efficacy of laser acupuncture applied at the basic and distal acupuncture points in the symptomatic management (pain, ROM and physical function) of knee OA

Methodology: The study was a randomized controlled trial with pre-test and post-test design. The participants were randomly assigned into three groups. The two experimental groups (A and B) were treated using a class IIIB laser with a wavelength of 830 nm and LED infrared probes with a frequency of 20 kHz. Each point was irradiated for one minute alongwith the intervention in the control group. The control group received ROM and strengthening exercises only. Treatment was administered three sessions per week for three weeks. Pain, ROM, and physical function were assessed pre-intervention and post-intervention using VAS, goniometer, and WOMAC index respectively.

Results: VAS scores and ROM scores showed significant improvement ($p=0.010$ and 0.0001) in all groups using ANOVA. However, post-hoc LSD analysis indicated more significant improvement in the experimental groups (A and B) over the control group. WOMAC scores also showed significant improvement in the experimental groups over the control group ($p<0.05$) using Kruskal Wallis analysis.

Conclusion: Laser acupuncture in combination with exercise was more effective than exercise alone in the symptomatic management of knee OA. Laser acupuncture can be used as an adjunct therapy in the symptomatic management of knee OA.

Key words: Osteoarthritis; Knee; Laser; Acupuncture, Relative Therapeutic Efficacy

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عنوان: گھٹنے کی ہڈی کے بھربھرے پن کی علامات کے علاج میں لیزر اکیوپنکچر کے مختلف مقامات پر استعمال کی تاثیر:

مقاصد: (i) گھٹنے کی ہڈی کے بھربھرے پن کی علامات کے علاج میں لیزر اکیوپنکچر کے بنیادی مقامات پر استعمال کی افادیت (ii) ان علامات کے علاج میں distal مقامات پر لیزر اکیوپنکچر کے استعمال کی افادیت (iii) دونوں بنیادی اور distal مقامات پر لیزر اکیوپنکچر کے استعمال کی طبی تاثیر جانچا۔

طریقہ: یہ تحقیق ایک Randomized Controlled Trial طریقے سے کی گئی۔ شرکاء کو تین گروپس میں تقسیم کیا گیا۔ دو تجرباتی گروپس اے اور بی پر کلاس III لیزر اور ایل ای ڈی انفراریڈ پروب استعمال کیے گئے جبکہ کنٹرول گروپ کو صرف ROM اور ورزشیں کرائی گئیں۔ تین ہفتے تک تین ہفتہ وار نشستیں کی گئیں۔ استعمال سے پہلے اور بعد میں درد، ROM اور جسمانی فعل کو جانچا گیا جس کے لئے VAS، گونیومیٹر اور WOMAC اعشاریہ استعمال کئے گئے۔

نتائج: VAS اور ROM کے شمار میں تمام گروپس میں خاصی بہتری ($p<0.05$) نظر آئی۔ لیکن بعد میں کیے گئے LSD تجزیے میں تجرباتی گروپس اے اور بی میں کنٹرول کی نسبت زیادہ بہتری دکھائی دی۔ Kruskal Wallis تجزیہ کا استعمال کرتے ہوئے WOMAC شمار میں بھی تجرباتی گروپس میں کنٹرول گروپ سے زیادہ بہتری نظر آئی۔

حاصل مطالعہ: اس مرض کی علامات کے علاج میں ورزش اور لیزر اکیوپنکچر اکھٹے زیادہ تاثیر رکھتے ہیں بہ نسبت فقط ورزش کے۔ لہٰذا لیزر اکیوپنکچر کو اضافی علاج کے طور پر استعمال کیا جا سکتا ہے۔

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INTRODUCTION

Osteoarthritis is currently a major public health problem worldwide, and the leading cause of disability in the elderly[1]. Knee joint is the commonly affected joint with pain, reduced range of motion (ROM), crepitus, and swelling as usual impairments[1]. Limitations of functional ability in patients with knee OA, like walking long distances, squatting, praying, and climbing stairs to mention but a few, may frustrate the patients as they

struggle with simple activities of daily living and slowly lose their jobs.

Symptomatic knee OA has become a growing burden for patients and the broader healthcare system. According to Hochberg[2], knee OA is one of the five leading causes of physical disability in non-institutionalized elderly men and women, but still no agent has been proven to be disease modifying in its treatment[3]. The condition was generally considered to be an irreversible consequence of aging; however, researches in the last decade had led to the view that OA is an active disease with potential for treatment[4].

Persons with OA of the joints of the lower extremities have lower quality of life compared to persons without OA[5] and utilize more healthcare resources[6,7]. Knee pain is the primary reason that people with knee OA seek medical care[8] and affected persons may experience both symptomatic joint pain as well as functional disability[9].

Given the fact that no agent can reverse knee OA, the current therapeutic interventions are directed towards reducing pain, increasing joint mobility, reducing disability, and minimizing disease progression[10]. Pharmacological interventions[11], surgical interventions,[12] and acupuncture[13] are thus used in the symptomatic management of Knee OA. Physiotherapy modalities commonly used in the management of knee OA include braces and orthoses[14], weight reduction, electromagnetic field[15], transcutaneous electrical nerve stimulation[16], low level laser therapy[17], thermotherapy[18], magneto therapy, electrical muscle stimulation, ultrasound[19], mobilization[20] and balneotherapy[21].

Low Level Laser Therapy (LLLT) is a form of phototherapy which has been employed as an effective treatment for a variety of conditions, including musculoskeletal and soft tissue injuries and chronic ulceration including osteoarthritis[22-25]. Such lasers have also been recommended as an effective alternative to metal needles for the stimulation of acupuncture or musculoskeletal trigger points; this form of therapy is commonly termed “Laser Acupuncture” to distinguish it from the wider therapeutic applications of such laser devices[26,27]. Low Level Laser Therapy (LLLT) has other advantages in that it can be used where other modalities are contraindicated, in addition to its efficacy. LLLT can be applied to patients with pacemakers, metal implants, burns and wounds, and to anatomically dangerous areas[28]. It is a low cost, short-application, and non-infectious treatment[26]. Acupuncture has been shown to be effective in pain relief and dysfunction associated with musculoskeletal conditions, including knee osteoarthritis[29]. Furthermore, laser therapy is safer and requires less time than needle acupuncture, and can avoid the pain and psychological fear of traditional acupuncture[26,30,31]. According to Tascioglu et al[32], laser therapy has anti-inflammatory effects, anti-edema effects and plays a role in pain reduction without side effects.

Studies[33,34] carried out on the use of laser therapy have documented evidence on its efficacy, with Al Rashoud et al[35] reporting 6-months post intervention improvement in patients with knee OA, however, there are limitations to some of the researches being conducted. Some of these studies are pilot studies[34], others are using a single acupuncture point[34,36] in the symptomatic management of knee OA using low level laser. Research has also been conducted on the use of low level laser therapy on basic acupuncture points around the knee[35]. However, the studies are limited on the relative efficacy of various acupuncture points specific for knee pain. Hence, the aim of this study was to evaluate the comparative efficacy of the use of low level laser therapy on basic acupuncture points located around the knee joint (ST35, ST36, SP9, GB34, and XiYan) and the distal acupuncture points located around the ankle joint, but specific to knee pain (SP6, KI3, BL60, and GB35).

METHODOLOGY

This randomized controlled trial was conducted in the Department of Physiotherapy, Murtala Mohammed Specialist Hospital, Kano and Aminu Kano Teaching Hospital, Kano (University Teaching Hospital of Bayero University, Kano, Nigeria). Ethical approval was appropriately sought for. Participants diagnosed with knee OA were selected, contacted, and procedures involved were explained to them. Time was allowed for the patients to ponder over the study and make consultation. The patients were then instructed to sign a written consent form after they were briefed about the study and consented to participate in the study.

A total of twenty (20) patients with knee OA were selected out of the entire population (using the Cohen table). The subjects were recruited using a simple random sampling technique.

Patients were randomly divided into three different groups: Group A (Laser Acupuncture at Basic Points), Group B (Laser Acupuncture at Distal Points), Group C (Control Group). It was ensured that patients from one group do not know the type of treatment received by the other group.

The subjects were recruited according to the American College of Rheumatology (ACR)[37] criteria: Patients having knee pain for more than 25 of the past 30 days,

morning stiffness of less than 30 minutes, osteophytes on x-ray examination of the knee, indicating knee OA[38], erythrocyte sedimentation rate <20 mm/1st hour, obliteration of joint space, patients with bilateral knee pain, either gender, crepitus in the knee, and pain score = 3 on visual analogue scale were included.

Thor LX laser and LED system, United Kingdom was used to radiate the acupuncture points in patients. Western Ontario and McMaster University osteoarthritis index (WOMAC) was used to evaluate patients' pain perception, symptoms and functional capabilities. WOMAC osteoarthritis index, which is a validated disease specific questionnaire, consists of three scales (five questions on pain, two questions on stiffness, and seventeen questions on functional disability), evaluated using five-points scales. The scale is the standard for assessment and monitoring of knee OA that is based on a Likert scale[39]. WOMAC subscale (pain, stiffness, and physical function) are internally validated with Cronbach's coefficient at alpha level of 0.91, 0.81 and 0.84 respectively, with Test-retest reliability satisfactory with intra-class coefficients of 0.86, 0.68 and 0.89 respectively[40]. Roos et al[41] also reported that the WOMAC osteoarthritis index is a reliable, valid, and responsive instrument with metric properties in agreement with the original widely used version.

All measurements i.e. BMI, stature, range of motion, flexion, and extension were taken on first appointment. The fulcrum was centered over the lateral epicondyle of the femur; the proximal arm was aligned with the lateral mid line of femur using greater trochanter for reference. The distal movable arm of the goniometer was aligned with lateral mid line of fibula using lateral malleolus and fibular head for reference. The subjects were positioned in prone lying with the hip in 0 degrees of flexion, extension, abduction, and adduction with the foot over the supporting surface. The knee and the femur were supported by pillow or sandbag. The procedure and the goniometer alignment were the same. The ROM at the knee joint was recorded pre- and post-intervention in each group. Pre and postoperative pain score was assessed by using VAS. Physical function was assessed using the WOMAC index. The WOMAC index was used to assess pain, degree of stiffness, and functional disability. The WOMAC index consists of three subscales with 24 parameters: 5 questions on pain, 2 on stiffness, and 17 questions on functional ability. The participants were instructed to rate the 24 questions on a five-point scale i.e. 0=none, 1=slight, 2=moderate, 3=severe and 4=extreme, with a total score range of 0 (best) to 90 (worst).

All patients received three treatment sessions a week for three weeks. This treatment duration was as recommended by Shen et al[34]. Data from these sessions were collected at baseline and at the last session. Laser Acupuncture at Basic Points group received laser acupuncture at the basic acupuncture points located around the knee joint (ST35, ST36, SP9, GB34 and Xi-Yan) coupled with the intervention in control group. Laser Acupuncture at Distal Points group received laser acupuncture at the distal acupuncture points located around the ankle joint (SP6, KI3, BL60 and GB36) but specific to knee pain, coupled with intervention in control group. Control group received isometric quadriceps exercises and cycle ergometer exercise. The procedure was explained to the patients.

Patients were instructed to appear in comfortable dressing. They received treatment in supine position, with the knee slightly flexed, and supported with a rolled towel. The therapist and patient wore protective goggles to shield the eyes from active laser radiation. On the affected knee, the laser probe was placed sequentially and perpendicularly at the basic acupuncture points at the knee joint (ST35, ST36, SP9, GB34, and Xi-Yan) and ankle joint (SP6, KI3, BL60, and GB36) (Protocol adopted from Al Rashoud et al[35]). Treatment duration of 1 minute per point with a total of 5 minutes per participant was used. A class IIIB laser with a wavelength of 830nm and an LED infrared probe was used (THOR International 1998). A frequency of 20 kHz was used to radiate the joints. It has been reported that a higher frequency has more effect on knee OA[22]. An intensity or dose of 1.2J was used[35]. After the treatment, the patients were given a rest period of three minutes after which patients were allowed to dress and any necessary incentive was duly offered.

The patients were placed in supine or sitting position with the knee in extension. A rolled pillow was placed beneath the posterior knee and patients were asked to contract the quadriceps or press down on the towel. The patients underwent 1 set of 10 repetitions with a 6 second hold and a 10 second rest between repetitions[34]. Stationary cycling was done on cycle ergometer. The seat height was determined individually to ensure that no more than 10 degrees of knee flexion were permitted at the lowest point in the rotation of the pedal. The patients were instructed to pedal the cycle ergometer for 5 minutes. A rest period of 10 minutes was given[40]. After the treatment session; patients were advised to continue static isometric quadriceps exercise at home. Data was entered and analyzed by using SPSS version 16. Mean ± SD were calculated for age, BMI, stature, and pain.

Kruskal Wallis test was used to determine differences in pre- and post-intervention scores in pain, stiffness, and functional disability subscales of WOMAC index across the three treatment groups. One way Analysis of Variance (ANOVA) was computed to compare the pre-and post- intervention scores of the range of motion of the knee and pain scores from VAS across the three treatment groups. The difference between pre- and post-intervention scores for WOMAC osteoarthritis index for each group was analyzed using the Wilcoxon signed rank test. The difference between pre- and post-intervention pain scores from VAS and ROM scores was analyzed using dependent t-test.

RESULTS

Table 1 show that on average, participants belonged to the old age and overweight BMI category in each group. There was no statistically significant (P>0.05) difference in baseline physical characteristics across all three groups.

Table 2 shows differences between pre-intervention and post-intervention pain score (VAS) and ROM scores for all the three groups using dependent t-test. Table 2 shows a significant (P<0.05) difference between pre-intervention and post-intervention pain VAS scores for group A, group B, and group C. For all the three groups, there was a decrease in pain following intervention. However, on average, group B had the lowest average pain value (close to 'no pain') compared to other groups. There was a significant (P<0.05) difference between the pre- and post-intervention ROM for groups A, B, and C, with an increase in ROM following intervention in all three groups.

Table 3 shows that there is a significant (P<0.05) difference in pre-intervention and post-intervention physical function and WOMAC pain scores for all the study groups.

Table 4 shows that there is no significant (P>0.05) difference in pre-intervention pain VAS and ROM scores across the three groups. This implies that at baseline, there is no difference in pain VAS and ROM across the three study groups. However, there is a significant (P<0.05) difference in post-intervention pain VAS and ROM scores across the three study groups.

LSD post-hoc analysis was computed to determine further difference in pain VAS and ROM. There was a significant (P<0.5) difference in post ROM between group A and B and also between group A and C. This implies that the experimental groups (Groups A and B) showed better scores compared to the control group (Group C).

Table 5 shows no significant (P>0.05) difference in pre-intervention physical function (PF) scores and WOMAC pain scores across all the three study groups. This implies that at baseline, there is no difference in pre-intervention physical function and WOMAC pain scores across the study groups. However, there is a significant difference (P<0.05) in post-intervention WOMAC pain scores across the study groups.

DISCUSSION

The study was conducted to determine the relative therapeutic efficacy of laser acupuncture applied at different acupuncture points in the symptomatic management of knee osteoarthritis. The target acupuncture points were the basic and distal acupuncture points situated around the knee and ankle joints respectively. Participants in the experimental groups (Groups A and B) were treated with LLLT radiated at acupuncture points around the knee and ankle joints plus intervention of control group, which included cycle ergometry and isometric quadriceps exercise for a period of three weeks (three sessions per week).

The results of this study show that laser acupuncture applied at both basic and distal acupuncture points in combination with exercise had a beneficial effect on pain reduction and improvement in knee joint function, with a substantial improvement in VAS and WOMAC scores over the control group. The exercise alone also was beneficial as demonstrated by improvements in most outcomes in relatively all participants. As posed earlier, the study indicated significant improvement in outcomes in all treatment groups. However, improvement was significantly more in both experimental groups over the control group, but there was no significant difference between the experimental groups.

Improvements seen in the experimental groups can be attributed to the anti-inflammatory properties of LLLT applied to specific points on the articular capsule, as reported by Alfredo et al[33]. Analgesia induced by LLLT, however, may have resulted in improved exercise performance and consequently improved outcomes in the experimental groups. Also, analgesia experienced by the experimental groups can also be a result of stimulating acupuncture points, where LLLT shows equivalent effects to needle acupuncture at skin level through an inhibitory mechanism via neural blockade[43]. Also, this improvement can be attributed to the ability of LLLT to stimulate reparative properties in human cartilage[44,45]. However, this may not be applicable to Distal Acupuncture Points group as LLLT may have had effect on the articular capsule of the ankle joint not the knee joint, thus this may support the effect of LLLT on acupuncture points specific for knee pain.

Table 1: Descriptive/Physical Characteristics of Participants (N=20)

Variables	Group A (Knee)		Group B (Ankle)		Group C (Control)		F	P-value
	M	SD	M	SD	M	SD		
Age (years)	53.00	5.568	63.50	8.019	59.00	7.853	0.480	0.866
BW (Kg)	73.01	9.077	70.83	8.035	68.29	4.990	2.438	0.252
Stature (m)	1.60	0.136	1.60	0.146	1.59	0.095	0.563	0.814
BMI (Kg/m^2)	28.82	3.191	27.77	3.370	27.47	4.658	1.500	0.575

Table 2: Pre and Post-intervention VAS Pain and ROM Scores (N=20)

Group	Variables		M±SD	t-value	P-value
A	Pain VAS	Pre-intervention	5.43±1.134	5.461*	0.002
		Post-intervention	3.57±1.134		
	ROM	Pre-intervention	127±1.976	3.104*	0.021
		Post-intervention	129±1.272		
B	Pain VAS	Pre-intervention	5.17±0.898	7.977*	0.000
		Post-intervention	1.83±0.687		
	ROM	Pre-intervention	130±1.291	-5.157*	0.001
		Post-intervention	133±1.106		
C	Pain VAS	Pre-intervention	5.43±0.976	11.500*	0.000
		Post-intervention	2.14±0.900		
	ROM	Pre-intervention	131±3.817	-3.200*	0.019
		Post-intervention	134±2.299		

$t_{(6)}$= 2.447 ; P<0.05

Table 3: Pre and Post-intervention Physical Function and WOMAC Pain Scores (N=20)

Variables	Group	n	Mean Rank	Sum of Ranks	Z	Sig.
Pre PF/Post PF	A	7	3.00	15.00	-2.041*	0.041
	B	7	4.00	28.00	-2.371*	0.018
	C	6	3.50	21.00	-2.207*	0.027
Pre/Post WOMAC Pain	A	7	3.50	21.00	-2.207*	0.027
	B	7	4.00	28.00	-2.371*	0.018
	C	6	3.50	21.00	-2.201*	0.028

Table 4: Pre and Post-intervention Pain VAS and ROM Scores Across the Three Study Groups (N=20)

Variables	Group	M±SD	F	P-value
Pre-intervention Pain VAS	A	5.43+1.134	0.466	0.710
	B	5.17+0.983		
	C	5.43+0.976		
Pre-intervention ROM	A	126.71+1.976	1.362	0.310
	B	129.17+1.722		
	C	129.14+4.220		
Post-intervention Pain VAS	A	3.57±1.134	6.078*	0.010
	B	2.00±0.817		
	C	2.00±0.894		
Post-intervention ROM	A	1.29±1.272	17.320*	0.000
	B	1.33±1.976		
	C	1.34±1.211		

$F_{(2,17)}$= 3.59; P<0.05

Table 5: Difference Between Pre-intervention Physical Function (PF) and WOMAC Pain Scores Across the Study Groups (N=20)

Variables	Groups	n	Mean Square	df	H	P-value
Pre-intervention PF	A	7	8.50	2	1.350	0.509
	B	7	11.07			
	C	6	12.17			
Pre-intervention WOMAC Pain	A	7	10.64	2	0.086	0.958
	B	7	10.00			
	C	6	10.92			
Post-intervention PF	A	7	14.00	2	4.894	0.087
	B	7	10.14			
	C	6	6.83			
Post-intervention WOMAC Pain	A	7	15.50	2	8.100*	0.017
	B	7	8.14			
	C	6	7.42			

Improvements observed in outcomes in the control group can be attributed to the fact that participants were placed on exercise (ROM and strengthening exercise). Patients with knee OA had a significant decrease in knee muscle strength, especially quadriceps muscles which increase knee pain. However, there is strong evidence that exercise can reduce pain and improve function in patients with knee OA.

Interestingly, average knee range of motion of participants in the current study was 128^0 at baseline evaluation which was more than that reported in similar studies[19,33,46] but similar to that reported by Al Rashoud et al[35]. This supports the finding[12] that participants with knee osteoarthritis who follow the Muslim faith have a greater range of motion. This may be attributed to the lifestyle practiced by Muslim societies, in which the Muslim way of praying requires their knees to be in deep flexion for long periods.

To the best of the researchers' knowledge, this is the second clinical trial to investigate the efficacy of LLLT when applied to more than one acupuncture point in patients with knee osteoarthritis, making it more comparable to clinical trials involving conventional acupuncture. Only three studies have been published on the efficacy of LLLT stimulation of acupuncture points in patients with knee osteoarthritis. Shen et al.[34] assessed the efficacy and safety of two types of laser irradiation in patients with knee osteoarthritis when acupuncture point ST-35 was irradiated. Yurtkuran et al.[36] investigated the efficacy of LLLT in patients with knee osteoarthritis when acupuncture point SP-9 was irradiated. Al Rashoud[35] investigated the efficacy of laser acupuncture in patients with knee OA when the five basic acupuncture points were irradiated. The studies showed conflicting results. The study by Shen et al[34] showed significant improvement in pain, stiffness and function of patients in the laser group compared with the placebo laser group, whereas the study by Yurtkuran et al.[36] did not, though it showed clinically significant improvement. While the results are similar to those of the current study, the study by Shen et al.[34] has been criticized for its small sample size, as experienced by this study, and the high dropout rate of patients in the placebo laser group. Al Rashoud et al[35] reported significant improvement in pain and physical function scores even after six months, but the ROM scores showed no significant improvement in contrast to the results of this study; this could be a result of baseline differences in physical characteristics of the participants in this study and previous studies. Numerous studies have investigated the efficacy of LLLT when applied in areas other than acupuncture points in patients with knee osteoarthritis. Alfredo et al[33] studied the effects of LLLT in combination with exercise. They suggested that LLLT is effective in reducing pain when associated with exercise, improving function and activity in individuals with knee osteoarthritis. Hegedus et al[46] conducted a clinical trial using LLLT in individuals with knee osteoarthritis; although, different doses were used, the laser parameters in their study were almost identical to those in the present study. Both studies showed a significant reduction in pain with the active laser compared with the placebo. Gur et al.[19] evaluated efficacy of LLLT in painful knee osteoarthritis. They also added the straight leg raise exercise to the LLLT regime, showing significant improvement in pain and function in the active laser group. Tascioglu et al[32] conducted a clinical trial to investigate the efficacy of LLLT in individuals with knee osteoarthritis; they found that LLLT had no effect on pain.

The present study is the second conducted with a Muslim population, using LLLT to treat individuals with knee osteoarthritis. It is the first study to use cycle

ergometry and isometric quadriceps exercise in combination with laser acupuncture. It is also the second study to irradiate more than one acupuncture point (knee-based and ankle-based) to treat individuals with knee osteoarthritis. Despite the dearth of published studies on the use of laser therapy in individuals with knee osteoarthritis, many problems and limitations were found, including the lack of standard protocols for inclusion and exclusion criteria. Furthermore, there were no standard therapy programmes regarding dose, period, type of laser, and therapy application. It was also conducted on individuals whose number was less than the required sample size of 52.

The present study demonstrates that short-term application of LLLT to basic and distal acupuncture points in conjunction with ROM and strengthening exercise are effective in reducing pain and improving quality of life in individuals with knee osteoarthritis. The results of this study support LLLT as an important adjunct intervention for the treatment of knee osteoarthritis and possibly for other joints.

CONCLUSION

Based on the findings of this study, it can be concluded that laser acupuncture applied at basic acupuncture points or distal acupuncture points in combination with exercise is more effective than exercise alone in the symptomatic management of knee OA. Also, irradiation of both basic and distal acupuncture points may have the same effects on knee OA.

RECOMMENDATIONS

From the results and discussion of this study, the following recommendations were made:

1. Clinical trial of this nature should be carried out with large number of subjects.

2. It is recommended that patients be followed up for longer period and assessed to evaluate maintenance of effects of laser acupuncture.

3. The results of this study support laser acupuncture as an important adjunct intervention for the treatment of knee osteoarthritis and possibly for other joints; thus, encouraging its use in clinics in the management of knee OA.

4. Laser acupuncture may be particularly relevant for patients who do not respond to medical therapy, in whom other physical modalities are contraindicated, who suffer adverse effects to drug therapy, or who are not candidates for surgery; thus, it is recommended that laser acupuncture be used on these patients.

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ORIGINAL ARTICLE

Undergraduate Students' Use of Laptops and Cellphones in Classrooms

Najya A. Attia[1] and Lubna Ansari Baig[2]

ABSTRACT

Objectives: To determine the frequency and reasons for using cell phones and laptops in classrooms by the students and to determine the student's perceptions of the usefulness of these devices in class
Methodology: This cross-sectional study was conducted at King Saud bin Abdulaziz University for Health Sciences, Jeddah, Saudi Arabia. The usage of digital devices was investigated through self-administered questionnaire given to 66 medical and 199 basic sciences students including 97 females and 168 males, aged 17 to 23 years in the academic years 2014 and 2015. Variables included students' frequency of and their reasons for using laptops and cell phones for academic and non-academic activities, on a 5-point Lickert scale.
Results: The results revealed that 58% of the students were using laptops for class presentations while 29% of students were using these for non-academic activities. In addition, 25% and 14% of students using cell phones and laptops respectively, were accessing these devices more than five times per 60-minute class period.
Conclusion: Students were using laptops and cell phones for both academic and non-academic activities, however, most of them did not perceive these devices as distraction. This could affect their concentration and ability to learn in the classroom, and may necessitate controlling technology use in the classroom.

Key words: Laptops, cell phones, students, learning

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عنوان: انڈرگریجویٹ طالبعلموں کا جماعت کے دوران لیپ ٹاپ اور موبائل فون کا استعمال

مقصد: انڈرگریجویٹ طلبہ وطالبات کا دورانِ جماعت لیپ ٹاپ اور موبائل فون کے استعمال کا شمار اور وجوہات معلوم کرنا۔

طریقہ: یہ عمومی جائیزہ تحقیق جدہ، سعودی عرب کی شاہ سعود بن عبدالعزیز جامعہ برائے طبّی علوم میں کیا گیا۔ ڈیجیٹل آلات کے استعمال کو ایک تحریری سوالنامے کے ذریعے شمار کیا گیا جو خود پر کیا۔ یہ سوالنامہ 66 علم طب اور 199 بنیادی علوم کے طلبہ وطلبات کو دیا گیا جن میں سے 97 خواتین اور 168 مرد تھے اور ان کی عمریں 15-2014 کے تدریسی سال میں 17 سے 23 سال کے درمیان تھیں۔ تغیر پذیر نکات میں طلبہ وطلبات کے کلاس روم میں لیپ ٹاپ اور موبائل فون کے تدریسی اور غیر تدریسی استعمال کا شمار اور وجوہات تھیں جنہیں پانچ نکاتی LICKERT اسکیل پر ناپا گیا۔

نتائج: 58 فیصد طلبہ وطلبات لیپ ٹاپ کلاس میں تعلیمی پریزینٹیشن کے استعمال کر رہے تھے۔ جبکہ 29 فیصد انہیں غیر تدریسی کاموں کے لیے استعمال کر رہے تھے۔ اس کے علاوہ 25 فیصد موبائل فون کے مالک اور 14 فیصد لیپ ٹاپ کے مالک ان آلات کو ایک گھنٹے کی جماعت کے دوران پانچ دفعہ سے زیادہ دیکھ رہے تھے۔

حاصلِ مطالعہ: طلبہ وطالبات دورانِ جماعت لیپ ٹاپ اور موبائل فون تدریسی اور غیر تدریسی سرگرمیوں کے لیے استعمال کر رہے تھے جس سے بلاواسطہ طور پر ان کی کلاس میں محویت اور تحصیل علم پر اثر پڑ سکتا ہے۔ اور جس کی وجہ سے کلاس روم میں ٹیکنالوجی کے استعمال پر کنٹرول کی ضرورت پڑ سکتی ہے۔

INTRODUCTION

Laptops and cell phones have become standard equipment for postgraduate students. Many universities offer free access to wi-fi technology and allow their use in classrooms.[1] Studies have shown that the students' use of cell phones and laptops in classrooms can negatively impact their learning.[2-4] Granberg and Witte compared the overall class grades of laptop and non-laptop using groups and found no difference.[5] A study by the University of Michigan examined how laptops are used in the classroom and found that the majority of the students used their laptops in class for non-educational activities such as social networking and checking emails.[6] Many faculty members have raised concerns about the distractions posed by digital

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devices when used in the classrooms.[7] Levine found that using a 'laptop-up, laptop-down' system, which prevents the students from using laptops during the lecture, makes students pay attention to the lecture.[8] Some US universities including the University of Pennsylvania,[9] Bentley College,[10] Michigan Law,[11] Kansas,[12] and Harvard, have taken measures to restrict the formal use of laptops in the classrooms.[13]

However, researchers have also reported that using laptops in class can increase students' knowledge, motivation, satisfaction, participation, and facilitate faculty-student interaction.[14-17] Levine suggests that the use of cell phones and laptops in the classroom should be monitored and controlled by instructors preferably through software.[18]

Cell phones ringing in classroom can have significant negative effects on cognitive performance and could distract both faculty and students.[19] A National Education Association study reported that 85% of a sample of higher education instructors in the United States agree that cell phones should be banned in the classroom.[20] Many educational institutions in the US have formal policies banning cell phone use in classrooms.[2,4]

The key question for most higher education instructors is whether the use of cell phones and laptops in classrooms has a positive impact on education. The issue has not been investigated in Saudi Arabia before. The goal of this study was to determine the frequency and nature of the use of laptops and cell-phones in the classrooms, and to determine the student's perceptions of the usefulness of these devices in class. The results of this study will be used to develop policy guidelines for the use of cell phones and laptops in health science institutions.

METHODOLOGY

This cross-sectional study was conducted at the King Saud bin Abdulaziz University of Health Sciences, Jeddah, Saudi Arabia. The total number of students in Basic and Medical Sciences was 293. Total 265 students out of 293 completed the surveys answering majority of questions, which is an over all response rate of 90.4%. The students were between 17 and 23 years of age, and belonged to the academic years of 2010-2014. Sixty-six students were from the medical college and 199 from the Basic Sciences college. All participants signed consent forms and were assured by the investigators that all data would be kept confidential and that survey results would not affect their grades. The study was conducted in classrooms where laptops and cell phones were allowed. All students in each class had laptops and cell phones with wireless networking capabilities, and classrooms were equipped with wi-fi. The students were asked to report on a 5-point scale, their frequency and purpose of use, and their perception of the utility of laptops and cell phones in classrooms. They were also asked about their satisfaction with the use of technology in the university.

RESULTS

Majority of students thought that the use of laptops enhanced learning (55.5%), the capability of self-learning (58.3%), communication skills (40.8%), faculty student interaction (43.2%), and 39.4% thought that attention is distracted (Table 1).

Out of 265 students, 77 (30.3%) reported using laptops during class for non-educational activities, 29% said they used it for surfing the net and 24% said they used it for checking emails during classes (Fig.1). As many as 25% reported accessing cell phones while 14% reported accessing laptops more than five times in an hour-long class. Further, 26% reported using cellphones and 15% using laptops twice to five times in an hour-long class. While, 33% and 26% reported using cellphones and laptops respectively once to twice during a class.

This study found that only 27% of the students used laptops to take notes. The main reason for the use as shared by 58% of students was for making presentations (Fig. 2). Majority (55%) of the participants felt that the use of laptops in the class enhances their problem-solving and self-learning capabilities. When we asked the students about their satisfaction regarding the university's infrastructure, IT support services, and network accessibility, 45-52% reported satisfaction (Fig. 3).

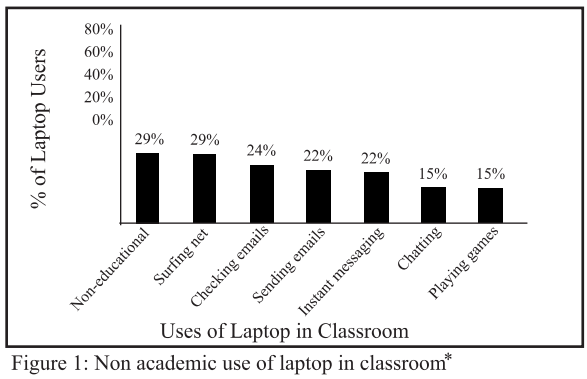

Figure 1: Non academic use of laptop in classroom*

* All percentages are out of 100 and do not add up as more than one response was positive

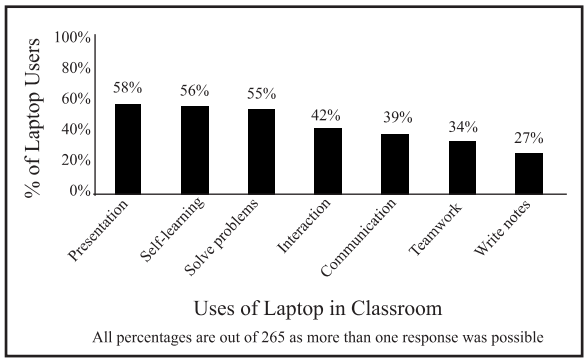

Figure 2: Student's uses of laptop in classroom

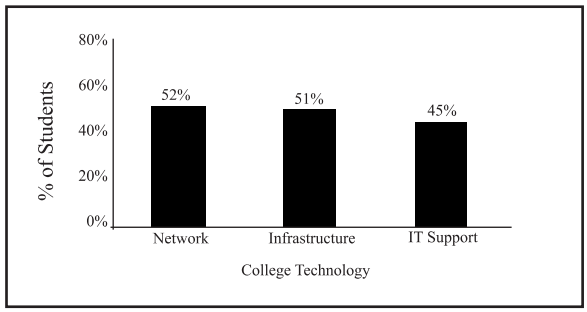

Figure 3: Student's satisfaction about college technology

Table 1: Uses of Laptop in Classroom

	5 Strongly Agree	4 Agree	3 Neutral	2 Disagree	1 Strongly Disagree
	n(%)	n(%)	n(%)	n(%)	n(%)
Laptops enhance students' learning.	54(21)	88(34.5)	59(23)	23(9)	32(12.5)
Laptops enhance students' capabilities of self-learning.	64(25.4)	83(32.9)	55(21.8)	34(13.5)	16(6.3)
Laptops improve students' communication skills.	43(16.9)	61(23.9)	76(29.8)	58(22.7)	17(6.7)
Laptops facilitate faculty-students interaction.	41(16.4)	67(26.8)	78(31.2)	48(19.2)	16(6.4)
Laptops enhance teamwork in class.	33(13)	55(21.7)	77(30.4)	63(24.9)	25(9.9)
Laptops improve class materials presentation.	70(28.5)	83(33.7)	53(21.5)	28(11.4)	12(4.9)
It is inconvenient to use my laptop during class.	25(9.9)	57(22.6)	70(27.8)	69(27.4)	31(12.3)
Laptops aid students to solve challenging problems.	45(17.9)	98(38.9)	63(25)	29(11.5)	17(6.7)
Students' attention is distracted due to the use of their laptops during lectures.	32(12.6)	68(26.8)	70(27.6)	56(22)	28(11)
Laptops are convenient for students to use during in-class exercises and exams.	29(11.4)	64(25.2)	86(33.9)	51(20.1)	24(9.4)
Student-instructor interaction is directly linked to the use of laptops.	10(3.9)	47(18.4)	97(38)	77(30.2)	24(9.4)
Students use their laptops actively during the lecture sessions.	23(9.2)	57(22.7)	82(32.7)	67(26.7)	22(8.8)
I use laptop during class to write notes.	26(10.3)	44(17.4)	77(30.4)	61(24.1)	45(17.8)
I use laptop during class for PowerPoint Presentations.	48(19.1)	67(26.7)	58(23.1)	40(15.9)	38(15.1)
I use laptop during class for sending and receiving assignments.	34(13.4)	57(22.4)	67(26.4)	55(21.7)	41(16.1)
I use laptop during class for sending emails.	16(6.3)	40(15.7)	46(18.1)	86(33.9)	66(26)
I use laptop during class for checking emails.	20(7.9)	43(16.9)	56(22)	85(33.5)	50(19.7)
I use laptop during class for creating discussions and discussion groups among students.	9(3.5)	31(12.2)	73(28.7)	91(35.8)	50(19.7)
I use laptop during class for other non-educational purposes.	14(5.5)	63(24.8)	49(19.3)	66(26)	62(24.4)
I use laptop during class for taking notes.	30(12.2)	53(21.6)	59(24.1)	58(23.7)	45(18.4)
I use laptop during class for instant messaging.	20(8)	47(18.8)	64(25.6)	68(27.2)	51(20.4)
I use laptop during class for playing games.	9(3.6)	31(12.4)	41(16.4)	69(27.6)	100(40)
I use laptop during class for surfing the net.	15(6)	61(24.6)	58(23.4)	61(24.6)	53(21.4)

DISCUSSION

Our study had two major significant findings: one was that a large percentage of students were using cell phones and laptops for non-academic activities. However, the percentage of students accessing these more than five times in an hour is less than what the studies have reported before from other parts of the world. The other finding was that the students think it enhances communication skills, learning, and faculty interaction and do not view it as distraction.

In our study, the nature of the use of laptops and cell phones in the classrooms indicates that the percentage use of laptops for non-academic purposes during one class period (60 min) was 29%, which is lower than reported in the study by Fried which found that 64% of students were using their laptops for non-academic activities during one class period.[7] This percentage is also lower than that reported in the Gilroy study which found over 70% of the students using laptops for non-educational activities during the class.[21] In our study, less than 25% students were using these gadgets for

checking and sending emails, which is lower than the Duncan study which reported 90% of students using the devices for checking email during a class.[22] Our assumption is that this self-reported data may not be accurate as students may have given lower estimates of their usage, since the majority does not view cell phones and laptops as distractions.

All of our participants from both medical and basic sciences classes owned laptops and tablets. However, only 27% used them for taking notes. The main purpose cited for its use in classrooms was to make class presentations (45.8%). Our results are similar to the nursing students' study which showed that 28.5% of students took notes on their laptops or tablets and almost 6% used both paper and laptops or tablets.[23] This data is suggesting that the use of laptops in the classroom is unstructured and the students are struggling with the optimal use of laptops/tablets and cell phones.

Our study also showed that students used cell phones more frequently than they used laptops during the class, which seems reasonable given the smaller sizes of cell phones, ease of use, and multiple shared features with laptops. The concerning fact here is the frequent use of both laptops and cell phones for non-educational activities and lack of awareness in students about the distractions these devices caused, as seen in earlier studies.[2-7] In an indirect fashion, the students are distracting themselves by using digital devices in classrooms. This endorses the importance of controlled use of laptops and cell phones during class time as suggested by Levine.[24]

Our study also showed that the students think that such use enhances communication, faculty interaction, and self-learning, and do not view it as distraction. This result is in conformity with the studies that have shown that it increases class participation of students and faculty-student interaction.[14-17] Interestingly, it is contrary to the claim made by earlier researchers who have shown that faculty is concerned with the unstructured and uncontrolled use of cell phones and laptops in the class room.[3,6,7] Consequently, another debate begins about the need to train students in appropriate use of cell phones and laptops in the classrooms. Both of these conflicting claims are from more developed countries. Based on our findings, we think that in a set up like Saudi Arabia, Middle East, and South East Asia, cell phones and laptops use should be structured and controlled for the benefit of the students.

One limitation of the study is that it was carried out at a single institution and may not present a complete picture of cell phones and tablets use in Saudi Arabia and other similar countries. Therefore, further research is needed to confirm our findings in other universities of the region. The other limitation is self-reported data, which is affected by the respondents' need for social desirability and may lead to under reporting of the perceived negative effects of technology.

CONCLUSION

The use of cell phones and laptops for non-educational activities in the classrooms is high among students in a medical college in Saudia Arabia and the students do not perceive its negative effects on learning. We believe that the students' use of cell phones and laptops in classrooms should be structured and controlled. Additionally, students should be trained in the use of these devices for enhancing learning.

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- Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications—International Committee of Medical Journal Editors

ORIGINAL ARTICLE

Effectiveness of Training on De-Escalation of Aggressive Behaviour in Improving Healthcare Workers' Knowledge Regarding Aggression Management in Healthcare

Ibrahim Hashmi[1], Sana Tanzil[1], Zahra Iqtidar Siddiqui[1], Lubna Mazharullah[1], and Mirwais Khan[2]

ABSTRACT

Objective: To assess the effectiveness of de-escalation of training in improving the knowledge of healthcare workers to manage aggressive behaviour and to prevent and control violence in workplace settings
Methodology: A quasi-experimental study was conducted among different cadres of healthcare personnel working in Karachi, Pakistan between August and December, 2016. A pre-post assessment of 214 healthcare workers was conducted to examine the effect of de-escalation training on the knowledge of healthcare workers regarding de-escalation of violence in healthcare settings. One sample t-test was applied to identify possible significant improvement in knowledge scores after de-escalation training.
Results: The study found statistically significant difference in mean scores of knowledge in pre and post-training assessments with a mean score of 5.91 + 2.69 and 6.57 +2.75 respectively. A significant increase in knowledge scores was observed among healthcare providers aged between 25 and 35 years, with work experience of less than five years and among those who were doctors ($p < 0.001$).
Conclusion: De-escalation training was found to be effective in improving knowledge about the de-escalation of violence among different cadres of healthcare providers in Karachi.

Key words: Violence, De-escalation training and Healthcare provider

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عنوان: صحت کے شعبے میں کام کرنے والوں پر جارحیت کم کرنے کی تربیت کے اثرات۔

اس تحقیق کا مقصد شدت پسندی کم کرنے کی تربیت کا صحت کے شعبے میں کام کرنے والوں کی جارحیت پسندی کے برتاؤ کو قابو میں رکھنے کے ادراک کو بہتر کرنے اور کام کرنے کی جگہ پر تشدد کی ممانعت اور اس پر پابندی پر اثر انداز ہونے کا تعین کرنا تھا۔

کراچی، پاکستان میں صحت کے شعبہ میں کام کرنے والے افراد کی مختلف جہتوں پر اگست سے دسمبر 2016 کے درمیان ایک Quasi-experimental تحقیق کی گئی۔ 214 صحت کے شعبہ میں کام کرنے والوں کا تربیت سے پہلے اور بعد کا تخمینہ لگایا گیا تا کہ شدت پسندی کم کرنے کی تربیت کا صحت کے شعبہ میں کام کرنے والوں کے کام کرنے کی جگہ پر شدت پسندی کم کرنے کے ادراک پر اثر کو جانچا جا سکے شدت پسندی کم کرنے کی تربیت کے ادراک میں ممکنہ معنی خیز بہتری کی شناخت کے لئے t-test کا اطلاق کیا گیا۔

تحقیق میں ادراک کے اوسطاً شمار میں تربیت کے پہلے اور بعد کے تخمینے میں، اعداد و شمار میں معنی خیز فرق پایا گیا۔ جس میں اوسطاً شمار، حسب ترتیب 2.69±5.91 اور 2.75±6.57 تھا۔ ادراک کے شمار میں معنی خیز بہتری، 25 سے 30 سال کی درمیانی عمر کے صحت کے شعبہ میں کام کرنے والوں جن کے کام کا تجربہ پانچ سال سے کم اور جو ڈاکٹر تھے، میں پائی گئی۔ ($p<0.0001$) شدت پسندی کم کرنے کی تربیت کو کراچی میں صحت کے شعبہ میں کام کرنے والے افراد کے مختلف جہتوں میں شدت پسندی کم کرنے کے ادراک میں بہتری کے لئے مؤثر پایا گیا۔

INTRODUCTION

Violence against healthcare personnel is a globally emerging public health concern due to its devastating long-term impact, not only on healthcare workers but on the society over all. The situation is dismal in both developed and developing countries. Studies from China, India, United States of America, and Turkey

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identify increasing burden of violence against healthcare workers[1-4].

Pakistan is a country currently facing a considerable rise in the burden of violence against healthcare workers at all levels; mostly initiated by patients and their attendants. However general public and political mobs in unstable circumstances, also contribute to violence against healthcare personnel. Literature suggests that the common acts of violence prevalent in the Pakistani society, range widely from verbal abuse to physical violence.[5-8] Lack of communication skills, unjustified expectations of patients and their attendants, poor quality of healthcare, and unexpected health outcomes are identified as major reasons behind increasing burden of violence in healthcare settings[5-8]. Exposure to violence may severely hamper the performance of healthcare providers which may have serious individual and societal consequences[9]. Literature from developed countries also supports the effective role of de-escalation training of healthcare providers in reducing frequency of violent events and improving patient-providers` interactions[10-13]. A systematic review of 35 studies also supports the role of educational programmes and trainings in reducing violence. The review suggests that trainings of healthcare workers for management of aggression can be used as an effective intervention to prevent and control violence against healthcare[14].

Hence, APPNA Institute of Public Health and International Committee of the Red Cross designed a training to provide essential skills to healthcare workers for de-escalation of aggression among patients and their attendants. The purpose of this training was to increase self-efficacy and to provide essential skills to deal with aggression and to control aggressive behaviours to prevent verbal and non-verbal violence with healthcare providers[15]. However, before scaling up this intervention, sufficient local evidence of its effectiveness in improving knowledge about de-escalation of aggressive behaviour is required. Hence, this study aims to assess the effectiveness of training of de-escalation in improving healthcare workers' knowledge regarding de-escalation of violence against healthcare personnel. Findings of this study may establish local evidence supportive of scaling up de-escalation trainings at national level and will help in including these trainings in the curriculum of healthcare workers at all levels.

METHODOLOGY

A quasi-experimental study was conducted among different cadres of healthcare providers working in Karachi, Pakistan between August and December, 2016. The variety of healthcare cadres who participated in this study included ambulance services, hospitals, and non-government organizations working in Karachi at the time of study.

A sample of 214 healthcare providers was obtained by calculating sample size using 1 % level of significance and 80% power to detect a difference of + 2 standard deviation in the mean scores for knowledge assessment pre- and post-de-escalation training. The sample size was also adjusted for an expected 15% non-response rate among healthcare providers.

Healthcare providers from different institutions (including a tertiary care public hospital, an ambulance service organization, a private tertiary care hospital, and two NGOs working with vulnerable communities in Karachi) were contacted for this study. Those who provided informed consent were included in the study by applying non-probability convenient sampling. The selected participants mainly included doctors, technicians, nurses, guards, and nursing attendants.

Specifically designed de-escalation training was provided to all selected study participants from each participating institution with the approval of relevant authorities. For this purpose, a team of experts from APPNA Institute of Public Health developed a training manual. The training comprised five different modules. The first module covered understanding violence and stress. It included results from the baseline study, major causes, and the perpetrators of violence. The second module emphasized on the de-escalation of aggressive behaviour by different techniques. There were verbal as well as non-verbal cues to undertake these scenarios. The third, fourth, and fifth modules were focused on the management of post-traumatic stress disorder, patient communication protocol (including breaking bad news), and rights and responsibilities of healthcare providers respectively[15].

The de-escalation training was conducted using effective teaching-learning methodologies including simulation and specifically designed videos. A team of master trainers was formulated by APPNA Institute of Public Health (AIPH) with ICRC, which conducted trainings with healthcare providers in different organizations in Karachi. Each training session was four hours long. Total six trainings were conducted with an average group size of 18 participants.

Data was collected using structured self-administered questionnaire comprising two main sections. The first section enquired about demographic and occupational characteristics of study participant while the second section had a list of multiple choice questions specifically designed to assess the participants' knowledge regarding de-escalation of aggression in

healthcare settings. Knowledge assessment section had questions related to patient communication, handling of aggression, and signs of escalation and application of de-escalation techniques. The study participants were asked to fill the same questionnaire before and just after the completion of de-escalation training.

Data was analyzed using SPSS version 20. Descriptive statistics were reported as frequencies and percentages to describe characteristics of study population. The data was positively skewed hence, mean scores for pre- and post-training knowledge assessment were compared by applying Wilcoxon signed-rank Test. P-value of less than 0.01 was considered significant for both statistical tests. Sub-group analysis was conducted for various categories of healthcare providers classified based on demographic and occupational characteristics. Ethical approval for this study was obtained from the Institutional Review Board of Jinnah Sindh Medical University, Karachi after taking approval from all participating institutions.

RESULTS

The median age of the study participants was 25 years with IQR of 7 years and majority of the participants were aged between 15 and 35 years (53.7%). Total 62.6% (n =134) of all study participants were male and 36.4% (n=80) were females. The median work experience of study participants was 2 years with an IQR of 4 years while majority of study participants (79%) had work experience of less than 5 years (n =171, 79%). Total 21.5% (n =46) of all study participants were doctors, 25% (n=55) were community midwives, 36.9% (n =79) were nurses and emergency technicians, while 15.9% (n=34) of all study participants were support staff including guards, nursing attendants, and helpers.

The study observed increase in mean scores of study participants in post-training assessments (6.57+2.75) as compared to pre-training assessment scores (5.91+ 2.69). The study found a mean difference of 0.66 in pre- and post-assessment scores. The difference in mean scores for pre- and post-training assessments was statistically significant (p<0.001).

Mean differences in pre- and post-training assessment scores were also compared among different subgroups of study participants based on differences in their characteristics such as age, work experience, and category of healthcare cadre or providers. The study found no significant differences in mean scores of pre-post knowledge assessment among participants with different background characteristics.

Table:1 Demographic and Occupational Characteristics of Study Participants (n =214)

Median Age (IQR)	25 (7) years
Age Categories	
15–25 years	53.7% (115)
25–35 years	31.8% (68)
>35 years	14.5% (31)
Sex	
Male	134 (62.6%)
Female	80 (37.4%)
Designation	
Doctors	46 (21.5%)
Midwives	55 (25.7%)
Technicians/Nurses	79 (36.9%)
Others (Guards, Helpers, Attendants)	34 (15.9%)
Institutions	
Private Hospital	38 (17.8%)
Private Hospital	62 (29.0%)
Ambulance Services	31 (14.5%)
Community workers	38 (17.8%)
Others	45 (21.0%)
Median Work Experience (IQR)	2 (4)
Work Experience categories	
<5 years	171 (79.9%)
6–10 years	30 (14%)
>11 years	13 (6.1%)

Table:2 Comparison of Pre-Post De-escalation Training Assessment Scores (n =214)

Assessment Scores	Mean (SD)	p-value
Pre-Training Scores	6.57+2.75	<0.001
Post-Training Scores	5.91+ 2.69	<0.001

P<0.001 is significant

DISCUSSION

This experimental study assesses the effectiveness of an intervention i.e. training on de-escalation of aggressive behaviour in improving knowledge about de-escalation and aggression management among healthcare workers. The de-escalation training aimed to provide essential information helpful in managing aggression in healthcare settings to reduce the existing burden of violence on healthcare workers. This study found significant increase in the mean post-training knowledge scores of study participants compared to their pre-training scores for the same. This points towards the substantial role of de-escalation trainings in improving knowledge and skills of healthcare workers for the management of aggression in healthcare settings as also supported by previous studies. A study conducted in the USA found significant

improvements in the performance of nurses who received aggression management training[16]. Another study conducted by Brodie and colleagues found significant improvements in knowledge and behaviour of healthcare workers after completion of educational training on short term management of violence[17]. A randomized controlled trial conducted in healthcare settings of United Kingdom found significant improvements in the residents' knowledge of dealing with aggression as well as in their performance after they received simulation-based trainings on management of acute aggression[18].

The effectiveness of de-escalation training among healthcare workers can be influenced by various individual and environmental factors including cognition level, educational background, performance motivation, and quality of training sessions conducted[19]. However, our study found no differences between pre and post training mean scores on the basis of differences in age, work experience, and specific role or designation of healthcare worker. This can be explained by the small sample size which is insufficient to detect any possible differences in sub-group analysis.

This study is among the few preliminary studies which demonstrate the short-term positive impact of de-escalation training on knowledge among healthcare workers from a variety of backgrounds. Moreover, assessment of pre-post training knowledge by using structured self-administered questionnaires might have increased the confidence of study participants and may have improved the quality of the collected information.

Nevertheless, this study has a few inherent limitations due to methodological issues. First, the design did not include a control group hence external factors, such as organizational issues and trainings in communication may have accounted for the observed changes in knowledge assessment scores. Secondly, with regard to training outcomes in this study, we only focused on change in knowledge scores and did not measure any perceived changes in the patients' ability to manage aggression or its impact on behavioural outcomes such as temperament and attitude towards patients and attendants. Hence, further research is required to evaluate the impact of training programmes on objective measures, such as the number of violent incidents, given that changes in objective measures[20].

Moreover, limited number of covariates in the study did not allow us to conduct multivariate analyses, which would have been particularly useful to more accurately assess the impact of socio-demographic variables on the effectiveness of de-escalation training. Furthermore, the effectiveness of de-escalation training is widely assessed by researchers for specific behaviour outcomes including confidence in coping with aggression, improved temperament, and increased empathy towards patients and their attendants[21,22]. Hence, more research is required to evaluate all possible benefits of de-escalation trainings to reduce violence in healthcare settings.

CONCLUSION

This study suggest that de-escalation training can improve the staff's knowledge and ability to de-escalate violent and aggressive behaviour and can play an important role in ensuring safety of the healthcare workers. Further research is required for more comprehensive assessment of possible knowledge and behaviour outcomes of de-escalation training in the local context.

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Writing Statistical Section in Manuscript

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as the use of P values, which fails to convey important quantitative information. Discuss the eligibility of experimental subjects. Give details about randomization. Describe the methods for and success of any blinding of observations. Report complications of treatment. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for the design of the study and statistical methods should be to standard works when possible (with pages stated) rather than to papers in which the designs or methods were originally reported. Specify any general-use computer programs used.

Put a general description of methods in the Methods section. When data are summarized in the Results section, specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlations," and "sample." Define statistical terms, abbreviations, and most symbols.

- Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications—International Committee of Medical Journal Editors

ORIGINAL ARTICLE

Injected Leptin Improves Performance of Rats, Relationship with Circulating Corticosterone and Serotonin

Qurrat-ul-Aen Inam

ABSTRACT

Objective: To monitor the changes resulting from injecting leptin into rats on their spatial memory and serum corticosterone, serotonin, and tryptophan secretion
Methodology: Animals were trained in Morris water maze. Immediately after training, animals were injected 0.1 and 0.5 mg/kg doses of leptin intraperitoneally. Memory was assessed at 2 and 24 hours after administration.
Results: Results of Morris water maze test showed enhanced memory acquisition and retention. This indicates that injected doses of 0.1 mg/kg and 0.5 mg/kg leptin effectively decreased the collective food intake at 24hr period in freely fed rats. Leptin injected animals showed increased serum serotonin level and decreased tryptophan level. Administration of a lower dose of leptin showed increased level of corticosterone.
Conclusion: The results indicate a correlation between levels of leptin and memory enhancement which also affects serotonin, corticosterone, and tryptophan levels in body.

Key words: Leptin, Cognition, Peripheral serotonin

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لیپٹن کے انجکشن سے چوہوں کی یادداشت میں بہتری اور خون میں کورٹیکوسٹیرون اور سیروٹونن کے اوپر اثرات۔

مقصد: یہ مطالعہ چوہوں میں لیپٹن کے انجکشن کے بعد ان کی یادداشت، اور خون میں کورٹیکوسٹیرون اور سیروٹونن اور ٹرپٹوفین کے اخراج پر ہونے والے اثرات دیکھنے کے لیے تھا۔

طریقہ: چوہوں کو مورس کی آبی بھول بھلیوں میں تربیت دی گئی۔ تربیت کے فوراً بعد نہیں 0.1 ملی گرام فی کلوگرام اور 0.5 ملی گرام لیپٹن کے انجکشن لگائے گئے۔ یادداشت کا امتحان دو گھنٹے اور 24 گھنٹے بعد کیا گیا۔

نتائج: مورس کی آبی بھول بھلیوں کے امتحان کے مطابق یادداشت پر واضح اچھا اثر پڑا۔ 0.1 ملی گرام اور 0.5 ملی گرام فی کلوگرام لیپٹن کے انجکشن سے تمام چوہوں کی 24 گھنٹے میں لی گئی خوراک میں کمی آئی۔ لیپٹن کا انجکشن لینے والے چوہوں میں سیروٹونن کی مقدار بڑھی ہوئی پائی گئی جبکہ ٹرپٹوفین کی مقدار کم ہوئی۔ لیپٹن کم مقدار میں دینے سے کورٹیکوسٹیرون کی مقدار بڑھی ہوئی پائی گئی۔

حاصلِ مطالعہ: نتائج سے ظاہر ہوتا ہے کہ خون میں لیپٹن کی مقدار یادداشت پر اثر انداز ہوتی ہے اور اس کا اثر خون میں سیروٹونن، کورٹیکوسٹیرون اور ٹرپٹوفین کی مقدار پر بھی ہوتا ہے۔

INTRODUCTION

Adipocytes predominantly synthesize leptin hormone and show positive correlation with body fat content[1]. Leptin crosses the blood brain barrier and exerts its action through receptors located in the hypothalamus[2] to regulate appetite and energy expenditure[3]. When leptin levels increase, they indicate sufficient stores of energy resulting in decreased appetite and increased use of energy. Otherwise, when leptin level is low, it produces the signal for the initiation of a meal[3]. Elevated levels of leptin fail to reduce excess adiposity in obese individuals, indicating leptin resistance[4]. Leptin binds to the target receptors located in different areas of the brain influencing body functions involved in affecting emotions, mood, cognition, and reproduction[5-7].

Effects of leptin administered exogenously are inconclusive in showing clinically significant improvement in cognition level. Intravenous injections of leptin at 5 or 50µg/kg have shown improved cognitive performance in Passive avoidance and Morris water maze tests while increased doses (500µg/kg) show no significant effect[8]. Leptin administration to the ventral hippocampus inhibits memory for the spatial location of food in rats[9] but bilateral injections of leptin into the hippocampus have been shown to improve memory consolidation on tasks recalling the location of an aversive event (food shock) in mice[10]. The leptin-deficient mice show hyperactive hypothalamus-pituitary-adrenal (HPA)-axis, and sudden administration

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of leptin leads to decreased plasma corticosterone levels[11]. Four hours later[12], injected leptin doses of 2 or 4µg/g in the same mice showed blocked corticosterone and elevations of ACTH which were induced by stress. Adipocytes express serotonin receptors, serotonin transporter, tryptophan hydroxylase 1, and influence serotonin availability through synthesis and reuptake[13]. Serotonin regulates leptin production in adipocytes both in vivo and in vitro[13]. Daily systemic injected doses of serotonin at 25 mg/kg for short term (5 days) and long term (4 months) decrease circulating levels of leptin[13].

The current research is intended to study the post administration effects of leptin on learning acquisition and memory retention using the Morris water maze test. Factors affecting 24-hour food intake, corticosterone level, tryptophan as well as serotonin were also determined.

METHODOLOGY

Albino Wistar male rats, weighing about 180-200g, were purchased from Dow University of Health Sciences (Karachi, Pakistan), a week before the start of the experiment. The rats were housed individually under a 12-h light dark cycle (lights on at 06:00 h), with free access to standard rodent diet and tap water for familiarization. Behavioural tests were performed in the light phase. All animal experiments, approved by the Institutional Ethics and Animal Care Committee, were conducted in strict accordance with the National Institutes of Health Guide for Care and Use of Laboratory Animals (Publication No. 85-23, revised 1985)

The drug recombinant rat leptin (ALX-201-231), obtained from Farmingdale, NY, USA, was injected intraperitoneally (i.p.) after dissolving in saline, at doses of 0, 0.1 and 0.5mg/kg.

Trial Method: Total of 24 animals were allotted to (a) 0mg/kg, (b) 0.1mg/kg, and (c) 0.5mg/kg leptin injected groups each containing eight animals. Animals were trained in Morris water maze at 10:00-11:00 hours. Leptin was injected in respective doses immediately after training. Control animals were injected with saline in volume of 1 ml/kg bodyweight. Two hours after training at 12:00-13:00 hours, the learning acquisition test was performed. The memory retention test was conducted the next day at 09:00–10:00 hours. Cumulative test was conducted after 24 hours. Food monitoring was done by taking difference of food given on day 1 before injection and food left immediately before monitoring memory retention on day 2. All animals were immediately decapitated after performance in water maze. Samples of serum were taken for the determination of corticosterone, serotonin, and tryptophan.

Water Maze Test: The water maze test was mentioned in earlier studies[15]. The water maze test used in current study consists of a circular pool which is white in colour, 90cm in diameter, and 60cm in height. It was filled with opaque water (22±2°C) to a depth of 30 cm. It was placed in a room with constant visual signals (posters, doors, windows, etc.) left unchanged until the end of the experiment. Four quadrants on the four compass directions (north, south, east, and west) were made. A square platform (10x10cm) was put in position at the center of the north quadrant 2cm below the water surface. This test was aimed to assess spatial or place learning in terms of latency to locate a hidden escape platform.

In the preparation phase, animals were put through three trials in every quadrant (except the one quadrant with the hidden platform), to locate the platform. In each trial round, a rat was placed in water facing the wall of the maze and had 120 seconds to discover and arrive at the hidden platform. The rats which successfully located the platform, were allowed to stay there for 10 seconds whereas those who failed to find it during the allocated time, were gently guided onto the platform. Afterwards, animals were placed in a holding cage with dry towels for one minute until the other trial.

Learning acquisition and memory retrieval was monitored by placing the animal in the south quadrant (just opposite the hidden platform quadrant) and observing latency to locate the hidden platform. The animals were beheaded to collect blood and serum. The serum was stored at -70° C until the analysis of tryptophan, serotonin, and corticosterone. The ELISA kits used for tryptophan, serotonin, and corticosterone analysis, were supplied by Demeditee Diagnostics GmbH Germany.

Statistical Analysis: Data were analyzed by one-way analysis of variance (ANOVA), using SPSS version 18. Post-hoc analysis was done by Newman-Keul's test and p-values less than 0.05 were taken as significant.

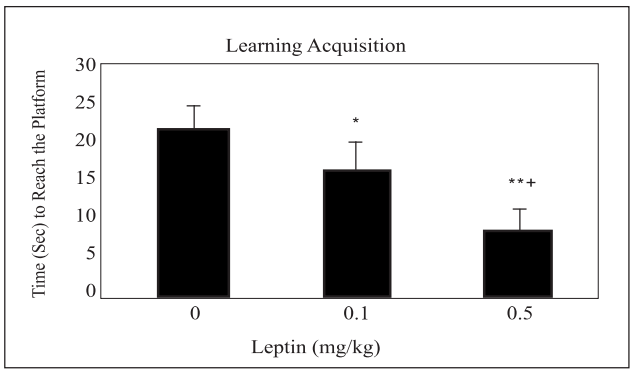
RESULTS

Fig. 1 shows Morris water maze test results of memory retention as well as learning acquisition after injected doses of leptin at 0, 0.1 and 0.5mg/kg. Results showed significant effects by One-way ANOVA after 2 hours

(F=21.3 df=2.21 p<0.01) and 24 hours (F=46.6 df=2.21 p<0.01) of leptin administration. Results of Post-hoc test showed that injecting leptin at doses of 0.1mg/kg and 0.5mg/kg improved learning and memory acquisition. The improvement was good and significantly greater in 0.5 mg/kg group as compared to the group injected with 0.1mg/kg leptin. The effects of 0.5mg/kg dosage over memory retention, monitored 24 hours after training, were found to be better than 0.1mg/kg leptin group.

Fig. 2 shows effects of leptin in different doses of 0, 0.1 and 0.5 mg/kg with food. One-way ANOVA showed significant effects on food intake (F=12.8 df=2.21 p<0.01). Post-hoc test showed that 24h food intakes were smaller in leptin injected groups than in saline treated animals.

Fig. 3 shows effects of leptin injection at different doses of 0, 0.01 and 0.5 mg/kg, on serum corticosterone, serotonin, and tryptophan levels. One-way ANOVA demonstrated significant effects on serum level of corticosterone (F-6.32 df=2.21 p<0.01), tryptophan (F=24.9 df=2.21p<0.01), and serotonin (F=11.9 df=2.21 p<0.01). Post-hoc test showed higher levels of corticosterone in 0.1mg/kg compared to 0.5 mg/kg leptin group. Serotonin levels increased and tryptophan levels decreased in 0.1mg/kg and 0.5mg/kg leptin group.



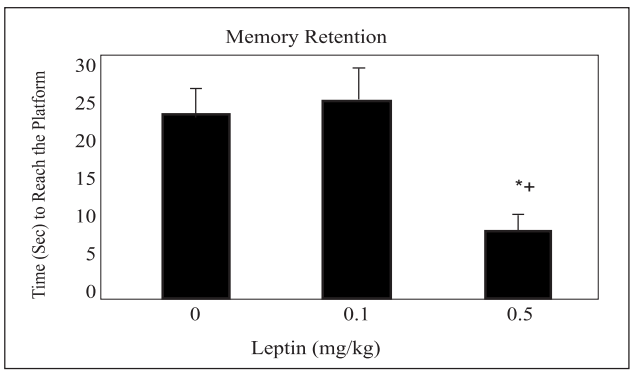


Figure 1: Effects of systemic administration of leptin on learning acquisition and memory retention in Morris water maze test. Values are mean ± S.D (n=8) 2hr after administration of leptin. Significant difference by Newman-Keuls test p<0.05, P<0.01 from respective saline-injected animals, p<0.01 from 0.1mg/kg leptin injected animals following one-way ANOVA.

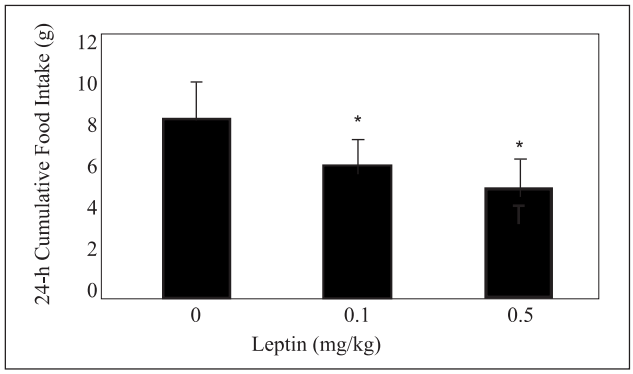
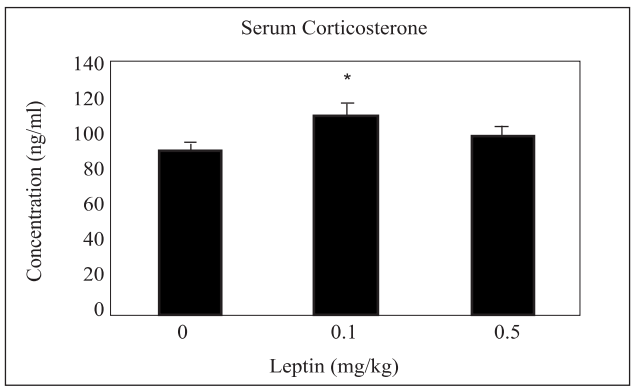
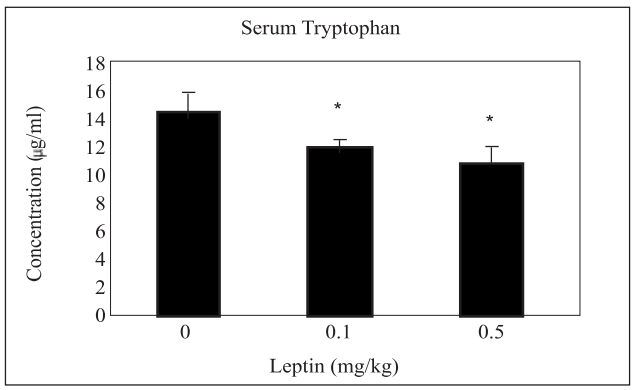


Figure 2: Effects of systemic administration of leptin on 24-h food intake. Values are mean ± S.D (n=8). Significant difference by Newman-Keuls test p<0.01 from saline injected animals following one-way ANOVA.





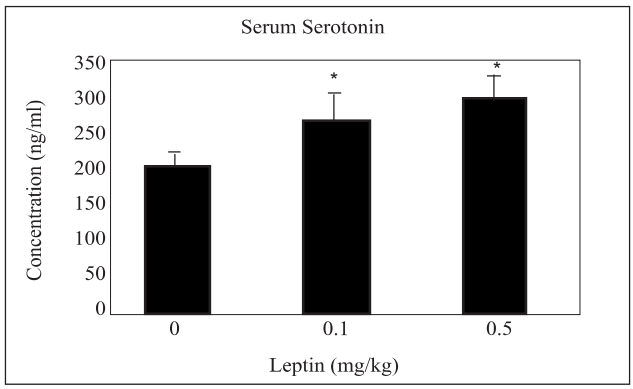


Figure 3: Effects of systemic administration of leptin on serum corticosterone, tryptophan, and serotonin levels in rats. Values are mean ± S.D (n=8) 24hr after the administration. Significant difference by Newman-Keuls test p<0.01 from saline injected animals following one-way ANOVA.

DISCUSSION

Effects of leptin on memory and learning behaviour are often evaluated in leptin-deficient mice or leptin receptor-deficient mice[16,17]. Deficiency of Leptin shows exhibited hippocampal plasticity in mice and Morris water maze test results indicate ability to perform spatial memory tasks test[18]. In a related research, no impairment in memory was observed in the Y-maze test in leptin receptors-deficient mice[17]. In another study, enhanced hippocampal long-term potentiation after injected moderate leptin dose into the dentate gyrus of living rats was seen whereas high and low doses of leptin impaired it[19].

In our study, leptin was administered by i.p. route in doses of 0.1 and 0.5mg/kg. The 0.1mg/kg dose enhanced learning acquisition with little or no effects over memory retention, while higher doses of 0.5mg/kg of leptin improved both memory acquisition and retention (Fig. 1). Previously, the above-mentioned doses were found to have anxiety relieving effects in an open field environment as well as in the light transition test. Maze test values were also elevated in rats[20]. Present research suggests that during maze learning, the improved performance in Morris water maze test due to leptin, reduces anxiolytic-like effects.

Leptin receptors are present in arcuate nucleus of the hypothalamus and produce anorexigenic effects after activation, because of increased release of melanocyte stimulating hormone (MSH)[21,22] and inhibited production of neuropeptide Y (NYP), which stimulates food intake[23]. Current study shows exogenous leptin-stimulated decrease in food intake (Fig. 2), which can explain anorexigenic effects of leptin administration. The leptin hormone plays a vital role in HPA-axis functioning[24]. Injected leptin attenuates stress induced HPA-axis activation[20]. Our study shows slightly increased levels of corticosterone after low dose administration of leptin (Fig. 3), which supports that under normal physiological environment, leptin administered in low doses increases the activity of HPA-axis[7].

An important finding of the present study is that systemic injection of leptin decreased serum tryptophan levels, which is the precursor of serotonin, and increased serotonin levels in serum (Fig. 3). Leptin effect is very important on serum serotonin because more than 95% of serotonin of the whole body is located in the gastrointestinal enterochromaffin cells and 10% is present in enteric nervous system of GIT[25] between the intestines and the brain. Serotonin plays an important role in creating sensation in the GIT (e.g. nausea, emesis, satiety). Present study shows that when serum serotonin level is increased, greater serotonin synthesis releases in GIT tending to suggest a potential role of serotonin in the meditation of leptin in anorexia (Fig. 2).

CONCLUSION

In conclusion, a preclinical approach shows memory enhancing effects of leptin which help to understand hormone leptin and its enhancing effects. Further studies may be conducted to understand the role of leptin in cognitive dysfunctions. Leptin effects on peripheral serotonin can be helpful to modulate its therapeutic efficacy in comorbid conditions.

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ORIGINAL ARTICLE

Correlation Between Serum Leptin and Serum Testosterone in Male Infertility Patients at a Tertiary Care Hospital of Karachi

Fareena Khalil Ahmed[1], Abdul Shakoor Memoon[1] and Intesar Burney[1]

ABSTRACT

Objective: To study the correlation between serum leptin and serum testosterone in male infertility patients presenting in a tertiary care hospital of Karachi

Methodology: This case control study was conducted in the Department of Physiology, Basic Medical Sciences Institute (BMSI) in collaboration with Reproductive Health Sciences, (Male Infertility Clinic) at the Jinnah Postgraduate Medical Centre (JPMC), Karachi. Samples of 100 infertile married males was divided into two groups. Group A as a control group had 25 subjects. Group B as a case group had 75 subjects, which were subdivided into three groups of infertile males i.e. (B1=Azoospermia, B2=Oligospermia, and B3=others). The ages, Body Mass Index (BMI), serum leptin and serum testosterone were measured. Serum testosterone and serum leptin were quantitatively measured by enzyme immunoassay.

Result: The BMI examination of the control and case groups showed significant association across all the four groups with the $p<0.05$. In serum leptin and serum testosterone levels, significant associations were found between control and cases across all the four groups i.e. $p<0.05$.

Conclusion: This study showed a strong inverse correlation between serum leptin levels, Body Mass Index (BMI), and serum testosterone levels. This suggests that BMI and hormone levels contribute significantly to male infertility.

Key words: Serum leptin, serum testosterone, male infertility, correlation

How to cite this article: Ahmed FK, Memoon AS, Burney I. Correlation between serum leptin and serum testosterone in male infertility patients at a tertiary care hospital of Karachi. Ann Jinnah Sindh Med Uni 2017; 3 (2):64-69

عنوان: کراچی کے ایک تیسرے درجے کے اعلیٰ ہسپتال میں مردانہ بانجھ پن کے مریضوں میں سیرم لیپٹن اور سیرم ٹیسٹوسٹیرون کے باہمی تعلق کا جائزہ۔

مقصد: اس مطالعے کا مقصد کراچی کے ایک تیسرے درجے کے اعلیٰ ہسپتال میں مردانہ بانجھ پن کے مریضوں میں پائے جانے والے سیرم لیپٹن اور سیرم ٹیسٹوسٹیرون کے باہمی تعلق کا جائزہ لینا تھا۔

طریقہ: یہ کیس کنٹرول اسٹڈی جناح پوسٹ گریجویٹ میڈیکل سینٹر کے RHS سینٹر (مردانہ بانجھ پن کلینک) کے تعاون سے BMSI کے شعبۂ طبیعات میں کی گئی۔ سو (۱۰۰) بانجھ شادی شدہ مرد مریضوں کے نمونوں کو دو گروہوں میں تقسیم کیا گیا۔ کنٹرول گروہ اے میں پچیس افراد تھے جبکہ کیس گروہ بی میں پچھتر افراد تھے۔ گروہ بی کو مزید تین گروہوں میں تقسیم کیا گیا جو کہ یہ تھے۔ بی ۱: ایزوسپرمیا والے افراد۔ بی ۲: اولگوسپرمیا۔ بی ۳: دیگر۔ ان میں عمر، وزن، سیرم لیپٹن اور سیرم ٹیسٹوسٹیرون کی مقدار کو جانچا گیا۔ ٹیسٹوسٹیرون اور لیپٹن کو اینزائم امیونو ایسے کے ذریعے شمار کیا گیا۔

نتیجہ: دونوں کنٹرول اور کیس گروہوں کے وزن (BMI)، سیرم لیپٹن اور سیرم ٹیسٹوسٹیرون میں گہرا تعلق پایا گیا جس کی پی ویلیو صفر اعشاریہ صفر پانچ تھی۔

حاصلِ مطالعہ: اس مطالعے میں سیرم لیپٹن، وزن، اور سیرم ٹیسٹوسٹیرون کے درمیان باہمی طور پر منعکس تعلق پایا گیا۔ جس سے ظاہر ہوتا ہے کہ مردانہ بانجھ پن پر وزن (BMI)، سیرم لیپٹن اور سیرم ٹیسٹوسٹیرون کے باہمی تعلق سے گہرا اثر پڑتا ہے۔

INTRODUCTION

Leptin is a kind of proteic hormone secreted by white adipose tissue. Its function is to regulate energy balance and control body weight. Seminal leptin may play a functional role in sperm capacitation[2]. Although many documents are found describing connections between body weight status and reproductive axis in females, not many studies have investigated the correlation between leptin and problems of fertility in male patients, especially in idiopathic asthenozoospermia cases[4].

Very few studies have been conducted on male infertility in Pakistan as men are reluctant to participate because of social pressures.

The purpose of this study was to estimate the levels of serum leptin and serum testosterone in male population and compare the levels of serum leptin with serum testosterone in male infertility. The hypothesis of our study was that a negative correlation exists between serum leptin and serum testosterone.

Leptin levels were found to be related with normal functioning in the reproductive system. Leptin receptors are present in testicular tissue and the discovery of

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leptin in semen creates a link between leptin and male reproductive function[5]. The relationship between leptin and androgens in men, showed that excess of leptin in bloodstream was an important contributor to the development of decreased androgens in male obesity[10].

A negative correlation between leptin and testosterone is seen in males of reproductive age[12], that is adipose secretion of leptin. Low testosterone concentrations were found in overweight infertile males[1] indicating that leptin excess in these overweight patients had caused reduction in androgens concentrations[16,20].

Inverse correlation can be explained by the paracrine inhibitory effect of leptin on testosterone production by Leydig cells. Also, testosterone increased lipolysis on binding with androgen binding receptor on adipocytes[9]. The main aim of our study was to correlate the levels of serum leptin and serum testosterone in infertile males and also to see the impact of their correlation on semen parameters and assess the role of BMI in this correlation.

METHODOLOGY

This case control study was done in the Department of Physiology, BMSI in collaboration with RHS (Male Infertility Clinic) at JPMC.

Approval was taken from ethical committee of BMSI, JPMC for conducting the research (Ref.No.F.1-2/ BMSI-E.COMT/040/JPMC).

One hundred subjects were selected from RHS A Centre, Department of Obstetrics and Gynaecology, JPMC. The study was conducted during October 2014 and May 2015. The following data and results were collected.

One hundred subjects were enrolled in our study. They were divided into two groups:

Group A (control group) = Normal fertile males (25 subjects)

Group B (case group) = infertile males (75 subjects)

B1 = Azoospermia (25 subjects)
B2 = Oligospermia (25 subjects)
B3 = Asthenospermia, Aspermia, Necrospermia, Oligo-asthenospermia, Teratospermia (25 subjects)

Determination of Biophysical and Biochemical Parameters

Biophysical Parameters

i. Age (years)
ii. Body Mass Index (BMI) (kg/m^2)
iii. Waist circumference if BMI > than 30
iv. Size of the testicles measured with vernier caliper
v. Pubic hair pattern

Biochemical Parameters:

i. Semen analysis
ii. Serum leptin in ng/ml
iii. Serum testosterone ng/ml

Quantitative measurement of testosterone and leptin in serum was carried out by enzyme immunoassay using testosterone-ELISA kit no. KAPD1559 DIA source Belgium and leptin-ELISA kit no. KAP2281 DIA source Belgium.

Data were stored and analyzed using SPSS 16. Count with percentages were reported for different variables. Mean and standard deviation were given for all quantitative variables like age in years, BMI, sperm count, serum leptin, and serum testosterone. ANOVA and post hoc test was applied.

RESULTS

In this case control study, we investigated subjects attending the male infertility clinic at RHS Centre, JPMC.

Table 1 shows the basic information of biophysical parameters and their association across all the four study groups. The BMI and examination of the control and case groups show significant association across all the four groups with the p-value < 0.05. With age and secondary sexual characteristics, no significant association was found across all the four studied groups with p-value > 0.05.

Table 2 reports the mean values of serum leptin as the highest in azoospermia, and the lowest in oligospermia group. It also gives significant p-value 0.01 that showed the mean of serum leptin varying across the groups. Serum testosterone in azoospermia patients was decreasing. It also gave significant p-value of 0.017 that tells us that mean of serum testosterone was different across four groups.

*[1]: B_1 was significantly different from B_2 and B_3.

*[2]: B_1 was significantly different from B_2.

Table 3 is the correlation matrix that shows the direction of relationship and its significance between any two variables using Pearson correlation. It shows that serum testosterone had a significantly negative relationship with serum leptin and significantly positive association with sperm count and BMI. Significant negative correlation was seen between serum testosterone and sperm count. Physical characteristics showed significant positive correlation with semen analysis. Similarly, pH gave significant positive association with sperm count. Remaining correlations did not have any significance. All correlations were estimated by taking the whole sample.

Table 1: Biophysical Parameters of Case and Control Groups

Parameters	Control Group A (Fertile) n=25		Case Group B (Infertile) n=75						P value
	Group A n=25 Proven Fathers		Group B1 n=25 Azoospermia		Group B2 n=25 Oligospermia		Group B3 n=25 Others		
	n	%	n	%	n	%	n	%	
Age (in years)									
Less or Equal to 35 Years	17	68	13	52	17	68	15	60	0.60
More Than 35 Years	8	32	12	48	8	32	10	40	
BMI (kg/m^2)									
Underweight (Under 18.5)	-	-	1	4	4	16	-	-	
18.5–24.9 (Normal)	12	48	7	28	9	36	-	40	0.049*
25–29.9 (Overweight)	11	44	9	36	6	24	10	48	
Over 30 (Obese)	2	8	8	32	6	24	12	12	
Examination									
Normal	25	100	22	88	20	80	15	60	<0.01*
Have Problems	-	-	3	12	5	20	10	40	
Secondary Sexual Characteristics									
Normal	25	100	23	92	25	100	23	92	0.244
Not Normal	-	-	2	8	-	-	2	8	

*p<0.05 was considered significant using Pearson chi-square test

Table 2: Comparison of Serum Leptin and Serum Testosterone Between Case and Control Groups

Parameters	Control Group A (Fertile) n=25	Case Group B (Infertile) n=75			P value
	Group A n=25 Proven Fathers Mean ±S.D	Group B1 n=25 Azoospermia Mean ±S.D	Group B2 n=25 Oligospermia Mean ±S.D	Group B3 n=25 Others Mean ±S.D	
Serum Leptin (ng/ml)	4.35±4.81	8.51±11.02	3.1±2.93	3.43±2.48	0.01*[1]
Serum Testosterone (ng/ml)	4.56±1.25	3.33±1.78	4.9±1.93	4.53±2.36	0.017*[2]

*p<0.05 was considered significant using ANOVA

Table 3: Correlations Between BMI, Semen Parameters, Serum Leptin, and Serum Testosterone

Variables	Serum Leptin ng/ml	Serum Testosterone ng/ml	Volume (ml)	pH	Sperm (million/ml)	BMI (Kg/m^2)
Serum Leptin ng/ml	1					
Serum Testosterone ng/ml	-.037**	1				
Volume (ml)	-0.136	0.096	1			
pH	-0.047	0.027	-0.057	1		
Sperm Count (million/ml)	0.25*	0.019	0.209	.402**	1	
BMI (kg/m^2)	0.39**	-.404**	0.101	-0.152	-0.028	1

** Correlation is significant at the 0.01 level (2-tailed).

* Correlation is significant at the 0.05 level (2-tailed).

Table 4: Comparison of Seminal Parameters Between Case and Control Groups

Parameters	Control Group A (Fertile) n=25	Cases Group B (Infertile) n=75			P value
	Group A n=25 Proven Fathers Mean ±S.D	Group B1 n=25 Azoospermia Mean ±S.D	Group B2 n=25 Oligospermia Mean ±S.D	Group B3 n=25 Others Mean ±S.D	
Volume (ml)	2.38±0.7	2±1.16	2.59±1.2	1.94±1.41	0.144
PH	8.1±0.36	7.8±0.46	7.79±0.33	7.97±0.43	0.018*[1]
Motility Activity (%)	0.64±0.17	0 ±0	0.25±0.24	0.37±0.3	<0.01*[2]
Morphology Normal (%)	0.64±0.16	0±0	0.27±0.26	0.43±0.29	<0.01*[3]
Morphology Abnormal (%)	0.35±0.16	0±0	0.61±0.28	0.57±0.28	<0.01*[4]
Sperm (million/ml)	77.92±27.02	0±0	8.2±5.52	28.78±30.84	<0.01*[5]

*p<0.05 was considered significant using ANOVA

Table 4 shows that pH was high in proven fathers on average, while it was decreasing in other groups. A significant change across the four groups was found with p=0.018.

*[1]: Control was significantly different from B_1 and B_2.

*[2]: Control was significantly different from B_1, B_2 and B_3. B_1 was also significantly different from B_2 and B_3.

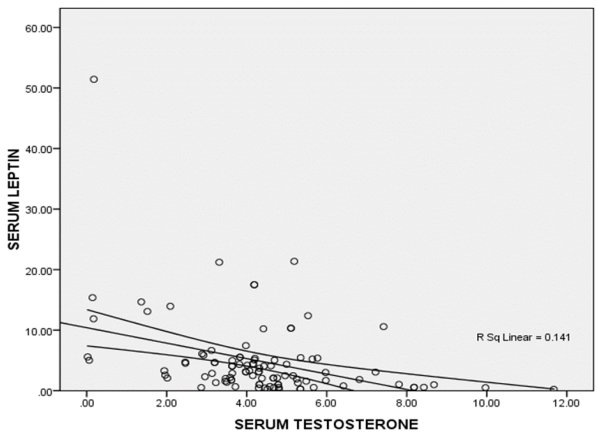
*[3]: Control was significantly different from B_1, B_2 and B_3. B_1 was significantly different from B_2 and B_3. B_2 was also significantly different from B_3.

*[4]: Control was significantly different from B_1, B_2 and B_3. B_1 was significantly different from B_2 and B_3. B_2 was also significantly different from B_3.

*[5]: Control was significantly different from B_1, B_2 and B_3. B_1 and B_2 were also significantly different from B_3.

The mean and standard deviation of motility activity (%), morphology normal (%), morphology abnormal, and a significant p-value is evidence that mean values of these parameters were varying across the groups. Mean sperm count in oligospermia group was the lowest, as compared to proven fathers. The p<0.01 declared that sperm count was varying significantly across the groups.

Graph 1: Scatter plot shows negative correlation between serum testosterone and serum leptin; r square was obtained to be 0.141, that says 14.1% variation explained in serum leptin by the help of serum testosterone.



Graph 1: Scatter Plot Between Serum Leptin and Serum Testosterone for Whole Samples

DISCUSSION

The results were compiled statistically under proper SPSS version 16. In this study, a negative correlation was found between the levels of serum leptin and serum testosterone and a positive association between levels of serum leptin and BMI. A significant negative association was found between serum testosterone levels and BMI.

A study conducted in Egypt[8] analyzed that there was a strong correlation between serum leptin and male reproduction. The result showed a strong negative correlation between serum leptin and serum testosterone and a positive association between age and BMI. These findings agreed with ours.

Another study found that there was a negative association of BMI with the serum level of testosterone, which was also in agreement with our study[3].

Our study was strongly associated with the study done which also showed that BMI and obesity had significant

inverse correlation with serum testosterone[18]. Pauli and Legro[23] also found out in their study that BMI was negatively correlated with serum testosterone[22]. Zorn and Osredkar[22] also discovered a negative correlation of BMI with testosterone.

Tunc et al.,[19] in their study conducted in Iraq, found a highly significant negative correlation between serum leptin and serum testosterone. This result was suggestive of a link between the adipocyte hormone leptin and male reproduction which showed that obesity may represent an actual threat to male fertility, causing a decrease of total testosterone with hyperleptinemia. This was in agreement with our study.

Jahan et al.[11] conducted a study in Islamabad in which they also observed a negative correlation of serum leptin with serum testosterone and a significant association of BMI with serum leptin levels.

Ellithy et al.[6] conducted a study in Egypt which found significant negative correlation between serum leptin and serum testosterone in azoospermia patients. In our study, the circulating leptin and BMI were inversely related with serum testosterone and we concluded that excess leptin may be an important contributor to the development of reduced androgens in male infertility. An increase in BMI leads to alteration in the semen parameters due to the suppression of hypothalamic pituitary-gonadal axis by elevated estrogen derived from peripheral aromatization, and resulting decreased testosterone production is reflected in low levels of testosterone, this was reported by Hammoud and Griffin[7] and agrees with our study.

As our study also determined, leptin directly inhibits the production of testosterone after binding to Leydig cells and then spermatogenesis becomes defective due to increase in leptin and its expression on leptin receptors in the testis[9].

In our study, a negative correlation between serum leptin and serum testosterone concentration was found, which was in agreement with many studies[8,22,14,11]. Proper reproductive and sexual health education is needed at all levels of education and for adults to inform them about the threats to their reproductive health. Impact of obesity and high BMI on male infertility should also be highlighted. Measures to improve reproductive health and safeguard from common problems in the light of scientific studies must be included in health education and awareness programmes.

CONCLUSION

Our study shows strong inverse correlation between serum leptin, BMI, and serum testosterone. These parameters can be used as tools to investigate the nature of neuroendocrine causes of male infertility as both these hormones put together, influence fertile as well as infertile males.

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ORIGINAL ARTICLE

Racial Disparities in Patients with Oral Cavity Squamous Cell Cancers Presenting in a Tertiary Care Hospital in Karachi, Pakistan

Beenish Nisar Ahmed[1], Muhammad Waqas Nisar Ahmed[2], and Mehwish Nisar[3]

ABSTRACT

Background: Oral cavity squamous cell cancer is the third most commonly occurring malignancy among head and neck cancers worldwide. Different factors contribute to the development of this disease including cultural habits like chewing betel leaf with betel nuts, using addictive substances like *manpuri, gutka, niswar,* smoking, which are strongly associated with lifestyles practiced by different races. Therefore, the disease outcome may be the result of several factors identified as cultural influences and socioeconomic circumstances of people belonging to different races.

Methodology: This prospective study was conducted at Jinnah Postgraduate Medical Center (one of the major and the biggest tertiary care centers of Karachi, Pakistan). Samples of 208 proven cases of oral cavity squamous cell cancers were collected from the department of E.N.T. Surgery and Otorhinolaryngology. Oral cavity squamous cell cancers were matched on clinical characteristics, age, site of lesion, stage, race, socioeconomic status, and addiction.

Results: Mean age of the patients was 45±10.26 years ranging from 25 to 65 years. Among the patients who presented with oral cavity squamous cell cancer at JPMC, Indo-Aryan population was found to have the highest incidence. Majority of patients presented in stage 3 involving oral mucosal non-healing ulcers. Smoking and betel nut with betel leaf chewing were common addictions. Patients presented in third and fifth decades of life and were socioeconomically poor.

Conclusion: Differences in disease outcome may be attributed to a combination of racial factors, tumour stages, socioeconomic status, and access to health care.

Key words: Squamous cell cancer, race, socioeconomic, oral cavity

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عنوان: کراچی پاکستان کے ایک تیسرے درجے کے اعلیٰ ہسپتال میں منہ کے کینسر کے مریضوں میں نسلی عدم مساوات۔

پس منظر: دنیا بھر میں سر اور گردن کے سرطان کے مریضوں میں منہ کے کینسر کے مریضوں کی تعداد تیسرے نمبر پر ہے۔ اس مرض کی وجوہات میں ثقافت میں شامل روایات جیسے پان، چھالیہ کا استعمال اور نشہ آور اشیاء جیسے نسوار، گٹکا، مین پوری کا استعمال شامل ہیں۔ یہ عادات پاکستان میں آباد مختلف نسل کے لوگوں سے ان کی ثقافت کے طور پر منسلک کی جاتی ہیں۔ لہٰذا مرض کے علاج کا نتیجہ ثقافتی سماجی اور معاشی اقدار پر منحصر ہوسکتا ہے۔

طریقہ: یہ پراسپیکٹو مطالعہ جناح پوسٹ گریجویٹ میڈیکل سینٹر میں کیا گیا جو کہ کراچی اور پاکستان کے بڑے اور اعلیٰ درجے کے اسپتالوں میں شمار ہوتا ہے۔

سر اور گردن کی جراحی اور ناک کان حلق کے امراض کے شعبہ جات سے ۲۰۸ کیسز کے اعداد و شمار اکٹھے کئے گئے۔ منہ کے سرطان کے مریضوں کو طبی خصوصیات، سرطان کی جگہ، اور درجہ، مریض کی عمر، معاشی اور سماجی پس منظر، اور نشہ آور اشیاء کے استعمال کے حوالے سے جانچا گیا۔

نتائج: مریضوں کی عمریں 25 سے 65 سال کے درمیان تھیں جبکہ اوسط عمر 45 (±10.26) سال تھی۔ ہندوستانی آرین نسل کے مریضوں میں منہ کا کینسر سب سے زیادہ پایا گیا۔ زیادہ تر مریض مرض کی اسٹیج 3 پر ہسپتال پہنچے تھے۔ سگریٹ اور چھالیہ کے ساتھ پان سب سے عام مستعمل نشہ پایا گیا۔ زیادہ تر مریض اپنی زندگی کی تیسری اور پانچویں دہائی میں تھے اور سماجی اور معاشی لحاظ سے غریب تھے۔

حاصلِ مطالعہ: مرض اور اس کے علاج کے نتائج پر بہت سارے عوامل اثر انداز ہو سکتے ہیں جیسے کہ نسل، مرض کا درجہ معاشی و سماجی پس منظر اور صحت کی سہولتوں تک رسائی۔

INTRODUCTION

Oral cavity squamous cell cancer is the third most commonly occurring malignancy among head and neck cancers worldwide. A short review of literature on cancer trends in Pakistan showed it to be the second most frequently found cancer in both sexes[2]. A recent study also showed it as the second most common tumour in Karachi South[3].

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Different factors contribute to the development of this disease including age, gender, socioeconomic status, and cultural habits like chewing betel leaf with betel nut, smoking, using addictive substances like *manpuri, gutka, and niswar*. However, a major factor affecting all of these characteristics is racial disparity[4]. Different races have their own habits and customs that, in many ways, either lead to this disease or save from it. Therefore, the disease outcome may be the result of a combination of tumour stage, socioeconomic status, and access to health care affected by racial differences. Recently, the inclusion of biological markers, human papilloma virus (HPV) status is under study.

Multiple studies have been done all over the world showing racial factors and determinants of oral cavity squamous cell cancer survival. Chen L M conclude that minority and non-Hispanic, white, head and neck squamous cell cancer patients, receiving similar multidisciplinary-team directed care at a tertiary cancer center, have similar survival results overall. These results encourage reducing health disparities in head and neck squamous cell cancers through public health efforts to improve access to multidisciplinary oncologic care (and to preventive measures) and through individual clinicians' efforts to make the best multidisciplinary cancer treatment choices available for their minority patients. The subgroup findings suggest a biologically based racial/ethnic disparity among oro-pharyngeal patients and that prevention and treatment strategies should be tailored to different populations that these patients belong to[5].

Gourin CG compared non-Hispanic white and black citizen of USA and described that insurance status, treatment, and extra capsular spread differentially affected the survival of black patients compared with white patients. Only insurance status had a significant effect on survival in black patients after controlling for other variables. This data suggests that racial differences in head and neck cancers outcomes are primarily related to differences in access to healthcare[6].

Settle K for the first time did a prospective assessment of confirmed HPV status in black versus white head and neck squamous cell cancer patients. These findings have important implications for the etiology, prevention, prognosis, and treatment of head and neck cancers[13].

Worsham MJ did a cohort study comprising 358 patients with head and neck squamous cell cancer who self-reported race as Caucasian American (CA) and African American (AA) and revealed no correlation with stage or survival, suggesting that head and neck squamous cell cancer outcomes with race may be owing to social/behaviour factors rather than biological differences[8].

This study examined the racial predominance and clinico-pathological features (including age, incidence, cultural habits, site of lesion, stage of disease, and socioeconomic status) of 208 cases of oral cavity squamous cell cancers in Pakistani population.

Pakistan is a country inhabited by multiple races. Races can be broadly classified into Turko-Iranians comprising Baloch (Urban and Rural Baloch) and Pathan; Indo-Aryans comprising Urdu-Speaking people as majority and Punjabi, Sindhi, and Saraiki; Scytho-Dravidians comprising Gujarati and Sindhi, and Aryo-Dravidians comprising Gujaratis and Sindhis of different localities[9].

This racial disparity is leading to a great difference in disease outcome. This study links the causes of oral cancers with the cultural habits of different races. Age, site, and clinical characteristics are associated with racial habits also. Socioeconomic statuses of different races also have a deep impact over disease prognosis. Tobacco and alcohol are globally accepted etiological factors for head and neck cancers but in our populations, chewing betel nut and leaf, gutka, manpuri, and niswar are the leading etiological factors in addition to smoking.

Thus, oral cavity squamous cell cancers are the result of a combination of poor nutrition, chemical carcinogens, viruses, race-related cultural influences, and socioeconomic statuses and not just any one factor. The present study was designed to analyze and integrate clinical data in order to explore the oral cavity squamous cell cancer with new dimensions in Pakistan. Here, we report the data regarding clinico-pathological features and racial profiles of oral cavity squamous cell cancers in Pakistani population presenting at our hospital.

METHODOLOGY

The study consisted of total 208 proven cases of oral cavity squamous cell cancer collected from the department of E.N.T. Surgery and Otorhinolaryngology, JPMC (one of the major and the biggest tertiary care centers of Karachi, Pakistan). It was a prospective study. Information regarding age, race, clinical presentation (including presenting complaints i.e. non-healing ulcers in oral cavity, burning sensation, sub-mucosal fibrosis, etc.), site of involvement (i.e. tongue lateral border, oral mucosa, alveolus, and lower lips), culturally influenced habitual addictions smoking, *niswar*, betel nut chewing with betel leaf, *manpuri, gutka*, stage of disease using AJCC, TNM classification via thorough examination and investigations, and socioeconomic status were recorded on a proforma. Inclusion criteria were patients between the ages of 25 and 65 years of any gender, Pakistani nationals, with biopsy-proven squamous cell cancer of oral cavity.

Data was analyzed on SPSS 22 and frequencies were measured. Incidence within different races, standard deviations, and mean were calculated.

RESULTS

This study was designed to analyze and integrate the clinical data in order to explore the oral cavity squamous cell cancer with new dimensions in Pakistan. It was conducted at JPMC in Karachi, Pakistan which is the biggest tertiary care center in Karachi representing the population of Pakistan.

Study group consisted of 208 patients. Their ages ranged from 25 to 65 years. Mean age was 45 years. Study was conducted over two years from January 2009 to December 2010 prospectively and patients were followed as per regular standard protocol of oral cavity cancer patients.

Pakistan has four races including Turko-Iranians, Indo-Aryans, Scytho-Dravidians, and Aryo-Dravidians. Indo-aryans most commonly presented with oral cavity squamous cell cancers and Aryo-Dravidian were the least represented race. Over all, oral mucosa was the most common site for all races while lower lip was the minimally involved site. Majority of patients presented in the fifth decade of life and in stage 3. People presented with advance disease and very few reached with early stage 1 disease. Commonest presenting complaint was non-healing ulcer. Smoking and betel nut with betel leaf chewing were major addictions. Socioeconomic statuses were found to be low. Here we are presenting the details of each race with all characteristics that we have measured on SPSS.

Indo-Aryan was the most commonly presenting race in our hospital. Patients typically presented in the third and the fourth decades of life. Incidence was the highest i.e. 51.44 % in this racial group. Their major addiction was smoking, betel nut chewing while a small number used *manpuri* and *gutka*. The site of involvement was oral mucosa and tongue for few patients. They were socio-economically poor. They presented in advance stages 3 and 4. Their presenting complaints were non-healing ulcers, burning sensation in oral cavity, and sub mucosal fibrosis leading to difficulty in eating.

Turko-Iranians can be further divided into two races, Baloch and Pathan. Incidence in Turko-Iranians was 30.78%. Out of these, Pathan comprised 1.94% and Baloch 28.84%. Urban Baloch showed incidence of 19.23% and rural only 9.60%. Culturally influenced habits of the Baloch were found to be smoking, chewing betel leaf and nut, *manpuri*, and *gutka* while Pathans used *niswar* more frequently. The most frequent site of tumour was oral mucosa for the Baloch and lower alveolus and lower lip for the Pathans. They presented in late stages (i.e. 3rd and 4th) of the disease in the 5th and 6th decades of life. Socioeconomically, all were poor. Majority had presenting complaints of non-healing ulcers.

Scytho-Dravidians were less frequently affected by this disease. Incidence was 11.05 %. Site of tumour was tongue (lateral border). Patients were socioeconomically poor and presented with stage 2 disease in the 5th and 6th decades of life. Few of them chewed betel nut. Their presenting complaints were non-healing ulcers.

Aryo-Dravidians were the least commonly affected race presenting with oral cavity squamous cell cancer. Incidence was the lowest i.e. only 6.73%. People presented in 5th and 6th decades of life. They were found to have no addictions. Predominant site was oral mucosa and socioeconomic standards were poor. This group presented in early stages of disease i.e. stage 1 and their presenting complaints were non-healing ulcers.

We reported the data regarding clinicopathological features and racial factors of oral cavity squamous cell cancers in Pakistan. (Tables 1-2 and Figures 1-2)

Table 1: Incidence of Different Races in Pakistan

Total Number of Patients N = 208
Races Represented as
T-I =Turko-Iranians
I-A=Indo-Aryans
S-D=Scytho-Dravidians
A-D=Aryo-Dravidians

Races in Pakistan	Incidence of Cancer
T-I	30.78%
Baloch	28.84%
Urban	19.23%
Rural	9.60%
Pathans	1.94%
I-A	51.44%
S-D	11.05%
A-D	6.73%

Table 2: Age, Stage, and Site of Lesion of Different Races in Pakistan

Races Represented as
T-I = Turko-Iranians (B) Baloch and (P) Pathan
I-A = Indo-Aryans
S-D = Scytho-Dravidians
A-D = Aryo-Dravidians
Number of Patients = n

Race	Site of Lesion	Stage of Disease	Age of Patients
T-I (B)	Oral Mucosa (n=60)	Stage 3 (n=58) Stage 4 (n=2)	5th Decade (n=55) 6th Decade (n=5)
T-I (P)	Alveolus (n=3) Lower Lip (n=1)	Stage 3 (n=4)	5th Decade (n=4)
I-A	Oral Mucosa (n=100) Tongue Lateral Border (n=7)	Stage3 (n=87) Stage4 (n=20)	3rd Decade (n=78) 4th Decade (n=29)
S-D	Tongue Lateral Border (n-23)	Stage 2 (n=23)	5th Decade (n (n=20) (6th Decade =30)
A-D	Oral Mucosa (n=14)	Stage 1 (n=14)	5th Decade (n=10) 6th Decade (n=4)

Figure 1: Presenting Complaints of Different Races of Pakistan

*X-axis of graph represented races as
T-I = Turko-Iranians
I-R = Indo-Aryans
S-D = Scytho-Dravidians
A-D = Aryo-Dravidians
*Y-axis of graph represents the number of patients with presenting complaints as
SMF = Sub mucosal fibrosis (GREEN)
BS = Burning sensation of mouth (RED)
NHU = Non-healing ulcers (BLUE)

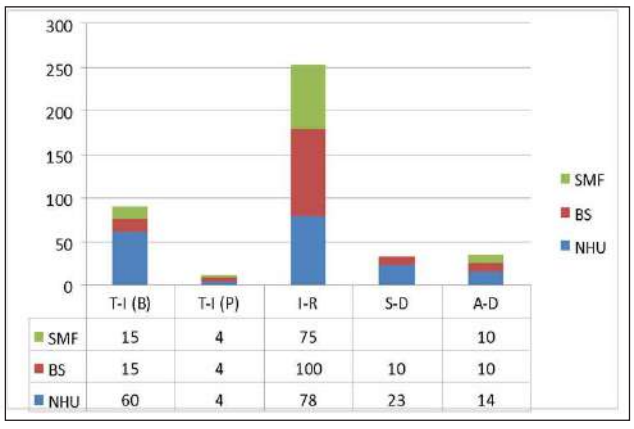
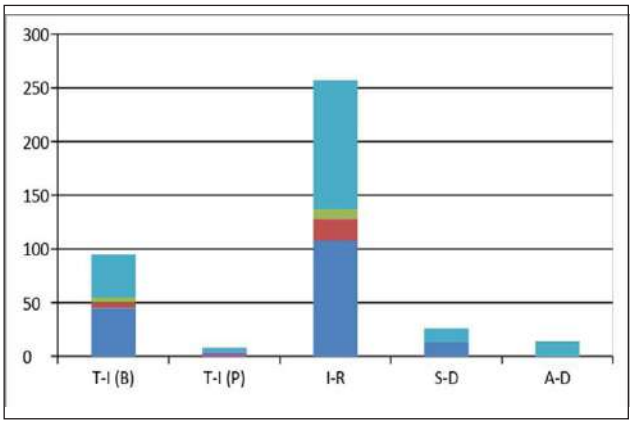


Figure 2: Different Addictions of Races in Pakistan

*X-axis of graph, races represented as
T-I =Turko-Iranians
I-R=Indo-Aryans
S-D=Scytho-Dravidians
A-D=Aryo-Dravidians
*Y-axis shows number of cases of different addictions in different colours
SMO=Smoking (SKY BLUE)
NW=Niswar (PURPLE)
GK=Gutka (GREEN)
MP=Manpuri (RED)
P+B=Betel nut chewing with betel leaf (BLUE)



DISCUSSION

Pakistan is inhabited by different races. These races have different lifestyles, cultural practices, and habits with several influencing factors. Addiction trends, socioeconomic status, and access to health care centers are also comparable among these races. Oral cavity squamous cell cancer is one of the most commonly occurring cancers in Pakistan. Differences in culture lead to varying results in patients of oral cavity squamous cell cancers.

Urdu speaking Indo-Aryans are the most affected by oral cavity squamous cell cancer followed by the Urban Baloch from Turko-Iranian group. This increased incidence was found to be the result of their cultural habits of chewing betel nut with betel leaf, manpuri, smoking, and gutka. Socioeconomically poor status was also a factor contributing towards presenting in advance stages of disease and delayed i.e. 5th decade of life presentation. Tobacco and alcohol are globally accepted factors for head and neck cancers but in Pakistan, other than smoking, chewing betel nut and leaf, and consuming addictive substances like *gutka, manpuri*, and *niswar* are leading etiological factors. In comparison, the races which do not habitually consume betel leaf and nut and *gutka* etc. were found to be less involved with tumour. Tumour site depends upon the route involved in using the carcinogenic addictive agents and presenting complaints were also dependent upon the site of involvement of tumour. The most common site was found to be oral mucosa here. Multiple studies have been done around the world

showing racial disparity affecting oral cancers in various manners. We have done a prospective study to calculate the results of racial disparity among different races which are affecting the disease outcome and prognosis. These results encourage reducing health disparities among races in head and neck squamous cell cancer through public health efforts to improve access to multidisciplinary oncologic care (and preventive measures) and through individual clinician efforts to make the best multidisciplinary cancer treatment choices available to their minority patients. These finding suggest a racial/ethnic disparity among oral cavity cancer patients and that prevention and treatment strategies should be tailored to different populations[5]. We conclude that the differences in results as shown in tables 1-4 are strongly associated with the culturally influenced habits and socioeconomic statuses of different racial groups.

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ORIGINAL ARTICLE

Patterns of Sleep and the Metabolic and Neurobehavioral Effects of Sleep Deprivation Reported by Medical Students

Ghazala Usman[1], Kiran Abbas[2], Misbah Zaheer[3], Tahir Mustansir Kaghazwala[4], Ashba Mushtaque[5] and M Rehan Alamgir[6]

ABSTRACT

Objectives: To determine the pattern of sleep among medical university students and to identify the medical university students' perceptions of the effects of sleep deprivation on their metabolism and daily performance
Methodology: A cross-sectional study was conducted to assess sleep duration, and its perceived metabolic and neurobehavioural effects on body using a self-reported sleep questionnaire. Sample was calculated to be 270. The students were inquired about their sleep habits, studies duration, routine before going to bed, caffeine intake, and routine during examinations. Data was analyzed using SPSS version 21.
Results: Our study reported that out of 270 participants, 96% (n=259) of individuals self-reported sleeping less than 7 hours per night and 13.7%(n=37) were found to be overweight. Furthermore, 81.6% (n=220) of individuals took at least one serving of caffeine daily, and 40% of students used internet for more than 5 hours which also had an additional effect on short sleep duration.
Conclusion: Many studies have shown that the direct effects of sleep deprivation are fatigue, irritability, and altered neurocognitive function. In our study, about 81.6% of students reported sleeping for even less than 6 hours and reported experiencing sleepiness, loss of interest in work, and weight changes after admission into the university. However, we could not find any remarkable weight changes. Therefore, it suggests that majority of medical university students studied in Karachi suffered from sleep deprivation and its after effects.

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علم طب کے طالبعلموں میں نیند کے معمولات اوران کی رائے میں کم خوابی سے ہونے والی جسمانی، عصبی اور مزاجی تبدیلیاں۔

مقصد: علم طب کے طلبہ وطالبات میں نیند کے معمولات جانچنا۔ علم طب کے طالبعلموں کی رائے میں کم خوابی کے ان کی ذہنی وجسمانی صحت اور تعلیم پر ہونے والے اثرات کا جائزہ لینا۔

طریقہ: ایک عمومی جائزہ تحقیق میں طالبعلموں کے خود بھرے ہوئے سوالنامے کے ذریعے نیند کے معمولات اور کم خوابی کے خود پر اثرات کے بارے میں ان کی رائے اکٹھی کی گئی۔ 270 کا گروہ بنایا گیا۔ طالبعلموں سے ان کی نیند کی عادات، پڑھائی کا دورانیہ، سونے سے پہلے کے معمولات، کیفین کا استعمال، اور امتحانات کے دوران معمولات کے بارے میں سوالات کیئے گئے۔ اعداد وشمار کو SPSS ورژن 21 پر جانچا گیا۔

نتائج: ہمارے مطالعے کے مطابق 270 میں سے 96 فیصد طالبعلموں نے ہر رات 7 گھنٹے سے کم سونے کا اعتراف کیا۔ 13.7 فیصد کا وزن بڑھا ہوا تھا۔ طالبعلموں میں سے 81.6 فیصد دن میں کم از کم ایک دفعہ کیفین کا استعمال کرتے تھے۔ اور 40 فیصد طالبعلم پانچ گھنٹے سے زائد انٹرنیٹ استعمال کرتے تھے جس کا اثر ان کی نیند کے اوقات پر پڑ رہا تھا۔

حاصلِ مطالعہ: اس تحقیق سے ثابت ہوا ہے کہ کم خوابی کے براہِ راست اثرات میں تھکن، بدمزاجی اور ذہنی وعصبی حالات میں تبدیلیاں شامل ہیں۔ ہمارے مطالعے کے مطابق تقریباً 81 فیصد طالبعلم چھ گھنٹے سے بھی کم سوتے تھے اور انہیں تھکن، بے وقت نیند، یکسوئی کی کمی اور کالج میں داخلے کے بعد وزن میں زیادتی کی شکایات تھیں۔ مگر وزن میں کوئی قابلِ ذکر تبدیلی نہیں پائی گئی۔ لہٰذا ہم یہ نتیجہ اخذ کر سکتے ہیں کہ کراچی میں علم طب کے اکثر طلبہ کم خوابی اور اس کے اثرات کا بڑی حد تک شکار ہیں۔

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INTRODUCTION

Adequate sleep is essential for the healthy development of brain and body and to regulate mental functions. Yet, it is the most ignored of all human necessities. Average sleep requirement of a young individual (18–25 years of age) is from 7 to 9 hours[1]. Adequate sleep is a prerequisite not only for relaxation but also for improving comprehension, analytical skills, and mental health especially during education years. Sleep deprivation is known to be associated with increased day time sleepiness, altered neurocognitive function, and fatigue[2]. Lack of sleep remains common in university going population, owing to hectic schedules,

peer pressure, excessive social gatherings, and opportunities for physical or leisure activities[4]. This affects their lives with increased daytime sleepiness, neurocognitive deficits, and mood and behavioural changes. Most evident effects are seen on higher cognitive functions like memory, problem solving, learning ability, and academic performance.[3]

Various studies report that short sleep duration is linked to decreased levels of leptin, glucose tolerance, insulin sensitivity, and increased levels of ghrelin affecting hunger, and appetite.[5-9] It also activates stress response leading to high cortisol in blood, inflammatory response activation, and hormonal disturbance[10]. Sleep is a vital physiological phenomenon which maintains the normal homeostasis in biochemical metabolism. Disturbance in this mechanism leads to metabolic and neuroendocrine abnormalities in the long run[3]. Poor quality of sleep in students is associated with increased health related issues, depression, fatigue, irritability, decreased concentration, weight gain, and memory and cognition disturbance leading to poor academic performance.[11,12]

Sleep deprivation is also associated with behaviours that are known to promote weight gain including low physical activity and unbalanced diet[13]. Recent studies have also shown that lack of sleep or inadequate amount of sleep is associated with weight gain[14].

In Pakistan, few studies have been carried out on this subject and only limited data is available correlating lack of sleep with psychomotor or behavioural aspects of life. Therefore, it was necessary to identify the after effects of sleep deprivation in young medical students.

METHODOLOGY

Signed consent forms were obtained from students at the beginning of the study. A self-administered questionnaire was designed after reviewing the literature on related topics. It was used to collect information on demography, their sleep, and daily routine.

Sample size

Sample size was calculated using open EPI software assuming the sleep deprivation frequency in university students to be 39.5%.[17] On confidence interval of 90%, sample size was 258. On adjusting the non-response rate of 5%, the sample size was calculated to be 270.

Study Population

Medical students (enrolled in public medical universities including Dow University of Health Sciences, Jinnah Sindh Medical University, and Jinnah Medical and Dental College). The students selected for this study were in the age group of 18–25 years. All the students who were selected for this study were free from physical disabilities, congenital diseases, and/or any diagnosed medical condition that might have potentially interfered with metabolism.

Data Items

Sleep Duration: This was assessed using the self-administered question i.e. "*How many hours per day do you spend sleeping?*"

Short sleep duration was defined as less than seven hours of sleep according to the definition of the National Sleep Foundation for adolescent population[1].

Participants were also inquired about the number of hours they spent on studies, internet, and social media. They were asked about their interest in work, cognitive function, and mood changes after inadequate sleep; whether they saw themselves as sleep deprived; and how they thought lack of sleep affected their lives. BMI was considered the parameter to assess perceived metabolic effects of sleep deprivation.

The cutoff of BMI was <18.5kg/m^2 for underweight; 18.5–25kg/m^2 normal range; 25–30kg/m^2 for overweight; and >30kg/m^2 as obese. It was fixed according to the definition of International Obesity Task Force (IOTF)[18].

Statistical Analysis

Data was analyzed using SPSS Version 21. Frequency and percentages were calculated for categorical variables. Mean and standard deviation were calculated for quantitative variables. P-value <0.05 was taken as statistically significant.

RESULTS

A total of 270 students selected from different public and private medical institutions participated in the study, out of whom 68% (n=183) were females and the remaining 32% (n=87) were males.

According to our study, 96% (n=259) of individuals were found to be sleep deprived according to the definition of National Sleep Foundation for adolescent population[1] i.e. (sleep of less than 7 hours per day). Total 45.4% of students were not satisfied with their sleep duration and considered themselves sleep deprived, 41.8% reported that they feel they need more sleep when they wake up in the morning, and 15.5% reported feeling drowsy during the day. As many as 59% reported feeling sleepy at work during the day due to lack of sleep. A total of 51.6% students reported taking a nap of 1 to 2 hours during the day however, they still could not complete the 7–9 hours requirement of sleep per day as recommended by NSF.

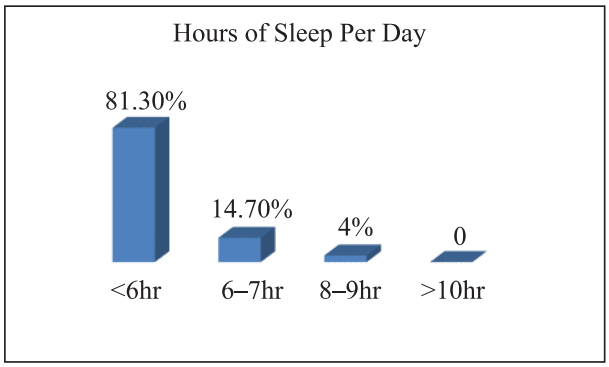

Figure No. 1

Analysis showed that approximately 64% felt irritable the next day if they could not sleep well and 50% of individuals had noticed that they could not maintain interest in their everyday activities. Total 68.5% students shared that sleep deprivation was causing academic loss to them as they felt sleepy or suffered memory and concentration problems. About 70% agreed that a good night's sleep improved their class performance.

Data analysis showed that 62.22% (n=177) spent more than two hours on studies whilst 32.2% (n=87) of individuals spent more than three hours daily and 2.2% (n=6) spent about five hours every day on studies in addition to the time spent at the university. This shows that the number of hours spent on studies might have a direct effect on sleep deprivation. As many as 47.3% reported that their sleep duration decreased to less than four hours during exams.

Another factor that contributes to sleep deprivation is internet usage especially social media during sleep hours. Forty percent students admitted using social media/listening to music/watching TV before going to sleep.

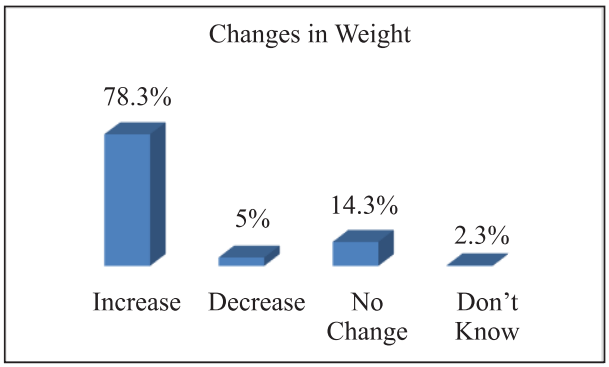

Figure No. 2

When inquired about the changes in weight, 78.3% (n=212) of participants shared noticing a recent increase in their body weight after joining classes. The results are shown in Figure no.3.

The Body Mass Index (BMI) of 13.7% (n=37) respondents were found to be greater than 25kg/m^2, who were subsequently termed overweight according to the definition of International Obesity Task Force (IOTF), while 20.6% (n=56) were found to be underweight. The results are shown in Figure no.3.

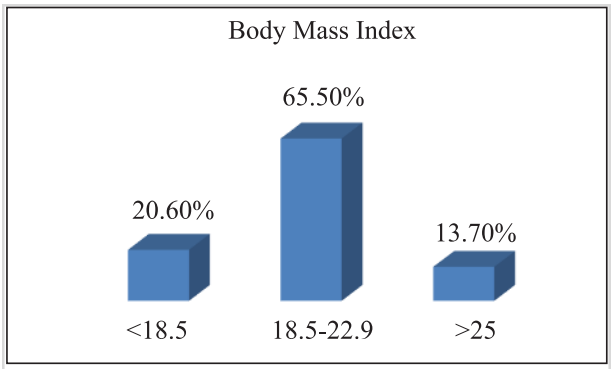

Figure No. 3

About 81.6% (n=220) individuals admitted consuming energy drinks. Of these, caffeine was the most common one which the respondents reported using daily in one or the other form. Out of these, 34% (n=92) of individuals had had at least one serving of caffeine daily, 28.3% (n=76) of participants had at least two servings daily whilst the remaining 19.3% (n=52) of individuals had more than two servings of caffeine daily in any form like tea, coffee, or energy drinks. Approximately, 60% (n=162) of our sample population preferred tea as a source of caffeine, while 27% (n=73) preferred soft drinks, and 13% (n=35) preferred coffee. The results are summarized in Figure No. 4.

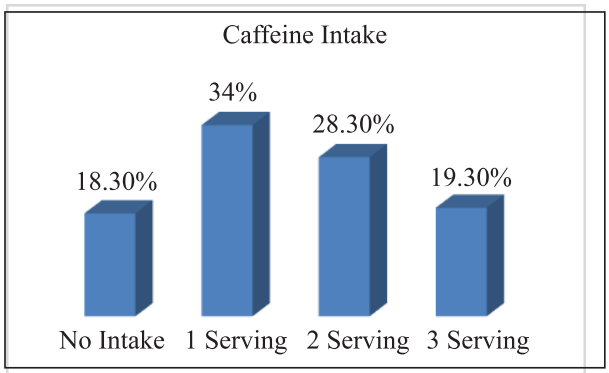

Figure No. 4 Number of servings per day

DISCUSSION

A healthy lifestyle includes a good sleeping routine. Human beings spend almost one-third of their lives sleeping, and adequate sleep is essential for their health and wellbeing[19,20]. A survey showed about only 20% of adolescents reported getting a healthy 8-hours sleep[24]. Similarly, 96% of individuals in our study were found to be sleep deprived. The same study described the factors associated with sleep deprivation to be caffeine consumption and multitasking but technology use was not found directly linked with sleep deprivation. Our

population showed somewhat similar results as 81% were consuming caffeine. Workload was also a contributing factor as 47% reported sleep duration of maximum four hours during exams. However, our study showed that about 40% respondents admitted using social media during rest hours. Studies have shown technology use during night decreases or delays melatonin production due to the bright light of the devices used[21].

Caffeine also alters the chemicals in the brain and increases alertness but its regular use affects the normal homeostasis of sleep[25,26]. Our findings demonstrate that, despite feeling the need to sleep, students stay awake late at night to use the internet aided by caffeinated energy drinks. Subsequently, excessive daytime sleepiness and lack of concentration was found in about 50% of our study participants. About 71% students also reported suffering academic losses attributable to the lack of interest reported by 68% of students, which may be due to the altered metabolism of adenosine in brain caused by lack of sleep[22,23].

Our analysis showed that at least 81.6% respondents took one serving of caffeine daily in the form of tea, coffee, and soft drinks. It is also a known fact that caffeine causes decreased total sleep time, frequent awakening, shortening of deep sleep time, and increase in light sleep. Alongwith caffeine, exam stress and increasing use of social media and technology were major factors affecting sleep. About 60% reported feeling sleepy during regular activities and 51% took a daytime nap which also disturbed their performance. These results emphasize the importance of proper sleep duration and restricted use of caffeine for healthy sleep. Many studies have also linked weight gain to lack of sleep[6,7] but in our study only 13% of respondents were found to be overweight. Although 78% of students reported weight gain after getting into university, these results cannot establish a direct relation of sleep deprivation and weight gain.

Other problems arising from poor sleep routine are psychomotor disturbances such as agitation, irritability, and interest loss reported by 64% of individuals. Regardless of the cause and effect relationship, given the existing evidence, encouraging adequate sleep among this age group is important to improve neurocognitive and psychomotor performance.

Study limitation

There are many limitations of this study which may be improved by other researchers. First, the study population selected for this research was not as large as other researches conducted on this topic throughout the world. The cross-sectional study precludes the establishment of causal relationship. The quality of sleep was also not measured. Another limitation was that no difference between sleep duration on weekdays and weekends was examined.

CONCLUSION

The current study confirms that young people are getting less sleep than recommended. This short sleep duration affects their memory, mental alertness and academic performance, causing irritability, anxiety, and confusion. Students who are sacrificing their sleep are in fact playing with their physical as well as mental health. Good sleep routine can help them improve their functional capabilities and productivity.

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References should be numbered consecutively in the order in which they are first mentioned in the text. Identify references in text, tables, and legends by Arabic numerals in parentheses. References cited only in tables or in legends to figures should be numbered in accordance with the sequence established by the first identification in the text of the particular table or figure.

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- Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications—International Committee of Medical Journal Editors

ORIGINAL ARTICLE

Pattern of Maxillofacial Injuries due to Motorcycle Related Road Traffic Accidents at A Tertiary Care Hospital in Karachi, Pakistan

Faisal Hameed[1], Waheed Gul Shaikh[2], Irfan Ali[3] and Tahira Hanif[4]

ABSTRACT

Objective: To determine the frequency and pattern of maxillo-facial injuries related to motorcycle accidents and to find out the association of helmet use and maxillo-facial injuries

Methods: Two years (January 2014 - December 2015) retrospective data of maxillofacial trauma patients was collected from the department of Oral & Maxillofacial Surgery of Civil Hospital Karachi (CHK). Analysis, method?

Results: A total of 316 trauma patients were brought to the hospital during the study period. Out of these, 2.5% were children and 6.6% were adolescents. The majority 84.5% was aged 20 to 40 years, 5.4% were between 41 and 60 years and 1% were above 60 years of age. Males comprised 90.5% of the total. Total 8.9% had higher education while 15.2% were illiterate. Frequency of motorcyclists among the study patients was 84.2%. Out of these, 67.4% were drivers while 16.8% were passengers. Only 8.9% were wearing helmets. Soft tissue injuries were reported in 61.4% (194), 8.2% had dentoalveolar fractures, 47.78% mid-face fractures, 56% mandibular fractures, 61% isolated mandibular fractures and 39% presented with complex fractures. Twenty-nine percent had ZMC fractures, 92.6% were isolated ZMC, 9.5% had Le Fort II Fractures and 6% Le Fort III fractures; 5% had frontal sinus and 3.5% had pan-facial fractures. Significant relation was found between motorcyclists and helmet usage ($p<0.05$).

Conclusion: Road Traffic Accidents are rising day by day in the developing countries. The causes include low use of safety devices, poor infrastructure, and rising number of vehicles on the roads. This study shows that mostly young men in their 20s and 30s are involved in these accidents. In more than 50% of these accidents, the mandible is fractured. The impact of this kind of injury on the young patients' quality of life is significant and traumatic. These fractures can be prevented by promoting the use of safety methods (mandatory wearing of crash helmets), improving road infrastructure, and regulating the number of registration of motorcycles. Safety regulations regarding helmet use need to be enforced strictly and awareness needs to be raised among the masses regarding safe use of motorcycles.

Key words: Road Traffic Accidents, Motorcycle Related Injuries, Maxillofacial Trauma

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عنوان: موٹر سائیکل حادثات کے نتیجے میں لگنے والی منہ اور جبڑے کی چوٹوں کا جائزہ

مقصد: موٹر سائیکل کے حادثوں کے نتیجے میں لگنے والی منہ اور جبڑے کی چوٹوں کی تعداد اور ان چوٹوں اور ہیلمیٹ کے استعمال کا تعلق معلوم کرنا۔

طریقہ: یہ عمومی جائزہ سول ہسپتال کراچی کے شعبہ برائے منہ، جبڑا و دہن سرجری میں کیا گیا جس میں دو سال (جنوری 2014-دسمبر 2015) میں آنے والے مریضوں کا ڈیٹا ریکارڈ سے حاصل کیا گیا۔

نتائج: اس مطالعے کے دوران 316 ٹریفک حادثے کے مریضوں کو ہسپتال لایا گیا۔ ان میں سے 84.2 فیصد موٹر سائیکل جن میں سے 67.4 فیصد ڈرائیور تھے اور 16.8 فیصد مسافر صرف 8.9 فیصد نے حادثے کے وقت ہیلمٹ پہنا ہوا تھا۔ اس مطالعے سے معلوم ہوتا ہے کہ زیادہ تر 20 سے 30 سال عمر کے نوجوان موٹر سائیکل حادثوں کا شکار ہوتے ہیں۔ اور پچاس فیصد سے زائد کیسز میں نچلے جبڑے پر چوٹ آتی ہے۔

حاصلِ مطالعہ: اس تحقیق سے معلوم ہوا کہ نوجوان مریضوں کی زندگی پر ایسی چوٹوں کا گہرا اثر ہوتا ہے۔ ہیلمیٹ کے استعمال سے ایسی چوٹوں سے بچا جا سکتا ہے۔ ہیلمیٹ کے استعمال سے متعلق قوانین کو سختی سے لاگو کرنے کی ضرورت ہے اور عوام میں اس سے متعلق شعور پیدا کرنا ضروری ہے۔

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INTRODUCTION

Human face is anatomically divided into three segments that is tripartite composition[1,2] . These segments, from inside to outside, are (1) hard tissue, (2) soft tissue (muscles fats and subcutaneous connective tissue, and (3) skin superficial layer[2].

Presently in western countries, assault is becoming the most frequent cause of facial trauma[3] but in the developing world, road traffic accidents are among the

most common causes of maxillofacial fractures[3-5]. A huge difference has been observed between developed and developing countries that may be because of stringent implementation of laws and regulations in developed countries. As many as 39%[4] to 54%[3] of all maxillofacial traumas in Pakistan are related to road traffic accidents[6].

Two-wheel vehicle (motorcycle) is considered as the riskiest vehicle ever due to its design, balancing issues, and absences of installed safety devices like airbags. Absence of a safety vessel around the driver and the passenger make both vulnerable to crashes during collision or slipping[7]. Many other risk factors compound the situation including the condition and nature of the roads, traffic flow, poor visibility at night as well as the human factors: the attitude and behaviour of motorcyclists on the roads, speeding, ignoring safety measures like wearing crash helmets and protective clothing, alcohol and substance abuse prior to riding[8].

In Pakistan, comprehensive information about the epidemiological characteristic of this problem is needed in view of the great impact of maxillofacial traumatic injuries on a person's quality of life. This study would help to identify the anatomical site of fractures and associated injuries, to evaluate the frequency of maxillofacial trauma, the incidence of fractures while riding a motorcycle, and the pattern of maxillofacial injuries sustained by helmet-wearing or non-helmet-wearing motorcyclists.

METHODOLOGY

Retrospective data of maxillofacial trauma patients, irrespective of age and gender was included and patients having pathological fractures from other causes were excluded from the study. Patients admitted at the department of oral and maxillofacial surgery of Civil Hospital Karachi (CHK), a tertiary care teaching hospital, were included in study. The duration of the study was two years (from January 2014 to December 2015). All data collected was consequently processed and analyzed using the Statistical Package for Social Sciences (SPSS) version-17 for statistical analysis and descriptive variables.

RESULTS

Total 316 trauma patients registered with maxillofacial department of Civil Hospital, Karachi during the study period. Eight of the patients (2.5%) were children and 21 (6.6%) were adolescents. Most of the patients 84.5% (267) were between the ages of 20 to 40 years. Total 5.4% patients (17) were middle aged 41-60 years and 1% (3) were older than 60 years of age. Over all, 90.5% (n=286) patients were male. Twenty-eight patients (8.9%) had education higher than intermediate while 15.2% were illiterate. Frequency of motorcyclists among study patients was 84.2%(n=266), out of whom 80%(n=213) were drivers while 20% (n=53) were passengers. All those riding as passengers on the motorcycles, were not wearing helmets while only 11%(n=28) of drivers were wearing helmets. Percentage of road traffic accidents during the day was 58% and 42% in the night.

There were 61.4%(n=194) patients with soft tissue injuries out of whom only 2.6% (n=5) patients had only soft tissue injuries without facial fractures and were admitted to the department. Twenty-six patients (8.2%) had dentoalveolar fractures. A total of 151 fracture were reported in the midface region (48%). Mandible, the lower jaw bone, was fractured in 177 patients (56%). Out of these, 62%(n=109) were isolated mandibular fractures and 39% (n=69) were complex fractures. Total 29%(n=91) had ZMC, out of whom 92.6%(n=75) had isolated ZMC fractures and others were concomitant with other fractures. As many as 9.5%(n=30) had Le Fort II Fractures and 6%(n=19) had Le Fort III fractures. Five percent (n=16) had frontal sinus fractures and 3.5% (n=11) patients had sustained pan-facial fractures.

Sixteen patients (5%) were managed conservatively, 45 patients (14%) were managed with closed reduction ± MMF while 250 (79%) patients were managed with open reduction and internal fixation. Five patients (2%) had to go through both ORIF with MMF. Significant relation of safety helmets was checked with mandibular fractures (complex and compound). Midface fractures (Le Fort I, II, III, and ZMC fractures), pan-facial and frontal bone fractures????. No significant relation of the use of safety helmet was found with the above-mentioned variables except with ZMC fractures which was found to be significant (p= 0.05). Le Fort I and Le Fort II fractures were more common in bikers as compared to three-wheel and four-wheel vehicle users (p= 0.05).

DISCUSSION

Maxillofacial region involves soft and hard tissues forming the face extending from frontal bone superiorly to the mandible inferiorly[9]. The face, being the most exposed part of the body, is particularly prone to trauma[10]. Facial traumatic insults include soft and hard tissues including teeth, alveolus, jaw bones, and specialized structures such as eyes, ears, and nose.

Table No. 1: Detailed Distribution of Maxillofacial Injury Patients

		Gender		Qualifications		Victim status			Vehicle Status		Safety device	
		Male	Female	=Inter	=Graduate	Driver	Passenger	Pedestrian	Bikers	Others	Helmet/ seat belts	NO safety device
Gender	Male	286 (90.5%)	30 (9.5%)	262 (82.9%)	24 (7.6%)`	237 (75%)	36 (11.4%)	13 (4.1%)	246 (77.8%)	40 (12.7%)	2 (0.6%)	28 (8.9%)
	Female			26 (8.2%)	4 (1.3%)	0 (0%)	24 (7.6%)	6 (1.9%)	20 (6.3%)	10 (3.2%)	28 (8.9%)	2 (0.6%)
Qualifications	=Inter	262 (82.9%)	26 (8.2%)	288 (91.1%)	28 (8.9%)	216 (68.4%)	55 (17.4%)	17 (5.4%)	246 (77.8%)	42 (13.3%)	30 (9.5%)	258 (81.6%)
	> Inter	24 (7.6%)	4 (1.3%)			21 (6.6%)	5 (1.6%)	2 (0.6%)	20 (6.3%)	8 (2.5%)	2 (0.6%)	26 (8.2%)
Victim status	Driver	237 (75.0%)	0 (0.0%)	216 (68.4%)	21 (6.6%)				213 (67.4%)	24 (7.6%)	29 (9.2%)	208 (65.8%)
	Passenger	36 (11.4%)	24 (7.6%)	55 (17.4%)	5 (1.6%)	237 (75%)	60 (19%)	19 (6%)	53 (16.8%)	7 (2.2%)	3 (0.9%)	57 (18.0%)
	Pedestrian	13 (4.1%)	6 (1.9%)	17 (5.4%)	2 (.6%)				0 (0.0%)	19 (6.0%)	0 (0%)	19 (6.0%)
Vehicle Status	Bikers	246 (77.8%)	20 (6.3%)	246 (77.8%)	20 (6.3%)	213 (67.4%)	53 (16.8%)	0 (0.0%)	266 (84.2%)	50 (15.8%)	32 (10.1%)	234 (74.1%)
	Others	40 (12.7%)	10 (3.2%)	42 (13.3%)	8 (2.5%)	24 (7.6%)	7 (2.2%)	19 (6.0%)			0 (0%)	50 (15.8%)
Safety device	Helmet/ seat belts	30 (9.5%)	2 (0.6%)	30 (9.5%)	2 (0.6%)	25 (7.9%)	5 (1.6%)	2 (0.6%)	28 (8.9%)	4 1.3%)	32 (10.1%)	284 (89.9%)
	NO safety device	256 (81.0%)	28 (8.9%)	258 (81.6%)	26 (8.2%)	212 (67.1%)	55 (17.4%)	17 (5.4%)	238 (75.3%)	46 (14.6%)		

Table No. 2: Distribution of Mandibular Fracture with Respect to Complexity of Fracture

		Isolated / Complex Mandibular Fracture		
		No Fracture	Isolated Mandibular Fracture	Complex Mandibular Fracture
Mandible	No Fractures	140 44.3%		
	Fracture		111 35.1%	65 20.6%
Dentoalveolar Region	No Injury	130 41.1%	102 32.3%	58 18.4%
	Dentoalveolar Injury	10 3.2%	9 2.8%	7 2.2%
Angle of Mandible	No Fractures	140 44.3%	91 28.8%	17 5.4%
	Angle Fracture		20 6.3%	48 15.2%
Parasymphysis Region	No Fractures	140 44.3%	60 19.0%	17 5.4%
	Parasymphysis Fracture		51 16.1%	48 15.2%
Mandibular Condylar	No Fractures	140 44.3%	71 22.5%	37 11.7%
	Condyle Fracture		40 12.7%	28 8.9%

Table No. 3: Distribution of Maxillary Fracture with Respect to Complexity of Fracture

		Isolated / Complex Midface Fracture		
		No Fracture	Isolated Midface Fracture	Complex Midface Fracture
Midface Fractures	No Fractures	165 52.2%		
	Fracture		135 42.7%	16 5.1%
Le Fort I	No Fractures	165 52.2%	123 38.9%	14 4.4%
	Le Fort I Fracture		12 3.8%	2 .6%
Le Fort II	No Fracture	165 52.2%	107 33.9%	14 4.4%
	Le Fort II Fracture		28 8.9%	2 0.6%
Le Fort III	No Fractures	165 52.2%	120 38.0%	12 3.8%
	Le Fort III Fracture		15 4.7%	4 1.3%
ZMC Fracture	No Fractures	165 52.2%	55 17.4%	5 1.6%
	ZMC Fracture		80 25.3%	11 3.5%

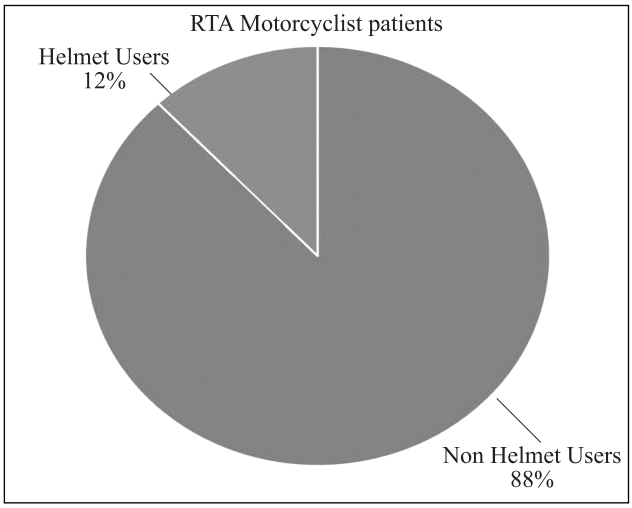

Figure 1: Frequency of Helmet Usage Among Motorcyclist

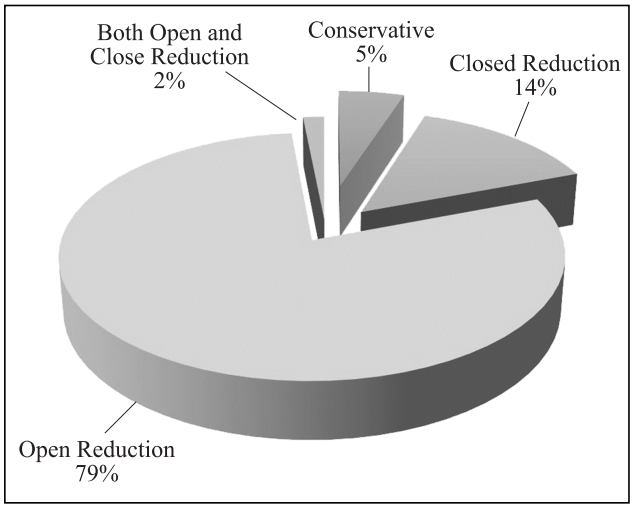

Figure 2: Distribution of Treatment Provided to Maxillofacial Injury Patients

ncidence of maxillofacial trauma is significantly increasing in Pakistan both in severity as well as frequency[4]. The causes of maxillofacial trauma vary and include RTAs, interpersonal violence, falls, sports and missile injuries[11-13]. Maxillofacial injuries are the most commonly attributed to Road Traffic Accidents[14,15]. Third world countries have issues in implementation of traffic regulations strictly in addition to low-level infrastructure and deficiencies in urban transport network. This leads to the increased incidence of motorized vehicle injuries as motorcycle is considered a convenient and cheap transport vehicle for goods and pillion passengers[16]. Face is a prominent part of body which is exposed while riding a motorcycle, if not protected with helmet. Absence of helmet makes both driver and passenger vulnerable to maxillofacial injuries[17,18].

Asian Countries have higher dependency on motorcycles because they are inexpensive, readily available, and easy to maintain leading to rising numbers of their registration[19] (Motorcycles registrations comprise 95%[20]. 67%[21], and 63%[21], of all registered vehicles in Vietnam, Taiwan, and Malaysia, respectively). By contrast, , motorcycling is undertaken as a form of recreation and leisure in the developed countries, for example in the United States of America, motorcycles comprise 2% of registered motor vehicles[22].

In western industrialized countries, 65 to 67% of maxillofacial trauma is caused by Road Traffic Injuries (RTAs)[23,24]. Chinese population shows a low incidence of 31%[25]. While in Pakistan, RTAs contribute to about 56% of maxillofacial trauma[6]. Obekue et al[26] reported motorcycle crashes as the second commonest cause (27.2%) of maxillofacial injuries in 312 patients studied in Nigeria. Ogini et al[7] reported that injuries to soft tissue were the most prevalent, followed bony and dental injuries (38%,15%) respectively in 221 studied patients also in Nigeria.

Motorcycle is considered to be a dangerous motorized vehicle due to its nature and design e.g. absence of airbags to reduce impact in the event of a collision and therefore riders and passengers alike are vulnerable to road traffic crashes[7]. Risk factors include the condition and nature of the roads, traffic flow, poor visibility at night while human factors include the attitude and behaviour of motorcyclists on the roads, speeding, ignoring safety measures like wearing of crash helmets and protective clothing, alcohol and substance abuse prior to riding[8].

RTAs are a global health problem and the leading cause of maxillofacial trauma worldwide[26]. The pattern and presentation of maxillofacial injuries have been studied in many parts of the world with varying results. Rodrigues et al. carried out a cross-sectional study in Brazil and reported the RTA in 45.7% traumas resulted with motorcycle crashes and 18.9% were mainly responsible for RTA[27].

In Nigeria, various studies, which are mainly hospital based, have documented the road traffic accidents as the main reasons for maxillofacial injuries all over the country except for in the North zone where assault is the main cause[26].

South Asia is a region where maxillofacial trauma resulting from RTA has been rising steadily over the past decades and is expected to increase by two and half times in the next two decades[19].

The demographic pattern in this study is similar to previous studies by Oginni et al[7], Oginni et al[28]; Iribhogbe, P.E & Odai[29]. The peak incidence 0f maxillofacial injuries is in the second and third decades of life i.e. victim is aged between 21 and 40 years.

The most prominent mechanisms responsible for crashes were found to be head on collisions, slips, and speeding. The reasons could be low maintenance of roads, inexperienced driving, and disobeying traffic rules. Another important finding was the low prevalence of helmet use at only 8.9% which is again almost similar to Oginni et al[7]. The relevant authorities should enforce the use of helmets to reduce maxillofacial injuries.

CONCLUSION

Road traffic Accidents are rising in the developing countries and becoming a leading cause of Maxillofacial Injuries. The present study provides a relevant pattern and outcome of victims involved in these injuries with the highest occurrence reported in the younger population. The main contributory factor is accidents involving motorcyclists with low use of safety devices.

Road Traffic Accidents are predictable and preventable provided the basic knowledge and awareness regarding safety measures and traffic rules is given to people. More research is needed to implement the measures that have reduced RTAs in developed countries like regulating the public transportation systems, enforcing safety registrations, and restrictions on mobile-phone use while driving. It is imperative that the government should make this issue a priority. Registration of motorcycles should be reduced to match the infrastructure and traffic load of cities.

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REVIEW ARTICLE

Comparison of Efficacy of Metformin against Flaxseeds and Nigella Sativa in Type 2 Diabetes

Kausar Aamir[1], Arfa Azhar[1], Fatima Abid[2], and Muhammad Azhar Mughal[3]

ABSTRACT

Background: Diabetes is a metabolic and endocrine disorder characterized by hyperglycemia. It will affect 350 million people by the year 2030. There are many ways of treating diabetes in herbal and modern medicine. Commonly used herbal medicines are flaxseed and Nigella sativa for their blood glucose lowering properties, while metformin is the commonly used conventional medicine. This review includes 150 articles comparing the efficacy of these commonly used drugs .

Objective: To compare the efficacy of Metformin against flaxseeds and Nigella sativa in type 2 diabetes

Methodology: A systematic review was done and literature search was conducted from year 2006 to 2016 using relevant keywords i.e. diabetes, hypoglycemia, metformin, flaxseed, nigella sativa. A total of 50 articles were selected for the study (17) of metformin. Randomized control trials—8 for dose comparison, 4 as monotherapy, and 5 with the combination of insulin with metformin—were pooled (31,474 patients) in the final analysis.

Data sources: Medline, Embase, Lilacs, Cochrane library, Pubmed, Web of science

Results: Extensive decrease was found in HbA1C levels under large doses of metformin as compared to small doses, with no striking increase in side effects (16). Descriptive and analytical articles of flaxseed (n=1450 patients) showed valuable differences in blood sugar and HbA1C levels in patients using different doses (17). Eligible articles of Nigella sativa (n=1980 patients) showed obvious differences in blood sugar levels, while long standing supplementation of Nigella sativa corrected glucose homeostasis and augmented the antioxidant effects in type 2 patients treated with oral hypoglycemic drugs.

Conclusion: It has been proven that flaxseed and Nigella sativa are very effective with minimum side effects but it also needs further scientific research.

Key words: Diabetes, hypoglycemia, metformin, flaxseed, nigella sativa,

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ذیابیطیس قسم 2 میں میٹ فارمن کی اثر پذیری کا کلونجی اور السی کے بیجوں کے اثرات سے تقابلی جائزہ۔

پس منظر: ذیابطیس ایک میٹابولک اور اینڈوکرائن بیماری ہے جس میں خون شکر کی مقدار بڑھ جاتی ہے۔ سال 2030 تک یہ عارضہ 350 ملین افراد کو لاحق ہوگا۔ جدید اور نباتیاتی طب میں ذیابیطس کے علاج کے کئی طریقے ہیں۔ کلونجی اور السی کے بیج نباتیاتی طب میں عام طور سے استعمال ہوتے ہیں کیونکہ ان میں خون میں شکر کم کرنے کی خصوصیات ہیں۔ جبکہ جدید طب میں میٹ فارمن استعمال کی جاتی ہے اس تقابلی جائزہ میں 150 مضامین شامل ہیں جن میں ان عام ادویات کے اثرات کا جائزہ پیش کیا گیا۔

مقصد: ذیابیطس قسم 2 میں میٹ فارمن کے اثرات کا کلونجی اور السی کے بیجوں کی اثر پذیری کا تقابل

طریقہ: سال 2006 سے سال 2016 تک چھپنے والے مضامین میں مندرجہ ذیل الفاظ کی ایک منظم طریقہ سے تلاش کی گئی: ذیابیطس، خون میں شکر کی کمی، میٹ فارمن، السی کے بیج، کلونجی۔ میٹ فارمن کے بارے پچاس مضامین میں (31,474) مریضوں کا ڈیٹا اکٹھا کیا گیا۔

نتائج: میٹ فارمن کی کم مقدار کی نسبت زیادہ استعمال کرنے کی صورت میں HbA1C خون کے ٹیسٹ میں خون میں شکر کی مقدار بہت حد تک کم پائی گئی اور زیادہ مقدار کے کوئی خاص ذیلی اثرات بھی نہیں پائے گئے۔ السی کے بیجوں کے اثرات کا جائزہ لینے والے مضامین میں مختلف مقداریں استعمال کرنے والے مریضوں میں خون میں شکر اور HbA1C کے نتائج میں بہت فرق پایا گیا۔ کلونجی کے بارے میں لکھے گئے مضامین میں کلونجی کا استعمال کرنے والے مریضوں کے خون میں شکر کی مقدار میں واضح فرق بتایا گیا۔ طویل عرصے تک کلونجی استعمال کرنے والے مریضوں میں شکر کو انسولین کے ذریعے کنٹرول کرنے کے عمل میں پائی جانے والی خرابی دور ہوگئی جبکہ خون میں شکر بڑھانے والی ادویہ کا استعمال کرنے والے ذیابیطس قسم 2 کے مریضوں کے خون میں اینٹی آکسیڈنٹ کی مقدار کلونجی کے مسلسل استعمال کے بعد بڑھی ہوئی پائی گئی۔

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INTRODUCTION

Diabetes mellitus

Diabetes is a metabolic disease characterized by hyperglycemia due to lack of insulin release, insulin action, or both. Long-term hyperglycemia of diabetes is linked to failure and lack of various organs, particularly eyes, kidneys, nerves, and blood vessels in the heart[1].

Significance

To see the control of blood sugar level and complications of diabetes using flaxseed and Nigella sativa

Aim and Objective

To compare and evaluate the efficacy of metformin against flaxseed and Nigella sativa (black seeds) in type 2 diabetes

Prevalence

In 2016, the global prevalence of diabetes in adults (20–79 years) was 6.4%, approaching 285 million adults in 2010, while an increase of up to 7.7% and 439 million adults is expected between 2010 and 2030. By 2030, the number of adults with diabetes mellitus is expected to rise by 69% in the developing countries and by 20% in the developed countries[2].

Metformin

Metformin is the only biguanide accessible in most parts of the world. Its main effect is to reduce the production of liver glucose and to decrease fasting blood glucose. Normally, metformin monotherapy will reduce HbA1C by 1.5 percentage points. It is usually well accepted, with the most frequent gastrointestinal adverse effects. Metformin monotherapy is typically not accompanied by hypoglycemia and has been utilized safely in patients with pre-diabetes having increased blood glucose levels. The major non-glycemic outcome of metformin is weight consistency or reduction in contrast to many of the other drugs that lower blood glucose[3].

Metformin is the most widely prescribed drug used as the first-line management of type 2 diabetes in combination with diet and exercise. It exerts its pharmacological effect on blood sugar level by:

- Inhibition of liver glucose production (gluconeogenesis)
- Increased uptake of glucose by peripheral tissues
- Reduction of intestinal absorption of glucose, leading to a reduction of postprandial hyperglycemia.

Collectively, this action results in a reduction in the level of glycosylated HbA1C, the reduction in low density lipoprotein, and a boost in high-density lipoprotein cholesterol. It also improves insulin sensitivity[6].

Metformin increases insulin kinase activity by insulin mediated tyrosine receptor which activates the insulin signaling pathways. Therefore, metformin directly and indirectly affects liver and muscles thus improving hepatic and peripheral sensitivity of insulin.

It mainly suppresses gluconeogenesis by activating insulin's effect, decreasing hepatic extraction of various substrates (e.g. lactate), and antagonizing the effects of glucagon. It is also effective in enhancing the functional properties in glucose sensitive bodies. The excessive cellular uptake of sugar is associated with maximum activity of glycogen synthase and storage of glycogen turnover mainly in visceral beds[8].

Metformin alone is often insufficient to maintain glycemic targets in view of the progressive failure of the beta cells and increasing insulin resistance[7].

Flaxseed

The Latin name of flaxseed is derived from a word that means "very useful". It has many useful components with numerous health benefits which is why flaxseed has received widespread attention in the field of research on diet and disease. Each part of the plant is used commercially. Its rich content of á-linolenic acid (ALA) is drawing attention as a functional food ingredient. Flaxseed is the main dietary source of lignan, in which the glycosides of secoisolariciresinol (SECO) i.e. secoisolariciresinol diglucoside (SDG) and mataresinol (MAT) are the key components.

Flaxseed contains SECO as diglucoside and part of an ester-linked complex or oligomer containing 3-hydroxyl-3-methylglutaric acid and a rich source with highest content of omega-3 fatty acids (alpha-linolenic acid). Flax is seen as a beneficial food and as it contains alpha-linolenic acid, lignans, and polysaccharides[10].

The main lignan linseed, is SDG as an antioxidant, function of seco and enterodiol is advanced than vitamin E. After intake, vegetable lignans are changed into enterodiol and enterolactone by human intestinal bacteria. These metabolites are liable for natural effects in humans[9]. Linseed oil is SDG/yield or contain the basis of omega-3 fatty acids and release of arachidonic acid from the erythrocyte membrane and also on possible reduction of hyperhomocysteinemia[17].

There is evidence that flaxseed reduces insulin resistance by regulating oxidative stress in overweight individuals. Intake of flaxseed decreases sugar limits and enhanced insulin sensitivity in a normal diet among obese or overweight people with prediabetes[18]. Flaxseed significantly decreases postprandial blood glucose[21]. Lignin supplements on diabetes have been documented that SDG appreciably prevented or postponed the inception of diabetes and improved glycemic control with type 1 diabetes[22], and type 2 diabetes as well[23].

In diabetes mellitus, hyperglycemia causes an increase in the production of free radicals such as reactive oxygen species (ROS) from all tissues of protein glycosylation and glucose auto-oxidation[11]. Elevated levels of oxidative radicals and the decline of antioxidant systems can lead to weakening of cell enzymes and various organelles, increased lipid peroxidation and development of diabetes mellitus[12].

In addition, diabetes mellitus increases inflammation by the stimulation of arachidonic acid cell membranes that turns into active cellular mediators such as thromboxanes, prostaglandins, and leukotrienes[13], in addition to elevation of the homocysteine level which is a good biomarker for risk of diabetic complications. Higher levels of homocysteine are linked to retinopathy, nephropathy, neuropathy, and cardiovascular diseases[14].

Hyperhomocysteinemia has been documented in patients with vascular disorders[15]. Several studies have indicated that increased homocysteine levels are well defined risk factors for thrombosis and atherosclerosis[16]. Lignans of flaxseed are organically active so have anti-cancer, antiviral effects and can defend against estrogen-allied illnesses like pain, menopause, and osteoporosis. Linseeds have a lot of beneficial and helpful effects on health like reduced atherosclerosis events, decreased risk of cardiovascular diseases, diabetes mellitus, arthritis, autoimmune and neurological disorders, and fall of blood cholesterol and helps in sustaining standard performance of the immune system.

Nigella sativa

It is a medicinal herb of religious importance for Muslims that has been described as ‘a treatment for all diseases except for death’ (Prophetic Hadith)[26] and as "the blessed seed" (*habatul baraka*)[27]. Seeds are the main curative component; oil extracted from the seeds (black cumin oil or black seed oil) has some bioactivity[28]. Scientific literature reveals that the plant has antioxidant activity due to the presence of oxidative radicals, concentrated in the fixed or essential oil including tocopherols, phytosterols, polyunsaturated fatty acids, thymoquinone, P-cymene, carvacrol, T-anethol and 4-terpineol[29].

Significant hypoglycaemic effects were seen when 2.5 ml of Nigella sativa oil was given twice daily for six weeks in patients with metabolic syndrome[37]. A powerful antioxidant effect of Nigella sativa and its constituents contributes to its hypoglycemic effect[39-41,43,45]. Increasing antioxidant potency in diabetics could lead to the preservation of â-islet cells and cellular mechanism involved in glucose homeostasis. Numerous histopathological studies on different species with different diabetic models have reported the preservation of â-cells in animals treated with N. sativa and its derivatives[38,40-42,44-46] as were expected in all the foregoing studies. The protection of islet cells was related with rise in insulin as an anti-oxidant effect of Nigella sativa. Ethanolic extract of Nigella sativa has been reported to induce insulin-like stimulation of glucose uptake in skeletal muscle and adipocytes cells after 18 hours of treatment[47].

The anti-diabetic nature of the Nigella plant is a result of insulinotropic action, antioxidant properties, inhibition of hepatic gluconeogenesis, antioxidant effects due to inhibition of eicosanoid generation, and lipid peroxidation of membrane. N. Sativa improves insulin sensitivity by avoiding the intensity of oxidative stress. It is seen that Nigella improves insulin sensitivity in peripheral tissues and increases its secretion in â-cells of islets of pancreas, since it has been proposed that N. Sativa has the ability to restore the structural integrity of pancreatic â-cells in diabetic patients. Some histopathological and immuno-histochemical studies performed on rats to investigate the architecture of pancreatic islets, observed that N. sativa has the ability to restore the integrity of the â-cells of the pancreas. Studies have shown that Reactive Oxygen Species (ROS) are liberated by chronic exposure to hyperglycemia and ROS are known to be neurotoxic and enhance neuronal apoptosis. N. sativa also has the ability to decrease complications linked with diabetes mellitus such as diabetic nephropathy[48].

Data sources: Medline, Embase, Lilacs, Cochrane library, Pubmed and Web of science

METHODOLOGY

A systematic review through literature search was conducted from year 2006–2016 using relevant keywords i.e., (diabetes, hypoglycemia, metformin, flaxseed, Nigella sativa); a total of 50 articles were selected for the study (17) of metformin. Randomized controlled trials, in which eight were for the comparison of doses and four as monotherapy (31,474 patients), were pooled in the final analysis. Extensively greater cutback in HbA1C was reported under larger doses of metformin as compared with small doses, with no noteworthy increase in side effects (16), i.e. descriptive and analytical articles of flaxseed (n=1450 patients) showing valuable difference in blood sugar and HbA1C levels in patients using different doses (17). Eligible articles of Nigella sativa (n=1980 patients) showed marked difference in blood sugar levels, while long standing supplementation of Nigella sativa corrected glucose homeostasis and amplified the antioxidant effects in type 2 patients treated with oral hypoglycemic drugs.

DISCUSSION

Metformin

Type 2 diabetes is like an outbreak. Its prolonged complications result in massive human suffering and economic burden. The disease is mainly associated with lasting microvascular and neuropathic complications which can be considerably reduced by

Articles Published Regarding Metformin

References	Design	Sample	Intervention	Control	Duration	Outcome
Nauck M, et al 2009	Double blind	1091 randomly selected subjects	1 gm metformin twice daily with liroglotide, glimepride all in combination with metformin	Placebo	3 months	Reduced glycemic control. Reduced weight. Occurrence of hypoglycemia
Rosentslock J et al 2012.	Double blind	451 randomly selected.	Caragliflozin 100mg, 200mg, 300mg OD. Or 300mg BD with metformin monotherapy	Placebo	3 months	Significantly improved, glycemic control and weight loss in type 2.
De'Fronzo AR et al 2009	Randomized double blind	1462 randomized subjects.	Saxaplitim as add on with metformin alone in inadequate glycemic control.	Placebo	6 months	Saxaplitin with added metformin resulted as improving in glycemic index.
Goldstein JB, Feinglos NM, Luceford KJ, et all. 2007	Randomized double blind	1091 randomized Pts.	Sitagliptin	Placebo	6 months	Combination of Sitagliptin with metformin had sustained and additive glycemic improvement.
Defronzo A R et al 2005	Triple blind RCT	272 patients	Exenlind with maximum metformin dose were given in type 2 DM patients for improving glycemic control	Placebo	7 months 2 weeks	Reduced HbA_1C, no increased induced glycemic in patients with metformin with exemlid.
Christensen LL et al. 2015	Randomized Control Trial (RCT)	275 patients	Insulin analogue regimen with metformin on change in carotid intema media thickness in patients with type 2 DM.	Placebo	18 months	Reduced HbA_1C with weight gain with insulin doses with metformin in patients with Metformin and insulin.
Turner RC, Cull AC, Righi V, Holman RR. 2012	Randomized Control Trial (RCT)	4075 patients	Glycemic control with diet, sulphonylurea metformin or insulin in patients with type 2 DM.	Placebo	3 months	Therapeutic agents as monotherapy increased 2 and 3 fold in the patients who attained HbA_1C below 7% compared with diet alone. Majority of patients need multiple therapies to attain glycemic control.
Ghosh R, et al	Prospective RCT	71 patients	Bromocriptine add on metformin for the efficacy and safety in type 2 DM patients	3 Controls groups 1. Metformin 2. Met + Bromocriptine 3. Met in increased dose + bromocriptine	3 months	Phase IV clinical trials showed that add on therapy of bromocriptine with metformin is more effective as compared with metformin alone.
Boussagoen R, et al 2012	Randomized Control Trial (RCT)	13110 patients	Type 2 DM patients have given metformin for trial effect	Placebo	60 years 1952–2010 Meta-analysis	Metformin is gold standard but benefits remain uncertain.
Hirst AJ, et al 2012	Double blinded RCT	4511 in (12 articles only Metformin) 1025 in (13 articles + insulin treatment)	Effect of metformin on HbA1c in all types of diabetes and examining effects on different doses	Placebo	3 months	Metformin therapy reduced HbA_1C by 1.12% and with other oral anti-hyperglycemic by 0.9% and insulin by 0.83%.
Charbonnel B, Karassic C, Liu J	Single blind	701 patients	The effect of dipeptidyl peptidase-4 inhibitor sitagliptin with metformin in type 2 diabetes	Placebo	6 months	Sitagliptin 100mg with metformin have good glycemic control as compared to metformin alone.
Schweizer A, Couturier A, Foley JE, Dejager S.	Double blind Randomized Control Trial	780 patients	Vildagliptin with metformin to reduce HbA_1C in type 2 diabetes for 1 year treatment period	Placebo	1 year	Comparison between vildagliptin and metformin to sustain reductions in HbA_1C over 1 year in drug-naïve patients with type 2 diabetes
Agular DK et al 2006	Double blind RCT	31 patients	To investigate the vascular affect of metformin in metabolic syndrome of type 2 diabetic patients	Placebo	3 months	Metformin improved vascular endothelial in 1st degree relative with metabolic syndrome of type 2 diabetes.
Hassan KAA, Urooj AM, Ibrahim M. 2016	Observational count study	384 patients	Hypoglycemic effect of vildagliptin relative sulfonylurea as dual therapy with metformin in type 2 DM patients.	Placebo	4 months	Anti-hyperglycemic treatments with vidagliptin, results are good glycemic control with control.
Ahren B, et al 2014	Randomized double blind active control	1012 patients	Efficacy and safety of albiglutide sitagliptin with glimepride along with metformin in type 2 diabetes.	Placebo	2 years (104 weeks)	Hyperglycemic rescue rate at week 104 was 25.8 % for albiglutide with 59.2% for placebo 36.4% sitagliptin 32.0% glimepiride and produced superior reduction in HbA_1C.
Nauck M et al 2012	Double blind phase with randomized trials	1091 patients	To investigate efficacy and safety of dual therapy region for type 2 DM.	Placebo	6 months and 2 weeks. After completion of 26 weeks this phase enters in 18 months open label extension prospective study of 2-26 weeks.	Decrease HbA_1C significantly with liraglutide versus metformin monotherapy and glimepiride.
Letier AC, et al 2015	Randomized double blind phase 3 study	1450 patients	Efficacy and safety of canagliptozin and glimepiride in type 2 diabetic patients along with metformin.	Control group	2 Years (104 weeks)	Canagliflozin have durable glycemic improvement as compared with glimepiride in type 2 DM patients receiving back ground treatment with metformin.

Articles Published Regarding Flaxseed

Reference	Design	Sample	Intervention	Duration	Outcome
Barre ED, et al 2008	Randomized Control Trial (RCT)	40	To see the effect of high dose flaxseed oil on fasting glucose	3 months	No change in serum fasting glucose level
Thakur G, et al 2009	-	60	Effect of flaxseed on FBS and total cholesterol	3 months	Decrease in FBS from 154 to 136 mg/dl
Pan A, 2006	RCT Double blind	68	To see effect of flaxseed in glycemic control, lipid profile, insulin sensitivity		Significantly enhanced glycemic control in type 2 diabetics
Taylor G et al, 2013	Randomized Control Trial (RCT)	34		3 months	Milled FXS and FXO intake does not affect glycemic control
Pan A, et al 2007	Randomized Control Trial (RCT)	73	The study aimed to investigate the effect of a flaxseed-derived lignan supplement on glycemic control, lipid profiles and insulin sensitivity in type 2 diabetic patients.	12 weeks	Daily lignan supplementation resulted in modest, yet statistically significant improvements in glycemic control in type 2 diabetic patients without apparently affecting fasting glucose.
Bleodon T, et al 2013	Randomized Control Trial (RCT)	60	Flaxseed containing baked products or matching wheat bran for 10 weeks	10 weeks	Reduced insulin resistance by 23.7 %
Prasad, Kailash;et al 2013	Animal study (comparative)	40	Beneficial dietary effects of flexseed oil n fish oil in d stz induced diabetic rats	35 days	Both oils have beneficial effects on type 2 diabetes.
Müslüm Gök 2016	Animal study (comparative)	60	Flaxseed protects against diabetes-induced glucotoxicity by modulating pentose phosphate pathway and glutathione-dependent enzyme activities in rats	10 weeks	Flaxseed has beneficial effects against diabetes-induced glucotoxicity
Meng Wang et al 2016	Animal study (comparative)	75	Dietary á-linolenic acid-rich flaxseed oil prevents against alcoholic hepatic steatosis viaameliorating lipid homeostasis at adipose tissue-liver axis in mice	3 weeks	Have good control over cholesterol and blood sugar levels
Gabriela Camara et al 2016	Animal study (comparative)	24 wistar rats	Perinatal consumption of flexseed flour has beneficial eefects on experimental diabetic rats	100 days study	Diet with flaxseed and its oil protects diabetic rats from diabetes .
Gabriela Camara et al 2016	Animal study (comparative study)	18 wistar rats	Evaluation of bp and aortic elasticity of offspring of diabetic rats who have consumed flaxseed oil during pregnancy n lactation	100 days study	Flaxseed oil reduced the damage caused by maternal hyperglycemia .
Muslum et al 2015	Animal study (comparative)	24 wistar rats	Flaxseed protects against diabetes induced glucotoxicity by modulating pentose phosphate pathway and glutathione dependent enzyme activies in rats	12 weeks	Flaxseed have beneficial effects against diabetes induced glucotoxicity .
Andre manoel et al 2015	Animal study (comparative)	24	Maternal use of flexseed oil during pregnancy and lactation prevents morphological alterations in pancreas of female offspring from rats with experimental diabetes	180 days	Flaxseed oil reduced the damage caused by maternal hyperglycemia.
Jiqu xu et al 2016	Animal study (comparative)	40 male rats	A combination of flaxseed oil and astaxanthin improves hepatic lipid accumulation and reduced oxidative stress in high fat diet fed rats.	100 days	Flaxseed oil and astaxanthin improved and positive effects.
Gabriela Camara vicenete et al 2014	Animal study (comparative)	24 female rats	Maternal use of a diet rich omega 3 from flaxseed improves aortic remodeling but not the biochemical parameters of female offspring of diabetic rats	100 days	Maternal consumption of flaxseed meal and oil against diabetic rats have beneficial effects
Abhijit ghadge et al 2016	Animal study (comparative)	24	Comparative anti-inflammatory and lipid normalizing effects of metformin and omega 3 fatty acid through modulation of transcription factors in diabetic rats.	30 days	The protective effects of flaxseed are useful on lipid metabolism and liver and renal function tests

Articles Published Regarding Nigella Sativa

Reference	Design	Sample	Intervention	Duration	Outcome
Bamosa AO, et al, 2010	Randomized Control Trial (RCT)	94	Capsules containing Nigella sativa for the glycemic control of patients with type 2 diabetes mellitus.	Three months	Nigella sativa at a dose of 2 gm/day caused significant reductions in FBG, 2hPG, and HbA1C in type 2 diabetic patients.
Qidwai W1, Hamza HB, Qureshi R, Gilani A.2009	Randomized Control Trial (RCT)	123	Effectiveness, safety and tolerability of powdered Nigella sativa (Kalonji) seed in capsules on blood sugar, and body weight in adults.	1 year	Statistically insignificant
Najmi A	Prospective study	60	adjuvant effect of Nigella sativa oil for the metabolic syndrome	6 weeks	Significant therapeutic effect
Kaatabi H, et al 2015	Blinded clinical trial	114	Nigella sativa improves glycemic control and ameliorates oxidative stress in patients with type 2 diabetes	3 months	Nigella sativa improves glucose homeostasis
Hosseini MS et al	Double blinded (RCT)	70	Effects of Nigella sativa L. Seed Oil in type 2 diabetic patients	3 months	Improves glycemic control in type 2 diabetic patients
Shah SA, et al	Clinical trial	159	Nigella sativa provides protection against metabolic syndrome.	6 weeks	Effective as an adjuvant therapy in patients of hyperglycemia.
Doa'a A. Ibraheem 2011	Clinical trial	18	The effect of Nigella sativa role in regulating blood glucose in healthy volunteers	2 weeks	Has pronounced antidiabetic activity as it has significantly reduced FBS.
Saeid Hadi et al 2015	Randomized, Double blind, placebo-Controlled Clinical Trial	43	Effect of Nigella sativa oil extract on blood sugar in type 2 diabetic patients	2 months	Has pronounced anti-diabetic activity
Dr.Sameena Alam et al 2013	Animal study (Comparative)	30 Wistar rats	Evaluation of anti-diabetic and anti-lipidemic potential of Kalonji sugar powder water extract in stz induced diabetic rats	2 weeks	Kalonji sugar powder) has antidiabetic effect.
Sibghatullah Muhammad Ali Sangi et al 2014	Animal study (comparative)	36 Wistar rats	Antihyperglycemic effect of thymoquinone and oleuropein, on streptozotocin-induced diabetes mellitus in experimental animals	2 months	N. sativa and thymoquinone in diabetic animals have hypoglycemic and antioxidant effect
Juraiporn Somboonwong 2015	Animal study (comparative)	25 Wistar rats	Minimization of the risk of diabetic microangiopathy in rats by Nigella sativa	2 months	N. sativa may be used to minimize the risk of cutaneous diabetic microangiopathy, possibly at least partly due to its glycemic control activity
Kaleem, M et al 2006	Animal study (comparative)	45 Wistar rats	Biochemical effects of Nigella sativa L seeds in diabetic rats	30 days	N. sativa seeds showed antioxidant and antidiabetic activity, its administration is useful in controlling the diabetic complications
Murli L. Mathur2013	Animal study (comparative)	36 rats	Antidiabetic properties of a spice plant Nigella sativa	2 months	N. sativa, its constituents or their synthetic analogues, are used in prevention and control of diabetes
ikram f 2014	Animal study (comparative)	28 rabbits	Antidiabetic efficacy of nagella sativa in alloxan induced diabetic rats	3 months	N. sativa extracts have curative effects in terms of diabetes induced disturbance s in glucose and lipid.
Abbasi P et al 2015	Animal study (comparative)	30 Spargue dawley rats	blood glucose lowering effect of Nigella sativa in alloxan induced diabetic rats		N.sativa significantly ameliorates free radicals and improves antioxidant status in animal models.
Ola. M 2013	Animal study (comparative)	60 adult albino rats	Effects of thymoquineone stz-induced diabetic nephropathy	60 days	Thymoquineone has protective effects on experimental diabetic nephropathy.
Towheedur Rahman et al, 2014	Animal study (comparative)	24 rats	Nigella sativa oil potentiates the effects of pioglitazone on long term alloxan induced diabetic rats.	4 weeks	Treatment with combination therapy was more effective than monotherapy for preventing diabetes.

interventions that achieve levels close to the non-diabetic range. New medicines and several combinations have been proven to reduce glucose levels. In the systematic review of 17 eligible articles—primarily double-blinded, randomized, controlled trials were examined that included metformin treatment both as alone and add-on therapy to other oral hypoglycemic agents and with insulin to compute effects on glycemic control. As metformin monotherapy, it reduced HbA1C levels by 1.12%. While in combination with other oral anti-hyperglycemic treatment or insulin therapy, its use reduced HbA1C by 0.95 and 0.83% respectively for type 2 diabetic patients. Using a higher metformin dose resulted in increased gastric side effects, if it was used to maximize HbA1C reduction.

Flaxseed

Finally, 16 eligible articles (7 human trials, 9 animal models) were selected. In brief, animal studies recommend that SDG is protective against diabetes. The studies are affected by demographic variables in species and strains. Comparison cannot be easily established among different species and varying doses of tested herbal drugs, as animal doses are less than those given to human subjects. The wide variability in the techniques used in human trials complicates the analysis of results, although data suggests that health effects of flaxseed, lignan, and SDG-containing flaxseed products propose health benefits. A study proposed that an amount of at least 500mg SDG per dose is required to examine the significant effects/benefits and this amount seems to be protective for a large number of people. However, animal studies have not yet proven the success of high dose exposure during pregnancy and lactation. We saw many studies which used and found flax lignan complex helpful in in treatment of insulin resistance by controlling HbA1C and blood sugar levels as compared to the treatment using metformin.

Nigella sativa

Finally, 17 suitable articles qualified (8 human trials, 9 animal models). These showed that N. sativa adjusted hyperglycemia through various possible mechanisms together with its antioxidant properties and its effects on insulin secretions, glucose absorption, gluconeogenesis, and gene expression. Studies have also compared effects of various forms i.e. (extract, oil, powdered) of N. sativa with each other and found varying characteristics. Some studies concluded that Nigella sativa can improve glycemic status. More multi-centre clinical trials are required to discover the most effective form of Nigella sativa in decreasing levels of HbA1c and blood sugar in the management of type 2 diabetes and its complications.

CONCLUSION

In this systematic review, a total of 70 eligible articles related to Metformin, flaxseed, and Nigella sativa were selected to see and prove the comparative efficacy of these three treatment modalities. It has been proven that flaxseed and Nigella Sativa are very effective with minimum side effects but it also needs further scientific research. In vitro and in vivo studies have shown that dietary polyphenolic compounds improve glucose homeostasis through potential multiple mechanisms of action in the intestine, liver, muscle adipocytes, and pancreatic cells, as well as through prebiotic effects in the digestive tract. Overall, most epidemiological studies have shown that dietary polyphenols were associated with a lower risk of T2D. Nigella sativa and flaxseed may be promising candidates for diabetes prevention and management. There have only been limited clinical studies in dietary polyphenols in relation to glucose and insulin homeostasis and these have been as successful as in vitro and in vivo studies, in terms of reduction in HbA1C levels and blood sugar levels. There is a need to conduct more randomized controlled multi-centre research trials to evaluate beneficial effects of metformin, flaxseed and Nigella sativa on set parameters related to type 2 diabetes and its complications.

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Abstracts
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NCDs AND RAMADAN FASTING

Professor Adel El-Sayed, Egypt

Noncommunicable diseases (NCDs) are now among the biggest health challenges worldwide. Global mortality attributed to NCDs has recently exceeded that of infectious diseases for the first time in human history and their prevalence is increasing. The most important NCDs are: Diabetes, cardiovascular diseases, cancer, and chronic lung diseases. Because of the common risk factors for developing these diseases, it is not uncommon for NCDs to coexist in the same patient. WHO, and consequently governments now put NCDs in one package and handle them together. So it may be logical to study the effects of Ramadan fasting on NCDs as a group in addition to studying them separately. This concept has not been raised before to the best of our knowledge. The purpose of this lecture is to try to explore this concept by searching to find out which NCDs had previously been studied in terms of their relationship to Ramadan fasting and to what extent and what are the gaps which are to be covered in future research either regarding to unstudied NCDs or to the coexistence of more than one NCD in the same patient.

SHOULD INSULIN TREATED PATIENTS WITH DIABETES NOT FAST?

Mafauzy Mohamed, Universiti Sains Malaysia

The most recent Ramadan and Diabetes Practical Guidelines 2016 by the International Diabetes Federation (IDF) state that diabeties on multiple doses or mixed insulin should not fast. However many patients insist on fasting as they want to fulfil their religious obligations. A few studies have been done on patients on mixed insulin during Ramadan fasting. The studies have shown that many patients were able to fast during Ramadan albeit with a small risk of hypoglycaemia but not significantly different from pre-Ramadan month especially with use of analogue insulin. The studies were, however, done in patients who had no history of recurrent severe hypoglycaemia or hypoglycaemic unawareness; no history of hyperosmolar coma or serious co-morbid conditions. This suggests that patients on mixed insulin without those conditions would be able to undertake Ramadan fasting without serious harm and with proper monitoring and adjustment of insulin doses. Though the Guidelines state that this group of patients should not fast, it however has recommendations as a guide to health care providers and patients if the patients insist on fasting despite being advised otherwise. The IDF Guidelines categorize patients with well controlled diabetes on basal insulin as moderate/low risk and can be allowed to fast.

MANAGING DIABETES SAFELY DURING RAMADAN FASTING BY OHAS AND INSULINS RESEARCH EVIDENCE AND EXPERIENCE FROM SAUDI ARABIA

Dr. Kamran Mahmood Ahmed Aziz, Saudi Arabia

Objectives: To study safe and effective Ramadan fasting (without significant hypoglycemia) with different OHAs and Insulins and significant HbA1c Reductions during Ramadan fasting. **Methodology:** Extensive pre-Ramadan diabetes education was provided to the patients. ANOVA statistical model was used to assess HbA1c levels among different education statuses. Serum creatinine was used to measure renal functions. Pre-Ramadan diabetes education with alteration of therapy and dosage adjustments for OHAs/insulin was done. Regression models for HbA1c before Ramadan with FBS before sunset were also synthesized as a tool to prevent hypoglycaemia and support successful Ramadan fasting in future. **Results:** Out of 1046 patients, 998 patients fasted successfully without any episodes of hypoglycaemia. Fourty -eight patients (4.58%) experienced hypoglycaemia. x^2 Test for CRD/CKD with hypoglycaemia was also significant (p-value < 0.001). Gliclazide-MR was found to be safer than other OHAs (glibenclamide, glimipride). Metformin, sitagliptin and vildagliptin (DPP-4 Inhibitors) were also safe during Ramadan fasting. Newer Insulin Analogs such as Humalog Mix50, Basal insulin glargine, and Rapid acting Insulin Analogs (lispro, aspart and glulisine) in basal bolus format were also demonstrated to be safer than traditional or old insulins (Human Regular Insulin, NPH and Mixtard Insulin). Significant associations and linear regression were found for HbA1c and sunset FBS; RBS post-dawn with RBS mid-day and FBS at sunset. The proposed regression models of this study can be used as a guide in future for Ramadan diabetes management. **Conclusion:** Although challenging, successful fasting can be accomplished if pre-Ramadan extensive education is provided to the patients. DPP-4 inhibitors, Gliclazide-MR, and newer Insulin Analogs (in basal bolus format) can be replaced with other OHAs and traditional Insulins during Ramadan fasting to reduce the risk of hypoglycaemia and successful Ramadan fasting.

RAMADAN AND FASTING, ADVANCES IN PRACTICE, INTRODUCING THE PRACTICAL GUIDELINE FOR DIABETES AND RAMADAN DEVELOPED BY INTERNATIONAL DIABETES FEDERATION IN COLLABORATION WITH DIABETES AND RAMADAN INTERNATIONAL ALLIANCE, 2016

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Ramadan is a whole month of intermittent fasting, from dawn to dusk, every year. Islam has over one billion followers worldwide. Fasting is one of the duties for every Muslim, although it is allowed just for those for whom fasting is not harmful. One of the most important question for diabetic patients and their physicians before Ramadan is whether fasting is safe for them or not. Considering the fact that many Muslims with diabetes prefer to fast in spite of inhibitory advice and to answer several conflicts and controversies regarding diabetes and Ramadan, IDF in collaboration with Diabetes and Ramadan (DAR) International Alliance decided to develop a comprehensive guideline to be used by health care professionals. This guideline was then developed in April 2016 by 12 main authors and 20 co-authors from around the world, and published by International Diabetes Federation. The guideline is provided in nine chapters: 1) Introduction to the IDF-DAR Practical Guidelines, 2) Epidemiology of Diabetes and Ramadan Fasting, 3) Physiology of Ramadan Fasting, 4) Risk Stratification of Individuals with Diabetes before Ramadan, 5) Diabetes and Ramadan: A Medico-religious Perspective, 6) Pre-Ramadan Education, 7) Ramadan Nutrition Plan (RNP) for Patients with Diabetes, 8) Management of Diabetes during Ramadan and 9) Identifying and Overcoming Barriers to Guideline Implementation. This guideline tries to answer three main questions: 1) Is fasting during Ramadan associated with a significant risk? 2) What are the criteria that predispose patients with diabetes to increased risk during fasting? 3) What is the most appropriate oral anti-diabetic drug(s) or type and regimen of insulin for patients with type 2 diabetes who fast? IDF-DAR Practical Guideline is now available at: http://www.idf.org/sites/default/files/IDF-DAR-Practical-Guidelines-Final-Low.pdf. **Key words:** Ramadan; Diabetes; Guideline

SAFETY OF ORAL HYPOGLYCAEMIC AGENTS DURING RAMADAN

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Sulphonylureas (SU's) are mainstay of type 2 diabetes management. SUs act by glucose independent stimulation of insulin release from beta cells. SUs have been in use for several decades, but the risk of hypoglycaemia, weight gain and some concern about cardiovascular safety is well known. Despite this adverse effect, They are effective agent, with long global experience. Being economical, they are widely used in the developing world despite the introduction of newer and safer agents. Muslims constitute approximately 25% of the world population and globally there are about 1.6 billion Muslims. The epidemiology of diabetes and Ramadan (EPIDIAR) is a population based study conducted in 13 Islamic countries which enrolled 12,243 patients. The EPIDIAR study showed that about 79% of people with type 2 diabetes observed fasts during Ramadan but only 25% of them had their oral anti diabetics adjusted during this month. This study also revealed that only 2% of the people with type 2 diabetes had at least one episode of severe hypoglycaemia and only 4% of them had one episode of severe hyperglycaemia needing hospitalization. Sulfonylureas and insulin secretagogues are widely used during Ramadan. The STEADFAST study, a double-blind randomized controlled trial (RCT), compared vildagliptin with gliclazide as an add-on therapy to metformin during Ramadan. In that study, there were no significant differences in weight, glycated haemoglobin (HbA1c), or in the frequency of hypoglycaemia between treatment groups. Glibenclamide may be associated with higher risk of hypoglycaemia in comparison with second and third generation sulphonylureas like gliclazide and glimepiride. The GUIDE study, a double blind randomized trial, comparing once daily gliclazide MR and glimepiride in people with type 2 diabetes who were fasting, showed 50% lower risk of hypoglycaemia with gliclazide MR in comparison with Glimepiride. Zargar et al in their study used Gliclazide MR as a monotherapy in 136 male diabetic subjects who fasted during Ramadan. His study showed no change in status of diabetes control, which remained well controlled, with no weight gain and few hypoglycaemic events. A prospective observational study from six countries showed that once daily evening dose of glimepiride taken at Iftar did not alter hypoglycaemic rates or glycaemic control. In summary, if the glycaemic control before the start of Ramadan is good, then those taking twice daily equal doses of sulphonylureas are recommended to take the usual evening dose at Iftar but the morning dose should be reduced to half at suhur time. If the person is taking sulphonylureas twice daily with higher doses in the morning and a smaller dose in the evening, the higher morning dose should be shifted to Iftar and the smaller evening dose to suhur, which may be reduced further if the control of diabetes is good. Individuals on once daily glimepiride or gliclazide-MR should take their medications at Iftar and the dose may remain unchanged or reduced depending upon their pre-Ramadan glycaemic control.

PRE-RAMADAN SPECIFIC DIABETES EDUCATION: LESSONS LEARNT

Professor Muhammad Yakoob Ahmedani

Ramadan Specific Diabetes Education (RSDE) is compulsory for patients, doctors and diabetes educators, it includes self monitoring of blood glucose, diet and fluid intake, drug dosage and timing alteration, knowledge regarding symptoms of hypo and hyperglycaemia, physical activity, breaking the fast, taking insulin while fasting, etc. Research evidences show a significant lack of knowledge, attitude and practice among patients and healthcare professionals regarding Ramadan specific diabetes education. When we compared Ramadan specific education level in patients with diabetes at primary and tertiary care diabetes centres of Karachi, Pakistan, we found Ramadan specific education level of patients with diabetes as significantly better at a tertiary care than a primary care diabetes centre. it is practicable to implement Ramadan specific diabetes education through health care providers because by implementing the Ramadan specific diabetes management recommendations, a significant result was that none of the patients developed ketoacidosis, no one required hospitalization, and no one was found to have hyperglycaemic hyperosmolar state. Diabetic patients who receive RSDE, follow the Ramadan specific diabetes management recommendations better as compared to those who did not receive education. It is concluded from our observation that RSDE is mandatory for safe fasting in patients with diabetes during Ramadan as we have seen less complications in patients who receive education as compared to those who do not receive RSDE.**Key words:** Ramadan specific diabetes education, Ramadan, Diabetes

DIET IN DIABETES DURING RAMADAN

Professor Jamal Zafar

As the prevalence of diabetes is on the rise all over the world, Muslim, have to face the special problem of medical nutrition therapy (MNT) during the month of Ramadan. The duration for fasting and the weather conditions vary from country to country. Moreover, the cultural and dietary pattern differs in different countries and in various part of same country. So it is very important that MNT should be individualized after broad guidelines are made for the Muslims observing fast in the Holy month of Ramadan. This MNT will not only help to maintain good glycaemic control but can also help in reducing weight in overweight diabetic patients.

DIABETES AND RAMADAN — WHAT SHOULD BE CHANGED?

Professor M. Zaman Shaikh
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There are 1.5 billion Muslims all over the world who observe the holy month of Ramadan. This consists of 25% of the world population. There are several routines to be changed and following points to be kept in mind: **High Risk Patients:** History of severe hypoglycaemia/ hyperglycaemia within 3 months needing hospitalization. Type one diabetes, because they are taking at least 2 insulin injections in 24 hours, patients on dialysis and with pregnancy, doing laborious job, old age patients with ill-health and living alone, patients on sedative. **Moderate Risk:** Type 2 DM well-controlled on oral hypoglycaemic drugs. **Low Risk:** Type 2 diabetic patients, well-controlled on diet alone or some mild oral drugs. **Risks Associated with Fasting**: Severe hypoglycaemia, severe hyperglycaemia with unconsciousness, dehydration. **Pre-Ramadan Assessment & Counselling:** Involve whole family, wear medical alert bracelets. Patients should be educated about blood sugar monitoring with glucometer and keepin record, meal planning, and physical exercise. No exercise during day time, but may be taken 2 hours after iftar meals. **Timings of monitoring blood sugar:** At least 3 times per day: Just before iftar (which is equivelent to fasting blood sugar during Ramadan), 2-hr after iftar, 2-hr after sehri. **Care about nutrition:** Increase water intake to about 10 glasses between Iftar and Sehr, avoid food rich in fat and sugar, advise foods with complex CHO with fibres. Take sehri as late as possible. avoid dates, juices and0 traditional food items like samosa, pakora, khajla, and pheni. **Break The Fast**: If blood sugar is less than 60 or blood sugar is more than 350 during fast. Avoid fasting on days with fever or vomiting and diarrhea. The diabetic patients on insulin should get expert advice from their doctors for necessary changes in type, timings, and the doses of insulin during Ramadan.

UPDATED GUIDELINES ON THE MANAGEMENT OF DIABETES DURING RAMADAN

Dr. Osama Ishtiaq

Ramadan has a major impact on the management of diabetes in the Muslim population. With the worldwide prevalence of diabetes increasing, and the number of fasting Muslims rising, the importance of effective guidelines for the management of diabetes during Ramadan fasting is established. Majority of Muslims with diabetes, want to fast in Ramazan, therefore, treating physicians should know how to treat these patients. A cornerstone of Ramadan diabetes management is patient education, which should include information on risks, glucose monitoring, nutrition, exercise and medication adjustments. Last year, International Diabetes Federation (IDF) in collaboration with the Diabetes and Ramazan (DAR) International Alliance, formulated comprehensive practical guidelines on Diabetes and Ramazan. The present presentation, would highlight the practical points related to management of diabetes in Ramazan, in the light of these guidelines.

MANAGEMENT OF THYROID DISORDERS DURING RAMADAN

Dr. Najmul Islam

No major changes in management of patients with thyroid disorders are necessary during the month of Ramadan and patients are able to fast safely without any major health risks. Hypothyroid patients on thyroxine can safely take their tablet on empty stomach at bedtime or half an hour before sehar. Hyperthyroid patients on methimazole or carbimazole can continue their medication as once or twice daily doses while patients on propylthiouracil require switching their medication. Patients with severe hyperthyroidism require immediate treatment and may have to avoid fast after consultation with physicians and religious scholars. **Key words:** Hyperthyroidism, Hypothyroidism, Ramadan

MATERNAL RAMADAN FASTING AND SCIENTIFIC STUDIES: WHERE ARE WE?

Professor Nazli Hossain
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There is a dearth of literature on the effects of maternal fasting on foetus. There is also a lack of longitudinal studies on the above subject. This talk focuses on the available scientific data on maternal and fetal health and fasting. This will also include the unpublished research conducted in my department, three years ago. The outline includes perceptions of women about fasting, available scientific data on whether it affects maternal and fetal health? This data will be compared with our local data as well. We should encourage our students about conducting meaningful research and longitudinal studies about the effects of maternal fasting, in order to answer commonly asked questions by the mother. I also take this opportunity to invite fellow researchers from neighboring Islamic countries to collaborate in studies on these subjects for the benefit of our population.

EFFECTS OF RAMADAN FASTING ON HYPERTENSIVE AND DIABETIC PATIENTS OF KARACHI

Nazeer Khan, PhD
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This presentation will cover three studies conducted by the author and his undergraduate students. The first study was conducted on 75 Type 2 diabetic patients and the objective was to assess the effect on Ramadan fasting on blood pressure, fasting glucose, cholesterol, triglyceride, high density and low density lipoproteins. The second study was conducted on 117 hypertensive patients and the objective was to find out the effect of Ramadan fasting on blood pressure, physical activities, and obesity. The third study was performed on hypertensive and diabetic patients with controls. One hundred and fifty five subjects were included in this study. First study showed that Ramadan fasting is safe for Type 2 diabetic patients and associated with weight loss and overall diabetic control. Furthermore, fasting also reduces the waist measurement, systolic blood pressure, triglyceride and HDL. The second study concludes that fasting does not incur any harm for the hypertensive patients. Nevertheless, it significantly reduces the systolic and diastolic blood pressures. Factors such as changes in physical activities, sleeping patterns, and weight reduction, except for the number of fasting days, do not affect the fasting hypertensive patients. The third study inferred that fasting benefitted, healthy subjects and also reduces weight, blood pressure, and fasting blood sugar.

GUIDELINES FOR CARDIAC PATIENTS DURING RAMADAN

Professor Dr. Mansoor Ahmad

Fasting in the month of Ramadan is mandatory for all adult Muslims. However, there are exceptions for those who are not in good health or suffer from problems, making fasting detrimental to health & safety. Most patients with cardiovascular diseases, including hypertension should be able to fast, based on individual advice from their doctors, there is a substantial number who may be advised against fasting. There is a data, albeit small, that is suggestive that it is safe for majority of patients with CV problem to fast. However, a substantial number will need caution and clear advice, while many cannot fast. The message has to be clear and passed on in unequivocal terms.

FASTING AND BRAIN HEALTH

Professor Mohammad Wasay Shakir

Brain and mental health are considered one of the most important aspects of human health. Brain diseases constitute 8-10% of total burden and are associated with high disability and morbidity. Fasting and brain health has been a important research topic in last decade. Fasting slows down neurodegenerative process and promotes neurogenesis and synaptic connections which helps neurogeneration. Fasting leads to significant improvement in depression and depressive symptoms. Proposed mechanism is increase in Serotonin levels in frontal and temporal lobes. There are a number of studies indicating improvement in anxiety, panic attacks and mood swings among bipolar disorder patients after two to three weeks of fasting. One study showed improvement in mania and hypomania after fasting. Stroke is one of the most disabling disease with second highest mortality in the world. Stroke incidence is reduced due to fasting. Suggested mechanisms are better blood pressure, sugar and lipid level control, and abstinence from tobacco use during fasting. Fasting leads to increased cytokines and BDNF levels in brain which may have neuroprotective effects. Fasting may help better control of seizures among epilepsy patients. There are reports of positive effects of fasting in patients with Huntington's disease and Alzheimer's disease. Most notable effect of fasting is reported in refractory schizophrenia patients. 60% patients with refractory schizophrenia improved after two weeks of fasting. Overall fasting improves cognitive functions, self-control, and discipline among healthy individuals.

IS IT SAFE TO FAST DURING PREGNANCY?

Dr. Shabeen Naz Masood

Background: Ramadan fasting is obligatory for every Muslim adult and sane individual [*Al-Baqarah 2:183*]. About three quarters of pregnant Muslim women worldwide choose to fast during Ramadan despite the clear flexibility they are given by Islamic Sharia to show decide not to fast. Few studies have examined the untoward effects of maternal fasting on the wellbeing of the mother and fetus. However the fasting pregnant woman has no inappropriate effect on intrauterine growth and birth-time indices and does not reach maternal ketonemia or ketonuria. Some studies suggested that pregnant women can fast at no risk of premature birth up to the 20th week, however, it could be dangerous between the 21st and 37th week. Similarly CTG changes in fetal heart rate tracings are found to be insignificant in mothers who fast during Ramadan. **Conclusion:** The practice of fasting during Ramadan by mothers of infants and young children should not be viewed solely from the perspective of feeding and nutrition. It is generally safe to fast during pregnancy in the absence of obstetrics and medical complications.

EFFECT OF FASTING ON FREQUENCY OF DEPRESSION, ANXIETY AND STRESS SYMPTOMS IN TYPE 2 DIABETICS

Dr. Alvina

Background: Fasting (abstaining from food water, smoking, beverages and sexual intercourse) before dawn (Sehri)till sunset (Iftar) in the month of Ramadan (9th lunar month), is one of five fundamental pillars of Islam, duration of fasting may range from 11 to 18 hours in our country which may affect mental condition. It is well recognized that many individuals with chronic illnesses such as diabetes also have co-morbid unrecognized mental health disorders. The International Federation of Diabetes has stressed the importance of integrating psychological care in the management of diabetes. The prevalence of mood and anxiety disorders is higher among persons living with diabetes compared to those without diabetes. Diabetes might increase the risk of depression and anxiety because of feelings of threat and loss related to the announcement of the diagnosis and the need to make life style changes. Risk of developing depression is 50-100% higher among patients with diabetes compared to that among the general population. Similarly, the prevalence of anxiety disorders among patients with diabetes is considerably higher compared to the general population, with the prevalence rate of generalized anxiety disorder (GAD) to be around three times higher than that reported in the general population. Other anxiety conditions associated with diabetes are needle and injection phobia and phobia of hypoglycaemic episode. The rationale of the present study is that local data regarding effects of fasting on this subject is very limited so there is a need to do more research and broadcast the importance of screening for depression, anxiety, and stress in our population. **Objective:** To assess the effect, of fasting on the level of anxiety and depression and stress symptoms in patients of diabetes **Operational Definitions: Depression**: Those whose score is > 4 on Depression Anxiety Stress Scale (DASS) will be labeled as having depression symptoms. **Anxiety:** Those whose score is >3 on Depression Anxiety Stress Scale (DASS) will be labeled as having anxiety symptoms. **Stress**: Those whose score is >7 on Depression Anxiety Stress Scale (DASS) will be labeled as having stress symptoms. **Diabetes**: Fasting plasma glucose = 7.0 mmol/l (126 mg/dl) or a glycated haemoglobin (HbA1c) of =48 mmol /mol (= 6.5DCCT %) **Materials and Methods:** This study was conducted at Baqai institute of diabetes and endocrinology Karachi. Duration: 2 months, June and July (pre Ramadan and post Ramadan) **Sample Size**: 100 **Sampling Technique**: Consecutive non-probability sampling. **Study Design**: Descriptive study (cross sectional study). **Inclusion Criteria:** Patients having diabetes, patient who fasting more than 15 days during Ramadan. **Exclusion Criteria:** Patients having gestational diabetes, known cases of any mental illness patients on any drugs for mental illnesses, who are not willing to fast, patients who did not consent. **Data Collection**: The study was conducted after seeking approval from Ethical Review Committee of Baqai Institute of Diabetes and Endocrinology. Patients selected from Institute of Diabetology and Endocrinology, Baqai Medical University Hospital, Karachi. The purpose procedure, risk and benefits of the study were explained, confidentiality was ensured and informed consent was taken from the patients fulfilling the inclusion criteria. Information such as demographics like age, gender, BMI, education, occupation, family support (financial support), social support, history of diabetes will be noted and entered by the researcher into the Proforma attached as annexure. **Data Analysis**: Data will be analyzed on SPSS version 20. **Result:** Will be presented in the conference. **Conclusion:** Will be presented in the conference.

PATIENTS' PERCEPTIONS ON FASTING IN RAMADAN AND DOSAGE ADJUSTMENT OF DIABETIC MEDICATIONS

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Ramadan, the month of fasting, is observed by Muslims all over the world. Fasting is obligatory for all healthy adult Muslims which is refraining from eating and drinking from pre dawn to sunset. The dietary patterns therefore totally change. Nutritional variations may also take place in terms of more fried foods, fruits, and sugary drinks. This may pose a problem in patients with pre-existing diseases like dislipidemias and diabetes on one hand and on the other hand, increased intake of fruits is beneficial for health. Fasting during Ramadan for patients with diabetes carries a risk of an assortment of complications. In general, patients with type 1 diabetes are at very high risk of life-threatening complications. Patients with type 1 diabetes who have a history of recurrent hypoglycaemia or hypoglycaemia unawareness or who are poorly controlled are at very high risk for developing severe hypoglycaemia. On the other hand, an excessive reduction in insulin dosage in these patients (to prevent hypoglycaemia) may place them at risk for hyperglycaemia and diabetic ketoacidosis. Hypo- and hyperglycemia may also occur in patients with type 2 diabetes, but is generally less frequent and has less severe consequences than in patients with type 1 diabetes. A patient's decision to fast should be made after ample discussion with a health care provider concerning the risks involved. Patients who insist on fasting should undergo pre-Ramadan assessment and receive appropriate education and instructions related to physical activity, meal planning, glucose monitoring, and dosage and timing of medications. **Background:** The present study aimed to assess fasting in Ramadan in diabetic patients and their perceptions regarding dosage adjustment of diabetic medications; and complications faced if any during fasting. **Methods:** Hundred adult diabetic patients were randomly selected from Diabetes OPD of Sir Syd Hospital. Aquestionnaire was designed to evaluate their fasting patterns, dosage adjustment of their diabetic medications, and to record the incidence of any problems that they faced during fasting. We also assessed as to who they considered to be the most appropriate person to educate them regarding fasting in Ramadan. **Results:** Majority of these diabetic patients (n=80) fasted during Ramadan, while only 20% (n=20) expressed that they did not fast during Ramadan. Of those who did not fast, the majority suffered from dizziness, vertigo and incidences of hypoglycaemia at some point. **Conclusions:** In a cohort of diabetic population present in the OPD of Sir Syed Hospital, the majority of patients were adjusting the dosage of their diabetic medications in consultations with their doctor. Majority of patients were interested in discussing their medications with their doctors, but a few also relied on internet. When asked if they wanted their doctor to give them more information on fasting in Ramadan, majority said yes. When asked who would they like to give them this information, a majority (n=58) responded that they wanted their diabetologists to give them the information about fasting in Ramadan. A few wanted to get this information from their GPs (n=26). Only one person mentioned diabetic educator.

FIRST DAY OF RAMADAN HEADACHE AND GASTROINTESTINAL EFFECTS

H.M. Aamir, Fiza Khan, Aruba Khan, Hannah Paul, Adiya Dossal

Introduction/Objective: The holy month of Ramadan compels all the Muslim believers to practice a 30 day fasting ritual that begins everyday at dawn and ends with sunset. During this time period Muslims engage themselves in prayers while refraining from food, beverages, oral medications and sexual activities. The Circadian rhythm and eating habits during this month change which affect the body's physiology and may precipitate or exacerbate headache and GIT complains. Therefore this study is carried out to evaluate the possible role of first day of Ramadan fasting in precipitating headache and GIT complaints. Another objective was to estimate the frequency of such effects in males and females both, before and after Iftar. **Methodology:** This cross sectional study was conducted in the Ramadan of 2015 after the approval of the institutional review board. Our sample size was 385, which included both males and females aged from 18-70 years. The data was collected from the faculty members, staff, and, medical students of Jinnah Sindh Medical University, Ziauddin University, and DIKIOHS. A questionnaire was designed to collect data from the respondents, selected through simple random sampling. Chi square test was applied to see the association, and the frequency was also calculated. P-level = 0.05 was considered as significant. **Results:** The sample included 19.2% males and 80.8% females out of which 80.7% respondents were between the ages group of 18 and 25 years and 19.3% respondents were from 25-70 years of age. Out of the total 385 respondents included in the study, 31.4% suffered from headache before Iftar, with a higher frequency of females i.e. 32%, whereas 17.1% suffered headache after Iftar, including a majority of males i.e. 27%. However, the association of headache with different age groups was found to be in significant both before and after Iftar. It was also found that among all GIT complaints that were included in the study (nausea, vomiting, diarrhoea, heartburn, constipation, stomachache), heartburn was a significant symptom found in 10% of the respondents before Iftar, with males suffering more than females. However, heartburn and other GIT complaints were found to be insignificant after iftar in both the genders. **Conclusion:** From our study, we established that a significant association was found between headache and the first day of Ramadan fasting. The frequency of headache before iftar was more in females while it became higher in males after breaking the fast. The most common GIT complaint both before and after Iftar was heartburn, with males being more affected than females. To validate our findings, we need to carry out studies on a much larger scale.

CHANGES IN LIPID PROFILE, GLUCOSE LEVEL, PROTEIN, AND URIC ACID DUE TO PHYSICAL ACTIVITY AND FASTING AMONG MEDICAL STUDENTS OF KARACHI

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Objective: To determine the change in lipid profile, glucose level, protein, and uric acid due to Ramadan fasting among fasting and non-fasting medical students with physical activity in a public medical university. **Methodology**: Eighty-six Muslim students who intended to fast at least 20 days in Ramadan consented to participate in the study. Only 26 non-Muslim students consented to participate in the study as control. Students were requested to visit three times (last 10 days of Shaban, Ramadan, and Shawwal) to fill a questionnaires, and give blood samples for biochemical analysis. Blood pressure, height and weight were also measured in each visit. By the end, we had only 59 Muslims students with at least 20 days of fasting and 11 non-Muslims who had visited all the three times. Blood samples were analyzed for lipid profile, glucose level, protein, and uric acid at reference laboratory of Jinnah Postgraduate Medical Center. Metabolic Equivalent (MET) value was calculated for each respondent and a subject was considered 'Healthy' if the MET value was more than 600. **Results:** Mean cholesterol level increased insignificantly among Muslim students in Ramadan, but decreased significantly in Shawwal. However, there was a significantly different trend among non-Muslims. There was continuous increase in mean HDL value from Shaban to Shawwal in both Muslim and non-Muslim students. Shawwal level was significantly different from Ramadan and Shaban. Mean LDL increased a little bit among Muslim students in Ramadan but decreased significantly in Shawwal. For mean triglyceride, Muslim students showed significantly sharp decrease than non-Muslim students. There was no significant change in mean protein values in three visits, but there was a trend of dropping values in Ramadan and then increasing in Shawwal. Mean glucose level increased significantly in Ramadan and then decreased in Shawwal among Muslim students. Mean uric acid increased significantly in Ramadan and reversed in Shawwal among Muslim students, but trend was opposed among non-Muslim students. There was no significant effect of BMI of any of the analyzed elements. Only 6 (9.7%) respondents appeared as 'healthy using the MET criteria. This criterion (healthy/unhealthy) has only affected the glucose level. **Conclusions:** Study showed that the change in Ramadan have mixed effects in lipid profile, glucose, protein and uric acid levels, and there were some differences of these elements among Muslims and non-Muslims and healthy and unhealthy subjects.

EFFECTS OF FASTING ON PATIENTS WITH DIABETES DURING RAMADAN

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Background: Fasting during Ramadan is one of the five fundamental pillars of Islam. During fasting, adult Muslims are required to abstain from food, water, smoking, beverages and sexual intercourse from dawn till sunset. However, the patients on health risks are exempted from fasting. Many of the patients with diabetes, want to fast despite the medical advice against it. It is the challenge for the treating physician to treat and manage this group of patients. The evidence regarding complications in patients with diabetes during fasting is insufficient. Therefore, the aim of this study is to observe the effect of fasting in high risk patients with diabetes during Ramadan. **Study Design:** Obsevational study **Sample Size**:100 **Sampling Technique**: Non probability convenient method **Methods:** This prospective observational study was conducted from May 2017(1438 A.D) till August 2017(1438 A.D) in patients presenting at the outpatient department of Baqai Institute of Diabetology and Endocrinology, Karachi. All patients with diabetes regardless of age, gender, co-morbids who had fasting voluntarily in Ramadan and in any one of the three categories of IDF-DAR risk stratification groups 2017, were recruited a month before Ramadan after a proper education counselling session. Those patients who did not fast, did not consent to participate in study or patients with known psychiatric illness were excluded. Ethical approval was taken from Institution Review Board (IRB). Questionnaire was designed in two sections. Section 1 comprised data from a month before Ramadan which included patient's demographic profile and questions regarding categorization according to risk stratification groups. Section B comprised questions regarding complications (major hypoglycaemia, major hyperglycaemia, DKA/HHS, breaking the fast and/or hospitalization) during Ramadan. **Results**: (Awaited, will be presented in symposium). **Conclusion**: (Will be presented in symposium). **Key words**: Diabetes, Ramadan, Complications during fasting

THE EFFECT OF FASTING ON RENAL FUNCTION IN PATIENTS WITH DIABETES MELLITUS TYPE 2

Dr. Hina Khan

Background: Fasting in the month of Ramadan is the one of five fundamental pillars of Islam. Ramadan is the 9th month according to the Lunar Calendar. During Ramadan, Muslims fast from just before dawn (Sehri) till sunset (Iftar). During this, one has to abstain from eating or drinking. Children, elderly people, and Muslims on risk for health are exempted from fasting. Duration of fasting can range from 11 to 18 hours and may affect water balance and renal function especially in sick patients. Evidence regarding renal function in patients with diabetes mellitus type 2 in relation to fasting is insufficient. Therefore the main purpose of this study is to observe the renal functions in fasting patients with diabetes mellitus type 2 during Ramadan. **Objective:** To observe the effect of fasting on renal functions in patients with diabetes mellitus type 2 **Study design:** Prospective observational study. **Study population:** All patients with diabetes mellitus type 2 who fast voluntarily in Ramadan visiting in OPD at Baqai Institute of Diabetology and Endocrinology. **Sample size:** 100 **Material and Methods:** Prospective observational study was done in June, July 2017 among patients was attended outpatient department of Baqai institute of Diabetology and endocrinology, Karachi. Patients were selected by non probability convenient sampling technique. All patients with type2 DM were selected except the patients who did not consent or were critically ill. Data was gathered using pre designed close ended questionnaire, which contained patient's demographic profile, renal function test, and frequency of hypoglycaemia. Data analysis was done on SPSS version 20. **Results:** Results will be presented in conference. **Conclusion:** Conclusion will be added after completion of study.

FREQUENCY OF MAJOR COMPLICATIONS IN HIGH RISK FASTING INDIVIDUALS WITH DIABETES

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Background: Fasting during Ramadan is one of the five fundamental pillars of Islam. During fasting, adult Muslims are required to abstain from food, water, smoking, beverages and sexual intercourse from dawn till sunset. However, patients on health risks are exempted from fasting. Many of the patients with diabetes want to fast despite the medical advice against it. It is the challenge for the treating physician to treat and manage this group of patients. The evidence regarding complications in patients with diabetes during fasting is insufficient. Therefore, the aim of this study is to observe the frequency of major complications in high risk fasting individuals with diabetes. **Methods:** This prospective observational study was conducted from May 2017(1438 A.D) till August 2017(1438 A.D) in patients presented at the outpatient department of Baqai Institute of Diabetology and Endocrinology, Karachi. All patients with diabetes regardless of age, gender, co-morbids who had fast voluntarily in Ramadan and fall in any one of three categories of IDF-DAR risk stratification groups, 2017 were recruited a month before Ramadan after given a proper education counselling session. Those patients who didn't fast, didn't give consent to participate in study or patients with known psychiatric illness were excluded. Ethical approval was taken from Institution Review Board(IRB). Questionnaire was designed in 2 sections, section 1 comprised of data a month before Ramadan which included patient's demographic profile and questions regarding categorization according to risk stratification groups while section B comprised of questions regarding complications(major hypoglycemia, major hyperglycemia, DKA/HHS, breaking the fast and/or hospitalization) during Ramadan. **Results:** (awaited, will be presented in symposium). **Conclusion:** (will be presented in symposium). **Key words**: Diabetes, Ramadan, Complications during fasting

EFFECT OF FASTING ON WEIGHT IN DIABETIC PATIENTS DURING RAMADAN

Sommiya Abdul Latif[1],M.Yakoob Amedhani[2],Mariam Abdeali[2]

Introduction: Ramazan is the ninth month in the lunar calender of Muslims when muslims fast. Fasting is practiced by adult, healthy Muslims. There are several potential benefits of fasting during Ramadan. Fasting helps Muslims to feel compassion for those who are less fortunate and underprivileged; it also allows one to build a sense of self-control and willpower, and learn to control natural urges such as hunger and thirst. The fasting period of Ramadan among Muslims requires special attention for diabetic patients in particular. The vast majority of Muslims with diabetes will practice fasting during the month of Ramadan, even in the presence of diabetic complications. **Aim:** To provide health care practitioners with new data regarding the impact of fasting during Ramadan focusing on weight change based on dietry compliance **Methods:** Prospective, observational study carried out in two phases; a pre-Ramadan recruitment interview (visit A) and a post-Ramadan follow up interview (visit B) of the same patients. Ethical approval for the study has been obtained from the Institutional Review Board of Baqai Institute of Diabetology & Endocrinology (BIDE).Visit A commenced 1.5 months prior to Ramadan of 2017 (Hijri year, 1438) including all demographic data, pre Ramadan diet and education provided, weight obtained. The second interview (visit B) was performed within a month after the end of Ramadan, 2017 in which diet follow up was taken and post ramadan weight was obtained. Health care providers (diabetologists or diabetes educators), involved in the care of patients with diabetes were assigned the task to enroll patients for the study after obtaining informed consent. **Inclusion Criteria:** The diabetic patients who attended OPD and consented to participate in the study, irrespective of socioeconomic or demographic factors. **Exclusion Criteria:** Children below eight years of age and non-Muslims were excluded from the study. **Result:** To be shared in symposium. **Conclusion:** Would be shared in symposium.

CHANGES IN ANTHROPOMETRIC MEASUREMENTS, BLOOD PRESSURE AND PHYSICAL ACTIVITIES DUE TO RAMADAN FASTING AMONG MEDICAL STUDENTS OF KARACHI

Nazeer Khan, S.M. Tariq Rafi, Shameem Siddiqui, Saba Shakeel*, Haseeb-ur-Rahman,
Jinnah Sindh Medical University, Karachi

Objective: To determine the change in anthropometric measurements, blood pressure, and physical activities due to Ramadan fasting, categorized by gender among Muslim and non-Muslim medical students in a public medical university **Methodology**: Fifty-nine Muslim students with at least 20 days of fast not and 11 non-Muslims students participated the complete duration of the study. Students were requested to visit thrice times (last 10 days of Shaban, Ramadan, and Shawwal) to fill questionnaires and give blood samples for biochemical analysis. Blood pressure, height, and weight were also measured in each visit. The study was funded by Jinnah Sindh Medical University (JSMU) and approved by Institutional Review Board of JSMU. **Results:** Mean age of Muslim students was 1.25 years higher than non-Muslim students. However, there was no significant difference in height, weight, waist, and hips measurements between Muslim and non-Muslim students in the first visit. Mean weight was reduced insignificantly from Shaban to Ramadan, but trend was the same for Muslim and non-Muslim students. As expected, the gender showed significant difference as co-factor. BMI showed same results as weight of the students. However, gender also did not show any significant difference. Waist and hips ratio also did not show any significant difference in three readings. Systolic blood pressure reduced significantly in Ramadan. However, diastolic blood pressure did reduce in Ramadan, but not significantly. Muslim students showed better physical exercise activities than non-Muslim students. However, these activates were reduced to more than 50% for Muslim students during the Ramadan period. **Conclusions:** Study showed that the changes of eating and physical habits in Ramadan have mixed effects in anthropometric measurements and blood pressure. Gender showed significant effects as co-factor, but there was no significant difference among Muslim and non-Muslim students.

EFFECTS OF RAMADAN AND CLIMATIC CHANGES ON PREVALENCE OF DIARRHOEA IN KHYBER PAKHTUNKHWA, PAKISTAN

Dr. Zafar Mahmood

Objective and background: Diarrhoea is the second only common disease to pneumonia which has been attributed to lack of good food, climatic effects and constitutes a major cause of morbidity and mortality worldwide. Many studies agree that morbidity and mortality are results of interactions among numerous factors in developing countries. The interactions of behavioural, socio-economic, demographic and environmental factors influence morbidity. Understanding human morbidity requires explaining the relations and interactions of these factors with diarrhoea. The main purpose of this study was to assess the effects of Ramadan and climatic changes on prevalence of diarrhoea in Khyber Pakhtunkhwa, Pakistan. **Methodology**: A generalized linear regression was applied to analyse the data and to select the model. The response variable for the study was the incidence of diarrhoea. **Results**: The results of the analysis show that fasting, pattern of food intake during the month of Ramadan, rainfalls and temperature are significant variables of diarrhoea in the target population of Khyber Pakhtunkhwa, Pakistan.

WATERMELON: A MIRACULOUS FRUIT IN DIABETES

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Watermelon (**Citrullus lanatus**), botanically considered as a fruit, belongs to the family **Cucurbitaceae.** Watermelon is a valued source of natural antioxidants with special reference to lycopene, ascorbic acid, and citrulline. These functional ingredients give protection against chronic health problems like cancer, heart diseases, and diabetes. The antidiabetic potential of watermelon in rats was evaluated by giving 1% watermelon rind ethanol extract on alloxan induced diabetic rats. In this study, 30 Male Wistar rats, body weight of 150-200 gram were divided into three groups. Diabetes was induced by intra peritoneal injection of 160 mg/kg Alloxan. Group A served as positive control while groups B and C received 100 mg/kg and 200 mg/kg ethanolic watermelon extract respectively. The duration of the watermelon extract treatment was 30 days in which single dose of watermelon extracts were orally administered to diabetic rats. Blood glucose levels were estimated with glucometer before treatment, 2h and 1–4 weeks after administration of extracts. Results showed that the treatment with watermelon extract significantly decreased blood glucose level ($P<0.05$) and increased serum insulin levels ($P<0.05$). These results suggest that watermelon is useful in controlling the blood glucose levels and could be a better option to treat diabetes in future. **Key words:** Watermelon extracts, Diabetes mellitus, Alloxan, Blood glucose level, Insulin

REASONS TO EXPLORE ATTITUDE OF PHARMACISTS TOWARDS ANTIMICROBIAL AGENT DISPENSING WITHOUT PRESCRIPTION IN KARACHI CITY

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Antimicrobials such as antibacterial, antiviral, antifungal have saved millions developed from life threatening infections, but these agents lose their effectiveness because of resistance due to their irrational and unindicated use (i.e. antibiotics is not indicated for particular disease) or use of antibiotics without micro-organism susceptibility test. Present study was aimed to access the perception of community pharmacist regarding the dispensation of antibiotics without prescription in Karachi city of Pakistan, and to explore the etiologies of patient self-medication without concerning practitioners. The study was approved by the Clinical Pharmacy Department of Jinnah Sindh Medical University and was conducted in the period from May to June 2017 in Karachi, Pakistan. Questionnaire forms have been filled at the workplace by community pharmacists who were found to be geographically more accessible and have more experience (>1 year), thus assumed to provide better insight. Out of 25 community pharmacist, 11 agreed to fill the questionnaire giving response rate of 44%. Most participants consider the absence of implementation of monitoring of good dispensing practices by regulatory health authorities and most of the pharmacists donot fulfill their duties and only dispense antibiotics because of their commercial interest as well as lack of patient trust towards pharmacist. However, the studies showed that irrational use of antibiotics leads to emergence of these antimicrobial agents which is a current global problem that also causes failure to indicated therapy due to the loss of their effectiveness. **Key words:** Antimicrobials, Irrational dispensing, Community Pharmacist, Irrational use

KNOWLEDGE, ATTITUDE, PRACTICE AND PROVISION OF HEALTHCARE TO THE FASTING PATIENTS WITH DIABETES DURING RAMADAN: A MULTI CENTER SURVEY

Maheen Nizam, Muhammad Yakoob Ahmedani

Background: Fasting during Ramadan is obligatory for all adult healthy Muslims across the world. Through literature review, it has been found out that various articles are published for the awareness of patients and general population regarding safe fasting during Ramadan. In Pakistan, most of the patients with diabetes prefer to fast. However, nationwide data regarding knowledge, attitude, practices of fasting patients with diabetes and provision of care to these patients during Ramadan is scarce. **Aim:** To observe the knowledge, attitude, practice, and availability of appropriate healthcare to the fasting patients with diabetes during Ramadan. **Research Design and Methods:** This observational study was conducted at multi tertiary and primary care centers all over Pakistan, started from November 2016 to March 2017(Muslim year 1437). Ethical approval for the study was obtained from the Institutional Review Board of Baqai Institute of Diabetology and Endocrinology (BIDE). Fasting patients with diabetes across the country who gave informed consent were included in the study. Patients with diabetes who do not fast, non-Muslims, and children less than 12 years of age were excluded from the study. At each center, health care professionals involved in the care of patients with diabetes were requested to complete the questionnaire using convenience sampling. An identical standardized questionnaire-based interview was conducted on one-to-one basis across the country. Information regarding demographic, anthropometric measurements, number of days of fasting, type of treatment of diabetes, Ramadan related knowledge, attitude, and practices was collected. Pre-Ramadan diabetes education, adjustment of medication dosage and timings, frequency of blood glucose monitoring, development of hypoglycaemia and hyperglycaemia symptoms and their frequency during Ramadan were also taken. All the data was centralized into the computer database of BIDE. Statistical Package for Social Sciences (SPSS) version 20 was used to analyze the date. **Results:** Will be presented in the conference **Conclusion:** Will be presented in the conference.

EFFECTS OF RAMADAN FASTING ON BLOOD PRESSURE AND GLUCOSE LEVEL ON DIABETIC AND HYPERTENSION PATIENTS

Nazeer Khan, Sumayia Khan, Rashid Qadir, Aymen Sattar, Sarim Memon, Naveen Khawaja, Kiran Naseem, Sidra Nehal, Afreen Kazmi, Fatima Zuberi

Objective: To determine the effects of Ramadan fasting on blood pressure and glucose level on diabetic and hypertensive patients of Karachi **Methodology**:A hundred and sixty three volunteers were enrolled in the study, using convenient sampling and were categorized into four groups, namely 1) diagnosed hypertensive, 2) diagnosed diabetic, 3) diagnosed hypertensive, and diabetic 4), healthy control group. Out of these, 155 completed all the visits. The information was collected in the last ten days of Shaban, Ramadan and Shawwal 1437 H. In each visit, blood pressure was measured and a drop of a sample was taken. A questionnaire regarding demographic information, family history, drug used for diabetes or hypertension, physical activities and eating habits, number of *Traveeh* and fasts were asked. Anthropometric measurements were also taken. If the person had fasted less than 20 days, he/she was excluded from the study. **Results:** Forty of them were healthy individuals, 42 patients were hypertensive only, 32 patients were diabetic only and 41 patients were hypertensive and diabetic both. Sixty seven (43.2%) participants were male. The mean age of participants was 54.88 (9.6) years. The height and weight of the participants in Shaban was 1.63 (0.097) mand70.54 (13.92) kg, respectively. The mean weight of the subjects was significantly reduced from Shaban to Ramadan, but returned to almost the same level of Shaban in Shawwal ($p<0.0001$). Systolic blood pressure (SBP) significantly decreased in all the four groups from Shaban to Ramadan ($p<0.0001$). Mean diastolic blood pressure (DBP) also reduced from Shaban to Ramadan in all the four groups ($p=0.008$). The changes in the DBP in four groups were also significant ($p<0.0001$). Mean fasting blood sugar (FBS) also reduced from Shaban to Ramadan, but was statistically insignificant. However, the changes in four groups were statistically significant ($p<0.0001$). **Conclusion.** The study concludes that fasting is not only safe for hypertensive and diabetic Type 2 patients, but it gives some beneficial effects of reducing the blood pressure and fasting blood sugar.

CHANGES IN BLOOD PRESSURE AND GLUCOSE LEVEL ON DIABETIC AND HYPERTENSION PATIENTS DUE TO RAMADAN FASTING, ANTHROPOMETRIC IDENTITIES AND PHYSICAL ACTIVITIES.

Nazeer Khan, Sumayia Khan, Rashid Qadir, Syeda Saadia, Ushna Fatima, Hira Farooq, ZakiaHaq,Farzeen Waheed, Maheen Javed

Objective: To determine the changes occurring in blood pressure and glucose level on diabetic and hypertensive patients due to Ramadan fasting and anthropometric measurements and physical activities. **Methodology:** The methodology has been explained in the earlier abstract Nazeer Khan et al. **Results:** One hundred fifty five patients were divided in four groups: 40 healthy subjects, 42 patients hypertensive only, 32 patients diabetic only and 41 patients hypertensive and diabetic both. Sixty seven (43.2%) participants were male. The mean age of participants was 54.88 (9.6) years. The height and weight of the participants in Shaban was 1.63 (0.097) m and 70.54 (13.92) kg, respectively.The physical activities increased by 23% from Shaban to Ramadan due to inclusion of Taraweeh of Ramadan as exercise and then decreased by 30% in Shawwal. The mean MET (Metabolic Equivalent of Task) of Shaban, Ramadan and Shawwal was 274.9 (± 563.4), 760.0 (±687.7) and 233.9 (±401.4). There was significant increase in Ramadan. Using MET value of 600 as the cut point for physically active and inactive subjects, the data showed that the active individuals in Shaban, Ramadan and Shawwal were 16%, 56.1% and 16.8% respectively. The systolic blood pressure decreased significantly from Shaban to Ramadan, but increased marginally in Shawwal.The changes in four groups were significantly different. However, there was no significant effect due to initial BMI and physical activities. Diastolic blood pressure also decreased from Shaban to Ramadan, but bounced back in Shawwal almost at the same level of Shaban. But these changes were not statistically significant. The changes in the four groups were statistically different from each other. Fasting blood sugar also decreased from Shaban to Ramadan and returned to the same level in Shawwal. Changes were not statistically significant. The groups behaved differently in those changes. The initial BMI and physical activities did not show any significant effect. **Conclusion**: The Ramadan fasting affects positively and reduces systolic and diastolic pressures and fasting glucose level. Healthy and hypertensive patients gain more benefits than other groups.

LOOSE AND TIGHT GLYCEMIC CONTROL RAMADAN STUDY

Miss Erum

Aims: To observe the effects of keeping loose glycemic control during fasting and tight control during non-fasting hours in insulin treated people with type 2 diabetes during Ramadan. **Method: I**n this prospective study, people with T2DM who were on the treatment of free mixing insulin were recruited from the outpatient department of Baqai **I**nstitute of Diabetology and Endocrinology (BIDE), a tertiary care diabetes center of Karachi, Pakistan from June 2014 to August 2014. HbA1c test of each participant was conducted prior to the month of Ramadan. A pre- designed questionnaire was filled for baseline data. One to one education was provided regarding diet and diabetes self-management during Ramadan. A glucometer with 100 testing strips, a self-monitoring (SMBG) log book and food intake diary was provided to each participant. The blood glucose targets were given between 100-200 mg/dL. A separate 24/7 telephonic help line service was also provided for insulin dose adjustment and to encounter emergency situations. Each participant was contacted every third day. **I**nsulin dose was adjusted according to the respective blood glucose values and dietary intake of the last three days. Drug dosage adjustments were provided by a trained diabetes educator. Post Ramadan data was collected on the SMBG log book, last adjusted insulin dose during fasting and HbA1C test values after the month of Ramadan. SPSS version 13.0 was used for data analysis. **Results:** A total of 75 people with T2DM were included in the study. Morning dose of short acting insulin was shifted to sunset with the reduction of 8%, however at the end of Ramadan it was observed that the dose should be increased by 10% instead of reduction. Similarly, morning dose of basal insulin was shifted to sunset with the reduction of 20% but at the end of Ramadan, it was observed that the dose should be reduced to 10%. The evening dose of short acting insulin was shifted to pre-dawn with reduction of 50% and at the end of Ramadan, results suggested that the change made was accurate. Likewise evening dose of basal insulin was shifted to pre-dawn with reduction of 40% but at the end of Ramadan, results showed that the dose should be reduced to 30%. Mean HbA1c was reduced to almost one percent within 60 days which was statistically significant ($p<0.05$) **Conclusion:** This study demonstrates that fasting during Ramadan is safe for people with diabetes with reinforcement of diabetes education, continuous attention to dietary intake, daily physical activity, frequent self-monitoring of blood glucose and insulin dose adjustments. Hypoglycemic events can be minimized with conventional control during fast and intensive control during non-fasting hours. Further large scale studies are needed to validate our findings.

IMPACT OF 24-HOURS STATION BASED TELEPHONIC HELPLINE SERVICE FOR PEOPLE WITH DIABETES DURING RAMADAN FASTING

Dr. Nadeem

Aims: To assess the impact of 24 hours station-based helpline support for people with diabetes during Ramadan. **Methodology:** In this prospective study, all people with type 1, type 2, and gestational diabetes who wished to fast during Ramadan were recruited from the outpatient department of Baqai Institute of Diabetology and Endocrinology (BIDE), a tertiary care diabetes center of Karachi, Pakistan from May 2015 to July 2015. Ethical approval for this study was obtained from Institutional Review Board of BIDE. Pre-Ramadan medical assessment and diabetes education was provided to all participants, 24-hours station-based help line service was also provided for drug/insulin dose adjustment and to encounter the emergency situation during Ramadan. Trained educators adjusted insulin dose according to self-monitoring of blood glucose (SMBG)of last three days. Appropriate suggestions was provided on each telephonic call after consulting medical history, treatment plan, and lab reports. The details of each call and given suggestions were recorded on electronic health care management software (HMS) of BIDE. SPSS version 13 was used for data analysis. **Results:** This is a prospective study. Five hundred and one people with diabetes from both genders were included in the study. There were 241 (48.1%) males and 260 (51.9%) females. Mean body mass index (BMI) was 29.03 ± 11.36 kg/m^2. Mean duration of Diabetes was 5–10 years. The means HbA1c and Serum creatinine were 9.67 ± 2.21 and 1.11 ± 0.50 respectively. During the month of Ramadan, 948 calls were received. Insulin dose was adjusted in 594 (62.7%) calls according to the respective SMBGs. Sixty one (6.4%) calls were received for severe hyperglycaemia and correction dose was administrated in two-thirds of the patients and hospital admissions were saved. Hypoglycaemia was treated in 48 (6.4%) calls. **Conclusion:** Twenty four hours station-based helpline service can be a good support for people with diabetes during Ramadan fasting to achieve good glycaemic control and safe fasting. Further large scale studies are needed to validate our finding.

EFFECTS OF RAMADAN FASTING ON BLOOD PRESSURE AND GLUCOSE LEVEL ON DIABETIC AND HYPERTENSION PATIENTS

Nazeer Khan, Sumayia Khan, Rashid Qadir, Aymen Sattar, Sarim Memon, Naveen Khawaja, Kiran Naseem, Sidra Nehal, Afreen Kazmi, Fatima Zuberi

Objective: To determine the effects of Ramadan fasting on blood pressure and glucose level on diabetic and hypertensive patients of Karachi. **Methodology:** A hundred and sixty three volunteers were enrolled in the study, using convenient sampling and were categorized into four groups, namely 1) diagnosed hypertensive 2) diagnosed diabetic 3) diagnosed hypertensive and diabetic 4) healthy control group. Out of these, a hundred and fifty five completed all the visits. The information was collected in the last ten days of Shaban, Ramadan and Shawwal 1437 H. In each visit blood pressure was measured and a drop of a sample was taken. A questionnaire regarding demographic information, family history, drug used for diabetes or hypertension, physical activities and eating habits, number of Traveeh and fasting were asked. Anthropometric measurements were also taken. If the person has fasted less than 20 days, he/she has been excluded from the study. **Results:** Forty of them were healthy individuals, 42 patients were hypertensive only, 32 patients were diabetic only and 41 patients were hypertensive and diabetic both. Sixty seven (43.2%) participants were male. The mean age of participants was 54.88 (9.6) years. The height and weight of the participants in Shaban was 1.63 (0.097) m and 70.54 (13.92) kg, respectively. The mean weight of the subjects was significantly reduced from Shaban to Ramadan, but tuned back to almost the same level of Shaban in Shawwal ($p<0.0001$). Systolic blood pressure (SBP) significantly decreased in all the four groups from Shaban to Ramadan ($p<0.0001$). Mean diastolic blood pressure (DBP) also reduced from Shaban to Ramadan in all the four groups ($p=0.008$). The changes in the DBP in four groups were also significant ($p<0.0001$). Mean fasting blood sugar (FBS) also reduced from Shaban to Ramadan, but is=t was statistically insignificant. However the changes in four groups were statistically significant ($p<0.0001$). **Conclusion.** The study concludes that fasting is not only safe for hypertensive and diabetic Type 2 patients, but it give some beneficial

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