



Impact of Pre-Ramadan Intervention Program on Diabetic Patients
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From the Editor

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This is the first issue this year and we would like to thank our readers, authors, the editorial board, reviewers, and our publishing manager and company for their continuous support for the success of this landmark journal in the field of family medicine.

In this issue two papers from Saudi Arabia deal with use of audiovisual technology in the healthcare sector. Alghamdi J.S et al; evaluated the effectiveness of educational videos against patients' fixed beliefs and lack of knowledge in comparison with traditional educational methods. It investigates the effectiveness of these tools in overcoming patients' psychological barriers toward insulin therapy. This randomized, controlled trial used the validated insulin treatment appraisal scale (ITAS) to evaluate patients' psychological barriers. An educational video and brochure were developed, each containing the same contents. The study was conducted in King Abdulaziz city housing with a total sample size of 126, divided into an intervention group (shown the video) and a control group (given the brochure). This study showed no superiority of the video over the brochure, which costs less and required less effort to produce. Algahtani F et al; tried to validate an audiovisual tool created for the evaluation of its usefulness in breaking the insulin barrier, by making a video which is simple, accessible and informative at the same time. The video explains the nature of type two diabetes, the progression of the disease and the options of treatment and the side effects. The subject included 178 staff persons that met the inclusion and exclusion criteria. The staff consisted of family medicine physicians and residents, medical interns, nurses, medical students and other medical staff e.g. clinical

pharmacist, dietitian, medical educator. The study shows a positive response by healthcare personnel toward the audio-visual material which aimed to break insulin barriers in diabetic patients. This material can be used by a diabetic multidisciplinary team as an educational tool as it will leave the patient with better understanding of insulin which will lead to better control of diabetes and increase compliance.

AL-Alwan, A.A et al; evaluated the role of ultrasound in congenital cataract. A total of 242 patients aged less than one year referred from pediatrics ophthalmologist in their hospital (Queen Rania children hospital) with clinical suspicion of congenital cataract over the period June 2015 till December 2017 and were evaluated by orbital ultrasound to evaluate the posterior chamber. The authors concluded that Ultrasound is a valuable diagnostic modality in assessing the posterior chamber in patient with unilateral or bilateral congenital cataract to rule out associated posterior chamber abnormalities which will influence the prognosis and management plan.

Mohamed, O.M.I et al; evaluated the effectiveness of a Pre-Ramadan structured educational program for diabetic patients. A Randomized single blinded control trial was conducted in Al Bateen Primary Healthcare Clinic in Abu Dhabi, Ambulatory Health Services (AHS). Patients were allocated randomly to either an intervention or control group; 60 diabetic patients were chosen using simple randomization. The intervention group received a pre-Ramadan structured educational program by a trained family physician. The control group received standard/usual diabetic care. Pre-/post-Ramadan data was collected for both groups. Comparison between both groups was done using Chi-square test and independent samples Student's t-test, $p = 0.05$ was considered statistically significant. The authors concluded that a pre-Ramadan structured educational program as per IDF/DAR guidelines for diabetic patients who intend to fast in Ramadan, significantly reduces their risk of hypoglycemia by up to 50%. The physician review and modification of medications, in accordance guidelines is one of the most important factors in reducing the frequency of hypoglycemia.

Helvacı, M.R et al; looked at the effect of excess weight on blood pressure (BP) which may be the major cause of inflammation. The authors took consecutive patients between the ages of 35 and 70 years. There were 105 cases (18.9%) in the normal weight, 240 cases (43.2%) in the over-

weight, and 208 cases (37.4%) in the obesity groups with similar mean ages (48.0, 50.4, and 52.3 years, respectively, $p > 0.05$ for both). Parallel to BP, prevalence of diabetes mellitus (DM), hyperbetalipoproteinemia, dyslipidemia, and coronary artery disease (CAD) increased parallel to increased body mass index again ($p < 0.05$ nearly in all steps). The authors concluded that excess weight affects 80.7% of the population at and above the age of 35 years in Turkey, and obesity is found nearly four-time more common in females. Parallel to the increased body mass, prevalence of sustained NT decreased and WCH and HT increased beside the increased prevalence of other parameters and consequences of the metabolic syndrome including DM, hyperbetalipoproteinemia, dyslipidemia, and CAD.

A report on micro-needling and lymphadenitis as side effects is also included. Micro-needling and platelet-rich plasma (PRP) is recently gaining popularity; growing internationally, highly enriched plasma that contains a large concentrations of platelets which secrete various growth factors, and is used in a wide variety of surgical and cosmetic procedures, including hair re-growth, facial wrinkles and skin rejuvenation. To conclude, micro-needling is a minimally invasive procedure. Therefore, I urge that every individual and every medical practitioner pay more attention to the impending side effects of the procedure, in order to document the cases and report them with their reasoning. Also, to not underestimate the procedure because many think it's a trivial, simple procedure with no potential risks, and it is not.

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Role of ultrasound in congenital cataract: Our experience

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Abstract

Aim: To evaluate the role of ultrasound in congenital cataract.

Method: 242 patients aged less than one year referred from pediatric ophthalmologists in our hospital (Queen Rania Children Hospital) with clinical suspicion of congenital cataract over the period June 2015 till December 2017 were evaluated by orbital ultrasound to evaluate the posterior chamber.

Patients were divided into 2 groups: the first group, 169 patients who presented with bilateral congenital cataract (69.8%) and the second group 73 patients who presented with unilateral congenital cataract (30.2%).

Results: Of the first group of patients (bilateral congenital cataract): 130 patients (76.9%) had normal posterior chamber on ultrasound bases.

39 patients (23.1%) had abnormal posterior chamber; 24 patients (66.6%) had retinal detachment, 12 patients (25.74%) had vitreous hemorrhage, 2 patients (5.1%) had posterior staphyloma and 1 patient (2.56%) had bilateral persistent hyperplastic primary vitreous.

Of the patients in the second group (unilateral congenital cataract): 44 patients (60.3%) had normal posterior chamber and 29 patients (39.7%) had abnormal posterior chamber, 15 patients (51.7%) had retinal detachment, 8 patients (27.6%) had persistent hyperplastic primary vitreous, 5 patients (17.2%) had vitreous hemorrhage and 1 patient (3.5%) had retinoblastoma.

Conclusion: Ultrasound is a valuable diagnostic modality in assessing the posterior chamber in patients with unilateral or bilateral congenital cataract to rule out associated posterior chamber abnormalities which will influence the prognosis and management plan.

Key words: Ultrasound, congenital cataract, posterior chamber.

Background / Introduction

Cataract is the opacification of the normally transparent crystalline lenses, and is considered rare in the paediatric age group [1]. Paediatric cataracts are classified as congenital, developmental, or traumatic; it is considered congenital when found in the first year of life while the developmental occur after infancy. Cataract is one of the preventable and curable causes of visual disability. Approximately affecting 200 thousand children worldwide, with the prevalence of 3-6/10 thousand life births [2-4]. In addition to the clinical examination; ultrasonography plays a role in discovering and detecting any pathology in the posterior part of the globe in dense cataract and helps in guiding the ophthalmologist to approach pre-operatively [5]. Ultrasound was first used in ophthalmology in 1956 by the American ophthalmologists Mundt and Hughes [6].

Materials and Methods

This is a retrospective study for infants who were suspected to have congenital cataract at Queen Rania Children hospital. All patients were scanned with Philips Ultrasound machine using linear high frequency transducer (3-9) MHZ in the period from June 2015 to December 2017. We included all infants (less than one year) with suspected congenital cataract, either unilateral or bilateral and isolated or associated with other abnormalities, excluding premature and trauma patients. No special preparation was needed to perform orbital ultrasound, where it is considered a straightforward procedure. The exam is started by closing the patient's eye and scanning directly through the eyelid using ultrasound gel to ensure adequate visualization. The two standard views were taken; involving the transverse and sagittal dimensions and was completed by color Doppler flow if there is suspicion of tumor or vascular lesion. All

patients were examined by two pediatric ophthalmologists and two pediatric radiologists in two separate sessions and the results were analyzed by simple statistical method.

Ethical concern

Our study had ethical committee approval from our institution and all data was obtained lawfully.

Results

The total number of the sample was 242 patients and the age group included less than one year regardless of the gender. All underwent orbital ultrasound to assess posterior chamber in patients who have congenital cataract. The study revealed that ultrasound is a valuable method for detecting posterior chamber pathology. The patients were divided into two groups: the first group (bilateral congenital cataract) which included 169 patients (69.8%) and the second group (unilateral congenital cataract) which included 73 patients (30.2%) (Figure 1). In both groups the majority of patients were not found to have any pathology in the posterior chamber on ultrasound bases in that: 130 patients (76.9%) in the first group and 44 patients (60.3%) in the second group. In the first group about 39 patients (23.1%) had posterior chamber pathology where (Figure 2) 24 patients (66.6%) had retinal detachment (Figure 3), 12 patients (25.74%) had vitreous hemorrhage, 2 patients (5.1%) had posterior staphyloma and one patient (2.56%) had bilateral persistent hyperplastic primary vitreous. While in the second group 29 patients (39.7%) had posterior chamber pathology where (Figure 4) 15 patients (51.7%) had retinal detachment, 8 patients (27.6%) had bilateral persistent hyperplastic primary vitreous (Figure 5), 5 patients (17.2%) had vitreous hemorrhage and one patient (3.5%) had retinoblastoma (Figure 6).

Congenital Cataract

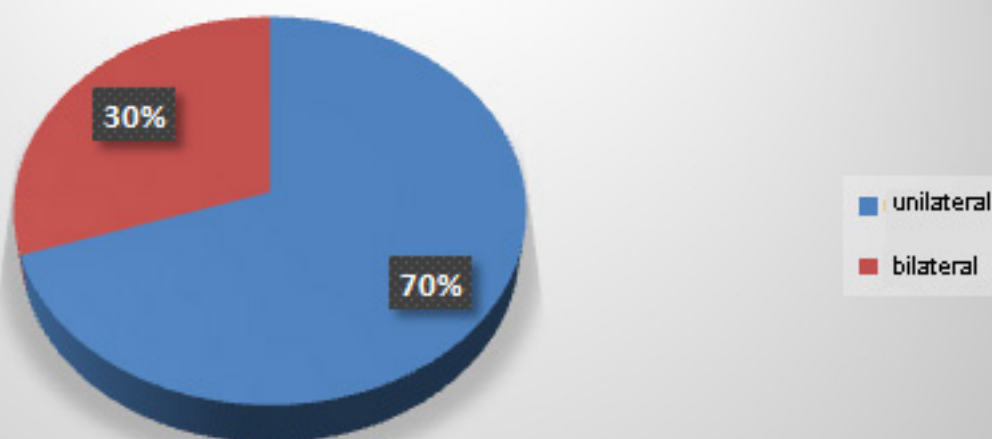


Figure 1

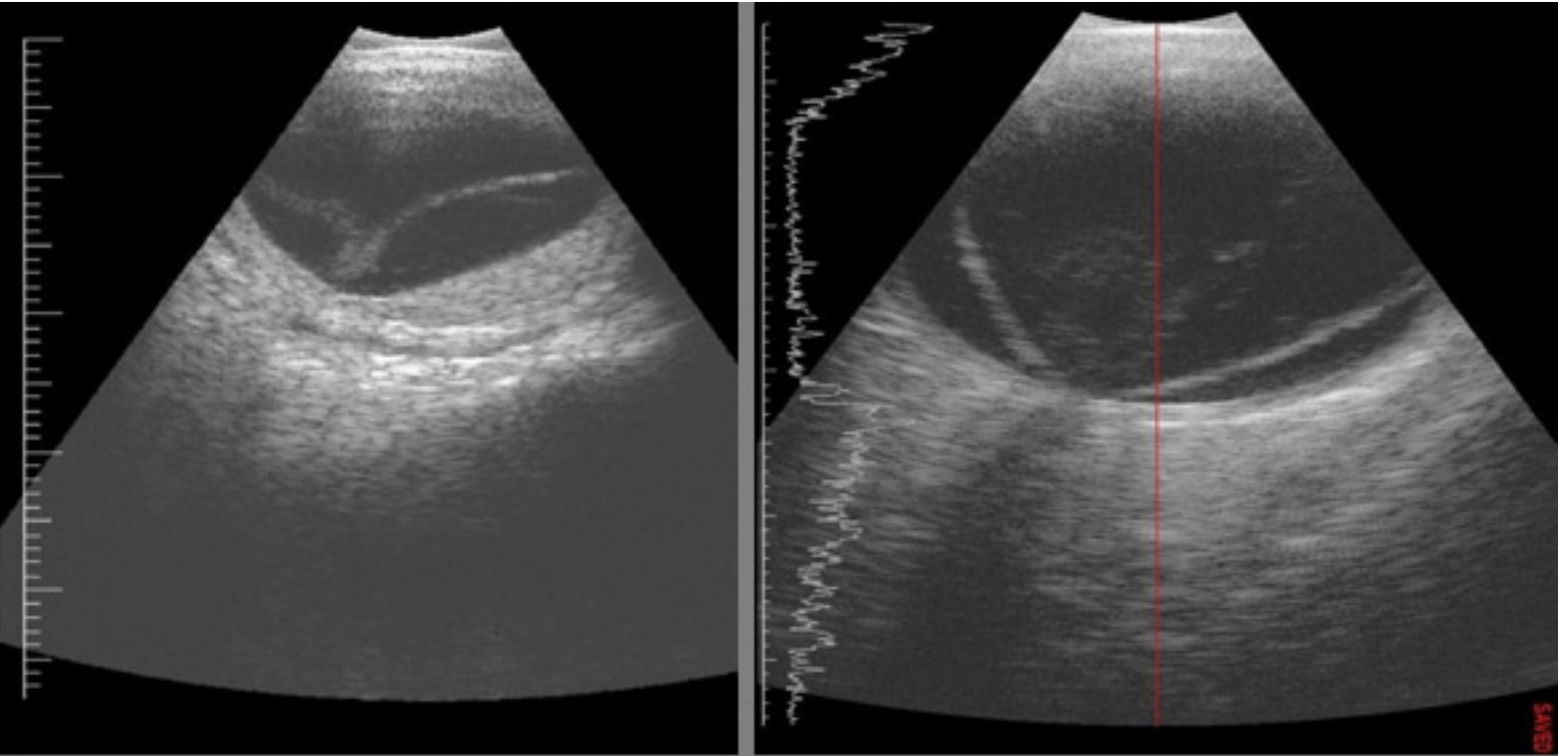
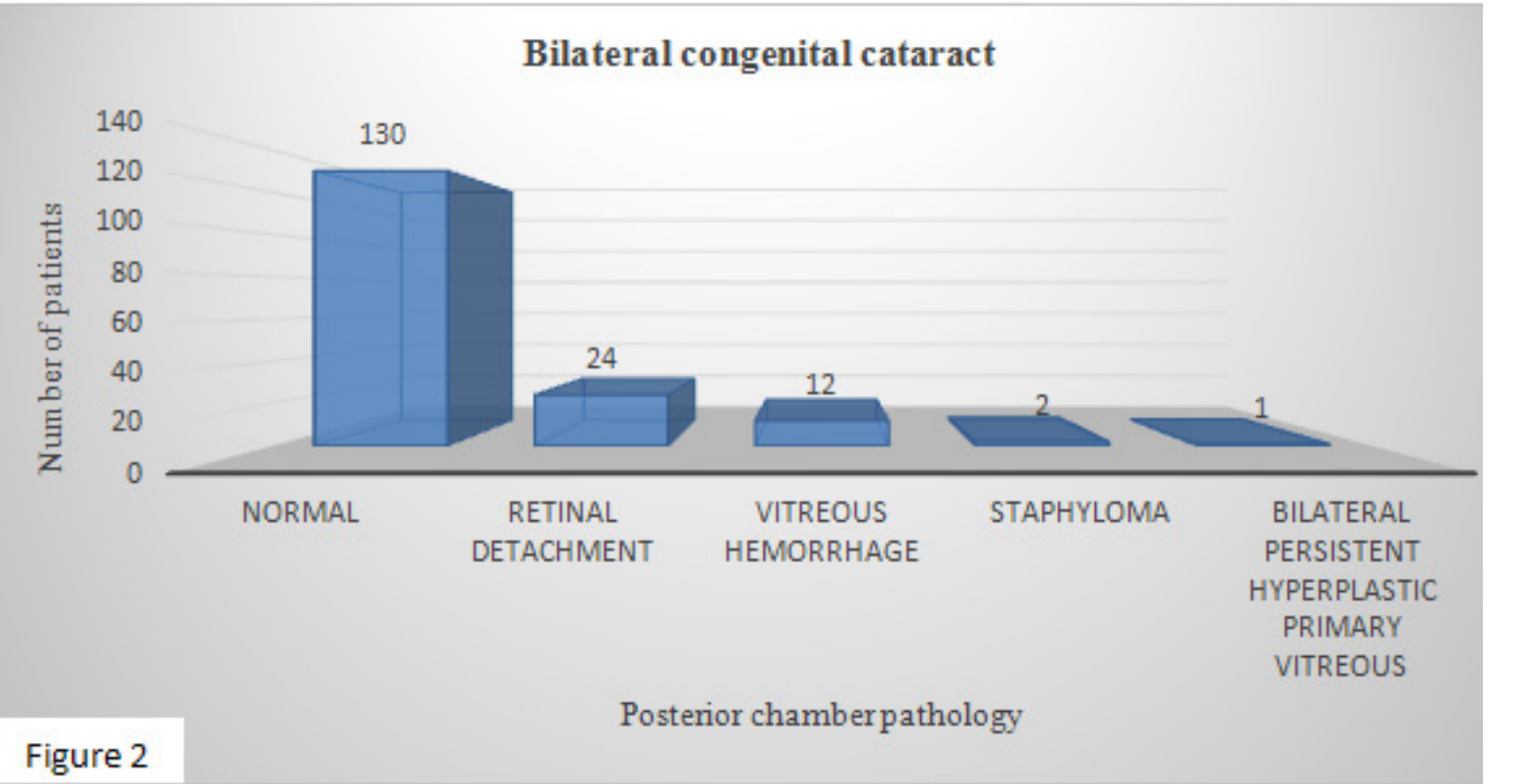


Figure 3, Ultrasound shows bilateral retinal detachment in 6 months baby with bilateral cataract

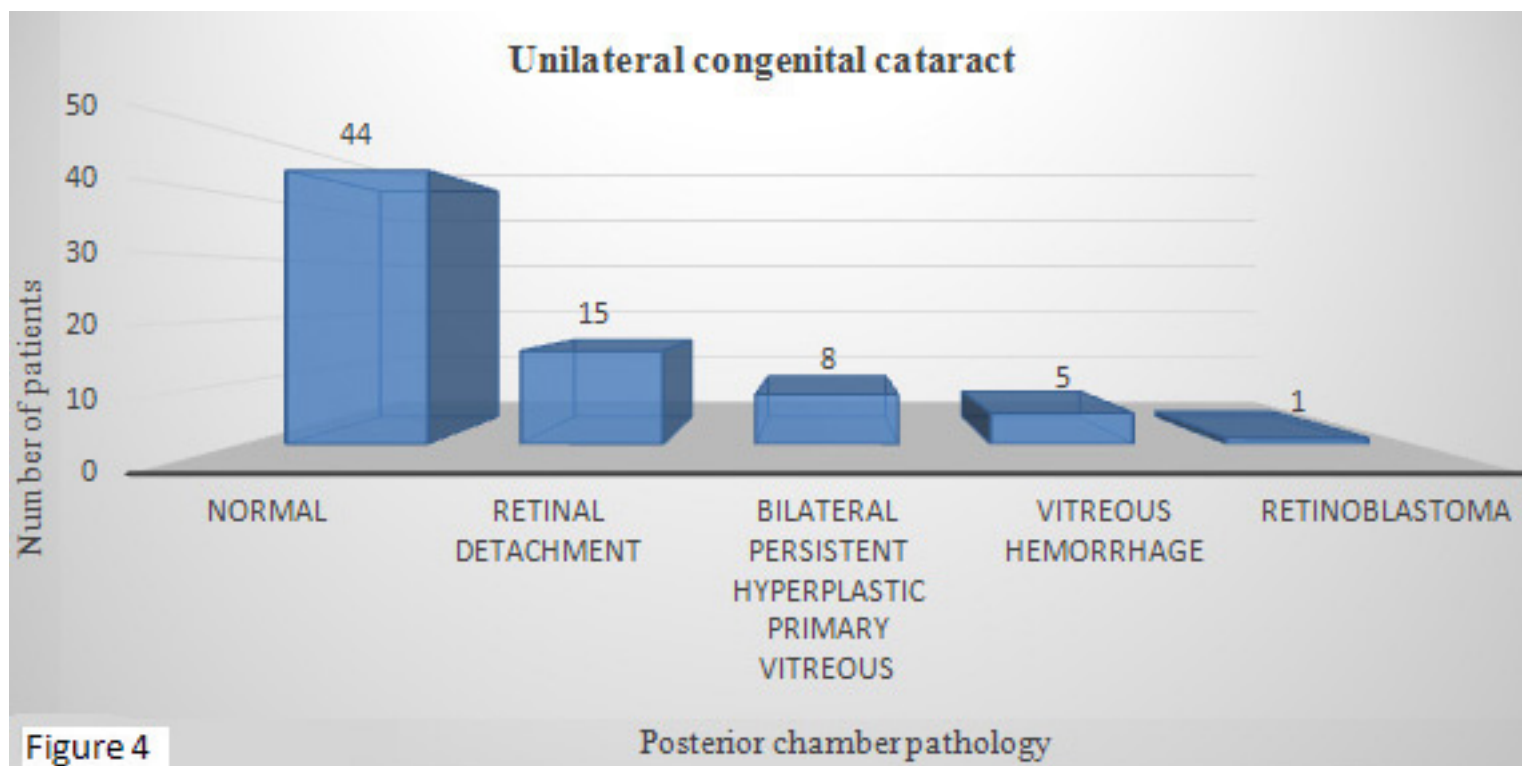


Figure 5, Ultrasound shows persistent hyperplastic primary vitreous in 4 months baby with unilateral cataract.



Figure 6, Ultrasound shows retinoblastoma in 3 months baby with unilateral cataract.

Discussion

As there were no previous studies that had a similar experience (the role of ultrasound in infants who were suspected to have congenital cataract), we share our experience in highlighting the importance of the ultrasound as a non invasive and informative modality. A cataract is an opacification of the lens; if the cataract is diagnosed in the first year of life it is considered congenital, which is divided into unilateral or bilateral. The unilateral is usually sporadic, though it may be associated with trauma or infection (intrauterine) in a minority of cases, while the bilateral is often inherited and may be associated with other disease. The possible underlying causes are intrauterine infection, trisomy and hypoglycemia. Due to that genetic and metabolic workup are required [7]. The congenital cataract may cause significant visual impairment that eventually, if not treated, may lead to blindness, in spite of that fortunately, it is a treatable and preventable disease if diagnosed early. The diagnosis of cataract requires a detailed history and prompt ocular examination, including anterior segment exam by indirect ophthalmoscope and intraocular pressure measurement using air puff, in addition as a complementary orbital ultrasound might be required, especially if there is a dense cataract. Our study revealed that more than half of the patients showed normal posterior chamber in both groups; while when there is posterior chamber pathology, the second group, is countered with a higher percentage than the first group in about 40%. In both groups; the retinal detachment is the most common posterior chamber pathology in about 67% in the first group and 52% in the second group. The vitreous hemorrhage is the second common finding in the

first group, about 26%, while it is the third common in the second group, about 17%. The minority of patients in the first group had bilateral persistent hyperplastic primary vitreous with a percentage of 2.6% and this pathology is considered the second most common in the second group, about 28%. In the first group the patients had staphyloma in a percentage of 5% which was not found in the second group; the same for retinoblastoma that was found in the second group in a minority of patients, about 3.5%, and not found in the first group.

Limitation: It was a single center study and without taking into consideration the gender, in addition to that the ultrasound is operator dependent.

Conclusion

Ultrasound is a non invasive, valuable and reliable method to assess the posterior chamber in patients with congenital cataract and help the surgeon to map the surgery accurately. It is considered a complementary method to the traditional ophthalmic examination. Further studies are warranted.

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Impact of Pre-Ramadan Intervention Program on Diabetic Patients (PRINTED 1): A Randomised Controlled Trial in a Family Medicine Clinic - Abu Dhabi

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Abstract

Fasting during the month of Ramadan carries risk for some diabetic patients. Many Guidelines recommend providing pre-Ramadan structured education to all diabetic patients who intend to fast during Ramadan.

The aim of this study was to evaluate the effectiveness of a Pre-Ramadan structured educational program for diabetic patients. Before Ramadan, patients were risk stratified into low, moderate, high and very high risk for fasting in Ramadan. The content of the program was adapted from DAR/IDF guidelines and was delivered during patient-physician clinical encounters. This included: a medication review, categorization of patients individual fasting risk, as well as advice on risk of fasting for high risk groups, nutrition plan, monitoring of blood glucose and when to break the fast.

Methods: A Randomized single blinded control trial was conducted in Al Bateen Primary Healthcare clinic in Abu Dhabi, Ambulatory Health Services (AHS). Patients were allocated randomly to either an intervention or control group; 60 diabetic patients were chosen using simple randomization. The intervention group received a pre-Ramadan structured educational program by a trained family physician. The control group received standard/usual diabetic care. Pre/Post-Ramadan data was collected for both groups. Comparison between both groups was done using Chi-square test and independent samples Student's t-test; $p \leq 0.05$ was considered statistically significant.

Results: A total of 60 diabetic patients were included in the study: 30 patients in the intervention group and 30 patients in the control group. The duration of diabetes was 14.28 (SD±11.44) years in the study group and 10.52 (SD±6.94) years in the control group; mean years of age was 55.83 (SD±13.71) in the study group and 56.76 (SD±14.98) years in the control group. Approximately 90% of patients in each of the groups intended to fast during the forthcoming month of Ramadan. Approximately 33% of patients in each group intended to modify their medication during Ramadan. In terms of patient risk stratification for fasting amongst the two groups, there was no statistically significant difference: each group contained approximately one third low risk, one third high risk and one third very high-risk patients. The frequency of pre-study hypoglycemia was approximately similar, 40% intervention v 33% control in both groups. Medications were physician reviewed and modified when necessary

in all patients (100%) in the intervention group. In the control group 11 patients (36.6%) had their medications modified, either self-modification or by their health care providers. ($P < 0.5$).

The pre-study frequency of hypoglycemia was 12 (40%) in the intervention group and 15 (33%) in the control group ($p > 0.05$). In the intervention group, the frequency of hypoglycemia decreased significantly from 40% before the study to 16.7% during the study period (50.15% reduction) (P was 0.003). In the control group, the incidence of hypoglycemia remained the same (33.3%) before and during the study period. There was more than 50% reduction of post intervention hypoglycemia in the study group ($p < 0.003$).

In terms of dietary food intake and exercise practices during Ramadan, there was no significant difference between the intervention and control groups. There was also no significant difference in the mean score of knowledge of hypo/hyper-glycaemia symptom awareness, or when the fast should be broken. Pre-/post-Ramadan biomedical parameters changes including lipids, eGFR, BMI, HbA1c and blood pressure BP were statistically insignificant in both groups. The Mean number of days fasted during this Ramadan was 27(±7.1) in the study group and 28 (±6.3) in the control group.

Conclusions: A pre-Ramadan structured educational program as per IDF/DAR guidelines for diabetic patients who intend to fast in Ramadan, significantly reduces their risk of hypoglycemia by up to 50%. The physician review and modification of medications, in accordance with guidelines is one of the most important factors in reducing the frequency of hypoglycemia.

Key Words: Diabetes, Ramadan, randomized controlled trial, Focused Education, hypoglycemia

Introduction

Fasting in the holy month of Ramadan is one of the five pillars of Islam. All healthy Muslims are obliged to fast during Ramadan each year once they reach puberty. Individuals must refrain from eating, drinking, and using oral medication between dawn and sunset. Depending on the season and geographic setting, the duration of the daily fast may range from 12 to 20 hours, around 15 hours in Abu Dhabi in 2017. Ramadan fasting has several potential benefits particularly to healthy individuals but may adversely affect sick patients including those with Diabetes Mellitus (DM). Adverse effects which may affect patients with DM during Ramadan fasting include hypoglycemia, hyperglycemia, diabetic ketoacidosis, dehydration, and increased risk of thrombosis, resulting in stroke and retinal artery occlusion.(1) Patients with DM are classified as low risk/moderate risk, high risk, and very high risk for the development of such complications. Those in the categories of high risk and very high risk are usually advised not to fast.(2) In general, the Quran exempts an individual from fasting if the health of that individual can be adversely affected by fasting (3).

All patients with diabetes wishing to fast during Ramadan should receive proper counseling 1-2 months before the onset of Ramadan. Asking the patients not to fast, even though it may be based on scientific evidence, may not only lead to the patient fasting without telling his doctor but may also offend the patient's cultural values. The physicians should work with their patients to prepare an appropriate and individualized life-style, diet and drug plan (4).

The EPIDAR study showed that fasting during Ramadan increased the risk of severe hypoglycemia (defined as hospitalization due to hypoglycemia) some 4.7-fold in patients with type 1 diabetes and 7.5-fold in patients with type 2 diabetes. Severe hypoglycemia was more frequent in patients in whom the dosage of oral hypoglycemic agents or insulin was changed and in those who reported a significant change in their life style.(5)

The READ study demonstrated that Ramadan-focused education in diabetes can empower patients to change their lifestyle during Ramadan. It minimizes the risk of hypoglycemic events There was a significant decrease in the total number of hypoglycemic events in group A (those who attended a structured education program about physical activity, meal planning, glucose monitoring, hypoglycemia, dosage and timing of medications), from nine to five, compared with an increase in group B (who did not attend the program) from nine to 36 ($P < 0.001$) (6).

A prospective nonrandomized interventional controlled design was run in three phases: before, during, and after Ramadan on 262 type 2 diabetes patients and demonstrated that Ramadan educational program had a positive impact with reduction of hypoglycemic risk, HbA1c, and low-density lipoprotein cholesterol (7).

Another prospective interventional controlled design was carried out on patients with type 2 diabetes. There was a significant impact of pre-Ramadan educational program on reduction of hypoglycemic risk and other acute complications, reduction of low-density lipoprotein cholesterol and improvement of high-density lipoprotein cholesterol (8).

The results of a systematic review which included Randomized Controlled Trials (19 trials)(9,378 participants) showed that structured diabetes education has a positive impact on biomedical and quality of life on diabetic patients especially with some degree of reinforcement at additional points of contact (9).

The randomized controlled trial (RCT) is considered to provide the most reliable evidence on the effectiveness of interventions because the processes used during the conduct of an RCT minimize the risk of confounding factors influencing the results. Because of this, the findings generated by RCTs are likely to be closer to the true effect than the findings generated by other research methods (10).

Effectiveness of such educational programs has not been well studied in a randomized controlled study. The aim of this study was to evaluate the effectiveness of RCT of pre-Ramadan educational program to patients attending one of the Family Medicine clinics, Ambulatory Health Care Abu Dhabi Health Services Company - SEHA.

Objectives

1. To assess the risks of fasting during Ramadan among diabetic patients
2. To assess fasting pattern among diabetic patients.
3. To evaluate patients with diabetes knowledge, attitude and practices during Ramadan fasting regarding safe fasting.
4. To educate diabetic patients regarding adjusting medications, risk of fasting, indications to break fasting, meal plans, and exercise.
5. To assess impact of pre-Ramadan intervention program on improving Diabetic patients' knowledge on safe fasting reducing hypoglycemia, and biomarkers namely: lipids, eGFR, blood pressure, BMI, HbA1c level.

Methods

1. Study Design: A Randomized controlled study was conducted in a primary care clinic, Ambulatory Health Care.

2. Study Population: Patients who presented to Al Bateen Family Medicine Clinic with physician-diagnosed Diabetes based on the A1C above or equal 6.5% and met the inclusion and exclusion criteria were included in the study.

Inclusion Criteria were: Adult (above 18) diabetic patients and willing to fast during Ramadan.

Exclusion criteria were: Patients who were not willing to fast during Ramadan.

3. Sample size: Based on patients' inclusion and exclusion criteria and 21.7% anticipated frequency of hypoglycemia in fasting patients at 95% confidence interval (11). Sample size was estimated to be 60 diabetic patients, 30 in each group.

4. Randomization: First 30 eligible patients with diabetes who attended the clinic were included in the intervention group and the second 30 eligible patients with diabetes who attended the clinic were included in the control group.

5. Patient Informed consent was obtained before study; AHS research and ethical committee approval was obtained.

6. Socio demographic characteristics including age, gender, education, diabetes duration, smoking, attended structured Ramadan management program, planning to fast this Ramadan, were included in the interview questionnaire.

7. Pre-Ramadan diabetes education included the following 6 Key areas (Face to Face education during consultation) according to IDF/DAR recommendations(4).

- 1 -Risk quantification
- 2 -Blood glucose monitoring
- 3 -Fluids and dietary advice
- 4- Exercise
- 5- Medication adjustments during fasting
- 6 -When to break the fast

8. Risk Quantification: Patients were categorized into three categories based on DAR IDF classification of Fasting risk(4):

- Category 1 (very high risk),
- Category 2 (high risk)
- Category 3 (moderate/low risk)

Patients in categories 1 and 2 were advised not to fast while patients in category 3 were allowed to fast if they wish. Doctors were aware that fasting during Ramadan is a personal decision and many patients, in spite of their awareness of the risk, chose to fast against medical advice. This decision was respected, and the patient was given advice and support that allowed them to fast as safely as possible.

9. Medical nutrition education during fasting in Ramadan: was adapted from DAR SAFA medical nutritional therapy, Diabetes and Ramadan (DAR) Alliance (12).

Patients were advised to:

- Distribute the carbohydrate intake between Iftar and Suhoor meals
- Avoid drinks and deserts containing excess sugars. Fruits should be consumed instead.
- Drink plenty of water/fluids from Iftar to Suhoor
- Delay Suhoor to as late as possible
- Take regular light to moderate exercise such as brisk walking for 30 minutes
- Taraweeh prayers can be considered as part of the daily exercise plan.

The educational intervention included material and written brochures focused on Safe fasting in Ramadan, including signs and symptoms of hyper- and hypoglycemia, self-

monitoring of blood glucose, physical activity, nutritional advice when to break the fast.

10. Knowledge of hypo and hyperglycemia: The intervention group was educated regarding symptoms of hypoglycemia in terms of Trembling Sweating/chills, Palpitations, Hunger Altered mental status. Confusion, Headache and the symptoms of Hyperglycemia as well as Extreme thirst, Hunger, Frequent urination, Fatigue, Confusion, Nausea/vomiting, Abdominal pain. Each symptom scored one if answered right or zero if wrong; total score of hypoglycemia or hyper glycaemia ranged from 0 to maximum 7 out of 7.

11. Hypoglycemia assessment: All patients were evaluated regarding hypoglycemia by Hypoglycemic Health Association Hypoglycemia Questionnaire(13) introduced by the Hypoglycemic Health Association of Australia. The questionnaire was translated into Arabic; it included 10 questions to check hypoglycemia symptoms, including:

1. Become tired or exhausted.
2. Forget things easily.
3. Feel sleepy during the day.
4. Get down or depressed.
5. Get down over nothing.
6. Have trouble concentrating.
7. Get nervous or shaky.
8. Easily get angry.
9. Eat or crave sweets, or once used to.
10. Awaken during the night.

Total the number of ticks in each column for RARELY, OCCASIONALLY and USUALLY, calculated as follows:-

RARELY (Total) x 1 = _____
 OCCASIONALLY: (Total) x 2 = _____
 USUALLY: (Total) x 3 = _____
 Add together for TOTAL SCORE _____

If TOTAL SCORE IS:

Less than 8: Hypoglycemic disease is unlikely.

Between 8 to 15: Hypoglycemic disease is possible.

Above 15: Hypoglycemic disease is present.

12 Medication Review: During Ramadan medications are adjusted according to IDF/DAR guidelines and included a 20–30% reduction in dose in patients on insulin and sulphonylurea (4).

13. Written educational Arabic or English version of educational program was given to diabetic patients in the intervention group.

14. Statistical Analysis: data was entered in Excel Spreadsheet and analyzed using SPSS14 for Windows. Analysis used simple frequency distribution of key variables in the study. Comparison was made with selected base line demographic variable age gender educational status and socioeconomic status. The level of significance was set at $p < 0.05$. Data collected by the investigators was checked for consistency.

Results

A total of 60 patients (30 intervention group and 30 control group) with type 2 diabetes (women 10 (33.3%), men 20 (66.7%) in the control group, 15 (50.0%) women and 15(50.0%) in the study group) participated in this study. The mean diabetes duration was 14.28 (± 11.44) year in study group and 10.52 (± 6.94) years in control group; the patient mean age was 55.83 (± 13.71) in the intervention group and 56.76 (± 14.98) years. Both groups did not differ in baseline characteristics in terms of education, smoking and employment (Table 1).

Table 1: Socio-demographic characteristics

Variable	Study group 30	Control Group 30	Test Value	P Value
Mean age in years (SD)	55.83(± 13.71)	56.76(± 14.98)	t- 0.247	0.80
Mean Diabetes duration	14.28(± 11.44)	10.52(± 6.94)	t- 1.512	0.13
Gender				
1.Male	15(50.0%)	10(33.3%)	χ^2 - 1.714	0.19
2.Female	15(50.0%)	20(66.7%)		
Education				
1. No school	3(10.0%)	4(13.3%)	χ^2 - 4.919	0.42
2. Literacy classes	0 (0%)	1(3.3%)		
3. Elementary	7(23.3%)	6(20.0%)		
4. High school	12(63.2%)	7(36.8%)		
5. College	5(16.7%)	4(13.3%)		
6. Higher education	5(16.7%)	4(13.3%)		
Employment				
Employed	11(36.7%)	8(26%)	χ^2 - 0.693	0.40
Tobacco use				
Smoker	3(10.3%)	3(10.3%)	χ^2 - 0.000	1.00

χ^2 = Chi square test, t = Student t test, SD Standard Deviation

There was no statistically significant difference between study and control group in their intention to fast during Ramadan or in intention to modify their treatments (Table 2); 90% of both groups said that they will fast during the coming Ramadan and only one third of each group said that they will modify their medication before the coming Ramadan. Patients in both groups fasted most of Ramadan; the main reason for breaking the fast was hypoglycemia (Table 2).

Table 2: Days fasted in previous Ramadan and this Ramadan, patients whose medications had been modified before Ramadan

Variable	Study Group	Control Group	Test Value	P Value
Patients who had their medications modified before Ramadan	30 (100%) y	11(36.6%)	χ^2 -17.60	0.0027*
Patients who intended to fast during Ramadan	27(90%)	27(90%)	χ^2 -1.71	0.19
Mean number of days fasted in this Ramadan	27(± 1.1)	28(± 0.3)	t -0.56	0.57
Reasons for Not Fasting during Ramadan				
1-Hypoglycemia	8/19 (42.1%)	11/19(57.9%)	χ^2 -0.04	1.00
2-Hyperglycemia	1/19(11.1%)	1/19(11.1%)		

χ^2 = X² t = Student t test * Significant difference

Both intervention and control groups were similar in baseline characteristics in terms of medications used for treatment of diabetes. Almost half of patient were using oral medications only and the other half were using insulin plus oral medications (Table 3).

Table 3: Diabetes treatment medications

Diabetes medications	Study group	Control Group	Chi square	P value
Oral medications	14(48.3%)	17(58.6%)	0.698	0.719
Insulin only	3(10.3%)	3(10.3%)		
Oral medications and Insulin	12(41.4%)	9(31.0%)		

There was no significant difference between intervention and control group in terms of dietary food intake and exercise practices as shown in (Table 4). Approximately one third of control group had not received hypoglycemia education and more than 50 % were doing exercise as Taraweh prayer. Most patients in both groups used to drink enough fluids.

Table 4: Patients' practices regarding Dietary and physical activities in Ramadan

Practice	Study group	Control group	Chi square	P Value
Received dietary advice for fasting before Ramadan	30(100%)	8(32.0%)	1.059	.0058*
Food intake during Ramadan			1.072	0.585
1-increased	4(13.8%)	3(10.3%)		
2-decreased	12(41.4%)	7(24.1%)		
3-unchanged	13(44.8%)	19(65.5%)		
Sweets intake in Ramadan			2.639	0.267
1-increased	7(24.1%)	9(32.1%)		
2-decreased	8(27.6%)	3(10.7%)		
3-unchanged	14(48.3%)	16(57.1%)		
Suhoor (pre-dawn meal) contained high sugary or oily food	4(14.8%)	6(21.4%)	0.404	0.525
Usually have a large meal for Iftar?	12(41.4%)	9(32.1%)	0.605	0.437
Included plenty of fruit, vegetables and salads in your food?	22(75.9%)	22(75.9%)	0.000	1.000
Usually drink enough fluids in between Iftar and Suhoor?	29(100.0%)	25(89.3%)	3.280a	.070
Exercise (walking, Tarweeh payer etc.)	18(62.1%)	17(58.6%)	0.072	0.788

* Significant difference

Patients' knowledge regarding hypoglycemia was similar in both groups where the mean score of hypoglycemia knowledge in pre and post intervention study and control group were statistically not significant even in the intervention group as shown in (Table 5).

Table 5: Hypoglycemia and hyperglycaemia knowledge

Variable	study	control	t test	P value	95% Confidence Interval
Pre intervention Mean Score (SD) of hyperglycemia knowledge	1.58(±0.90)	1.48(±1.03)	3.242	0.20	0.54-2.33
Post intervention Mean Score (SD) of hyperglycemia knowledge	3.04(±1.8)	1.60(±1.3)	.334	0.74	0.52-0.72
Pre intervention Mean Score(SD) of hypoglycemia knowledge	2.64(±1.17)	2.16(±.898)	1.570	0.12	-.135-1.08
Post intervention Mean Score (SD) of hypoglycemia knowledge	3.09(±1.27)	2.33(±1.11)	2.081	0.04*	.023-1.48
Mean score of knowledge when to break the fast	2.8(±.847)	1.63(±.850)	0.761	0.04*	-.272-.605

* Significant difference

Approximately two thirds of each group checked their blood glucose during fasting without statistically significant difference between intervention and control group. There were statistically significant more patients in intervention group checked their blood glucose during fasting compared to control group before pre-dawn meal (Suhoor), mid-afternoon, pre sunset meal and at any time when feeling unwell as shown in (Table 6).

Table 6: Self-monitoring blood Glucose

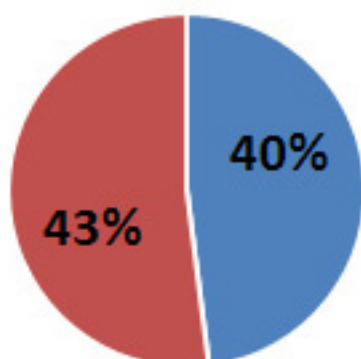
Variable	study	control	Test value	P value
Number of Patients who checked Blood Glucose During Fasting Hour	19/26(73.1%)	18/25(72.0%)	χ^2 0.699	0.12
Mean (SD) number of SMBG per day during Ramadan	2± (1.3)	1.3± (0.60)	t- test 0.57	0.02*
1. Pre-dawn meal (Suhoor)	17(56.7%)	8(26.7%)	χ^2 9.231	0.018*
2. Morning	6(20.0%)	5(16.7%)	χ^2 0.111	0.739
3. Midday	11(26.7%)	2(13.3%)	χ^2 1.667	0.197
4. Mid-afternoon	16(53.3%)	5(16.7%)	χ^2 8.864	0.003*
5. Pre-sunset meal (Iftar)	15(33.3%)	6(20.0%)	χ^2 1.364	0.043*
6. Two-hours after Iftar	3(10.3%)	1(3.4%)	χ^2 1.074	0.300
7. At any time when feeling unwell	16(53.3%)	8(27.6%)	χ^2 4.051	0.044*

χ^2 = chi square test, t = student t test, * significant difference

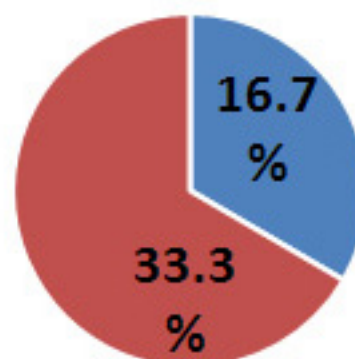
Table 7 and Figure 1: show the frequency of hypoglycemia symptoms. There was no significant difference in hypoglycemia symptoms in both groups before Ramadan and before the intervention program. The impact of the intervention program in reducing the frequency of hypoglycemia is presented in Table 8, and Figure 2; there was significantly less hypoglycemia in the study group compared to the control group.

Table 7: Pre-intervention frequency of hypoglycemia before fasting during Ramadan

Hypoglycemia	Number/percent	Group		Chi square	P Value
		Study30	Control028		
Unlikely	Number (%)	6(20.0%)	7(23.3%)	11.627	0.579
Possible	Number (%)	12(40.0%)	11(36.6%)		
Present	Number (%)	12(40.0%)	13(43.3%)		

Figure 1 : Hypoglycemia frequency before Ramadan

■ intervention group ■ control group

Figure 2 : Hypoglycemia frequency during Ramadan

■ intervention group ■ control group

Table 8: Frequency of hypoglycemia during fasting for Ramadan

Hypoglycemia	Number/percent	Group		Chi square	P Value
		Study	Control		
Unlikely	Number (%)	19(63.3%)	6(20.0%)	1.094	0.003
Possible	Number (%)	6(20.0%)	14 (46.7%)		
Present	Number (%)	5 (16.7%)	10 (33.3%)		

Patients were stratified according to IDF DAR recommendation by their physician as low, moderate and high risk and very high risk of fasting during Ramadan. There was no statistically significant difference between the two groups; for total population the risk was approximately one third low risk, one third high risk and another one third very high risk (Table 9).

Table 9: Risk quantification of Fasting during Ramadan in study and control groups

Risk quantification	Number/percent	Group		Total	Chi square	P Value
		Study	Control			
Very high	Number (%)	9(30.0%)	13(43.3%)	22(36.7%)	1.08	0.42
High	Number (%)	11(36.7%)	9 (30.0%)	20(33.3%)		
Moderate/low	Number (%)	10 (33.3%)	8 (26.7%)	18(30%)		

There was no statistically significant difference in HbA1c among intervention or control groups either before or after the intervention; mean HbA1c was above 7% in all patients (Table 10).

Table 10: HbA1c before and after Ramadan in intervention and control group

Group	N	Mean	SD	t test	P value	95% Confidence Interval	
A1Cpre study	30	7.893	1.58	-.167	.868	-1.02	.87
control	25	7.972	1.92	-.164	.870	-1.04	.89
A1CPost study	20	7.465	1.24	-.236	.815	-.96	.76
control	24	7.566	1.54	-.241	.811	-.95	.74

(Table 11) Biochemical marker showing no significant difference in blood pressure, lipids, BMI, A1c or eGFR could be demonstrated. Pre Ramadan mean A1c was 7.89 % in intervention group and was 7.97 % in control group, After intervention (post Ramadan) A1c was 7.46% in the intervention group and was 7.56% in the control group. Pre Ramadan BMI was 31.09 in the intervention group and was 32.88 in the control group. Post Ramadan BMI was 30.05 in the intervention group and was 33.00 in the control group.

Table 11: Biochemical marker changes before and after Fasting during Ramadan

Variable		Mean	(SD)	T test	P - Value	95% Confidence Interval	
TC pre intervention	study	3.95	1.03	-1.360	.180	-0.983	0.189
	control	4.35	1.12				
TC Post intervention	study	4.62	2.61	.693	.492	-.77107	1.57503
	control	4.21	00.86				
HDL pre intervention	study	1.10	00.39	-1.075	.287	-.2978	.0900
	control	1.21	00.30				
HDL Post intervention	study	1.15	00.26	-.895	.376	-.24735	.09561
	control	1.23	00.27				
LDL pre intervention	study	2.16	00.87	.067	.946	-.466	.499
	control	2.14	00.73				
LDL Post intervention	study	2.20	00.95	-.144	.886	-.58255	.50522
	control	2.24	00.69				
TG pre intervention	study	1.84	1.11	-.403	.689	-.97382	.64876
	control	2.01	1.73				
TG Post intervention	study	1.54	00.56	-1.077	.289	-.92546	.28481
	control	1.86	1.09				
eGFR pre intervention	study	86.86	24.46	1.162	.251	-6.340	23.718
	control	78.17	28.88		.		
eGFR Post intervention	study	89.67	25.43	1.990	.054	-6.340	23.718
	control	73.40	20.00				
Wt pre intervention	study	79.95	14.03	-1.178	.244	-12.2661	3.1955
	control	84.48	13.70				
Wt Post intervention	study	78.49	15.93	-1.219	.230	-14.548	3.591
	control	83.97	13.82				
BMI pre intervention	study	31.09	5.44	-1.144	.258	-4.93117	1.34917
	control	32.88	6.03				
BMI Post intervention	study	30.05	4.64	-1.906	0.063	-.538	.496
	control	33.00	5.39				

TC: total cholesterol, HDL: High density Lipoprotein, LDL: Low density Lipoprotein, TG: Triglycerides, eGFR: estimated glomerular filtration rate, Wt : Weight, BMI : Body Mass Index

Discussion

This is the first randomized controlled trial to evaluate the impact of focus pre Ramadan education and reviewing medications for diabetic patients who were wishing to fast during Ramadan. There are many studies that have evaluated the effect of pre-Ramadan health education for safe fasting and medications adjustment (6,7,12,15,16,17,18), although these studies demonstrated positive effects on reducing acute complications i.e. hypoglycemia, hyperglycemia, diabetic ketoacidosis or dehydration, most of these studies were observational, case control or pre-post evaluation of the same group. These studies led to safer fasting during Ramadan, weight loss, and improved glycemic control among the intervention group. The care provided in some of the interventions, however, was not standardized; and some studies did not attempt to quantify the effect of interventions. None of these studies had a robust design and response rates were either low or not provided. Power calculations were not reported in many instances. None of the included interventions were large robust randomized control trials (RCTs); some were pre-post studies and others were parallel group quasi-experimental studies (19).

Intervention research in this area requires robustly designed and structured interventions that can be tested in different contexts. A literature review study revealed many gaps regarding diabetes management in Ramadan. Health professionals are willing to provide services for fasting diabetes patients but need upskilling. In our study we tried to evaluate the impact of a pre-Ramadan simple, face to face, concise and clear message for safe fasting and medication adjustment in a RCT that has shown less hypoglycemia episodes in intervention group compared to control group (20).

Ramadan-focused education was shown to be beneficial in reducing hypoglycemia in observational studies but not RCTs (0.25 versus 1.00). Ramadan-focused education shows to be a promising strategy but more rigorous examination from RCTs are required (19, 21, 22).

Our study demonstrated that most of the participants in each group fasted almost all Ramadan month days. Mean number of days fasted in this Ramadan was 27 (SD7.1) in the study group and was 28 (SD6.3) in the control group. These results are similar to those found in the CREED study (11), which demonstrated Fasting by ADA risk status during Ramadan. The average number of days fasted according to ADA risk status for the Type 2 cohort was 27.4 (low risk), 26.9 (moderate risk), 27.5 (high risk), and 25.3 (very high risk). The range for average number of days fasted per region was: Asia, 27.4 (low risk) to 25.7 (very high risk); Middle East, 29 (low risk) to 27 (very high risk); North Africa, 29.1 (low risk) to 25.4 (very high risk); and Europe, 24.3 (moderate risk) to 21 (very high risk) (23). Approximately 76% of participants reported fasting during Ramadan; moreover, the medication dosage and timing had changed for 71% of diabetic patients during this same period (24).

In this study the base line frequency of pre-Ramadan hypoglycemia was (40.0%) in the control group and was (33.3%) in the study group before the intervention; there was no significant difference in hypoglycemia symptoms in both groups before Ramadan and before the intervention program. Baseline rate of hypoglycemia in our study was similar to the incidence of hypoglycemia in many other studies (5,6,13,14). Hypoglycemia frequency was significantly reduced to 16.7% in the intervention group; after intervention, it was almost 50% reduction in hypoglycemia incidence in the intervention group which can be considered as a great improvement in fasting Ramadan safety, putting into consideration that fasting during Ramadan in diabetic patients without medical advice increases risk of hypoglycemia by 7.5-fold in patients with type 2 diabetes (5).

In our study incidence of symptomatic hypoglycemia before Ramadan and before the intervention was nearly similar (43.3% in the intervention group, 40.0% in the control group). After the intervention program the incidence of hypoglycemia was significantly reduced in the intervention group (16.7%) compared to the control group (33.3%); almost 50% reduction. Although hypoglycemia was evaluated by symptoms only and not by documentation of low blood glucose, this assessment was conducted using validated hypoglycemia questionnaire. Moreover the questionnaire was translated to Arabic language. Symptomatic hypoglycemia in fasting patients was evaluated in other studies (24) which showed higher rates of symptomatic hypoglycemia seen in 8.3% of patients with type 1 diabetes and in 60.3% of patients with type 2 diabetes. Hypoglycemia assessment in a later study was very subjective and based on one question (Did you experience the symptoms of hypoglycemia?) which could be interpreted in different ways by different patients which reduces result validity.

In our study, regarding diabetes treatment, 10.3% of patients in both groups were on insulin therapy; 14 (48.3%) study group and 17 (58.6%) in control group were on oral glucose-lowering agents (OHAs), and 12 (41.4%) in the study group and 9 (31.0%) in the control group were on combined oral medication (OHA) and insulin therapy. These results are consistent with results of a study conducted by Jabbar et al, they found that the proportion of participants on oral anti-diabetic medication alone ranged from 68.4% (Middle East) to 80.5% (Asia); the proportion on insulin alone ranged from 3.7% (Middle East) to 8.6% (Europe) (25).

In this study the most effective strategy to reduce hypoglycemia was focused pre Ramadan education and medication review which was adapted from DAR /IDF which reduced frequency of hypoglycemia from 33.3% to 16.7% (50.15% reduction). Ramadan-focused education was shown to be beneficial in reducing hypoglycemia in observational studies but not RCTs (0.25 versus 1.00) (26).

Our study demonstrated that there was no significance difference in anthropometric and biochemical parameters including lipid profile, weight, BMI eGFR and HbA1c in baseline and after the study. Our results were not consistent with results of a study(27) that found significant reduction after fasting during Ramadan among those who received individualized education, their body mass index (-1.1 ± 2.4 kg/m² vs -0.2 ± 1.7 kg/m², $p < 0.0001$) and glycated hemoglobin ($-0.7 \pm 1.1\%$ vs $-0.1 \pm 1.3\%$, $p < 0.0001$) after Ramadan. The explanation of discrepancy between our results and results in other studies regarding anthropometric parameters may be attributed to study design; we conducted RCT but others were observational studies or a short duration study which was conducted in 4 weeks (Ramadan month).

Study limitations: Symptomatic assessment of hypoglycemia was main tool to assess hypoglycemia during fasting; further studies are needed to assess hypoglycemia by monitoring and documenting blood glucose documenting. As sample size was small, further study is needed also in more patients to increase study power.

Conclusions: A pre-Ramadan structured educational program as per IDF/DAR guidelines for diabetic patients who intend to fast during Ramadan, significantly reduces their risk of hypoglycemia by up to 50%. The physician review and modification of medications, in accordance with guidelines is one of the most important factors in reducing the frequency of hypoglycemia.

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Validation of Audiovisual Educational Tool that discusses psychological insulin barriers for type 2 diabetic patients

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Abstract

The purpose of the study was to validate an audio-visual tool created for the evaluation of its usefulness in breaking the insulin barrier, by making a video which is simple, accessible and informative at the same time. The video explains the nature of type two diabetes, the progression of the disease and the options for treatment and their side effects. The video also addresses the patients' concerns regarding insulin therapy and helps to overcome the barriers towards starting insulin therapy. The subjects included 178 staff personnel who met the inclusion and exclusion criteria. The personnel consisted of family medicine physicians and residents, medical interns, nurses, medical students and other medical staff (including clinical pharmacist, dietitian, and medical educator). The participants were asked to fill out a validated questionnaire which contained questions about the relevance, clarity, completeness, reassurance, efficiency and accuracy of the information in the video. The study showed a positive response by healthcare personnel toward the audio-visual material which aimed to break insulin barriers in diabetic patients. This material can be used by the diabetic multidisciplinary team as an educational tool as it will leave the patient with a better understanding of insulin which will lead to better control of diabetes and increase compliance.

Key words: validation, video, education, insulin resistance, type 2 diabetic

Introduction

Diabetes is one of the most common diseases worldwide; in 2013 it was estimated that 382 million people had diabetes, which is approximately 8.4% of the adult population. This number is expected to increase up to 55% by 2035, and includes all types of diabetes but type two is the highest in particular (1). Due to the nature of the disease in type two diabetes, which is the progressive diminishing of the function of beta cells, oral hypoglycemics alone are not enough (2). Insulin plays a major role in managing type 2 diabetic patients. According to the UKPDS 50% of the newly diagnosed cases will require insulin in the next 6 years (3). Despite the well-established results of insulin in the management of diabetes, insulin is still considered as a last resort (4). This delay in the initiation of insulin therapy is related to a phenomenon that is found in about 28% of type two diabetic patients, (5) which is known as (PIR) "psychological insulin resistance". This Insulin resistance is considered as a major obstacle for diabetic patients to adhere to their insulin therapy, which raises a concern of avoiding insulin in uncontrolled diabetic patients. The PIR is caused by many reasons such as fear of needle injections, worries about hypoglycemic episodes, patients' feelings of guilt and failure, sense of loss of control over patients' own life, and reduced quality of life. Because these barriers are not entirely valid, it is believed that these barriers are based on wrong information received by patients (6–10).

Self-management plays an important role in diabetes management, therefore patient's self-management education is also an important aspect of the management. Usually the primary care team is responsible for educating diabetic patients, but the level of skills and resources between primary care team members could create a variation in the quality and quantity of education given to the patients (11). A meta-analysis of heart failure management found that education reduces mortality and may improve quality of life for patients (12).

The use of video could be an effective educational tool to change attitudes toward insulin barriers in diabetic patients. A meta-analysis found that video education encourages self-care behavior devotion, (12) while another meta-analysis showed a significant increase in overall knowledge of their target group (11). Another study which was conducted in Brazil, indicated that the educational video helped to improve cognitive knowledge among nursing students (13). To add to the potential of the video as an educational tool, a video cannot only be used in a primary care facility but can also be posted easily on different social media platforms. In 2018, 88% of 18- to 29-year-old Americans indicated their use of any social media platform, with 78% use among age group of 30 to 49, 64% use among age group of 50 to 64 and 37% use among those who are 65 and older (14). Furthermore, 26% of internet users use social media platform to search about their health issues (15).

Locally, in Makkah city in Saudi Arabia a study showed that half of the patients think that treatment with insulin should be stopped when they are symptom free, also almost half of the patients (45.5%) believe that oral medications are better at controlling diabetes in comparison with insulin. This shows that insulin-related misconceptions are relatively frequent. These misconceptions might be due to deficiencies in the educational programs at hospitals. Therefore, this necessitates the need for developing appropriate interventions to improve the outcome of diabetes care. One of these interventions is to create a valid video to help diabetic patients who need insulin therapy to overcome its barriers (16). This study aims to create a valid video to help diabetic patients who need insulin therapy, to overcome their barriers, by combating each of these barriers in a short, simple message with respect to the patients' culture and language.

Material and Methods

The study took place from February 2017 to end of June 2017. It was conducted on personnel because we wanted to know if the video was good enough to educate the patients. This study used a cross-sectional method. The subject included 178 staff personnel who consisted of family medicine physicians and residents, medical interns, nurses, medical students and other medical staff (clinical pharmacist, dietitian, medical educator), who were recruited after screening to check the inclusion and exclusion criteria. The target population of the study was: personnel of Saudi National Guards and King Saud bin Abdulaziz University for Health Sciences in the city of Riyadh, medical related personnel and other personnel who watched the video, with the exclusion of personnel who do not know the basics of diabetes and diabetes management and personnel who could not speak Arabic.

The audio-visual material used in the study was developed by the researchers (17) and was ethically approved. The contents of the audio-visual material were developed based on the American Diabetes Association "ADA" Standards of Medical Care in Diabetes 2017 (18) and reviewed by a family medicine expert. Translation of the "ADA" content to Arabic was done by using back translation method. In the development of the audio-visual material the following aspects were considered: evidence based updated materials, short duration to avoid boredom, simple language, the use of local accent and the use of a character which presents the culture of Saudi Arabia. The audio-visual material was piloted by 20 individuals from the public and health care providers. The audio-visual material aimed to break the insulin barriers found in type 2 diabetic patients by explaining the pathophysiology of type 2 diabetes in brief, types of type 2 diabetes management with special focus on insulin and introducing a new way of delivering insulin, which is the insulin pen.

The study used a validated questionnaire(19). The questionnaire was revised to match the objective of the study. "Permission was taken from the developer of the validated questionnaire". The questionnaire consisted of nine questions and contained both close and open-ended questions. There were six close-ended questions which contained questions about the relevance, clarity, completeness, reassurance, efficiency and accuracy of the information about type two diabetes. The remaining three questions were open-ended questions asking for the participants' feedback. For example, what they liked the most about the video, what they did not like and the things they wanted to add to the video.

The participants were approached by the researchers themselves in their locations. For example, physicians were approached in the department ground round, while residents were approached in the journal club. The data collection started by presenting the audio-visual material for the participants on a big screen, after which the questionnaire was distributed and they were asked to fill it in immediately. Participants provided informed consent to publish their responses in this study.

Firstly the audio-visual material was developed commencing 15th of June 2016, and was completed on 13th of September 2016; the piloting was done on October 2016 and after the piloting the audio-visual material was modified according to the feedback.

For the analysis of the qualitative data, SPSS (64 bit) 20 was used and for the quantitative data, descriptive statistics were used. The qualitative data was collected by qualitative content analysis.

Results

The study included 178 personnel who included 34 (19.1%) family physicians, 39 (21.9%) family residents, 10 (5.6%) interns, 10 (5.6%) nurses, 70 (39.3%) medical students and 15 (8.4%) other staff (including clinical pharmacist, dietitian, medical educator).

The quantitative data collected from close-ended questions are shown in Table 1. Figure 1 shows that 94.9% "q2" of the participants thought of the content of the audio-visual material as clear/understandable from a patient point of view, 94.4% "q1" saw the content as relevant to the diabetic patient population. 86.5% "q6" saw the content as accurate. 72.5% "q5" felt that the audio-visual material would leave the patient with less or no questions for the staff. 71.3% "q3" though that the audio-visual material provided most or all the information that the patient needs about Insulin therapy. 66.3% "q4" believe that the audio-visual material would leave the patient feeling confident about starting insulin therapy. A reliability test was done for the 6 quantitative questions using Cronbach's Alpha test, which gave 0.68 α , Item-Total Statistics as shown in Table 2.

The survey also contained three open-ended questions. The first question asked for the positive points about the video, the second and third questions asked for the negative points about the video and for more comments from the participants. The qualitative data from the first question consisted of 92 comments. 23 of the comments mentioned the animation and graphics as their most liked aspect of the video, 21 comments mentioned the use of easy language and 30 comments mentioned simplicity, clearance and short duration of the video.

The qualitative data from the second and third questions consisted of 61 comments. 28 comments pointed out the need for more information about insulin types, how to use the pen and hypoglycemia symptoms. 4 comments mentioned the use of Arabic language as a negative point and suggested adding English subtitles.

Table 1: Close-ended questions

Questions	Responses	N	%
Q1- I thought the video content was "from a patient prospective": ____ relevant to diabetic patient population	Not at all	0	0.0%
	Somewhat	10	5.6%
	Mostly	64	36.0%
	Completely	104	58.4%
Q2- I thought the video content was, "from a patient perspective": ____ understandable	Not at all	0	0.0%
	Somewhat	9	5.1%
	Mostly	81	45.5%
	Completely	88	49.4%
Q3- I thought the video: __ the information patients need about Insulin therapy	Provided none of	0	0.0%
	Provided some of	42	23.6%
	Provided most of	85	47.8%
	Provided all of the	42	23.6%
	Provided too much	9	5.1%
Q4- I think the video would leave patients feeling: __ confident about having insulin therapy	Not at all	3	1.7%
	Somewhat	57	32.0%
	Mostly	89	50.0%
	Completely	29	16.3%
Q5- I would expect patients who watched the video (compared to those who did not watch it) to have: __ questions for staff	More	28	15.7%
	About the same	21	11.8%
	Fewer	121	68.0%
	No	8	4.5%
Q6- In its depiction of the insulin therapy process, I feel that the video was: __ accurate	Was not at all	1	0.6%
	Was somewhat	23	12.9%
	Was mostly	101	56.7%
	Was completely	53	29.8%

Table 2: Item-Total Statistics

Questions	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
I thought the video content was	15.12	5.612	0.31	0.669
I thought the video content was, from a patient perspective	15.21	5.284	0.451	0.63
I thought the video	15.55	4.554	0.47	0.618
I think the video would leave patients feeling	15.84	4.743	0.511	0.603
I would expect patients who watched the video (compared to those who did not watch it) to have	16.04	4.976	0.346	0.666
In its depiction of the insulin therapy process, I feel that the video	15.49	5.246	0.397	0.644

Figure 1. Participants who answered mostly/completely



Discussion

The study examined medical professionals and students' ideas toward audio-visual material aimed to break the insulin barriers in diabetic patients and showed a positive response to the audio-visual material especially to the aspects of material clarity, relevance to diabetic patient and accuracy. The participants gave positive feedback on the use of animation and graphics and the easy language that was used in the audio-visual material. Negative feedback was also given which focused on the need for more insulin information.

The result comes in line with other studies that tested audio-visual material on both patients and healthcare providers(19) or only patients(11,12). This suggests that audio-visual material could be a useful tool for delivering information and raising awareness among patients. Looking at the low cost of the production of such materials, and the easy access for audio-visual material by patients through smart phones and social media which makes it more appealing to the patient, this can open new doors in patient education and reduce medical

cost if used(12). The use of these materials to target not only patients but also possibly patients and the whole community through social media, which has a rising use among the population,(14) may help change some of the negative ideas or stigma that follows certain diseases and makes the community more supportive toward patients. A drawback of such materials is that its effectiveness may vary depending on multiple factors such as quality of production, accuracy of information, language used and keeping it short and entertaining while informative. Further research is needed to study the impact of audio-visual materials on the attitude of patients and the community.

The study carries strengths in aspects like the high response rate, involvement of different professions in the healthcare team and testing the first audio-visual material that targets breaking insulin barriers. Limitations of the study is that it is a targeted population from one institution; the audio-visual material was for Arabic speakers only and did not involve diabetic patients.

Conclusion

The study shows a positive response by healthcare personnel toward audio-visual material aimed to break insulin barriers in diabetic patients. This material can be used by the diabetic multidisciplinary team as an educational tool as it will leave the patient with a better understanding of insulin and with fewer questions for the team.

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An Audiovisual Intervention's Effects on Psychological Barriers toward initiating Insulin Therapy among diabetic type 2 patients: A randomized controlled trial

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Abstract

Introduction: This study evaluates the effectiveness of educational videos against patients' fixed beliefs and lack of knowledge in comparison with traditional educational methods. It investigates the effectiveness of these tools in overcoming patients' psychological barriers toward insulin therapy.

Methods: This randomized, controlled trial used the validated insulin treatment appraisal scale (ITAS) to evaluate patients' psychological barriers. An educational video and brochure were developed, each containing the same contents. The study was conducted in King Abdulaziz city housing with a total sample size of 126, divided into an intervention group (who were shown the video) and a control group (who were given the brochure). Both groups filled out the same questionnaire before the intervention, immediately after the intervention, and six weeks later.

Results: Neither educational method showed superiority to the other. Most of the questionnaire items had a nonsignificant p-value for both methods, and even when one intervention method was effective, the other method showed similar effectiveness.

Conclusion: This study showed no superiority of the video over the brochure, which cost less and required less effort to produce.

Trial registration number: NCT03544645

Key words: audiovisual; diabetes type 2; educational intervention; insulin therapy; psychological insulin barriers.

Introduction

Insulin should be prescribed more frequently among type 2 diabetic patients, especially when oral medications alone are not effective anymore [1]. Despite being the most effective diabetes treatment, patients often feel reluctant to initiate insulin therapy when it is needed. Many studies relate this reluctance to reasons such as fear of disease progression, needle anxiety, feelings of guilt and failure, concerns about hypoglycemia, sense of loss of control over one's life, reduced quality of life, and the fear of being stigmatized [1-7]. All these reasons have contributed to the prevalence of uncontrolled diabetes; a survey conducted in the USA showed that the percentage of controlled diabetic patients was only 36% [8], and a 2012 study in the Al Hassa region of Saudi Arabia showed that the percentage of uncontrolled diabetic patients was 69% [9].

The impact of most of these reasons are overestimated by patients and can be overcome with an insulin analogue and a new delivery method. For example, a *novo pen*, which many studies have found to be less painful, is easier to carry around than traditional delivery methods and leads to less hypoglycemic events [10-12]. The fact that patients still so frequently cite the reasons above indicates that up-to-date methods are not being provided to patients, which could be accomplished through traditional educational methods such as brochures, leaflets, or face-to-face discussions [13].

A newer educational technology is educational videos, and many studies emphasize the effectiveness of this method [14-18]. In one study, a video-based lifestyle educational trial was designed for newly diagnosed type 2 diabetics, who were divided into a video education group and a control group. The video education group showed more improvement in general knowledge related to lifestyle than the control group [14]. Another study about heart failure patients revealed that patients who received video education showed less signs and symptoms of heart failure, such as edema, fatigue, and dyspnea, than another group that received only traditional education [15]. Even if we compare video education with other newer methods such as internet research, video education is more effective because patients are more likely to review all the information provided to them [16]. In addition, another study found that video intervention was one of the best methods to increase the knowledge of health issues, such as certain disease complications, in people with low literacy [17].

Furthermore, a systematic review that included 40 studies related to video intervention showed how video education was effective in three major ways: supporting the treatment decision, reducing anxiety, and supporting coping skills to increase self-care practices [18]. Since there have been no previous studies comparing the difference in effects between traditional and non-traditional education methods on diabetic patients' attitudes in Saudi Arabia, this study aims to compare the impact of audiovisual educational materials versus printed educational materials on type

2 diabetic patients' knowledge, attitudes, and practices towards insulin therapy. It does so by assessing the patients before, immediately after, and 6 weeks after the intervention.

Methods

We conducted a randomized controlled trial on type 2 diabetic patients who agreed to participate in the study after screening them for inclusion and exclusion criteria. The target population of the study was type 2 diabetic patients who had an A1c of 8 mg/dL or above, were aged 30 to 70 years, and had not yet begun insulin therapy. Patients currently experiencing pregnancy, blindness, profound vision loss, or severe mental problems such as psychosis were excluded.

The study was conducted from March to June 2017 in a community-based polyclinic located in the King Abdulaziz city housing for the National Guard in Riyadh, Saudi Arabia. This polyclinic includes primary care centers and serves about 60,000 individuals, consisting of soldiers and their families as well as the professionals who work there and their families. We developed an educational video and brochure, both of which contained the same content about knowledge, attitude, behavior, and psychological barriers toward insulin therapy. The intervention group was shown the educational video and the control group was given the brochure. Both groups filled out a questionnaire before the intervention, then immediately after the intervention filled out the same questionnaire to assess the materials' immediate effects. Six weeks later, both groups filled out the same questionnaire once more to measure the long-term effects. The immediate and long-term effects of both groups were compared to assess the materials' effects on participants' knowledge, attitudes, behaviors, and psychological barriers toward insulin therapy.

A computerized sequence in Microsoft Excel 2016 generated a randomized list of patients, allocating participants into 2 groups: an audiovisual intervention group and a printed material control group. A serially numbered opaque sealed envelope (SNOSE) contained these group assignments. The total sample size was 126 patients (63 in each group), which afforded us an 80% power to detect a difference of at least 5% in the mean knowledge percentage between the two groups, with an equal standard deviation of 10% and a significance level (α) of 5% using two proportions (z-test).

The validated insulin treatment appraisal scale (ITAS) questionnaire was used [19]. It is available on the internet free of charge, and permission to use it was obtained. The questionnaire measured the following variables: attitude, knowledge, practice, and behavior. It was translated into Arabic and pre-tested.

The educational video, which we developed and validated for this study and presented to the intervention group, aimed to address the psychological barriers mentioned in the questionnaire and tried to correct patients'

misconceptions about insulin therapy. More specifically, it aimed to overcome the barriers by briefly explaining the pathophysiology of type 2 diabetes and the ways to manage type 2 diabetes, focusing especially on the advantages, adverse effects, and misconceptions about insulin therapy. Its content was developed based on the American Diabetes Association's 2017 Standards of Medical Care in Diabetes [20]; the validation process included family physicians to ensure that the content was appropriate for the patients and medical students to ensure the quality of the design and avoid any language mistakes; it also included type 2 diabetic patients with similar inclusion and exclusion criteria of this study to ensure that the video is suitable for them in terms of language and approach. The validation paper has been published separately (27), and the video with English subtitles can be accessed from the link in the reference list [21]. For each item on the questionnaire, two p-values were measured. The first was obtained with McNemar's test, to measure the effect of each intervention individually. The second was obtained using a two-proportion z-test to compare the two interventions and determine if either was superior. Results with a $p < 0.05$ were considered significant. IBM SPSS Statistics 20, manufactured by IBM Corp., was used for data analysis.

Ethics

This study was sponsored and ethically approved by King Abdullah International Medical Research Center's (KAIMRC) ethic committee with ID number (SP16/235), and all patients provided written consent. It was also registered in the trial registry, clinicaltrials.gov, with a trial registration number of NCT03544645.

Results

The study included 126 diabetic patients, with no losses during the study. Patients' demographics are presented in Table 1 (next page). Table 2 shows the effects of the two intervention methods (the video and the brochure) regarding patients' fixed beliefs, namely their psychological barriers to insulin therapy (determined through 10 questions), and regarding their understanding of insulin therapy as the ideal treatment for their condition (2 questions, q6 and q7, in Table 2). The percentages in Table 2 represent the participants who agreed with the questions' statements, and each question had 3 main p-values: one for the effect of the video, one for the effect of the brochure, and the last to show any superiority in method, whether it was for the video or the brochure. The different p-values measure the reductions in barriers between before and immediately after the intervention, as well as the reduction between before and 6 weeks after the intervention.

As determined by McNemar's test, the questions related to the psychological barriers to insulin therapy (questions 1 and 3: "I am worried about starting insulin therapy" and "Taking insulin means my health will deteriorate") showed significant p-values (<0.05) for both the video and the brochure. Interestingly, questions 11 and 12 ("Taking insulin increases the risk of low blood glucose levels" and "Insulin causes weight gain") showed positive p-values for

both the brochure and video, but the reductions were of negative value and, since the question was not a negative statement, these values were significant for their reverse outcomes. A reverse outcome here means that instead of decreasing the barriers, the intervention methods increased them, although these barriers were addressed directly with both methods.

There were no significant p-values for the other barriers related to insulin therapy, indicating that neither intervention was effective in this regard. However, q6 and q7 ("Taking insulin helps to prevent complications of diabetes" and "Taking insulin helps to improve my health," respectively), which were related to the benefits of insulin but not psychological barriers toward insulin therapy, showed significant p-values for both interventions.

As for the two-proportion z-tests used to compare the two interventions, most p-values were non-significant. That is, even when the video showed effectiveness, the brochure showed an equal effect; thus, neither method appeared superior to the other.

Discussion

Although both interventions had a slight effect, it was still not large enough to alter patients' fixed beliefs and behaviors. The interventions reinforced the positive ideas patients already had about the benefits of insulin therapy, but were not sufficient to break their psychological barriers to insulin therapy, such as feelings of guilt and failure, fear of disease progression, feelings of a loss of control over one's life, and the fear of being stigmatized, even though both intervention methods addressed these beliefs directly. In fact, patients' worries about hypoglycemic attacks and weight gain increased at the mere mention of them in the interventions, even though the interventions indicated that new methods could help overcome these problems. Overall, neither method was found to be superior.

A meta-analysis has shown that video interventions are effective in some settings such as breast self-examination, prostate cancer screening, sunscreen adherence, self-care in patients with heart failure, and HIV testing and treatment adherence [22]. However, this study shows that such an intervention is not effective in changing overall behaviors or attitudes, nor fixed beliefs toward insulin therapy, such as psychological barriers. Thus, the intervention's goal plays an important role in its impact.

The result of this study raises the question of whether multifaceted intervention could be more effective than one-method intervention. One study that targeted diabetic patients with multifaceted interventions, such as problem-based learning sessions and educator-patient face-to-face sessions, showed improvements in their A1C and blood pressure [23]. In addition, two studies on multifaceted interventions showed improvements in drug adherence for post ACS and anti-depressant drugs using booklets, voice messages, and counseling interventions [24-25].

Table 1: Participants' Demographics

		N	%
Age (years)	<= 40	11	8.7%
	41 – 50	61	48.4%
	51 – 60	30	23.8%
	61+	24	19.0%
Sex	Male	61	48.4%
	Female	65	51.6%
Education	Illiterate	38	30.2%
	Primary school	31	24.6%
	Intermediate school	13	10.3%
	High school	32	25.4%
	College	12	9.5%
Marital status	Unmarried	10	7.9%
	Married	116	92.1%
Job	Military	47	37.3%
	Civil	12	9.5%
	House wife/unemployed	67	53.2%
Exercise	More than an hour and a half per week	43	34.1%
	Less than hour and a half per week	42	33.3%
	Do not exercise	41	32.5%
Diet	On a diet	40	31.7%
	Not on a diet	86	68.3%
Smoke	Non-smoker	96	76.2%
	Ex-smoker	15	11.9%
	Smoker	15	11.9%

Table 2: Questionnaire Items

N	Questionnaire items	Group	Before intervention	Immediately after intervention	Six weeks after intervention	Reduction1	P-value *	Reduction2	P-value *
1	I am worried about starting insulin therapy	V	82.5%	65.1%	63.5%	17%	0.013	19%	0.008
		B	85.7%	77.8%	68.3%	8%	0.063	17%	0.013
		p-value ** for Video vs. Brochure				0.1282		0.1282	
2	Taking insulin means other people see me as a sicker person	V	58.7%	58.7%	50.8%	0%	1.000	8%	0.267
		B	71.4%	69.8%	66.7%	2%	1.000	5%	0.607
		p-value for Video vs. Brochure				0.2612		0.4963	
3	Taking insulin means my health will deteriorate	V	33.3%	17.5%	14.3%	16%	0.013	19%	0.008
		B	39.7%	27.0%	25.4%	13%	0.039	14%	0.049
		p-value for Video vs. Brochure				0.6339		0.4514	
4	Taking insulin means I have failed to manage my diabetes with diet and tablets	V	73.0%	76.2%	81.0%	-3%	0.754	-8%	0.332
		B	84.1%	88.9%	88.9%	-5%	0.375	-5%	0.508
		p-value for Video vs. Brochure				0.5836		0.5836	
5	Taking insulin means my diabetes has become much worse	V	68.3%	71.4%	81.0%	-3%	0.754	-13%	0.077
		B	71.4%	79.4%	77.8%	-8%	0.227	-6%	0.424
		p-value for Video vs. Brochure				0.2459		0.225	
6	Taking insulin helps to prevent complications of diabetes (reverse-worded)	V	57.1%	81.0%	71.4%	-24%	<0.001	-14%	0.064
		B	49.2%	77.8%	76.2%	-29%	0.001	-27%	0.005
		p-value for Video vs. Brochure				0.6293		0.1437	
7	Taking insulin helps to improve my health (reverse-worded)	V	54.0%	81.0%	77.8%	-27%	<0.001	-24%	0.001
		B	49.2%	76.2%	74.6%	-27%	<0.001	-25%	0.002
		p-value for Video vs. Brochure				1		0.9194	
8	Taking insulin makes it more difficult to fulfil my responsibilities (at work and home)	V	50.8%	42.9%	41.3%	8%	0.267	10%	0.238
		B	50.8%	52.4%	47.6%	-2%	1.000	3%	0.815
		p-value for Video vs. Brochure				0.001		0.1124	
9	Being on insulin causes family and friends to be more concerned about me	V	63.5%	66.7%	60.3%	-3%	0.687	3%	0.754
		B	84.1%	85.7%	85.7%	-2%	1.000	-2%	1.000
		p-value for Video vs. Brochure				0.7269		0.0001	
10	I have no problem injecting myself in the presence of my colleagues at my workplace (reverse-worded)	V	50.8%	52.4%	58.7%	-2%	1.000	-8%	0.302
		B	46.0%	58.7%	60.3%	-13%	0.008	-14%	0.049
		p-value for Video vs. Brochure				0.0303		0.3371	
11	Taking insulin increases the risk of low blood glucose levels.	V	61.9%	77.8%	77.8%	-15.9%	0.006	-15.9%	0.031
		B	68.3%	87.3%	85.7%	-19.0%	0.004	-17.4%	0.019
		p-value for Video vs. Brochure				0.7019		0.8491	
12	Insulin causes weight gain.	V	49.2%	79.4%	77.8%	-30.2%	<0.001	-28.6%	<0.001
		B	38.1%	79.4%	71.4%	-41.3%	<0.001	-33.3%	<0.001
		p-value for Video vs. Brochure				0.3731		0.6798	

* McNemar test

** two proportion z-test

Reduction 1: the difference between before intervention and immediately after intervention.

Reduction 2: the difference between before intervention and six weeks after.

The present study had several limitations and strengths. The limitations included a sample limited to a clinic located in housing for National Guard soldiers, which may not represent the population of Riyadh as a whole. The strengths include the study's randomized approach, which helped minimize bias, as well as the high response rate, strict inclusion criteria, the consistency of the research method, the follow-up after six weeks, and the fact that the educational video was validated by the authors of this study.

Conclusion

Audiovisual methods such as educational videos are important sources for delivering different kinds of information. This study demonstrates that these methods can be useful for delivering new information and increasing people's general knowledge, but sometimes fall short in changing people's pre-existing fixed beliefs, such as psychological barriers regarding insulin therapy.

Practice Implications

The results of the study raise the question of whether educational materials are indeed superior to doctor-patient educational sessions, which are more interactive and allow the patient to ask questions. It also suggests that a multifaceted intervention could be more effective than a one-method intervention. Future research should consider what further efforts are required to change misleading information that people believe.

Determining what new technologies should be utilized as intervention methods is a wide research field with a promising future. One such technology is social media, which is now widely accepted and has many active users. One study has demonstrated that social media can be effective as an intervention method to increase patients' physical activity [26], but further research on this subject is lacking.

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Body mass and blood pressure

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Abstract

Background: Probably metabolic syndrome is a chronic low-grade inflammatory process on vascular endothelium, and effect of excess weight on blood pressure (BP) may be the major cause of inflammation.

Methods: We took consecutive patients between the ages of 35 and 70 years.

Results: There were 105 cases (18.9%) in the normal weight, 240 cases (43.2%) in the overweight, and 208 cases (37.4%) in the obesity groups with similar mean ages (48.0, 50.4, and 52.3 years, respectively, $p>0.05$ for both). Female ratio was significantly higher in the obesity group (78.8%) than the others (47.6% and 47.5%, $p<0.001$ for both). Prevalence of sustained normotension (NT) decreased gradually from the normal weight towards the obesity groups (74.2%, 52.5%, and 26.9%, $p<0.001$ for both). Whereas prevalence of white coat hypertension (WCH) increased gradually in the same direction (17.1%, 34.1%, and 51.9%, $p<0.001$ for both). Similarly, prevalence of hypertension (HT) increased gradually in the same direction again (7.6%, 13.3%, and 21.1%, $p<0.01$ for both). Parallel to BP, prevalences of diabetes mellitus (DM), hyperbetalipoproteinemia, dyslipidemia, and coronary artery disease (CAD) increased parallel to increased body mass index again ($p<0.05$ nearly in all steps).

Conclusion: Excess weight affects 80.7% of the population at and above the age of 35 years in Turkey, and obesity is found nearly four-time more common in females. Parallel to the increased body mass, prevalences of sustained NT decreased and WCH and HT increased beside the increased prevalences of other parameters and consequences of the metabolic syndrome including DM, hyperbetalipoproteinemia, dyslipidemia, and CAD.

Key words: Body mass index, blood pressure, metabolic syndrome, endothelial inflammation

Introduction

Due to the prolonged survival of human being, systemic atherosclerosis may be the major health problem in this century, and its association with sedentary lifestyle, excess weight, smoking, and alcohol is collected under the heading of metabolic syndrome (1, 2). The syndrome is characterized by a chronic low-grade inflammatory process on vascular endothelium in whole body (3). The inflammatory process is particularly accelerated by some factors including sedentary lifestyle, excess weight, smoking, alcohol, chronic inflammation and infections, and cancers (4, 5). The syndrome can be slowed down with appropriate nonpharmaceutical approaches including lifestyle changes, diet, exercise, cessation of smoking, and withdrawal of alcohol (6). The syndrome contains reversible parameters including overweight, white coat hypertension (WCH), impaired fasting glucose, impaired glucose tolerance, hyperlipoproteinemias, alcohol, and smoking for the development of irreversible consequences including obesity, hypertension (HT), type 2 diabetes mellitus (DM), chronic obstructive pulmonary disease, cirrhosis, chronic renal disease, peripheral artery disease, coronary artery disease (CAD), and stroke (7). In another perspective, the metabolic syndrome may be the most significant disease of human being decreasing quality and duration of human lifespan at the moment. The syndrome has become increasingly common all over the world, for instance 50 millions of people in the United States affected (8). The syndrome induced accelerated atherosclerosis in whole body may be the leading cause of end-organ failures, early aging, and premature death for both genders. For example, CAD is the leading cause of death in developed countries. Although sedentary lifestyle, excess weight, smoking, alcohol, chronic inflammation and infections, and cancers induced chronic low-grade inflammation on vascular endothelium may terminate with significant health problems, there is not enough knowledge about direct effects of excess weight on blood pressure (BP) in the literature.

Material and methods

The study was performed in the Internal Medicine Polyclinic of the Dumlupinar University between January and September 2006. We took consecutive patients between the ages of 35 and 70 years to be able to see the possible consequences of excess weight on BP and to avoid debility induced weight loss in elder individuals.

Their medical histories including smoking habit and already used medications were learnt, and a routine check up procedure including fasting plasma glucose (FPG), low density lipoproteins (LDL), triglyceride, high density lipoproteins (HDL), and an electrocardiography was performed. Current daily smokers at least for the last 12-month and cases with a history of five pack-years were accepted as smokers. Insulin using diabetics and patients with devastating illnesses including malignancies, acute

or chronic renal failure, chronic liver diseases, hyper- or hypothyroidism, and heart failure were excluded to avoid their possible effects on weight. Additionally, body mass index (BMI) of each case was calculated by the measurements of the Same Internist instead of verbal expressions. Weight in kilograms is divided by height in meters squared, and obesity is defined as a BMI of 30 kg/m² or greater, overweight as between 25.0 and 29.9 kg/m², normal weight as between 18.5-24.9 kg/m², and underweight as lower than 18.5 kg/m² (9). Office blood pressure (OBP) was checked after a 5-minute of rest in the seated position with the mercury sphygmomanometer on three visits and no smoking was permitted during the previous 2-hour. A 10-day twice daily measurement of blood pressure at home (HBP) was obtained in all cases, even in the normotensives in the office due to the risk of masked HT, after a 10-minute education about proper BP measurement techniques (10). The education included recommendation of upper arm while discouraging wrist and finger devices, using a standard adult cuff with bladder sizes of 12 x 26 cm for arm circumferences up to 33 cm in length and a large adult cuff with bladder sizes of 12 x 40 cm for arm circumferences up to 50 cm in length, and taking a rest at least for a period of 5-minute in the seated position before measurement. A 24-hour ambulatory blood pressure monitoring (ABPM) was not required due to its equal effectiveness with HBP measurements (11). HT is defined as a BP of 135/85 mmHg or greater on average HBP (11). WCH is defined as OBP of 140/90 mmHg or greater, but average HBP of less than 135/85 mmHg, and sustained normotension (NT) as average HBP of lower than 135/85 mmHg and OBP of lower than 140/90 mmHg, so the white coat effect is defined as the difference between the office and average HBP (11). Masked HT is defined as OBP of lower than 140/90 mmHg, but average HBP of 135/85 mmHg or greater (11). Cases with an overnight FPG level of 126 mg/dL or greater on two occasions or already using antidiabetic medications were defined as diabetics. An oral glucose tolerance test with 75-gram glucose was performed in cases with a FPG level between 100 and 126 mg/dL, and diagnosis of cases with a 2-hour plasma glucose level of 200 mg/dL or greater is DM. Additionally, patients with dyslipidemia were detected by means of the National Cholesterol Education Program Expert Panel's recommendations for defining dyslipidemic subgroups (9). Dyslipidemia is diagnosed with a LDL value of 160 mg/dL or greater and/or a triglyceride value of 200 mg/dL or greater and/or a HDL value of lower than 40 mg/dL. A stress electrocardiography was performed in suspected cases, and a coronary angiography was obtained just for the stress electrocardiography positive cases. Eventually, all cases were divided into four groups as underweight, normal weight, overweight, and obesity, and their mean ages, gender distributions, and prevalences of smoking, sustained NT, WCH, HT, DM, hyperbetalipoproteinemia, dyslipidemia, and CAD were compared between them. Mann-Whitney U Test, Independent-Samples T Test, and comparison of proportions were used as the methods of statistical analyses.

Results

The study included 555 cases (328 females and 227 males), totally. There were just two cases (0.36%) within the underweight, 105 cases (18.9%) within the normal weight, 240 cases (43.2%) within the overweight, and 208 cases (37.4%) within the obesity groups. In another word, 80.7% of the cases at and above the age of 35 years have excess weight. Due to the just two cases (two males) of the underweight group, this group was not taken for comparison. The mean ages of the normal weight, overweight, and obesity groups were similar (48.0, 50.4, and 52.3 years, respectively, $p>0.05$ for both). Although the female ratios were similar in the normal weight and overweight groups (47.6% versus 47.5%, respectively, $p>0.05$), 78.8% of the obesity group were female ($p<0.001$). On the other hand, prevalence of smoking was significantly lower in the obesity (19.2%) than the overweight (31.6%, $p<0.001$) and the normal weight groups (35.2%, $p<0.001$) but the female

predominance of the obesity group was probably the cause of such difference since 112 of 153 smokers were male in the present study. In another word, smoking was found as nearly three-time more common in male gender. As the most significant results of the study, prevalence of sustained NT decreased from 74.2% of the normal weight to 52.5% of the overweight ($p<0.001$) and 26.9% of the obesity groups ($p<0.001$), significantly. Whereas prevalence of WCH increased from 17.1% of the normal weight to 34.1% of the overweight ($p<0.001$) and 51.9% of the obesity groups ($p<0.001$), significantly. Similarly, prevalence of HT increased from 7.6% of the normal weight to 13.3% of the overweight ($p<0.01$) and 21.1% of the obesity groups ($p<0.01$), significantly. Parallel to the BP results, prevalences of DM, hyperbetalipoproteinemia, dyslipidemia, and CAD increased significantly from the normal weight towards the obesity groups nearly in all steps as the other parameter and consequences of the metabolic syndrome ($p<0.05$ nearly in all) (Table 1).

Table 1: Characteristic features of the study cases

Variables	Normal weight	p-value	Overweight	p-value	Obesity
Ratio	<u>18.9% (105)</u>	<u><0.001</u>	<u>43.2% (240)</u>	Ns*	37.4% (208)
Mean age (year)	48.0 ± 8.7 (35-70)	Ns	50.4 ± 9.6 (35-70)	Ns	52.3 ± 8.8 (35-70)
<u>Female ratio</u>	47.6%	Ns	47.5%	<u><0.001</u>	<u>78.8%</u>
<u>Prevalence of smoking</u>	35.2%	Ns	31.6%	<u><0.001</u>	<u>19.2%</u>
<u>Prevalence of sustained NT†</u>	<u>74.2%</u>	<u><0.001</u>	<u>52.5%</u>	<u><0.001</u>	<u>26.9%</u>
<u>Prevalence of WCH‡</u>	<u>17.1%</u>	<u><0.001</u>	<u>34.1%</u>	<u><0.001</u>	<u>51.9%</u>
<u>Prevalence of HT§</u>	<u>7.6%</u>	<u><0.01</u>	<u>13.3%</u>	<u><0.01</u>	<u>21.1%</u>
<u>Prevalence of DM </u>	<u>9.5%</u>	<u><0.001</u>	<u>19.5%</u>	Ns	20.1%
<u>Prevalence of hyperbetalipoproteinemia</u>	11.4%	Ns	14.5%	<u><0.05</u>	<u>19.7%</u>
<u>Prevalence of dyslipidemia</u>	<u>20.0%</u>	<u><0.001</u>	<u>32.9%</u>	Ns	36.0%
<u>Prevalence of CAD¶</u>	10.4%	Ns	10.4%	<u><0.001</u>	<u>17.7%</u>

*Nonsignificant ($p>0.05$)

†Normotension

‡White coat hypertension

§Hypertension

|| Diabetes mellitus

¶Coronary artery disease

Discussion

Probably obesity is found among one of the irreversible endpoints of the metabolic syndrome, since after development of obesity, nonpharmaceutical approaches provide limited benefit either to heal obesity or to prevent its complications. Excess weight probably leads to a chronic low-grade inflammation on vascular endothelium that is associated with many coagulation and fibrinolytic abnormalities (12). The chronic inflammatory process is characterized by lipid-induced injury, invasion of macrophages, proliferation of smooth muscle cells, endothelial dysfunction, and increased atherogenicity (13, 14). Elevation of C-reactive protein (CRP) levels in serum carries predictive power for the development of atherosclerotic end-points (15, 16), and excess weight is considered as strong factors for controlling of CRP concentration in serum, because adipose tissue produces biologically active leptin, tumor necrosis factor- α , plasminogen activator inhibitor-1, and adiponectin. So adipose tissue is involved in the regulation of cytokines, and individuals with excess weight have elevated CRP levels in serum (17, 18). On the other hand, individuals with excess weight will have an increased circulating blood volume as well as an increased cardiac output, thought to be the result of increased oxygen demand of the extra tissue. The prolonged increase in circulating blood volume may also lead to myocardial hypertrophy and decreased compliance. In addition to the atherosclerosis and HT, fasting plasma glucose and serum total cholesterol levels were elevated with the increased BMI again (19). Similarly, prevalences of CAD and ischemic stroke increased with an elevated BMI (20). On the other hand, the chronic low-grade inflammatory process may also cause genetic changes on the epithelial cells, and the systemic atherosclerotic process may decrease clearance of malignant cells by the immune system, effectively (21). Eventually, the risk of death from all causes including cardiovascular diseases and cancers increased throughout the range of moderate to severe weight excess in all age groups (22).

It was shown in many studies that excess weight causes significant health problems (23), and the risk of all-cause mortality increases with the increasing BMI, gradually (22). Similarly, the BP pattern changed from the sustained NT to WCH and HT parallel to the increasing BMI in the present study. WCH is a condition characterized by elevated BP in medical settings combined with normal ABPM or self-measured HBP, and it may be an indicator of something going bad for health. As already detected in the above study that the ABPM and self-measured HBP were equally effective for the diagnosis of WCH (11). Similarly, recent HT guidelines propose self-measurement of HBP as an important means to evaluate response to antihypertensive therapy, to improve compliance with therapy, and as an alternative to ABPM to confirm or refute the WCH (24). Therefore, we preferred measurement of HBP due to its simplicity in the present study. We detected very high prevalences of WCH in early decades such as 33.3% in

the second, 46.6% in the third, and 50.0% in the fourth, 48.9% in the fifth, 36.9% in the sixth, 19.2% in the seventh, and 8.3% in the eighth decades of life, and prevalence of HT initially started to be higher than 40.0% in the sixth decade, and it reached up to 75.0% in the eighth decade of life (11). The high prevalences of WCH in the society were also shown in some other papers (25, 26). So as a hypothesis, we come to the result that all HT cases may arise from the previously WCH cases but WCH probably is an acute phase reactant for several other health problems. Although it was postulated in a recent review that patients with WCH are characterized by absence of target organ damage induced by HT, absence of risk of future cardiovascular disease related to HT, and absence of lowering of BP from antihypertensive therapy (27), we evaluated WCH not a cause of HT or atherosclerosis alone but as an acute phase reactant mainly alarming gaining weight and many associated disorders in the future in another study (28). Similar to the present study, when we compared the underweight, normal weight, and overweight groups according to BP variability, beside the significantly decreased prevalences of sustained NT from the underweight towards the normal weight and overweight groups, the prevalences of WCH increased in the same direction, significantly (28). Eventually, the prevalence of WCH reached up to 68.4% in the overweight group, and only 31.5% of the overweight cases had sustained NT although the very young mean age of them (24.8 years) (28). On the other hand, when we compared the sustained NT, WCH, and HT groups in the previous study (4), WCH cases were found in between according to the prevalences of almost all of the following disorders including obesity, impaired glucose tolerance, DM, hypertriglyceridemia, hyperbetalipoproteinemia, and dyslipidemia, and nearly all of the above disorders showed a gradual and significant progression in frequency from the sustained NT towards the WCH and HT cases. On the other hand, 19.6% and 35.6% of WCH cases in the underweight and normal weight groups, respectively, may indicate that WCH may be an acute phase reactant influenced by several factors instead of BMI alone (28-30), but the BMI may be the major determining factor of BP. In addition to the WCH and HT, other parameters and consequences of the metabolic syndrome including DM, hyperbetalipoproteinemia, dyslipidemia, and CAD showed significant increases parallel to the increasing BMI in the present study.

As a conclusion, excess weight affects 80.7% of the population at and above the age of 35 years in Turkey. Additionally, obesity was found nearly four-time more common in females, which probably can be explained by the physical inactivity of them. Parallel to the increased body mass, prevalences of sustained NT decreased and WCH and HT increased beside the increased prevalences of other parameters and consequences of the metabolic syndrome including DM, hyperbetalipoproteinemia, dyslipidemia, and CAD.

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Retroauricular lymphadenopathy post micro-needling

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Dear editor: I am sending this short report to complement a recent publication, by the journal of cosmetic dermatology, on 28 September 2018, about micro-needling and lymphadenitis as side effects.

Cervical lymphadenopathy from PRP treatment with micro-needling therapy, by Solomon Geizhals BA, Joseph Grunfeld BA, Hyeokchan Kwon BA, Joshua Fox MD.

Abstract

Procedures of micro-needling and platelet-rich plasma (PRP) are recently gaining popularity and growing internationally, with highly enriched plasma that contains large concentrations of platelets which secrete various growth factors, and is used in a wide variety of surgical and cosmetic procedures, including hair re-growth, facial wrinkles and skin rejuvenation(1,2).

Micro-needling is a simple, reliable and rapid method to rejuvenate facial skin and can induce taut, youthful skin in the long run.

There are different techniques of applying PRP into the skin. However, micro-needling is also used solo or combined with platelet-rich plasma to potentiate patient's cosmetic effects. Micro-needling involves a small tool that uses fine needle sizes to puncture the top skin layer, the epidermis and create micro-tunnels. These micro-wounds stimulate the release of growth factors and induce collagen production.

Although micro-needling therapy is well known and has been used for a while, there are not any reported side effects in the existing literature apart from the transient erythema and post-inflammatory hyperpigmentation all of which are scarce, negligible, and limited, regarding side effects.

Summary

I personally tried the micro-needling on my face, with 0.5mm and 1mm size and I noticed personally, development of painful retro-auricular lymph nodes on both sides, or a brief period the following day. I looked up and consulted the internet for any literature reporting a similar incident. However, I could not retrieve any and I was quite certain of the cause of my condition. I thought it could be attributed to the tiny micro tunneling being created by the micro-needle across the skin, where the surface bacteria would get inside and consequently the lymph nodes swell. Though I used antiseptic means for both the skin and the derma roller, it still kept developing when I performed it on my facial skin. Also, I believe it could be the vigorous use and the intensity that could cause this effect. .

I started at that time, to apply the micro-needle in light strokes across my facial skin, in order to avoid the painful uncomfortable incident. Yet, I kept developing painful lymph nodes. I treated myself with a short course of antibiotics to alleviate and shorten the effect and the enlarged painful lymph node.

When I read your article, I realized I have been right in my intuition since two years ago and probably no one had noticed it before. I even told some of my colleagues, who denied and disapproved my observation.

To conclude, micro-needling is a minimally invasive procedure. Therefore, I urge that every individual and every medical practitioner pay more attention to the impending side effects of the procedure, in order to document the cases and report them with their reasoning. Also, to not underestimate the procedure because many think it's a trivial, simple procedure with no potential risks, and it is not.

Additionally, there is no history of this happening before in the existing literature, and thus this would be the first reported case.

It is after all still all empirical and we need to see other colleagues' opinions and experiences. Moreover, not all patients would tell of their experiences. Many for instance will not notice any changes or complaints, or merely let it pass.

Also, larger and more randomized controlled trials are needed with follow-ups to document any side effects. After all, we all learn from new procedures through ourselves and patients.

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