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SAUDI JOURNAL OF INTERNAL MEDICINE
VOLUME 1 NO. 1 1432 H - 2011 G

SAFETY OF A PULMONARY EMBOLISM AMBULATORY TREATMENT PROGRAM

Mahir M. Hamad[1], MD, FRCP, Elrasheed A. Ellidir[1], MD, MRCP, Charlotte Routh[1], MD, MRCP, Siraj O. Wali[2], FACP, FCCP, and Vincent M. Connolly[1], MD, FRCP

[1]Department of Acute Medicine, James Cook University Hospital, Middlesbrough, UK
[2]Department of Medicine, Faculty of Medicine, King Abdulaziz University, Jeddah, Saudi Arabia

ABSTRACT

Objective: Evidence has emerged that out-patient management of pulmonary embolism may be an appropriate option in selected patients. This report is based on a safety data on a Pulmonary Embolism Ambulatory Treatment program.

Methods: An observational study in acute assessment unit from 2000 – 2006, of all consecutive patients with confirmed pulmonary embolism (high probability ventilation perfusion scan or Computerized Tomography Pulmonary Angiography) have been evaluated. Exclusion criteria were oxygen saturation less than 92%; systolic blood pressure less than 100 mm Hg; significant cardiopulmonary or renal disease, and a bleeding risk. Patient treated initially with low molecular weight heparin followed by oral anticoagulants when diagnosis was confirmed, and were assessed at 3 and 6 months.

Results: Sixty-one patients (33 females), median age 55 (range; 16-89 years) were eligible. Patients needed a maximum of 13 appointments. Risk factors included surgery (8.2%), cancer (8.2%), long travel (14.8%), previous thromboembolism (14.8%), hormonal replacement therapy (3.3%) and contraceptive pill (8.2%). No risk factor was identified at 37.7%. The mortality was zero at 6 months. No complications were recorded. Four patients required hospital admission, all within the first week; all were discharged within 24 hours. The median length of stay for patients with uncomplicated pulmonary embolism was 7 days; implementation of the pulmonary embolism ambulatory treatment program saved 427 bed days.

Conclusion: The pulmonary embolism ambulatory treatment program was cost effective and was not associated with serious complications. Further evaluation of these programs could help establish the safety and cost effectiveness of this approach.

Keywords: Pulmonary embolism, Ambulatory treatment, Cost effectiveness

Address for Correspondence:

DR. MAHIR M. HAMAD
Consultant Physician and Clinical Director of Acute Medicine
James Cook University Hospital,
Middlesbrough, Cleveland, TS4 3BW, UK
e-M: mahir.hamad@stees.nhs.uk

INTRODUCTION

Suspected pulmonary embolism is a common diagnostic presentation to emergency services, requiring a complex diagnostic pathway, treatment protocol and significant bed use. The advent of once daily low molecular weight heparin (LMWH) has the potential to be used in an out-patient setting. LMWH has been shown to be as efficacious as fractionated heparin in the treatment of deep vein thrombosis or pulmonary embolism[1]. Furthermore, randomized studies have established that out-patient management of deep vein thrombosis (DVT) with LMWH is at least as effective as in-hospital management with unfractionated heparin[2-3]. The British Thoracic Society Guidelines recommended that the current organisation for outpatient management of DVT should be extended to include patients with stable pulmonary embolism (PE) (level C)[4]. Although randomized controlled trial to validate the safety of this approach is still underway, many studies have suggested that treatment of PE as an outpatient is cost-effective and is safe in selected low risk patients[5-8]. Treatment of PE in the outpatient setting, however, has not been widely adopted in the UK. In this study, it was evaluated the safety and the cost-effectiveness of Pulmonary Embolism Ambulatory Treatment (PEAT) program at James Cook University Hospital.

METHODS

An observational study of all consecutive patients with confirmed PE who presented to the Acute Admissions Unit (AAU) at the James Cook University Hospital from 2000 – 2006. All patients were evaluated for clinical probability for PE according to the Wells score[9]. All patients were risk stratified according to the set exclusion criteria (Table 1), modified from Pulmonary Embolism Severity Index[10,11], Geneva Criteria[12] and other studies[6-7]. Only those with low risk were regarded suitable for outpatient treatment, and included in the study.

For the sake of the study, confirmed PE was defined as one of the following: 1. High probability ventilation / perfusion scan (VQ scan); 2. Intermediate probability ventilation / perfusion scan with DVT, present in compression Doppler ultrasound of the leg; and 3. Positive Computerized Tomography Pulmonary Angiography (CTPA).

VQ scan or CTPA were usually performed within 48 hrs. Probability of VQ scan was classified into low, intermediate or high according to defined criteria.

The treatment protocol (Fig. 1) was a daily subcutaneous injection of low molecular heparin. Patients with confirmed PE were started on warfarin and monitored by the

Table 1. Criteria for outpatient therapy of pulmonary embolism at James Cook University Hospital. KEY: HIT stand for heparin induced thrombocytopenia, ICH for intra-cerebral haemorrhage, GI/GU bleed for gastrointestinal bleeding, mo for month, O2 sat for oxygen saturation, BP for blood pressure, RR for respiratory rate.

1 – Compatible for outpatient therapy	• Outpatient follow-up feasible • No allergy to warfarin / heparin • No history of HIT
2 – Low bleeding risk	• Coagulopathy • Active bleeding • ICH (anytime) GI / GU bleed, trauma, surgery (1 mo) • Platelets <50 $X10^9$ per litre
3 – Absence of severe renal dysfunction	
4 – Patient in stable condition	• No acute syncopal episode • O2 Sat > 92% on RA • No prior cardiopulmonary disease • Hemodynamically stable – Bp > 110 / 60 – Pulse < 90 – RR < 24 • Chest pain managed with simple analgesics

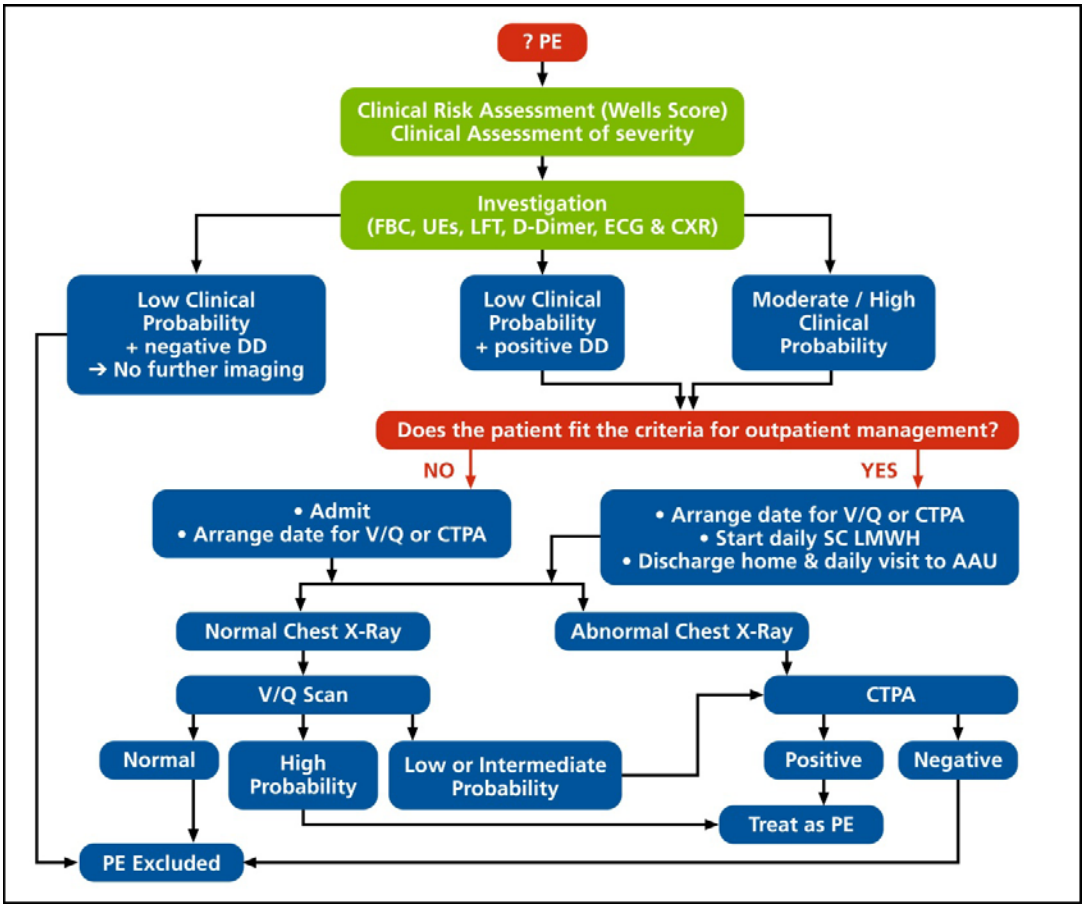

Figure 1. Diagnostic algorithm of pulmonary embolism at James Cook University Hospital. Key: PE stand for pulmonary embolism, FBC for Full blood count, U&Es for Urea and electrolytes, LFT for Liver function tests, ECG for Electrocardiograph, DD for D-dimer, CXR for Chest X-ray, V/Q for perfusion ventilation scan, CTPA for computerized tomographic pulmonary angiography scan, SC LMWH for subcutaneous low molecular weight heparin, and AAU for acute assessment unit.

Ambulatory Emergency Clinic. Once targeted, International Normalized Ratio (INR) was achieved (INR between; 2-3), on two occasions the patient was discharged from the AAU clinic and then followed up by the GP, but were reviewed in the clinic after 3 and 6 months.

All patients were evaluated for symptoms or signs suggestive of bleeding, thrombocytopenia, DVT and PE.

RESULTS

Sixty-one patients (33 females and 28 males) with confirmed PE were managed on the PEAT program. Median age of the included patients was 55 (range; 16-89 years). The duration of Ambulatory Care follow up; patients needed follow-up for 5-13 days. In our hospital the median length of stay for patients with uncomplicated PE is 7 days, and therefore implementation of the PEAT program saved 427 bed /days.

Figure 2 demonstrates the percentage of patients according to risk factors for PE. Risk factors for PE included: surgery (8.2%), cancer (8.2%), long travel (14.8%), previous thromboembolism (14.8%), HRT (3.3%) and the contraceptive pill (8.2%). However, 37.7% had no risk factor identified.

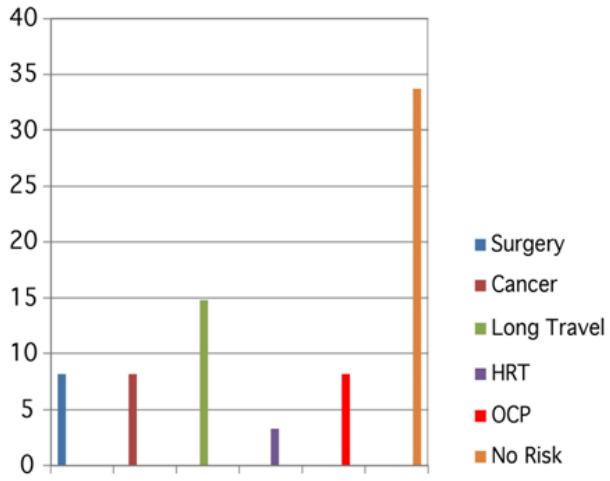

Figure 2. Percentage of risk factors for venous thrombocytopenia among patients included in the study. Key: HRT stand for hormonal replacement therapy and OCP for oral contraceptive pill.

Table 2. Adverse events reported during the study.

Adverse Event	Number Reported
Mortality	None
Bleeding adverse effect	None
Thrombocytopenia	None
Patient needing admission within a week of presentation	4
Causes of hospital admission were	
Pain management	n = 1
Breathlessness	n = 1
Viral illness	n = 2

No complications including bleeding and thrombocytopenia were recorded. Four patients required hospital admission, all within the first week, for symptom control; all of them discharged within 24 hrs. Causes of hospital admission were pain management (n = 1), breathlessness (n = 1), and viral illness (n = 2). Those admitted with chest pain and breathlessness were regarded as cases of symptomatic recurrence of PE (2/61; 3.2%). No deaths or cardio pulmonary arrests were recorded (Table 2).

DISCUSSION

This present study has demonstrated the feasibility and the safety of providing outpatient care to patients with stable PE. Patients enrolled in our PEAT program have shown no mortality or evidence of venous thromboembolism recurrence over a period of 6 months follow-up. Only 4 patients required hospital admission (for pain control, breathlessness and viral illness), all within the first week for symptom control and discharged within 24 hrs. The two patients admitted for pain control and breathlessness were not evaluated for PE recurrence by imaging, and even if they had been regarded as recurrence of symptomatic PE, the percentage will be very low (2/61; 3.2%). There were no complications, including bleeding, related to this approach.

Several studies have evaluated the safety of outpatient treatment of PE with comparable results to our study[6-8]. Wells have already examined the feasibility of outpatient management in 34 patients with PE as part of DVT outpatient setting with good overall outcome as in DVT[6]. The same authors evaluated the role of patient self-injection compared with injections administered by a homecare nurse in the outcome of outpatient management of PE, and found that both systems were safe and effective[7]. Similarly, Kovacs *et al.* in a non-randomised prospective study examined the safety of outpatient treatment of PE in 108 hemo-dynamically stable patients requiring no oxygen therapy, and with no severe pain requiring parenteral analgesia, or high risk of bleeding[8]. These authors found that of the 108 PE patients treated in the outpatient setting, the symptomatic recurrence rate of thrombo-embolism was 5.6% (6/108), which was the same as in the large randomised trials examining predominantly outpatient management of DVT[13,14]. Kovacs showed the rate of major bleeding was 1.9% (2/108), although 4 patients died, none were directly due to PE or major bleeding[8]. The symptomatic recurrence rate in our study was slightly lower (2/61; 3.2%) than these studies with no death, but this probably could be explained by the smaller number of patients included in our study. In addition, the criteria used in our study may be slightly different. Perhaps, the authors were a little overcautious in selecting patients for out-patient care, asking for systolic BP above 110, and oxygen saturation above 92% on room air, plus are probably more selective in the risk stratification of our patients. Indeed, recently Davies *et al.* in an early discharge/outpatient treatment of PE study (n 157) showed no recurrence of PE or major bleed, but there were 3 non-PE related deaths[15]. The selection process of outpatient management was not very clear in this study, and it was possible that the zero rate of recurrence was a reflection of a highly selected group of patients. Moreover, the fact that the study was not entirely conducted in the outpatient setting[15].

Different criteria were used by different studies to risk stratify patients. In particular, the pulmonary embolism severity index (PESI) has been validated by Aujesky *et al.* in a prospective study involving 119 European hospitals and 899 patients diagnosed with PE. In this study, 47% of the patients (426/899) were classified as low-risk, suitable for outpatient management. Low-risk patients had overall mortality of only 1.2% (5/426) and PE-specific mortality of 0.7% (3/426) [12]. The authors believe that PESI is time consuming, while the Geneva score requires blood gas measurement. Our criteria (Table 1) were derived from PESI as well as from other studies with satisfactory outcome[6-7]. As mentioned above, the authors felt a little overcautious in selecting low risk patients, looking for systolic BP above 110 and oxygen saturation above 92% on room air. Being more selective in our criteria may reflect our low mortality and recurrence rate. Further studies are needed to validate the criteria used in this present study.

In the James Cook University Hospital, normally the median length of stay for patients with uncomplicated PE is 7 days, suggesting that implementation of the PEAT program saved 427 bed days. This is an equivalent to One Hundred Forty-Nine Thousand Five Hundred Pound Sterling (£149,500). It's believed that the cost saving achieved by PEAT program was more than this amount, if taken into account, that many patients were investigated as an outpatient as part of PEAT program will have no thromboembolism, and these patients were not included in our study or calculations. Therefore, implementing PEAT program is cost effective and will lead to considerable saving of beds and funds. Surprisingly, this program has not been widely utilised in the UK and worldwide. Although, randomised trials evaluating the safety of outpatient *vs.* inpatient management of PE are underway, there is a strong amount of evidence available to support the safety of this outpatient approach in selecting low risk patients. Moreover, outpatient management may be preferred by the patients as indicated in Davies *et al.* study, in which 81 patients gave a score of 10 out of 10, while 97% of the patients indicated that they would prefer outpatient therapy if they had a subsequent PE[15].

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SAUDI JOURNAL OF INTERNAL MEDICINE
VOLUME 1 NO. 1 1432 H - 2011 G

DIABETES COMPLICATIONS AND THEIR RELATION TO GLYCEMIC CONTROL AMONG PATIENTS ATTENDING DIABETIC CLINIC AT KING KHALID NATIONAL GUARD HOSPITAL IN JEDDAH, SAUDI ARABIA

Abdullah M. Karawagh[1], MD, FRCPC, Abdullah M. Alzahrani[2], ABFM, MRCGP, and Tariq A. Naser[1], MBChB, ArBIM

[1]Department of Medicine and [2]Department of Family Medicine
King Abdulaziz Medical City, National Guard Health Affairs
Jeddah, Saudi Arabia

ABSTRACT

This study addresses the prevalence of ischemic heart disease, hypertension and long term complications of *diabetes mellitus* among patients attending the diabetic clinic and their relation to glycemic control.

Methods: A study was conducted on a cross section on all consecutive patients attending the diabetic clinic at King Khalid National Guard Hospital in Jeddah, Saudi Arabia, from January 2007 to January 2008. The degree of glycemic control was gauged using blood level of glycosylated hemoglobin (HbA1C) and classified into good (less 7%), fair (7.1-8%), poor (8.1-9%) and very poor (greater than 9%). All patients were screened for hypertension, ischemic heart disease and micro vascular complications.

Results: Two hundred and ten patients were recruited in the study. Glycemic control was good in 17 (8.1%), fair in 49 (23.2%), poor in 56 (26.6%) and very poor in 88 (41.9%). There was high prevalence of retinopathy (76; 36%), microalbuminuria (80; 37.9%), neuropathy (108; 51.2%) and ischemic heart disease (51; 24.2%), especially among patients with poor and very poor control. Although the presence of hypertension, frank nephropathy and peripheral vascular disease was also disturbingly high among diabetic patients, their frequency was the same among good, fair, poor and very poor glycemic control groups.

Conclusion: The prevalence of long-term complications of *diabetes mellitus* was alarmingly high among Saudi nationals. Microvascular complications and ischemic heart disease were also noticed to be more common in diabetics with poor and very poor glycemic control. This emphasizes the need of national awareness program about the gravity of the problem.

Keywords: *Diabetes mellitus*, Complications, Glycemic control

Address for Correspondence:

DR. ABDULLAH M. KARAWAGH
Consultant Endocrinologist
King Abdulaziz Medical City, National Guard Health Affairs
P.O. Box 9515, Jeddah 21423, Saudi Arabia
e-M: a_karawagh@yahoo.com

INTRODUCTION

Diabetes mellitus (DM) has become one of the most important chronic public health problems worldwide[1]. It is estimated that the global number of adults suffering from any form of diabetes will reach 285 million in 2010 and may increase to 439 million in 2030, most of them Type 2 DM cases[2,3]. The reported prevalence of DM among Saudi adults between the ages of 30 to 70 years was 23.7%[4].

Diabetes mellitus is a growing cause of morbidity and mortality through macrovascular complications (stroke, myocardial infarction, and coronary artery disease) and microvascular diseases (retinopathy, nephropathy and neuropathy)[5]. Prevalence reports from studies worldwide on microvascular and macrovascular complications of Type 2 diabetes show varying rates. The prevalence of cardiovascular complications is varying between 10% to 22.5%[6-9]. The rate of recurrence of cataracts is 26% to 62%[10], nephropathy 17% to 28%[11] and neuropathy 19% to 42%[12,13]. Recent studies have shown that intensive glycemic control decreases the risk of micro-vascular complications[9].

A study from Saudi Arabia showed that diabetes is associated with significant high rate of long term complications. Famuyiwa and co-workers studied the prevalence of diabetic complications among Type 1 and Type 2 diabetes. This study found that ischemic heart disease was present in 41.3%, stroke in 9.4%, foot infections in 10.4%, amputations in 5.1%, cataract in 42.7%, neuropathy in 35.9%, retinopathy in 31.5%, hypertension in 25% and nephropathy in 17.8% of patients with Type 2 diabetes[14].

However, this study did address the correlation between the rate of complications and glycemic control. The undertake of the present study is to determine the prevalence of macrovascular and microvascular diabetic complications in patients with Type 2 diabetes attending diabetic clinic at King Khalid National Guard Hospital (KKNGH) in Jeddah, Saudi Arabia, and examine their relation to glycemic control level.

METHODS

The study was conducted on a cross-section of all consecutive patients with the diagnosis of Type 2 diabetes who was attending the diabetic clinic at KKNGH from January 2007 to January 2008. All patients with active follow-up visits were included in the analysis. Patients who were diagnosed to have Type 1 diabetes, gestational diabetes and pediatric patients (age less than 15 years) were excluded from the study.

Data included baseline characteristics of age, gender, blood pressure and laboratory results. Hypertension was based on a preexisting history of hypertension and measurement of blood pressure (BP), where systolic blood pressure (SBP) was greater than 130 mm Hg and/or a diastolic blood pressure (DBP) greater than 80 mm Hg. This was based on the seventh report of the Joint National Committee on the Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7). Blood pressure measurements from at least 3 readings per year were recorded as mean BP per year. The presence of ischemic heart disease (IHD) was based on clinical, electrocardiographic, biochemical and angiographic evidence of myocardial ischemia presenting as angina and/or myocardial infarction (MI).

All diabetics had lipid profile done as base line and at follow-up, especially upon treatment. Diagnosis of dyslipedemia was based on the 2004 American Diabetes Association (ADA) treatment guidelines, which recommend that the following lipid criteria should be met for patients with diabetes: low density lipoprotein-cholesterol (LDL-C) < 2.6 mmol/L (100 mg/dl), triglycerides < 1.7 mmol/L (150 mg/dl) for both gender and high density lipoprotein-cholesterol (HDL-C) > 1.0 mmol/L (40 mg/dl) in men and >1.3 mmol/L (50 mg/dl) in women.

Urine spot testing for microalbumin was done twice for each diabetic patient at least two weeks apart. Nephropathy was defined by the presence of three positive readings per year of persistent proteinuria by urinary dipstick.

Retinopathy was documented by the ophthalmologist by the presence of retinal hemorrhages, exudates and macular edema, or features of proliferative retinopathy. Neuropathy was considered if there was persistent numbness, paraesthesia, loss of a tuning fork tested the sense of vibration, or failure to elicit knee and/or ankle jerk after reinforcement.

The degree of glycemic control was gauged using blood level of glycosylated hemoglobin (HbA1C) and classified into good (less 7%), fair (7.1-8%), poor (8.1-9%) and very poor (greater than 9%).

Data management and analysis were conducted using Statistical Package for Social Sciences (SPSS) program, version 16. Continuous variables are presented as mean ± SD whereas categorical variables are presented as numbers and percentages. The t-test was used to compare means. The chi-square test was used to compare categorical variables. Results were regarded statistically significant when p-value is less than 0.05. Ethical approval was obtained from ethical committee. Patient information confidentiality was guaranteed and all data were used for research purposes only.

RESULTS

From study populations of 210 patients, hypertension was observed in 88 (41.9%) patients while significant IHD was noticed to be present in 51 (24.2%) subjects. Hyperlipidemia was observed in 131 (62.4%) patients. The prevalence of retinopathy was 76 (36%), microalbuminuria was 80 (37.9%), nephropathy was16 (7.6%) and neuropathy was 108 (51.2%). Neuropathy, hyperlipidemia, hypertention and microalbuminuria were more prevalent followed by retinopathy and IHD. Nephropathy was the least prevalent complication. Glycemic control was generally unsatisfactory in most of the patients and noticed to be good in 17 (8.1%), fair in 49 (23.2%), poor in 56 (26.6%) and very poor in 88 (41.9%).

There was a trend of high frequency of IHD (Fig. 1), and micro-vascular complications such as microalbuminuria (Fig. 2), retinopathy (Fig. 3), and neuropathy (Fig. 4) among patients with poor and very poor control, compared to those with fair and good control. In contrast the frequency of hypertension (Fig. 5), frank nephropathy (Fig. 6) and peripheral vascular disease (Fig. 7) was more or less the same among good, fair, poor and very poor control groups.

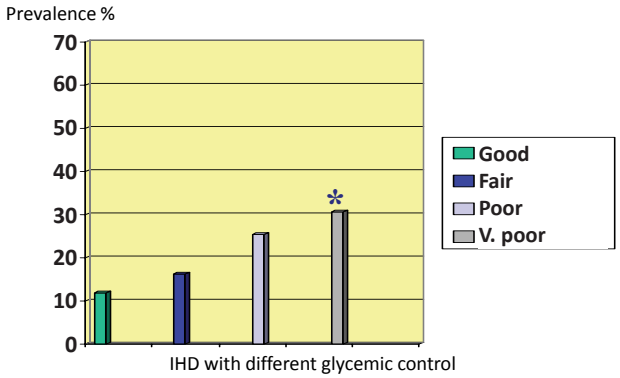

Figure 1. Prevalence of ischemic heart disease among diabetic patients at KKNGH.

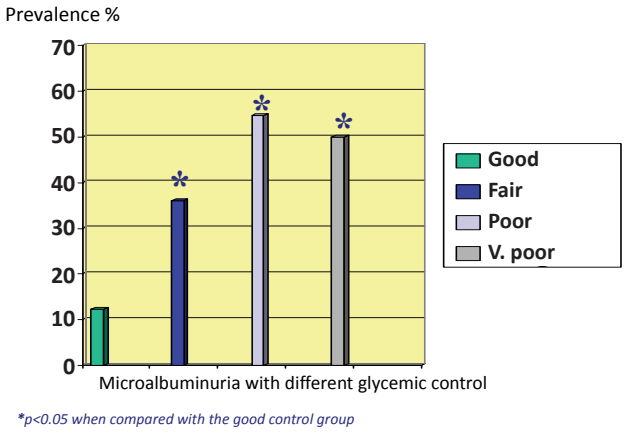

Figure 2. Prevalence of microalbuminuria among diabetic patients at KKNGH.

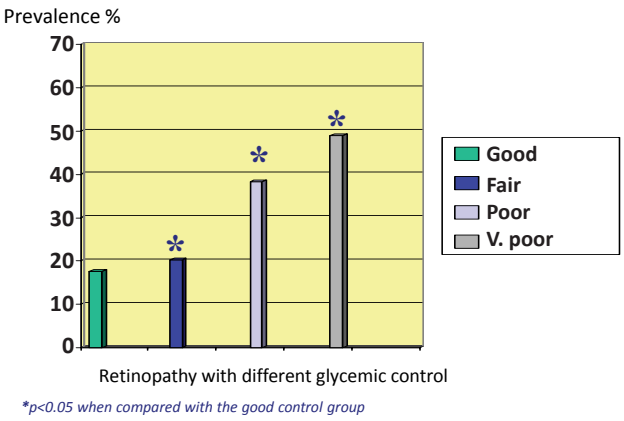

Figure 3. Prevalence of Retinopathy among diabetic patients at KKNKH.

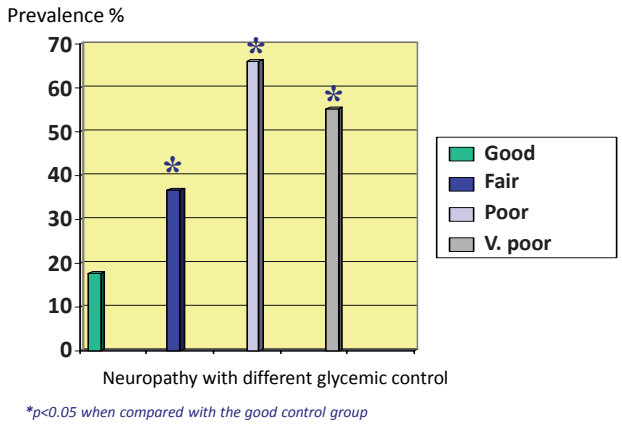

Figure 4. Prevalence of Neuropathy among diabetic patients at KKNGH.

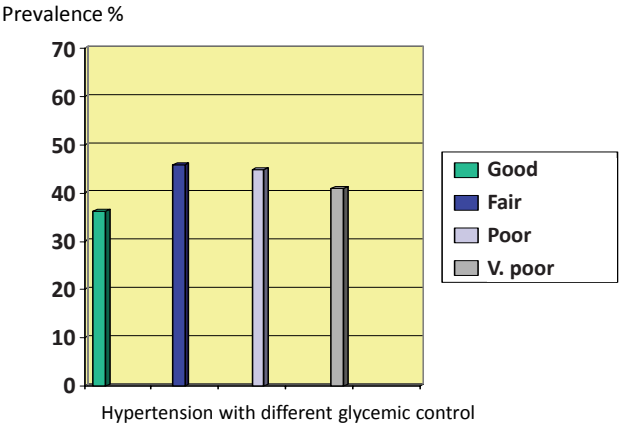

Figure 5. Prevalence of Hypertension among diabetic patients at KKNGH.

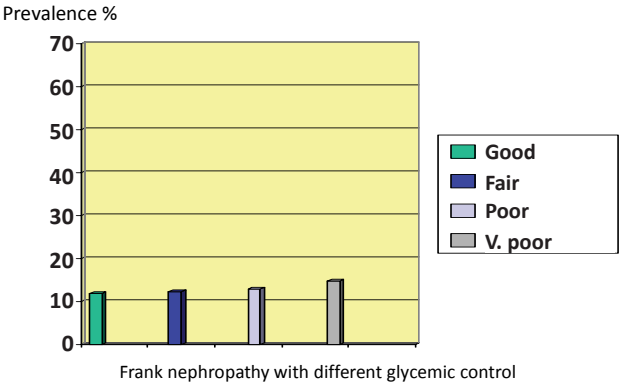

Figure 6. Prevalence of frank Nephropathy among diabetic patients at KKNGH.

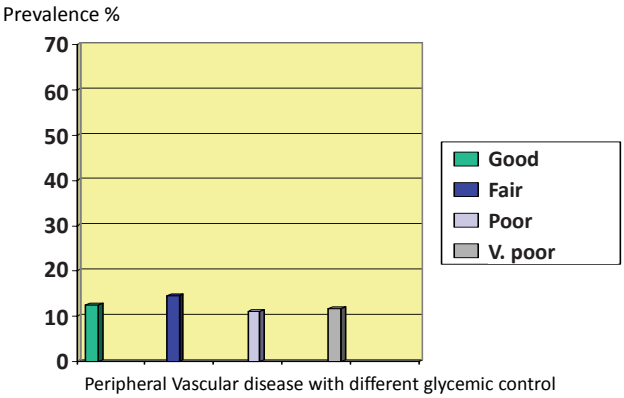

Figure 7. Prevalence of Peripheral Vascular Disease among diabetic patients at KKNGH.

DISCUSSION

In this study, it addresses the rate of Type 2 diabetes complications in a hospital setting. This study, like other studies from Saudi Arabia, showed a high prevalence of hypertension (41.9%) among Type 2 diabetes. Although, studies by Al Nozha *et al.*[4] and Famuyiwa *et al.*[14] reported a relatively lower prevalence rate of hypertension among diabetes (34% and 25%, respectively) compared to our study, nevertheless, the rate reported by these studies are still alarmingly high. On the other hand, studies by Alwakeel *et al.* and Akber *et al.* found that hypertension to be present in 78% and 60%, respectively, among diabetic patients, which is much higher than the prevalence rate reported in our study[15,16]. The prevalence of IHD in this study was 24%, which is similar to that reported in Alwakeel *et al.* study of 23.1%[15]. However, less than 41% rate reported by Famuyiwa *et al.*[14]. Nevertheless, studies from Saudi Arabia, including our study as well as these studies, demonstrated a higher prevalence of IHD compared to reports from Western countries[6,9]. This may be attributed to the lack of awareness of the complications of hypertension and hyperglycemia, in addition to an increased prevalence of other cardiovascular risk factors among Saudis. In fact, our studies showed that dyslipidemia was disturbingly very high (62%) among diabetic patients, and may partly contribute to the increased prevalence of IHD among our patients.

On the other hand, the frequency of retinopathy among our patients was 36%, which is comparable to other studies from Saudi Arabia[17] as well as United Kingdom[9]. Similarly microalbuminuria prevalence was 37.9% and nephropathy was 7.6%, which are in concordance with to those reported by other local studies[15,18,19]. Also, the rate of progression of diabetic nephropathy in Saudi diabetes patients was noticed to be fast when compared with data reported from other part of the world[20].

The reported neuropathy in this study was 51% and was higher than that reported by Famuyiwa *et al.*[14] and Alwakeel *et al.*[15] (35.9% and 13.7%, respectively). However, the high rate of this complication in our study was not surprising, as preliminary data from the western part of Saudi Arabia suggested that, the overall prevalence of neuropathy in diabetic patient is 82%, which is one of the highest in the world[16]. This probably could be due the lack of early screening for this debilitating condition, which can lead to other serious complications. In fact, Qidawi *et al.* in 2001, reported that 29% of Saudi patients with diabetic peripheral neuropathy have some features suggestive of diabetic neuroarthropathy and that 18% of those patients underwent foot amputations[21].

The incidence of chronic complications in Type 2 DM patients was significantly correlated to the degree of hyperglycemia and diabetic control, as measured by the plasma glucose or the HbA1c level. In the present study, IHD and micro-vascular complications of DM were noticed to be more common in diabetics with poor and very poor glycemic control, which is concordance with international studies. Stratton *et al.* in a cohort study found that 1% reduction in average HbA1c was associated with reductions of 14% for myocardial infarction and 37% for microvascular complications[9]. On the other hand, the prevalence of hypertension, frank nephropathy and peripheral vascular disease seems not to be related to the degree of glycemic control.

The present study has some limitations, including the number of patients enrolled in the study was not large enough and may not be very representative of the whole country. Additionally, our study was cross sectional and hospital based. Nevertheless, our study showed that the diabetic control among Saudi nationals was probably unsatisfactory in which most of the patients have poor and very poor control. It was also documented, that the macrovascular complications and microvascular complications of Type 2 diabetes in a single area from the Kingdom, and this may help as a reference for future larger scale studies. The prevalence of macrovascular and microvascular complications of diabetes is considerably high among our diabetic patients and many patients had multiple complications. These are very alarming findings and emphasizes the need for a national awareness program (for both patients and physicians) about the gravity of the problem. Earlier and frequent screenings in patients with Type 2 diabetes for the development of complications is crucial and that will lead to identify patients at high risk. In addition, our study has highlighted the importance of good glycemic control in preventing these long term complications.

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