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A Three Year Cohort Prospective Type 2 Diabetes Control Study in Basrah

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Abstract

Background: In Iraq, diabetes affects 10.4 % of people according to the 2006 WHO survey. The aim of this study is to see how a diabetic center in a developing country can control type 2 diabetes mellitus over 3 years period.

Methods: This is 3-year open-label, non-randomized, treat-to-target, single center study in the Al-Faiha Diabetes and Endocrine Center in Basrah. Patients with type 2 diabetes, regardless of the duration or treatment were enrolled in January 2007.

Results: We had 998 patients complete the study. The mean HbA1c levels at the start of the study was 9.8 ± 1.9 % and after 3 years it was 8.1 ± 1.6 %. The target of HbA1c levels < 7 % were achieved only in 25.6 %. Those on insulin achieved HbA1c levels < 7 less than those on oral anti-diabetic drugs (16.9 % versus 67.9 % with p value of <0.0001). On univeriate analysis for variables associated with poor outcome and non achieving target HbA1c were only insulin use (OR =2.318, 95 % CI = 1.705-3.152;p < 0.0001) and duration of diabetes >5 years (OR =1.688 , 95 % CI = 1.261-2.259;p < 0.0001). On logistic regression analysis (table-4),only the insulin use remain significantly associated with poor outcome (OR =0.475 , 95 % CI =0.344 -0.656, p < 0.0001).

Conclusion: This study confirms that we are still lagging in diabetic control from guidelines, but no worse than neighboring countries in the Middle East. Implementing local guidelines will probably solve some of the obstacles in diabetic care locally.

Keywords: Type 2 diabetes; Glycemic control; Glycosylated haemoglobin; Insulin

Guidelines suggest that glycosylated haemoglobin (HbA1c) is maintained in diabetes mellitus at < 7%. Such levels of glucose control cannot generally be maintained with oral glucose lowering agents alone [1] and often require use of insulin in addition to, or in place of, oral medications. The efficacy of present antihyperglycaemic agents is limited and most patients do not achieve glycated haemoglobin targets [2]. Despite advances in pharmacotherapy and diabetes treatment devices and the emphasis placed on treatment adherence over the last decade, National Health and Nutrition Examination Survey (NHANES) data showed 43-45% of patients with diabetes did not achieve glycemic targets of <7%. [3]Almost 1 million people die because of diabetes each year; two-thirds of these are in developing countries [4]. Single-site studies have identified several promising interventions to improve quality of diabetic care at the patient, provider and system levels in developing countries. [5] In Iraq, diabetes affects 10.4 % of people according to the 2006 WHO survey. [6] The aim of this study is to see how a diabetic center in a developing country can control type 2 diabetes mellitus over a 3 year period?

Methods

Study design

This was a 3-year open-label, non-randomized, treat-to-target, single center study in the Al-Faiha Diabetes and Endocrine Center in Basrah (Southern Iraq). Patients with type 2 diabetes regardless of the duration or treatment were enrolled in January 2007. The data analysis was done at the end of December 2009. The basic characteristics were studied in the first and last visit in the study. Patients were seen at least once each month over 3 years. Hypertension was defined as two blood pressure readings at two separate visit (with systolic blood pressure having a cutoff point of 140 mm Hg or higher and diastolic blood pressure having a cutoff point of 90 mm Hg or higher) or the use of hypertension medication. Participants reported their education level, residency, self monitoring blood glucose (SMBG) use, and smoking status.Body weight was taken while the patients were barefooted and in light clothing. Standing height was measured without shoes to the nearest cm using a stadiometer with the shoulders in a relaxed position and the arms hanging freely. Body mass index (BMI) (kg/m2) was calculated as the ratio of weight (kilograms) to the square of height (meters).Early morning urine was checked for albumin in the first and the last visit. Patients found with albumin in urine by albustic method as positive, were considered proteinuric.HbA1c was measured using a fully automated glycohemoglobin analyzer which uses high performance liquid chromatography (HPLC).

The oral anti-diabetic drug (OAD) metformin therapy was started concurrently with lifestyle intervention at diagnosis in the absence of specific contraindications (in particular renal impairment). A sulfonylurea is usually added to metformin, when metformin and lifestyle no longer maintain glucose control to target levels. Basal insulin therapy {neutral protamine Hagedorn(NPH)} was added if the above therapy failed, followed by premixed insulin twice and than basal-bolus insulin with metformin. Sulfonylurea was stopped once basal insulin was started. [7] The main insulin was human soluble, NPH, or premixed human insulin {Biphasic human insulin 30 (BHI 30), 30% human insulin and 70% NPH insulin} using vial and syringes or pen. Premixed analogs insulin {biphasic insulin aspart 30 (BIAsp

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30)} in Flexpen was used for some in the year 2008-2009 and according to their availability. Patients assigned the life style and drugs therapy continued to receive dietary advice at 3-monthly intervals.

Outcome measures

Outcome measures were HbA1c levels: the proportion of patients with a HbA1c level of < 7%. The HbA1c levels were measured at baseline, and then every 12 weeks. The primary 3-year outcome was the HbA1c level. Secondary outcomes were the proportion of patients with a HbA1c level of < 7% and the degree of HbA1c reduction.

Statistical analyses

Data were analyzed using Statistical Package for Social Sciences (SPSS) version 15 (SPSS Inc., Chicago, IL, USA). Continuous variables were summarized as the mean ± SD. Categoric variables were summarized as percentages. Chi-square test was used for used for univariate analysis. Odds ratios (ORs) and their 95% confidence intervals (CIs) were used to indicate the strength of influence. The level of significance was set to be < 0.05 throughout the analysis. Univariate analysis was performed to determine each variable's association with poor outcome and non-achieving target HbA1c. Variables found associated with poor outcome and non-achieving target HbA1c in univariate analyses were then entered into a multivariable model using logistic regression to determine the power of each variable for associated with poor outcome.

Results

Patient characteristics

The total enrolled patients with type 2 diabetes mellitus were 1600 (Figure 1). There were 602 dropouts and 998 patients completing the study. Those on OAD were 567 and insulin was used in 431. Patient characteristics are presented in (Table 1). The mean age was 51.3±14.7 years; 58.5 % of them were above age of 50 years and 41.8 % were males. Less than half (47.2 %) were diabetic for > 5 years. Overweight and obese constituted 63.7 %. Illiterate constituted 40 %. At the end of the study, 14.3 % were smokers , 32 % were hypertensive, 16.6 % were proteinuric and 43.2 % were on insulin .More patients (62.4 %) were from urban dwellings and 4.8 % were from outside Basrah. Only 31.1 % of all patients and 31.3 % of those on insulin, were doing SMBG.

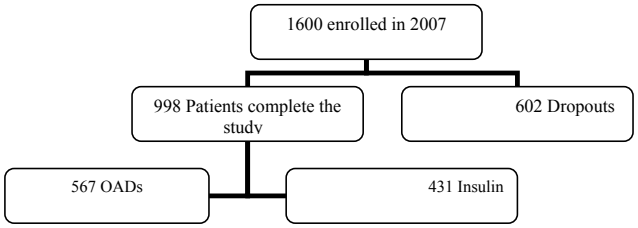

Figure 1: Enrollment and Outcomes.

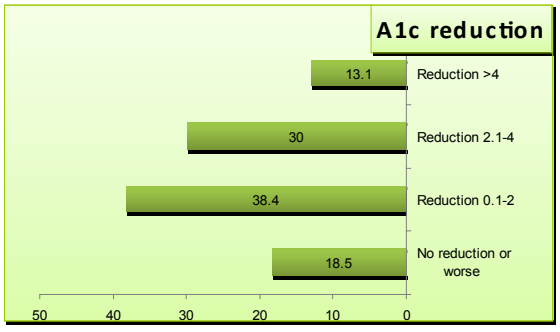

Figure 2: Proportion of HbA1c level reduction.

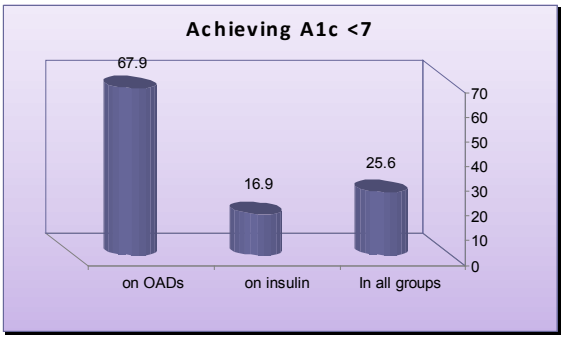

Figure 3: Target HbA1c percentage achieved in all groups and according to treatment.

Variable name		Number (%)
Age (year)	Means ±SD	51.3±14.7
	>50	584(58.5)
Male	Means ±SD	417(41.8)
Duration of diabetes(year)	Means ±SD	7.2± 6.3
	>5	471(47.2)
BMI (kg/m2)	Means ±SD	27.1± 5.8
	≥ 25 (1)	636 (63.7)
Qualification (year)	Means ±SD	5.8 ±5.6
	Illiteracy	399(40.0)
Insulin use		431(43.2)
Hypertension		319(32.0)
Proteinuria		166(16.6)
Current smoker		143(14.3)
Duration of diabetes (year)	Means ±SD	7.2± 6.3
	>5	471(47.2)
Urban dwellers		623(62.4)
Rural dwellers		375(37.6)
Outside Basrah		48(4.8)
SMBG	All	310(31.1)
	Patients on insulin	135(31.3)

Table 1: Basic characteristics at the end of the study.

		Number (%)	
A1c at the start of the study (Mean ±SD)		9.8 ± 1.9	Median 9.8 %
A1c at end of the study (Mean ±SD)		8.1 ± 1.6	Median 8.1 %
A1c reduction	No reduction or worse	185(18.5)	
	Reduction 0.1-2	383(38.4)	
	Reduction 2.1-4	299 (30.0)	
	Reduction >4	131(13.1)	
Achieving A1c <7	In all groups	255(25.6)	
	on insulin	73 (16.9)	P value <0.0001
	on *OAD	385 (67.9)	
*OAD –Oral antidiabetes			

Table 2: Hemoglobin A1c changes throughout the study period.

Main outcomes

Table 2 shows the main outcome. The mean HbA1c levels at the start of the study was 9.8 ± 1.9 % (median of 9.8 %) and after 3 years its was 8.1 ± 1.6% (median of 8.1 %). The proportion of HbA1c level reduction is seen in (Figure 2). There were HbA1c levels reduction of > 4 % in 13.1 %, reduction of 2.1-4 % in 30.0 % and 0.1-2 % in 38.4 % of our patients. Unfortunately 18.5 % had no reduction in HbA1c levels or had worsening of levels. The target of HbA1c levels < 7 % were achieved only in 25.6 % of whole study sample (Figure 3). Those on insulin achieved HbA1c levels < 7 less than those on OAD (16.9 % versus 67.9 % with p value of <0.0001).On univeriate analysis (Table 3)

Variable name	*OR (95% Confidence Interval)	P value
Age >50 year	0.843(-0.630-1.129)	0.270
Male	0.889(0.667-1.185)	0.462
BMI ≥ 25	0.841(0.623-1.135)	0.291
Illiteracy	1.305(0.971-1.754)	0.088
Insulin use	2.318(1.705-3.152)	< 0.0001
Hypertension	0.988(0.729-1.340	0.938
Proteinuria	1.345(0 .899-2.014)	0.172
Current smoker	0.980(0.654- 1.469)	0.918
Duration of diabetes >5 years	1.688(1.261-2.259)	< 0.0001
Rural	1.004(0.749-1.347)	1.000
Outside Basrah	1.031(0.528-2.014)	1.000
SMBG	0.869(0.641-1.177)	0.388
*OR - Odds-Ratio		

Table 3: Univeriate analysis for factors associated with non-achieving target glycemic control.

Variable name	*OR (95% Confidence Interval)	P value
Insulin use	0.475 (0.344 -0.656)	< 0.0001
Duration of diabetes >5 years	0.749 (0 .550 -1.021)	0.067

Table 4: Multivariable logistic model.

for variables associated with poor outcome and non-achieving target HbA1c were only insulin use (OR =2.318, 95 % CI = 1.705-3.152;p < 0.0001) and duration of diabetes >5 years (OR =1.688 , 95 % CI = 1.261-2.259;p < 0.0001)

On logistic regression analysis (Table-4),only the insulin use remain significantly associated with poor outcome (OR =0.475 , 95 % CI =0.344 -0.656, p < 0.0001).

Discussion

In this study, 63.7 % of patients were obese or overweight in comparison with Kuwaiti patients who were 91.3 % obese or overweight. [8]Literates constituted 60% in our sample while 22% of patients were literate in the Saudi study. [9] More patients (62.4 %) were from urban dwellings in this study. Similar findings are also seen in Iran where there was a higher prevalence of type 2 diabetes among urban dwellers compared to that of the rural subgroup. [10] In the Saudi study [9], 16% are smokers which is comparable to our study of 14.3%, and in Kuwaiti type 2 diabetes patients [9], 13.3 % were smokers.

Hypertension was seen in 32 % of diabetic patients in this study which was similar to the previous study of 32.1% at the end of 2007 in the same center. [11] The low figures were because we adopted the 1997 JNC VI on the definition of hypertension in the general population (140/90 mmHg). [12] These definitions may seem conservative today [13], but the same definition was used in an Iranian study. [10] In Kuwait, 59.3% of patients with type 2 diabetes were hypertensive, [8]and in Jordan, the prevalence rate was 72.4% (BP >130/80). [14] Proteinuria was seen in 16.6 % in our study. Macroalbuminuria was prevalent in 6.8% of Egyptians, 12.8% of Saudis, 12.7% of Lebanese and 12%–23% of Iranians. [15,16] Only 31.1 % of all our patients and 31.3 % of those on insulin were doing SMBG and in Saudi Arabia, around half of their patients treated with OAD with insulin do SMBG. [9]

The main outcome of our study was that only 25.6 % reached the HbA1c target of <7 %. In Saudi Arabia among 353 type 2 diabetic subjects, only 27 % reached the HbA1c target of <7 % , [9] while in Kuwait it was 16.2 % [8], in Spain 41% [17] and in Germany 46.6% achieved this treatment target. [18] In the same center in the year 2007, 23.7 % of patients achieved HbA1c < 7 % and in this study at the end of 2009 only 25.6 % achieved the target of HbA1c in that center [11]. This means that after 2 years from the first study only an extra 1.9 % achieved the guidelines of HbA1c. We achieved the latest HbA1c of 8.1 ± 1.6 % while in Saudi Arabia the last HbA1c was 8.20±1.89% [9] and the mean HbA1c of the United Arab Emirates diabetic patients was 8.3±2.5 % [19]of our patients, 43.2 % were on insulin and in Saudi Arabia insulin was used in 35.4 %. [9] Those on insulin achieved the target HbA1c <7, less than those on OAD (16.9 % versus 67.9 %). Again the achievement of the HbA1c target was higher among patients treated with OAD alone than patients treated with OAD with insulin (32.4 % versus 18.8 %) in Saudi Arabia. [9]

Study limitations

This is single center experience (the only center in Basrah), however it's the first study to explore the experiences with the management of increasingly recognizable non-communicable disease.

Conclusion

This study confirms that we are still lagging in diabetic control from guidelines, but no worse than neighboring countries in the Middle East. Implementing local guidelines probably will solve some of the obstacles in diabetic care locally.

Competing Interests

There are no competing interests.

These authors contributed equally to this work.

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