Research Article

The Pattern of Anti-hyperglycemic Medication use in Subjects Attending the Diabetes Center in Basrah, Iraq

Abbas Ali Mansour*, Ali Hussein Ali Alhamza and Ammar Mohamd Saead Almomin

Department of Medicine, Basrah College of Medicine, Iraq

Department of Medicine, Al-Faiha Diabetes Endocrine and Metabolism Center, Iraq

***Corresponding author:** Abbas Ali Mansour, Department of Medicine, Basrah College of Medicine, Hattin post office. P.O Box: 142, Basrah–61013, Iraq, Phone: 009647801403706; Email: aambaam@gmail.com

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Abstract

Background: Metformin remains the most widely used first-line drug and is the cornerstone of type 2 diabetes treatment. The aim of the study is to explore the prescribing trends for anti-hyperglycemic agents used among a cohort of diabetics before they registered in the Diabetes Center in Basrah for the first time.

Methods: This is a cross sectional study conducted for the period from January 2010 to December 2011.

Results: Results of 2,123 consecutive patients with type 2 diabetes, who participated, were analyzed. Oral anti-hyperglycemic therapy was given for 64.8 % of our patients with type 2 diabetes mellitus. The majority of prescriptions were self-prescriptions (44.1%). Most of the general practitioners prescribe glibenclamide alone (74.5%). Eighty point four percent didn't receive metformin. General practitioners mainly prescribe for illiterate people (29.3%) while internists mainly prescribe for university graduates (34.3%). Twenty nine point seven percent received no drug therapy despite poor glycemic control.

Conclusion: Most of our patients with type 2 diabetes mellitus were already on oral antihyperglycemic therapy, but the majority didn't receive the first line drug, metformin. The attitude of physicians in primary care about management of type 2 diabetes mellitus needs to be re-evaluated urgently.

Keywords: Metformin; Type 2 diabetes mellitus; Oral anti-hyperglycemic drugs; Prescription

Background

The use of guidelines in the management of diabetes has been promoted as one method of ensuring the translation of evidence based medicine into clinical practice, thus standardizing care across the spectrum. Yet various quantitative and qualitative studies show a wide variation of adherence to guidelines for various reasons [1,2]. Diabetes treatment guidelines recommend initiating treatment with anti-hyperglycemic medication either concomitantly with, or following a brief period of lifestyle intervention (3-6 months) [3].

Treatment with anti-hyperglycemic agents, as monotherapy, led to a 2-to 3-fold increase in the proportion of patients with an HbA1c < 7% relative to diet alone in patients with newly diagnosed type 2 diabetes [4]. Early initiation of anti-hyperglycemic medication is associated with reductions in microvascular events and long-term, legacy effects with reductions in myocardial infarction and death in patients with newly diagnosed type 2 diabetes [5].

At diagnosis, highly motivated patients with HbA1c already near target (e.g. <7.5% [<58 mmol/mol]) could be given the opportunity to engage in lifestyle change for period of 3–6 months before embarking on pharmacotherapy (usually metformin). Those with moderate hyperglycemia or in whom lifestyle changes are anticipated to be unsuccessful, should be promptly started on an anti-hyperglycemic agent (also usually metformin) at diagnosis, which can later be modified or possibly discontinued if lifestyle changes are successful [3,6-8].

Since publication of the results of the UK Prospective Diabetes Study (UKPDS 34) in 1998, metformin, a biguanide glucoselowering agent, has been recommended as the first-line treatment [9]. Metformin remains the most widely used first-line drug and is the cornerstone of type 2 diabetes treatment [10]. However, 55% to 70% of patients who initially achieve their glycemic targets with metformin therapy have a progressive deterioration of glucose control in 2 to 3 years [11,12]. Continuation of metformin once started on insulin reduced HbA1c, with less weight gain, and less insulin dose in comparison with insulin alone [13].

After lifestyle change and metformin failure, there are limited data to guide us. Sulfonylurea (least expensive) is second line but studies have demonstrated a secondary failure rate that may exceed other drugs, ascribed to an exacerbation of islet dysfunction [14,15]. Metformin could achieve a similar glycemic control to sulfonylurea, but metformin did not cause weight gain, hypoglycemia or increase insulin concentration. The UKPDS clearly demonstrated that sulfonylurea had no protective effect on progressive β-cell failure in newly-diagnosed type 2 diabetic patients over the 15-year study duration [17]. Moreover, sulfonylurea were shown not to have a significant protective effect against atherosclerotic cardiovascular complications, and some studies even gave the notion that sulfonylurea may accelerate the atherogenic process [18]. Iraq is facing epidemic of type 2 diabetes that doubled over short period of time to reach now ~20% [19]. The aim of the study is to explore the prescribing trends for anti-hyperglycemic agents used among a

cohort of diabetics before they registered in the Al-Faiha Diabetes and Endocrine Center in Basrah (FDEMC) for the first time.

Methods

Study design

This is a cross sectional study conducted for the period from January 2010 to December 2011. Data was collected on patients from FDEMC in Basrah (this is the secondary referring diabetic center in Basrah, Southern Iraq). The enrolled patients were from primary care referred to secondary care center. The finding indicates the state of care in whole Basrah, because this center receives patients from all primary care of Basrah and probably from whole Iraq.

Once patients registered in the center for the first time a full history is taken with proper clinical examination. Baseline investigations with glycated hemoglobin are taken, as is lipid profile with plasma glucose and urine for protein. All the treatment is going to be re-evaluated and changed according to guidelines.

Inclusion criteria: patients aged over 18 with type 2 diabetes, defined in accordance with WHO criteria that had disease duration for at least one year before registration in the center.

Table 1: Patient characteristics and clinical measures in 2, 123 diabetic patients.

		Mean ± SD or n (%)	
	Mean ± SD	51.7±11.7	
Age (years)	< 40 years	388(18.3)	
	40 and above	1735(81.7)	
Mele gender	Men	976(46.0)	
male gender	Women	1147(54.0)	
	Mean ± SD	6.4±5.6	
	Illiterate	735(34.6)	
Education (years)	1-6	479(22.6)	
	7-12	545(25.7)	
	University	364(17.1)	
	Unemployed	480(22.6)	
Occurrentianel status	Employed	498 (23.5)	
Occupational status	Retired	133 (6.3)	
	*House maker	1012(88.2)	
Marital status	Married	1817(85.6)	
Marital status	Unmarried	306(14.4)	
	Mean ± SD	3.2±1.3	
Duration of diabetes (years)	1-3	1143(53.8)	
(years)	4-5	980(46.2)	
Family history of diabetes		1291(60.8)	
BMI kg/m²		28.0± 5.8	
Hypertension		474(22.3)	
Current smoker		356(16.8)	
Glycated haemoglobin (HbA1c, %)		9.2±2.1	
* of women			

The objective of the study was explained to the participants and their verbal consent was acquired before conducting the interview.

The objective of the study was explained to the participants and their verbal consent was acquired before conducting the interview. Verbal consent taken from each patient separately in front of the authors of the study at FDEMC. Simply, the verbal consent was taken from the patients by explaining to them the benefit of prescription pattern of oral anti-hyperglycemia drugs and the need for uniform prescription all over Iraq. The patients told that they are going to be enrolled in this study aiming to know the drugs used in the past period before attain the center to correct the inappropriate drugs in the future in the primary care setting. The ethical committee of Basrah Directorate of Health agrees on the study. No written consent was obtained because its cross sectional verbal communication study .The patients asked what treatment gives in the past period. No new treatment given.

Through a structured face- to- face interview socio-demographic data (age, sex, marital and educational status) were taken from each patient with information on smoking, duration of diabetes, medication used to treat diabetes currently, and who prescribed the drugs. Those on herbal remedies produced locally or imported from outside are considered in the category of no drugs as self prescription. Self prescription of prescription medications is feasible in Iraq from any pharmacy without medical advice is feasible all over the country.

Hypertension was defined as either resting systolic or diastolic blood pressure \geq 130 or \geq 80 mmHg respectively, recorded at two different clinical visits or the prescription of anti-hypertensive medication. Body Mass Index (BMI) was calculated as weight (in kilograms) divided by squared height (in meters squared).

Glycated hemoglobin was measured using cation exchange column chromatography methods on an automated HPLC instrument (Bio-Rad D-10, Bio-Rad Laboratories, Hercules, California, USA).

Exclusion criteria

Pregnant women, those with type 1 diabetes mellitus, those on insulin, those with no HbA1c, less than 1 year of diabetes, patients with serum creatinine above 1.4 mg/dl or those with heart failure were excluded.

Statistical analysis

Continuous variables are presented as means and Standard Deviations (SD), categorical data as frequencies and percentages. Data collected were analyzed by chi- square test as appropriate.

Results

Of 14135 registered patients with diabetes in this center, results of 2,123 consecutive patients with type 2 diabetes who participated were analyzed.

Clinical characteristics of the study population are summarized in Table 1. Mean age was 51.7±11.7 year with 81.7% of them above age of 40 years. Women were slightly more than men (54.0%) and 34.6% were illiterate and only 23.55% of the study sample were employed. 88.2% of women were house makers and 85.6% of all were married. More than half of the patients (53.8%) had diabetes duration 1-3 years. Family history of diabetes in first degree relatives was present in

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Prescribers	No drug n (%) 747 (35.2)	Glibenclamide n (%) 890 (41.9)	Metformin n (%) 164 (7.7)	Glemperide n (%) 70(3.3)	Glemperide metformin n (%) 44 (2.1)	Glibenclamide metformin n (%) 208 (9.8)	Total n (%) 2123 (100)
General practitioner	52(10.7)	*363 (74.5)	17 (3.5)	8 (1.6)	5 (1)	42 (8.6)	487(22.9)
Internist	13 (2.1)	*213 (35.1)	136 (22.4)	54 (8.9)	37 (6.1)	154 (25.4)	607(28.6)
Self-prescription	*616 (65.8)	288 (30.8)	10 (1.1)	8 (0.9)	2 (0.2)	12 (1.3)	936(44.1)
Don't know	*66(71.0)	26 (28.0)	1 (1.1)	0(0)	0(0)	0 (0)	93(4.4)
School achievement							
Illiterate	200 (27.2)	*406 (55.2)	39 (5.3)	20 (2.7)	9 (1.2)	61 (8.3)	735 (34.6)
1-6	176 (36.7)	197 (41.1)	27 (5.6)	11 (2.3)	6 (1.3)	62 (12.9)	479 (22.6)
7-12	210 (38.5)	193 (35.4)	54 (9.9)	17 (3.1)	17 (3.1)	54(9.9)	545(25.7)
University	*161 (44.2)	94 (25.8)	44 (12.1)	22 (6.0)	12 (3.3)	31 (8.5)	364(17.1)
*P value < 0.0001							

Table 2: Treatment patterns according to the prescribers and education level of 2, 123 diabetic patients.

Table 3: Treatment patterns according to the glycated hemoglobin of 2, 123 diabetic patients.

Glycated hemoglobin %	No drug n (%)747 (35.2)	Glibenclamide n (%) 890 (41.9)	Metformin n (%) 164 (7.7)	Glemperide n (%) 70(3.3)	Glemperide& metformin n (%) 44 (2.1)	Glibenclamide& metformin n (%) 208 (9.8)	Total n (%) 2123 (100)
<7	*115(41.4)	93 (33.5%)	35 (12.6)	5 (1.8)	5 (1.8)	25 (9.0)	278 (13.1)
7-8	293 (38.4)	300 (39.3)	66 (8.6)	25 (3.3)	14 (1.8)	66 (8.6)	764(36.0)
9-10	207(31.8)	291 (44.7)	49 (7.5)	23 (3.5)	15 (2.3)	66 (10.1)	651(30.7)
>10	132 (30.7)	51 (11.9)	14 (3.3)	17 (4)	10 (2.3)	*206 (47.9)	430(20.3)
*P value < 0 0001							

value < 0.0001

Table 4: Comparison between prescribers and education level of 2,123 diabetic patients.

School achievement	GP	Internist	Self-prescription	Don't know
Illiterate	215 (29.3)	199 (27.1)	*293 (39.9)	28 (3.8)
1-6	112 (23.4)	130 (27.1)	216 (45.1)	21 (4.4)
7-12	115 (21.1)	153 (28.1)	251 (46.1)	26 (4.8)
University	45 (12.4)	125 (34.3)	*176(48.4)	18 (4.9)
*P value < 0.0001				

60.8%. Mean BMI was 28.0±5.8 kg/m². Hypertension was present in 22.3% and 16.8% were current cigarette smokers with mean glycated hemoglobin 9.2±2.1 percent.

Drugs prescription according to the prescribers and education level of diabetic patients are shown in Table 2. The majority of prescriptions were self-prescriptions (44.1%); internists prescribed in 28.6% and general practitioners in 22.9%. Most of the general practitioners prescribed glibenclamide alone (74.5%) and the same applied for internists (35.1%). The self-prescription groups were commonly prescribed no drug (65.8%) and those who didn't know were also prescribed or used no drug, in 71.0%. Illiterate people used glibenclamide alone in 55.2% while those who were university graduated commonly used no drug. In our study oral anti-hyperglycemic therapy was given for 64.8 %. Eighty point four percent of our patients didn't receive metformin.

Drug prescriptions according to the glycated hemoglobin of 2123 diabetic patients are shown in Table 3. For those with glycated hemoglobin less than 7%, the majority used no drug or glibenclamide in 41.1% and 33.5 % respectively, while patients with glycated hemoglobin of 7-8 percent mostly used glibenclamide or no drug in 39.2% and 38.4 % respectively. The same applied for those with glycated hemoglobin of 9-10 percent where glibenclamide or no drug was used in 44.7% and 31.8 % respectively. In those with glycated hemoglobin more than 10%, a combination of glibenclamide and metformin was most commonly used in 47.9% and no drug in 30.7%. Twenty nine point seven percent of our patients received no drug therapy despite that their glycated hemoglobin was 7% or above.

Comparison between prescribers and education level is shown in Table 4. General practitioners mainly prescribe for illiterate people (29.3%) while internists mainly prescribe for university graduates (34.3%). Self-prescription and 'don't know' was mainly in university graduates in 48.4% and 4.9% respectively.

Discussion

Self-prescription is the commonest mode of prescription in our type 2 diabetic patients. In Iraq medications are not classified as prescription only or over-the-counter drugs. The general public has a wider access to different types of medications than would have been the case. Hence self-medication is a very common habit in Iraq and as such, drugs can be bought in the pharmacy or from street vendors [20]. General practitioners in our study prescribe glibenclamide alone in 74.5%. In the prescribing of oral hypoglycemic agents, general practitioners were less likely to recommend a change in treatment for patients inadequately controlled on sulphonylureas, despite ample evidence of side effects and their inability to sustain long term glycemic control [21]. Glibenclamide available in Iraq as generic, very cheap and can be used without prescription.

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Illiterate people used glibenclamide alone in more than half of the sample while those who were university graduates commonly used no drug. We have patients who take glibenclamide from their relatives on no medical advice. Some patients consider drug therapy as harmful to pancreases and cause dependency. The majority of our patients didn't receive the first line drug, metformin (80.4%). Although metformin failure may occur rapidly in clinical practice, initiating treatment soon after diabetes diagnosis and while HbA1c levels are low might preserve β -cell function, prolonging the effectiveness of metformin [22,23]. Sulfonylurea while effective in controlling glucose levels, its use is associated with modest weight gain and risk of hypoglycemia. In addition, studies have demonstrated a secondary failure rate that may exceed other drugs, ascribed to an exacerbation of islet dysfunction [6].

In our study, oral anti-hyperglycemic therapy was given for 64.8 % patients with type 2 diabetes mellitus and the majority of our patients didn't receive the first line drug, metformin (80.4%). In Dutch patients , drug treatment was given for 75% of new diagnoses of type 2 diabetics, sulphonylureas were used in 51.8% and metformin in 18.2% and 53% started oral therapy in the first month of diagnosis in 2004 [24]. Different findings were seen in a study from the UK, in a cohort of patients with newly diagnosed type 2 diabetes, where they found that the proportion of patients who had anti-hyperglycemic therapy initiated after 2 years of follow up was 51%, with lower rates of treatment initiation observed in older compared to younger individuals [25]. In the USA, in 2008, a study on new cases of type 2 diabetes mellitus found that the proportion of patients initially treated with metformin increased from 51% to 65%, whereas those receiving sulfonylurea decreased from 26% to 18%. This means approximately 35% of patients initiating an oral hypoglycemic drug did not receive recommended initial therapy with metformin [26]. Furthermore in the USA, younger patients, women and patients receiving drug benefits through Medicare were least likely to initiate treatment with metformin.

Of those with glycated hemoglobin >10%, 47.9% were used combination of glibenclamide and metformin in our study .This is consistent with ADA/EASD and AACE recommendations for use of dual agents in those with severe hyperglycemia [6,8]. Glemperide is the least drug used in this study, because it's not cheap and this also mentioned where the least expensive sulfonylurea is to be used [3,6]. In Africa different patterns of prescription are seen, whereas in Ethiopia, in 2010, glibenclamide was prescribed in 74.3% and metformin in 25.7% [27] and in Ibadan, Nigeria, the prescription was metformin in 65.9%, and sulphonylureas in 54.2% in 2006 [28].

About 35.2% of our patients and 40% of patients with diagnosed type 2 diabetes mellitus over the world remain untreated with antihyperglycemic agents despite having inadequate glycemic control [24,29-31]. General practitioners mainly prescribe for illiterate patients and internists mostly prescribe for university graduates, but unfortunately self-prescription was more in the university graduates. Most cases of type 2 diabetes, around the world are managed in primary Care [32].

Study limitation

This study assessed the pattern of prescription when the patient presented to our center at least one year after diagnosis. Duration between diagnosis and starting medication and first drug prescribed at diagnosis was not discussed with patients.

Conclusion

Most of our patients with type 2 diabetes mellitus were already on oral anti-hyperglycemic therapy, but the majority didn't receive the first line drug, metformin. Findings from this study enrolling patients from a secondary referral center can be applied to the whole nation in Iraq. The attitude of physicians in primary care about management of type 2 diabetes mellitus needs to be re-evaluated urgently.

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Authors' Contributions

All authors were involved concept and design of the study, in the data collection and/or analysis, interpretation of the results and conclusion.

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