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RESEARCH ARTICLE

Evaluation of adherence to international guidelines for treating patients with type 2 diabetes mellitus in Kuwait

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Abstract *Background* Clinical guidelines derived from scientific evidence provide the basis of consistent standardized prescribing. Despite an alarming increase of diabetes in Kuwait, no studies related to the quality of prescribing in diabetes were found. Before pharmaceutical care can be implemented to improve the quality of care of patients with diabetes, it is important to determine whether prescribers are compliant with comprehensive international guidelines for cardioprevention and glycaemic control. *Objective* To evaluate the adherence to clinical guidelines for treating patients with type 2 diabetes mellitus in primary care centres and secondary care centres (hospitals) using a developed and validated medication assessment tool with reference to international guidelines. *Setting* Outpatient diabetes clinics in 8 primary care centres and 4 secondary care centres across four healthcare regions in Kuwait. *Method* A quantitative, cross-sectional study involving a sample of 652 Kuwaiti patients with type 2 diabetes, who were selected using systematic sampling from the study settings. Data were collected retrospectively from the patients' medical records using a validated 43-criterion medication assessment tool (MATKW) designed to assess cardioprevention and treatment in patients with type 2 diabetes. Descriptive and comparative analysis was conducted using SPSS version 17. *Main Outcome Measure* Frequency of prescribing adherence to agreed definitions of criteria derived from international guidelines. *Results* Overall adherence to prescribing diabetes guidelines was 77.7 % (95 % CI 76.7–78.6 %). Significantly higher prescribing adherence was found in the secondary care facilities, 82.4 % (95 % CI 81.2–83.6 %) compared to primary care 72.5 % (95 % CI 71.0–73.9 %) ($p < 0.001$). Nineteen criteria out of 43 achieved an adherence >80 % in secondary care compared to ten criteria in primary care. The documentation of patients' records was found to be inconsistent at the study healthcare facilities. Nonoptimal achievement of target goals for HbA1c, blood pressure and BMI was prevalent among the study population. Conclusion: A tool such as MATKW highlights areas for review and possible improvement in prescribing adherence. Our findings reveal problem areas in prescribing practices and documentation of patients' records. Cost-effective multifaceted interventions are needed to improve current prescribing practices and documentation.

Keywords Clinical guidelines · Kuwait · Pharmaceutical care · Prescribing · Type 2 diabetes

Impact on practice

- MATKW is a useful tool for quantifying guidelines adherence and might serve as a valuable outcome measure in routine practice as part of clinical audits and identification of specific care issues that need to be addressed in the absence of locally generated guidelines.
- MATKW can be used to document and identify non-adherences to guidelines and prompt pharmacists to identify target patients who might best benefit from extended pharmaceutical services.
- Criteria with low adherence identified by MATKW can be potential areas for pharmacists to become involved

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in the care of patients with diabetes, especially in the absence of locally generated guidelines.

Introduction

Diabetes is a chronic illness that is considered as one of the most challenging health problems in the 21st century. In 2011, the number of people worldwide living with diabetes was 336 million people, but it is expected to increase to 552 million by 2030 [1]. The prevalence of diabetes in Kuwait has doubled in the last 15 years, reaching 21.2 % in 2011 [1].

Diabetes results in chronic complications including microvascular and macrovascular disorders. Evidence has also shown that cardiovascular disease is the major cause of morbidity and mortality for patients with diabetes and has significant contribution to the direct and indirect costs of diabetes [2]. Diabetes and its complications affect the society's economic status and have a great impact on individuals, families, healthcare systems and countries, not only due to cost of treatment, but also social costs and loss of working days [3, 4].

The measurement of the quality of healthcare has been identified as a priority in many health policy agendas worldwide [5]. The need for change in diabetes management and the standardisation of care by healthcare professionals to offer consistent provision of best quality care is repeatedly expressed. However, in order to plan and implement changes to healthcare, there is a need to measure and assess current practice. Healthcare systems need to develop a quality measurement framework at every level to allow the improvement of patient care. A previous audit in Kuwait measured the quality of diabetes care in primary care settings by reviewing the administrative structure at the selected clinics, as well as personnel and access to specialized and laboratory services involved in diabetes care [6]. However, no current published studies have been conducted in Kuwait to evaluate prescribing practices for patients with diabetes.

The goal of evidence-based clinical practice has led to an increased interest in the development of tools to measure prescribing adherence to national guidelines. This aids in detecting and measuring inappropriate prescribing to specific patient groups by using quality standards extracted from evidence-based guidelines. Medication assessment tools (MATs), based on standards recommended by UK clinical guidelines have been used in previous research to quantify the level of adherence of prescribers to clinical guidelines for different disease states including cancer and diabetes [7–9]. However, one limitation identified when using the MAT in international settings for diabetes management was that it needed further modification to embrace other internationally recognised guidelines that heterogeneous healthcare providers might recognise and access.

The Kuwaiti healthcare system provides healthcare through both a governmental sector and a private sector. Primary care is delivered through 80 healthcare centres, spread amongst 5 healthcare regions, a total of 51 diabetes clinics existed in primary care centres. Secondary care is provided through 6 general hospitals, and tertiary care is provided through 15 specialised centres. There are 5 general hospitals in Kuwait which provide outpatient diabetes care. In addition to graduates from Kuwait University, the doctors, nurses, and pharmacists in Kuwait have different educational backgrounds, with training from countries such as USA, UK, India, Egypt, and other Middle Eastern countries.

In Kuwait, the latest diabetes guidelines were produced in 2001, with no regular updates. There is no published data on prescribing practices for patients with diabetes. This information is needed as part of a quality assurance framework aimed at ensuring optimal patient care.

Aim of the study

The present study was designed to evaluate the adherence to clinical guidelines for treating patients with type 2 diabetes mellitus in primary care centres and secondary care centres (hospitals) using a developed and validated medication assessment tool (MAT_{KW}) derived from internationally recognised diabetes guidelines.

Methods

Study design

This is a quantitative, cross-sectional study designed to evaluate the quality of prescribing at primary and secondary care settings of patients with type 2 diabetes in Kuwait. It was conducted between January and June 2010. The Medical Research Ethics Committee of the Ministry of Health and the Human Ethical Committee, Health Sciences Centre, Kuwait University approved the study protocol.

Inclusion criteria and exclusion criteria

Patients included in this study were those who had been diagnosed with type 2 diabetes mellitus and had started treatment at least 6 months prior to the study period, currently alive and had attended the clinics during the past 2 years prior to the study period. Patients with type 1

diabetes mellitus and those who had not attended the clinic within the last 2 years prior to the study period were excluded from the study sample. In addition, patients ≥75 years old were excluded as more conservative goals are often used for this population.

Study sample

The sample size was determined using Java Applets for Power and Sample Size [10]. It was calculated that a sample size of 650 patients would be required to determine a 10 % difference in proportions between two groups (primary and secondary care facilities) with a 90 % power and a 5 % significance level. Four secondary care centres out of the five in Kuwait that provide outpatient diabetes clinics were selected to be included in the study. In each centre, 80 patients' medical records were collected using systematic sampling. The 51 primary care centres that provide diabetes clinics were stratified according to healthcare regions and systematic random sampling was used to select a total of 8 primary care centres across four healthcare regions (2 centres from each region). A total of 332 patients' medical records were collected using systematic random sampling.

Development and validation of MAT_{KW}

A variety of guidelines are used to treat patients with diabetes due to the heterogeneous nature of physicians in Kuwait. This led to the decision to undertake an iterative process that involved updating and modifying standards in previous studies conducted in the UK. The recommendations from the American Diabetes Associations' standard of medical care, the European Association for the study of diabetes, Scottish Intercollegiate Guidelines Network guidelines and the National Institute for Health and Clinical Excellence (NICE) guidelines were used to develop the MAT_{KW} [2, 11–13]. A total of 55 criteria were developed from these guidelines. Each criterion is composed of 2 segments: a qualifying statement and a standard. The qualifying statement would initially be viewed in order to identify those patients eligible for application of the standard. Application of the standard on eligible patients involves choosing an answer category from 5 different possible answers: Yes—standard is met; No (J)—standard is not adhered to but an explicitly justified reason is present and documented in the patient's notes; No (U)—standard is not adhered to and there is no explicitly apparent or documented reason in the patient's notes; IDQ—insufficient data on part of the qualifier; IDS—insufficient data on part of the standard. If a patient is not eligible for application of the standard, N/A is recorded.

Content validity was established by means of an email survey to an expert group of 7 consultant endocrinologists (5 from secondary care, 2 from primary care) in Kuwait. The expert group decided whether they strongly agreed/agreed/neutral/disagreed/or strongly disagreed with each criterion. Criteria were eliminated if they were into either 'disagree' or 'strongly disagree' fields. Face validity was established by means of a peer review by the research group before field-testing. The MAT_{KW} was pre-tested on a sample of 20 patients' medical records in a primary care centre. Following the validation and a further peer review after field-testing, the final MAT_{KW} was produced with 43 criteria that were conveniently included into five subheadings.

Data collection and statistical analysis

Data were collected from the selected patients' medical records retrospectively from each health facility. Descriptive and comparative data analysis was performed using SPSS, version 17 (SPSS Inc., Chicago, IL., USA). Adherence to every single criterion was calculated as well as the MAT score, which is the total percentage adherence. This was calculated from the summation of the total number of cases where the standard is adhered to (Yes answers) over the summation of the total number of applicable cases, where the standard should be adhered to (i.e., Yes, No(U) and IDS answers). The criteria adherence was judged using arbitrary cut-offs based on a previous study of similar design (high, ≥80 %; intermediate, 50 to <80 %; low <50 %) [14]. The comparison of data between primary and secondary care facilities was carried out using Chi square and Mann–Whitney test. $p < 0.05$ was considered to be statistically significant.

Results

Table 1 shows the patients' characteristics among the primary and secondary care facilities included in the study. The overall results showed that the mean (SD) age was 56.2 (9.6) years, the mean BMI (SD) was 33.6 (6.8) kg/m^2, the mean HbA_{1c} (SD) was 8.5 (1.8) %. There were no significant differences between patients attending primary and secondary healthcare facilities in relation to age, BMI and HbA_{1c} ($p > 0.05$). Three hundred and sixty-nine (56.6 %) were females. Oral antidiabetic therapy alone was used by 374 (57.4 %), insulin therapy alone by 7 (1.1 %), and 271 (41.6 %) used both types of medications.

In the overall study sample, only 59.2 % of patients had their BMI recorded, of which 67.1 % had a BMI ≥30 kg/m^2. However, 75.0 % of the entire study sample had their HbA_{1c} recorded, with only 19.2 % of patients reaching the target of HbA_{1c} <7 %. Target blood pressure (BP) was achieved in 46.0 % of patients in general, while only 38.7 % of patients with diabetes complications reached their target BP.

Table 1 Patients' characteristics at primary and secondary healthcare facilities (n = 652)

	Primary care	Secondary care	*p* value
Total number of patients n (%)	332 (50.9 %)	320 (49.1 %)	
Gender			0.43
Male n (%)	139 (41.9 %)	144 (45.0 %)	
Female n (%)	193 (58.1 %)	176 (55.0 %)	
Age (Years)			0.21
Mean (SD)	56.6 (9.3)	55.7 (9.8)	
BMI (kg/m^2)[a]			0.98
Mean (SD)	33.5 (6.4)	33.7 (7.4)	
HbA_{1c} (%)[b]			0.99
Mean (SD)	8.6 (1.9)	8.5 (1.8)	

[a] 228 Patients at primary care and 158 patients at secondary care, total of 386 patients

[b] 207 Patients at primary care and 282 patients at secondary care, total of 489 patients

The documentation of patients' records was variable when comparing primary and secondary care. In primary care, BMI and HbA_{1c} were recorded in 68.7 and 62.3 % of cases, respectively, while in secondary care 49.4 % for BMI and 88.1 % for HbA_{1c}. Annual visits were recorded in 65.8 % of cases for foot examinations, 64.7 % for eye examinations and 79.0 % for BP measurements in primary care; however in secondary care, they were recorded in 78.0 % for foot examinations, 78.2 % for eye examinations and 98.3 % for BP measurements.

Target HbA_{1c} (<7 %) was achieved in 21.7 % of patients in primary care compared to only 15.4 % in secondary care. BMI ≥30 kg/m^2 was found in 68.4 % of patients in primary care compared to 82.4 % in secondary care. Target BP was achieved in 52.4 % of patients in primary care compared to only 38.9 % in secondary care. Target BP in patients with diabetes complications was achieved in 60.0 % of patients in primary care compared to 45.1 % in secondary care.

The level of overall adherence was judged as intermediate adherence (77.7 %, 95 % CI: 76.7–78.6 %). There was very low applicability (less than 10 patients) in criteria 6, 7, 13, 14, 17, 27, 38, 39 and 40; and criterion 26 was not applicable to any patients. Significantly higher total adherence was found in the secondary healthcare facilities 82.4 % (95 % CI 81.2–83.6 %) compared to primary care 72.5 % (95 % CI 71.0–73.9 %) ($p < 0.001$). Moreover, 19 criteria achieved a high adherence (>80 %) in secondary care compared to 10 in primary care (Table 2).

Out of the 28,036 criteria, only 16,136 relevant criteria were investigated among the study population, 7,563 (46.9 %) of which were found to be applicable. There were 991 cases of insufficient data (ID), of which 787 (79.4 %) were considered as IDQ and 204 (20.6 %) were IDS. Overall non-adherence [(No(J) + No(U)] was observed in 1,483 (19.6 %), of which 134 (1.8 %) cases were justified. Table 3 shows the non-adherence to criteria (both justified and non-justified) at primary and secondary healthcare facilities.

Discussion

To the best of our knowledge, this is the first study to be performed in Kuwait using a criterion-based approach with reference to international treatment guidelines to evaluate the adherence to international guidelines for treating patients with type 2 diabetes mellitus at healthcare settings.

The developed and validated MAT_{KW} would be a useful instrument in routine practice as part of clinical audits for giving feedback to the diabetes care team and identifying specific care issues that need to be addressed in the absence of intrinsic locally generated guidelines. It may also be used as an outcome measure in future intervention studies. The main findings of this study were an intermediate overall adherence (77.7 %) to international diabetes guidelines and inadequate documentation of patients' records.

The results showed that there were no significant differences between patients attending primary and secondary health care facilities in relation to their age, BMI and HbA_{1c}. Little is known about the proportion of patients with diabetes being cared for in primary or secondary care settings. In general, people with complications or co-morbidities are seen by more specialised doctors at the secondary care settings, while those in need of general care and less complicated cases attend primary care. These findings showed a greater tendency for those patients who were insulin dependent to be visiting secondary care (52.8 %) compared to primary care (32.8 %). With the dramatic increase in prevalence of patients with diabetes, the Ministry of Health is working towards increasing diabetes care services in primary care. A study conducted in the UK showed that a major barrier to comprehensive and systematic diabetes care in primary care is lack of "organisation" [15]. Nowadays, countries worldwide are more inclined to shift care from secondary care to primary care, as secondary and tertiary care are more likely to be disorganised, discontinuous, uncoordinated and costly, while development of highly organized systems of primary care have proven to have lower health care costs.

This study revealed incomplete documentation of patients' records at both primary and secondary care settings. In order to ensure optimum continuity of care between health institutions and personnel, attention to

Table 2 Adherence to the audit tool criteria at primary and secondary healthcare facilities

Criterion no.	Descriptor	% Adherence (95 % CI)	
		Primary care	Secondary care
Secondary prevention of CHD, Stable angina and Post-MI Criteria			
1	Use of aspirin in secondary prevention	66.7 (44.9, 88.4)	90.9 (83.3, 98.5)
2	Appropriate dose of aspirin	85.7 (67.4, 100.0)	100 (100.0, 100.0)
3	Use of statin in secondary prevention	66.7 (44.9, 88.4)	96.4 (91.4, 100.0)
4	Use of ACE inhibitor in secondary prevention	55.6 (32.6, 78.5)	81.8 (71.6, 92.0)
5	Use of sublingual glyceryl trinitrate (GTN)	22.2 (3.0, 41.4)	20.0 (9.4, 30.6)
8	Correct timing of oral nitrate dose in patients with stable angina	–	92.9 (79.4, 100.0)
9	Use of third line anti-anginals	–	100 (100.0, 100.0)
10	Use of ACE inhibitors post-myocardial infarction (MI)	45.5 (16.0, 74.9)	87.2 (76.7, 97.7)
11	Use of beta blockers post-MI	45.5 (16.0, 74.9)	84.6 (73.3, 95.9)
12	Achievement of ACE inhibitor target dose in normal left ventricular function	–	59.4 (42.4, 76.4)
Primary prevention			
15	Use of aspirin in primary prevention	66.9 (61.5, 72.2)	77.3 (72.1, 82.5)
16	Safe use of aspirin (BP < 145/90 mmHg)	79.9 (74.0, 85.8)	76.9 (70.3, 83.5)
18	Use of statin in primary prevention	56.4 (50.3, 62.5)	89.5 (85.6, 93.3)
19	Use of statin if LDL > 2.6 mmol/L	79.6 (73.7, 85.4)	97.8 (95.9, 99.7)
Diabetes-control specific criteria			
20	Use of metformin in overweight patient	90.6 (87.4, 93.9)	86.3 (82.4, 90.1)
21	Safe use of metformin	62.2 (56.5, 67.8)	91.7 (88.3, 95.0)
22	Safe use of thiazolidinedione	–	95.5 (86.8, 100.0)
Hypertension specific criteria			
23	Use of antihypertensive therapy	93.1 (89.3, 96.9)	99.0 (97.6, 100.0)
24	Achievement of target BP	52.4 (44.8, 60.1)	38.9 (32.1, 45.7)
25	Use of ACE inhibitor/Angiotensin-receptor blockers (ARB) for hypertension	82.9 (77.3, 88.6)	91.8 (87.9, 95.6)
27	Safe use of thiazide diuretic	47.8 (33.4, 62.3)	–
28	No co-prescribing of thiazide and beta-blocker	89.1 (84.8, 93.4)	99.5 (98.5, 100.0)
29	Plan to exclude drugs that elevate BP	90.2 (85.6, 94.8)	94.4 (91.1, 97.6)
Management of diabetes complications			
30	Annual BP measurement	79.0 (71.9, 86.2)	98.3 (96.1, 100.0)
31	Use of anti-hypertensive therapy in presence of complications	83.3 (66.1, 100.0)	97.3 (93.5, 100.0)
32	Achievement of target BP in presence of complications	60.0 (35.2, 84.8)	45.1 (33.5, 56.6)
33	Use of ACE inhibitors in patients with microalbuminuria	64.0 (50.7, 77.3)	52.6 (42.6, 62.5)
34	Use of ARB in patients with microalbuminuria as ACE inhibitor substitute	45.0 (23.1, 66.8)	88.8 (79.7, 98.1)
35	Annual eye screen	64.7 (59.1, 70.2)	78.2 (73.6, 82.8)
36	Annual foot screen	65.8 (60.3, 71.4)	78.0 (73.4, 82.5)
37	Use of tricyclic antidepressants, gabapentin or duloxetine for neuropathy	–	62.5 (38.8, 86.2)
Miscellaneous criteria			
38	Use of ACE inhibitors in left ventricular systolic dysfunction (LVSD)	8.3 (73.4, 97.2)	–
39	Use of ARB as ACE inhibitor substitute in LVSD	58.1 (40.7, 75.4)	–
40	Use of clopidogrel as substitute to aspirin	96.6 (89.9, 100.0)	–
41	Advice on smoking cessation	45.5 (32.3, 58.6)	24.0 (7.3, 40.7)
42	Use of fibrate if triglyceride levels > 4.5 mmol/L	81.1 (68.5, 93.7)	–
43	Use of fibrate if on statin and triglyceride levels 2.3–4.5 mmol/L	58.6 (40.7, 76.5)	39.1 (19.2, 59.1)
	Total adherence (%) (95 % CI)	72.5 (71.0, 73.9)	82.4 (81.2, 83.6)
	p value	<0.0001	

Only criteria with applicability greater than 9 patients are included in the table

Table 3 Non-adherence to the audit tool criteria at primary and secondary healthcare facilities

	Primary care n = 3,569[a]	Secondary care n = 3,994[a]
No (Justified)	48 (1.3 %)	86 (2.2 %)
No (Unjustified)	794 (22.2 %)	555 (13.9 %)
Total non-adherence	842 (23.6 %)	641 (16.0 %)

[a] Number of applicable criteria

adequate documentation should be encouraged. All primary care centres in Kuwait have computerised patient medical records which are very user-friendly but, unfortunately, underutilised. Physicians tend to leave many data fields blank, maybe out of habit or due to the heavy workload and time restraints. On the other hand, secondary care settings only use paper medical records. The introduction and promotion of information technology in healthcare management has shown great improvements in patient safety, quality of care and adherence to evidence-based practice [16]. However, despite these improvements, practices and physicians varied greatly in how extensively they used electronic medical records. It has been shown that one potential solution to the adoption of electronic medical records is by providing practice support as well as financial incentives for quality improvement [16]. In Kuwait, there is a need for methods to encourage clinicians' use and adoption of electronic medical records, and audits to be undertaken to measure any quality improvement pre- and post-implementation of electronic medical records systems.

One major contributing factor to the intermediate overall adherence to prescribing diabetes guidelines identified by this study could be due to the lack of up-to-date national guidelines. Furthermore, no other members of the healthcare team takes part in decision making, which make the guidelines more difficult to adapt into practice. Common reasons for this are a process which is non-participatory and/or not widely consultative, which results in a product to which most of the target group do not feel a sense of ownership. In addition, a process of implementation needs to be harmonised with that of distributing the clinical guidelines to improve engagement by health workers and use of the new material, changing their habitual practices [17, 18]. In, Kuwait, diabetes treatment guidelines need to be regularly updated and appropriately implemented to maintain authority.

Total adherence was found to be significantly higher in the secondary healthcare facilities (82.4 %) compared to primary care (72.5 %). This could be attributed to physicians in hospitals being equipped with more research and/or clinical-based training in diabetes, while those in primary care are specialised in "family medicine" and rarely have specialised qualifications in diabetes and/or interest in diabetes. A study conducted in the UK showed that of all the doctor related factors (personality, knowledge, consultation style), only a special interest in diabetes was shown to be significantly associated with better diabetes control [19].

This study was not primarily designed to study the outcomes of treatment, but it strongly indicates non-optimal achievement of target goals for HbA_{1c}, BP, and BMI among the study population. It is recommended that the therapeutic goals for patients with diabetes to reduce the increased risk of cardiovascular events include achieving HbA_{1c} <7 %, BP <130/80 mm Hg, LDL-cholesterol <2.6 and 1.8 mmol/L for those at very high risk [2]. Inappropriate prescribing practices, poor patient adherence to medication, unawareness of the importance of therapeutic goal attainment, and lack of knowledge with regard to therapeutic goals have been recognised as limitations to patients achieving these goals [20].

In Kuwait, diabetes care is mainly provided by the physicians, a potential intervention should be the integration of an effective multi-disciplinary team approach including physicians, pharmacists, nurses, and dieticians to encourage patient education and self-care, and share responsibility for patients achieving diabetes therapeutic goal [2]. In Kuwait, there has been little discussion about the potential role of the pharmacist in the multi-disciplinary team. This highlights the need for recognition of areas for pharmacists to become involved in this team. Several studies have acknowledged the importance of the pharmacist providing counselling, encouraging effective use of medicines to achieve glycaemic targets, promoting healthy lifestyles, supporting self-care, carrying out medication reviews, and managing disease systemically within multi-professional teams [21–23]. Further qualitative studies to allow a comprehensive understanding of the factors associated with the specific problems identified by this study, and cost-effective multifaceted interventions are highly needed to secure the quality of diabetes management in the healthcare settings of Kuwait.

Limitations

Our study design used nested sampling and our sample size calculation did not take nested structure into consideration; a post hoc power analysis was done using PASS software with our sample size to compare the total adherence between secondary and primary care using a clustered design, and we found statistical power of 90 % holds as long as the intra class correlation (ICC) is less than 0.3. Our

data indicated that ICC is much less 0.3 and therefore we believe our study is not under powered.

Conclusions

The developed and validated MAT_{KW} provides a method for quality assurance of drug therapy use in clinical settings and may provide a means of establishing acceptable standards of prescribing adherence to international guidelines for diabetes care.

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