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RESEARCH

The achievement of glycaemic, blood pressure and LDL cholesterol targets in patients with type 2 diabetes attending a South African tertiary hospital outpatient clinic

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Objectives: To determine differences in the control of multiple diabetes control parameters in a select group of subjects with type 2 diabetes (T2DM) after a four-year follow-up period.
Design: Cross-sectional study.
Setting and subjects: The initial 2009 study population consisted of 666 T2DM patients of whom only 261 (39.2%) were audited at the Charlotte Maxeke Johannesburg Academic Hospital.
Outcome measures: Using a public sector database, retrospective data were obtained on the treatment of participants with T2DM attending a tertiary care setting and a descriptive analysis was done.
Results: The mean age was 64 (SD 10.6) years, women represented 55% of the cohort and the mean duration of diabetes was 16 years (range 2–40 years) in 2013. Fewer patients achieved an HbA1c goal (of < 7%) in 2013 (15.5%) compared with 2009 (25.4%), whilst an additional 13.7% and 25.0% of the 261 patients reached blood pressure targets (< 140/80 mmHg) and LDL-C targets (< 2.5 mmol/L), respectively.
Conclusion: Overall, more patients in the study reached blood pressure and LDL-C targets but there were difficulties in achieving optimal glycaemic levels over the four-year period. This study highlights the complexities of managing risk factors in T2DM, especially glucose control.

Keywords: diabetes mellitus, management, risk factors, targets

Introduction

South Africa has a staggering 3–10% prevalence rate of type 2 diabetes mellitus (T2DM) amongst its urban and peri-urban population.[1] In addition to risk factors such as raised blood pressure (BP) and glycaemic levels, dyslipidaemia is the primary cause of morbidity and mortality in T2DM patients.[2] Randomised clinical trials have convincingly demonstrated that effective glycaemic control decreases microvascular complications, whilst treatment of blood pressure and dyslipidaemia reduces the incidence of cardiovascular complications.[3,4] For this reason, clinical trial results have been incorporated into evidence-based guidelines that advocate intensified treatment of these risk factors.[5]

Despite strong evidence of improved outcomes through lifestyle and medication effectiveness, only a minority of total T2DM patients in clinical practice reach target goals.[6] Risk-factor management as recommended by guidelines is often neglected, e.g. insufficient testing, physician reluctance to initiate or intensify pharmacotherapy, poor patient education or counselling and general lack of follow-up visits to evaluate response of the intervention. Clinical trials are often characterised by more frequent follow-up visits, motivated practitioners/patients and protocols that are more aggressive at targeting risk factors. Perhaps this difference is what complicates translating robust evidence into clinical practice.

The objective of this study was to audit and compare the achievement of targets of individual control parameters in a select cohort of T2DM patients, after a four-year-time period in a tertiary care setting.

Methods

Study design

This study was a continuation of a previous 2009 cross-sectional study, which can be considered as a baseline.[7] The study was designed to further evaluate the extent to which diabetes guidelines were followed in a cohort of tertiary-based T2DM patients. Using patient records, the latest levels of blood pressure, glycated Hb (HbA1c) and lipid levels in treated patients were obtained. Achievement of treatment targets at the two points in time was compared.

Setting

The study was conducted at Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) between May and October 2013. Patients normally attend the hospital's diabetes clinic every 3–6 months, depending on their individual treatment requirements. The authors of this study assumed that the patients attending this particular diabetes clinic required a level of care not normally offered in a primary care setting (as T2DM is a progressive disease that brings about many challenges in managing this condition). This study was an audit conducted in

2013 over a five-month capture period, which permitted us to access data of patients previously seen in the 2009 audit. Medical practitioners, with the assistance of nurses at the clinic, were responsible for the care, prescribing and check-ups of diabetic patients attending the clinic.

Patients

In the 2009 audit, 666 patients with T2DM as defined by the guidelines at the time of the study were enrolled.[7,8] Patients excluded in 2009 were: < 18 years of age, had type 1 diabetes, gestational diabetes, steroid-induced diabetes and chronic pancreatitis that had led to secondary diabetes. As one of the primary measurements was a serum lipid reading, a decision was taken to exclude patients with triglyceride levels > 4.5 mmol/L as this may have been a source of error when calculating low-density lipoprotein (LDL) cholesterol, as measured by the Friedewald formula,[9] or could have been noncompliance with overnight fasting, leading to anomalous lipid values and, in particular, falsely low LDL cholesterol measurements. For the purposes of this study, patients with laboratory HbA1c results of '>14%' were assigned an HbA1c of 14.0%.

Similarly to the previous audit, patients were considered lost to follow-up if their last recorded entry or appointment in their file was dated before 2011 (at least two years prior to the start of the 2013 study).[7] Patients were also lost to follow-up if their hospital records were missing or filed in the 'non-returns' section of the clinic, deceased or down-referred to a separate treatment facility. Patients from the earlier (n = 666) 2009 audit whose files were not found in the 2013 audit were excluded from the analysis of this current study. For the purposes of this study, the data from the 2009 audit were re-analysed to include and compare only those 261 patients found in the later audit.

Unfortunately, most patient files had missing details of weight, height, diet details and smoking status. These parameters, especially the first two, would have been used to calculate body mass index (BMI). On the same note, due to omitted waist measurements, patient classification of metabolic syndrome (MS) was also excluded from the study.[10] As with the previous study, missing details of ethnicity from patient records were denoted as 'unknown'.[7] Patients defined as having diabetic nephropathy using laboratory data, i.e. micro-albumin-to-creatinine ratios, serum creatinine concentrations or glomerular filtration rate (GFR) often proved inconsistent due to numerous patients not having these laboratory reports available in their records. It was also found that some patients were concurrently being managed at the hospital's renal clinic, separate from the diabetic clinic. For the purposes of this study, patients deemed as having diabetic nephropathy were those patients who had one or more of the following in their records: chronic kidney disease (CKD), chronic renal disease (CRD), chronic renal failure (CRF), nephropathy and diabetic nephropathy. Current patients attending the diabetes clinic at the CMJAH were scheduled for their routine appointments at different times throughout the year, which meant that data captured from files for this 2013 audit were reliant on the latest information from patient files, from their last visit to the clinic. To the best of our knowledge, only the most recent records and laboratory reports of the patient were utilised for the purposes of this study. Data from patient records were entered into case report forms and later into a secure database at the University of the Witwatersrand, Faculty of Health Sciences, Johannesburg, South Africa. Prior to the study, the University of Witwatersrand's Human Research Ethics Committee (HREC) granted ethical approval for the study.

Clinical parameters

Registered nurses were in charge of drawing of study patients' bloods using standardised techniques at the diabetes clinic. Patients were informed of the fasting requirements of laboratory tests before having their blood drawn for specific tests in prior appointments/visits.

As CMJAH is a state hospital, the National Health Laboratory Services (NHLS) was responsible for all the laboratory measurements of study patients. Once the results were available, the NHLS issued laboratory results delivered by hospital staff to the diabetes clinic and filed under respective patient files by clinic administration staff. HbA1c was measured using the Tina-Quant Haemoglobin A1c II immunological assay, fasting LDL-C was calculated by means of the Friedewald formula, fasting high density lipoprotein cholesterol was measured by direct enzymatic methods (3rd Generation), fasting total cholesterol was also measured by direct enzymatic methods and TG was measured by enzymatic colorimetric methods. All measurements were done using the Modular Analyser P800 System (Roche Diagnostics-Hitachi, Mannheim, Germany). Blood pressure values were measured by registered nurses or treating doctors in accordance with the South African Hypertension Guidelines and the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII).[11,12] Once data were captured into case report forms, the Society for Endocrinology Diabetes and Metabolism of South Africa (SEMDSA) 2 Guidelines for T2DM treatment targets were applied to the cohort, namely HbA1c < 7.0%, TC < 4.5 mmol/L, LDL-C < 2.5 mmol/L, HDL-C > 1.0 mmol/L (men), HDL-C > 1.2 mmol/L (women) and Triglyceride < 1.7 mmol/L.

In patients with established vascular disease such as ischaemic heart disease, cerebrovascular disease or peripheral vascular disease, the LDL-C target was < 1.8 mmol/L. Hypertension was considered to be present if patients were receiving antihypertensive treatment.

In order to compare blood pressure levels across the two different time points, the 2012 SEMDSA targets of systolic BP < 140 mmHg and diastolic BP < 80 mmHg were applied to both the 2009/2013 data, as previously the SBP was < 130 mmHg. This allowed for a consistent target against which both data sets could be compared in order to evaluate achievement of these targets.

Statistical and data analysis

A descriptive analysis was conducted with summary measures such as mean (standard deviation, SD) calculated for age, gender, race, blood pressures, HbA1c and fasting lipids. The percentage of previous coronary artery disease (CAD), stroke, retinopathy, neuropathy and nephropathy history in patients was reported through frequency tabulations. Frequency tables of patient usage of chronic medication for the treatment of hyperglycaemia, hypertension and lipids as well as those receiving antiplatelet treatment were also produced. The percentage of patients reaching SEMDSA treatment goals for various clinical parameters was calculated. Where necessary, the chi-square test was used to investigate any associations with key measures. Microsoft Office Excel 2009 (Microsoft, Redmond, WA, USA) was utilised for creating the study's databases and statistical analysis was done using Stata version 13 (64-bit) (StataCorp, College Station, TX, USA).

Table 1: Characteristics of type 2 diabetes patients

	Year 2009 (*n* = 261)	Year 2013 (*n* = 261)	*p*-value
Age (years)	60 ± 10.6	64 ± 10.6	–
Female sex, *n* (%)	143 (55%)	143 (55%)	–
Ethnicity: African/Caucasian/Asian or Indian/Mixed Ancestry (%)	42.9/25.3/26.1/5.7	42.9/25.3/26.1/5.7	–
Duration of diabetes (years)	12 ± 10.6	16 ± 10.6	–
CAD, *n* (%)	34 (13.0%)	58 (22.2%)	< 0.05
Stroke, *n* (%)	6 (2.3%)	10 (3.8%)	NS
Retinopathy, *n* (%)	18 (6.9%)	39 (14.9%)	< 0.05
Neuropathy, *n* (%)	16 (6.1%)	42 (16.1%)	< 0.05
Nephropathy, *n* (%)	24 (9.2%)	60 (23.0%)	< 0.0001
HbA1c (%)	8.5 ± 2.2	8.7 ± 2.0	NS
SBP (mmHg)	134 ± 17.8	139 ± 22.0	< 0.05
DBP (mmHg)	78 ± 10.5	73 ±11.4	< 0.0001
Total cholesterol (mmol/l)	4.5 ± 1.1	4.0 ± 1.0	< 0.0001
Triglycerides (mmol/l)	1.7 ± 0.9	1.6 ± 1.2	NS
LDL Cholesterol (mmol/L)	2.6 ± 0.9	2.1 ± 0.9	< 0.0001
HDL Cholesterol (mmol/L)	1.2 ± 0.4	1.2 ± 0.3	NS
Glucose-lowering drugs			
No orals, *n* (%)	94 (36.0%)	53 (20.3%)	< 0.0001
1 oral, *n* (%)	114 (43.7%)	172 (65.9%)	< 0.0001
≥ 2 orals, *n* (%)	53 (20.3%)	36 (13.8%)	< 0.05
Insulin (with or without oral hypoglycaemic drugs), *n* (%)	187 (71.6%)	209 (80.1%)	< 0.05
Cardiovascular drugs			
Statin lipid-lowering drugs, *n* (%)	150 (57.5%)	203 (77.8%)	< 0.001
Antihypertensive drugs, *n* (%)	236 (90.4%)	244 (93.5%)	NS
ACE-inhibitors or ARBs, *n* (%)	208 (79.7%)	207 (79.3%)	NS
Antiplatelet drugs, *n* (%)	128 (49.0%)	119 (45.6%)	NS

Note: *p*-value for differences, significant if *p*-value < 0.05. CAD = coronary artery disease, DBP = diastolic blood pressure, HbA1c = haemoglobin A1c, HDL = high-density lipoprotein, LDL = low-density lipoprotein, NS = non-significant, SBP = systolic blood pressure, ACE = angiotensin converting enzyme, ARB = angiotensin receptor blockers.

Results

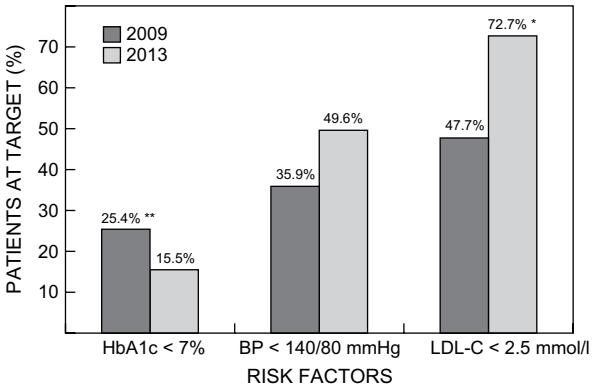
The initial 2009 study population consisted of 666 T2DM patients of whom only 39.2% (*n* = 261) were audited, 4 years later. The rest of the study population were assumed to have died, relocated or been down-referred to another healthcare facility and were therefore excluded from the analysis. This suggests that the almost 40% of patients followed up may differ significantly from the larger cohort of patients from the earlier baseline study. Data were captured twice over two time periods– once during the 2009 audit, then once again during the 2013 audit. The data from the 2009 audit were re-analysed to include only those 261 patients' files that could be located in the 2013 audit. A comparison of the two data sets was conducted as part of this study. Of the 261 patients, the mean age was 64 (SD 10.6) years (Table 1). Women represented 55% (*n* = 143/261) of the cohort and the mean duration of diabetes for the population was approximately 16 years in 2013. The study population consisted of the following patient ethnicities: African (42.9%), Caucasian (25.3%), Indians/Asian (26.1%) and Mixed Ancestry (5.7%).

Glucose management

Previously in 2009, 96.6% (*n* = 252/261) of patients had HbA1c measurements, whereas in 2013 it was found that all patients had HbA1c values present in their records. There were apparently no differences in the mean HbA1c of the study population after the four-year period (8.7% (±2.0) (2013) vs. 8.5% (±2.2) (2009), *p* = 0.063). In 2013, the mean HbA1c value for males was 8.8% (±2.0) compared with 8.3% (±2.2) in 2009, with the pattern not different for females [8.7% (±2.0) vs. 8.6% (±2.2)].

We note a declining trend with time in achieving the HbA1c goal (< 7%) among these patients. In 2013, it was observed that only 15.5% compared with 25.4% in 2009 achieved the HbA1c goal (Figure 1), despite overall more insulin and oral hypoglycaemics being prescribed. Almost 70% (175) of patients remained above HbA1c target in 2009 and 2013, whilst only 13 patients (5.2%) improved their HbA1c in 2013 after not being at goal in 2009. There were 26 patients (10.3%) who improved and reached HbA1c targets in 2013.

Alone or in combination, more patients began to use oral hypoglycaemics with 79.7% in 2013 compared with 64.0% in 2009. Similarly, insulin utilisation also increased (80.1% vs. 71.6%) respectively. Of the total number of patients not at target for HbA1c in 2013, 86.2% were using insulin (*p* < 0.001). Patients using basal insulin (Actraphane®, Humulin 30/70®, Humulin-N® and Protaphane®) were using on an average of 0.64 units per kg, whilst for pre-meal insulin (Actrapid® and Humulin-R®), the dose was 0.78 units per kg.



Note: BP = blood pressure, HbA1c = haemoglobin A1c, LDL-C = low-density lipoprotein cholesterol, *$p < 0.05$; **$p < 0.001$.

Figure 1: Difference in patients achieving goals between the two time periods.

Blood pressure management

In the 2013 audit, 99.6% of patient blood pressure values were available from files, which is an improvement of 15% compared with the measurements in the 2009 audit. More patients reached targets (SBP and DBP < 140/80 mmHg) in 2013 (49.6%) than in 2009 (35.9%) (Figure 1), albeit similar numbers of patients were recorded to be receiving treatment (244/261(93.5%) and 236/261 (90.4%)) during the two time points. Patients used an average of 2.5 anti-hypertensives over both study periods. A further 63 patients (28.6%) reached the combined BP targets in 2013, but 78 (35.5%) remained not at goal at both time points. SBP increased, whereas DBP decreased compared with 2009 values (Table 1).

In 2013, more females were receiving hypertension treatment than males (95.8% vs. 90.7%, $p = 0.095$), which may have accounted for the lower, although not statistically significant SBP (female SBP 138 mmHg (SD 19.1) vs. male SBP 140 mmHg (SD 25.0), $p = 0.556$). In 2009, females also received more treatment than males (93.0% vs. 87.3%, $p = 0.118$) but had higher systolic blood pressure measurements than males (female SBP 136 mmHg (SD 16.2) vs. male SBP 131 mmHg (SD 19.4), $p = 0.062$), both not statistically significant.

Over the study period, angiotensin-converting enzyme inhibitors/angiotensin receptor blockers were the most commonly prescribed hypertension treatments and their usage remained constant over the study periods (79.7% vs. 79.3%). Also noteworthy is that angiotensin receptor blockers' usage increased from 6.4% to 9.0% in 2013.

Lipid management

Lipid monitoring improved, with 97.7% of patients having at least one LDL-C measurement available in their records, as opposed to the previous 90.8% in the 2009 audit. The mean LDL-C of the study population tended to improve over time (2.6 mmol/L (±0.9) vs. 2.1 mmol/L (±0.9) in 2009 and 2013 respectively). More patients without previous cardiovascular disease (CVD) or stroke achieved LDL-C targets of 2.5 mmol/L in 2013 (72.7%). Only 47.7% achieved target in 2009 (Figure 1). Of these, there were 75 patients (32.5%) who improved over the time period and 21 patients (9.1%) who deteriorated, whilst 47 patients (20.3%) remained not at goal over both periods.

It was found that 77.8% of patients were using statin lipid-lowering treatment in 2013, which meant an additional 20.3% of these patients (vs. 2009, $p < 0.001$) started statins over the four-year period. Not surprisingly, the control of LDL-C for patients with previous CVD or stroke (target 1.8 mmol/L) improved by almost 30% in 2013.

In 2009, there seemed to be no apparent differences in statin usage amongst males and females (58.5% vs, 56.6%, $p = 0.766$, respectively), whilst in 2013 there was a marked difference (male 70.3% vs. female 83.9%, $p < 0.05$). Gender subgroup analysis revealed that females were less controlled for LDL-C than the males for the entire study duration. The mean LDL-C of females (2.6 mmol/L (±0.9) vs. 2.2 mmol/L (±0.9), $p < 0.05$) and males (2.5 mmol/L (±0.9) vs. 2.1 mmol/L (±0.8), $p < 0.05$) improved respectively from 2009 to 2013.

As seen in the past, simvastatin continued to be the most frequently prescribed statin in 2013 (61.1% vs. 94.7% in 2009) with the 20 mg strength being the most prescribed. Atorvastatin usage increased from 5.3% to 38.9% over time, again with the 20 mg strength being the most frequently prescribed dose.

Discussion

As the global spread of diabetes propels out of control, this condition can undeniably be heralded as a pandemic. Developed countries have faced urbanisation and adoption of many unhealthy lifestyle choices leading to diabetes over the past few decades and South Africa is no exception to this. In order to identify where T2DM treatment gaps lie, this study aimed to determine the disparities of management of diabetes control parameters in a cohort of complicated T2DM patients after a four-year period at a state-run tertiary hospital. Given this, we found that hypertension and lipid targets were more easily achieved, whereas glycaemic control was harder to achieve, with fewer patients achieving adequate glycaemic control after the four-year period.

Diabetes is a progressive disease that often necessitates lifestyle modification and use of multiple therapies. There was increased use of glucose, lipid and blood pressure lowering treatment observed in the study compared with the previous 2009 audit; however, results indicated marked improvement in blood pressure and lipid levels only. LDL-C has a central role in the pathogenesis of CVD in T2DM and this can be minimised through aggressive statin therapy. More patients achieved LDL-C targets in the 2013 audit, which may be attributed to increased statin utilisation and, in addition, some patients were changed to a more potent statin. The link between HbA1c and CVD still remains theoretical. In a post-hoc analysis of the United Kingdom Prospective Diabetes Study (UKPDS) a clear but modest reduction in CVD events was demonstrated through tighter glycaemic control.[13] In the current study, glycaemic control was shown to be the most challenging risk factor to correct as it worsened significantly over the study period, potentially leading to further risk of CVD events.

Disappointingly, a significant portion of patients still did not achieve targets, even those adapting healthier lifestyles or receiving more aggressive treatment. Of the total number of patients not at target for HbA1c in 2013, most were on insulin. The problem could lie with patients not complying with the regimen. One could argue that there is a lag period of adoption of guideline recommendations by physicians; however, only blood pressure targets changed with the release of the newer 2012 guidelines during the study period. There may have been reluctance amongst physicians to intensify treatment due to assumed poor treatment adherence in patients already using multiple drug classes.[14,15] Studies have shown that patients with diabetes have difficulties with lifestyle modifications and are averse to taking medication in general.[16,17] Furthermore, as

previously seen in the Action to Control Cardiovascular Disease in Diabetes (ACCORD), aggressive targeting of HbA1c was harmful to certain patients.[18] Cost of medication was not a factor in restricting physicians from prescribing, as most medications supplied to patients in the public sector were government subsidised. The findings from the landmark UKPDS indicated that, despite intensification of treatment, disease progression through declining pancreatic B-cell function and mass over time cannot be excluded. Perhaps the latter can be said about this particular group of complicated or possibly treatment-resistant T2DM patients who attended the tertiary care setting in this study.[19,20]

Many prospective studies have identified common co-morbidities in T2DM patients. These include obesity, dyslipidaemia and hypertension in addition to hyperglycaemia. The Steno-2 study revealed the benefits of multiple risk-factor interventions, especially in those T2DM patients at high risk.[21] In the 2013 audit, more patients in comparison with the 2009 audit had weight, smoking status, HbA1c, LDL-C and blood pressure levels assessed, which may indicate that a more individualised and combined risk approach was being implemented.

Patients enrolled in the study did not represent newly diagnosed T2DM individuals. Webb et al. screened 599 patients with diabetes in the district of Tshwane district and found that HbA1c targets were achieved by 27%, with the majority of almost 50% of patients in the study having had a self-reported duration of diabetes of < 5 years.[22] The average duration of diabetes diagnosis for patients in the present study was 16 years (range 2–40).

Not necessarily representing the majority of South African T2DM patients, the study focused on those select patients being treated at the tertiary level. Unlike patients attending primary care facilities, it was assumed that the participants in this retrospective study had an advanced form of the disease, necessitating the need for specialist care.

Limitations of this study include the large numbers of patients lost to follow-up and data being collected at times when files could have been in use or not available at the administration office. No detailed individual data assessments were carried out on patients responding to intensification of treatment. Furthermore, this observational study may lend itself to selection or survivor bias in that the patients followed up after four years potentially represented only a select group of individuals more adherent with their treatment regimen. Patients attending this hospital clinic undoubtedly have further developed or carry a high risk of developing T2DM-related complications. It was assumed that practitioners managing these T2DM patients in this study had good reason to keep almost 40% of those initially observed patients enrolled at this level of care, even after four years.

This study may have undervalued the outcomes achieved at this clinic as many of the patients treated have exhausted the therapeutic options available to them, reflecting lower numbers of those achieving targets. This is not to say that challenges do not exist in other, lower levels of healthcare settings. As this was a select group of T2DM patients in a specialised setting it may be difficult to extrapolate results of these patients to the general diabetes population.

Conclusion

Patients with T2DM are burdened with a plethora of diabetes control parameters. Studies and guidelines in the management of these risk factors exist, yet challenges to reach these targets still remain, even in a specialised tertiary care setting. In the current study, more patients reached blood pressure and LDL-C targets but not HbA1c over the four-year period. Improved willingness of physicians to monitor risk factors and start additional therapy in the majority of T2DM patients was observed (especially lipid-lowering treatment). Going forward, more focused advice on lifestyle and therapeutic interventions may be necessary to improve the cardiovascular outcomes of patients.

Conflict of interest – The authors of this article declare that there is no conflict of interest with regard to this work.

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