

Coronary Heart Disease Prevention For Diabetic Patients In Primary Care – An Audit of Clinical Practice.

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ABSTRACT

Background: Type 2 diabetes mellitus (T2DM) represents a state of increased cardiovascular risk with the prognosis of diabetic patients with cardiovascular disease (CVD) much worse. The imperative on physicians, principally those in primary care, is to focus on strategies to reduce cardiovascular risk factors in patients with established diabetes. The main risk factors for CVD are hypertension, dyslipidemia and hyperglycemia. This audit reviewed clinical practice at a GP surgery in the drug management of cardiovascular risk factors in diabetic individuals who had suffered a previous cardiovascular event. Current clinical practice was compared with the standards as set out in The Quality and Outcomes Framework (QOF) guidance 2011/12.

Methods: Analysis was carried out by collecting data from the general practice database system containing over 317 patients with a confirmed diagnosis of T2DM. Variables collected included patient demographic details, diagnostic data, previous coronary vascular interventions and most recent cardiovascular risk factor measurements (blood pressure, total cholesterol levels and glycaemic levels (HbA1c)). Multivariate analysis was performed to examine the relationship between a confirmed diagnosis of diabetes and cardiovascular sequelae. Patients were classed into 4 standards (gold, silver, bronze and none) as per defined by QOF guidance based on their cardiovascular risk factors.

Results: Patients were excluded if they had a confirmed diagnosis of type 1 diabetes mellitus (n=19) or had no diagnosed cardiovascular pathology secondary to diabetes including myocardial infarction, heart failure, angina or left ventricular systolic dysfunction (n=258). A total of 59 patients were thus included in the audit analysis. Multivariate analysis noted a clear relationship between a diagnosis of type 2 diabetes and cardiovascular disease sequelae (p-value= 0.002). Results demonstrated that 59% of patients fell within in gold standard, 3.3% of patients fell within the silver standard, 22% of patients fell within the bronze standard and 15.3% failed to meet any standard cardiovascular risk standard.

Conclusions: There is scope for improved management within the practice since 40.6% of diabetic patients have need for reduction in their cardiovascular risk factors to attain optimum control. Cardiovascular risk factors that primarily require treatment include improved treatment of glycaemic levels and blood pressure.

Key Words: Cardiology; Diabetes; Clinical Audit

Research in Context

Diabetes mellitus is an important public health problem, with significant impact on mortality, morbidity and quality of life. According to the Framingham study Type 2 diabetes is associated with a 2 to 4 fold increased risk of both coronary heart disease (CHD) and stroke.¹⁻³ Furthermore, rates of morbidity and mortality from cardiovascular disease (CVD) are 2 to 5 times greater in patients with diabetes than non diabetics.⁴⁻¹⁰ Importantly, diabetes causes excess mortality compared to patients with only cardiovascular disease. Both men and women who are diagnosed with type 2 DM at the age of 40 have their life expectancy reduced by 8 years compared to non diabetics.¹¹⁻¹² It is suggested that cardiovascular risk factors in diabetic patients are under-identified and there is an under-use of preventive medication both in primary care and in secondary care.¹³

Currently, up to 28% of total healthcare expenditure for patients with type-2 diabetes is for drug therapy. Although diabetic medications make over half of current spending, 42% of the current diabetic medication budget is used for medications to manage CVD risk factors.¹⁰ The development of clinical guidelines by organizations, such as the Scottish Intercollegiate Guidelines Network (SIGN) follow rigorous and transparent procedures to rank evidence and develop recommendations.⁴ SIGN have developed a series of clinical guidelines, including guidelines on the management of blood pressure and blood lipids in people with diabetes, with the particular aim of limiting the development of complications.⁵⁻⁶

The objective of this study was to compare the management of blood pressure, glycaemic levels and cholesterol levels in diabetic patients in primary care who had previously suffered a cardiovascular event (angina, myocardial infarction, left ventricular dysfunction and/or heart failure). This patient group is at the highest risk and rigorous control of their CVD risk factors is vital. The standards as set out in the QOF guidance for General Medical Services (GMS) contract 2011/12. The Quality and Outcomes Framework (QOF) is a UK system for monitoring general practitioner (GP) activity and performance, introduced in 2004. QOF sets about rewarding contractors for good practice based on workload and participation in an annual quality improvement cycle. Guidelines for quality improvement are based on SIGN guidelines.

Cardiovascular Risk Factors

Hyperlipidaemia

Hyperlipidaemia is commonly associated with Type 2 DM.¹¹ Increased concentrations of either total cholesterol or LDL cholesterol is an independent risk factor for morbidity and mortality in cardiovascular disease.¹⁴⁻¹⁵ The commonest presentation of hyperlipidaemia in diabetic patients would be a biochemical combination of raised triglycerides, LDL cholesterol and low HDL cholesterol.¹⁶ It has been shown that 1 mmol/l reduction of LDL cholesterol levels results in a 21% reduction risk of developing CVD.¹⁷ Another important independent marker of increased risk of cardiovascular disease in type 2 diabetes is triglycerides.¹⁸ Three major RCTs (CARDS, ASCOT, HPS) investigated the use of statins against placebos in diabetic patients with no cardiovascular disease.¹⁹⁻²⁰ The three studies concluded that the use of statins (simvastatin 40 mg or atorvastatin 10 mg) had a significant reduction in cardiovascular events such as acute coronary events and stroke. Importantly, these reductions in cardiovascular events was seen regardless of baseline cholesterol levels.²⁰ Hence lowering of lipid levels with either 40 mg simvastatin or 10 mg atorvastatin is recommended for primary prevention in diabetic patients aged ≥ 40 years old regardless of cholesterol levels.

Hyperglycaemia

Increased glycaemic levels as measured by HbA1c is associated with the development of CVD morbidity and mortality as suggested by the UKPDS study.¹⁵ For every 1% drop in HbA1c this lowered the risk of death due to diabetes by 21% and reduced the risk of having a myocardial infarction (MI) over the next 10 years by 14%.²¹ The Action to Control Cardiovascular Risk in Diabetes (ACCORD) trial was designed to determine if a therapeutic strategy targeting HbA1c levels below 6% would lead to the reduction of cardiovascular events when compared to targeting HbA1c levels from 7-7.9% in type 2 diabetic patients. Results demonstrated higher mortality in the intensive-therapy group and terminated the use of an aggressive treatment to lower HbA1c under 7%.²² Meta-analyses across a large number of RCTs stated that tight control over glycaemic levels, between 7-7.9%, reduced the risk of cardiovascular disease by 10% as compared to standard diabetic care.²² The importance of patient HbA1c levels for cardiovascular prevention are increasingly recognised, with HbA1c levels being used to stratify patients in to standards in the SIGN guideline for diabetes.²³

Hypertension

Hypertension is an independent risk factor related CVD death with steady increases in risk associated with rising systolic blood pressure measurements.^{14-15,24} A recent study noted that for every 10mm Hg reduction in systolic reduction in blood pressure there is a 15% reduction in risk of CVD over the next 10 years and a reduced risk of both macrovascular and microvascular disease.^{21,25-26} Hence diabetic patients should have their blood pressure controlled aggressively both with lifestyle modification as well as medication use. The Hypertension Optimal Treatment (HOT) study demonstrated a reduction of 51% of cardiovascular events occurred with target patients being treated with a diastolic blood pressure target of ≤ 80 mm Hg compared to another target group of patients with a target blood pressure of ≤ 90 mm Hg.²⁷ With regards to the systolic pressure an epidemiological analysis showed that the lowest risk was observed in patients with a systolic blood pressure of ≤ 120 mm Hg.²⁶ SIGN 97 (Risk estimation and the prevention of cardiovascular disease) suggested the systolic blood pressure for diabetic patients be ≤ 130 mm Hg.²⁸

Standards and Audit Criteria

The authors undertook an audit assessing the effectiveness of managing blood pressure, glycaemic levels and total cholesterol in patients with previous cardiovascular event and Type 2 diabetes against 100% standard as set out in the QOF guidance for GMS contract 2011/12 (Fig. 1). These QOF guidelines were issued in April 2011. All patients had blood HbA1c levels categorized into 4 categories based on QOF guidance targets for ideal ranges of HbA1c levels. The levels of HbA1c in each target range were as follows: HbA1c $\leq 7.5\%$, HbA1c $\leq 8\%$, HbA1c $\leq 9\%$ and HbA1c $\geq 9\%$. Blood pressure (BP) optimal target was set at 140/80 and a suboptimal target of 150/90 as per QOF guidance for diabetic patients. The standard for total cholesterol was set as ≤ 5 mmol/l.

Fig 1:- Standards as set by QOF guidance for GMS contract 2011/12 ³⁶

HbA1c	HbA1c ≤ 7.5 HbA1c $\leq 8\%$ HbA1c $\leq 9\%$
Blood Pressure	Optimal :- BP $\leq 140/80$ Sub-Optimal :- BP $\leq 150/90$
Total Cholesterol	Total Cholesterol ≤ 5 mmol/L

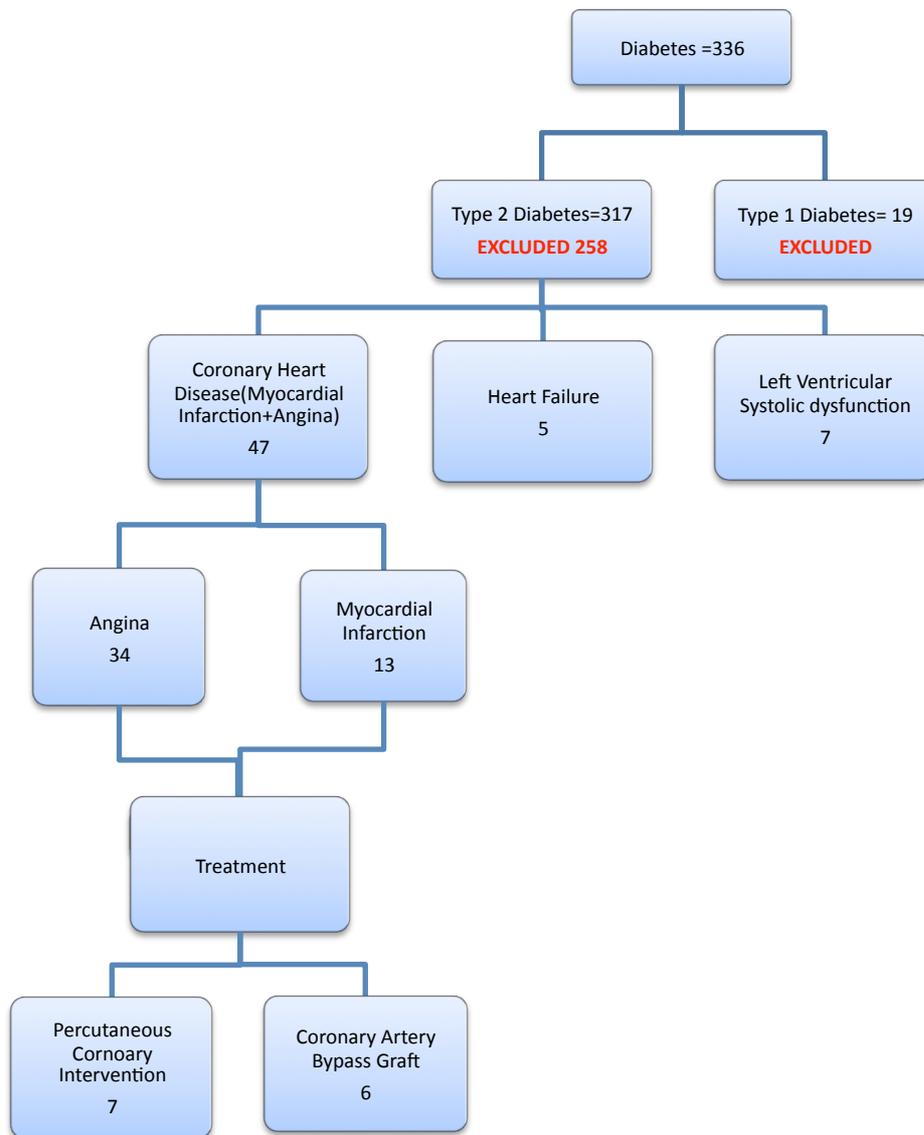


Figure 2:-
Schematic representation of patients included in clinical audit

Data Collection

Data on patients was collected by using the practice computer database system and required variables pulled out of each patient's case notes. The following variables were collected:-

- Demographic details: age, sex and patient CHI number
- Diagnostic data: Diabetes Type 1 or Type 2, angina, heart failure, left ventricular systolic dysfunction, and myocardial infarction
- Coronary vascular interventions: Requirement for treatment with either PCI or CABG.
- Most recent recording of cardiovascular risk factors: blood pressure, total cholesterol levels and glycaemic levels (HbA1c).

Patients were excluded if they had a confirmed diagnosis of type 1 diabetes mellitus or had no diagnosed cardiovascular pathology of MI, heart failure, angina or left ventricular systolic

dysfunction. The primary researcher ensured that patients with multiple pathologies (eg- angina and heart failure) were not counted more than once by reviewing CHI numbers. Patients were classed into 4 standards as per defined by QOF guidance. The 4 standards were gold standard, silver standard, bronze standard and no standard. Patients were separated into their respective standard based on meeting the criteria for each standard. Criteria for each standard are as shown in Figure 1. Multivariate analysis was performed to examine the relationship between a confirmed diagnosis of diabetes and cardiovascular sequelae. Figure 2 provides a schematic diagram noting patient diagnoses and complications of their diabetes.

Results

Patients were excluded if they had a confirmed diagnosis of type 1 diabetes mellitus (n=19) or had no diagnosed cardiovascular pathology of MI, heart failure, angina or left ventricular systolic dysfunction (n=258). A total of 59 patients were thus included in the audit analysis. Multivariate analysis noted a clear relationship between a diagnosis of type 2 diabetes and cardiovascular disease sequelae (p-value= 0.002).

Standard	Cardiovascular Risk Factor Criteria	Number of Patients (%)
Gold Standard	HbA1c \leq 7.5, BP \leq 140/80 Total Cholesterol \leq 5 mmol/L	35/59 (59.0%)
Silver Standard	HbA1c \leq 8% BP \leq 140/80 Total Cholesterol \leq 5 mmol/L	2 /59 (3.3%)
Bronze Standard	HbA1c \leq 9% BP \leq 150/90 Total Cholesterol \leq 5 mmol/L	13/59 (22%)
No Standard	HbA1c \geq 9% BP \geq 150/90 Total Cholesterol $>$ 5 mmol/L	9/59 (15.3%)

Table 1. Separation of patients into each standard based on meeting cardiovascular risk factors as per QOF guidance.

Analysis of Audited Patients

72% (43) of the patients were male whilst 27% (16) were female. Results demonstrated that 59% of patients in gold standard and had the best cardiovascular risk control followed by silver standard 3.3% which had sub-optimal treatment control whilst 22% of patients fell into the bronze category and 15.3% had failed to meet no standard for cardiovascular risk control. Out of the patients combined in the silver, bronze and no standard group who defaulted on the cardiovascular risk factor parameters, 66.7% of patients had HbA1c out of

the recommended guideline range, 20.8% had their blood pressure out of the recommended guideline range and 12.5% had their cholesterol levels out of the recommended guideline range.

Discussion

Since the combination of the defaulting patients of HbA1c values in both the silver standard and no standard (66.7%) showed the greatest impediment in modifying cardiovascular risk factor it begs the question over its superiority over maintaining recommended blood pressure standards and recommended cholesterol standards.

In an epidemiologic analysis of the United Kingdom Prospective Diabetes Study (UKPDS), Stratton et al. demonstrated that the incidence of myocardial infarction increased 2-fold across an HbA1c range from 6% to 10%, which was highly significant.³⁴ The effect of HbA1c on microvascular complications in the UKPDS over a similar range of HbA1c values was nearly 10-fold. These findings suggest that HbA1c levels have a more modest, albeit significant, effect on cardiovascular disease than on microvascular disease. The intent-to-treat analysis of the UKPDS trial revealed similar findings. During a period of 10 years, the effect of 0.9% difference in HbA1c value (7% with intensive treatment vs. 7.9% with conventional treatment) was considerably greater for decreasing risk of microvascular disease than of macrovascular disease such as myocardial infarction. The highly intense treatment group had a 25% reduction in the risk of microvascular complications and a 16% risk reduction for myocardial infarction. Similar audits in primary care have yielded similar results with the conclusion being the under-treatment of cardiovascular risk factors. A study examining cardiovascular risk factors in 26 practices in England demonstrated similar results; discrepancy was also seen between males and females.¹³ In this study 21% of women and 16% of men had a blood pressure above 160/100 mmHg (utilizing NICE guidelines as standard). Cholesterol levels were ≥ 5 mmol/L in 46% of women and 38% of men. The study highlighted the need for further improvement in managing cardiovascular risk factors and addressing sex inequalities.

Study Limitations

As with all clinical audits the results should be interpreted with a degree of caution. Firstly, not all the relevant variables were collected for analysis and no variables were collected on treatment regimens for control of cardiovascular risk factors limiting further analysis. Secondly, the audit was based on data collected on the last recorded entry over the previous 15 months. This could result in bias, as there may have been an adjustment in therapy following a raised reading, with the follow-up result yet to be recorded. Thirdly, the audit did not review patient compliance, known to be a major problem across both primary and secondary care. Fourthly, currently the emphasis in primary care has been placed on following clinical guidelines as they are seen as markers for best practice. However, there has been considerable evidence to suggest that their relevance for patients with multiple comorbidities is very limited and there is room for improvement in this respect.³⁵⁻³⁶ Currently basing standards for quality of care in older patients with multimorbidity on clinical guidelines has the potential to lead to a complex and potentially contradictory treatment regime with high risk of adverse drug reactions.³⁵⁻³⁶ Therefore, general practitioners may have avoided prescribing all cardiovascular risk factor modifying drugs in this group of patients as the risks of cardiovascular prevention may outweigh any potential benefits. Finally, the patients in this practice were located in relatively affluent area and will therefore not be representative of the average UK general practice.

Implication for Practice

Although identification of cardiovascular risk factors with diabetes has improved since the introduction of the QOF, the above results demonstrate that there is further scope for improvement since 40.6% (15.3%+22%+3.3%) of diabetic patients have need for reduction in their cardiovascular risk factors to attain optimum gold standard control. The Practice has been handed in a patient list with the CHI numbers of patients in each standard of treatment including the cardiovascular risk parameter that each patient defaulted on with the objective in the long term being to try and push the patients treatment standard from their current standard to the next best level of treatment standard till the next audit cycle is to be carried out. The practice should also need the identification of patients most at risk from cardiovascular risk factors and explore patients concerns regarding treatment and utilize therapies for optimal treatment of their risk factors.

Conclusion

A significant proportion of people with diabetes, more men than women, have cardiovascular risk factors that are poorly controlled, and are consequently at high risk of vascular events. More detailed and regular feedback of routinely collected practice data is needed to inform if the practice is adequately addressing the management of people with diabetes. This data will be re-audited in the next 12 months.

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