

Combining Population Health and Baseline Risk strategy by determining an age cut-offs for initiating statins in patients with diabetes: A population-based study

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Short title: Age-cut for statins in patients with type 2 diabetes

Objective: Strategies for initiating statins among adult patients with diabetes for primary CVD prevention include treating all patients (assuming diabetes is a coronary risk equivalent) or treating patients who are at risk of developing CVD. The aim of the study was to combine both strategies to derive an appropriate age cut-off for prescribing statins. By considering different strategies, we also aim to assess the effectiveness and the efficiency of different strategies to reduce CVD events.

Design: Cross-sectional primary care population study using electronic patient files from 304 general practitioner practices in England and Wales. Out of 60258 patients with diabetes, 11005 men and women aged 30-74 years fulfil criteria for primary CVD prevention. Model outcomes were extrapolated to an estimated national diabetes prevalence of 3.6%.

Results: The age transition from low-risk to moderate-risk category for diabetic men and women occurred at ages 40.6 and 44.2 years respectively, sensitivity and specificity for fulfilling moderate CVD risk criteria were 97.9% and 61.8% for men and 92.0% and 77.0% for women. When applied to the national population, the age cut-off strategies was an effective and efficient strategy, potentially avoiding 11094 events with number need to treat of 25.1.

Conclusions: A strategy to treat all men and women with diabetes above the age of 40 and 45 respectively with statins showed good compromise between high effectiveness and high efficiency for reducing CVD events in patients with diabetes. Strategy to intervene if cholesterol > 5mmol/l was the least effective and efficient in preventing CVD events

INTRODUCTION

The concept of diabetes as a coronary risk equivalent(1) has led many to recommend the use of statins for all patients with diabetes without pre-existing cardiovascular disease (CVD) irrespective of their cholesterol levels. The success of this ‘population health’ strategy however (2) is based on the assumption that the risk of coronary heart disease (CHD) is evenly distributed within a given population. Yet, individuals with diabetes have different baseline CHD risks. The benefit of statin therapy in subgroups of diabetic patients varied across trials – significant reductions in CHD mortality was observed in the HPS, 4S and CARDS (3-5) but not in ASCOT, CARE, LIPID, ASPEN studies (5-6). These discrepancies are due to differences in baseline risk profiles of patients in each study. Higher risk individuals are likely to gain the most in absolute terms, i.e. the greater the baseline risk, the greater the benefit of statin therapy. Whilst ‘blanket’ use of statins may confer clinical benefit in many patients, this approach will expose people at lower risk to life long treatment with attendant adverse effects, lack of compliance and polypharmacy. Thus, the use of risk assessment tables to identify individuals at risk of CVD events (7) appears to be the most cost-efficient model in preventing CVD among patients with diabetes. However, since predicted algorithms to calculate absolute risks have shown that age is the most important predictor of CVD events (8), we aimed to determine an appropriate age cut-off to prescribe statin therapy, taking into account various CVD prevention strategies.

In this study, we considered four different strategies to reduce CVD events by initiating statins in patients

with diabetes: (i) population health strategy (coronary equivalent) – treating all patients; (ii) baseline risk strategy (NICE) (7) – treating patients whose baseline CVD risk is moderate or high; (iii) individual risk factor strategy (General Medical Services, GMS contract) (9) – treating patients whose cholesterol >5mmol/l; and (iv) age cut-off strategy (10)– treating patients above an appropriate gender specific age derived from combining strategies (i) and (ii). Within each strategy, we calculated (a) the number of people eligible for statins (b) the effectiveness (potential number of CVD events that could be prevented, and (c) the efficiency (the number needed to treat to prevent one CVD event). We used an outcome model extrapolated to an estimated diabetes prevalence of 3.6% in England and Wales (11).

METHODS

Patients

This was a cross-sectional cohort study using The Health Improvement Network (THIN) dataset which contains anonymous patient data from 304 general practices throughout England and Wales (12). Information obtained from the dataset included patient demographic, medical history, laboratory results, prescription information and lifestyle characteristics. THIN has been validated at both practice and dataset level (13) by comparing its demographics, morbidity, mortality, prevalence, and geographical rates with various national data sources, including Department of Health issued read codes for the Quality and Outcomes Framework – QOF, 2001 census and the National Statistics and the Office for National Statistics (ONS); (www.statistics.gov.uk).

We identified a 60,258 of patients with diabetes and took their biochemical and

demographic profile available on the 31st of December 2005. Patients would have been registered by their practices for the whole of the preceding 12 months to be included in the analysis. 11,005 patients with diabetes aged between 30 and 74 years, not prescribed any lipid lowering drug therapy and without arterial disease (no history of ischaemic heart disease, cerebrovascular disease and peripheral vascular disease recorded in general practice databases were suitable for analysis. This large patient cohort reflects the clinical and biochemical parameters of patients prior to the full of implementation of the JBS2, NICE and GMS contract guidelines. We utilised the above age criteria because decisions to initiate statins beyond that criteria should be based on individual risk basis rather than from a public health perspective. National estimate was calculated by the multiplication factor of 32 derived from the ratio of the number of people with diabetes in England and Wales (1,922 051) with the total cohort obtained from the THIN dataset (60,258). The study was approved by the Eastern Multi Centre Research Ethics Committee.

Risk assessment methods

We used the JBS risk calculator derived from the Framingham risk algorithm which utilises eight risk factors [age, sex, systolic or diastolic blood pressure, smoking status, diabetes status, left ventricular hypertrophy (LVH), total and HDL cholesterol] to calculate CVD risk. We used a Framingham based risk engine (14) rather than the UKPDS (15) because our dataset did not include duration of diabetes and microalbuminuria status. Although Framingham risk calculation is thought to underestimate mean CVD risks of patients with diabetes (16), previous work has shown that such underestimation is only relevant when considering patients whose 10 year

CHD risk is > 20% (17). Thus, when determining CHD risk of <20% within the context of threshold for prescribing statins, the difference between the two methods of risk assessment is negligible.

Assessing different CVD risk reduction strategies

We considered 4 strategies to reduce CVD risks in patients with diabetes. For each strategy, we determined the number of patients with diabetes eligible for statin treatment (and the cost incurred). We calculated the number of CVD events potentially avoided (effectiveness) using the product of patient's five year baseline risk and an estimate of 33% relative reduction of CVD events (based on the effect of simvastatin, 40mg in preventing CVD event over 5 years within a primary prevention cohort in the HPS trial) (3). The number needed-to-treat (NNT) (efficiency) to prevent one CVD event over 5 years was estimated as the sum of number of treated divided by the number of CVD events prevented. We calculated population based estimates for England and Wales (53,390,300 people) with an estimated diabetes prevalence of 3.6% (11). We chose simvastatin 40mg instead of atorvastatin 10 mg because for every new patient treated with generic simvastatin 40mg rather than atorvastatin 10 or 20 mg, the NHS saves £921-£1352 over five years without compromising lipid lowering efficacy (18). The cost of simvastatin 40mg (based on the NHS reimbursement price) is £44.20 per patient per year.

Deriving an appropriate age cut-off by combining population health and baseline risk strategy

In the first part of the analysis, we examined the relationship between age and baseline 10- year CVD risk according to age. We used a regression technique to plot the relationship between age (x) and baseline CVD risk

(y), using a linear, exponential or quadratic equation. We used the line of best fit between these two variables to establish the mean age at which men and women with diabetes moved from low risk (<10%) to moderate/high 10-year CVD risk (>10%). These thresholds were chosen on the basis of corresponding 10-year CVD risk estimates used by various clinical practice guidelines using the Framingham risk algorithm (19). In addition, 10% 10-year CVD risk has been advocated by the US task force as the threshold level above which the cardio-protective benefit of aspirin therapy will outweigh its risk of bleeding (20).

Statistical analysis

All analysis was performed using the Statistical Package for Social Sciences (SPSS version 14) for Windows and SAS version 8.2. Normally distributed data were presented as means \pm standard deviation (SD), skewed data as the median (ranges) and categorical data as percentages. Student *t*-test, chi-square and regression analysis were used. As there is clustering [patients within practices], the random effects logistic regression technique were used. Multivariate regression models were used to assess the predictive power of variables in determining the need to initiate statins (based on 10-year CHD risk >10%). Sensitivity and specificity values for age criteria to initiate statins were determined using the receiver operating characteristic (ROC) plot.

RESULTS

The study population consisted of 60,258 patients with diabetes aged between 30-75. Of this, we identified 11,005 patients with complete dataset, not taking any lipid lowering agent, free from any history of atherosclerotic arterial disease and therefore eligible for primary CVD prevention. Table 1

shows the baseline characteristics of patients. Mean age was 53.7 years; 55.9 (men) and 53.4 (women). The mean 10-year CVD risk for the total population was 20.7%, [i.e. 21.3% and 17.8% for men and women respectively].

For both men and women, the baseline CVD risk increases with age (figure 1). Using the quadratic equations (best fit for our data): $y = -13.99 + 0.388(\text{Age}) + 0.005(\text{Age}^2)$ for men; and $y = -13.99 + 0.388(\text{Age}) + 0.005(\text{Age}^2)$ for women; the transition from low to moderate/high baseline risk of developing CVD occurred at about age 40.6 for men and 44.2 for women. If a high baseline risk is used as a threshold, the age transition from low/moderate to high baseline risk of developing CVD took place at ages 52.4 for men and 59.3 for women (table 2). We set the optimal cut-off for prescribing statin at 10%, 10-year CVD risk for both sexes. Using age 40.6 years as the cut-off for prescribing statin in men gives a sensitivity and specificity of 92.2% and 84.4% respectively. Using age 44.2 years for women gives a sensitivity and specificity of 90.3% and 81.3% respectively.

Total number of patients eligible for statin therapy based on different primary CVD strategies extrapolated to the national estimate are: 352,160 (treating all); 172,736 (treating high baseline risk); 264,608 (treating moderate/high baseline risk); 127,456 (treating cholesterol >5mmol/L) and 278,800 (treating patients above new age cut-off criteria). In financial terms, based on the cost of simvastatin 40mg/day, these represents an annual statin expenditure of: £15,565 472; £7 634 931; £11,695,670; £ 5,633,555 and £12,322,960 respectively. The population health, baseline moderate/high risk and the age cut-off

strategy were the most effective, potentially avoiding the most cardiovascular events over five years (12,050, 11,214 and 11,094 events respectively). Strategies to treat if: (i) cholesterol >5mmol/l based on the GMS contract or (ii) if baseline risk is high based on the previous NICE guideline criteria, were the least effective. Using the moderate/high baseline risk and the age cut-off strategies are the most efficient and cost-effective with the lowest number needed to treat, 23.6 and 25.1, while recommending statin treatment to a relatively low number of patients. Thus, utilising the age cut-off strategy instead of the population health strategy will confer a cost saving of £16,212,560 over five years to the NHS, with lower number need to treat and without compromising effectiveness (table 3).

Discussion

Our findings highlight the scientific rationale for combining population and baseline risk strategy for preventing CVD in patients with diabetes without overt atherosclerotic disease. We showed that statin prescribing guidelines for primary CVD prevention varied in their effectiveness (potential to prevent CVD events) and efficiency (number needed to treat to prevent one CVD event). A desirable strategy is one that would potentially prevent the largest number of CVD events, while recommending treatment to the least number of patients. Age appears to be the most important determinant of an individual's baseline CVD risk. Baseline CVD risk in people with diabetes reached a threshold for moderate/high risk at approximately 40 years for men and 45 years for women. This age cut off confers high sensitivity and specificity for individuals with diabetes to have a moderate baseline risk of developing CVD. Because the numbers of patients with diabetes at risk

of CVD are large and statins are highly effective in reducing CVD events, even small changes in guidelines have large consequences on the number of patients eligible for statins, the potential for preventing CVD events and the millions of pounds spent each year by the NHS.

Current UK guidelines for prescribing statins using age cut-off strategies are largely based on the minimum age of patients recruited into the HPS (3) and the CARDS (4) study. This approach however does not take into account patients gender, their baseline CVD risk as well as the effectiveness of statins in patients with low CVD risk within both intervention and placebo arms of these studies. Our findings concurred with findings from Booth et. Al (21) which showed that the transition to a high CVD risk category occurred at the ages of 41.3 and 47.7 years for men and women with diabetes respectively. Some however, recommend the routine use of statins in all patients with diabetes irrespective of age (22). While this concept of 'coronary risk equivalent' (i.e. all patients with diabetes without atherosclerotic disease should be considered as already had a myocardial infarction or at 'high risk' defined as CVD risk >20% over 10 years) has gained significant momentum following the study by Haffner et al, which utilises a patient cohort from Finland (23), subsequent studies from UK, USA(24-25) and Canada (21) did not support this observation. Our data suggest that, although the mean 10-year CVD risk of patients with diabetes in England and Wales was indeed approximately 20%, baseline CVD risks varied considerably between individuals with diabetes, based on patients' age and gender. Hence, the absolute risk reduction potentially conferred by the use of statin in these patients will also likely to vary. Previous guidelines have also taken into account duration of diabetes – a

surrogate for prior glycaemic exposure – as an indication for statin use (26). While our study was not designed to investigate the validity of this strategy, previous observational studies of CVD prediction in young people with diabetes showed that duration of diabetes did not appear to be an independent predictor (27). Given the various uncertainties in predicting CVD risk for younger people with diabetes, we would recommend that primary CVD prevention strategy be individualised in this group of patients.

When comparing how well different treatment strategies perform, a compromise needs to be achieved between effectiveness and efficiency. Thus, although a strategy to treat all patients with diabetes was shown to be highly effective, it would involve treating the largest number of patients to prevent one CVD event. Conversely, whilst a strategy to treat patients whose 10-year CVD risk >20% is the most efficient (lowest number needed to treat), this strategy was not very effective (potentially preventing a relatively small number of CVD events). The GMS contract criteria was shown to be the least effective while the two most effective and efficient strategies are those which advocate statin therapy for patients with diabetes whose 10-year CVD risk >10% or for those whose age is above the previously mentioned cut offs values. From a public health approach, the latter strategy is perhaps the more attractive given the practicalities of implementing such a simple strategy.

Several limitations of our study must be acknowledged. The presence of diabetes was dependent on patients attending the general practitioner and would therefore not identify people with undiagnosed diabetes. The dataset did not allow us to determine diabetes

duration, microalbuminuria status or to distinguish between type 1 and type 2 diabetes. This however should not affect the outcome of this study because primary CVD prevention strategies in the UK do not distinguish between types of diabetes nor take diabetes duration into account, whereas the presence of microalbuminuria is an indication for statins on the basis of secondary prevention. Another limitation is our use of a Framingham based risk algorithm to estimate CVD risk in patients with diabetes. We believe however that our use of the Framingham algorithm is valid for two reasons. Firstly, it has been validated in the UK population (28-29) and secondly, it has been shown to provide a CVD risk estimate which is equivalent to that of the UKPDS engine when assessing risk below 20% over 10 years (17,29).

When implementing a policy for statin treatment in patients with diabetes, it is necessary to utilise a strategy which will give a high pick up rate but will also identify patients who will benefit most. From this study, we advocate that in the absence of specific indication for statin therapy (e.g. microalbuminuria, strong family or personal history of CVD risk, etc), statins should still be routinely prescribed to all men and women with diabetes above the ages of 40 and 45 years respectively for primary CVD prevention. This strategy is highly effective and efficient to prevent CVD events from a public health perspective. Further studies however are required to clarify whether this treatment strategy can be extrapolated to diabetic patients outside the UK and longitudinal data is required to confirm the absolute risk reduction estimated using this strategy.

All authors declare that the answer to the questions on your competing interest

form are all No and therefore have nothing to declare

Authors' contribution: *SS¹ and UB and was involved in study design, coordination and data acquisition, JS performed the statistical analysis, SS participated in the design of the study and data interpretation, DF was involved in the study design, coordination and data interpretation. II*

conceived the study, obtained ethical approval, participated in its design, coordination and drafted the manuscript. All authors read, contributed towards and approved the final manuscript. II is the guarantor

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Table 1

	Men (n=6134)	Women (n=4871)	Total (n=11005)
Age (years)	55.9 (12.1)	53.5 (12.9)	54.0 (12.6)
Systolic BP (mmHg)	135.0 (16.0)	132.8 (17.3)	133.8 (16.8)
Diastolic BP (mmHg)	79.5 (9.6)	78.5 (9.9)	78.9 (9.8)
HDL cholesterol (mmol/L)	1.2 (0.4)	1.4 (0.4)	1.3 (0.4)
Total cholesterol (mmol/L)	4.7 (0.9)	4.9 (0.9)	4.8 (0.9)
HbA1c (%)	7.0 (2.5)	7.1(2.5)	7.0 (2.4)
LDL cholesterol (mmol/L)	2.8 (0.8)	2.8 (0.8)	2.8 (0.8)
Triglyceride (mmol/L)	1.8 (1.4)	1.7 (1.2)	1.7 (1.3)
Body Mass Index (BMI)	29.8 (6.1)	31.3(7.6)	30.3(6.9)
Framingham 10 year CVD risk (%)	23.1 (13.0)	17.8(11.3)	20.7 (12.5)

Clinical and biochemical characteristics of the study population

Table 2

Age (years) of transition from between risk levels

	Men	Women
Low to moderate risk	40.6	44.2
Moderate to high risk	52.4	59.3

Moderate risk cut off (10% 10-year CVD risk)

	Men	Women
Sensitivity (%)	92.2	90.3
Specificity (%)	84.4	81.3

High risk cut off (20% 10-year CVD risk)

	Men	Women
Sensitivity (%)	92.4	90.2
Specificity (%)	77.7	79.8

Age which crosses from low to moderate and from moderate to low risk, derived the line of best fit from the equation between age and 10 year CVD risk.

Sensitivity and specificity values for a given age cut off to have a 10-year CVD risk estimate of moderate or high risk respectively.

Low risk <10%; Moderate risk 10-20%; High risk >20% 10 year CVD risk

Table 3

Strategy	No (%) of population treated	Annual cost of statin (£)	Effectiveness	Efficiency
Population health (Treat all)	352 160 (100)	15 565 472	12050	29.2
High Baseline risk	172 736 (49.1)	7 634 931	8949	19.3
Moderate Baseline risk	264 608 (75.1)	11 695673	11 214	23.6
Individual risk (GMS) chol >5	127 456 (36.2)	5 633 555	4588	27.8
JBS2 age criteria	300 288 (85.3)	13 272 729	11 564	25.9
New age criteria	278 880 (79.2)	12 326 496	11 094	25.1

Effects of different primary CVD prevention strategies based on criteria for prescribing statins among primary care population in England and Wales with diabetes, age 30-75, not on lipid lowering drugs and suitable for primary CVD prevention (i.e no history of atherosclerotic disease).

Effectiveness (potential number of CVD events that could be prevented); Efficiency (the number needed to treat to prevent one CVD event).

Number of patients shown are after extrapolation to the national estimate for prevalence of type 2 diabetes in England and Wales

Figure 1

Relation between age and baseline 10-year CVD risk estimates in women (F) and men (M). Line of best fit fitted according to polynomial equation.

