Cholesterol management in patients with IHD: an audit-based appraisal of progress towards clinical targets in primary care

This study – the largest published audit in secondary prevention in English general practice – looks at the clinical impact of partial progress towards the delivery of national targets for managing cholesterol in patients with ischaemic heart disease (IHD).

Abstract

Anonymised data collected from 24 participating localities in England have been aggregated for this report. The data are taken from general practice computer records using a validated extraction tool Morbidity Information Query and Export SynTax (MIQUEST). The number of patients with heart disease, a cholesterol measure, whether they had been prescribed a statin, their quality of control, and its implications are reported.

In the population studied of 2.4 million, 89,422 patients had a diagnosis of ischaemic heart disease; a prevalence rate of 3.7%. Cholesterol measurement was available for half (48.3%) of these patients, of whom half (55.2%) were taking a statin. As a result of this treatment gap, 118 excess myocardial infarctions annually are predicted, equivalent to around 7,150 events nationally.

Compared to previous audits carried out in UK general practice, considerable progress has been made towards the achievement of treatment goals. The treatment gap is represented by a combination of lack of measurement and recording of data as well as poor quality of control.

Key words: coronary heart disease, secondary prevention, primary care, computerised medical record, health informatics.

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Introduction

In this report we describe the progress made in English general practice towards controlling cholesterol in patients with established coronary heart disease (CHD) as recommended by national policy.[1] The clinical implications of the remaining treatment gap are also described.

UK national policies currently endorse a 'treat to target' approach, with achievement of a total cholesterol level of 5.0 mmol/L or a low density lipoprotein (LDL) cholesterol level of 3.0 mmol/L being considered an acceptable treatment standard. Although the results of the Heart Protection Study (HPS)[2] suggest such a lower limit of treatment is no longer justifiable, it appears that this target-based approach will remain for the moment. Despite clear consensus as to the value of statin therapy, published research in the late 1990s suggested that only a minority of eligible patients in the UK were receiving adequate therapy and that many treated patients had failed to achieve their target levels.[3-5] A three-fold increase in the prescription of statins over the past five years,[6] may mean that this picture is now changing. One recently published study, relating to the period 1994–2001, shows a steady increase in the appropriate use of statins in UK general practice.[7]

Our study examines current statin utilisation patterns within a large UK general practice population, in patients with established cardiovascular disease. Based on the lipid levels achieved and an understanding of the potential clinical impact of adequate statin therapy, these data have been used to estimate the potential clinical benefit remaining, if current treatment targets were to be consistently achieved.

> ***'In untreated populations, a new fatal or non-fatal MI will occur in 2.5% of patients with established CHD every year'***

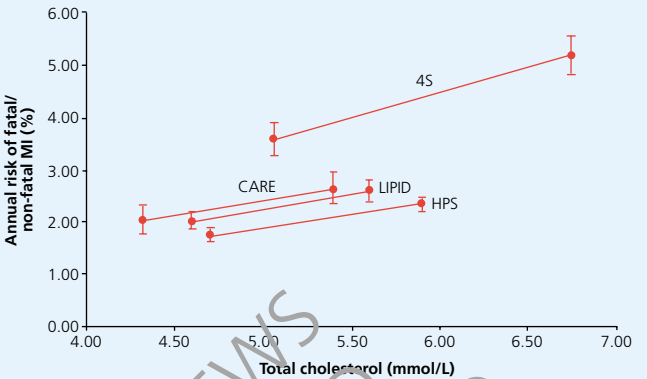
Background

Data quality and health improvement intervention

Data for this analysis were derived from pooled anonymised patient information collected in the course of the work done by the Primary Care Data Quality (PCDQ) programme. This programme, developed in collaboration with Primary Care Organisations (PCOs), aims to improve the quality of their computerised clinical records and the implementation of evidence-based practice.[8] Implemented at practice level, the PCDQ programme constitutes an educational intervention, with learning opportunities created around

data directly extracted from the practice computer systems. The data were analysed, processed and fed back to the practice, in a non-judgemental educational context. Data were extracted using a Department of Health sponsored tool called MIQUEST (Morbidity Information Query and Export SynTax), a customised tool that enables anonymised data to be extracted from general practice computer systems.[9] The CHD population has been identified through searching the database using Read codes for ischaemic heart disease. These data are then entered into a Microsoft Access database, which has full referential integrity. Although it is possible to 'decode' which pieces of data came from which practice, the individual patient could only be identified by a clinician in the originating practice.

Figure 1. Relationship between cholesterol lowering and reduction in myocardial infarction in randomised controlled trials of statins in high-risk patients.[2,10-12] Each study is represented by a line, the upper point of which plots the mean baseline total cholesterol and event rate in the control group. The lower point plots the mean achieved total cholesterol and event rate in the treated group. Vertical bars represent the 95% confidence intervals for the observed coronary risk



Key: 4S = Scandinavian Simvastatin Survival Study; CARE = Cholesterol and Recurrent Events; LIPID = Long-term Intervention with Pravastatin in Ischaemic Disease; HPS = Heart Protection Study

Clinical impact model

Over the past decade, seven large randomised controlled trials[2,10-15] – involving a total of 57,000 patients – have demonstrated beyond any reasonable doubt the reduction in adverse cardiovascular outcomes associated with the use of statins (HMG CoA reductase inhibitors). Although the populations studied have varied considerably in terms of their baseline lipid profiles and calculated cardiovascular risk, there has been consistent benefit from treatment: around 20% reduction in total cholesterol is achieved and is associated with relative reductions in coronary event rates of around 25–35%.[16]

The absolute magnitude of treatment benefit varies with the underlying risk of the population being treated. In an appraisal of statin treatment benefit based on a published meta-analysis,[17,18] it was calculated that, in primary prevention, 48 people would need to be treated with statins for 4.6 years to prevent one CHD event. Amongst patients with established CHD, (i.e. secondary prevention, the subject of this paper), just 14 people would need to be treated for a mean of 2.9 years to achieve the same outcome. The clinical and financial consequences of this observation underlie the policy decisions made in the UK to target statin treatment principally at those individuals at highest risk of suffering a coronary event.[1,19,20]

Four large randomised controlled trials have explored the impact of statin therapy in the secondary prevention of heart disease.[2,10-12] In these studies, the control groups showed an annual risk of experiencing a fatal or non-fatal myocardial infarction (MI) of between 2.4%–5.2%. Over the course of these studies – duration 5.0–6.1 years – mean total cholesterol was reduced by between 1.0–1.7 mmol/L in the active treatment arms, with the consequence that event rates were reduced to 1.8–3.6%. Figure 1 illustrates the changes observed in both total cholesterol and annual event rates for each of these four studies. Although the absolute figures vary between studies, the four lines run almost parallel, suggesting that, for a given reduction in total cholesterol, there will be a consistent and predictable reduction in coronary event rates. In these four studies, a 1 mmol/L reduction in total cholesterol reduced the mean risk of MI by 22.6% (range 20.2–24.0%.)

Two studies – HPS[2] and Long-term Intervention with Pravastatin in Ischaemic Disease (LIPID)[11] – have looked at patient groups with a mixed pattern of pre-existing vascular disease and comparable baseline cholesterol levels – 5.9 mmol/L and 5.6 mmol/L respectively. In both cases, the annual risk of fatal or non-fatal MI in the untreated group was around 2.5%.

Method

Data extraction strategy

The following data items were extracted from the GP computer systems of each participating practice and are reported in this paper:

- Age and sex
- Presence of Read code for ischaemic heart disease, and its subcodes. Within this ischaemic heart disease subset the following items were also extracted:
  - Result of most recent total cholesterol measurement. A cholesterol with a numerical value was taken as a 'valid' reading. Where a Read code for cholesterol was used that did not have an associated numerical value, e.g. 'cholesterol normal', 'cholesterol raised', this was considered invalid, since these values have changed with

time. Likewise one of the computer systems associated a zero value with a cholesterol test request. These values were also considered invalid and excluded, as they would have artificially lowered the mean.

– Statin prescriptions.

The data were extracted using MIQUEST,[9] which draws data directly from individual practice computer systems. Paper records which had not been entered on to practice computers were not identified in this study.

These data were then pooled to identify the following:

- Prevalence of ischaemic heart disease by age and sex
- Prevalence of statin usage in CHD population
- Proportion of CHD population with cholesterol record
- Proportion of CHD patients with total cholesterol < 5 mmol/L, broken down by statin use
- Distribution of total cholesterol levels in CHD population, broken down by statin use.

The prevalence of the CHD data was age–sex standardised compared with that reported in the Health Survey for England in 1998.[21]

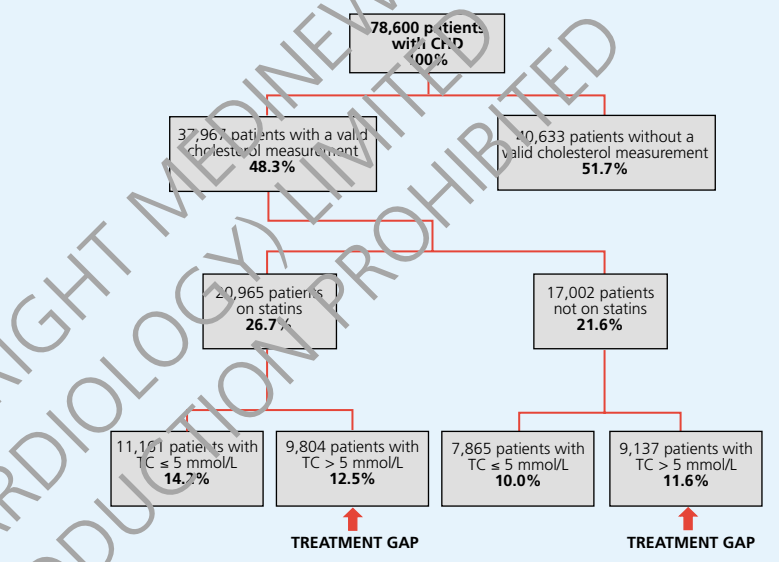
A clinical impact model was constructed, based on the underlying untreated event rates and the mean risk reduction associated with statin use, identified from clinical trials as outlined in the introduction. This model was then applied to patients – both treated and untreated – who had failed to reach the total cholesterol target of 5 mmol/L, in order to estimate the potential scale of the unmet need.

Table 1. Comparison of age/sex specific CHD prevalence in PCDQ sample with that found in the Health Survey for England 1998[21]

	CHD prevalence in PCDQ sample		CHD prevalence in HSE 1998	
Age group	**Male (%)**	**Female (%)**	**Male (%)**	**Female (%)**
35–44 years	0.5	0.3	0.9	0.3
45–54 years	3.0	1.3	4.3	1.8
55–64 years	9.0	4.4	13.6	6.3
65–74 years	19.4	10.7	20.2	12.5
75+ years	25.1	16.7	23.4	18.4

Key: CHD = coronary heart disease; PCDQ = Primary Care Data Quality Programme; HSE = Health Survey for England

Figure 2. Characterisation of lipid treatment gap in ischaemic heart disease patients. All percentage figures relate to the total number of CHD patients included (78,600)



Key: CHD = coronary heart disease; TC = total cholesterol

Results

Study population and CHD prevalence

There were 2.4 million patients registered to practices within the 24 localities that participated in the PCDQ programme. The localities involved were self-selected and were predominantly located in London and the South East. There is representation from the North West and North East of England but none from the South West region, Scotland, Wales or Northern Ireland. Within this population there were 89,422 individuals with a recorded diagnosis of ischaemic heart disease. When standardised to the English age/sex structure, this represents an overall CHD prevalence rate of 7.0% of the population aged 35 or over. Table 1 compares these data with those derived from the Health Survey for England in 1998[21] and demonstrates a small but consistent under-recording of CHD, across the full age and sex range.

Cholesterol recording and statin prescribing in the CHD population

Of the 89,422 patients with a diagnosis of CHD, valid data regarding statin use and cholesterol levels were available for 78,600 (88%). These data are summarised in figure 2. A valid cholesterol measurement was recorded for 37,967 of the patients with a diagnosis of ischaemic heart disease – 48.3% of the total. Of the CHD patients with a valid cholesterol reading, 55.2% were taking a statin and, of these, 53.2% had a total cholesterol level at

or below the target level of 5.0 mmol/L.

The mean total cholesterol level in patients prescribed a statin was 5.13 mmol/L (95% CI 5.11–5.14), while the mean total cholesterol level in non-statin users was 5.26 mmol/L (95% CI 5.24–5.27). Amongst non-statin users, 46.3% had a total cholesterol of 5.0 mmol/L or less, compared to 53.2% of statin users (see figure 3). This difference, while numerically small, is highly statistically significant ($p<0.0000001$).

Considerable variation was apparent between both practices and PCOs. This probably indicates differences in both clinical performance and data recording. The variation between PCOs is illustrated in figure 4, which looks at the percentage of CHD patients with a cholesterol measurement recorded.

Figure 3. Cumulative frequency distribution of total cholesterol levels in treated (n=20,965) and untreated (n=17,002) populations, with coronary heart disease

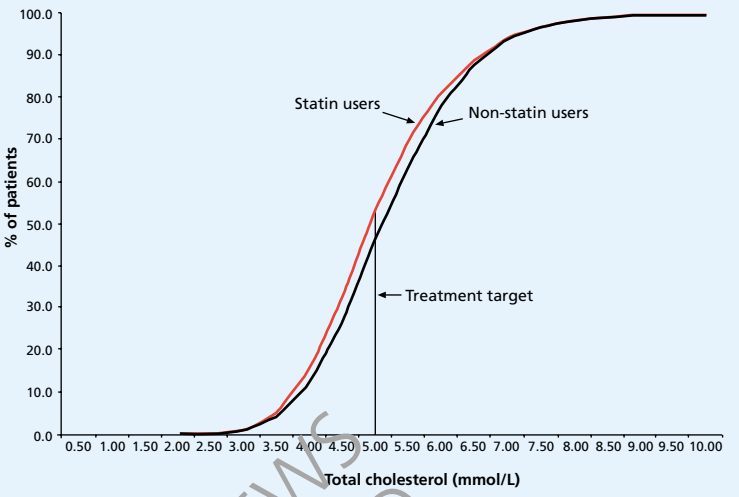
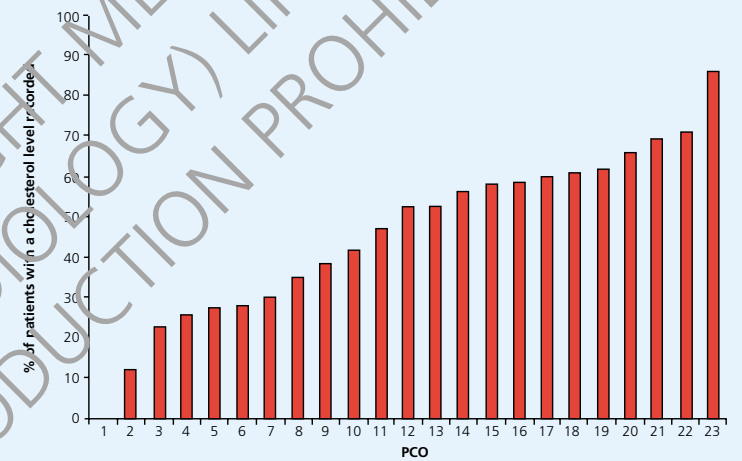


Figure 4. Percentage of total CHD patients with a cholesterol level recorded, broken down by PCO



Key: PCO = Primary Care Organisation; CHD = coronary heart disease

Clinical impact model

As figure 2 shows, amongst the group with established ischaemic heart disease who have had their cholesterol measured, there are two distinct groups of patients who constitute the 'treatment gap'. These are:

- Group 1: patients not prescribed a statin, with a total cholesterol > 5 mmol/L
- Group 2: patients prescribed a statin but failing to meet the 5 mmol/L target.

To model the clinical impact of the treatment gap, we must first form an estimate of the coronary risk associated with each of these groups. Based on the data from untreated populations in the statin secondary prevention studies (see Background section), we can conservatively estimate a new fatal or non-fatal MI will occur in 2.5% of patients with established CHD every year. If this event rate is applied to both groups 1 and 2, we can predict that, in these 18,941 patients, there will be 474 events seen annually.

The potential for treatment benefit will hinge on the starting cholesterol in the population at risk. Surprisingly, despite the significant difference in lipid levels between treated and untreated populations as a whole, the mean total cholesterol in both group 1 and group 2 is identical, at 6.06 mmol/L (95% CI: 6.05–6.07 mmol/L).

If every one of these under-treated patients was to have their total cholesterol brought down to 5 mmol/L, this would require a mean reduction of 1.1 mmol/L. Given that we can estimate a coronary risk reduction of 22.6% for every 1 mmol/L total cholesterol reduction (see Background section), this may be expected to yield an estimated overall risk reduction of about 25%. This reduction should be applied to the baseline MI rate of 2.5% per annum, assuming a typical treatment duration of five to six years. The predicted outcome would therefore reduce from the initial figure of 474 events per year, to 356 events in the treated population, a net reduction of 118 events per year.

Discussion

Principal findings

This study represents the largest published audit in secondary prevention ever carried out in English general

practice. Its major finding is that currently the 'rule of halves' applies to the management of the cholesterol of patients with CHD: half had a record of a cholesterol measurement, half of these were being prescribed a statin, and half of these had been treated to target. This study also suggests that the level of use of statins in patients with CHD has not progressed substantially beyond the levels reported by deWilde *et al*.[7] and that the Department of Health's optimism that the arrival of the *National Service Framework for Coronary Heart Disease* would further improve things, has yet to be realised.

Study implications

The study suggests that there will be an excess of 118 coronary events per year in this population as a result of sub-optimal therapy. Given that this number of events is accrued in a studied population of 37,965 CHD patients, it is possible to estimate the number of events in England as a whole. By applying the whole population prevalence rate for CHD of 4.7%, found in the Health Survey for England, to the total population of 49.2 million in England, we can estimate that there are approximately 2.3 million CHD patients in England, with around 7,150 new events occurring annually as a result of patients falling into the treatment gap.

Study weaknesses

The study PCOs are a self-selected group, who opted to take part in the programme. The limitations of the data used in this study are that it only looks at computer records. Key data could still exist, be on paper, or not recorded at all. Some patients may have had their raised cholesterol measured and now be on treatment and the treated level may not have been recorded yet. We know from the PCOs that have been in the PCDQ programme for some time that none have reached a plateau: there continues to be scope for improved management.[22]

Collecting statin prescriptions may not equal statin consumption. It is clear from the literature that compliance with statin prescriptions tends to be poor.[23] Equally, data are presented as if there is an even spread between PCOs and practices when in fact there are considerable differences. Patients who are inadequately treated may not be receiving the full dose of statins that the trial evidence suggests is necessary to achieve benefit. This appears to be a common phenomenon in primary care. In England in 2001,[6] 30% of prescriptions for pravastatin, 50% of prescriptions for simvastatin, and

> ***'We estimate around 7,150 new events occur annually in CHD patients in England as a result of sub-optimal statin therapy'***

68% of prescriptions for atorvastatin were for the lowest dose available. The mean doses prescribed for each of these agents were 23.5 mg, 16.7 mg, and 15.1 mg respectively, suggesting that there remains considerable scope for up-titration of treatment regimes.

A further weakness of the clinical model is that it is only MI that is considered as an 'event'. Angina, stroke and peripheral vascular disease are other important morbidities not considered. Whilst this omission reflects the need to choose a common outcome from multiple studies with different primary outcome measures, it should not be interpreted as implying that these other problems lack clinical importance. The results of this study should therefore be considered as a minimum case, with the actual number of avoidable events being considerably higher.

Comparison with the literature

A similar primary care audit – Healthwise[4] – was carried out in 137 UK practices in 1997. It identified an adult CHD prevalence of 2.5% and 58% of CHD patients had a valid cholesterol measurement, of whom 76% had a total cholesterol above 5.0 mmol/L. Just 16% of patients were taking a statin. There have been improvements compared with this low baseline. In the Health Survey for England (HSE)[21] in 1998, a random sample of 16,000 adults were identified and interviewed regarding their cardiovascular health: 4.6% of women and 7.1% of men aged over 16 were found to have ischaemic heart disease. When the current study population is standardised to an equivalent population (i.e. including all over 16s), overall adult CHD prevalence is found to be 4.7%, a figure very similar to that identified in HSE. However, if we can make the assumption that the worse data recording PCOs will improve (figure 4), then the study population may have a 'true' prevalence higher than this.

Call for further research

Further research is needed to examine this area in detail. We need sub-group analysis to look at those at greatest risk (e.g. diabetics) to look at the dosages of statin used, and to examine the population who are receiving a statin yet do not have a diagnosis of CHD. As yet largely unexplored are the implications of extending this work into the high-risk primary prevention sector and the prospect of treatment targets being reduced in the light of the HPS. In addition, it is necessary to examine what information is recorded in the computer as 'free text' and not coded. Narrative is not found on computer searches. Similarly there is information in the written notes and hospital letters that has not been entered into the computer and, finally, there is information elsewhere within the health service that never reaches general practice.

Conclusions

Notwithstanding its limitations, this study provides a valuable insight into progress that has been made in the

Key messages

- General practice has improved the management of patients with heart disease and raised cholesterol but further improvement is needed
- A large general practice audit using information technology has shown that, despite wider use of statins, many IHD patients are still not reaching a target cholesterol of < 5.0 mmol/L. These patients constitute a treatment 'gap'
- The levels of computer recording may under represent the level of care; critical information may remain on written records in the practice or in secondary care
- An educational intervention is an acceptable mechanism for achieving quality improvement

management of CHD over the past few years. When compared to previous audit data, a substantially higher proportion of CHD patients have been identified and a majority of these patients are on an appropriate treatment regime. The current challenge for primary care is to mop up the remaining eligible patients who are not being treated and to ensure that the highest proportion possible of those on treatment are achieving target.

On the evidence of the current audit, systems are now falling into place to improve the management of patients with CHD. Although clinically important measurement, recording and treatment gaps still exist, there is every prospect that these will be closed.

Conflict of interest

PCDQ was partially funded by Merck Sharp & Dohme Ltd, through an unconditional educational grant. This covers approximately half of the costs of the programme with participating PCOs contributing the other half of the funding.

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