Research findings
August 2006 number 12

A population-based case control study of cataract

This publication summarises findings from research conducted by Dr Liam Smeeth and Professor Astrid Fletcher, Department of Epidemiology and Population Health, London School of Hygiene and Tropical Medicine, and Dr Richard Hubbard, University of Nottingham.

Cataract is the leading cause of low vision and blindness in the world. Any common exposure that increases the risk of cataract therefore has the potential to have a major impact on levels of visual impairment. Thomas Pocklington Trust commissioned a study to look at whether two different commonly prescribed drugs increased the risk of cataract: inhaled corticosteroids (prescribed for asthma) and statins (prescribed for coronary heart disease).

This study found that:
• the use of inhaled corticosteroids increased a person’s risk of cataract by about 10%
• at high doses inhaled corticosteroids increased the risk of cataract by about 70%
• the longer people had been using inhaled corticosteroids, the higher their risk of cataract
• the risk of cataract associated with high doses of inhaled corticosteroids needs to be more widely appreciated
• in the short and medium term statins do not seem to be associated with an increased risk of cataract
• concurrent use of statins with other drugs that increase the levels of statins in the circulation also did not increase the risk of cataract
• the need to assess the effects of long term statin exposure on the eye remains.

Introduction
Inhaled corticosteroids are drugs used by more than 5% of the UK population to treat their asthma and other airways disease. The risk of cataract associated with systemic steroid use (such as steroid tablets taken by mouth) is well established, but the extent to which inhaled corticosteroids increase the risk of cataract is unclear.

Statins are potent cholesterol reducing drugs introduced in the early 1990s. They are effective in helping to prevent coronary heart disease. Increased cataract formation has been found in dogs treated with statins, but studies in humans have been too small to tell us reliably whether statins increase the risk of cataract in humans.

Thomas Pocklington Trust commissioned a large study to look at whether these types of drug increased the risk of cataract. Over 15,479 people with a diagnosed cataract were compared with the same number of people who had never had a cataract.

Cataract
A cataract is a severe opacification or clouding of the lens. The term lens opacity is often used for early stage disease, with cataract referring to the more advanced vision impairing stages.

Surgical extraction with intraocular lens implantation is an effective treatment. Over 170,000 cataract operations were performed in the United Kingdom in 1998. However, despite high levels of cataract surgery, population based studies in developed countries show that between a third and a half of elderly people with cataract who would benefit from surgery are not in touch with eye health services. The situation in low income countries is even worse, with many millions of people unable to obtain the treatment they need.

Inhaled corticosteroids
Inhaled corticosteroids were first used successfully to treat severe chronic asthma in the early 1970s. Recognition of their efficacy has led to a progressive increase in their use. Many patients with asthma
now use inhaled corticosteroids for long periods of time, whilst oral corticosteroids are reserved for particularly severe asthma or to treat exacerbations. Currently more than 5% of the UK population use an inhaled corticosteroid; only antibiotics, analgesics, bronchodilators and diuretics are prescribed more.

**Statins**
Statins are potent cholesterol reducing drugs introduced in the early 1990s. They are effective in reducing cardiovascular morbidity and mortality in both people with coronary heart disease and in people at high risk of developing coronary heart disease. Although statins are already commonly prescribed, a number of factors are likely to lead to even wider use of statins in the future making an accurate assessment of any possible harmful effects essential.

Increased cataract formation has been found in dogs treated with statins and other studies in animals have suggested statins may encourage cataract growth. None of the studies undertaken in humans has had sufficient power to detect reliably or exclude a significant risk of cataract associated with use of statins.

**Methods used in the study**
The study was based on data derived from the United Kingdom General Practice Research Database. This is a collection of the computerised general practice medical records of over 2 million people.

The database contains complete prescribing and diagnostic information and represents the largest source of continuous data on illness and prescribing habits in the United Kingdom. The quality of the information in the database has been validated in a number of independent studies and has been found to be high. In particular, a recent study of cataract included a review of hospital eye service discharge summaries.

This review found that among 262 cases identified from their electronic general practice record, 94% had their diagnosis confirmed.

The information obtained from the database is entirely anonymous.
We sampled 15,479 people with a diagnosis of cataract from everyone included in the database. These people are called the “cases”. For each case, we then identified a “control” patient – someone who has never had a cataract.

The controls were the same age and sex as their case, and were registered with the same general practice. This process of making cases and controls similar is called “matching”. We looked at the medications cases had been prescribed before their diagnosis, and compared these with the medications controls had taken. This study design is called a case-control study in epidemiology.

Cases tended to consult their general practitioners more than controls, and this could have increased the likelihood of their being prescribed a specific drug. We therefore adjusted for differences in consultation behaviour in the analyses.

**Results**
The average age of cases was 75 years: the youngest person was 40 years old and the oldest 101 years old. Almost two thirds of cases were female and one third were male. Because cases and controls were matched, controls were the same ages and the same sex as the cases.

**Inhaled corticosteroids**
Among cases 11.4% had used an inhaled corticosteroid compared with 7.6% for controls. After taking into account differences between people with and without cataract, the use of inhaled corticosteroids increased a person’s risk of cataract by about 10%.

At high doses (greater than 1600mcg per day) inhaled corticosteroids increased the risk of cataract by about 70%. This sort of dose is only rarely used, and for a typical user of asthma inhalers would mean 16 puffs per day. The longer people had been using inhaled corticosteroids, the higher their risk of cataract.

**Statins**
Among cases 2.6% had used a statin compared with 1.9% for controls. After taking into account differences between people with
and without cataract, use of statins was not associated with an increased risk of cataract.

When looking separately at higher doses and longer duration of use of statins, there was still no increased risk of cataract. However, only a small proportion of people in the study had been using statins for over 5 years, limiting the ability to assess long term effects.

Using statins at the same time as other drugs that increased the levels of statins in the circulation also did not increase the risk of cataract.

**Conclusions**
High doses and prolonged use of inhaled corticosteroids appear to be associated with an increased risk of cataract independent of exposure to other types of corticosteroid medications. This risk adds to the growing literature on the potential for adverse effects from the use of inhaled corticosteroids.

These risks need to be considered in the light of the large beneficial effects value of inhaled corticosteroids for many patients with asthma and for some patients with chronic obstructive pulmonary disease (COPD). While lower doses have not been shown to be completely without risk, there is good evidence to suggest that lower doses are associated with a reduced risk of adverse effects.

Optimal management of airways disease should aim for the lowest appropriate dose of inhaled corticosteroids. In the short and medium term statins do not seem to be associated with an increased risk of cataract. However, treatment with a statin is likely to be lifelong for most people. With the increasing trend for initiating statin therapy among younger people at high risk of cardiovascular disease, the need to assess the effects of long term statin exposure on the eye remains.

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How to obtain further information
This research has been published as:


Cataract and the use of statins: a case-control study by L. Smeeth, R. Hubbard, and A.E. Fletcher, QJM. 2003 May; 96(5): 337-43.

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Background on Pocklington
Thomas Pocklington Trust is the leading provider of housing, care and support services for people with sight loss in the UK. Each year we also commit around £600,000 to fund social and public health research and development projects. Pocklington’s operations offer a range of sheltered and supported housing, residential care, respite care, day services, home care services, resource centres and community based support services.

A Positive about Disability and an Investor in People organisation, we are adopting quality assurance systems for all our services to ensure we not only maintain our quality standards, but also seek continuous improvement in line with the changing needs and expectations of our current and future service users.

We are working in partnership with local authorities, registered social landlords and other voluntary organisations to expand our range of services.
Our research and development programme aims to identify practical ways to improve the lives of people with sight loss, by improving social inclusion, independence and quality of life, improving and developing service outcomes as well as focusing on public health issues.

We are also applying our research findings by way of pilot service developments to test new service models and develop best practice.

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Published by Thomas Pocklington Trust
Registered Charity No. 1113729
Company Registered No. 5359336
ISBN 0-9550647-6-7