

The Cataract National Dataset electronic multicentre audit of 55 567 operations: antiplatelet and anticoagulant medications

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Abstract

Aims This study aims to establish the prevalence of aspirin, dipyridamole, clopidogrel, and warfarin use in patients undergoing cataract surgery, and to compare local anaesthetic and intraoperative complication rates between users and non-users.

Methods The Cataract National Dataset was remotely extracted and anonymised on 55 567 operations at 12 NHS Trusts using electronic patient records (EPRs) between 2001 and 2006.

Results This report analyses 48 862 of the 55 567 operations from the eight centres, which routinely recorded a drug history. In all, 28.1% of the 48 862 patients were taking aspirin, 5.1% warfarin, 1.9% clopidogrel, and 1.0% dipyridamole. The recording of any complication of a sharp needle or subtenon's cannula local anaesthetic block was increased in patients taking clopidogrel, 8.0% ($P < 0.0001$) or warfarin, 6.2% ($P = 0.0026$) vs non-users, 4.3%, but no increase in potentially sight-threatening complications was identified. The incidence of subconjunctival haemorrhage was increased in patients taking clopidogrel, 4.4% ($P < 0.0001$) or warfarin, 3.7% ($P < 0.0001$) vs non-users, 1.7%. The recording of any operative complication was increased in those taking clopidogrel, 7.3% ($P = 0.0002$) vs non-users, 4.4%, but the haemorrhagic operative complications of choroidal/suprachoroidal haemorrhage and hyphaema were not significantly increased. The non-haemorrhagic complication of posterior capsular rupture (PCR) was increased in those taking clopidogrel, 3.23% ($P = 0.0057$) vs non-users, 1.77%.

Conclusions Clopidogrel or warfarin use was associated with a significant increase in minor complications of sharp needle and subtenon's cannula local anaesthesia but was not associated with a significant increase in potentially sight-threatening local anaesthetic or operative haemorrhagic complications.

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Keywords: cataract surgery; Cataract National Dataset; complications; haemorrhage; antiplatelet; anticoagulant

Introduction

The vast majority of patients undergoing cataract surgery are elderly and take regular systemic medications. During the cataract care pathway, it is a normal practice in the United Kingdom, usually at a nursing pre-assessment visit, to take a drug history. Important classes of drugs to identify include antiplatelet and anticoagulant medications, which may increase the risk of haemorrhagic anaesthetic or operative complications. These medications are, however, taken to reduce the incidence of potentially life-threatening thromboembolic events in patients with cardiovascular conditions;^{1–5} therefore, so long as they do not threaten the success of cataract surgery, it is desirable to continue them before surgery.

The management of patients taking aspirin or warfarin at the time of cataract surgery has previously been investigated. The largest reported series involved 19 283 cataract

operations,⁶ which in common with other reports, did not identify an increased risk of haemorrhagic complications during local anaesthesia^{6,7} or cataract surgery.^{6,8,9} Other studies have reported an increased risk of minor haemorrhagic, but not visually threatening complications in patients taking warfarin.^{10–14} The Royal College of Ophthalmologists' Cataract Surgery Guidelines (2004) recommends that patients taking aspirin should continue it before cataract surgery, and patients taking warfarin should continue this medication but that the INR should be within the therapeutic level.¹⁵ These guidelines were predominantly based on a 2001 literature review.¹⁶

Clopidogrel and dipyridamole are newer antiplatelet medications and have not been subject to the same scrutiny as potential risk factors for haemorrhagic complications during cataract surgery. Clopidogrel use has been shown to increase the risk of bleeding associated with coronary artery bypass surgery^{17,18} and in other procedures.¹⁹ Dipyridamole has been shown to produce no increase in haemorrhage during cardiac surgery.²⁰ A case of unexpected bleeding during phacoemulsification in a patient on aspirin and clopidogrel has been reported.²¹ Only one small study has addressed the risk of clopidogrel in cataract surgery, focusing exclusively on subtenon's anaesthesia.²² In this study, 40 patients on clopidogrel and 65 patients on warfarin were found to have a significant increase in the incidence of subconjunctival haemorrhage compared to controls but no sight-threatening haemorrhagic complications occurred in any patients.

This paper aims to document the prevalence of the use of anticoagulant and antiplatelet medications in patients undergoing cataract surgery, and to compare the incidence of local anaesthetic and intraoperative complications between users and non-users.

Materials and methods

The methods employed in this study have been described in detail in the first paper in this series.²³ Briefly, the Cataract National Dataset (CND)²⁴ was remotely extracted on 55 567 cataract operations performed between November 2001 and July 2006, from 12 NHS trusts that all used the same electronic patient record (EPR) system (Medisoft Ophthalmology, Medisoft Limited, Leeds, UK; <http://www.medisoft.co.uk>).

For this study, only data from the eight sites that routinely recorded a drug history as part of the nursing pre-assessment were included in the analysis. Patients not on antiplatelet or anticoagulant medications formed the comparison group.

Either the anaesthetist or the operating surgeon could complete the anaesthetic data collection fields. To balance

completeness, speed, and accuracy of data entry, the EPR allows some fields to be defaulted for individual surgeons or anaesthetists (eg, grade, anaesthetic technique, usual anaesthetic drugs used, and many of the operative technique fields), but a compulsory choice must be made each time the anaesthetic or operative complication fields are completed. In earlier versions of this software, the anaesthetic complications field was only available for sharp needle and subtenon's cannula local anaesthetic techniques, and it was not possible to record an anaesthetic complication of topical/intracameral anaesthesia. This, therefore, limits our ability to comment on complications of topical or intracameral anaesthesia, but haemorrhagic complications would not be expected with these techniques. For the purpose of this report, anaesthetic or operative complications were defined by the authors as serious if they were considered to be potentially life-threatening (systemic) or sight threatening (ocular/orbital), and minor if worthy of recording but not in the serious category. The haemorrhagic complications of anaesthesia available on the EPR were subconjunctival haemorrhage, eyelid haemorrhage/bruising, and retrobulbar/peribulbar haemorrhage. The haemorrhagic operative complications available were hyphaema and choroidal/suprachoroidal haemorrhage.

Dichotomous variables were compared by the χ^2 or Fisher's exact tests as appropriate. Continuous variables were compared with unpaired *t*-tests. A *P*-value of less than 0.05 was considered statistically significant (two tailed). Because an unknown number of operations were performed on two eyes of the same patient in this dataset, caution is advised when interpreting results where $0.05 < P < 0.01$. Analyses were performed using iStat software (<http://www.handango.com>).

Results

The Cataract National Dataset was remotely extracted on 55 567 cataract operations performed between November 2001 and July 2006 at 12 NHS Trusts widely scattered throughout the United Kingdom. For this study, analysis was restricted to the 48 862 cataract operations performed at eight NHS Trusts, where the EPR system was routinely used to record a reliable drug history.

Of the 48 862 operations performed at sites that routinely recorded drug history, 41 006 or 83.9% were recorded as taking one or more medications preoperatively with 16 961 or 34.7% taking one or more antiplatelet or anticoagulant medications. Overall, aspirin was used in 28.1%, warfarin in 5.1%, clopidogrel in 1.9%, and dipyridamole in 1.0% (Table 1). In all, 1.3% of operations performed were on eyes of patients who were taking more than one of these medications. Further,

Table 1 Absolute numbers of patients on each medication, and patient characteristics (N = 48 862. Note, 639 patients took more than one medication, and 71 patients did not have gender recorded)

Antiplatelet/ anticoagulant used	Total	Age (range)	Gender Male: Female:	Diabetes	Copathology predictive of poor visual outcome
None (comparison)	31 901 (65.3%)	74.2 (5–104)	M: 10 990 (34.5%), F: 20 864 (65.4%)	3225 (10.1%)	8865 (27.8%)
Aspirin	13 717 (28.1%)	77.9 (38–103) $P < 0.0001$	M: 5961 (43.5%), F: 7737 (56.4%)	3155 (23.0%), $\chi^2 = 132.41$, $P < 0.0001$	3994 (29.1%), $\chi^2 = 8.29$, $P = 0.0038$
Clopidogrel	933 (1.9%)	76.8 (46–97) $P < 0.0001$	M: 431 (46.2%), F: 500 (53.6%)	195 (20.9%), $\chi^2 = 113.12$, $P < 0.0001$	286 (30.7%), $\chi^2 = 3.56$, $P = 0.0665$
Dipyridamole	471 (1.0%)	79.3 (43–97) $P < 0.0001$	M: 240 (51.0%), F: 231 (49.0%)	109 (23.1%), $\chi^2 = 83.93$, $P < 0.0001$	151 (32.1%), $\chi^2 = 4.0024$, $P = 0.0508$
Warfarin	2485 (5.1%)	78.3 (29–96) $P < 0.0001$	M: 1221 (49.1%), F: 1261 (50.7%)	452 (18.2%), $\chi^2 = 157.60$, $P < 0.0001$	661 (26.6%), $\chi^2 = 1.5698$, $P = 0.2227$

31 901 or 65.3% of the operations were on patients who were not on any anticoagulant on antiplatelet medications, and they formed the comparison group (Table 1).

The mean age was significantly higher in patients on aspirin (77.9 years, $P < 0.0001$), clopidogrel (76.8 years, $P < 0.0001$), dipyridamole (79.3 years, $P < 0.0001$), or warfarin (78.3 years, $P < 0.0001$) than in patients in the comparison group (74.2 years; Table 1). There was a significant increase in the recording of a preoperative eye condition predictive of a poor visual prognosis in those taking aspirin (29.1%, $P = 0.0038$) compared with those not on antiplatelet or anticoagulant medications (27.8%). Recording of preoperative copathology predictive of poor visual outcome was not significantly increased in those on warfarin, clopidogrel, or dipyridamole (Table 1). Diabetes was present significantly in more patients taking aspirin (23.0%, $P < 0.0001$), clopidogrel (20.9%, $P < 0.0001$), dipyridamole (23.1%, $P < 0.0001$), or warfarin (22.2%, $P < 0.0001$) compared to those not on such medications (10.1%).

Complications of local anaesthetic

Operations performed under topical alone or combined topical and intracameral anaesthesia were excluded for reasons of data completeness in relation to recording of local anaesthetic complications. Sharp needle or subtenon's cannula anaesthesia was used in 32 686 or 66.9% of cases. Of these, 11 685 or 35.7% of blocks were in patients taking one or more anticoagulant or antiplatelet medications, with the remaining 21 001 or 64.3% of blocked cases not using such medications, and forming the relevant comparison group (Table 2).

The incidence of any complication of local anaesthesia was significantly higher in those on clopidogrel alone, 8.0% ($P < 0.0001$) or warfarin alone, 6.2% ($P = 0.0026$) than in the control group, 4.3%. There was no significant increase in the overall recording of complications of sharp needle and subtenon's cannula local anaesthesia in those on aspirin or dipyridamole, or those on aspirin used in combination with clopidogrel, warfarin, or dipyridamole (Table 2).

Of the haemorrhagic complications, the recording of subconjunctival haemorrhage was significantly increased in those on clopidogrel alone, 4.4% ($P < 0.0001$) and in those on warfarin alone, 3.7% ($P < 0.0001$), as well as those on a combination of aspirin and warfarin 6.6% ($P = 0.0041$) compared to those not on antiplatelet or anticoagulant medications, 1.7%. No significant difference in the recording of subconjunctival haemorrhage was observed in those on aspirin or dipyridamole alone, or aspirin in combination with clopidogrel or dipyridamole (Table 2). No significant increase in eyelid haemorrhage/bruising was found in any group. No significant increases in the potentially sight-threatening haemorrhagic complications of retrobulbar/peribulbar haemorrhage were found in any of the anticoagulant or antiplatelet groups.

Operative complications

Data on operative complications were available for all 48 862 operations. Patients on clopidogrel alone had a significant increase in the recording of any operative complications, 7.3% ($P = 0.0002$) vs 4.4% in the comparison group. No increase in the recording of any operative complications was found in any other group

Table 2 Complications of sharp needle and subtenon's cannula local anaesthesia *vs* medications used ($N = 32\,656$. Note, 30 patients on other combinations of medications excluded from the table due to small group numbers)

Antiplatelet/ anticoagulant used	Total	Any complication of LA	Subconjunctival haemorrhage	Eyelid haemorrhage/ bruising	Retrobulbar/ Peribulbar haemorrhage
None (comparison)	21 001	894 (4.3%)	353 (1.68%)	44 (0.21%)	7 (0.03%)
Aspirin only	9101	406 (4.5%), NS, $\chi^2 = 0.5917$, $P = 0.4385$	182 (2.00%), NS, $\chi^2 = 3.3885$, $P = 0.0738$	28 (0.31%), NS, $\chi^2 = 2.1562$, $P = 0.156$	4 (0.04%), NS, $\chi^2 = 0.6661$, $P = 0.8388$
Clopidogrel only	524	42 (8.0%), $\chi^2 = 16.46$, $P < 0.0001$	23 (4.39%), $\chi^2 = 20.3$, $P < 0.0001$	1 (0.19%), NS	0, NS
Dipyridamole only	78	3 (3.8%), NS, $\chi^2 = 0.0119$, $P = 0.84$	2 (2.56%), NS	0, NS	0, NS
Warfarin only	1525	95 (6.2%), $\chi^2 = 8.9123$, $P = 0.0026$	56 (3.67%), $\chi^2 = 30.52$, $P < 0.0001$	4 (0.26%), NS, $\chi^2 = 0.207$, $P = 0.8303$	0, NS
Aspirin + clopidogrel	134	6 (4.5%), NS, $\chi^2 = 0.0078$, $P = 0.8445$	4 (2.99%), NS	1 (0.75%), NS	0, NS
Aspirin + dipyridamole	217	9 (4.1%), NS, $\chi^2 = 0.008$, $P = 0.8443$	2 (0.92%), NS	0, NS	1 (0.46%), NS
Aspirin + warfarin	76	7 (9.2%), NS, Yates, $\chi^2 = 3.411$, $P = 0.0728$	5 (6.58%), $\chi^2 = 8.15$, $P = 0.0041$	1 (1.32%), NS	0, NS

(Table 3). No significant increase in the potentially sight-threatening haemorrhagic complications of choroidal/suprachoroidal haemorrhage or hyphaema was identified in any group (Table 3). Clopidogrel use was associated with a significant increase in the recording of posterior capsule rupture (PCR) with or without vitreous loss, 3.23% ($P = 0.0057$) *vs* 1.77% in the comparison group. No significant increase in PCR was identified in any other group, including those on combined aspirin and clopidogrel.

Discussion

This study of the use of anticoagulant and antiplatelet medication in patients undergoing cataract surgery is the largest ever reported. We have identified the prevalence of aspirin and warfarin use in the UK cataract population as 28.1 and 5.1%, respectively, higher than the reported prevalence in a large study of cataract operations performed in the United States and Canada.⁶ Clopidogrel is used in 1.9% of patients undergoing cataract surgery and dipyridamole in 1.0% and patients using these medications will, therefore, be encountered regularly. We

have identified an increase in the overall recording of sharp needle and subtenon's cannula local anaesthetic complications, in particular, an increase in subconjunctival haemorrhage in patients using clopidogrel or warfarin. Furthermore, clopidogrel use was associated with a significant increase in the overall recording of operative complications, including a significant increase in posterior capsule rupture. Perhaps, most importantly, we did not demonstrate an increased risk of serious haemorrhagic complications in patients using any antiplatelet or anticoagulant medications.

Our review of the patient characteristics of those on anticoagulant and antiplatelet medications demonstrate significant differences, compared with the comparison group that may act as confounding factors when considering anaesthetic or operative complication rates. Patients taking any antiplatelet or anticoagulant medications were on average older and more likely to have diabetes. However, only patients taking aspirin demonstrated a significant increase in the recording of preoperative ocular comorbidity predictive of a poor visual outcome, although colpidogrel use ($P = 0.0665$ and

Table 3 Intraoperative complications *vs* medications used ($N=48\,824$. Note, 38 patients on other combinations of medications excluded from the table due to small group numbers)

Antiplatelet/ anticoagulant used	Total	Any operative complication	Choroidal/suprachoroidal haemorrhage	Hyphaema	Posterior capsule rupture
None (comparison)	31901	1407 (4.4%)	22 (0.07%)	14 (0.04%)	564 (1.77%)
Aspirin only	13110	575 (4.4%), NS	7 (0.05%), NS, $\chi^2 = 0.1498$, $P = 0.7046$	8 (0.06%), NS	248 (1.89%), NS, $\chi^2 = 0.7345$, $P = 0.3878$
Clopidogrel only	712	52 (7.3%), $\chi^2 = 12.97$, $P = 0.0002$	2 (0.28%), NS, $\chi^2 = 1.86$, $P = 0.187$	1 (0.14%), NS, $\chi^2 = 0.092$, $P = 0.7571$	23 (3.23%), $\chi^2 = 7.6194$, $P = 0.0057$
Dipyridamole only	128	5 (3.9%), NS, $\chi^2 = 0.0038$, $P = 0.849$	0, NS	0, NS	3 (2.34%), NS, $\chi^2 = 0.0247$, $P = 0.826$
Warfarin only	2372	90 (3.8%), NS, $\chi^2 = 1.86$, $P = 0.1864$	1 (0.04%), NS	2 (0.08%), NS, $\chi^2 = 0.1497$, $P = 0.7047$	38 (1.60%), NS, $\chi^2 = 0.2627$, $P = 0.6156$
Aspirin + clopidogrel	190	8 (4.2%), NS	0, NS	0, NS	4 (2.11%), NS, $\chi^2 = 0.0057$, $P = 0.8469$
Aspirin + dipyridamole	317	19 (6.0%), NS, $\chi^2 = 1.5043$, $P = 0.2317$	0, NS	0, NS	5 (1.58%), NS, $\chi^2 = 0.0018$, $P = 0.8513$
Aspirin + warfarin	94	5 (5.3%), NS, $\chi^2 = 0.0313$, $P = 0.819$	0, NS	0, NS	3 (3.19%), NS, $\chi^2 = 0.4265$, $P = 0.5164$

dipyridamole use ($P = 0.0508$) did come close to significant levels.

The analysis of local anaesthetic complications was restricted to complications of sharp needle and subtenon's cannula local anaesthesia (66.9%). These were deemed to be the situations where haemorrhagic complications of the anaesthetic were most relevant and, as indicated in the methods, anaesthetic complications data were not available for topical/intracameral anaesthetic techniques. The overall recording of a complication of local anaesthesia was significantly higher in those on clopidogrel or warfarin. In keeping with previous studies, there was an increase in subconjunctival haemorrhage rates in those on clopidogrel or warfarin,²² although the overall recorded rates were almost ten-fold lower in our study. Underreporting bias is a feature of all major studies of complications of local anaesthesia and are discussed in full in our paper on local anaesthetic techniques and complications.²⁵ No sight-threatening haemorrhagic complications (retrobulbar/peribulbar haemorrhage) were recorded as a complication of sharp needle or subtenon's cannula local anaesthesia in patients on

clopidogrel or warfarin alone, or when used in combination with aspirin. Retrobulbar/peribulbar haemorrhage was recorded for four local anaesthetics in patients on aspirin (0.044%) and one on combined aspirin and dipyridamole (0.461%), but this was not significantly different from controls (0.033%). Serious haemorrhagic complications of local anaesthesia are very uncommon, and, even with this large sample size, the rate would have had to be >4-fold higher (>0.13%) among aspirin users than control groups for our sample to have had 80% power to detect a difference. Similarly, this study does not have sufficient statistical power to draw conclusions about the incidence of potentially sight-threatening haemorrhagic local anaesthetic complications in patients on clopidogrel or warfarin. From our sample, we can however exclude substantial excess rates, ie, this sample would have 80% power to detect a >14-fold excess rate for clopidogrel and a >8-fold excess for warfarin (two tailed). The absence of any reported case of retrobulbar/peribulbar haemorrhage or expulsive/suprachoroidal haemorrhage in 524 patients on clopidogrel and 1525 on warfarin does suggest a low incidence, which is important if

considering stopping medications, an approach that may have serious systemic implications.

The analysis of operative complications was carried out on 48 862 operations. Patients on clopidogrel showed a significantly higher overall incidence of any operative complication than the comparison group. Antiplatelet and anticoagulant use was, however, not associated with a higher incidence of the haemorrhagic operative complications of choroidal/suprachoroidal haemorrhage or hyphaema. Unexpectedly, clopidogrel use was identified as being associated with a significantly increased rate of the non-haemorrhagic complication of posterior capsule rupture. It is possible that this finding reflects a difference in the characteristics of patients receiving clopidogrel. These patients, as previously noted, were on average significantly older than those in the comparison group, but did not have significantly higher rates of copathology recorded. This unexpected finding is difficult to understand but could reflect 'surgical difficulty', where there is increased superficial haemorrhage or simply the fact that users were older, an association highlighted in our previously reported multivariate analysis of risk factors for posterior capsule rupture or vitreous loss or both.²⁶

Data for this study were extracted from the EPR system in accordance with the CND and some of the potential shortcomings of the analysis in this study may reflect limitations of the CND. Most notable for this analysis, there is no indication in the extracted data as to whether the anticoagulant/antiplatelet medication was stopped before surgery or, if the patient was on warfarin, whether an INR was performed or its result. Underreporting bias of operative complications is also a potential problem in any study of this kind, but with both anaesthetic and operative complications, the EPR system used does force the user to answer the question in 100% of the cases.

Although the numbers of operations involved in this analysis are large, the numbers of patients on some combinations of aspirin, dipyridamole, clopidogrel, or warfarin are small and are of limited use for analysis, particularly, of rare complications. Aspirin taken with clopidogrel ($n = 190$) or warfarin ($n = 94$) was encountered regularly enough to merit inclusion in the analysis, and dipyridamole was actually encountered more frequently in combination with aspirin ($n = 317$) than dipyridamole alone ($n = 128$), reflecting the availability of and indication for dipyridamole combined with aspirin as a second-line treatment in stroke prevention.⁵ With increased EPR uptake future similar analyses of even larger samples may shed light on these questions.

The Cataract Do Once and Share²⁷ programme has facilitated the collection of the details of 55 567 operations for audit purposes. The use of EPRs allows information

to be recorded in accordance with the CND,²⁴ which is then readily available for audit purposes. Observational information on rare events and interactions is made possible at minimal cost in areas where expense and logistical limitations preclude randomised controlled trials.²⁸ This paper has addressed specific questions regarding the use and complications of anticoagulant and antiplatelet medications in patients undergoing cataract surgery.

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