Fucithalmic, chloramphenicol or no treatment after squint surgery in children
A single blind randomised study

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Abstract. One hundred and four children undergoing strabismus surgery were randomised post-operatively to one of three treatment groups; 1) fucithalmic drops twice daily; 2) chloramphenicol (chloromycetin) ointment twice daily; 3) no treatment. Allocation to the 'no treatment' group had to be stopped after 3 of the first 8 patients in the group developed severe mucopurulent conjunctivitis. A parental questionnaire and clinical assessment, carried out in a single blind fashion revealed that nearly all parents were able to apply the prescribed treatment and that both treatments were effective in preventing bacterial conjunctivitis. Post-operative antibiotics seem to be necessary following squint surgery in children, and fucithalmic viscous drops are a useful alternative to chloromycetin ointment.

Key words: conjunctivitis - chloramphenicol - fucithalmic - strabismus.

The issue as to whether post-operative treatment following strabismus surgery in children is necessary, is the subject of some debate (Hagan & Dining 1987; Wortham et al. 1990).

Some surgeons use antibiotics, others steroids and some nothing at all. It has long been the practice in our department to use antibiotics in the general belief that a red, inflamed eye, constantly being rubbed by an often grubby hand, is likely to become infected. We tend to use oculentum, as parent find it easier to manage than drops and less frequent applications are necessary. However, many parents complain of great difficulties even with this.

Fucithalmic, a recently developed preparation of fucidic acid, has been very popular with adult patients in the treatment of conjunctivitis because of ease of administration and it's twice daily dosage. We were encouraged by this to undertake the following study to compare fucithalmic with chloramphenicol ointment in children following squint surgery, and to look again at whether any treatment is necessary at all.

Methods

From June 1989 all children under 14 years of age undergoing strabismus surgery in our department were randomised to one of three groups post-operatively; 1) gutte fucithalmic twice daily; 2) chloramphenicol ointment (Occ. chloromycetin) twice daily; 3) no treatment. Operations were performed by a total of 8 surgeons. Operations consisted of recession/resection of horizontal rectii in the main, with a number of inferior oblique, inferior rectus and faden procedures. Muscles were sutured to sclera using 5/0 vicryl, 6/0 catgut to conjunctiva. No pre-operative antibiotics were used. Patients were discharged home in the afternoon or early evening of the day of operation, or the following morning. Treatment was continued until review, between 9 and 11 days post-operatively. At review patients were assessed according to a standard assessment chart, and parents were then asked to
complete a questionnaire. The objective assessment, carried out by the surgeon who performed the surgery without knowing what treatment group the patient had been allocated to, recorded four features; redness, discharge, lid swelling and distress. These were quantified as ‘none’, ‘mild/moderate’ and ‘severe’. The parents’ questionnaire similarly assessed these features over the post-operative period, as well as difficulty getting treatment in and whether treatment caused any distress. They were also asked how often they managed to apply treatment; as often as directed, some of the time or not at all? Statistical tests included Chi squared and Fishers Exact Tests.

Results

After only 25 patients had been entered into the trial, of the 8 who had been randomised to the no treatment group 3 developed a severe mucopurulent conjunctivitis and had to return to hospital. In each case this occurred on the third post-operative days. Swabs were taken from only one patient, which provided no bacterial growth. However, on instituting treatment (g. chloramphenicol in two cases, g. fucithalmic in the third) there was a prompt improvement. We therefore felt it unethical to continue with no treatment, and thereafter patients were only allocated to groups one or two.

Our study was completed in April 1990 by which time 45 patients had been allocated to the chloramphenicol group, 51 to the fucithalmic group. Including those in the no treatment group, this gave a total of 104 patients. Results are shown in Table 1.

In the fucithalmic group 15/51 reported some difficulty in administering treatment. 10/51 also felt that treatment caused some distress to the child. However, only 1/51 was unable to comply with the treatment regime. On objective assessment only 2 children had more than mild findings; one had had not treatment at all. Another patient had returned 3 days post-operatively because of marked conjunctivitis. Haemophilus influenzae was grown, and responded to g.chloramphenicol. At 10 days after operation the eye was quiet.

In the chloramphenicol group 12/45 parents reported difficulty in applying treatment, 8/45 said it caused distress, 3/45 were unable to put treatment in as frequently as directed; none of these 3 had more than mild signs on assessment. Four patients needed additional treatment; 3 returned on the second or third after operation and were prescribed 2 hourly g.chloramphenicol because of frank mucopurulent conjunctivitis. (A swab was taken in only one case; no growth was obtained). The fourth still had discharge at 9 days; this cleared on changing to g.fucithalmic. All remaining patients had no more than mild signs at review.

Discussion

This study suggests that post-operative treatment with antibiotics is necessary. 3/8, almost 50%, of those discharged on no treatment developed severe mucopurulent conjunctivitis compared with a total of 5/96, 5% of those discharged on treatment (P=0.028; Fisher’s exact test two-tailed). This is clearly at odds with the two recent studies which recommended that the post-operative use of

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<th>Table 1. Results of parental questionnaire.</th>
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Numbers in brackets are results of objective assessment.
antibiotics was unnecessary (Hagan & Dinning 1987; Wortham et al. 1990). It could be argued that the parents of children discharged without treatment (and without placebo) were to some extent biased. However, despite the absence of bacteriological confirmation of infection, the fact remains that 3 out of 8 children had conjunctivitis severe enough to justify re-admission. The practical point remains, therefore, that the use of an antibiotic post-operatively reduced the occurrence of attendance and consequent re-admission, irrespective of whether this represented a true reduction in the incidence of infection.

Fucithalmic has been shown to be effective in treating bacterial conjunctivitis and compares favourably with chloramphenicol (Hvidberg 1987; Dirdal 1987; Sinclair & Leigh 1988). In our study more patients on chloramphenicol developed infection compared with those on fucithalmic, though the numbers were too small to show statistical significance (Chi squared test with Yates' correction). Four patients in the chloramphenicol group required more intense treatment with frequent topical drops suggesting that, in some cases at least, chloramphenicol administered twice daily as occludentum is inadequate. Fucithalmic achieves sustained therapeutic levels when given twice daily (Hansen 1985). Although individual parents were not making a direct comparison between the two regimes, the fucithalmic preparation seemed to be popular with most because of the ease of application.

We would therefore suggest that antibiotic should be used routinely in children after squint surgery and that fucithalmic is a useful alternative to chloramycin ointment.

Proprietary statement

Neither author has any commercial nor proprietary interest in either of the preparations used in this study.

References


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