

A randomised controlled trial of azithromycin following surgery for trichomatous trichiasis in The Gambia.

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Abstract

Background/aim: Trichomatous trichiasis frequently returns following surgery. Several factors may promote recurrence: preoperative disease severity, surgeon ability, surgical procedure, healing responses, and infection. This study investigates whether enhanced control of infection, both of *Chlamydia trachomatis* and other bacteria, with azithromycin can improve surgical outcome in a trachoma control programme.

Methods: Individuals with trichomatous trichiasis were examined and operated. After surgery patients were randomised to the azithromycin or control group. The azithromycin group and children in their household were given a dose of azithromycin. Antibiotic treatment was repeated at 6 months. All patients were reassessed at 6 months and 12 months. Samples were collected for *C trachomatis* polymerase chain reaction and general microbiology at each examination.

Results: 451 patients were enrolled. 426 (94%) were reassessed at 1 year, of whom 176 (41.3%) had one or more lashes touching the eye and 84 (19.7%) had five or more lashes. There was no difference in trichiasis recurrence between the azithromycin and control group. Recurrent trichiasis was significantly associated with more severe preoperative trichiasis, bacterial infection, and severe conjunctival inflammation at 12 months. Significant variability in outcome was found between surgeons. Visual acuity and symptoms significantly improved following surgery.

Conclusion: In this setting, with a low prevalence of active trachoma, azithromycin did not improve the outcome of trichiasis surgery conducted by a trachoma control programme. Audit of trichiasis surgery should be routine.

Implications of this study:

1) Azithromycin does not reduce trichiasis recurrence

This study did not find any difference in the outcome of surgery between those who were given peri-operative azithromycin and those who were not. The Gambia is an area with low levels of *Chlamydia trachomatis* infection. It is possible that in areas with a high prevalence of endemic trachoma this intervention may be effective – a question that is currently being tested in a highly endemic country. Therefore, we currently do not advocate the additional use of azithromycin following surgery. All patients should continue to receive a topical antibiotic ointment for at least two weeks following the surgery.

2) High recurrence rate

There was a high trichiasis recurrence rate in this study, which is consistent with other studies. This is an important observation. At a national programme level it is important to remember when planning the provision of surgical services for a region that some of the trichiasis will return and need further surgery, may be as much as 20% by one year. On an individual level, patients should be warned before the operation that the trichiasis can come back. They should be clearly advised to seek help if there is a recurrence. Where possible, it is ideal for programmes to develop follow-up mechanisms to monitor patients for recurrence. For example, this follow-up could be done when a community is visited for an annual distribution of antibiotic for trachoma control.

3) Patients benefited from surgery

Despite the high recurrence rate, overall, patients really benefited from the surgery. There was a marked reduction in the pain experienced from trichiasis. There was a significant improvement in the visual acuity (objective and subjective), probably related to reduction in secretions and improvement in the health of the ocular surface. Even with recurrent trichiasis, the overall burden of trichiasis and associated bacterial infection was markedly reduced. Therefore, in counselling patients prior to surgery the surgeon can reasonably tell the patient that they will probably feel much more comfortable and that there may even be a modest improvement in vision in those who do not already have a lot of corneal scarring.

4) Significant inter-surgeon variability in results – audit / training

An important observation in this study is the variation in results between the surgeons. There is very little published data on inter-observer variation. However, it is likely that such variations in results occur in other trachoma control programmes. This highlights the need to periodically audit the results of individual surgeons. It is vital that such an audit process is conducted in a supportive manner. If the results of a particular surgeon are less good, then steps will need to be taken to provide additional training and support to try to identify any technical problems and so improve the results.

5) Understanding recurrence

Recurrent trichiasis probably has a number of different causes. In addition to a significant effect from inter-surgeon ability, this study identified a number of other factors that contribute. Individuals with more severe entropion and trichiasis are more likely to get a recurrence. Therefore, where possible, such cases should be operated on by more experienced surgeons, to maximise the chance of a good outcome. Bacterial infection was commonly found in eyes with trichiasis, indicating the importance of cleaning the eyes with povidone iodine at the beginning of the surgery. Bacterial infection may be important in promoting conjunctival inflammation which can result in additional scarring.

6) Progression of corneal opacification

A worrying observation, which needs to be confirmed in other studies, is that corneal opacification may develop in eyes after trichiasis surgery even when there is no recurrence of the trichiasis. Bacterial infection may again be important in this process, but other factors such as ocular dryness and conjunctival inflammation may also have a role. An improved understanding of the development of corneal opacification is needed, in order to develop strategies to combat this.