Does single application of topical chloramphenicol to high risk sutured wounds reduce incidence of wound infection after minor surgery? Prospective randomised placebo controlled double blind trial

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ABSTRACT

Objective To determine the effectiveness of a single application of topical chloramphenicol ointment in preventing wound infection after minor dermatological surgery.

Design Prospective randomised placebo controlled double blind multicentre trial.

Setting Primary care in a regional centre in Queensland, Australia.

Participants 972 minor surgery patients.

Interventions A single topical dose of chloramphenicol (n=488) or paraffin ointment (n=484; placebo).

Main outcome measure Incidence of infection.

Results The incidence of infection in the chloramphenicol group (6.6%; 95% confidence interval 4.9 to 8.8) was significantly lower than that in the control group (11.0%; 7.9 to 15.1) (P=0.010). The absolute reduction in infection rate was 4.4%, the relative reduction was 40%, and the relative risk of wound infection in the control group was 1.7 (95% confidence interval 1.1 to 2.5) times higher than in the intervention group. The number needed to treat was 22.8.

Conclusion Application of a single dose of topical chloramphenicol to high risk sutured wounds after minor surgery produces a moderate absolute reduction in infection rate that is statistically but not clinically significant.

Trial registration Current Controlled Trials
ISRCTN73223053.

INTRODUCTION

Chloromycetin ointment consists of 10 mg/g of chloramphenicol in plastibase 30W and soft white and liquid paraffin.^{1,2} Chloramphenicol has a broad spectrum of activity against Gram positive and Gram negative bacteria, rickettsias, and *Chlamydia*.³ Chloramphenicol ointment is indicated for treatment of bacterial conjunctivitis, but little evidence exists for its effectiveness in prophylaxis or treatment of wound

infection. Despite this, it is regularly used in areas outside its main indication. Before our study, several of the investigating general practitioners had applied it to sutured wounds as prophylaxis against wound infection. A survey of UK plastic surgeons reported that 66% used chloramphenicol eye ointment in their practice, mainly as prophylaxis against infection.⁴ The ointment has been used as an adhesive for replacement of the nail bed.⁵ A comprehensive Medline search found only one other study relating to the use of topical chloramphenicol ointment on wounds; this study investigated the application of chloramphenicol ointment to wounds after hip replacement.⁶ The incidence of wound infection in the intervention group was reduced (4% v 8%), but the sample size was small and the results were not statistically significant.

Topical ocular chloramphenicol is widely used in the United Kingdom and Australia for the treatment of conjunctivitis, but is very rarely prescribed for this indication in the United States.⁷ Some controversy previously existed about the link between aplastic anaemia and topical ocular chloramphenicol, on the basis of a small number of single case reports,⁷ but two international case-control studies provided no support for this association. Although the association between ocular chloramphenicol and aplastic anaemia cannot be excluded, the risk is less than one in a million per treatment course.⁸ No incidences of aplastic anaemia after dermatological application have been reported, despite widespread use.

A previous study of wound infection after minor surgery involving general practitioners in Mackay, Queensland, showed an overall incidence of wound infection of 8.6%.^{9,10} This incidence was higher than expected on the basis of the published results of a similar Australian general practice cohort (1.9%), a skin cancer clinic cohort (1.5%), and a European dermatology clinic cohort (2%).¹¹⁻¹³ The acceptable rate of infection after clean minor surgery is suggested to be

Fig 1 | Study protocol for patients

less than 5%.¹⁴⁻¹⁶ The low risk of infection after clean surgery means that studies of more than 1000 procedures (sometimes many more) are needed, under normal circumstances, to detect a reduction in infection from an intervention with statistical confidence.¹⁷ Because of the high incidence of infection in our patient cohort, and a high minor surgery workload,¹⁸ we decided to use the increased capacity to investigate a strategy to reduce the infection rate. In this trial, we sought to establish the effectiveness of topical chloramphenicol ointment in preventing wound infection after dermatological surgery. We used the Chloromycetin brand of chloramphenicol ointment applied as a single dose postoperatively, with paraffin ointment as placebo control.

METHODS

This was a randomised controlled double blind multi-centre trial involving patients presenting for minor skin excisions.

Setting and participants

We did the study in three private general practices in Mackay, Queensland, between June 2007 and March 2008. One of the participating practices consisted of one general practitioner working in an “open access” designated skin cancer clinic. Fifteen doctors working in the three practices recruited between one and 200 patients each.

We purposely selected the general practitioners as working at practices that had previously successfully participated in a wound management project.⁹ Practice

nurses invited consecutive patients presenting for minor skin excisions to take part in the trial. The nurses collected demographic information on all patients, as well as clinical information on the presence of diabetes or any other predetermined important medical conditions. They used a body site map to define the excision site. At the end of the study we asked the practice nurses to re-examine computer records to fill in any missing data. The principal researcher visited participating general practitioners and practice nurses to provide training and ensure that recording was standardised.

Eligibility criteria

All patients presenting to a participating general practitioner for “minor skin excision” from all body sites were eligible to participate in the study. Skin flaps and two layer procedures were recorded and included. We excluded patients who were already taking oral antibiotics, for whom oral or topical antibiotics were clinically indicated immediately postoperatively, or who were on immunosuppressive drugs. Other exclusion criteria were excision of sebaceous cyst, history of allergy to any of the ingredients of Chloromycetin ointment, and personal or family history of aplastic anaemia.

Surgical wound management protocol

We ran a workshop for participating general practitioners to develop guidelines to ensure that excisions were managed in a standardised manner. We were unable to reach consensus about skin preparations, so normal saline was used at one centre and chlorhexidine at two centres. The procedure shown in box 1 was agreed.

Intervention

We could not get information about the exact proportions of the constituents of the base of Chloromycetin ointment from the manufacturer. The principal investigator visited a compounding pharmacist to develop a close match to the vehicle of the Chloromycetin ointment by using a mixture of soft white and liquid paraffin, prepared single doses of the ointment in sterile jars, and stored them in a refrigerator. Immediately after suturing, the doctor applied either paraffin ointment or chloramphenicol ointment to the sutured wounds by using sterile forceps. Sufficient ointment was applied to cover the surface of the wound.

Recruitment, randomisation, and blinding

We used computer generated random numbers and opaque sealed envelopes to randomise patients. Only the principal investigator was aware of the identity of the coded ointments. The practice nurses enrolled patients and assigned participants to their groups. All participating patients received written instructions on postoperative wound care. Both groups were asked to

Box 1 Excision procedure

1. Skin preparation—normal saline or chlorhexidine
2. Usual sterile technique (standard precautions), including sterile gloves
3. Local anaesthetic (type and volume recorded)
4. Suture material—nylon (size recorded)
5. Dressing type—melolin and tape
6. No antibiotics, either topical or oral (if required, or already prescribed, exclude from study); no topical antiseptics, such as betadine or alcohol; no antiseptic washes or medicated soaps
7. Removal of sutures according to body site: back—10 days; all other sites—seven days

take their dressing off after 24 hours and to avoid the using antiseptics (fig 1).

Clinical outcomes

The practice nurse or the doctor assessed wounds for infection on the agreed day of removal of sutures or sooner if the patient re-presented with a perceived infection. Practice nurses and doctors assessing outcome were blinded to the allocation of intervention and control groups. We adapted our definition of wound infection from standardised surveillance criteria for defining superficial surgical site infections developed by the Centre for Disease Control's National Nosocomial Infection Surveillance System (box 2).¹⁹ We also developed our own wound scale, after reviewing several existing scales in the literature,²⁰ in order to improve rigour. This wound scale differentiated no infection or erythema; stitch abscess; less than 1 cm erythema from the wound margin; greater than 1 cm erythema from the wound margin; and deep infection or systemic symptoms. The primary researcher briefed all participating doctors and nurses on the definition of infection and also gave them written information. We asked practice nurses to swab any discharging infections to investigate any pattern of antimicrobial resistance.

Sample size

We calculated sample size on the basis of our previous study, which showed an infection rate of 8.6%.⁹ On the basis of a projected infection rate of 10%, we decided that an absolute decrease in incidence of infection of 5% would be clinically significant. To come to this conclusion with statistical confidence—a power in excess of 80% and a significance level of 0.05—we needed a total of 473 patients in the intervention group and 473 patients in the control group.

Statistical analysis

We based all analysis on the intention to treat principle. Depending on the distribution, we describe numerical data as mean value and standard deviation or median value and interquartile range. We present percentages with 95% confidence intervals. Because the sample was recruited through 15 different general practitioners and outcome might be more similar for patients from one medical professional (clustering) than from several, we adjusted confidence intervals and P values for this cluster sampling approach. Participating doctors were the primary sampling unit, and we applied the survey

Fig 2 Flowchart of enrolment, randomisation, and follow-up of patients. *See table 1 for reasons for exclusions

commands of Stata (release 8). We considered P values less than 0.05 to be statistically significant.

RESULTS

Practice and study characteristics

Of the total of 1246 patients who attended for skin excisions during the period from June 2007 to March 2008, 232 patients were excluded (table 1). Of the remaining 1014 patients, 509 were randomised to the intervention (chloramphenicol) group and 505 to the placebo (paraffin) group. A total of 42 patients were eventually lost to follow-up because they had their sutures removed elsewhere. Follow-up was completed in 972 (95.9%) randomised patients (fig 2).

Comparisons at baseline

Large differences existed between the intervention and the control groups at baseline (table 2). In the intervention group, 71.7% of patients were diagnosed with non-melanoma skin cancer or solar keratosis compared with 65.1% in the control group.

Incidence of infections

Infection occurred in 85 (8.7%) of the 972 excisions. The incidence of infection in the chloramphenicol group (6.6%; 95% confidence interval 4.9 to 8.8) was significantly lower than the incidence in the control group (11.0%; 7.9 to 15.1) ($P=0.010$; adjusted for cluster sampling). The relative risk of infection was 1.7 times higher in the control group compared with the intervention group (table 3). The number needed to treat (number of wounds treated for each infection prevented) was 22.8 (488/21.4).

We found no significant difference in the wound score between the control and intervention groups ($P=0.253$), although 5.5% of patients showed erythema greater than 1 cm in the intervention group compared with 9.1% of patients in the control group (table 3). Wound swabs were done for 24 of the 85 infections. These revealed *Staphylococcus aureus* infections that were resistant to benzylpenicillin but sensitive to all other antibiotics in 22 cases. In one case, additional resistance to erythromycin but sensitivity to all other antibiotics was noted. In another case, *Pseudomonas*

Box 2 Definition of surgical site infection

- Infection must be within 30 days of excision
- Purulent discharge from the wound must be present, or
The general practitioner must diagnose a wound infection, or
The general practitioner prescribes antibiotics
- Stitch abscess must not be counted as an infection

Table 1 Reasons for exclusion from study

Reasons	No (%) patients (n=232)
Patient declined participation	139 (60)
Patient on oral antibiotics	39 (17)
Doctor did not follow study protocol	20 (9)
History of allergy to Chloromycetin	2 (1)
Patient did not plan to return for removal of sutures	12 (5)
Shave biopsy done	6 (3)
Patient on immunosuppressive drug	4 (2)
Patient with infected sebaceous cyst	10 (4)

aeruginosa was cultivated from the wound. These last two swabs were taken from patients in the control group.

DISCUSSION

The results of this study suggest that a single dose of topical chloramphenicol to sutured wounds can produce a relative reduction in infection rate of about 40%. The absolute reduction was 4.4%, which fell short of our pre-determined reduction for clinical relevance (5%), so this was essentially a negative trial. The incidence of infection in our control group (11%) is much higher than reported in the published literature

Table 2 Baseline comparisons of intervention (chloramphenicol) and control (paraffin) groups. Values are numbers (percentages) unless stated otherwise

Characteristics	Intervention group (n=488)	Control group (n=484)
Patients		
Mean (SD) age (years)	59.5 (23.2)	59.0 (27.5)
Male	266 (54.5)	262 (54.1)
Smoking status:		
Never smoked	298 (61.1)	299/483 (61.9)
Ex-smoker	109 (22.3)	108/483 (22.4)
Current smoker	81 (16.6)	76/483 (15.7)
Diabetes mellitus	37 (7.6)	50/483 (10.4)
With medical condition*	79/478 (16.5)	86/475 (18.1)
Lesions		
Body site:		
Neck and face	166 (34.0)	152 (31.4)
Upper extremities	139 (28.5)	140 (28.9)
Trunk	108 (22.1)	102 (21.1)
Lower extremities	75 (15.4)	90 (18.6)
Histology:		
Melanoma and naevi	64 (13.1)	74 (15.3)
Non-melanoma skin cancer and precursor	350 (71.7)	315 (65.1)
Other†	74 (15.2)	95 (19.6)
Procedures		
Mean (SD) length of excision (mm)	20.9 (25.6)	21.0 (28.8)
Median (interquartile range) No of days until removal of sutures	7 (7-9)	8 (7-10)
With flap	1 (0.2)	3 (0.6)
With two level procedure	4 (0.8)	4 (0.8)

*Chronic obstructive pulmonary disease (n=14), aspirin or clopidogrel (n=120), oral steroids (n=3), continuous inhaled steroids (n=9), warfarin (n=42), ischaemic heart disease (n=7), peripheral vascular disease (n=6), and current cancer (n=21).

†Included seborrhoeic keratosis, re-excisions of melanoma and basal cell carcinoma, sebaceous cyst, epidermal cyst, wart, and dermatitis.

looking at similar cohorts.¹¹⁻¹³ The intervention thus may not produce a worthwhile absolute reduction in infection in low risk settings where infection rates are already low; the number needed to treat in these circumstances would be much higher than our figure of 22.8.

Limitations

The study had several limitations. Various characteristics influence the occurrence of infections; although we recorded information on as many variables as possible, ensuring that the baseline data were comparable proved difficult. For example, inadequate data were recorded on suture size and occupation, so we could not compare these factors. In addition, the prevalence of diabetes and of other medically important conditions was probably under-recorded, and power to analyse these subgroups was limited. Surgical training and technique of the general practitioners involved is a potential confounder that would be difficult to quantify and was not recorded. However, we adjusted the statistical analysis for the cluster sampling, taking the doctor as the primary sampling unit. The type of skin preparation used by the three participating practices differed, but we found no previously published evidence that this makes any difference to infection rates.²¹ A total of 42 participants were lost to follow-up. If all 21 participants who were lost to follow-up in the intervention group had developed an infection, the rates of infection in both groups would have been similar (10.4% and 11.0%); however, we believe that this scenario is extremely unlikely.

Diagnosis of infection—even when guidelines are used—is still subjective, and inter-observer and intra-observer variation may occur.²⁰ The definition we used is the most widely implemented standard definition of wound infection,¹⁹ and by developing our own wound assessment scale we hoped to reduce the subjectivity of diagnosis of infection. We have no evidence to support the intra-practice and inter-practice reproducibility of measurement and recording procedures.

The study did not have an arm in which no ointment was applied, so we do not know if the ointment itself had any pro-infective or anti-infective properties. The ointment base of Chloromycetin consists of a mixture of soft white paraffin, liquid paraffin, and plastibase 30W, which is a plasticised hydrocarbon gel consisting of 95% mineral oil and 5% polyethylene glycol. We could not get information about the exact proportions of these constituents from the manufacturer. Our placebo ointment consisted of 50% soft white paraffin and 50% liquid paraffin and was not completely identical to the ointment base of Chloromycetin as it did not contain plastibase 30W. We cannot determine if this substance has an effect on infection, although we think that this is unlikely. Our trial used only a single dose of chloramphenicol ointment. We have no reason to surmise that repeated doses might lead to a greater reduction in infection rate.

Table 3 | Incidence of wound infections in intervention (chloramphenicol) and control (paraffin) groups

Infections	Intervention group (n=488)	Control group (n=484)	Combined results (n=972)
No of infections	32	53	85
Incidence of infection	6.6%	11.0%	8.7%
Relative risk (95% CI) of infection	1 (reference category)	1.7 (1.1 to 2.5)	NA
Wound score:	(n=487)	(n=483)	(n=970)
Stitch abscess	14 (2.9%)	14 (2.9%)	28 (2.9%)
<1 cm erythema	67 (13.8%)	62 (12.8%)	129 (13.3%)
>1 cm erythema	27 (5.5%)	44 (9.1%)	71 (7.3%)

NA=not applicable.

Generalisability

Some limits to generalising these findings exist. The population of Mackay is slightly older than the general Australian population and has a lower median household income.²² Mackay is a provincial town in tropical North Queensland. The climate is hot and humid, with a mean daily maximum temperature ranging between 24.2°C and 30°C during the summer months and a relative humidity of 75–79%.²³ These tropical conditions could increase sweat production and produce damp dressings, which might reduce the effectiveness of wound dressings as a potential barrier against exogenous bacteria.^{24–26} This would make wounds more prone to infection in a tropical environment, so the results may not necessarily be generalisable to a temperate climate, although no published evidence shows that heat and humidity increase infection rates. This might also explain why our infection rates were higher than suggested by previous data from temperate climates.^{11–13}

Antibiotic use

Some concern exists about the overuse of topical antibiotics resulting in antibiotic resistance. British and Australian guidelines suggest that use of topical antibiotics should be restricted because of the capacity of most topical drugs to select resistant micro-organisms and to cause sensitisation. The guidelines also suggest that antimicrobials recommended for topical use should be selected from classes not in use for systemic treatment.³²⁷ A contrary argument says that the potential for antimicrobial resistance with topical antibiotics is actually lower than with systemic antibiotics because of the higher local concentration achieved by topical delivery.²⁸ Patterns of

antimicrobial activity and resistance have been examined for other antibiotic ointments.^{29,30} However, no evidence exists, over three decades of extensive use worldwide, to show that, with the exception of mupirocin, topical antibiotics administered on an outpatient basis contribute to any emerging resistance pattern.²⁸ Chloramphenicol eye drops have been shown to be effective in the treatment of methicillin resistant *Staphylococcus aureus* ocular surface infections.³¹

Some concern also exists about the incidence of allergic contact dermatitis with use of topical antibiotics. For topical neomycin, this has been shown to be as high as 11% in a population referred for diagnostic patch testing.³² However, some evidence shows that the incidence of this reaction is as low as 1% when the ointment is used in the general population.²⁸ The reaction is much more common among patients previously exposed to neomycin ointment.³² Contact allergy has been reported with the use of chloramphenicol ointment, but the incidence is thought to be low.^{33,34} Although any connection between the use of topical chloramphenicol and aplastic anaemia is unlikely,^{7,8} our study was not large enough to fully assess the risk in this setting.

Antibiotic prophylaxis is probably prescribed excessively or inappropriately for dermatological surgery and is thought to be best reserved for patients at high risk.^{19,35,36} No data are available on the current prescribing habits of Australian general practitioners regarding oral or topical antibiotic prophylaxis for minor excisions. Although no evidence is available on what reduction in the rate of infection we might reasonably expect from the use of oral prophylactic antibiotics for minor excisions, some evidence shows a 50% reduction in risk of infection when perioperative oral antibiotic prophylaxis is used after clean surgery.¹⁷ A similar reduction in infection rate from a single dose of topical antibiotic, as in this study, may encourage a reduction in the use of oral antibiotics.

The decision to prescribe antibiotic prophylaxis is complicated; in addition to efficacy, the antibiotic costs, adverse effects, and resistance should be taken into account. However, in some circumstances, topical delivery of antibiotic may be preferable to systemic administration.³²⁷ The results of this study could encourage the judicious use of topical antibiotics after minor skin surgery. However, topical

WHAT IS ALREADY KNOWN ON THIS TOPIC

A survey of UK plastic surgeons showed that 66% use chloramphenicol ointment in some capacity

A small pilot study suggested that chloramphenicol ointment might reduce the incidence of wound infection

No published studies have been done in a primary care setting

WHAT THIS STUDY ADDS

A single application of topical chloramphenicol to high risk sutured wounds reduced infection by 40%

chloramphenicol would be unlikely to produce a worthwhile absolute reduction in infection rates in low risk settings in developed countries. Future research could explore the possibility that important reductions may be seen in higher risk wounds or in more resource poor settings.

Conclusion

This study suggests that application of a single dose of topical chloramphenicol to high risk sutured wounds after minor surgery produces a moderate absolute reduction in infection rate.

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