A prospective, randomized pilot evaluation of topical triple antibiotic versus mupirocin for the prevention of uncomplicated soft tissue wound infection

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
Triple antibiotic ointment (TAO) was compared with mupirocin ointment (pseudomonic acid A) for the prevention of uncomplicated soft tissue wound infections. The TAO consisted of a combination of neomycin sulphate, bacitracin zinc and polymixin B sulphate.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with uncomplicated soft tissue wounds. The inclusion criteria specified patients presenting to the Emergency Department (ED) for uncomplicated soft tissue wounds within the last 24 hours, who were willing to return within 7 days for re-evaluation. There was no limitation on the underlying medical conditions. The exclusion criteria included puncture wounds, underlying fracture, use of antibiotics within the last 7 days, known allergy to the study agents, and wounds closed with Dermabond. Also excluded were patients with wounds that, in the opinion of the treating physician, required the use of oral or parenteral antibiotics, and wounds that were found to be infected at the time of presentation.

Setting
The setting was primary care. The study was conducted in the USA.

Dates to which data relate
Both the effectiveness and cost data related to 2001. The prices probably referred to the same year, although this was not explicitly stated.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients that was used for the effectiveness study.

Study sample
The study was designed to enrol 120 patients with the expectation that there would be a 20% dropout rate. It was
reported that the study was not powered to detect differences in efficacy between the groups. Patients were enrolled at presentation to the ED if they met the inclusion criteria. All of the patients initially received standard wound care and suturing. At the end of the follow-up period, 99 patients were available for the analysis. The mupirocin group consisted of 50 patients, and the remaining 49 patients formed the TAO group. The average age of the patients was 24.7 (±/17.8) years. There was no evidence that the initial study sample was appropriate for the clinical study question.

Study design
This was a randomised controlled trial (RCT) that was conducted in the ED of one hospital. Randomisation was conducted at the patient level. No details of the method of randomisation were reported. The follow-up period was one week. Twenty-one of the 120 patients initially enrolled were lost to follow-up. The patients, treating physicians and study investigators were blinded to the identity of the study medication.

Analysis of effectiveness
The medications examined were self-administered. Patient compliance was self-reported. Patients who did not completely comply with study procedures, but for whom follow-up data were available, were included in the analysis. The primary health outcome used was the presence of infection within 7 days. This was determined by an evaluation for fever, erythema, oedema, induration, swelling, warmth, exudate, adenopathy and lymphangitis. The secondary outcomes included pain associated with the wound, and adverse events caused by the agents administered. The two groups were shown to be comparable in terms of their baseline characteristics such as age and gender, wound characteristics, number and type of sutures, and pre-pain scores. Moreover, they had similar rates of self-reported compliance. No adjustments for potential confounding factors were reported.

Effectiveness results
The number of infected wounds within one week was 0 for the TAO group and 2 (4%) for the mupirocin group, \( p=0.5 \).

The rates of secondary outcomes were similar for the two groups.

Clinical conclusions
There was no significant difference in rate of wound infection, pain attenuation or adverse events between the two groups.

Measure of benefits used in the economic analysis
There was no summary measure of benefit. In effect, a cost-consequences analysis was conducted.

Direct costs
The perspective of the payer was adopted in the study. The costs covered medication and treatment in the event of an infection. Since neither of the two infections observed in the study sample were judged to require treatment, the cost analysis was a comparison of medication costs only, based on average wholesale prices. The total quantities of medications used were not accounted for in the analysis. The prices probably referred to 2001, the year during which the study was conducted. Discounting was unnecessary since the costs were incurred during one week.

Statistical analysis of costs
The costs were treated deterministically. No statistical analysis of the costs was conducted.

Indirect Costs
The indirect costs were not included in the analysis.
Currency
US dollars ($).

Sensitivity analysis
It was stated that it had been intended to carry out a sensitivity analysis by varying all cost estimates to determine their impact on the results. However it was not performed, as, in the end, the economic analysis was restricted to a comparison of the cost of medication.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The average wholesale price was $41.00 ($1.86/g) for a 22 g tube of mupirocin and $6.95 ($0.25/g) for a 28 g tube of TAO.

A tube of mupirocin cost $34.05 more than a tube of TAO.

Synthesis of costs and benefits
Not applicable.

Authors' conclusions
The triple antibiotic ointment (TAO) was equally effective and less costly than mupirocin. Therefore, TAO was cost-effective for the prevention of infections in uncomplicated soft tissue wounds.

CRD COMMENTARY - Selection of comparators
There was no explicit justification for the selection of the comparators. However, both interventions were known to be highly effective antibiotic treatments. You should consider whether any of these interventions reflects widely adopted practice in your own setting.

Validity of estimate of measure of effectiveness
The basis of the analysis was a triple-blinded RCT, which is the 'gold' standard method for the evaluation of effectiveness. Details of the method of randomisation were not provided. It was reported that the effectiveness results differed from those reported in other studies, and this might be due to selection bias. Patients were included in the study only if they presented to the ED when the study coordinators were present (and not, for example, if they arrived at the ED late at night), and only if they agreed to return in one week for re-evaluation. Therefore, the patient sample might not have been representative of the patient population. The two groups were shown to be comparable at analysis. A statistical analysis to account for potential biases and confounding factors was not conducted. The study power was inadequate to detect differences in efficacy between the groups.

Validity of estimate of measure of benefit
The analysis of benefits was based upon the therapeutic equivalence of the treatment alternatives. The economic analysis therefore included only the costs.

Validity of estimate of costs
The perspective of a payer was adopted in the study. All the categories of cost relevant to this perspective were included
in the analysis. Since the costs of treating wound infections were zero, the analysis was limited to a comparison of medication costs. Only the unit costs were used for the comparison. The total quantities of medication applied to the patient groups were not estimated, which limits the generalisability of the results. No statistical or sensitivity analysis of the costs was carried out. The date to which the prices related was not explicitly reported, which hinders the reproducibility of the results. Discounting was not relevant and was therefore not conducted. The authors' conclusions were based on the difference in medication costs only, which may have been specific to the USA and not generalisable to other settings.

**Other issues**

The authors made appropriate comparisons of their results with those from other studies. However, the issue of the generalisability of the results to other settings was not addressed. An additional limitation of the study, as the authors acknowledged, was the fact that patient compliance was self-reported. The study results were adequately presented. The authors reported that this was a pilot study with preliminary results, which should be confirmed in a larger trial. Their conclusions reflected the scope of the analysis.

**Implications of the study**

The authors suggested that their results be confirmed in a larger trial with design elements that control factors potentially affecting the validity of the results. They stated that, if their results are confirmed, TAO could be recommended for the prevention of infections in uncomplicated soft tissue wounds.

**Source of funding**

Supported by a grant from Pfizer Consumer Healthcare.

**Bibliographic details**


**PubMedID**

14724869

**Indexing Status**

Subject indexing assigned by NLM

**MeSH**

Administration, Topical; Adult; Anti-Bacterial Agents /administration & dosage; Bacitracin /administration & dosage; Bacterial Infections /prevention & control; Chi-Square Distribution; Drug Combinations; Female; Humans; Male; Mupirocin /administration & dosage; Neomycin /administration & dosage; Ointments; Pilot Projects; Polymyxin B /administration & dosage; Prospective Studies; Statistics, Nonparametric; Treatment Outcome; Wound Infection /prevention & control

**AccessionNumber**

22004000299

**Date bibliographic record published**

30/11/2004

**Date abstract record published**

30/11/2004