

A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention

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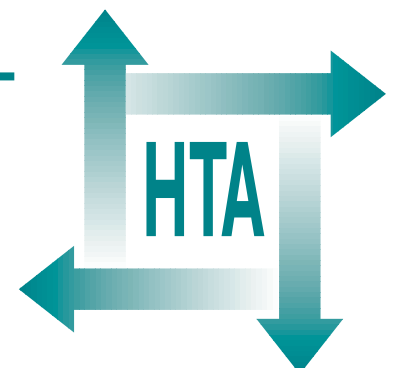
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Executive summary

Health Technology Assessment 2001; Vol. 5: No. 14

Health Technology Assessment
NHS R&D HTA Programme





Executive summary

Background

Most surgically sutured wounds heal without any complication. However, in some cases wound healing can be delayed due to the presence of infection or wound breakdown. This can result in the wounds becoming cavity wounds and thus necessitate healing by secondary intention. Other surgical wounds that are not sutured but left to heal by secondary intention include abscess cavities such as perianal abscesses or breast abscesses.

Surgical wounds healing by secondary intention are thought to heal more slowly than wounds healing by primary intention, especially if infection is present or healing is compromised by factors such as decreased blood supply, poor nutritional status or a general suppression of the immune response. Such wounds may contain dead tissue and have a moderate or high level of exudate.

Debridement involves the removal of devitalised, necrotic tissue or fibrin from a wound. There are many different methods that can be used to debride a wound, which are broadly classified as surgical/sharp, biosurgical, mechanical, chemical, enzymatic and autolytic. Although it is generally agreed that the management of surgical wounds which contain devitalised tissue and are healing by secondary intention requires debridement, it is not always clear as to what is the best method or agent to use. There is currently a large selection of products with debriding properties available on the market, which vary considerably in cost. It is important that the choice of both debriding method and product is based on the best scientific evidence available, taking into account both cost and effectiveness data.

Objectives

The review had two main objectives:

- To determine the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention.
- To evaluate the clinical effectiveness and cost-effectiveness of treating patients with surgical

wounds healing by secondary intention at specialised wound care clinics as compared to conventional care.

The review incorporated all debriding methods and any agent that is considered to have a debriding property.

Methods

The following databases were searched using strategies designed specifically for each database: MEDLINE, EMBASE, CINAHL, HMIC (Health Management Information Consortium), CCTR via the Cochrane Library, the National Research Register (NRR), the NHS Economic Evaluation Database (NHS EED), and the Health Economic Evaluations Database (HEED). Additional references were identified through reviewing manufacturer and sponsor submissions made to NICE, the bibliographies of retrieved articles, and conferences proceedings on the Internet.

Only randomised controlled trials (RCTs) or non-randomised controlled trials with concurrent controls and full economic evaluations were considered for inclusion. Only studies that evaluated some sort of debriding method or a specialised wound care clinic (a nurse with specialist training in wound care; care being provided by a multidisciplinary team; a fast-track referral system to other professions (e.g. dermatologist); or access to the latest health technology) were included in the review. Studies had to include participants with surgical wounds healing by secondary intention (e.g. cavity wounds, the consequences of wound dehiscence and abscesses) and report an objective measure of wound healing.

Data were extracted by one reviewer and checked by a second. Quality assessment was conducted independently by two reviewers. Disagreements were resolved by consensus and, when necessary, by recourse to a third reviewer. The primary outcomes of interest were wound healing and cost. Results of data extraction and quality assessment were presented in structured tables and also as a narrative summary. In addition, where feasible, ►

the results of individual studies were presented as forest plots. Studies were grouped according to the type of wound, debriding method and outcome measure used.

Results

Clinical effectiveness

Seventeen trials met the inclusion criteria, all of which used the autolytic method of debridement. No studies were found that investigated sharp/surgical, biosurgical, mechanical, chemical or enzymatic debridement in the treatment of surgical wounds healing by secondary intention. No studies were found which investigated specialised wound care clinics that included the provision of care within a clinical setting (based in either primary or secondary care). The type of surgical wounds investigated by studies included in the review were those that had broken down post-operatively, perineal wounds resulting from proctectomy or rectal excision, and those left open after pilonidal sinus excision or abscess incision, or wounds following a laparotomy. Four additional studies investigated treatment of postoperative wounds from toenail avulsions. The debriding agents investigated included foam dressings (silicone elastomer foam dressings and polyurethane foam dressings), alginate dressings, hydrocolloid dressings, and dextranomer polysaccharide bead dressings. For the purposes of this review these are referred to collectively as modern dressings. Most were compared to plain or impregnated gauze dressings. However, there was a great variation between trials with respect to the type of antiseptic solution that the gauze was soaked in or the type of gauze-based dressing used. Three trials included a direct comparison of two types of modern dressings. One trial compared polyurethane foam with alginate dressings and another trial compared it with silicone foam. The third trial compared dextranomer polysaccharide with silicone foam dressings. The heterogeneous nature of the included studies precluded statistical pooling of results.

Methodological quality of clinical effectiveness data

On the whole, included trials tended to have a small sample size (median = 43 participants) and the majority suffered from methodological flaws. The total number of participants included in the trials was 783. Detailed information relating to the randomisation procedure and blinding was not reported in most trials. Many trials failed to report the initial wound size and baseline characteristics

of included participants. The majority of trials that used the outcome measure 'time to complete healing' reported mean values instead of median values. Mean healing times may not represent the healing events in an appropriate way as they are greatly affected by outliers and, unlike median times, cannot be calculated if some wounds fail to heal. Almost half of the included trials did not report the results in sufficient detail to calculate a summary estimate of the treatment effect, for one or more outcome measures. The statistical test used to compare the treatment groups was often not reported or no statistical test was used.

Overall findings of clinical effectiveness

In summary, there is a suggestion that modern dressings have a beneficial effect on healing compared to traditional gauze dressings, especially for toenail avulsions, where significant benefits of modern dressings were found. However, these results should be interpreted with caution due to the poor quality of the studies, the fact that the direction of bias is unclear and the unknown effects of potential publication bias.

There is some evidence to suggest a beneficial effect of modern dressings for surgical wounds on other outcomes, such as pain, dressing performance and resource use, although a beneficial effect for these outcomes was not found for studies of toenail avulsions. However, in addition to the methodological problems highlighted above, these outcome measures are very difficult to assess and are particularly subject to bias, especially in unblinded studies.

In view of the lack of data and the poor methodological quality of the trials, there is no evidence to support the superiority of one type of modern dressing over another.

Cost-effectiveness

Four economic evaluations met the inclusion criteria. All four studies included a cost-effectiveness analysis of an autolytic debriding method compared with traditional gauze dressings soaked in various antiseptic solutions. The dressings investigated were silicone elastomer foam dressings, polyurethane foam dressings and calcium alginate dressings. No economic evaluations that compared the cost-effectiveness of two different types of modern dressings were found. No economic evaluations investigating specialised wound care clinics were found.

Conclusions

The results of the cost-effectiveness data suggest partial dominance in favour of the intervention, and only the cost data support the use of the intervention dressings (modern dressings were found to have lower costs than the gauze dressings, but with no difference in the outcome measures). However, the quality of the clinical effectiveness and cost-effectiveness analyses are poor.

Generalisability of the review findings

The majority of included studies were UK based, within the NHS setting. Two of the included trials were based in a military hospital and five trials were based outside the UK (Australia, USA, France, Italy and Spain). Studies were published between 1979 and 2000, four before 1984 and the remainder between 1991 and 2000.

Implications for future research

The review identified the following areas for future research:

- Large multicentre trials of good methodological quality comparing foam, alginate, hydrofibre, hydrocolloid or dextranomer bead dressings with standard treatment or, preferably, to each other. It is acknowledged that it may be difficult to recruit sufficient numbers of patients with similar wounds from a single centre/hospital.
- More good-quality economic evaluations of modern dressings that are based on sound scientific evidence, such as good-quality primary RCTs. This would mean that information relating to such outcome measures

as time taken to change the dressings, number of dressing changes required and number of nursing visits could be measured accurately. Economic evaluations would also need to utilise sensitivity analyses that investigate the effect on the overall findings of adjusting these variables.

- RCTs of other autolytic debriding methods not covered by included trials, such as hydrogels.
- Further research, in both clinical effectiveness and cost-effectiveness, into the use of other debriding methods, such as enzymatic, biosurgical and surgical methods, in the treatment of surgical wounds healing by secondary intention.
- Because there is no research available on the organisation of care, such as the use of specialist wound care clinics, research that includes studies looking at both the clinical effectiveness and cost-effectiveness of the use of specialised wound care clinics is required.
- Further epidemiological studies to evaluate the extent of the problem (i.e. the prevalence and cost to the NHS of treating surgical wounds healing by secondary intention where there is a delay in the healing process).

Publication

Lewis R, Whiting P, ter Riet G, O'Meara S, Glanville J. A rapid and systematic review of the clinical effectiveness and cost-effectiveness of debriding agents in treating surgical wounds healing by secondary intention. *Health Technol Assess* 2001;5(14).

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The research reported in this monograph was funded as project number 00/03/01.

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ISSN 1366-5278

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Published by Core Research, Alton, on behalf of the NCCHTA.
Printed on acid-free paper in the UK by The Basingstoke Press, Basingstoke.

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