

Negative-pressure wound therapy compared with standard dressings following surgical treatment of major trauma to the lower limb: the WHiST RCT

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Scientific summary

The WHiST RCT

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Scientific summary

Background

Major trauma is the leading cause of death worldwide in people aged < 45 years and a significant cause of short- and long-term morbidity. In 2010, the UK National Audit Office estimated that major trauma costs the NHS between £0.3B and £0.4B a year in immediate treatment, with an annual lost economic output of between £3.3B and £3.7B.

The limbs are affected in 85% of patients with major trauma. Rates of infection following surgery for fractures of the lower limb after major trauma have been reported to be as high as 27%. One of the factors that may reduce the risk of infection in the surgical wounds of major trauma patients is the type of dressing applied over the incision at the end of the operative procedure.

New techniques for wound management are being developed but are often implemented into the NHS without sufficient evidence. Negative-pressure wound therapy has provided promising preliminary results in different patient groups, but there is limited evidence in patients with surgical wounds associated with major trauma.

Objectives

The aim of this pragmatic randomised controlled trial was to compare standard dressings with incisional negative-pressure wound therapy for the treatment of surgical incisions associated with major trauma to the lower limb.

The primary objective of the randomised controlled trial was to:

- estimate differences in the rate of deep surgical site infection within 30 days of surgery for fractures associated with major trauma to the lower limbs between standard dressing and incisional negative-pressure wound therapy.

Any infection that required continuing medical intervention or had already led to amputation at the 30-day review was considered a deep surgical site infection.

The secondary objectives were to:

- estimate differences in the Disability Rating Index and health-related quality of life (measured using the EuroQol-5 Dimensions) in the 6 months after surgery for the major trauma
- estimate differences in general health-related quality of life in the 6 months after the surgery for major trauma
- estimate differences in wound healing using a validated, patient-reported assessment of the scar
- determine the number and nature of postoperative complications, including further surgical interventions related to the injury, in the first 6 months after surgery
- investigate, using appropriate statistical and economic analysis methods, the resource use, and therefore the cost-effectiveness, of incisional negative-pressure wound therapy versus standard dressing for wounds associated with major trauma to the lower limbs.

Methods

All adult patients presenting at the recruitment centres within 72 hours of sustaining major trauma and who required a surgical incision to treat a fractured lower limb were potentially eligible for inclusion. Patients were enrolled after prospective consent or agreement obtained from a consultee. For those patients enrolled through consultee agreement, consent was sought from the patients when they regained capacity. A randomisation sequence, stratified by recruitment centre, open versus closed fracture at presentation and Injury Severity Score of ≤ 15 versus ≥ 16 , was produced and administered by a secured web-based service. The random allocation was 1 : 1 to standard wound management or incisional negative-pressure wound therapy.

All patients had clinical follow-up to a minimum of 6 months, as per standard NHS practice after such injury. Photographs of the wound were taken at 30 days to assess wound healing and signs of infection. The quality of the surgical scar was assessed by participants using a validated self-reported tool. Disability and quality-of-life data were collected using the Disability Rating Index and the EuroQol-5 Dimensions questionnaire at 30 days, 3 months and 6 months post surgery. Questionnaires were administered centrally by a data administrator. In addition, at the same time points, information was requested with regard to resource use and any late complications or surgical interventions related to their injury, with specific note of continuing treatment for deep infection.

Outcome

The main analysis investigated differences in the primary outcome measure, the proportion of patients with deep infection at 30 days post surgery (post randomisation). The stratified randomisation procedure ensured balance in the recruitment centres, open fractures and Injury Severity Scores between test interventions. The within-trial economic evaluation was conducted in line with the reference case required by the National Institute for Health and Care Excellence for technology appraisal, such that costs were estimated from an NHS and Personal Social Services perspective, and health utilities were derived from the EuroQol-5 Dimensions instrument using UK tariffs.

Results

Between September 2016 and April 2018, 1629 patients were randomised for inclusion in the trial from 24 recruitment centres representing the UK Major Trauma Network. Of these, 1548 participants were willing and able to provide informed consent. The primary outcome measure of deep infection at 30 days was collected in 98% of participants.

The rate of deep infection at 30 days was 6.7% (50/749) in the standard dressing group and 5.8% (45/770) in the incisional negative-pressure wound therapy group (intention-to-treat odds ratio 0.87, 95% confidence interval 0.57 to 1.33; $p = 0.52$).

There was no evidence of a difference in the associated per-protocol analysis (analysis by treatment received) or in the secondary time point of deep surgical site infection at 90 days; 13.2% (78/590) in the standard dressing group and 11.4% (72/629) in the incisional negative-pressure wound therapy group developed deep surgical site infections over 3 months (odds ratio 0.84, 95% confidence interval 0.59 to 1.19; $p = 0.32$).

Similarly, there was no evidence of a difference between the groups in terms of the secondary outcome measures. Participants' self-reported Disability Rating Index at 6 months was 40.2 (standard deviation 26.73) in the standard dressing group versus 40.6 (standard deviation 24.98) in the incisional negative-pressure wound therapy group (mean difference 0.03, 95% confidence interval -2.82 to 2.88 ; $p = 0.98$). The health-related quality of life at 6 months was 0.6 (standard deviation 0.29) in the standard dressing group and 0.6

(standard deviation 0.28) in the incisional negative-pressure wound therapy group (mean difference 0.00, 95% confidence interval -0.03 to 0.04 ; $p = 0.86$). The patients' overall self-assessment of their surgical scar was 4.6 (standard deviation 2.65) in the standard dressing group and 4.4 (standard deviation 2.65) in the incisional negative-pressure wound therapy group (mean difference -0.18 , 95% confidence interval -0.46 to 0.10 ; $p = 0.22$). There was no evidence of a difference in the rate of other postoperative complications.

The incremental cost-effectiveness ratio in the base-case analysis was £396,531 per quality of life-year gained, which indicated that incisional negative-pressure wound therapy had higher costs and marginally better outcomes than standard dressings. The health economic evaluation therefore indicated that incisional negative-pressure wound therapy is very unlikely to be cost-effective.

Conclusions

There was no evidence of a difference in the rate of surgical site infection between those patients treated with incisional negative-pressure wound therapy and those treated with standard wound dressings. There was no difference in the rate of other wound healing complications, nor any difference in the patients' self-report of disability or health-related quality of life. Incisional negative-pressure wound therapy is very unlikely to be cost-effective.

In conclusion, and contrary to previous reports, incisional negative-pressure wound therapy did not provide a clinical or economic benefit for patients with surgical incisions associated with major trauma to the lower limbs.

Trial registration

This trial is registered as Current Controlled Trials ISRCTN12702354 and UK Clinical Research Network Portfolio ID20416.

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