

The epidemiology, management and impact of surgical wounds healing by secondary intention: a research programme including the SWHSI feasibility RCT

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Scientific summary

The SWHSI research programme and feasibility RCT

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Scientific summary

Background

Surgical wounds healing by secondary intention are open wounds that heal from the base up. Healing by secondary intention may be planned (e.g. due to infection) or unplanned [e.g. when a wound has been closed but then opens (dehisces), either fully or partially]. Surgical wounds healing by secondary intention may remain open for many months, are prone to infection and may prolong or require further hospital stays, adversely affecting patients' quality of life and incurring substantial NHS costs.

The lack of available research evidence regarding surgical wounds healing by secondary intention at the start of this programme meant that clinicians and patients lacked evidence regarding surgical wounds healing by secondary intention management, what treatment options were most effective and which treatments were best value for money. The lack of basic data regarding the frequency, characteristics, current treatments, healing trajectory and impact meant that it was difficult to plan new primary research.

Objectives

The overall aim of the programme was to derive a better understanding of the nature, extent, costs, impact and outcomes of surgical wound healing by secondary intention, effective treatments, and the value and nature of further research. The objectives were as follows:

- Workstream 1 – to describe the number, characteristics, current treatments, impacts and health outcomes of patients with surgical wounds healing by secondary intention.
- Workstream 2 – to use all available research data to estimate the cost-effectiveness of current treatments for surgical wounds healing by secondary intention (identified in workstream 1) and to assess whether or not investment in future research on treatments for surgical wounds healing by secondary intention was likely to be worthwhile and, if so, what research would offer best value for money.
- Workstream 3 – to determine the impact of surgical wounds healing by secondary intention on patients, specifically their perspectives and experiences of living with a surgical wound healing by secondary intention, of wound management and relevant wound outcomes, and to determine NHS health-care professionals' views of surgical wounds healing by secondary intention treatments and outcomes to measure treatment effects.
- Workstream 4 – to determine the feasibility of conducting further primary research on surgical wounds healing by secondary intention through a pilot feasibility randomised controlled trial.

Methods and results

Workstream 1

An inception cohort approach was used to enable accurate assessment of time to healing and treatment use. Given the lack of information on patient numbers and care locations, the cohort study was preceded by a cross-sectional survey, which enabled point prevalence of treated surgical wounds healing by secondary intention to be assessed.

Our cross-sectional survey, conducted in East Yorkshire, UK, obtained 200 responses, with the majority of responses received from community or district nurses ($n = 77$, 41.2%), followed by research nurses ($n = 44$, 23.5%). Data from 187 patients were analysed, giving an estimated point prevalence of treated surgical wounds healing by secondary intention of 4.1 per 10,000 population (95% confidence interval 3.5 to 4.7

per 10,000 population). Most patients had only one surgical wound healing by secondary intention (87.7%) and the most common surgical procedure resulting in a surgical wound healing by secondary intention was for pilonidal sinuses/abscesses (15.0%). Half of surgical wounds healing by secondary intention were planned (47.6%) and the median wound duration at the point of survey was 28 (95% confidence interval 21 to 35) days. Most patients (98.4%) were receiving active treatment, most commonly wound dressings (93.4%), and care was frequently provided in community settings (58.3%).

Our cohort study, conducted in eight primary, secondary and community care sites in Yorkshire and the Humber, UK, recruited 396 participants, with 393 participants included in the analysis (three patients were subsequently ineligible). Participants were followed up for a minimum of 12 months and a maximum of 21 months to collect key clinical outcome data (including healing, surgical site infection, hospital readmission, treatments received, changes to study involvement) and quality-of-life and pain assessments. The median age of participants was 55 years (range 19–95 years), 69.5% of participants were overweight or obese and 28.5% were current smokers. The most common comorbidities were cardiovascular disease (38.4%), diabetes mellitus (26.2%) and peripheral vascular disease (14.5%). Most patients had only one surgical wound healing by secondary intention (91.0%), had no previous history of surgical wounds healing by secondary intention (72.0%) and had a surgical wound healing by secondary intention that was planned (60.1%), with the most common site being the abdomen (33.6%), reflecting that colorectal surgery was the most commonly represented surgical specialty (39.7%). The most common treatment was hydrofibre dressings (65.9%), and 29.3% of participants reported receiving negative-pressure wound therapy during the study.

In our cohort study, data indicated that surgical wounds healing by secondary intention healed for 81.4% of participants ($n = 320$), with a median time to healing of 86 days (95% confidence interval 75 to 103 days). Area greater than the baseline median (6 cm²) ($p < 0.01$), surgical wound contamination level as determined at the point of surgery ($p = 0.04$) and surgical site infection at any point ($p < 0.01$) were significant predictors of prolonged time to healing. Quality of life remained constant during the study, whereas pain severity, interference and Short Form questionnaire-12 items scores improved over time.

Workstream 2

Econometric models were applied to cohort data collected in workstream 1 to assess the clinical effectiveness and cost-effectiveness of negative-pressure wound therapy, when compared with standard dressings; no published research data could be identified to complement the cohort data in the model. The lack of randomised controlled trial data on the relative effects of negative-pressure wound therapy in surgical wounds healing by secondary intention therefore resulted in much of the economic modelling being based on observational data. A Bayesian approach to inferences was used, computed using Markov chain Monte Carlo simulation. Time to healing was modelled using two approaches: ordinary least squares with imputation, using an instrumental variable regression to adjust for unobservable confounding (model A); and a two-stage model, using logistic regression followed by linear regression (model B). Instrumental variables were identified to adjust for unobservable confounding.

Model A identified that participants who received negative-pressure wound therapy were expected to take longer to heal than those who did not receive negative-pressure wound therapy: on average, 73 days longer (95% credible interval 33.8 to 112.8 days longer). This was maintained when interaction terms (treatment and surgical wound healing by secondary intention history) and expert opinions on censoring of healing times were included. Model B identified that participants who received negative-pressure wound therapy were estimated to have lower probability of healing (odds ratio 0.59, 95% credible interval 0.28 to 1.12) and time to healing was an additional 46 days (95% credible interval 19.6 to 72.5 days). Conclusions were similar in both approaches when adjusted for unobservables.

Cost-effectiveness estimates indicated that negative-pressure wound therapy was expected to be less cost-effective than standard dressings [associated incremental quality-adjusted life-years of -0.012 (standard error 0.005) (model A, observables) and -0.008 (standard error 0.011) (model A, unobservables),

–0.007 (standard error 0.004) (model B, observables) and –0.027 (standard error 0.017) (model B, unobservables)]. There was little decision uncertainty in this result.

Workstream 3

Semistructured qualitative interviews were conducted with 20 patients (with experience of a surgical wound healing by secondary intention), five surgeons and seven nurses, using topic guides. Interviews were audio-recorded, transcribed and analysed using a ‘framework’ approach.

Patients reported that unplanned surgical wounds healing by secondary intention resulted in feelings of alarm, shock, disbelief and disgust. Patients with previous experience of a surgical wound healing by secondary intention expected slow healing, whereas patients without previous surgical wound healing by secondary intention experience often had unrealistic expectations of time to healing. Patients were ever-hopeful that a new or untried treatment might accelerate or achieve wound healing, and there was a willingness to try any procedure or treatment to achieve this, even if it was unpleasant or lacked high-level evidence of efficacy. The main surgical wound healing by secondary intention treatments experienced were negative-pressure wound therapy, debridement, dressings and skin grafting. Patients would have liked more information in relation to the rationale for using different treatment methods and approaches.

Prolonged or multiple hospital admissions were not uncommon, and many patients reported feeling unsupported at the point of hospital discharge, owing to a lack of available information regarding follow-up care and infection management. Most patients received home visits from district, community or general practice nurses during their wound healing. Patients acknowledged that the nurses tried to attend to all needs during the visit, but felt that nurses had limited time to devote to each visit.

Wound-related symptoms had a negative impact on daily life, physical and psychosocial functioning, and well-being. Limited physical mobility was frustrating and disrupted normal activities, and patients felt unable to socialise due to concerns about their self-image. Disruption of roles and responsibilities within the family unit was common, and patients reported feeling burdensome and dependent. This appeared particularly difficult for younger male participants who were often the main earner in the family.

Surgeons and nurses agreed that a number of factors were associated with delayed healing, including surgical (e.g. reason for surgery, procedure type), patient comorbidity, systemic infection, medication, mobility and treatment compliance factors. In many instances, it was difficult to identify any specific reason for impaired wound healing. Specific wound factors reported to be associated with healing included wound size, presence of wound infection, slough and/or granulation tissue and condition of the wound edges. Nurses also emphasised psychosocial and practical issues that might have an impact on patients’ quality of life, such as family support and patients’ potential for self-care of the wound.

The majority of patients operated on by general surgeons had their wound care passed to nurses following discharge. Plastic and vascular surgeons were more likely to continue to care for ‘their’ patients through follow-up in specialist clinics. Surgeons relied on nurses to make appropriate dressing choices, which were influenced by wound-, patient- and dressing-specific factors. Surgeons or tissue viability specialists often initiated decisions regarding the use of negative-pressure wound therapy, as knowledge and expertise regarding negative-pressure wound therapy among general nurses was often limited. Tissue viability specialists were a frequent point of reference for nurses regarding the management of complex, non-healing open surgical wounds.

Surgeons reported that use of negative-pressure wound therapy was increasing and that complex, cavity wounds (e.g. extensive abdominal wounds) were ideally suited to benefit from negative-pressure wound therapy. Negative-pressure wound therapy was generally perceived as a cost-effective and transformative treatment, particularly for patients with hard-to-heal wounds. Surgeons noted the lack of research evidence relating to negative-pressure wound therapy, but felt that their own and colleagues’ experiences supported its use.

Workstream 4

A pilot, feasibility randomised controlled trial was designed to test the methods and the feasibility of conducting a larger randomised controlled trial to assess clinical effectiveness and cost-effectiveness of negative-pressure wound therapy compared with usual care (no negative-pressure wound therapy). In total, 41 participants were recruited from two secondary and one community care NHS trust in the north of England. Forty participants were subsequently included in the analysis (one participant was randomised in error). Using a 1 : 1 ratio, participants were allocated to one of two groups: negative-pressure wound therapy ($n = 19$, 47.5%) and usual care (no negative-pressure wound therapy) ($n = 21$, 52.5%). Participants were recruited over 9 months and followed up for 3 months. An intention-to-treat analysis was conducted.

The proposed primary clinical outcome for a larger trial (time to wound healing) was assessed along with other clinical and feasibility outcomes, including recruitment and retention rates; time to treatment start; duration of and changes to negative-pressure wound therapy; clinical events; resource use data; documentation acceptability; and feasibility of blinded outcome assessment.

Of the 248 patients screened for eligibility, 186 (75.0%) were ineligible (including the patient randomised in error) and 22 (8.9%) were eligible but non-consenting. Common reasons for ineligibility included having previously received negative-pressure wound therapy on the surgical wound healing by secondary intention ($n = 45$, 18.1%), having received negative-pressure wound therapy in theatre for surgery resulting in the surgical wound healing by secondary intention ($n = 7$, 2.8%) or both ($n = 24$, 9.7%). Randomised participants received a median of eight (negative-pressure wound therapy) and seven (usual care) post-randomisation assessments. Participant questionnaire response rates were $\geq 78\%$ at all time points.

Two of the 19 participants allocated to negative-pressure wound therapy (10.5%) did not receive negative-pressure wound therapy, 10 (52.6%) received negative-pressure wound therapy within 24 hours and 14 (73.7%) received it within 48 hours. The most common reason for delay was the machine being unavailable ($n = 6$, 85.7%). Participants received negative-pressure wound therapy for a median of 18 (range 0–72) days. Five usual-care participants (23.8%) received negative-pressure wound therapy at a median of 4 days after randomisation (range 0–17 days).

Ten wounds (25.0%) were deemed to have healed during the study and 17 participants (42.5%) experienced a wound infection. The mean total cost for negative-pressure wound therapy was £9490 (standard deviation £7346) and for usual-care it was £1153 (standard deviation £1806). A substantial proportion of negative-pressure wound therapy costs were attributed to hospital stays [£7710 (standard deviation £7557)].

Of those providing a response ($n = 31$), 28 participants (90.3%) found completing study questionnaires to be straightforward. Half of the eight nurse respondents ($n = 4$) found the case report forms to be straightforward and the majority ($n = 6$, 75.0%) found the frequency of clinical assessments to be manageable. There were mixed opinions regarding processes for identifying potential participants.

Blinded assessment of wound healing, by up to three reviewers, agreed with unblinded nurse healing assessment in 95.0% of cases. Treatment allocation was correctly identified in 37.5% of cases ($n = 15$, nine participants to negative-pressure wound therapy and six to usual care).

Conclusions

This research has provided new information regarding the nature, extent, costs, impacts and outcomes of surgical wounds healing by secondary intention, insights into uncertainty around current treatment effectiveness and the value and nature of future research in this area.

The cross-sectional survey of 187 patients in Hull and East Yorkshire, UK, has provided an estimate of treated surgical wound healing by secondary intention prevalence of 4.1 per 10,000 population (95% confidence interval 3.5 to 4.7 per 10,000 population) and inception cohort data has provided the first detailed analysis of surgical wound healing by secondary intention patients, treatments and wound healing trajectories. The heterogeneity of the surgical wound healing by secondary intention population, wide distributions of location sites of surgical wounds healing by secondary intention, surgeries resulting in surgical wound healing by secondary intention and treatments used, and predictors of slower healing of surgical wounds healing by secondary intention (wound area, surgical wound contamination as determined at the point of surgery and surgical site infection at any time), have also been identified as a result of this work.

Qualitative interviews identified the devastating effect that surgical wounds healing by secondary intention may have on patients' quality of life. Patients were focused on complete wound healing and were willing to try any treatment that promised this. Healing is therefore a crucial outcome for future research into treatments for surgical wounds healing by secondary intention.

Cost-effectiveness models, using the observational cohort data, demonstrated, with little uncertainty, that negative-pressure wound therapy is less effective and more costly than standard dressings. Should a lack of confidence in these conclusions from observational data mean that a future randomised controlled trial is considered necessary, the design of this trial should be informed by this programme of work.

Recruitment to a randomised controlled trial to assess clinical effectiveness and cost-effectiveness of negative-pressure wound therapy for patients with surgical wounds healing by secondary intention has been identified to be possible. This is therefore encouraging for future research, which we suggest should focus on enhancing evidence for clinically effective and cost-effective treatments for surgical wound healing by secondary intention, identifying factors predicting time to healing, assessing interventions to improve patient quality of life and potential improvements that could be made to care pathways for surgical wounds healing by secondary intention.

Trial registration

The pilot feasibility trial component is registered as ISRCTN12761776.

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