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Extended Research Article

Effectiveness of surgical interventions in patients with severe pressure ulcers: the SIPS mixed-methods exploratory study

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Scientific summary

Effectiveness of surgical interventions in patients with severe pressure ulcers: the SIPS mixed-methods exploratory study

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Scientific summary

Background

Surgical reconstruction (SR) to close a severe pressure ulcer (SPU) compared with management without reconstruction [no surgical reconstruction (NSR)] has not been evaluated. A planned randomised controlled trial (RCT) was unsuccessful because the surgical procedures requiring evaluation, the comparator, or the patient groups to be studied could not be defined.

Aim

This study investigated the feasibility of research to evaluate the effectiveness of SR compared to NSR.

Objectives

Three workstreams (WSs) addressed uncertainties in elements of the research question about the effectiveness and cost-effectiveness of SR. Objectives were to:

- perform systematic reviews and surveys (WS1) to:
  - Obj1 (a) estimate the effectiveness of SR to close SPUs (review 1) and (b) the impact of pressure ulceration on health-related quality of life (HRQoL; review 2)
  - Obj2 elicit responses from healthcare professionals to describe patients referred for a surgical opinion about SR, procedures performed and post-SR care, and usual care before initiating a referral
- use routinely collected primary care and hospital data (WS2) to:
  - Obj3 describe patients with incident SPUs and their care pathways
  - Obj4 describe patients diagnosed with SPU at hospital admission, their care pathways and health outcomes
  - Obj5 compare outcomes in groups of patients, similar on hospital admission, who did or did not have SR and explore subgroup interactions with SR
- seek consensus (WS3) about:
  - Obj6 appropriate treatments and management strategies.

Methods

Workstream 1

Reviews used established methods. Review 1 (Obj1) searched for RCTs and non-randomised studies of interventions (NRSI) of SR to close a SPU. Review 2 (Obj2) searched only for RCTs of pressure ulcer (PU) prevention or treatment.

Surveys were developed for general practitioners (GPs), and nurses and surgeons managing SPUs, using SurveyMonkey® (Palo Alto, CA, USA), with free-text boxes for additional responses. GPs were asked about their knowledge of SR, referrals to secondary care for SPUs, and factors influencing referrals. Nurses' and surgeons' surveys asked about SR and other treatments, how characteristics of SPUs and patients influenced referral decisions, SPU recurrence and barriers to SR.

A binary choice experiment (BCE; Obj2) explored how patient/SPU characteristics interact to influence decisions to consider SR. Nurse and surgeon participants made consider/do not consider decisions about suitability for SR for patients described in many hypothetical scenarios, created with different permutations of characteristics.

Workstream 2, hospital data (Hospital Episode Statistics cohort)

Participants
Hospital Episode Statistics (HES) data linked with Office for National Statistics (ONS) mortality data for 1 April 2010–31 March 2019 comprised data for adults (> 18 years) diagnosed in England with SPU (*International Classification of Diseases*-10 codes L89.2 or L89.3 or L89.9 or L89.X) during any finished consultant episode.

Intervention
Surgical reconstruction was defined by the Office of Population Censuses and Surveys (OPCS)-4 codes (S17–S20, S22, S24–S27).

Comparator
No surgical reconstruction was defined by the absence of a SR.

Outcomes
Surgical reconstruction during index admission (Obj4). After discharge, time-to-hospital-admission with SPU diagnosed on admission (primary); length of index admission; time to any admission; all-cause mortality; SR after discharge (Obj4 and Obj5).

Workstream 2, primary care data with linked hospital data (Clinical Practice Research Datalink cohort)

Participants
Clinical Practice Research Datalink (CPRD) data linked with HES and ONS mortality data for the period from 1 April 2008 to 31 March 2019 comprised data for adults (> 18 years) during up-to-standard registration with a Read or Systemized Nomenclature of Medicine code indicating a PU. Read codes for discharge from or referral to a service were identified. SR was defined as for the HES cohort.

Outcomes (Obj3)
Incident PU, events (referral, discharge, SR, death) after an incident ulcer.

Workstream 3 consensus
Summary findings of WS1 and WS2 were circulated to nurse and surgeon attendees before meeting online [Zoom (Zoom Video Communications, San Jose, CA, USA)]. Topic 1 was desirable features of a referral pathway for SR to close a SPU. Topic 2 was patient and ulcer characteristics influencing referral for SR. The first topic was important because it affects how many patients are referred for a surgical opinion. The second was important to inform eligibility for future research.

Statistical analysis

Workstream 1: Narrative syntheses were performed for the reviews.

Workstream 1: Descriptive statistics summarised quantitative data. Free-text responses were analysed by qualitative methods.

Workstream 2: Characteristics of patients in the HES cohort were summarised descriptively. Increasingly specific eligibility criteria were applied to identify SRs to close SPUs: SPU diagnosis on admission, SPU or osteomyelitis primary diagnosis, elective admission, absence of diagnoses/procedures incompatible with SR. Minimum and maximum SR numbers were based on applying these criteria or did not; SRs in the minimum subset were most likely performed to close SPUs.

We emulated a target trial to compare SR and NSR groups. Propensity scores for SR during the index admission were calculated, after applying eligibility criteria; SR defined the groups. Hazard ratios adjusted for propensity score and other variables were estimated using survival models.

Results

Workstream 1 review 1

No study compared participants who did and did not have SR. One RCT (20 participants; high risk of bias) and two retrospective cohort studies (165 participants and 181 ulcers; both at critical risk of bias) compared different flap techniques for SR. The average duration of follow-up was 19 months in the RCT, not described for one NRSI and 55 months in the other. Few relevant outcomes were reported numerically and fully. No study reported wound-free time. In the RCT, recurrence percentages were 10% and 60% in the alternative flap groups. Recurrence rates in the NRSIs were 19% (average follow-up duration not reported) and 16%.

Workstream 1 review 2

One prevention and two treatment RCTs were included. Two RCTs had low risk of bias and one had high risk of bias. HRQoL was measured with EuroQol-5 Dimensions in all RCTs and by Short Form questionnaire-12 items in one. Although HRQoL and ulcer outcomes were reported, no study observed a significant difference in ulcer outcomes, preventing estimation of the impact of ulceration on HRQoL.

Workstream 1 surveys

Surveys were initiated by 59 GPs, 146 nurses and 45 surgeons; all questions were answered by 44 GPs, 104 nurses and 26 surgeons. Most nurses worked in hospitals (60%) or the community (55%), with 25% working in multiple settings. Almost all (93%) were trained in wound care. Most surgeons were plastic surgeons (79%) in consultant roles (81%); 52% had ≥ 5 years' experience of SR to close SPUs.

Over half (54%) of primary care respondents did not know SR is a treatment option to close SPUs. Over half had never referred patients with SPUs to secondary care for a surgical opinion but 48% had referred them for other reasons. Most respondents (> 70%) stated that they would refer patients regardless of patient characteristics.

Most nurses (79%) had treated > 10 patients with a PU; 72% reported having considered SR for a SPU and most (81%) had referred a patient in the previous year, mainly to initiate a multidisciplinary team (MDT) meeting to discuss how to treat a patient's SPU. Over half (54%) believed that SR to close a SPU should be more widely available.

Surgeons reported that SR was not performed for most referred SPU patients; of referrals to them, 39% had never offered SR and 52% offered SR to < 50%. However, 68% believed that SR should be more widely available. Over half (59%) reported that referrals were often/always from/within hospitals; only 13% said that referrals were often/always from elsewhere. The most common procedure for SR was 'flap' surgery; very few surgeons performed primary wound closure, tissue expansion or skin graft surgery. Most (80%) reported an average length of postoperative stay after SR between 1 and 12 weeks with the reconstructed wound healing completely in > 50% and low recurrence of the same SPU.

Binary choice experiment

Fifty-two nurses and 10 surgeons made a decision about ≥ 1 scenario; 47 (75%) made decisions for all 16 scenarios. Nurses worked in one or multiple settings and all were trained in wound care, except for one. Six surgeons were plastic surgeons.

Decisions/scenarios ranged from 21 to 31; 843 were analysed and 60% were 'yes' (13–100%). Stage 4 SPU, no inflammation or scarring, no frailty and no comorbidity were moderately associated with 'yes' decisions (odds ratios between 1.5 and 2.0, borderline significance). Longer SPU duration, all non-surgical treatments attempted, no previous SR and adherence to PU prevention measures after surgery were strongly associated with 'yes' decisions (odds ratios > 2.0, $p < 0.001$).

Workstream 2 Hospital Episode Statistics cohort

The SPU admission cohort included 367,884 admissions over 7.5 years. Admitted patients had an average age of 78 years and many had comorbidities. Mortality after admission was high (> 50% by 12 months after admission), showing many admitted patients were elderly, probably with life-limiting conditions. Compared to the minimum subset comprising 404 admissions/SRs, the mean age in the whole ('maximum') SR group, comprising 1018 admissions/SRs,

was higher (58 vs. 52 years); comorbidities were more common and fewer had an inferred cause of impaired mobility (26% vs. 41% had an injury diagnosis and 16% vs. 26% had a neurodegenerative disease diagnosis). Time to first SR from first admission was shorter in the maximum than minimum SR subset but time to a second SR (when this occurred, in <20%) was shorter in the minimum SR subset. Survival was better in the minimum SR subset. SRs were identified by various OPCS codes. In the maximum SR subset, 86/124 English hospitals performed ≥ 1 SR in 7.5 years, the 10 performing the most accounting for 50% (505/1018) and the next 10 for 21% (216/1018). The remaining 66 hospitals accounted for only 29%.

In the target trial emulation comparing SR (n = 325) versus NSR (n = 1474), the time to next admission with a SPU diagnosis was longer in SR patients [adjusted hazard ratio = 0.79, 95% confidence interval (CI) 0.61 to 1.03; p = 0.07]; times to 15% cumulative probabilities of admission were ≈ 107 (72–137) and ≈ 189 (90–238) days in NSR and SR groups. For any next admission, the adjusted hazard ratio was 0.87 (95% CI 0.74 to 1.04; p = 0.12); median times to admission were ≈ 208 (182–238) and ≈ 258 (211–318) days in NSR and SR groups. Median length of stay was longer in the SR group. More patients in the SR than NSR group had a later eligible SR (16% vs. 4%). More patients died within 6 months in the NSR than the SR group (9% vs. 1%).

Workstream 2 Clinical Practice Research Datalink cohort

Median age of patients with an incident PU (n = 55,195) was 82 years; 58% were females. Incident PUs and an approximate CPRD denominator (≈ 20% of the 2011 mid-year England population of 53,107,000), yielded an observed PU annual incidence of ≈ 5/10,000. We aimed to describe patients' care pathways but just 0.4% of patients had a discharge code, preventing any exploration of episodes of PU care.

By comparing HES data linked to the CPRD cohort with the HES cohort, we estimated that incident PUs captured by coded activity in CPRD data accounted for only ≈ 1 of 7 that truly occurred. Observed incident PUs may represent a selected subgroup, for example patients with a spinal injury or a neurodegenerative disease.

Workstream 3 Consensus

Nine TVNs and one specialist plastic surgery nurse participated. Topic 1 covered issues captured by free-text survey responses about the referral pathway. Additional details included that: the pathway should include both community-led and surgically led MDT meetings; several services have relevant contributions to bring to each MDT. A referral pathway was also discussed with a team commissioned to provide care for SPUs in Wales. For topic 2, there was consensus, with qualifications, that:

1. A previous SR should not rule out another SR.
2. The time a SPU has been present should not influence referral for a surgical opinion about SR.
3. A stage 3 SPU could be referred for a surgical opinion about SR.
4. The cause of impaired mobility should not influence whether a patient is considered for referral.
5. Adherence to postoperative SPU prevention regimens is important.
6. Improving a patient's general health should be considered when deciding whether to refer a patient.

Strengths

Literature reviews used state-of-the-art methods. Surveys achieved high response rates and high quality, mainly complete, data; free text responses highlighted challenges in the referral pathway. The BCE supported the survey results. SRs performed in England over 7.5 years were quantified. We emulated a target trial of SR versus NSR. Challenges with further research on the effectiveness of SR are described, based on the consensus and feedback from the research team.

Limitations

The surveys considered factors only one by one; this limitation was mitigated by the BCE which gave consistent results. The BCE was able to investigate only a small number of factors.

Analyses of the HES cohort depended on coding accuracy. To address this uncertainty, we described maximum and minimum SR numbers based on different assumptions informed by the research team. The target trial emulation may have used an inappropriate comparator group due to limited understanding of the referral pathway to secondary care. We could not mitigate this limitation. Outcomes typically measured in wound research are not captured in HES data and could not be investigated. Analyses of the CPRD cohort underestimated PU incidence and episodes of PU care could not be described due to inadequate coding. The consensus meeting had to be online and did not include surgeons. We mitigated this limitation by discussing the findings with research team members, who had wide-ranging relevant expertise.

The COVID-19 pandemic caused delays, made team members less available and restricted face-to-face meetings. The last team meeting provided important insights about the referral pathway and factors that the patient and the surgeon need jointly to consider when deciding whether to have SR. The complexity of decision-making had not been evident or explored previously in virtual meetings.

Future work

We identified three areas of future work:

Qualitative research on the acceptability of SR to understand factors that predispose patients to want or decline SR, including sources of inequality in access and the impact of a SPU on a patient's HRQoL.

A core outcome set for interventions to treat PUs is needed; HRQoL should be carefully considered for inclusion, given the perceived importance of HRQoL in shared decision-making about whether to perform SR. HRQoL measured as quality-adjusted life-years is central to commissioning decisions.

Economic modelling may help to address the cost-effectiveness of SR. Prolonged non-surgical care and SR are both expensive and comparing their costs would inform whether SR might be cost-effective. HES data describe hospital resources, but data are lacking about resources to manage patients with SPUs in the community. The community services data set may provide these data in the future.

Conclusions

There is no high-quality evidence about the effectiveness of SR versus NSR nor how SPUs impact on HRQoL. SR is performed too infrequently in England to permit primary quantitative research. SR is commissioned in Wales, but the small population means few procedures are performed. There is indirect or anecdotal evidence that SR is effective and, were SR commissioned in England as in South Wales, a RCT might be feasible. SR procedures and the characteristics of suitable patients are known; relevant outcomes can be collected and should include HRQoL.

Study registration

This study is registered as PROSPERO Numbers: 2019 CRD42019156436 and 2019 CRD42019156450; ISRCTN Number: ISRCTN13292620.

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