FINAL REPORT: 2018 Efficient Studies funding.

1) Title of Project

Feasibility of an efficient study of surgical management of pressure ulcers

2) Abstract

The Efficient Studies Funding awarded for this project mainly funded a statistician to carry out analyses of anonymised hospital statistics episode data. Descriptive summaries of the characteristics of patients with index admissions to hospital with a diagnosis of severe pressure ulcer (ICD-10 codes L89.2, L89.3 and L89.9) and the frequency of reconstructive surgery (OPCS codes S17-S27) during these admissions were summarised.

Main findings were:

- ≈40,000 patients were admitted/year with a severe pressure ulcer diagnosis codes between 2014 and 2016;
- The pressure ulcer was the primary diagnosis in only 5%;
- Reconstructive surgery was recorded for severe pressure ulcers graded as stage 3, stage 4 or unstageable;
- In two years, only 165 (0.002%) had reconstructive surgery during the index admission;
- Reconstructive surgery was carried out in 55 of 267 hospitals (20.5%) admitting index patients; in 24 months, only two performed >10 procedures and 26 did only 1.
- Patients who had reconstructive surgery were about 20 years younger and had fewer comorbidities than those who did not; concomitant diagnoses were paraplegia, tetraplegia, spinal injuries or sequelae of a transport accident in about half;
- The proportions of admissions with reconstructive surgery decreased slightly between 2007-2016, whereas the total numbers of admissions with a severe pressure ulcer have remained relatively constant.

We concluded that a prospective cohort study would not feasible or efficient and proposed compiling retrospective cohort studies from routinely collected data in our funding application. Funding for a main project has been awarded (NIHR127850).

3) Introduction

Surgical management of pressure ulcers was the subject of a NIHR HTA commissioning brief (CB; ref 18/26). Funding was sought primarily to pay for statistician time to carry out analyses of anonymised hospital episode statistics (HES) data to inform an application for this topic.

The CB specified that, as part of the project, applicants should carry out an efficient cohort study to identify priorities for future research. The substantive research question was described in the brief: compared to usual care what is the effectiveness of surgical management for stage III and IV pressure ulcers refractory to conservative interventions? However, the surgical procedures that require evaluation and the patient groups who may benefit are currently unclear – hence, the study elements specified in the CB. The research

questions addressed with the feasibility funding are: how can we optimise the design of a feasible and efficient cohort study to address the research question specified in the CB and what are the particular challenges of designing a cohort study?

When designing a cohort study, the population and intervention of interest are usually prespecified, at least in broad terms. In this instance (as the brief recognised: choice [of setting] "to be defined and justified by applicants"), a key output of the research was intended to be "Identification of patient groups and interventions requiring primary research to determine effectiveness." As specified by the CB, this output could be achieved through survey and consensus methods. However, we are concerned that these methods alone would not yield reliable answers because severe pressure ulcers are rarely managed surgically in the UK.

4) Methods

The funding supported the following objectives:

A. preliminary literature review of research reporting surgical management of severe pressure ulcers
B. analyses of anonymised HES data, exploring: (a) the frequency of admissions to hospital with a severe pressure ulcer (ICD-10 codes L89.2, L89.3 and L89.9); (b) the frequency of reconstructive surgery (OPCS codes S17-S27, specified by a plastic surgeon who carries out such operations) among these admissions; (c) the demographic characteristics of the patients who did/did not have surgical reconstruction; (d) the distribution of the procedures carried out across hospitals (to investigate centres with greater experience).
C. investigation of potential efficiencies in the conduct or design of a cohort study
D. collating information to define eligibility criteria for the cohort, enabling us to design /professional networks and methods to ascertain eligible patients and recruit them.

5) Results and Conclusion

Objective A: preliminary literature review

Literature searches had been carried out by the HTA in relation to, and cited alongside, the Commissioning Brief for the topic 18/26. NICE guidance on pressure ulcers makes no recommendation about surgical management.[1] Other guidelines recommend obtaining "a surgical consultation for possible operative repair in individuals with stage III or IV pressure ulcers that are not closing with conservative treatment".[2] This recommendation does not specify specific operations or indicate the patients likely to benefit (other than "as appropriate to the individual's condition and goals of care, or for individuals who desire more rapid closure of the ulcer") and is based on indirect evidence or expert opinion.

We scoped the literature to explore available data on the number of people having reconstructive surgery. We found no relevant published data from the UK. Several international retrospective cohort studies described the numbers of people in a single facility having surgery and outcomes during follow-up, without defining the populations

from which these patients were drawn (hence no denominators).[3-6] Similar patterns were seen in all studies: data for reconstructive surgery in small numbers of patients over periods of between 5 and 10 years, typically less than 100 participants in total. Commonly reported outcomes included healing, complications and wound recurrence.

Objective B: analyses of anonymised HES data

Analyses of a sample of anonymised hospital episode statistics (HES) data showed that, in England:

- There were ≈40,000 admissions/year with ICD-10 diagnosis codes for a stage III, IV or unstageable pressure ulcer between 01/10/2014 and 30/09/2016 (81,383 index admissions in 2 years) and without a similarly coded episode in the preceding 6 months before the index record.
- In 75% of index records, the pressure ulcer was coded in the first of multiple episodes comprising the admission. The pressure ulcer was the primary diagnosis in only 5% (≈2,000 admissions/year).
- Ulcers graded as stage 3, stage 4 or unstageable (L89.2, L89.3 and L89.9 ICD-10 codes) accounted for 40%, 14% and 46% of index admissions. OPCS codes for reconstructive surgery were identified in admissions across the three ICD-10 codes for severe pressure ulcers: 37, 55 and 92 reconstructive surgeries were coded as L89.2, L89.3 and L89.9 respectively.
- In two years, only 165 (0.002%) had reconstructive surgery (OPCS codes S17-S27, specified by co-applicant Wong) during the index admission; another 63 patients had reconstructive surgery in a subsequent admission, including 6 who had also had surgery in the index admission. A total of 2013 patients (2.4%) had surgical debridement only (OPCS code S57.1).
- Reconstructive surgery was carried out in 55 of 267 hospitals (20.5%) admitting index patients; in 24 months, only two performed >10 procedures and 26 did only 1.
- Patients who had reconstructive surgery were about 20 years younger and had fewer comorbidities than those who did not. Diagnoses in addition to the pressure ulcer showed that about half had paraplegia, tetraplegia, spinal injuries or sequelae of a transport accident. These differences were also apparent between patients who had reconstructive surgery and those who had debridement only.
- The proportions of admissions with a reconstructive surgery OPCS S code or the code for surgical debridement decreased slightly over time between 2007-2016, suggesting a small decrease in the absolute number of surgical reconstructions, given that the total number of admissions with a severe pressure ulcer have remained relatively constant.

Objective C: potential efficiencies in the design of a cohort study

Severe pressure ulcers mainly in the following groups: (1) younger people with neurological conditions, e.g. spinal cord injury, multiple sclerosis, and spina bifida; (2) older people with chronic conditions, e.g. heart failure, COPD or other conditions that limit movement; (3) elderly people (largely) who are generally frail and then get an acute illness; (4) post-operative inpatients with very limited mobility.

A successful cohort study needs to establish standard pathways through which eligible people can be identified and recruited. Group 1 are usually self-managing wheelchair users; they present to a general practitioner with a wound that has not been checked so the ulcer only becomes apparent when symptoms become severe. Groups 2 and 3 are usually managed in community and nursing homes, where severe pressure ulcers must be declared as a serious untoward incident (so should be rare). Pressure ulcers that develop in inpatients (group 4) are managed in hospital and should be coded in HES data. The HES data should also capture people admitted for surgical treatment of a pressure ulcer. Thus, the HES sample analysed is likely to underestimate the population of severe pressure ulcers but should capture all instances of surgical management. The HES data are consistent with feedback from a plastic surgeon: "those that had that grade of pressure sore [are] self-selecting in terms of having premorbidity from severe disease or neurological or neuropathic processes – most surgeons shy away from complicated surgery [in such patients]".

We could not conceive how a prospective cohort study design would be feasible or efficient. Hence, in our application to address the CB, we proposed compiling retrospective cohorts from routinely collected data. We were unable to identify routinely collected for other jurisdictions in which surgical management is more common and proposed using only HES data and the CPRD-Gold database (Clinical Practice Research Datalink). Data sources for other countries would have to be large (i.e. similar to HES or CPRD) because of the very low frequency of surgical management of severe pressure ulcers; the periods of data collection for recent case series from countries other than the UK indicate that reconstructive surgical management is also very uncommon in those countries. Relevant sources of data in other countries would be likely to be subject the same constraints. Obtaining data from other countries is also time consuming and costly; we explored this briefly with respect to US data (Medicare and Kaiser Permanente) when we first realised the extremely low frequency of reconstructive surgery in the HES data. We concluded that non-UK data would not present a viable option due to the lack of clarity about the quantity and quality data that would be obtained. (For example, the Kaiser Permanente research bank suggests that quality of life data may be available for a specific cancer cohort, but not generically: https://researchbank.kaiserpermanente.org/our-research/for-researchers/); Medicare data primarily cover people >65 years of age and descriptions of uses of the data for health research make no mention of the availability of quality of life data [7,8].)

Objective D: information to define eligibility criteria for the cohort

Our exploration of HES data (objective B) led to identification of relevant OPCS-4 and ICD-10 codes for reconstructive surgery and debridement, and different stages of pressure ulcer, respectively. These codes were specified in our funding application.

6) Dissemination

The above results were used primarily in our funding application, which was successful. The protocol for the main project will shortly be in the public domain. Systematic reviews that are part of the project have been registered in the PROSPERO database and the proposed further analyses of anonymised HES data have been registered in the ISRCTN database. The

preliminary findings described above under objective B were reported in a poster presented at the International Clinical Trials Methodology Conference in October 2019 (and were uploaded to the NIHR MIS database).

References:

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