■ ANNOTATION

Preventing pressure sores after hip fracture

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Hip fractures commonly occur in older patients, with high levels of frailty and comorbidity. Many of these patients have limited mobility before their fracture, and even after surgery, their mobility may remain limited. It is therefore not surprising that they are at a high risk of developing pressure sores, particularly on their heels, and a variety of devices and interventions have been proposed to reduce this risk. Foam or air mattresses, designed to reduce contact pressure on the patient's whole body, are now routinely used in many healthcare systems. However, there is wide variation in their design. We developed the WHiTE 14;PRESSURE 3 trial to address the lack of evidence in this area. This is a three-arm multicentre randomized trial including health economic evaluation and recruiting patients from NHS hospitals in the UK. The trial compares standard strategies for the prevention of pressure sores with standard care plus a constant low-pressure device and with standard care plus a heel off-loading device. This annotation describes the development of this trial.

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Introduction

There are 1.3 million hip fractures per year worldwide, including nearly 70,000 in the UK, with a projected increase to > six million worldwide by 2050.[1–4] The global cost of these fractures has been estimated to include a loss of 1.75 million disability-adjusted life-years annually, and their management accounts for 1.4% of total healthcare expenditure, not including the considerable cost of informal care in the community.[1,3,5] These patients have a one-year mortality rate of 25% and those who survive have a permanent reduction in their health-related quality of life, similar to those who have a stroke.[6] Patients with a hip fracture are usually frail before their injury and take a long time to regain their normal activities afterwards. They are vulnerable to a range of complications associated with their reduced mobility, including pressure sores.

A pressure sore is a localized area of damage to the skin and underlying tissue as a result of mechanical forces including pressure, shear, and friction. The international classification of pressure sores from the National Pressure Injury Advisory Panel, European Pressure Ulcer Advisory Panel, and Pan Pacific Pressure Injury Alliance is: Category 1, non blanching erythma; Category 2, superficial blister/skin loss; Category 3/4, severe cavity wounds exposing fat, muscle, and bone; those which cannot be classified due to an inability to assess their severity, usually due to the presence of non-viable tissue; and suspected deep tissue injury.[7] Category 2 ulcers are reportable to the National Reporting and Learning System (NRLS)[8] and Category 3/4 are reportable as 'serious incidents' on the Strategic Executive Information System.[9]

Pressure sores are painful and confer a major burden on a patient's quality of life due to prolonged bed rest, symptoms (including pain, exudate, and smell), the requirement for frequent redressings, delayed discharge from hospital, nursing home care, and hospitalization for the management of severe infection or surgery.[10–15] Authors who have reported the prevalence of pressure sores, and their management in hospital, have identified that about 10% of these patients have one or more Category ≥ 2 pressure sores.[10,16,17] The reporting of adverse events to the NRLS indicates that about 0.5% of all patients admitted to hospital with a pressure sore develop a new Category ≥ 2 sore, with rates of between 7.8% and 25.2% in high-risk patients. The costs associated with pressure sores have previously been reported to represent 4% of the NHS expenditure (£1.4 to £2.1 billion; 2000 prices).[18] Effective prevention strategies targeting pressure sores may therefore generate savings and meet the cost-effectiveness criteria of health technology assessment agencies.[19]

A systematic review of the risk factors for the development of a pressure sore identified key mechanical factors including immobility, the tolerance of the skin, soft-tissue perfusion (including diabetes), and the status of the skin.[20,21] Factors which influence the tolerance of skin and

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soft-tissues, such as moisture, age, haematological issues, nutrition, and general health status, are also important, but are inconsistently recorded in studies reporting multivariable modelling. A systematic review which we published in 2014 created a conceptual framework for the reporting of the development of pressure sores, with the possible relationships between the key 'direct causal factors' including immobility/inactivity, perfusion, the status of the skin, and many other 'indirect causal factors' such as moisture, age, nutrition, and acute illness.[22]

Patients with a hip fracture are particularly prone to the development of pressure sores due to the immobility of the affected limb, overuse of the contralateral limb/heel when pushing up in the bed to change position, and lack of mental capacity or pain interfering with awareness and the ability or motivation to reposition. All these factors create repetitive pressure, shear, and friction. Those who develop a heel sore have particular problems as it may become more extensive when they start to wear shoes again, further interfering with mobility and physiotherapy and leading to a delayed discharge from hospital.

The authors of previous UK multicentre research reported that the routine management of high-risk patients should include the provision of a high-specification foam mattress or an air mattress (on a 50:50 basis), an electric profiling bed, and repositioning more frequently than three-hourly.[12,23]

Specialist devices for the prevention of heel sores include full heel off-loading and constant low-pressure (CLP) devices. It was recently reported in a mixed methods evaluation of routine management (PRESSURE 2)[23] that specialist heel prevention devices are not in common use in high-risk patients (about 10%), that off-loading devices are perceived to be more effective when patients are completely immobile and confined to bed, but may be a hazard for tripping when patients start to mobilize, and that CLP foam pads were found to be easy to keep in place, having no impact on movement in bed.[23,24]

Rates of Category ≥ 2 pressure sores of between 9.6% and 31.6% have been reported in patients following hip fracture.[25–27] Heel sores account for one-quarter of such pressure sores.[12,23,25,27] Heel sores are also more likely to deteriorate and take longer to heal than those elsewhere on the body,[10-12,23,2714,28–30] and fewer than 50% heal within 18 months of amputation or death.[14]

A systematic review and meta-analysis updated to June 2021, identified studies investigating the use of heel-specific devices to reduce the risk of pressure sores.[31,32] For heel off-loading devices versus standard care, there were three trials, including one randomized controlled trial (RCT) of patients with a hip fracture, which reported a significant reduction in heel sores with off-loading for both Category ≥ 1 (three trials, 18/258 vs 60/234; risk ratio (RR) 0.20 (95% CI 0.05 to 0.80); low quality) and Category ≥ 2 sores (two trials, 0/223 vs 10/199; RR 0.08 (95% CI 0.01 to 0.67); medium quality).[27,33,34] No eligible trials compared CLP with standard care. One trial compared off-loading with CLP and reported non-significant differences for Category ≥ 1 heel sores (9/163 (off-loading) vs 3/77 (CLP); RR 1.42 (95% CI 0.4 to 5.7); very low quality).[35]

These results suggest that off-loading may be effective in reducing the incidence of heel sores, but issues with compliance were mentioned in many studies.[27,33] One study, including 239 patients, used a structured questionnaire to elicit the patients' experience when using heel-lift suspension boots and reported that, while 59% of the patients reported that the boots were comfortable, they also reported that the boots interfered with sleep (32%) and affected movement in bed (41%). Reasons for non-compliance included the weight and bulk of the boot (36%), heat (31%), and discomfort (24%).[27] By contrast, CLP foam pads were reported to be easier to keep in place, having less impact on movement in bed.[36]

Thus, off-loading devices may reduce the incidence of heel sores, but there are issues relating to their use. CLP devices have clinical value, but their effectiveness as an adjunct to standard care is not known. All these options are available in the NHS and the costs are comparatively low, with some devices being reusable, but heel-specific devices are not commonly used even in high-risk patients such as those with a hip fracture.

In response to this lack of clarity about the prevention of heel sores in patients with a hip fracture, the UK National Institute for Health and Care Research recently funded a multicentre, three-group, randomized trial with parallel economic analysis. The World Hip Trauma Evaluation 14 – Pressure Ulcer Prevention 3 trial (WHiTE14:PRESSURE 3) is open to all adults aged > 60 years who have surgery for a hip fracture. Patients who lack mental capacity may be included into the comparison under a pre-specified representative agreement.

The trial will compare two heel-specific prevention devices with standard care. In this pragmatic randomized comparison, the forms of treatment which are prescribed for the prevention of a heel sore to patients in the standard care group will be at the discretion of the attending clinical team according to their hospital policy. Records will be made of the type of mattress and additional heel-specific devices which have been used by each patient. The second group will have standard care plus a CLP device for up to 30 days or discharge from hospital, whichever is sooner. Eligible devices include foam and gel pads which distribute pressure over a larger surface area and reduce the magnitude of the pressure applied to the heel by increasing the overall contact area. The third group will have standard care plus heel off-loading devices for up to 30 days or discharge from hospital. Eligible off-loading devices include heel lift or suspension boots designed to completely eliminate pressure on the heel.

The primary outcome measure for the trial will be the incidence of a new Category ≥ 2 heel pressure sore which develops during the hospital admission or within 30 days, whichever is sooner. Independent researchers will assess pressure areas in all patients twice per week during the inpatient stay. Secondary outcomes include the incidence of new Category 1 heel sores, the progression of Category ≥ 1 sores to a higher category, and healthcare costs from an NHS and personal social services perspective. The trial will also collect data on adherence and compliance and core outcomes for hip fracture trials at 120 days after surgery for all patients,[37] including health-related quality of life as measured by the EuroQol five-dimension five-level health questionnaire.[38]

The internal pilot for the WHiTE14:PRESSURE 3 trial was completed in April 2024 and showed that both patients and clinicians were happy to recruit into the study. The independent Data Monitoring Committee did not report any safety concerns.

More than 1,000 of the planned sample size of 3,102 patients from 30 centres have been recruited from ten hospitals in the UK. The trial is still open to new recruiting sites. We anticipate reporting the results in 2026.

Take home message

- Patients with hip fracture are particularly vulnerable to a range of complications associated with their reduced mobility, including pressure ulcers.
- Both heel off-loading devices and constant low-pressure devices are used as adjuncts to standard-pressure sore prevention policies in some hospitals, but these add extra cost and the evidence for their effectiveness is limited.
- WHiTE14:PRESSURE 3 is a three-group randomized trial and economic analysis designed to determine the best intervention for the prevention of heel pressure sores in patients with a hip fracture.

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