



# Prevention of heel pressure ulcers among older patients – from ambulance care to hospital discharge: A multi-centre randomized controlled trial



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## ABSTRACT

The aim was to investigate the effect of an early intervention, a heel suspension device boot, on the incidence of heel pressure ulcers among older patients (aged 70+).

**Background:** Pressure ulcers are a global healthcare issue; furthermore, the heel is an exposed location. Research indicates that preventive nursing interventions starting during the ambulance care and used across the acute care delivery chain are seldom used.

**Methods:** A multi-centre randomized control study design was used. Five ambulance stations, two emergency departments and 16 wards at two Swedish hospitals participated. Altogether, 183 patients were transferred by ambulance to the emergency department and were thereafter admitted to one of the participating wards.

**Results:** Significantly fewer patients in the intervention group (n=15 of 103; 14.6%) than the control group (n=24 of 80; 30%) developed heel pressure ulcers during their hospital stay (p=0.017).

**Conclusions:** Pressure ulcer prevention should start early in the acute care delivery chain to increase patient safety.

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## 1. Background

Pressure ulcers cause major healthcare problems. Their prevalence remains unacceptably high, ranging from 9.6 to 23% (Bååth, Idvall, Gunningberg, & Hommel, 2014; Igarashi, Yamamoto-Mitani, Gushiken, & Takai, 2013; VanGlider, Amlung, Harrison, & Meyer, 2009). Pressure ulcers usually occur over bony prominences, with the sacrum and the heel cited as the most common locations 1, 4–6 (Bales, 2012; Bååth et al., 2014; Clegg, Kring, Plemmons, & Richbourg, 2009; Langemo, Thompson, Hunter, Hanson, & Andersson, 2008). Typically in these areas, there is little subcutaneous tissue over the bones. (See Tables 1 and 2.)

Research confirms that pressure ulcers cause reduced health-related quality of life and negatively interfere with daily living activities and social life (Gorecki, Nixon, Madill, Firth, & Brown, 2012). They are also

known to be painful, having an impact on patients' overall wellbeing and perceived changed body image (Gorecki, Nixon, Lamping, Alavi, & Brown, 2014; Gunes, 2008). Pressure ulcers occur in many healthcare settings, where patients are subjected to prolonged pressure and a greater than usual amount of pressure to skin and tissue. Epidemiological studies consistently identify that mobility and activity limitations increase the risk of developing pressure ulcers (EPUAP/NPUAP, 2009). The consensus is that the majority of pressure ulcers are preventable and can be avoided through simple interventions. However, previous research on heel pressure ulcers seems to indicate that pressure ulcer prevention interventions in nursing are still not included in everyday practice (Bååth et al., 2014).

There are many circumstances that can affect pressure ulcer development. It is a complex phenomenon that can occur quickly (within hours), but is also highly dependent upon individual differences in terms of risk factors. Moreover, heel pressure ulcers may represent a distinct clinical entity. In terms of risk, they are worthy of specific scrutiny (McGinnis & Stubbs, 2014). In the heel, which is covered by a small volume of subcutaneous tissue, direct impact is transmitted at an angle to the bone. Given the small surface area of the heel, it is somewhat

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**Table 1**  
Demographical data for patients in the intervention group and control group.

	Intervention group, n=103	Control group, n=80	p-value
<b>Age</b> M (SD)	86.38 (7.3)	86.15 (7.2)	0.884
<b>Gender</b> n (%) <sup>*</sup>			0.337
Women	61 (62.2)	53 (69.7)	
Men	37 (37.8)	23 (30.3)	
<b>Risk for PU assessed at ED</b> n (%)			0.958
MNS ≤ 20 score	47 (61.0)	40 (60.6)	
<b>Transport time</b> M (SD)	29.0 (19.2)	30.0 (19.7)	0.520
<b>Hospital stay</b> M (SD)	7.9 (8.2)	10.4 (15.7)	0.739

\* Six unknown, no information available in the study protocol.

challenging to redistribute impact to it through the use of pressure-redistributing devices. The heel should be kept free of all pressure, using a pillow or heel devices to keep the heel from the bed's surface (EPUAP/NPUAP, 2009). Donnelly, Winder, Kernohan, and Stevenson (2011) have shown that a heel suspension device decreased the incidence of pressure ulcers in hip fracture patients (Donnelly et al., 2011). Still, there is sparse evidence to determine which device or pressure-relieving method should be used for the prevention of heel pressure ulcers (Greenwood, Nelson, Nixon, & McGinnis, 2014)

The task for healthcare settings is to provide safe healthcare through a caring and cost-effective approach. This includes risk assessment and appropriate interventions, within a time frame appropriate to the patients' needs (SFS, 1982:763). Common clinically hazardous situations that contribute to reduced mobility and activity are ambulance transports and emergency department visits for older patients. Emergency departments worldwide, struggle with long waiting-times. Patients may well find themselves waiting for hours in the emergency department, lying on simple trolleys (MuntlinAhtlin, Gunningberg, & Carlsson, 2008). According to recently developed guidelines, it is important for the nurse to conduct a skin assessment as soon as possible, but within eight hours of admission (National Pressure Ulcer Advisory Panel European Pressure Ulcer Advisory Panel and Pan Pacific Pressure Injury Alliance, 2014). Therefore, these patients are in great need of preventive measures to reduce the risk of pressure ulcers (Denby & Rowlands, 2010). Heyneman, Vanderwee, Grypdonck, and Defloor (2009) have shown that pressure ulcers occur in the first days of hospitalization. This reveals the need for a preventive approach throughout the entire continuum of care, including the early identification of the risk factors involved in the development of pressure ulcers, followed by immediate action (Heyneman et al., 2009).

Pressure ulcer preventive actions in nursing might be initiated at an earlier stage prior to hospital care, already during ambulance care. However, ambulances are usually equipped with conventional stretchers, which do not include a pressure reducing function. Some transports take as little as a few minutes, but some can take hours depending on the country and the area. To our knowledge, no study has examined the incidence of pressure ulcers across the continuum of care, from ambulance care to discharge from hospital.

The aim of this study was to investigate the effect of an early intervention starting in the ambulance, to offload patients' heels using a heel suspension device boot, on the incidence of heel pressure ulcers among older patients (aged 70+).

**Table 2**  
Number of hospital-acquired heel pressure ulcers in the intervention group and control group.

	Intervention group	Control group	p-value
<b>Pressure ulcers</b> n (%)	15 (14.6)	24 (30.0)	p=0.017

## 1.1. Primary and secondary outcomes

The primary outcome was incidence of hospital-acquired heel pressure ulcers, classified according to the European Pressure Ulcer Advisory Panel (EPUAP/NPUAP, 2009). The secondary outcomes were the comfort, usefulness and acceptability of the heel suspension device boot from the patients' perspective.

## 2. Methods

### 2.1. Research design

A multi-centre randomized controlled trial (RCT) design was used.

### 2.2. Settings and sample

The study included five ambulance stations, two emergency departments and 16 wards at two hospitals, a central hospital and a university hospital, in two county councils in Sweden. The participating county councils cover respective areas of more than 17,500 km<sup>2</sup> and 8,000 km<sup>2</sup>, providing care to about 273,000 and 342,700 inhabitants, respectively.

#### 2.2.1. Sample size

We based the sample size calculation on the findings from a Belgian study (Heyneman et al., 2009), which compared a wedge-shaped cushion to a standard pillow. The researchers identified a pressure ulcer incidence of 10% in the standard pillow group, compared to 2% in the wedge-shaped intervention group. A priori sample size calculation was performed (80% power; alpha 0.05) to detect a statistically significant difference, indicating that 88 patients per group would be required to detect a similar reduction as described by Heyneman et al., 2009. However, the sample size calculation was also done in the light of the pressure ulcer incidence and prevalence at the two included hospitals.

Participants were considered eligible for inclusion if they 1) were aged 70 years or older, and 2) suffered symptoms related to 'neurological symptoms' or 3) 'reduced general condition' according to the medical directives from the emergency centres (112) but were not in need of life-saving support, and 4) were assessed by the registered nurse (RN) in the ambulance as not having heel pressure ulcers (intact skin) in the ambulance at the pick-up place, and 5) were transferred by ambulance to the emergency department and thereafter admitted to one of the participating wards.

The choice of this patient group was based on knowledge and results from Swedish Association of Local Authorities and Regions (SALAR) point prevalence measurements that it is a vulnerable group of patients (i.e. at risk for pressure ulcer). However, in Sweden it is neither mandatory to assess pressure ulcer risk in pre-hospital or emergency care nor it is common to include these settings in prevalence studies. Therefore it was important to include the entire acute care delivery chain in this study.

When a patient was eligible for inclusion, the RN in the ambulance took out a sealed envelope from a box in the ambulance. The information in the envelope showed whether the patient was allocated to the intervention group or the control group. Allocation to the study to either intervention or control group was performed using a computer-generated block randomization schedule (<http://www.randomizer.org>) to randomly divide interventions and controls amongst the participating patients and ambulance stations.

### 2.3. Intervention and control group

#### 2.3.1. Ambulance care

The ambulance care consisted mainly of history taking and measuring vital signs. Depending on the patient's vital condition, an intravenous catheter and infusions were used. According to the study protocol (see below), the RN also performed a skin examination, of

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