ABSTRACT

Background
Heel pressure injuries (HPIs) are the second most common type of pressure ulcers. Despite their frequency, however, HPIs are poorly understood and remain difficult to treat.

Aim
To describe the rationale behind the need for a structured evidence-based approach to assessing and treating HPIs in adult, paediatric, and diabetic populations.

Methods
Several clinical questions were identified and incorporated into six domains to provide a framework for defining evidence-based recommendations for HPI assessment and treatment. This framework focuses on three populations: adults, paediatric patients, and patients with diabetes.

Conclusion
This article describes strategies, rationales, and efforts needed to generate a series of evidence-based recommendations in our six identified domains and three patient populations. The Italian Nurses’ Association for Wound Care (AISLeC) has organized a Consensus Conference on the assessment and management of HPIs to present these results and recommendations in November 2018.

BACKGROUND
A pressure ulcer involves localized injury to the skin and/or underlying tissue. Pressure ulcers usually occur over a bony prominence, and result from either pressure alone or a combination of pressure and shear.1 The heel is the second most common anatomical location for pressure ulcers.2 The prevalence rate of visible heel pressure injuries (HPIs) varies from 7.3%3 to 18.2%.4 HPIs are painful and physically debilitating. HPIs also can affect rehabilitation and may involve potentially fatal complications, including sepsis, osteomyelitis, cellulitis, or amputation of the affected limb.5 The main risk factors for the development of HPIs are type 2 diabetes and its associated neuropathy, low albumin concentrations, conditions that limit leg strength (including the hip and the knee), and arterial insufficiency of the lower limb associated with vasoconstrictor drugs.8

During standing and ambulation, the design of the heel allows it to withstand any incurred forces. The posterior region of the heel, however, is particularly prone to ulceration due to its thin skin and lack of protective fat and muscle coverage.9 Study models of the heel have identified a triad (Fig. 1) that makes the heel more susceptible to pressure, especially during bedrest. The heel is essentially characterized by “heavier foot–sharp posterior calcaneus–and thin soft tissue padding over the calcaneus”.10 These peculiar features are why even low amounts of pressure can cause extensive damage to the heel. Given the high prevalence of HPIs, a thorough understanding of the dynamics that cause tissue damage in this anatomical area is critical. Unfortunately, there have been no well-conducted studies to clarify the relationship between bedrest and the development of HPIs.11
The European Pressure Ulcer Advisory Panel (EPUAP) guidelines provide an internationally recognized pressure injury classification with 4 main stages: category/stage I: non-blanchable erythema; category/stage II: partial thickness skin loss; category/stage III: full thickness skin loss; and category/stage IV: full thickness tissue loss. The guidelines also include a classification for unstageable pressure injury, where the depth is unknown (DU) and/or with suspected deep tissue injury (SDTI)(1). Neither the National Institute for Health and Care Excellence (NICE) guidelines, nor the EPUAP guidelines provide clear indication on how to treat HPIs.5

Gefen noted that “despite being so common, despite imposing such high risks, and in spite of being so costly, heel ulcers are considerably understudied in the pressure ulcer literature”.10 The Heel Pressure Ulcer Risk Assessment Tool is one example of a tool that can be used to understand HPIs, but has not been validated.7 The Italian Nurses’ Association for Wound Care (AISLeC), therefore, has prioritized the need to produce evidence-based recommendations on HPIs to support best clinical practice and to improve outcomes in patients. The AISLeC has identified the Consensus Conference (CC) as the most suitable methodology among those available to identify these recommendations. Specifically, the CC will focus on the assessment and treatment of HPI; prevention is not considered here.

METHODS
We performed a preliminary review of the literature from the CHINAL, PubMed, Cochrane Wounds, and TRIP databases to identify studies that have assessed and treated HPIs. A Boolean search was conducted using the terms: “heel pressure ulcers”, “pressure ulcers”, “treatment, lightweight fiberglass heel cast”, “surgical treatment”, “negative topical pressure therapy”, “dressings, vascular assessment”, and “off-loading”. This search yielded systematic reviews, meta-analyses, randomized controlled trials (RCTs), guidelines, and primary and secondary research studies. All the studies included in our analysis were written in English and published between January 2000 and June 2018. Our search included studies in three patient populations: adult patients, paediatric patients, and patients with diabetes. The purpose of this review was to formulate evidence-based recommendations for each area of intervention that we identified in Table 1.

Table 1: Areas of intervention for heel pressure injuries (HPIs).

1. Vascular assessment
2. Treatment of stage I and II HPIs
3. Treatment of stage III and IV HPIs plus SDTI and DU
4. Biophysical agents
5. Off-loading devices
6. Referral criteria
For each area of intervention, we generated a set of background questions that we aimed to answer from the literature search and the opinion of experts (Table 2).

Table 2: Questions to address based on our literature search.

1. Can we define criteria for SIMPLE HPIs?
2. Can we define criteria for COMPLEX HPIs?
3. Can we define criteria for RECALCITRANT HPIs?
4. Can we define criteria for MILD infection in HPIs?
5. Can we define criteria for MODERATE infection in HPIs?
6. Can we define criteria for SEVERE infection in HPIs?
7. Should an interdisciplinary heel pressure ulcer service be created for this specific type of pressure injury?
8. How many clinicians should be involved as a minimum in an interdisciplinary heel pressure ulcer service?
9. Which timing criteria can potentially be defined to refer patients with grade III and IV to a specialist?

Following our initial search, two independent methodologists conducted a more in-depth search using approximately 65 clinical questions based on the EPICOT methodology to improve the accuracy of our initial literature search. The present article outlines the results of our preliminary literature review to provide the reader with a general understanding and rationale for our future Consensus Conference. More definitive literature results will be available at the end of August 2018.

**Results of the preliminary literature review**

Our initial search yielded 2 relevant guidelines (from 8), 2 relevant research articles (from 24) on CHINAL, 2 relevant research articles (from 68) on TRIP, and 10 relevant articles (from 55) on PubMed. No relevant RCTs were found in the Cochrane Wounds database.

**1. Vascular assessment**

Taylor and Palmer in 1987 described an angiosome as “…an anatomic unit of tissue (consisting of skin, subcutaneous tissue, fascia, muscle, and bone) fed by a source artery and drained by specific veins”. The foot includes six angiosomes (compared to the entire human body, which can be divided into 40 angiosomes). The posterior tibial artery feeds three of these angiosomes, whereas the anterior tibial feeds one angiosome and the peroneal artery feeds two angiosomes. Adjacent angiosomes are connected by a vast compensatory collateral web, which are also called “choke vessels”. The available data on angiosomes show that the blood supply in the heel is provided by two arteries: the lateral aspect of the heel and the skin is supplied by the lateral calcaneal branch of the peroneal artery, and the heel pad is supplied by the medial calcaneal branch of the posterior tibial artery (PTA). Peripheral vascular disease (PVD), which is also known as lower extremity arterial disease (LEAD), is a chronic,
progressive disease. Risk factors for PVD include dyslipidemia, advanced age, tobacco use, diabetes, hypertension, and chronic renal insufficiency. Blood supply to the heel is provided primarily to the posterior tibial and peroneal arteries. A recent observational study carried out in 506 patients with HPIs showed that 83% of those patients exhibited symptoms of PVD. One guideline suggests that "for people with pressure injuries in the lower extremities over bony prominences (e.g., the heel) or from sustained environmental pressure (e.g., footwear), a vascular assessment of the lower extremities is essential to ensure safety during treatment, identify barriers to healing, and determine appropriate treatment options".

The NICE guidelines provide the following recommendation for assessing individuals with suspected PVD: “Assess people with suspected peripheral arterial disease by: examining the legs and feet for evidence of critical limb ischemia, for example ulceration; examining the femoral, popliteal, and foot pulses; and measuring the ankle brachial pressure index”. Objective evidence to detect the presence or absence of significant LEAD in one or both legs may be obtained reliably (except in those with calcified vessels) using a non-invasive test called the ankle brachial pressure index (ABPI) during the initial visit. The ABPI is the ratio of the ankle to brachial systolic pressure and can be measured using a sphygmomanometer and a hand-held Doppler device. The reliability of this test may be questioned, however, because the data supporting its validity arises mainly from studies on symptomatic patients.

Other procedures exist to assess the blood supply in the legs. For example, a small study compared the ABPI and the toe brachial pressure index (TBPI). This study found low sensitivity of ABPI (69.2–71.4%) among patients with diabetes and/or chronic renal failure. This sensitivity is comparable to other diagnostic tests including the TBPI. The toe-finger index (TFI), which is derived from photoplethysmography, achieved the highest sensitivity (84.6–85.7%) in these patients.

Despite well-known recommendations and standard procedures for using the ABPI for vascular assessment, a recent study showed that the ABPI is not a sensitive index for diagnosing critical limb ischemia (CLI); only 14 of 237 patients (6%) had an ABPI < 0.4 despite having angiography-confirmed CLI. Furthermore, the ABPI does not provide information about the perfusion of the hindfoot; the ABPI can yield normal readings when the two main arteries (i.e., the dorsalis pedis and posterior tibial arteries) are used despite the presence of an ischemic heel, a concept known as “orphan heel syndrome.”

Based on these findings, a set of recommendations should be established to define what the ideal test is for ruling out vascular impairment in HPIs in the primary care setting. These guidelines should outline whether any additional vascular diagnostic procedures are more effective than the ABPI alone, such as TBPI or transcutaneous oximetry (TcPO2). If the TcPO2 is recommended, then the guidelines should also define whether hindfoot transcutaneous oximetry is a more useful than the dorsal approach in identifying heel ischemia.

2. Treatment of stage I and II HPIs

Stage I HPI refers to intact skin with non-blanchable redness in a localized area, usually over a bony prominence, whereas Stage II HPI refers to partial thickness skin loss presenting as a shallow open ulcer with a red/pink wound bed but without slough. In stage II, the ulcer may also present as an intact or open/ruptured serum-filled blister.

The wound assessment of stage 1 and 2 HPIs should be performed in a structured manner and based on scientific principles. The EPUAP guidelines suggest that all factors affecting the healing potential should be assessed, including impaired perfusion, impaired sensation, and systematic infection. The guidelines include specific recommendations for the vascular assessment of lower-limb pressure ulcers, which include physical examination, review of history of claudication, and assessment of either the ABPI or the toe Doppler.

For stage 1 ulcers, the only treatment considered by the EPUAP is to avoid repositioning the individual on the affected bony prominences. For stage 2 ulcers, which do not contain necrotic tissue, the NICE guidelines indicate that healable wounds should be treated with moisture-retentive dressings; however, NICE does not provide any specific recommendations for HPI treatment. Similarly, the EPUAP guidelines list hydrocolloid dressings as an option to manage stage 2 pressure injuries, but do not provide specific recommendations for HPIs. Polyurethane film dressings are recommended as useful for autolytic debridement but not for moderate and heavy exudates or in patients with fragile skin. The fragile skin is not an absolute contraindication, precautions have to be taken when they are used. Hydrogel dressings are indicated for shallow, minimally exuding wounds, whereas foam dressings should be considered for pressure ulcers of stage II and above.

Many guidelines suggest pressure off-loading, using a pillow or suspension device, as part of the treatment regime for existing pressure ulcers. Ideally, heels should be free of all pressure – a state sometimes called "floating..."
There is currently no specific indication about which device is most effective.

A formal series of recommendations for the treatment of stage 1 and 2 HPIs are needed. These recommendations should provide guidance on the following questions: (1) What is the ABPI cut-off or any other vascular assessment cut-off at which a moisture environment is required? (2) Is it safe to use a moisture environment in some specific conditions, e.g., is critical limb ischemia a contraindication for a moisture-retentive dressing? (3) What kind of examination should we perform to evaluate the healing potential before starting any local treatment? (4) Are low-friction technology devices helpful in managing friction and shearing forces when a stage I or II HPI already exists? (5) What are the most appropriate local treatment and off-loading devices to use in a bed-bound patient?

3. Treatment of stage 3 and 4 HPIs plus SDTI and DU

The remaining four stages of HPIs are Stage 3: full thickness skin loss; Stage 4: full thickness tissue loss; and Depth unknown (DU) and Suspected Deep Tissue Injury (SDTI)(1). As suggested by Bosanquet,9 the management of stage 1-3 HPIs is often achieved with appropriate pressure off-loading and a correct wound care approach, but successful healing of stage 4 HPIs is often possible only with surgical intervention. Generally, HPIs are more complicated to treat and the outcomes are more negative compared to ulcers on other areas of the foot, such as on the toes or on the metatarsal portion of the foot.26 Moreover, localization of tissue loss in the heel is a significant independent predictor for amputation when compared to other areas of the foot.27

Stage 3 refers to ulcers where the subcutaneous fat may be visible but bone tendon or muscle are not exposed. Slough may be present but does not obscure the depth of tissue loss, and it may also include undermining and tunnelling.1 Surgical intervention is common for stage 3 ulcers when extensive soft tissue infection, osteomyelitis, or vascular insufficiency is present.9 The literature does not provide specific recommendations for the treatment of stage 3 HPIs, however; the primary focus is generally on stage 4 ulcers and osteomyelitis-related disease.

The EPUAP guidelines indicate that an individual with stage 3 or 4 pressure ulcers with undermining, tunnelling/sinus tracts, and/or extensive necrotic tissue should be referred for surgical evaluation if the necrotic tissue cannot be easily removed with other debridement methods and when surgery is appropriate to the individual’s condition and goals of care. These recommendations are general and not tailored to the treatment of HPIs, however. The recommendation for HPIs is to maintain a stable dry eschar without attempting to debride the ulcer unless there are signs of infection or fluctuance.1 Thus, while the EPUAP guidelines provide general recommendations about dressings properties and their role in managing

**Figure 3: The four indicators linked with poor outcomes in heel pressure injuries.**
exudates and bacterial bioburden, no specific guidance on heel treatment is given. Such guidelines should be defined by clinical judgment along with standardized protocols.

Stage 4 refers to full thickness tissue loss with exposed bone, tendon, or muscle. Slough or eschar may be present on some parts of the wound bed. The lesion often includes undermining and tunnelling. Exposed bone or tendon is visible or directly palpable. This ulcer stage is usually caused by direct pressure with superficial damage due to friction and shearing forces. Nakagami et al. stated that vessel occlusion can also occur with the presence of shearing forces alone, even with lower interface pressure. The National Pressure Ulcer Advisory Panel (NPUAP) has recognized shear forces as a primary cause of pressure ulcers, which supports the notion that friction is not responsible for pressure ulcers.

Four indicators are linked with poor outcomes in HPIs (Fig. 3): (1) large ulcers; clinical evidence of PVD; (2) old wounds; and (4) soft tissue infection and osteomyelitis.

As previously noted, pressure injury guidelines do not provide specific recommendations for treating HPIs. There is also a paucity of strong evidence in the scientific literature. VIP assessment, where V stands for vascular supply, I stands for infection, and P stands for pressure offload, relates primarily to diabetic foot treatment, but has also been indicated for the assessment of HPIs.

A strong and structured approach to HPI treatment is needed for those with stage 3 and 4 ulcers, as the consequences related to poor management can seriously impact the patient’s activities of daily living and ability to salvage the limb. A few case reports are available in the literature. For example, near total calcaneotomy and flap closure is suggested as an alternative to a below-the-knee amputation in selected patients with deep HPIs with osteomyelitis. For these two pressure injury stages, well-defined recommendations should drive clinical practice and must provide the exact criteria for patient referrals; eligible treatments, including surgical or medical treatment; use of biophysical agents; the appropriateness of a conservative versus non-conservative approach; and evaluation of the healing potential.

SDTI and DU are two important lesion types where a formal approach should be defined. SDTI is an area of localized purple or maroon intact skin damage caused by pressure or shearing forces. The tissue may be warm, mushy, firm, or painful. Pressure off-load is critical at this stage, but there are no specific guidelines about the best heel suspension to use. If it is consistent with the patient’s general condition, then a pillow placed from the popliteal area to the Achilles tendon should be used to elevate the leg and protect the heel from shearing and pressure. An appropriate local treatment should also be considered based on the patient population, such as in patients with diabetes.

DU refers to a pressure ulcer that cannot be staged due to obstruction by slough and/or eschar. Such an ulcer is considered unstageable until the eschar or slough is removed to expose the base of the wound. Guidelines for unstageable ulcers indicate that dry eschar should not be removed from the heel because it serves as ‘the body’s natural (biological) cover’. There is a need, however, to define a formal local treatment to be used whenever possible, especially in neonatal, paediatric, and diabetic populations.

4. Biophysical Agents

Biophysical agents may promote healing in pressure ulcers. The EPUAP guidelines recognize the following biophysical therapies:

1. Electrical stimulation for recalcitrant stage 2, 3, and 4 pressure ulcers.
2. Pulsed electromagnetic field (PEMF) stimulation for recalcitrant stage 2, 3, and 4 pressure ulcers.
3. NPWT (negative pressure wound therapy) as an early adjuvant for the treatment of deep stage 3 and 4 pressure ulcers when osteomyelitis or other underlying issues are ruled out.

Although the EPUAP recognizes these treatments, there is a lack of strong recommendation for which treatment is best. There is also a high cost to these treatments; therefore, further recommendations are needed to take into consideration when these therapeutic approaches should be used given budget constraints.

5. Off-loading devices

The choice of off-loading device is important from a clinical practice point of view. A recent RCT reported that booties are more effective than cushions in preventing HPIs. There is a lack of guidance, however, about which off-loading device to use in patients with an existing HPI or after a surgical procedure on the heel. A pillow is not always a realistic solution, and is not recommended for stage 3 and 4 HPIs.

6. Referral Criteria

HPIs are often complex. It has been suggested by the scientific committee that an Interdisciplinary Heel Pressure Ulcer Service (IHPIS) could be helpful to achieve rapid diagnosis, assessment, and treatment of HPIs. A dedicated service is a well-known and proven strategy in patients...
with diabetic foot ulcers (DFUs). Such a service has been shown to improve treatment, outcomes, and patient quality of life among those with DFUs.35 Following this model, an HPI team should be defined as per the “toe and flow concept”,36 with a minimum number of essential members. Such a service can be helpful not only in terms of facilitating a correct diagnosis but also in identifying and allocating the best resources; choosing the most appropriate therapeutic pathways; outlining the need for surgical approaches, biophysical agents, and/or off-loading devices; and monitoring outcomes. We have highlighted the importance of such a service in our questions in Table 2 because we believe the creation of this service is critical for defining different pathways of referral criteria for adult, paediatric, and diabetic populations.

CONCLUSION
This article has described the strategies, rationale, and efforts needed to generate a series of evidence-based recommendations in our six identified domains and three patient populations for the assessment and treatment of HPUs. In November 2018, there will be a National Congress in Milan to celebrate the 25 years of AISLeC. We will also take the opportunity to celebrate the Consensus Conference, which will convene experts and recognized clinicians across the world. We would like to thank all the people who are helping us with this challenging project.

REFERENCES
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