AISLEC
ASSOCIAZIONE INFERMIERISTICA
PER LO STUDIO DELLE LESIONI CUTANEE
Società scientifica italiana a carattere interdisciplinare

Consensus Conference
"The Assessment and Management of Heel Pressure Injuries"

PROJECT

The Italian Nurses' Association for the Study of Wound Care (AISLeC), a non-profit association active since 1993 in the field of research and training in ulcers with different etiology, is pleased to announce the first International Consensus Conference on Assessment and Management of Heel Pressure Injuries.

Promoter Committee

AISLeC Board of directors

Scientific Technical Committee

Andrea Bellingeri, RN, IRCCS Policlinico San Matteo, Pavia

Fabio Bellini, RN, Boario Terme BS

Giacomo Clerici, MD, Istituto di Cura "Città di Pavia", Pavia

Matteo Martinato, RN, PhD, Azienda Ospedaliera di Padova, Padova

Annalisa Moscatelli, RN, ASST Ovest Milanese, Legnano, MI

Battistino Paggi, RN, Novara

Giovanni Pomponio, MD, Azienda Ospedaliero Universitaria Ospedali Riuniti, Ancona

Claudio Quartero, RN, Opera Don Orione - istituto Camaldoli, Genova

Massimo Rivolo, RN, MSc Wound Care, Italy

Silvia Scaffidi Domianello, RN, MSc, Padova

Fabrizia Toscanella, MD, Policlinico Luigi Di Liegro, Roma

Rosa Rita Zortea, RN, Turriaco GO

Background

Heel pressure Injuries (HPIs) are the second most common site for pressure injuries (PIs) in adults[(1)] with a prevalence ranging from 7.3% to 18.2%[(2)] accounting for up to one third of all PIs[(3)].

Despite the prevalence and associated social and economic costs, HPIs are poorly studied[(4)]. Research in this field is limited if compared to the implications for the patient: HPIs are painful and debilitating, have a significant impact on rehabilitation and can cause life-threatening

complications (sepsis, osteomyelitis, cellulitis/erysipelas, renal failure, amputations,)[5].
HPIs are often hard-to-heal wounds and are associated with poorer outcomes when compared with tissue loss in other areas of the foot (i.e. fingers and metatarsal area)[6-8]. The tissue loss in this area, has been identified as an independent predictive factor for amputation[9].
Literature does not provide a specific indication on how to treat HPIs at the stage I, II, III and the only evidence, of poor quality, focus on stage IV and on osteomyelitis[10]. HPIs are caused by direct pressure, but shearing forces can also cause capillary occlusion even when a low interface pressure is present[11]. Limb recovery is also 2-3 times less likely with a HPI compared to metatarsal area and are much more expensive, with a ratio of 1:5[12].
Recent epidemiological studies in paediatric and neonatal areas show a variable prevalence rate for PIs, ranging from 0.47% to 27.7%[13-19]. Heel pressure injuries are often included within these values which represent a percentage from 3.6% to 50%[13-17.19-22]. Given the anatomical and physiological characteristics of infants and children, serious concerns arise about the use of adults protocols and products for infants and children and therefore further research is required to elaborate evidence-based clinical recommendations to address the paediatric population needs[23].
To date there is no structured and shared approach for the assessment and treatment of HPIs and the lack of homogeneity of treatments poses clinical questions that need to be supported by research and evidence based indications[24].

Aims

AISLeC has prioritized the need to produce evidence based recommendations on Heel Pressure Injuries in order to support clinicians in best practice to improve the appropriateness of care, reducing associated costs, improving outcomes and ensuring the achievement of important outcomes for the patients; AISLeC has identified the CC (Consensus Conference) as the most suitable methodology among those available to create these recommendations.
Specifically, the CC will focus on the assessment and treatment of Heel Pressure Injuries.

Methodology

This CC, in a multidisciplinary and multi-professional approach to the above-mentioned problem, will involve all the potentially interested stakeholders, patients and their families, institutions, companies with commercial interests and all health care professionals.

The methodology adopted for the organization and management of the Consensus Conference is described in the methodological manual of the national system of guidelines of the National Institute of Health (available on http://www.snlg-iss.it/manuale_metodologico_consensus), though the Delphi method will be used [25]

Consensus conference topics

Six areas of interest have been identified with an additional one that will be used for the definition of the queries covered by the CC:

1. Vascular assessment of the lower limb in the presence of HPIs;
2. Assessment and local treatment of HPIs stage I and II;
3. Assessment and local treatment of HPIs stage III and IV, Depth Unknown and Suspected Deep Tissue Injury (SDTI);
4. Referral criteria to address patients to specialized centres;
5. Use of biophysical agents in recalcitrant ulcers;
6. Offloading devices in walking and non-walking patients;
7. Background questions.

Within these areas or in further other areas that will be identified by the Scientific Technical

Committee, three specific populations will be considered: **adult, diabetic and neonatal/paediatric**.

Background questions will be integrated after the Delphi method into the six main areas and flow charts will be created to address the therapeutic pathways.

Scheduled activities

The consensus conference took its first steps in Rome on 27th May 2017 with the meeting of the Promoter Committee that worked on the preliminary aspects of the consensus conference from June to September 2017.

The Scientific Technical Committee (STC) started its work in Rome on 29th September 2017.

The activities are split into a preparatory phase (October 2017 – February 2018) and in an operational phase (January 2018 – October 2018), Delphi method from 20th October to 11th November. From 12th to 17th November a draft of the document will be prepared and presented to the conference in November 2018 in Milan.

Preparatory phase

1. Fund raising and definition of the budget available for the conference (from January 2018 onwards);
2. Editorial policy definition of produced documents during the CC (December 2017-February 2018);
3. Preparation of definitive preliminary questions list (December 2017 - February 2018);
4. Use of EPICOT+ methodology for queries prepared by the methodologists for questions to be sent for selection (December 2017 - February 2018);
5. Technical Scientific Committee vote for questions and outcomes relevance for each queries (February 2018);
6. Publication of call for interest (February 2018);
7. Preparation of the final list of questions to be sent to working groups (March 2018)
8. Appointment of the jury and its president (March 2018);
9. Selection of the experts who responded to the call for interest (March 2018);
10. Set up of working groups (March 2018);

Operational phase

1. Working tools for gathering and evaluating scientific literature prepared by methodologists (March 2018);
2. Support to experts and working groups provided by methodologists (March 2018 - April 2018);
3. Literature search by a librarian, methodologists, experts and working groups (April 2018 – August 2018);
4. Working groups documentation delivered to the expert groups (April 2018);
5. Drawing up regulation for the jury (April-May 2018);
6. Reports of experts and working groups are reviewed by the TSC and made available to other experts/working groups for collection of any observations in a meeting (September 2018);
7. General regulation document, Recommendations/statements, COI and Consensus Conference Project will be sent to the jury for their approval. (October 2018)
8. Recommendations/statements will be read and voted by the jury (20th October to 4th November) with Delphi method. Second round of Delphi will be sent on 5th November and closed on 11th November.
9. Draft of document will be sent to the jury for further comments after the 24th November and

should return in 30 days for final approval.
10. Final document will be published on a dedicated journal.

Ad hoc surveys planned for the consensus conference

Among the preliminary activities useful to provide some elements to formulate the queries, a survey was set up to find out the opinion of health care professionals and the knowledge about the local treatment.

Scientific Technical Committee will prepare a dedicated study on the stakeholders perceived needs, especially for patients / users / citizens or their representatives.

Program for the dissemination and promotion of recommendations

Two different ways:

A. Press conference to show the results of the conference, publication on the AISLeC website (www.aislec.it), publication in a scientific journal, presentation at scientific conferences.

   AND/OR

B. Preparation of papers to be sent to the local health authorities or others such as public and private hospitals, nursing homes, associations of professionals, freelancers and regulatory bodies.

Monitoring programs for the impact of recommendations

A survey on treatments and a prevalence study will be carried out after 12 and 36 months from the publication of the recommendations.

A survey will be carried out in 6 months from the publication of the recommendations to explore the satisfaction of the needs perceived by the identified stakeholders before the start of the conference activities.

Roles, responsibilities and activities of the involved subjects

The **promoting committee (PC)**, after defining the objectives of the conference and gathering funds for the project, in line with the conflict of interest policy previously established and stated in writing (all the parties involved will sign the commitment to stick to this policy and declare potential conflicts of interest), has designed, planned and organized the stages of the conference, it has selected the members of the technical-scientific committee (TSC), asking the interested individuals (both institutional and not) of pointing out possible candidates and ultimately drafted the protocol of conference.

The PC must define the editorial policy of the documents produced during the CC, identifying which data, results, documents will be published, the rules related to data, results and documents' authorship (general and particular), and the rules concerning characteristics, form and content of these publications as well as the journals on which data, results and documents will be published.

The PC will identify the members of the jury based on defined criteria (intellectual autonomy, representativeness, scientific authority, moral and cultural status, etc.), and will propose to the TSC

the questions to which the jury will respond. The PC will identify, in collaboration with the TSC, experts while defining the working groups (both in terms of components and tasks).

After drafting the call of interest, the PC will disseminate it (Annex 1). The PC has established the publishing policy (expert reports, conference proceedings and recommendations) and defined the dissemination and measurement strategies for the impact of the recommendations.

The **scientific technical committee** (including methodologists, patients, users, citizens or their representatives) will process the questions to be submitted to the jury, and will identify, in collaboration with the PC, the experts and possible working groups which will have to submit to the jury the reports on the various topics covered by the conference and will provide the experts and working groups with the methodological indications needed to produce the assigned reports in order to guarantee the use of a common method for analysing and presenting the data to the jury.

The **jury** (multidisciplinary and multi-professional) will consist of doctors specialised in the different disciplines interested in the topic, researchers active in the different fields of study related to the topic of the conference, health professionals such as wound care specialist nurses, expert methodologists, representatives of administrative, social, ethical, legal and economical areas, representatives of patient associations, citizens and consumers.

Then the jury will sign up a general regulation document to endorse the methodology and procedures to be followed. It will assess, the documents drawn up by the experts and the working groups and any other materials commissioned by the PC and the TSC to gather further useful information on the topic.

The **president of the jury** will have the task of:

- drafting the general regulation and having it approved by the members of the jury,
- verify that all members of the jury promptly receive the materials produced by the experts and working groups;
- coordinate the jury and the writing committee until the draft of the final consensus document;
- moderate the jury discussions via email;
- check the voting results;
- maintain relations with the PC and act as a direct communication to the jury.

The **writing committee** (WC), will draw up, with the methods established and described in the jury's regulations, the definitive document of consensus, integrating the preliminary document of the jury with a summary of the evidence.

The **experts** and **working groups** will have the task of preparing a summary/synthesis of the scientific evidence available for each clinical question, providing the jury with the produced materials.

An organizational secretariat has been appointed to support the above activities. It will provide logistical support in the various phases of the consensus conference organization.

Management of potential conflicts of interest

With reference to potential conflicts of interest, the PC has established a policy regarding the conflict of interest.

According to the definition of "The new dictionary of medical ethics" (KM Boyd et al., 1997), we are faced with a conflict of interest when "we are in a condition in which the professional judgment concerning a primary interest (the health of a patient or the veracity of the results of a research or

the objectivity of the presentation of an information) tends to be unduly influenced by a secondary interest (financial gain or personal advantage)".

The conflict of interests must always be considered and treated as a condition and not as a behaviour. Likewise, the conflict of interests should not be understood as an evil in itself, but as something that must be identified, declared, processed and secured so that it is not detrimental to the professional's actions, while keeping it hidden can make unethical and illegal the professional action of the conflict of interest holder.

Based on above mentioned considerations, anyone who participates in any way in the CC is required to publicly declare, by completing a conflict of interests form (COI), any potential current and/or previous conflict of interest, of an economic nature.

The declaration on potential conflicts of interest (see the appendix 1) must be completed and sent together with your curriculum vitae, at the start of the work of the CC to the organizational secretariat. An update must be signed and delivered within 7 days of the change of any element in the declaration.

Bibliografy

(1) Fowler E, Scott-Williams S, McGuire JB. Practice recommendations for preventing heel pressure ulcers. Ostomy Wound Manage 2008 Oct;54(10):57.
(2) Helvig EI, Nichols LW. Use of high-frequency ultrasound to detect heel pressure injury in elders. J Wound Ostomy Continence Nurs 2012 Sep-Oct;39(5):500-508.
(3) Bosanquet DC, Wright AM, White RD, Williams IM. A review of the surgical management of heel pressure ulcers in the 21st century. International Wound Journal 2016 Feb;13(1):9-16.
(4) Gefen A. The biomechanics of heel ulcers. J Tissue Viability 2010 Nov;19(4):124-131.
(5) Sophera R, Nixon J, McGinnis E, Gefen A. The influence of foot posture, support stiffness, heel pad loading and tissue mechanical properties on biomechanical factors associated with a risk of heel ulceration. J MechBehav Biomed Mater 2011 May;4(4):572-582.
(6) Cevera JJ, Bolton LL, Kerstein MD. Options for diabetic patients with chronic heel ulcers. J Diabetes Complications 1997;11:358–66.
(7) Pickwell KM, Siersma VD, Kars M, Holstein PE, Schaper NC. Diabetic foot disease: impact of ulcer location on ulcer healing. Diabetes Metab Res Rev 2013;29:377–83.
(8) Dosluoglu HH, Attuwaybi B, Cherr GS, Harris LM, Dryjski ML. The management of ischemic heel ulcers and gangrene in the endovascular era. Am J Surg2007;194:600–5.
(9) Tukiainen E, Kallio M, Lepäntalo M. Advanced leg salvage of the critically ischemic leg with major tissue loss by vascular and plastic surgeon teamwork: Long-term outcome. Ann Surg 2006 Dec;244(6):958.
(10) Bosanquet DC, Harding KG. Wound duration and healing rates: cause or effect? WoundRepairRegen 2014 Mar-Apr;22(2):143-150.
(11) Nakagami G, Sanada H, Konya C, Kitagawa A, Tadaka E, Tabata K. Comparison of two pressure ulcer preventive dressings for reducing shear force on the heel. J Wound Ostomy Continence Nurs 2006 MayJun;33(3):267-272.
(12) Cevera JJ, Bolton LL, Kerstein MD. Options for diabetic patients with chronic heel ulcers. J DiabetesComplicat 1997 Nov-Dec;11(6):358-366.
(13) Willock J, Hughes J, Tickle S, Rossiter G, Johnson C and Pye H. Pressure sores in children – the acute hospital perspective. Journal of Tissue Viability 2000;10, 59–62.
(14)Baldwin KM. Incidence and prevalence of pressure ulcers in children. Advances in Skin & Wound Care 2002;15, 121–124.
(15) Groeneveld A, Anderson M, Allen S, Bressmer S, Golberg M, Magee B, Milner FM and Young S. The prevalence of pressure ulcers in a tertiary care paediatric and adult hospital. J Wound Ostomy Continence Nurs. 2004;31, 108–122.
(16) McLane KM, Bookout K, McCord S, McCain J and Jefferson LS. The 2003 national paediatric pressure ulcer and skin breakdown prevalence survey. J Wound Ostomy Continence Nurs. 2004 Jul-Aug;31(4):168-78.
(17) Dixon M, Ratliff C.Pediatric pressure ulcer prevalence--one hospital's experience. Ostomy Wound Manage. 2005 Jun;51(6):44-6, 48-50.
(18)Suddaby EC, Barnett S, FacteauL.Skin breakdown in acute care pediatrics. PediatrNurs. 2005 MarApr;31(2):132-8, 148.
(19) Schlüer AB, Cignacco E, Müller M, HalfensRJ.The prevalence of pressure ulcers in four paediatricinstitutions.JClinNurs. 2009 Dec;18(23):3244-52. doi: 10.1111/j.1365-2702.2009.02951.x.
(20) Curley MAQ, Quigley SM and Lin M.Pressure ulcers in paediatric intensive care: incidence and associated factors. Ped Crit Care Med. 2003; 4, 284–290.
(21) Willock J, Harris C, Harrison J, Poole C. Identifying the characteristics of children with pressure ulcers. Nurs Times. 2005 Mar 15-21;101(11):40-3.
(22) Visscher M, Taylor T.Pressure ulcers in the hospitalized neonate: rates and risk factors. Sci Rep. 2014 Dec 11;4:7429. doi: 10.1038/srep07429.
(23) Baharestani MM, Ratliff CR. Pressure ulcers in neonates and children: an NPUAP white paper. Adv Skin Wound Care. 2007 Apr;20(4):208, 210, 212, 214, 216, 218-20.
(24) McGinnis E, Stubbs N.Pressure-relieving devices for treating heel pressure ulcers. Cochrane Database Syst Rev. 2014 Feb 12;(2):CD005485. doi: 10.1002/14651858.CD005485.pub3.
(25) Candiani G, Colombo Cinzia, Daghini R, Magrini N, Mosconi P, Nonino Francesco, et al. Manuale metodologico - Come organizzare una conferenza di consenso. 2013th ed. Roma: Zadig; 2009.