

**EFFICACY OF THE USE OF A POLYURETHANE FOAM
MULTILAYER DRESSING IN THE SACRAL AREA, IN
ADDITION TO STANDARD HEALTHCARE, TO PREVENT THE
ONSET OF PRESSURE ULCER IN PATIENTS AT RISK.
MULTICENTRIC RANDOMIZED CONTROLLED TRIAL.**

ID: MULTISCHIUME

Funding

The dressing was supplied free of charge for all the patients in the study by Coloplast on the understanding that they only provided the dressings and signed an agreement to supply the free samples without influencing the methods and elaboration of the data collected in any way and had no role in data analyses or report writing.

Conflicts of interests

The authors declared no potential conflicts of interest with respect to the authorship and/or publication of this protocol.

Background

Pressure injuries (PI) represent one of the complications most closely related to the care of the bedridden patient. In literature, their incidence can range from 7% to 71.6% (Moore & Cowman, 2014), particularly in surgical patients (Gardiner, Reed, Bonner, Haggerty, & Hale, 2016). Orthopedic patients have a higher risk of developing pressure sores in this population: one study reports an incidence of such injuries of 11.9-19.2%, compared to an incidence of 8.8-9, 2% in surgical patients in general (Al-Shadedi, 2012). In the medical field, a recent Italian study has been found that indicates an incidence of LdP of 6.5% (Palese 2017) while in intensive care it stands at 13.1% (Santamaria 2015).

PIs are often difficult to heal, painful and have a negative impact on the patient's quality of life up to the risk of mortality (Jaul 2015 A; Jaul 2015 B). Interventions aimed at their prevention play an important role both in increasing the quality of care and in reducing health

expenditure as well as in ensuring a better quality of life for the patient (Bernabei 2011; NPUAP 2014). PDs can be prevented through risk assessment, skin inspection, nutrition and hydration balance and through the use of devices that distribute pressure. Strategies to increase patient mobility also contribute substantially to injury prevention (NPUAP 2014). Lastly, advanced dressings of different shapes and materials could help reduce pressure, friction, skin stretching and effectively manage the humidity level. (Santamaria 2015).

The rationale for the use in prevention of products useful for the treatment of pressure injuries is also described in the 2013 systematic review (Moore 2013). The incidence of PD is probably reduced through the ability of foam dressings to redistribute mechanical forces. The Guidelines of the European and United States National Pressure Ulcer Advisory Panels (EPUAP and NPUAP) also suggest that the use of foam dressings may protect parts of the body at risk of stretch injuries. The market offers different types of advanced dressings compared to the material they are made of (hydrocolloids, polyurethane foams), their thickness (single or multi-layer) and their dimensions.

Various in vitro comparative studies are available where the different abilities of the main brands of dressings are compared with the pressure redistribution (Call 2015; Matsuzaki 2015; Miller 2015), liquid management (Young 2007) and shear forces (Levy 20015 and Levy 20016) which are the main causative factors of PD development (NPUAP 2014). In these in vitro studies the material that seems to be most effective is polyurethane foam (Matsuzaki 2015; Miller 2015), especially multilayer (Black 2015).

Two systematic reviews published in 2013 and 2014 then evaluated the efficacy on patients of using advanced multi-layer polyurethane dressings in prevention to reduce the incidence of pressure injuries (Clark 2014; Moore 2013). The results of both systematic reviews, although in favor of the use of dressings, are considered by the authors to be inconclusive due to the weakness of the study design found and therefore the high risk of bias. Both reviews concluded by soliciting the production of methodologically more rigorous clinical studies (Clark 2014; Moore 2013). Recently, some trials have been published which confirm the preventive efficacy of polyurethane multilayer foams (Santamaria 2015; Kalowes 2016; Forni 2018; Santamaria 2018) but the populations investigated are very specific, limiting the generalizability of results.

AIM

The aim of the present study was to assess whether the application of a multilayered dressing made of hydrocellular polyurethane foam conformed to the sacral area (MSP) in addition to standard preventive care reduces the rate of pressure ulcer (PU) and their severity in population at risk admitted in acute care Hospital.

Study endpoint

Primary Endpoint

Incidence of PD to the sacrum of any category detected during the first 7 days of hospitalization.

The 7-day cut off derives from the data in the literature with respect to the average times of onset of the lesions (4th day in the medical field, 5 ° in the surgical field and 3 ° in the intensive care unit) with standard deviations that allow to affirm that after 7 days in the acute patients the PD event is extremely rare (Palese 2017; Chiari 2017; Santamaria 2015). PD is defined as a damage to the skin and underlying tissues due to pressure, stretching or friction or a combination of these factors (NPUAP 2014). The incidence of PD is represented by the PD who develop during hospitalization and are not present when the patient is admitted. The injuries will be classified according to the classification defined by the guideline prepared by NPUAP 2014. (attachment).

Secondary Endpoints:

- Incidence of PD to the sacrum category \geq II ° according to the NPUAP scale
- Skin irritation / damage due to adhesive dressing
- Day of onset of the PD
- Number of dressings used
- Number of patients who stop treatment due to discomfort caused by the dressing (withdrawal)

Other study variables / data collected

- Gender
- Age

- Origin of the patient: first aid, another ward or facility, Short Observation (OBI), Home
- Progressed (healed) PD to the sacred
- Patient risk level measured with the Braden scale (Pancorbo-Hidalgo PL 2006)
- Days in the study
- Use of the diaper
- Use of the bladder catheter
- Use of anti-decubitus surface (static, preventive dynamics, curative dynamics and air release)
- Daily presence of the caregiver (presence at least during a meal, never, always)

Study Population

Inclusion Criteria:

- Patients at risk of developing PD measured with the Braden scale (Braden \leq 16) with intact sacral skin and / or with signs of healing from previous sacral lesions.
- Patients or legal guardians who consent to the study
- Adult patients
- . Male and female gender
- Expected hospital stay and / or life expectancy > 72 hours
- Patients hospitalized for no more than 24 hours

Exclusion criteria:

- Patients with known allergy to the products under study or with dermatological pathologies that prevent the use of topical products
- Patient with, upon entering the ward, advanced preventive dressing in the sacral region

Design

Trial randomizzato e controllato di superiorità in cieco (elaborazione dati) a gruppi paralleli con rapporto di allocazione di 1:1 con randomizzazione a blocchi di 10 e bilanciati per reparto e per area. Non è possibile la cecità degli outcome assessor in quanto nei pazienti del gruppo sperimentale resta spesso una traccia cutanea della presenza della schiuma (impronta cutanea).

Randomized controlled superiority trial (blinded only data processing) with parallel groups. Allocation ratio of 1: 1 with randomization in blocks of 10 and balanced by department and by area. The blindness of outcomes assessor is not possible as in the patients of the experimental group there is often a cutaneous trace of the presence of the foam (skin impression).

Materials and methods

Areas involved

Surgical Area: general or specialist surgery departments.

Medical Area: geriatrics or neurology or internal medicine departments.

Intensive Area: intensive care or intensive care units.

For each area of each participating center a sample of 40 subjects is expected, randomization will be done by areas.

Intervention:

Application of MSP in the sacral region within 24 hours of admission and replaced when it comes off, gets wet or gets dirty in addition to standard preventive care (see below).

MSP is a multilayer foam consisting of: a multi-layered dressing consisting of a polyurethane foam and a super-absorbent hydrocapillary pad, two layers of polyurethane film, one external and one internal, and a pressure-sensitive adhesive (PSA) that holds together the two absorbent layers. The last layer, in contact with the lesion and the skin, is in delicate adhesive silicone, non-adherent, perforated.

The foam must be raised to the margins at least once a day to check the condition of the underlying skin. If on the seventh day after randomization the patient is still hospitalized, after the inspection of the skin, the data collection form (CRF) is closed and the study concluded.

The medication will be provided free of charge for all the subjects in the studio by the manufacturer. The company will only supply the dressings. A written agreement was signed in which the company agrees to provide free samples of the product being studied without

affecting in any way the methodology of drafting the protocol, conducting the study, analyzing the data and publishing the results.

Comparison:

Standard preventive care. If on the seventh day after randomization the patient is still hospitalized, after the inspection of the skin, the CRF is closed and the study concluded.

Standard preventive care

Evaluation of the risk of developing PD with a Braden scale within 24 hours of admission. Positioning of the patient on a preventive or curative anti-decubitus mattress (static or alternating pressure) if Braden value ≤ 16 or in any case according to the hospital policy, daily inspection of the skin and mobilization of the patient at least every 4 hours (in the surgical patient at least in the post-operative period) if the clinical conditions allow it (NPUAP 2014). Management of incontinence, humidity control and prevention of skin maceration and rubbing / friction during postural changes as per hospital policy.

Method

At the entrance of the patient in the ward, the nurse dedicated to the first reception assesses whether the person has the necessary criteria to be enrolled in the study. In the positive case, he/she will explain to the patient or to his legal guardian, the rationale of the study, he/she will submit the information requesting consent to the participation granting the necessary time for reading and consultation before any consent and signature. If the patient consents, the nurse has the consent signed and attached to the medical record by setting the first part of the CRF (attachment). If the patient at risk refuses the participation, if he/she has other exclusion criteria or if it is not possible to collect the consent, the nurse transcribes it on the CRF and files it. If the patient agrees to participate in the study, the dedicated nurse proceeds to randomization (see below for methods) taking the first opaque envelope according to the external progressive number. It transcribes in the CRF the date, the patient's ID, if he already has PD not to the sacrum and their category and location. It also sign the study arm and other variables of interest. If the patient is in the experimental arm, the nurse, in addition to the standard preventive care, applies the MSP to the sacrum and writes date and time on the CRF and on the MPS. However, the foam must be applied within 24 hours of admission. If this

time interval is exceeded, the researcher will mark the problem in CRF in the "NOTES" part and the patient leaves the study and the CRF is archived.

- Operating room: when the patient is eventually taken to the operating room to undergo surgery, the operating room nurse checks if the patient at risk is enrolled in the study. At the end of the surgical intervention, when returning to the ward, if the patient belongs to the MSP arm, check if the foam has been removed (surgery often necessary to proceed with the preparation of the sterile field for spinal anesthesia and for the procedure surgery) and repositions it.
- If the patient is transferred to the intensive care unit at any time during his or her treatment, the dedicated nurse will also enclose the data collection form with the documentation, which will continue to be filled in according to the protocol written by the dedicated intensive care nurse .
- If the patient leaves the operating room directly for intensive care, it is the duty of the dedicated nurse in the ward to send the CRF to the intensive care unit to continue the study, if it is not already attached (see previous paragraph). The Intensive care nurse will collect data with the same methods and timing.
- If the patient is transferred to a ward not involved in the study, the CRF is completed and the enrollment is closed (as if he were discharged).

Daily data collection

Every morning the data collection nurse:

- Assess the patient's skin (shoulder, sacrum, elbows, heels, back, calves, thighs, ankles...) and completed the daily CRF part;
- If the patient belongs to the intervention arm (MSP), the nurse will also check daily whether the dressing is still tight, dry and clean. If the dressing is detached even partially the MSP is replaced (do not put reinforcement patches) and the change is reported in the CRF.
- Every day (once a day) in patients with MSP, it removes an edge to check if the skin of the sacrum is still intact, marking the result of the inspection in the CRF.

- If it replaces the MSP (dirty, detached or wet) it marks it in the CRF and writes the date and time on the MPS itself. The foam will however be removed upon discharge regardless of the day of admission and in any case no more than 7 days (as per the indication of maximum permanence of the MSP provided by the manufacturer).
- Upon return of the patient from the operating room, the referring nurse verifies, as soon as possible, that the patient of the intervention arm still has the polyurethane foam in the sacrum. Otherwise apply it by marking it in the CRF.
- At discharge or on the appearance of pressure lesion on the sacrum \geq 2nd category, the CRF is closed and the patient ends the study. If the patient has developed PD the treatment of the lesion will be performed according to the hospital policy.
- The medication will be removed, however, no later than the first 7 days of admission after which the patient ends the study.

Study exit criteria

- Withdrawal of informed consent before randomization
- Not randomized within 24 hours of admission

Conclusion of the study in the single recruited subject

- Withdrawal of consent after randomization
- The appearance of irritation to the skin caused by the dressing. The dressing is removed, reported in CRF and irritation treated as per hospital policy.
- At the request of the patient due to discomfort due to preventive medication.
- On discharge / death / transfer to ward not involved in the study before the 7th day after randomization
- After 7 days from randomization in the absence of PD to the sacrum
- The appearance of pressure injury to the sacrum higher than the first category

Sample size

From a randomized monocentric study of at-risk patients with a hip fracture where polyurethane foams were used in prevention, the incidence in the experimental group was 4.5% while in the control group of 15.4%. Similar deltas had also been identified in other trials in intensive care patients. Assuming similar results in the population subject of the present study and taking into account an alpha error of 0.05 and a beta error of 20%, it is necessary to enroll at least 228 patients at risk. In order to allow analyzes by subgroup (see the "statistical analysis" section) the sample size must be guaranteed for each area (medical, surgical, intensive).

Taking into account also a possible loss at the follow-up of 10% and also assuming a 10% withdrawal rate, the necessary sample will be 280 patients per area and therefore a total of 840 patients (420 per arm) . Each hospital involved will enroll 40 patients per area involved in that specific hospital.

Randomization

At the Research Center for Health Professions of the Rizzoli Orthopedic Institute in Bologna (coordinating center), using the site: www.randomization.com, a randomization list will be generated in blocks of 10. A sequence of opaque envelopes will be prepared with outside a progressive number. Inside the envelope a label will be placed that will contain the words "yes" or "no", according to the sequence indicated by the generated list.

The envelopes will always be sealed at the Research Center and the list kept under lock and key. The envelopes will be placed in a dedicated box and delivered to the nursing research manager of the hospitals involved in the study. In each ward/area a reference nurse will be identified and 40 envelopes delivered.

Statistical analysis

The analysis of the results will be carried out for Intention to Treat.

All continuous data will be expressed in terms of average and standard deviation. One Way ANOVA will be used to evaluate the differences between the averages of the experimental and comparison group. If the Levene test for homogeneity of variance were significant ($p < 0.05$), the Mann Whitney test will be used. For all dichotomous variables the incidence, relative risk, relative risk reduction and number needed to treat will be calculated. The exact

Fisher test will be used to evaluate the differences between the incidences of different outcomes between the experimental group and the control group.

Subgroup analysis:

- by area of belonging (medical, surgical or intensive)
- by risk level according to the Braden classification: Severe (total score 9); High Risk (10-12) Moderate Risk (13-14); low Risk (15-16). (Pancorbo-Hidalgo PL 2006)
- by origin (domicile vs. other settings)

For all tests, a $p < 0.05$ will be considered significant.

The statistical analysis will be done using the "Statistical Package for the Social Sciences" (SPSS) software version 15.0 (SPSS Inc., Chicago, USA)

Possible deviations from the protocol and / or critical issues and related behavior to be followed in all situations

- If the dedicated nurse, during the daily inspection, realizes that the sacral MSP (in the patients of the experimental arm) has been removed without being positioned anymore, he provides to reposition it, marking in the CRF that the patient for that day remained without.
- If instead the MSP is present and the patient belongs to the control group, the dedicated nurse reports the violation of the CRF randomization but leaves the MSP and treats the patient as reported for the experimental group. At the analysis of the results, if these violations have occurred, we will proceed in addition to the analysis for Intention to Treat also for Protocol.
- If the patient is replaced by a different MSP (different brand) than the one in the studio, the dedicated nurse replaces it and marks the problem in CRF.

Safety / risk assessments for participants:

Patients are treated according to protocols and policy already in place (prevention and treatment of pressure injuries), and always in strict compliance with the Good Clinical Practice (GCP), there are no additional risks for the participants. The patient who eventually develops pressure ulcer will be treated as per hospital policy. If the patient develops a category I sacral lesion remains in the study. The event is marked in the data collection form (CRF). The rationale for this permanence involves both the difficulty in the differential diagnosis with skin redness (Sternier 2011) and the need to detect the secondary outcome

“Incidence of PD to the sacred category \geq II ° according to the NPUAP scale”. The treatment of a category I injury involves the use of creams or at the most of ultrathin advanced dressing. If used in the control group patient it will be reported in CRF. If the patient belongs to the experimental group, no additional action is necessary.

Duration of the study

The project lasts a total of 12 months which includes the training of the staff of the centers involved, the recruitment of patients, the collection and processing of data. The time per patient is 7 days or until discharge if it occurs before the seventh day of admission. The date of the start of the trial will be considered to be the approval of the Ethics Committee for each center.

The timing of the study includes the following subdivision:

- Months 1 training of the centers involved
- Months 2- 6- patient enrollment and database implementation
- Months 7-12 - Data analysis and results dissemination

Ethical and Administrative Aspects

Informed consent

Every potential participant will be fully explained the rationale of the study and will be given the opportunity to ask questions and receive answers to all his doubts. The informed consent form must be signed by the participant or a legally authorized representative prior to his participation in any of the procedures foreseen by the study. Patient documentation must be able to demonstrate that consent was given prior to participation in the study. A copy of the informed consent form must be left to the patient. The consent form, signed by the patient, must be kept at the site.

Approval by the Ethics Committee

This protocol, the informed consent form and all the necessary relevant information related to the study must be submitted to the Ethics Committee for evaluation and must be approved before the start of the study. The study will be conducted in accordance with international standards ISO 14: 155, with the Good Clinical Practice and with the national laws in force. In the event of amendments to the protocol (eg modification of the eligibility criteria, outcome, statistical analysis....) Specific amendment to the approval Ethics Committee will be required

Confidentiality, Data Management, and Property of Results

Adequate documentation will be maintained for everything concerning the patient's clinical data, work sheets, nursing notes, documentation and treatment of adverse events (CRF and nursing record) and study interruption. The confidentiality of the patient's sensitive data is guaranteed by the Investigator. The data is the property of the researchers. The data collected in the CRFs will be entered into a computerized and anonymous database. 10% of the CRFs will be randomly checked. The level of accuracy will be considered if more than 2% of input errors are not detected. The verification will be done by the Nursing and Allied Profession Research Unit of the IRCCS Rizzoli Orthopedic Institute.

Publication of Results

The main investigator undertakes to produce the final report, publish all the data collected as described in the protocol and ensure that the data is reported responsibly and consistently.

In particular, the publication of the data deriving from this study will take place regardless of the results obtained.

The transmission or dissemination of the data, through scientific publications and / or presentation at congresses, conferences and seminars, will take place exclusively following the merely statistical elaboration of the same, or in any case in an absolutely anonymous form.

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INFORMATION SHEET

Dear Madam / Sir _____

at the Rizzoli Orthopedic Institute IRCCS of Bologna is planning a medical-scientific research entitled: Effectiveness of the use of multilayer polyurethane foam dressing in the sacral area, in addition to standard care, for the prevention of pressure ulcer in patients at risk. The study is of a multi-center nature, ie other hospitals and treatment centers in Italy are involved.

To carry out this research we need the collaboration and availability of people who, like you, satisfy the scientific requirements suitable for the evaluation that will be performed. However, before you make the decision to accept or refuse to participate, please read carefully, taking all the time you need, these pages and ask us for clarification if you do not understand or need further clarification. Furthermore, if he wishes to do so, before deciding, he can ask an opinion to his family or to a trusted doctor.

What is this study proposed for?

The general objective of the study is to evaluate whether applying a polyurethane foam to the sacrum (it is a small soft sponge that is placed in the area of the sacrum held by a light plaster), in addition to the usual care, the probability of developing pressure injuries (wounds in the skin) and their severity. If you do not apply the soft sponge (polyurethane foam), the nurse of the department puts in place the care that you always do to avoid the formation of injuries: She often changes position if she cannot do it alone / a, The put a special mattress (antidecubitus) and guarantees you the cleaning to reduce the presence of moisture on the skin.

What does your participation in this study involve?

In case you decide to participate in the study, the experimental design of this research foresees that for a group of patients chosen at random (as would be done by throwing a coin) this sponge will be applied in addition to the usual preventive care during the first 7 days of hospitalization and for another group will be implemented only in the usual assistance (see description below). During the first 7 days of hospitalization, a nurse will check his/her skin and write down his characteristics and the assistance you received in the previous 24 hours in the data collection form (this information is always written in a folder). Moreover, if it belongs to the group of patients in which the sponge is applied (polyurethane foam), always on a daily basis, a nurse will also check whether it is still attached, dry and clean and will raise a border to examine the underlying skin . In this way, at the end of the study, it will be possible to understand whether using this sponge in addition to the usual preventive care reduces the probability of developing pressure injuries and their severity. Apart from the application and monitoring of the sponge by the nurse, you will not be asked and done anything other than what is already foreseen by your treatment plan.

To say that he will be "randomly chosen" means that, if he agrees to participate in the study, the nurse will open an envelope inside which it will be written whether it was assigned to the sponge group (polyurethane foam) or to the group of usual care. The envelopes are reserved and no one in the ward knows what it contains until they are opened.

The study will last 4 months and you will be involved only in the first 7 days of your stay or until you are discharged. Forty patients will participate in this research in this hospital, which will be chosen from all those who are in the same clinical condition.

If you agree to participate in this study you will be subjected to a first assessment to verify that your condition meets the criteria required by the study. If so and if you have agreed to participate in the study you will be asked to sign this form and nothing else.

Participation in the study does not entail any additional expenses for you compared to the normal clinical routine foreseen by this structure.

What other treatments are available?

No other experimental treatment is foreseen and you will be treated as normally foreseen in the assistance practice for patients with your pathology. If new information is published in the scientific literature relating to this treatment, during the conduct of the study, it would be interrupted.

What are the benefits you can receive by participating in this study?

The following benefits can be expected from participation in this study: possible decrease in the onset of pressure injuries and their severity.

What are the risks of participating in the study?

Participation in the study does not involve additional risks linked to the possible use of polyurethane foam as it is one of the advanced dressings for the treatment of pressure injuries. If data becomes available that may influence your willingness to continue participating in the study, you will be promptly informed.

Am I obliged to participate?

You are free not to participate in the study. In this case, however, you will receive all the standard therapies provided for your pathology, without any penalty, and the doctors and nurses will continue to follow you with appropriate care. Your participation in this research program is completely voluntary and if you have agreed to participate, you can still withdraw from the study at any time.

Will I have to incur costs to participate in the study?

Participation does not entail any cost for the patient.

Information about the results of the study

If you request it, at the end of the study the results in general and in particular those concerning you may be communicated to you.

Further information

The following personnel will be available for further information and communications during the study:

Cristiana Formi nurse responsible for research, telephone 0516366694

You can request information on the rights of study participants at the Local Secretariat of the AVEC Ethics Committee, via Pupilli 1, Rizzoli Orthopedic Institute 40136 Bologna, tel. 051 6366480 - Email: segreteria.ce@ior.it

The protocol of the study that was proposed to you was drafted in compliance with the European Union Good Clinical Practice Rules and the current revision of the Helsinki Declaration and was approved by the Ethical Committee of the Emilia Wide Area Center of the Emilia-Romagna Region (CE -AVEC).

DECLARATION OF CONSENT

I, the undersigned: _____

I declare that I have received from Doctor _____

comprehensive explanations regarding the request to participate in the experimental study in question, according to what is reported in the information sheet attached here, a copy of which was delivered to me with sufficient notice (date _____).

I also declare that I was able to discuss these explanations, to ask all the questions that I considered necessary and to have received satisfactory answers, as well as to have had the opportunity to inform me about the details of the study with a person I trusted.

I therefore freely agree to participate in the trial, having fully understood the meaning of the request and having understood the risks and benefits involved.

I accept

I do not accept

Date Signature of the patient

Date Signature of the nurse who informed the patient

[In case the patient cannot read and / or sign]

I, the undersigned: _____

I testify that Nurse _____

has fully explained to Mr. _____

the characteristics of the experimental study in question, as reported in the information sheet attached herein, and that the latter, having had the opportunity to ask all the questions he deemed necessary, freely accepted to join the study.

Date Signature of the independent witness