A Prospective, Longitudinal Study to Assess Use of Continuous and Reactive Low-pressure Mattresses to Reduce Pressure Ulcer Incidence in a Pediatric Intensive Care Unit

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Abstract

Pressure between bony prominences and sleep surfaces, as well as pressure from the use of medical devices, put children admitted to pediatric intensive care units (PICUs) at risk of developing pressure ulcers (PUs). To assess the effect of two pediatric-specific, continuous and reactive low-pressure mattresses on the incidence of PUs, an observational, descriptive, prospective, longitudinal (2009–2011) study was conducted among PICU patients. The two pediatric mattresses — one for children weighing between 500 g and 6 Kg and another for children weighing more than 6 Kg — were provided to patients at risk for PUs (Braden-Q ≤16, Neonatal Skin Risk Assessment Scale [NSRAS] ≤13, or per nurse assessment of clinical need). Between 2009 and 2011, 30 children (13 [43.3%] girls and 17 [56.7%] boys), ages 0 to 10 years, at risk of developing PUs (NSRAS risk: n = 14 [13.2 ± 3.03] and Braden-Q risk: n = 10 [10.4 ± 2.4]) were placed on the study mattresses for a median of 4 (range 1 to 25) days. Primary reasons for PICU admission included disorders of the respiratory system (40%), infectious and parasitic diseases (23.3%), and illnesses of the musculoskeletal system and connective tissue (10%). All other PU prevention strategies (eg, repositioning, specialty devices) used as part of standard care protocols also were implemented. Of the 30 participants, only one (3.3%) (confidence interval [CI] 95% = 0.08 –17.2%) developed a nondevice-related PU. No adverse events occurred. A 2008 incidence study in the same PICU, before use of these special surfaces, found a cumulative incidence of 20% nondevice-related PUs. The observed incidence rate of nonmedical device-related PUs in this high-risk population placed on these mattresses is encouraging and warrants future research.

Keywords: clinical study, pediatric, pressure ulcer, prevention, beds

Index: *Ostomy Wound Management* 2012;58(7):32–39

Potential Conflicts of Interest: Mr. Torra i Bou discloses he is Clinical Manager of Smith & Nephew Spain, the distributor of Carital Systems in Spain.

Literature review

Pressure ulcers (PUs) have always been considered an adverse event associated with adulthood and old age. However, in recent decades and closely related to the extension of the use of intensive therapeutic techniques such as extracorporeal membrane oxygenation (ECMO), high-frequency oscillatory ventilation, and noninvasive mechanical ventilation (VMNI) that limit mobility, pressure in the contact zones increases, resulting in tissue ischemia; thus, PUs in the pediatric population

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increasingly occur. In an observational study, Zollo et al[1] described a PU incidence related to devices and support surfaces of 26% in a population of 271 children admitted to a PICU. Neidig et al's observational study[2] found a prevalence of 16.9% of occipital PUs in a population of 59 children who received cardiac surgery. A retrospective study by Schmitd et al[3] of two cohorts of 32 children found a 53% prevalence of PUs in the group of children treated with high-frequency mechanical ventilation, compared to a prevalence of 12.5% in the control cohort without ventilation. In their multisite prospective cohort study involving 322 patients (ages 21 days to 8 years of age) admitted to a PICU, Curley et al[4] found a PU incidence of 27% related to support surfaces and medical devices.

In addition, pediatric patients with neurological or disabling illnesses (myelomeningocele, congenital myopathies, and the like) that involve long periods of immobility or forced positions, as well as patients generally cared for at home, also are at risk for PUs.[5]

Different intensive therapies used in the PICU and the medical conditions requiring hospitalization often reduce mobility. According to a report from the National Pressure Ulcer Advisory Panel (NPUAP),[6] children who remain immobile and insensate to the harm caused by pressure and the prolonged deformation of tissues between bony prominences and sleep surfaces or diagnostic or therapeutic devices are at higher risk for PUs. In their review of the literature, Willock et al[7] observed that the main locations of PU were the skin area in contact with therapeutic devices and sleep surfaces. In their multisite prospective evaluation pre- and post intervention study in 51 hospitals involving 2820 neonates, Lund et al[8] observed that higher PU risk was related to pulsioximeter probes, nasogastric tubes, and endotracheal tubes. In Waterlow's multi-centered study[9] involving 300 children ranging from neonates to children aged 16 years, 27.3% of PUs were related to medical equipment.

The most frequent locations of PUs differ between children and adults. This is mainly due to the fact that during the growth process, each age has a different body surface area and weight distribution. According to a review of the literature,[10] the most common locations of PUs in children <3 years old are the occipital area and the ears; in children older than 3 years, ulcers on the sacrum and heels are most common. In their study, Curley et al[4] reported that 32% of Stage I and Stage II PUs appeared on the heads of PICU patients. These anatomical locations are also the areas of greatest contact with the support or sleep surface (SS) on which they rest. In an observational study conducted among 13 healthy children ages 10 weeks to 13.5 years, Solis et al[11] measured interface skin pressures and observed a link between the body surface area and anatomical locations subject to the greatest levels of pressure. For body surface areas >1 m^2, the pressure was greater at the sacrum than in the occipital area. In older children, the distribution of PU locations becomes more similar to that of adults.

Ostomy Wound Management 2012;58(7):32–39

Key Points

- The authors of this study prospectively evaluated the incidence of nonmedical device-related pressure ulcers (PUs) among patients admitted to a pediatric intensive care unit (PICU).
- One of 30 patients evaluated developed a nondevice-related PU on the occiput.
- The authors are encouraged by these results because they compare favorably to their previously documented PU incidence rate.
- Prospective, randomized, controlled clinical studies are warranted.

Pressure management special surfaces (PMSS) — ie, mattresses, mattress pads, or cushions — are an essential resource both for preventing PUs in patients at risk and for improving the treatment outcome of existing ulcers. PMSS are designed to redistribute pressure and avoid shear in deep tissues between skin and bony prominences in order to reduce the pressure on the highest-risk areas.[12]

In the last decade, new pediatric PMSS (P-PMSS) have been developed with promising results. According to a review of the literature,[13] no scientific evidence base on clinical practice is available to help clinicians choose between the different devices available or to help distinguish various device features. However, adequately powered, double-blind, randomized controlled clinical studies of these surfaces are not easy to conduct. Thus, the literature and guidelines contain contradictory and sometimes controversial information. McLane et al[14] conducted an analytical, observational study among 54 healthy children of different ages that measured the pressure between the children's skin and the surface of five different mattresses and local pressure-relief devices: a mattress or a standard hospital baby crib, a foam overlay, a mattress with an E-Gel Donut® (Philips Respironics, Andover, MA) type cushion, a foam overlay with an E-Donut® type cushion, and a low-air-loss overlay. The authors observed that the combination of a foam mattress with a gel cushion exerted lower pressures on the whole of the body than the use of a dynamic low-air-loss mattress. However, the study was limited by the fact that the low-air-loss mattress could not be used with children weighing <22.7 Kg; also,. dynamic PMSS always have been associated with the alternating system. PMSS man-

Table 1. Patient demographics and characteristics (2009–2011 group)

	n	Frecuency (%)	Average	SD	Median
Age					
<1 month	5	16.7			
1 month to 3 years	22	73.3			
3 to 6 years	1	3.3			
6 to 10 years	2	6.7			
Total	30	100			
Pressure ulcer risk assessed					
<1 month (NSRAS)	5	16.7	13.2 points	3.03	14
>1 month (Braden Q)	25	83.3	10.4 points	2.4	10
Total	30	100			
Weight					
<1 month	5	16.7	4.6 Kg	2.4	3.8
>1 month	25	83.3	10.3 Kg	5.5	10
Total	30	100			
Mechanical ventilation					
CMV[a]	18	60	6.4 days	5.3	5
NIMV[b]	9	30	4.6 days	4.7	2
HFMV[c]	7	23.3	5.3 days	5.3	4
Medical treatments					
Sedation + vasoactive drugs	15	50% of 30			
Vasoactive drugs	5	16.7% of 30			
Sedation only	3	10% of 30			
Analgesics	4	13.3% of 30			
No drugs	3	10% of 30			
Nutritional support					
Parenteral	22	73.3% of 30			
Enteral	19	63.3% of 30			
Medical devices CVC[d]	28	93.3% of 30			
Arterial catheter	20	66.7% of 30			
Urinary catheter	22	73.3% of 30			

a: Conventional mechanical ventilation
b: Noninvasive mechanical ventilation
c: High-frequency mechanical ventilation
d: Central venous catheter

ufacturers advise against the use of this system in certain groups of children (eg, children with acute spinal cord injuries, unstable fractures, thoracic injuries, fractured vertebrae and/or cervical traction). Moreover, in the case of intubated children in the ICU, alternating surfaces are not recommended due to the risk of causing hemodynamic and/or respiratory instability (bronchospasms) when the mattresses inflate and deflate the cells (children may not be able to respond to this movement).[5]

In 2008, members of the nursing group for the improvement of quality in pediatrics at the Valencia University clinical hospital interested in the subject created a PU epidemiological monitoring system in the pediatric service. A 5-month incidence study[15] was conducted within this framework. Of the 80 participating PICU patients, 13 developed at least one PU. The cumulative incidence (defined as the probability that a particular adverse event, such as occurrence of a PU, has occurred before a given time) was calculated as 19.4%, with a total number of 45 new device- and nondevice-related PUs in 13 children with or without risk. Category 1 and category 2 PUs occurred mainly in areas where medical devices

were applied, such as pulsioximeter probes and nasogastric tubes. Most category 3 (three, 6.7%) or category 4 (one, 2.2%) PUs were in an anatomical location (ie, heel, sacrum, occipital area, ear) in contact with standard mattresses. The authors' PICU had no PMSS in 2008; the potential problems revealed the need for research into the use of PMSS that met the requirements in terms of safety and pediatric suitability for the children at the most risk.

Given the results of the incidence study (2008)[15] and the fact that the authors had no PMSS with specific features for pediatric patients, an observational descriptive study was conducted to evaluate the effect of the new PMSS's (Carital Neo® and Carital Juve®, ceded by the company in 2009) on the occurrence of PUs in PICU patients. This study focuses on the relationship between the sleep surface and the development of PUs. Wounds that may be related to other factors such as use of medical devices were not included.

Study goals were two-fold: 1) measure the incidence of the new PMSS-related PUs in PICU patients at risk of developing PUs with whom the preventive measure being assessed was used; and 2) compare the incidence in the group of patients studied with an estimated group value in a similar population (children with PU risk).

Methods

Study design and population. An observational, descriptive, prospective, and longitudinal (2009–2011) study was conducted among patients treated at the PICU of the Valencia University Clinical Hospital (HCUV), a 415-bed, third-level hospital located in Valencia, Spain. The PICU at this center has a capacity of five beds with an average number of admissions (2008 to 2011) of 220 a year.

Inclusion criteria. All patients admitted (with or without PUs previous to receiving the new PMSS) to the PICU during the study period were considered eligible, pending inclusion/exclusion criteria. Eligible patients were ages 1 day to 10 years old, admitted to the PICU for more than 24 hours for whatever reason, at risk of developing PUs according to the Braden-Q scale (for children >1 month old) or the Neonatal Skin Risk Assessment Scale (NSRAS, for children <1 month old).[16,17]

Exclusion criteria**.** Children admitted to the PICU for <24 hours, older than 10 years, lacking verbal consent from parents for the use of relevant clinical data, and/or who had not received the new PMSS were excluded from the study.

Ethical issues**.** For patients meeting these criteria, parents were asked for verbal consent for the use of relevant clinical data; it was not necessary to obtain written informed consent because no interventions different from usual hospital protocol (eg, skin surveillance) were performed in accordance with the clinical situation of children, and the study was carried out in the framework of a University Hospital where PU surveillance is a key quality control activity. When consent was not obtained, children were not included in the evaluation. When patients were eligible for the study mattresses but none were available, the children were assigned to the best existing standard mattresses or another PMSS (different to the study object) according to their risk scores, but were not included in the study.

The confidentiality of clinical data was guaranteed in accordance with the hospital's internal rules. In no case was any information that might directly or indirectly identify a patient included in the databases, in accordance with current legislation in Spain (the Spanish data protection act, Law 15/1999, December 13, 1999). Permission from parents to take photographs was obtained verbally, and the patients' anonymity was guaranteed. The nursing supervisors and the head of the pediatrics service provided authorization for conducting the study.

Materials. Patients included in the study were provided one of the two PMSS for pediatric use manufactured by Carital Ltd. (Finland) and distributed in Spain by Smith & Nephew. The PMSS were classified as continuous and reactive low-pressure special surfaces (CRLPSS) intended for use in high-risk patients, even when alternating systems are contraindicated (ie, patients with clinical instability, spinal injury). Carital Neo® is designed for use in children weighing between 500 g and 6 Kg; the mattress measures 65 cm x 35 cm. Carital Juve® may be used in children weighing between 6 Kg and 300 Kg; the mattress measures 120 cm x 50 cm x 8 cm. The CRLPSS utilize a specific and patented technology, the Carital Air-Float System®, which consists of a double air-cell construction in the shape of a tunnel (one within the other) that reacts to the pressure being supported (ie, weight, shape, and patient movement) in three different compartments (head, central or trunk section, and extremities). Using a computerized system, the mattress continuously adjusts to achieve a level of pressure in the interface between the skin and the mattress and allows the patient to "float" over the surface. The CRLPSS maintains the same level of support in each section, which is different than alternating air systems, which change the pressure, inflating and deflating cells with a prefixed time.[18,19]

These CRLPSS also facilitate care that involves inserting venous catheters, placing X-ray equipment underneath the PMSS, transfers, CPR manuevers, and general hygiene measures, such as bathing or sheet changes. Furthermore, they can be used as dynamic overlay mattress over another static mattress or as a replacement mattress on the bed frame itself without affecting the patient's safety or increasing the risk of falls or strangulation between the bars of the bed.

Procedures. Following admission, the risk of PU development was assessed using the Braden-Q Scale (for

Table 2. Time of use of the special surfaces in the PICU

Type	Patients	Days of use		
	n	Average	SD	Median (range)
Carital Neo™	4	5	3.6	4.5 (2–29)
Carital Juve™	26	7.3	7.4	4 (1–25)
Total	30	7	7	4 (1–25)

children >1 month old) and NSRAS (for children <1 month of age). Patients with scores ≤16 and ≤13, respectively, were considered at risk.[16] If the patient was deemed at risk, the appropriate CRLPSS (depending on age, weight, and size) was assigned by the nurse in charge within 24 to 48 hours of admission, depending on CRLPSS availability. The nurses in the unit making the mattress assignments were trained in the use of the CRLPSS in informal sessions by a member of the research team. When the children did not need the CRLPSS (ie, clinical improvement, risk reduction, discharge, death), the unit nurse informed a research team member about removing the CRLPSS. After patient use, the mattresses were cleaned, disinfected, and stored away until needed again.

All patients (with and without CRLPSS) also received standard PU prevention measures according to PICU procedures, including repositioning if consistent with goals of patient care and medically and clinically possible (every 3 to 4 hours). Hyperoxygenated fatty acid (linoleic acid oil used to hydrate the skin) was applied to at-risk areas every 8 hours, daily hygiene was provided, and protective hydrocellular dressings were applied between the skin and the different therapeutic and diagnostic devices.

Variables. Patient variables collected included anthropometric (height and weight) data, gender, diagnosis and PU risk score when admitted, length of hospital stay, use of vasoactive drugs, parenteral or enteral feeding, and presence of venous central, arterial or urinary catheters. Extrinsic variables noted in the data collection forms included use of mechanical invasive and noninvasive ventilation, and high-flux oxygenation (a respiratory device that provides an high oxygen pressure). Length of device use was monitored and recorded.

Outcomes. Patient skin was assessed daily and the presence/absence of a PU noted.

PUs were described using the four categories proposed by the European Pressure Ulcer Advisory Panel (EPUAP). Extrinsic factors were noted, along with the presence or absence of a medical device in the injured area. The nurse responsible for the patient's care assessed for PUs daily.

Repositioning schedules, the use of local pressure management devices (eg, heel support, cushioned type of PMSS [latex, foam, viscoelastic, air-alternating or continuous, and CRLPSS]) were recorded. In the 2008 study, the PICU had one standard mattress type (latex) and two PMSS types: static (foam and viscoelastic) and dynamic (one air-alternating mattress). The study conducted 2009–2011 only assessed the patients with CRLPSS. Reason for study discontinuation (eg, discharge, death) also was recorded.

Data collection and analysis. All information was recorded using a paper instrument and electronic system. Data were entered into IBM® SPSS® Statistics 19 database (SPSS, Chicago, IL) for analysis. Patients enrolled in the study but not assigned to a CRLPSS in accordance with the procedure were excluded from the study.

Data collection for the incidence study ceased when researchers had 30 patients in the CRLPSS sample (2009–2011) and could assess the CRLPSS effects. For the comparative analyses between the 2009–2011 and 2008 patients, the research team established a characteristic basis for comparison of groups: risk and resultant incidence of PU. The research team extracted the group of 2008 children who were at risk of developing PUs (n = 35) and compared data collected in the 2009–2011 study.

The cumulative incidence of PUs related to support surfaces during the entire two study periods was calculated as number of children at risk for PU related to support surfaces divided by the total number of children at risk in the sample. After this first analysis, the research team compared the cumulative incidence of two groups using a z-test for differences in proportions.

Results

A total of 30 children, 13 (43.3%) girls and 17 (56.7%) boys, met the study enrollment criteria and were placed on a CRLPSS. The majority of patients were 1 month to 3 years old (73.3%) and had been provided conventional mechanical ventilation (60%), sedation and drugs (50%), parenteral (73.3%) and enteral nutrition (63.3%), and medical devices, most commonly central venous catheters (93.3%), arterial catheters (66, 7%), and urinary catheters (73.3%). The majority were admitted due to disorders of the respiratory system (40%) (see Table 1). Patient average length of stay was 12.7 days (SD ± 10.3 days) for a total admission time of 380 days. Two (6.7%) patients died during the study. The CRLPSS were used for a total of 211 days (55.5% of the patient time in PICU). The average length of time of CRLPSS use was 7 days (SD ± 7 days) (see Table 2).

No repositioning schedules were implemented for 19 children (63.3%) due to their clinical instability, condi-

tion, or state of health.

Ten (33.3%) patients already had a PU at the time they joined the study. Of these, nine had one lesion and one patient had three. Seven children had nine PUs not related to medical or diagnostic devices before using the mattresses under evaluation; of these, six (66.6%) healed before the patient left the PICU.

Seven patients (23.3%) were provided a viscoelastic cushion specifically designed for fixing and protecting the head in pediatric patients (SEMPCARE® Visco 700, Smith & Nephew, UK), and six patients (20%) were given hydrocellular heel dressings (Allevyn® Heel, Smith & Nephew, UK) in addition to the study CRLPSS.

In the CRLPSS group, one (3% of total patients) of two (6.6% of total) patients who underwent craneosynostosis developed two PUs (category 2) related to support surfaces in the operating theater, before the patient received the CRLPSS in PICU.

Only one of the 30 children developed a new PU related to support surfaces (CRLPSS) during the study period (incidence: 3.3%). The child who developed a PU was 20 months old, weighed 10 Kg, was admitted for a non-Hodgkin lymphoma, and already had three PUs caused by care equipment before joining the study. The child had a Braden-Q risk score of 8, and no change of position was possible. Over 14 days with the continuous and reactive low-pressure support surface assigned, the child was intubated, received parenteral and enteral nutrition, and venous, arterial, and urinary catheters were used. Vasoactive and sedation drugs were administered, together with heel protection dressings. The new PU developed in the occipital area on the ninth day, and the patient died 15 days after admission in PICU.

Compared with the estimated group value from 2008 (incidence: 20% of children with support surface-related PUs in 35 children), the current study showed a PU incidence of support surface-related PUs of 3.3% — CRLPSS — (confidence interval [CI] 95% = 0.08% to 17.2%), representing a statistically significant difference of 16.7 points (P = 0.021) between the two data sets.

Discussion

Results of this study suggest that use of the CRLPSS had a positive impact on PU incidence, but all comparisons to previous studies must be interpreted with caution.

The use of dynamic PMSS in pediatrics is not widespread; traditionally, these surfaces have been considered more suitable for adults. Dynamic alternating PMSS in particular were designed to redistribute the weight of immobile adult patients. According to the Spanish Pressure Ulcers and Chronic Wounds (GNEAUPP) document regarding positioning and PMSS,[20] adapting adult alternating dynamic mattresses to children has not had the desired pressure-redistribution results due to the specific characteristics of children.

In 2004, McCord et al[21] published results of a case series involving 108 children to assess the influence of different risk factors and tools in PU prevention in a PICU; specifically, they examined the effectiveness of a dynamic low-air-loss PMSS in turning mode. The authors observed when these mattresses were used, many caregivers did not make postural changes, even when advised by vendors. Moreover, the use of turning mode caused the occipital area of the children to pivot at the same point, increasing friction and shear forces. The authors concluded that this type of PMSS had been designed for adult patients and should not be used with pediatric patients because they increased the risk of PUs.

The PICU in which the current study was conducted is a reference center for craniosynostosis surgery. These are long (from 6 to 10 hours), complex operations in which the child's head must be immobilized both during the operation and in the first few days following it, subsequently increasing the risk of PUs. During this study, one of these children developed two PUs (category 2) in the operating theatre, but had a positive healing evolution while using the CRLPSS .

The only PU that appeared while using the CRLPSS under evaluation developed in the occipital area. This is the area with the highest risk for PU in children under 3 years old, with the risk of PUs logically rising in the child at terminal phase (non-Hodgkin lymphoma disease). No local pressure-relieving device (eg, viscoelastic cushion) was applied, because clinical instability precluded any movement of the patient and any professional postural changes. According to the scientific literature[14] and recommended interventions from GNEAUPP in its specific document of literature review about PMSS,[20] using local pressure-relieving devices (such as occipital cushion, heel support), could be an effective option to maximize pressure redistribution in children in the terminal phase of their illness.

The current study found it advantageous to use a CRLPSS adapted to suit the specific anthropometry of children. The research team observed that not having to reposition young patients helped facilitate maintenance of pediatric patients' clinical stability (hemodynamic and respiratory). Use of the CRLPSS avoided the need for regular repositioning of the 19 patients with risk factors such as malnutrition, intubation, sedation, occipital edema, or skin problems related to their pathology (eg, bacterial meningitis). Patients (n = 11) who could change position were repositioned every 3 to 4 hours. In the study setting, the CRLPSS provided a solution to the disagreement between healthcare staff, some who wanted to make postural changes and others who did not.

In 2001, Jones et al[22] published the results of an observational prospective evaluation of three dynamic, alter-

nating air PMSS used to treat 22 children admitted to the PICU and the cardiac rehabilitation at the Royal Hospital for Sick Children in Edinburgh, UK. The researchers observed no child developed a PU. Length of dynamic alternating mattress use ranged from 1 to 7 days (one patient maximum of 46 days), which was similar to that in the current study where average time of CRLPSS use was 7 days (± 7 days). The Jones et al study is limited by the fact that the results obtained were not compared with any prior control value and the patients' risk level was not recorded.

Other support surface options considered included bubble mattress pads. However, in the authors' experience, because the cells are designed for adults' body surfaces, children tend to slide along the bed or become lodged between the cells. This was not a problem using CRLPSS; the designs accommodate the different body surfaces of each age group. No safety-related adverse events were observed. When the children became more mobile, the bed rails were raised. The support surface cell height allowed healthcare staff access to the children when the rails were raised, even though they were still effective in preventing falls.

According to data from the 5 Million Lives campaign,[5] the Children's Healthcare Hospital of Atlanta reduced the incidence of PUs by 59% in 2005. Preventive measures provided to high-risk pediatric patients included the use of dynamic alternating PMSS for adults (Kinair®, KCI, San Antonio, TX) and children (PediDyne® Crib, KCI, San Antonio, TX); however, the contraindications (eg, lumbar fracture) restricted use of these products. In the current study, the CRLPSS was used with children displaying hemodynamic and respiratory instability, polytrauma (skull and lower limbs), and unstable thoracic fractures.

Neidig et al[2] found that implementing a protocol that involved changing the head posture every 2 hours in postoperative pediatric patients who had undergone cardiac surgery reduced the incidence of PUs from 16.9% to 4.8%.

An analytical, observational study conducted among 54 healthy children of different ages by McLane et al[14] found that a dynamic low-air-loss PMSS (Efica®, Patmark Company, Batesville, IL) was more effective than a foam mattress pad alone or in combination with Gel E Donut® (Philips Respironics, Andover, MA) in reducing PUs. A limitation of this study was that the low-air-loss PMSS could not be used for children weighing <22.7 Kg.

Harris et al's[23] case study of a 38-week-old child under ECMO therapy who had developed PUs on a lambskin surface showed that a dynamic PMSS could not be used to redistribute the pressure because 1) the size was not compatible with the heated cradles in use with the child and 2) the supports surfaces were radio-opaque. The dynamic, constant low-pressure CRLPSS used in the current study can be placed in incubators and heated cradles; in addition, the surface for patients weighing >6 Kg can be used with adult or child-sized beds while maintaining pressure redistribution. During the current study, one of CRLPSS systems was successfully used with two children in incubators; however, they were not included in the study because these patients were admitted to a different (neonatal) ICU.

Limitations

The small sample size, limited number of support surfaces, and absence of a prospective control group limits the ability to draw definitive conclusions about the efficacy and effectiveness of these surfaces. Only two systems, one for newborns and the other for children weighing >6 Kg, were provided to the facility, which meant that many children who qualified for study inclusion could not benefit from these products. The products were assigned when a child was at obvious risk or upon the clinical judgment of the nurse responsible for assessment. For ethical considerations, when a CRLPSS was available, it was assigned to the child who needed it, even if that child was not included in the study (eg, admission in PICU less than 24 hours, children older than 10 years), further limiting the number of available surfaces.

Another limitation influences approaches to care. Participating nurses were trained informally by the research team. Although the training was intended to deal only with the use of the PMSS under evaluation, prevention-related topics also were discussed. The nurses knew their care was evaluated, which could have affected the low PU incidence observed.

This study attempted to monitor the limitations associated with the preventive measures taken with the group of children using CRLPSS. Even though 60% of the children were not repositioned due to their individual conditions, the other 40% of patients were repositioned every 3 or 4 hours whenever possible. Additional preventive measures were taken — ie, hyperoxygenated fatty acids were applied to risk areas every 8 hours, hygiene tasks were performed on a daily basis, and protective dressings were applied between the skin and the different therapeutic and diagnostic devices. These preventive measures are similar to those provided in the previous epidemiological survey that was used as a benchmark/comparison.

Another possible limitation of the study was the use of several local pressure-management devices in certain high-risk anatomical locations. These measures may bias some of the results, but from an ethical and professional point of view, providing measures shown by previous research to possibly benefit patients (safety principle) is part of a clinician's goal to ensure the best preventive care. Another possible limitation is that PUs caused

by medical devices were not considered in the analysis. Carefully controlled, prospective, clinical studies are needed to evaluate the safety, efficacy, effectiveness, and cost-effectiveness of these surfaces compared to standard care procedures and help answer remaining questions about optimal PU prevention strategies in high-risk pediatric patients.

Conclusion

The use of CRLPSS was prospectively evaluated in a group of 30 pediatric patients admitted to the PICU and who were at risk for developing PUs. The incidence of PU development not related to the use of a medical device was low (3.3%), much lower than the rate of similar ulcers in a previously conducted incidence study (20%) at the same facility. No adverse safety-related events occurred, and the surfaces were believed to be particularly beneficial for patients who cannot be repositioned. Additional controlled clinical studies are warranted to help develop evidence-based protocols of PU prevention in high-risk pediatric patients. n

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