

# Treatment of pressure sores in spina bifida patients with calcium alginate and foam dressings

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**Abstract.** – **STUDY DESIGN:** Prospective study on local treatment of pressure sores using calcium alginate and foam dressings in spina bifida patients.

**OBJECTIVE:** Investigate if this sequential approach is valid and safe for selected patients with neurological impairments.

**PATIENTS AND METHODS:** Using European Pressure Ulcer Grading System, after clinical evaluation of local sore, selected patients of Spina Bifida Center of Rome were treated with sequential calcium alginate and foam dressings for 12 weeks. Pressure ulcer surfaces were measured monthly by ulcer tracing. The endpoints were the mean absolute areas surface reduction during every month and number of patients achieving a 50% or more during study.

**RESULTS:** 14 patients (7 males aged 12-24 years) with spina bifida and pressure sores were treated. Mean and standard deviation of mean surface area reduction were  $12.5 \pm 7.5$  cm<sup>2</sup> at start of the study versus  $3.7 \pm 5.2$  cm<sup>2</sup> after 12 weeks,  $p < 0.001$ . 75% of the patients reached mean surface area reduction of 50% during trial. Dressing tolerance was good in every patient.

**CONCLUSIONS:** Calcium alginate and foam dressings are valid and safe approach in the treatment of pressure sores in selected patients with spina bifida. In fact, they protect the wound and create an environment favorable to healing.

*Key Words:*

Pressure sores, Spina bifida, Foam, Calcium alginate.

Compression of blood vessels that feeds soft tissues can obstruct blood flow causing local ischemia with the consequence of a local area of necrosis<sup>3,4</sup>.

There are extrinsic and intrinsic risk factors for the development of PU<sup>5</sup>.

Extrinsic factors are the pressure from a hard surface, such as bed or wheelchair and conditions that restrict mobility<sup>6,7</sup>.

The time it takes for a PU to form will depend on the amount of pressure and on the vulnerability of a person's skin.

Accurate assessment and clinical judgment based on inspection and palpation are crucial for the prevention and treatment of skin failure. The most common grading system to describe the severity of pressure ulcers is the European Pressure Ulcer (EUAP) Grading System, which classified the PU according to the degree of tissue damage<sup>6</sup>. In children with neurological impairments due to cerebral paralysis, spina bifida (SB) and spinal cord injury, PS often create significant complications respect adult<sup>8,9</sup>. In order to determine the right dressing for the treatment of each wound a focus on these characteristics is required such as wound measurement, appearance, exudates and conditions of the periwound skin. Local treatment of PS is based on careful nursing and use of dressings, to protect the wound and create an environment favorable to healing. Gel-forming dressings, which absorb the wound exudates to form a non-adherent gel and calcium alginate dressings which have been shown to help the debridement of PS, accelerate wound healing in a moist environment. Calcium alginate and foam dressings now appear to be one of the reference treatments of PU<sup>10-12</sup>.

SB is a complex congenital spinal defect in the formation of the neural tube from the embryonic neural plate. In these patients there is also a spec-

## Introduction

Pressure ulcer (PU) is a localized injury of the skin and underlying tissue usually over a bony prominence, as a result of pressure, alone or in combination with shear and friction<sup>1</sup> and occur especially on sacrum, ischium, elbows and heels<sup>1,2</sup>.

trum of impairments, such as lower limb paralysis and sensory loss, bladder and bowel dysfunction, and cognitive impairment<sup>13</sup>.

Patients with SB have specific risk factors for the development of PS, such as motor problems, sensory loss and metabolic derangements of neurologically impaired skin<sup>14</sup>. Furthermore, urinary and fecal incontinence, scoliosis, mental retardation, Arnold Chiari II malformation, hydrocephalus have also been mentioned as risk factors for PU in these patients<sup>14</sup>.

Involvement and education of patients and their family or caregivers are important in the prevention and treatment of PS<sup>15,16</sup>. There are no clinical studies regarding treatment of PS in selected patients with this condition. This article reports our case load with the management of PU in children and adult group of patients affected by SB.

## Patients and Methods

This is a prospective study of 12 weeks to evaluate the efficacy of foam and alginate dressing in pressure sores (grades III and IV of EUAP Grading System) in spina bifida patients. Subjects with an EUAP stage I and II pressure ulcer (i.e. a non broken, non exuding ulcer) were excluded regardless of ulcer area. A total of 16 subjects were enrolled in the study. During the trial two patients drop out because have discontinued controls.

### *Personal Data and Clinical Examination*

Before examination, we acquired personal data by asking each patient or parent, if the patient was younger than 12 years, to fill in a case form. Questions specifically concerned the following issues: educational level (e.g., school frequency, presence of assistant teacher for handicapped), urological and bowel aspects.

Medullar and brain magnetic resonance imaging were acquired (e.g., site of lesion, type of lesion).

Detailed clinical history, careful clinical examination (from the neurological and physical rehabilitation point of view) were always performed. Written consent was obtained from each subject before inclusion.

We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research.

### *Pressure Sores Treatment*

Each patient received a sequential strategy consisting of applying calcium alginate dressing (Seasorb) for 4-6 weeks and then foam dressing (Biatain) for 6-8 weeks. SeaSorb (Coloplast A/S, Humlebaek, Denmark) dressing and filler are highly absorbent alginate dressings with vertical absorption to reduce maceration. On contact with wound exudates, SeaSorb forms a translucent, cohesive, soft gel for managing moderate to heavily exuding wounds. Biatain dressing (Coloplast A/S, Humlebaek, Denmark) is composed of a soft, 4-mm thick hydrophilic polyurethane foam and an elastic semipermeable film backing. Biatain is an absorbent foam dressing providing exudate management. The exudate absorption and retention properties of Biatain overcomes two significant barriers to wound healing by minimizing maceration and leakage.

Foam dressings were removed every third day or more often, if the area discolored by exudates was less than 1 cm from the edge of the dressing or if a leakage was apparent. Calcium alginate dressings were removed every other day or more often if were saturated, especially when exudates appeared through the secondary dressing.

### *Outcome Measured*

The primary outcome was the evolution of the mean surface area reduction (MAR) during the trial. The second one was the percentage of patients whose ulcer reached a 50% or more MAR (MAR<sub>50</sub>) and was calculated as  $[(100 \times (\text{baseline surface area} - \text{actual surface area})) / \text{baseline surface area}]$ . The third endpoint was dressing tolerance. Sore surface area was measured by planimetry at start and every 4 weeks. After cleansing and drying, a sterile polyurethane film was applied to the target ulcer and its perimeter was marked. A photograph of the sore was also taken every month. When foam and alginate were removed, technician recorded information about features of the ulcer, to detect any side effects and to collect frequency of dressing changes during trial.

### *Statistical Analysis*

Safety and dressing performance data were analyzed for all subjects who had a study dressing applied. Descriptive statistics were calculated for each variable and are reported as the mean and SD. The nature and frequency of adverse events that occurred during the study were summarized overall by patient and also by relationship to

study treatment. Student's *t*-tests were used to test the significance of changes from baseline to final visit in ulcer appearance. All statistical calculations were performed with the SPSS/PC statistical software package, version 6 (SPSS Inc., Chicago, IL, USA). The level of significance for all statistical tests was < 0.05.

## Results

### Demographics and Ulcer Characteristics

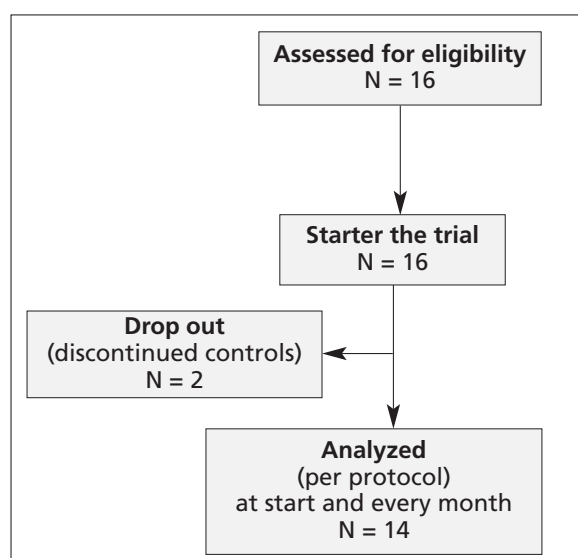
Demographics and baseline characteristics of the enrolled patients are summarized in Table I. Thus we analyzed 14 patients (7 males, mean age  $17.21 \pm 5.6$  years, range 12-24 years) (Figure 1). Topics and location of pressure sores are reported in Table I.

### MAR and MAR<sub>50</sub>

MAR and standard deviation were  $12.5 \pm 7.5$  cm<sup>2</sup> at baseline,  $9.1 \pm 5.4$  cm<sup>2</sup> after 4 weeks,  $6.2 \pm 3.9$  cm<sup>2</sup> after 8 weeks and  $3.7 \pm 5.2$  cm<sup>2</sup> after 12 weeks, *p* < 0.001 (Figure 2). Regarding MAR<sub>50</sub>, 40% after 4 weeks, 60% after 8 weeks and 75% of the patients reached MAR<sub>50</sub> during trial (Figure 3). In Figures 4 and 5 we report two patients of our study.

**Table I.** Patient characteristics at selection visit.

	N. of patients
Number of patients	14
Sex (male/female)	7/7
Age (years), mean $\pm$ s.d. (range)	$17.2 \pm 5.6$ (12-24)
Weight (mean, SD)	48.5 Kg (15.23)
Height (mean, SD)	1.46 m (0.24)
Body Mass Index (mean, SD)	23.8 Kg/m <sup>2</sup> (5.25)
Lesion level: thoracic	2
lumbo-sacral	10
sacral	2
Hydrocephalus related: DVP third ventriculostomy	10
Mobility: wheelchair	4
Using aid	8
Without anything	3
Sore location: Sacrum	3
Heel	3
Foot	3
Other	5
Bladder emptying: catheterisation	10



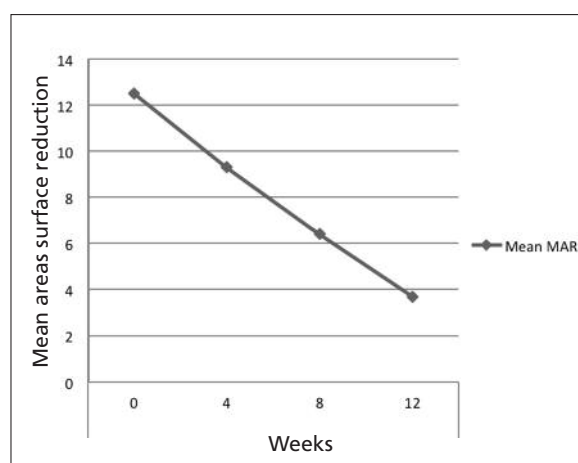
**Figure 1.** Flow-chart of participants to the study.

### Tolerance and Adverse Effects During Trial

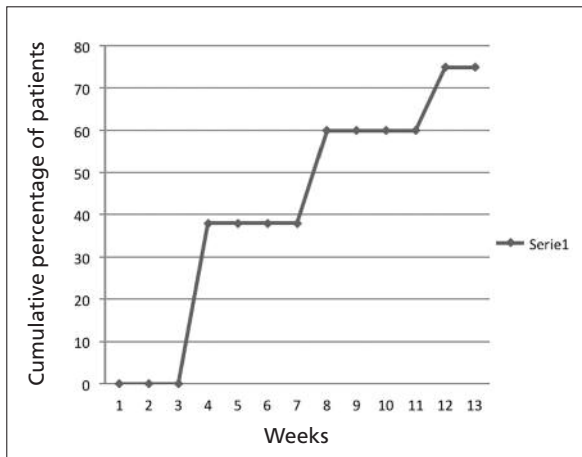
A good tolerance to treatment was recorded by all patients. Mean number of dressings removed per week was  $3.5 \pm 2.1$ . No severe side effects were recorded during the trial.

## Discussion

This prospective clinical trial shows that treatment of pressure sores of III and IV in patients with SB with sequential therapeutic strategy consisting of calcium alginate and foam dressings is a valid and safe approach. In fact, protects the



**Figure 2.** Mean areas surface reduction (MAR) of pressure sores in cm<sup>2</sup> during trial.



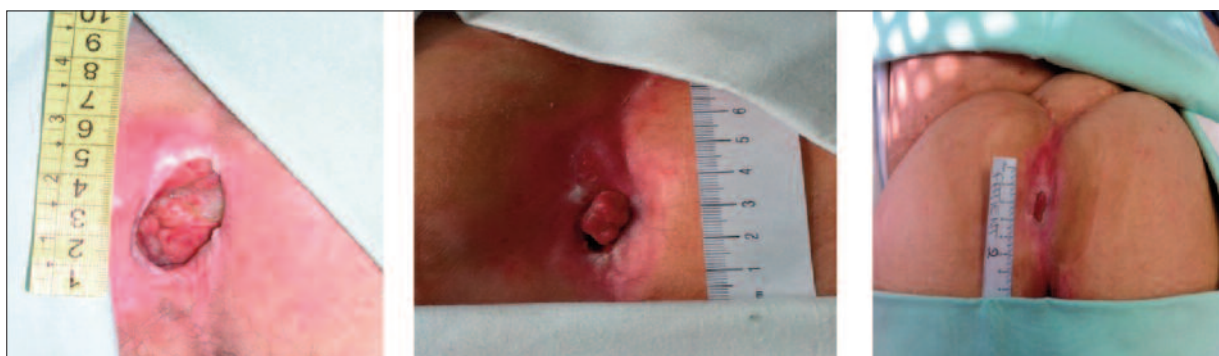
**Figure 3.** Cumulative percentage of MAR<sub>50</sub> in % during trial.

wound and creates an environment favorable to healing. Belmin et al<sup>9</sup> evidenced that sequential treatment with alginate and hydrocolloid dressings is the best treatment for PU in geriatrics patients. PU are caused by constant pressure on the skin and tissue. The pressure prevents the blood from circulating properly, and this causes tissue damage and the development of ulcers. Most PS develop over bony areas and pressure relief is essential for treatment. Patients with SB are at higher risk for developing PS. In fact they may also have a reduced circulation in the area due to their lack of movement. Moreover, in patients with SB paralysis and sensory loss render them unaware and unable to prevent the impeding or existing injuries caused by unrelieved pressure. They often use wheelchairs, plantars and other devices with hard surfaces, which make pressure over the dependent portions of their body. In addition, in individuals with SB the neural and

metabolic mechanism for the maintenance of adequate blood flow below the level of the injury are deregulated, vasomotor pathways are often interrupted, neurogenic and endothelial activities in relation to the regulation of tissue perfusion are weakened<sup>10</sup>. Neurologically impaired skin undergoes many metabolic derangements and may contribute to the refractoriness of PU with derangements that include a decreased availability of oxygen, loss of collagen and fibronectin and loss of elasticity and tensile strength<sup>17</sup>. According with literature, we observed that magnitude of scoliosis and kyphosis and level lesion correlate with history of PU. In our sample all patients had high lesion (toraco-lumbar level) with an important walking impairment and usually with a rotoscoliosis<sup>10</sup>. We think that PU prevention is more cost effective than treatment. We propose an evaluation of risk factors for each patient and precocious and daily examinations of the skin to identify any area that appear discolored with particular attention to areas most vulnerable to pressure ulcers. Skin integrity can be maintained using pressure reducing surfaces, cleaning and drying skin promptly after soiling, often shifting position of body in bed and wheelchair using support surfaces to protect heels or pressure-redistributing seat cushion<sup>18</sup>. We observed that it is especially important to protect skin surrounding the pressure ulcer and manage the exudate. When PU occur, nevertheless, a prevention, a strategy using dressings for different PS phase, for example alginate for debridement and hydrocellular foams for tissue granulation, might be better than standard treatment<sup>9</sup>. We suppose, according to literature, that alginate reacts with wound exudates to form a soft gel, facilitating autolytic debridement while hydrocellular foam dressings accelerates



**Figure 4.** Patient 1 at start, after 4 weeks and at the end of the trial. Pressure sore on the buttock dx.



**Figure 5.** Patient 2 at start, after 4 weeks and at the end of the trial. Pressure sore on sacrum.

the absorption of moderate-to-heavy exudates maintaining a moist wound environment<sup>19</sup>. Foam and alginate managed PU exudate well, with an average wear time of 3.5 days. We observed that these dressings mainly good performance ratings for ease of application, non traumatic removal and avoidance of leakage. Pressure relief is required for healing in subjects with pressure ulcers, but often it is difficult to achieve fully. Despite these difficulties, ulcer healing or improvement occurred in 60% of subjects during 8 weeks of treatment with a regimen that included alginate and foam dressings. Because this is the first clinical study on SB patients, a relatively small sample of subjects was enrolled and treated. Exudate management is particularly important in all wound care because maceration of the surrounding skin can occur in the presence of excessive wound exudate. In this investigation, a regimen including alginate and foam dressings was safe and effective in managing exudate, protecting surrounding skin and maintaining patient comfort in situ, while supporting pressure ulcer healing. Exercising regularly may improve circulation considerably lessening the risk of pressure sores and faster resolution of sore. In our sample PS of patients, which make physical activity, improve rapidly. Able body people do not develop pressure ulcers as their body automatically makes hundreds of regular movements that prevent pressure building up on any part of their body. In SB we can observe risk factors for pressure ulcers that could be divided into one of these two categories: intrinsic risk factors – with an underlying health condition or other factor that makes more vulnerable to developing pressure ulcers and extrinsic risk factors regarding immediate environment. PS are easily diagnosed by visual examination. According with literature, we

propose as part of the risk assessment, to evaluate in each patient blood and urine tests. Blood tests can be a good way of assessing general health state and whether diet is providing enough nutrition. Urine tests can be used to check how well kidneys are working and whether an urinary tract infection is present to avoid more serious complications. The removal of necrotic tissue is imperative to promote wound healing. Appropriate dressing selection can be overwhelming with multiple brands in each dressing class available. The pediatric literature has supported the use of hydrocolloids, hydrogels, transparent films, and foam dressings<sup>19,20</sup>. Advanced wound care dressings are designed to promote an optimal wound environment and do not include basic gauze dressings. When determining the type of wound dressing for a pediatric patient, especially a newborn, the fragile state of the skin must be considered. Epidermal stripping during dressing removal may occur. Therefore, the use of skin barrier wafers to prevent tape from adhering to the skin is recommended for frequent dressing changes.

## Conclusions

SB patients have higher risk to develop PS for intrinsic and extrinsic factors. Pressure ulcer prevention is the best approach. SB patients must understand the importance of physical activity, of shifting body position, to assess an appropriate and adequate intake of nutrition to control weight and to maintain optimal skin integrity. We propose an evaluation of intrinsic and extrinsic risk factors for each patient and precocious and frequent examinations of skin particularly where more frequent frictions and prolonged pressure

are present. Blood and urine tests are important to avoid infection by bacteria. When PU occur, for SB patients we propose a sequential treatment with calcium alginate dressings to control debridement and after with foam dressings to tissue granulation. This is a valid and safe approach in fact they protect the wound and create an environment favorable to healing.

#### Conflict of Interest

None.

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