



## ORIGINALES

### Prevention of iatrogenic ulcers produced by therapeutic immobilization with a lower limb splint in children. Clinical trial

Prevención de úlceras iatrogénicas por inmovilización terapéutica en niños con férula.  
Ensayo clínico

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#### ABSTRACT:

**Introduction:** Immobilization with plaster cast in lower limb is a frequent procedure for children in the emergency services, which is not without risks related to immobility and pressure, on these factors nurses have to adopt preventive care.

**Objective:** To verify the efficacy of the polymeric heel patch in the prevention of iatrogenic ulcers in children immobilized with a plaster splint in the lower limb.

**Material and method:** Preventive randomized clinical trial on pediatric patients aged 0 to 14 years who require immobilization with a lower limb cast. Simple blind non-probabilistic consecutive sampling was performed. Descriptive statistical analysis of the variables and X2 test with the application variables of the patch and the appearance of ulcers.

**Results:** A total sample of n = 74 patients was obtained. Ulcer was observed in 21.7% of patients, whole skin (48.2%) and erythema that pales 30.1%. The X2 test was applied for the application of polymer patch and ulcer appearance variables, obtaining X2 = 0.135 with p = 0.713, and therefore, there is no statistical significance between these two variables.

**Conclusions:** There is no direct relationship between the prevention of pressure ulcers in children immobilized with plaster splint and the application of polymeric protective patch. It is very important that nurses offer a quality health education in the care and maintenance of the splint to avoid complications.

**Keywords:** nursing, plaster splint, immobilization, lower limb, iatrogenic ulcer, nursing care.

## RESUMEN:

**Introducción:** La inmovilización con férula de yeso en miembro inferior es un procedimiento frecuente para niños en los servicios de urgencias, el cual no está exento de riesgos relacionados con la inmovilidad y presión, sobre estos factores los enfermeros tienen que adoptar cuidados preventivos.

**Objetivo:** Comprobar la eficacia del parche-talonera polimérico en la prevención de úlceras iatrogénicas en niños inmovilizados con férula de yeso en miembro inferior.

**Material y Método:** Ensayo clínico aleatorio preventivo sobre pacientes pediátricos de 0 a 14 años que precisen inmovilización con férula de yeso en miembro inferior. Se realizó muestreo consecutivo no probabilístico simple ciego. Análisis estadístico descriptivo de las variables y test de la  $X^2$  con las variables aplicación del parche y aparición de úlceras.

**Resultados:** Se obtuvo una muestra de  $n=74$  pacientes. Se objetivó úlcera en 21.7% de pacientes, piel íntegra (48.2%) y eritema que palidece 30.1%. Se aplicó el test de la  $X^2$  para las variables aplicación de parche polimérico y aparición de úlcera, obteniendo  $X^2=0.135$  con  $p=0.713$ , y por tanto, no existe significación estadística entre estas dos variables.

**Conclusiones:** No existe relación directa entre la prevención de úlceras por presión en niños inmovilizados con férula de yeso y la aplicación de parche protector polimérico. Es fundamental que los enfermeros/as ofrezcan una educación sanitaria de calidad en los cuidados y mantenimiento de la férula para evitar complicaciones.

**Palabras clave:** enfermería, férula de yeso, inmovilización, miembro inferior, úlcera iatrogénica, cuidados de enfermería.

## INTRODUCTION

Immobilization with plaster splint in lower limbs is a common procedure for children who go to the emergency services in order to achieve the healing of injuries such as fractures or sprains. However, the use of this therapy is not without risks related to immobility and the pressure that the splint can exert on the hardest planes of the foot<sup>(1)</sup>. According to the literature consulted, it is estimated that 0.56%<sup>(2)</sup>, 15%<sup>(3,4)</sup> and 38%<sup>(5)</sup> of plaster children will suffer an iatrogenic pressure ulcer depending on the lesion and the type of plastering, the casts being synthetic those that develop greater pressure on the tissues<sup>(6-8)</sup> and generating this ulcer in the first days of carrying immobilization<sup>(9)</sup>.

The prevention of these health problems associated with immobilization is a task that must be undertaken by nurses who perform this procedure in order to minimize risks to the population, not only when it is carried out with the utmost scientific and professional rigor, but reinforcing health education to patients in the care of the splint in order to prevent complications<sup>(10-12)</sup>.

Different studies have experimented with multiple methods of pressure ulcer prevention, such as heel padding with an extra amount of cotton layers or different types of padding<sup>(13)</sup> and even different ways of arranging the splint<sup>(14)</sup>. Other authors have taken into account the different materials, the pressure that is exerted and the temperature reached by the plaster during the execution<sup>(15)</sup> as well as the placement of a custom position valve with pressure relief in the heel<sup>(16)</sup>. Several investigations have opted for the use of patches or dressings of polyurethane in a preventive way, observing that there is even an economic saving with respect to the cost of the appearance of heel ulcers and their healing. We opt for this last preventive option for the support of the existing scientific literature, as well as the recommendations of the National Group for the Study and Advice on Pressure Ulcers and Chronic Wounds and the Registered Nurse Association of Ontario (RNAO).

This study attempts to reduce the rate of iatrogenic ulcers in the calcaneal area in the lower limbs (heel area) in pediatric patients with traumatic pathology who require

immobilization with plaster splint in this anatomical area, as well as minimize the dysfunctional consequences that cause for the patient a posteriori. In this way, it is intended to find the possible concomitant causes to be able to act on them, establish preventive nursing care and increase the quality of care together with patient satisfaction.

The objective of this study is to verify the efficacy of the polymeric heel patch in the prevention of iatrogenic ulcers in children immobilized with plaster splint in the lower limb. For which the following hypothesis is posed: Children to whom the polymeric heel patch is applied in the calcaneal area have a lower risk of developing an iatrogenic ulcer derived from immobilization with plaster splint in lower limbs than those to whom said patch is applied.

## MATERIAL AND METHOD

The present sresearch corresponds to a randomized clinical trial. The sample was formed with patients derived from the Emergency Department of Traumatology to the nursing gypsum room of the Virgen de la Arrixaca University Clinical Hospital (Murcia) who required immobilization with a lower limb splint. The selection criteria were an age range of 0 to 14 years and indication of a spinal or surropeic splint. Exclusion criteria included those over 14 years of age, indication of simple bandage or closed and negative plaster of the parents or the child to perform the immobilization and / or study. The type of sampling was performed by a simple non-probabilistic consecutive blind sampling. The randomization of the application of the polyurethane patch was carried out by means of the Epi Info™ version 7.1.4 program with a 1:1 allocation rate. In parallel, the cases of patients who came on their own initiative are also recorded due to discomfort in the member bottom splinted and not found within the study in order to gather complementary information.

To perform the procedure (table 1), the splint and protective material was placed in a consensual and unified manner through a protocol according to the latest scientific evidence for the 8 nurses participating in the study, with the difference that the experimental group the polymeric patch is also applied in the fifth step.

**Table 1. Procedure of splint placement with patch**

Order	Procedure
1 <sup>st</sup>	Observation, cleaning and drying of the skin.
2 <sup>nd</sup>	Placement and adjustment of heel patch in posterior lower area of calcaneus (from the sole of the foot to Achilles heel) adapting it in size and shape to the patient's heel if necessary.
3 <sup>rd</sup>	Placement of tubular mesh of the appropriate size ensuring that there is no wrinkle left in the posterior calcaneal area and on the back of the foot without pressing.
4 <sup>th</sup>	Padded with synthetic cotton bandage with 8 extra layers in longitudinal form from the base of the fingers to above the insertion of the Achilles tendon and bandage with cotton bandage to hold and finish the padding.
5 <sup>th</sup>	Measure the length of the splint according to the size of the leg from the fingers up to 4cm below the popliteal hollow (the cotton will be 2cm below the popliteal hollow). The number of layers will vary depending on the age and size of the lower limb (in children under 1 year 10-12 layers,

	from a year 12-14 layers). Moisten the splint in water with a thermometer temperature between 30-34°C, drain excess water slightly, vertically and with two hands, then place the splint adapting it to the shape of the leg.
6 <sup>th</sup>	Fastening the splint with crepe bandage with herringbone bandage and finishing fixation with herringbone cohesive bandage.
7 <sup>th</sup>	Health education insisting on free heel without support. Give health education report with preventive indications of ulcers and warning signs.
8 <sup>th</sup>	Quote for review in the next 4-6 days.
9 <sup>th</sup>	Revision: remove splint at 4-6 days and skin observation. Act according to established protocol in case of pressure ulcer occurrence (Chart 2). Place a new splint or other immobilization if applicable. Cite new review in 2 days in case of erythema or ulcer. Computerized record of data and observations.

The study period is from May 1, 2017 to May 1, 2018. The variables studied were: age, gender, background, date of placement, type of splint, group with or without patch, number of reviews, diagnosis, affected anatomical structure, symptoms after revision, signs of support or deterioration of the splint, degree of ulcer, therapeutic adherence, place of appearance of the ulcer, time of appearance of discomfort, care of the ulcer, subsequent immobilizer treatment, evolution and observations.

A form was made where the variables of the study were recorded and as a measuring instrument for the degree of ulcer and its care were taken as a reference the classification of pressure ulcers and protocols of the GNEAUPP (Table 2). In addition, those nursing observations were documented in the computerized record of the patient's medical history in order to achieve better patient follow-up in case of successive visits. The study was approved and validated by the Hospital Ethics Committee.

The statistical analysis was carried out by means of descriptive statistics of the studied variables of the sample together with inferential statistics through the  $X^2$  test with the variables application of the patch and appearance of ulcers. For this analysis the statistical program SPSS v. 20 was used.

**Table 2. Degree of ulcer and derived care**

Degree of ulcers	Characteristics	Cares
I	Cutaneous erythema that does not pale when pressed. Full skin.	Apply hyperoxygenated fatty acids and assess replace splint. New review in 2-3 days.
II	Partial loss of the skin affecting the epidermis and / or dermis. It manifests with flictena, abrasion or superficial crater.	If flictena: keep it. If exposed skin: Wet cure with hydrocolloid patch. New review in 2-3 days.
III	Total loss of skin thickness, involves injury or necrosis of subcutaneous tissue.	Chemical or surgical debridement Rate the type of patch according to ulcer characteristics. New review in 2 days. Rate referral to plastic surgery

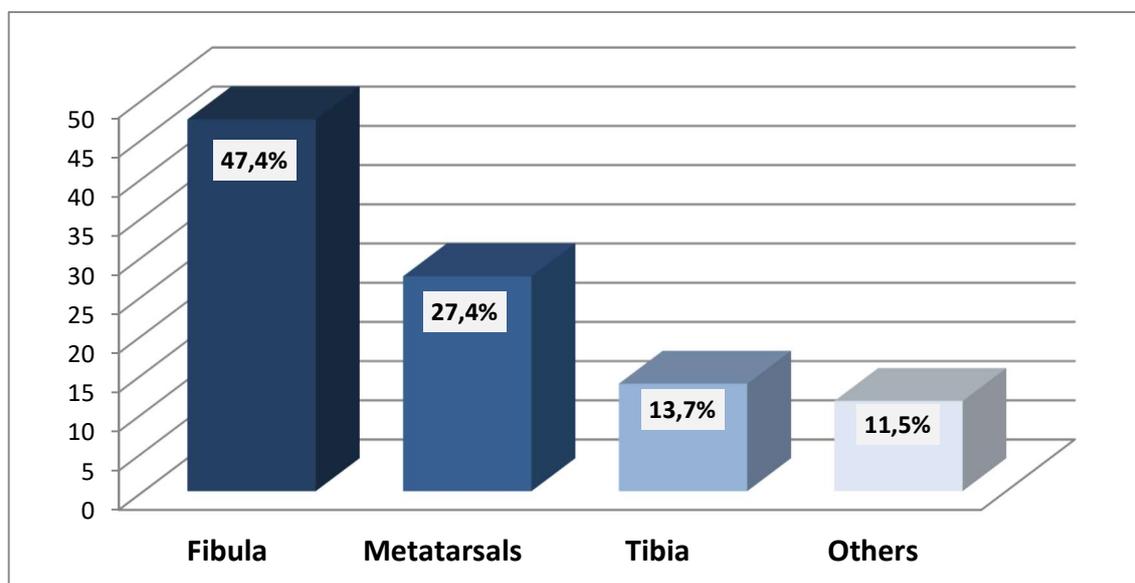
IV	Total loss of skin thickness, involves injury or necrosis in muscle, tendons, bone	Chemical or surgical debridement Rate the type of patch according to ulcer characteristics. New review in 2 days. Rate referral to plastic surgery
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## RESULTS

A total sample of n = 74 patients was obtained, of which 47.3% men and 52.7% women with a mean age of 8.47 years (standard deviation: 2,737) to which 94.6% of spinal splints were applied and 5.4 % cryuropathic This sample was randomly designated the application of patch at 55.3% and without patch at 47.4%.

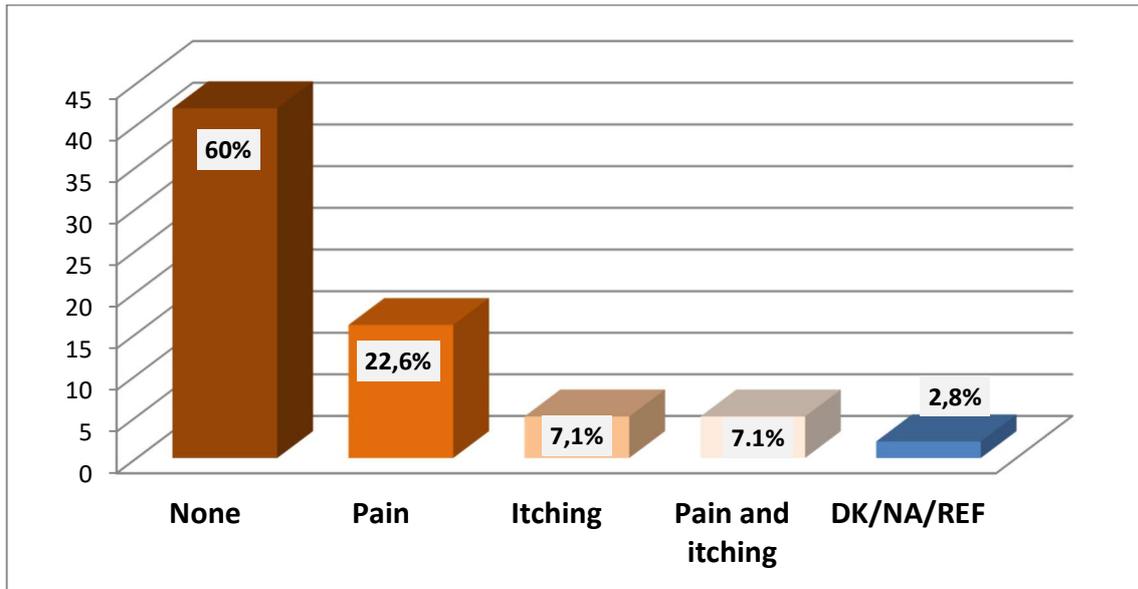
The most frequent reason for immobilization was grade I epiphysiolysis with 80.8%, fracture (8.2%) and grade II epiphysiolysis with the most affected anatomical structures being the fibula (52.1%), metatarsals (26%), tibia (11%) and tibia and fibula simultaneously with 6.8% (Graph 1). The therapeutic adherence affirmed according to the parents of the minors to the antiulcer preventive indications was 76.7% compared to a 19.2% non-adherence and 4.1% does not know / does not answer that contrasts with the objectification of 65.2% of complete splints against a 34.8% of splints with some sign of deterioration in revisions such as breakage, poor condition, absence of splint, etc.

**Graph 1: Affected anatomical structures that require immobilization**



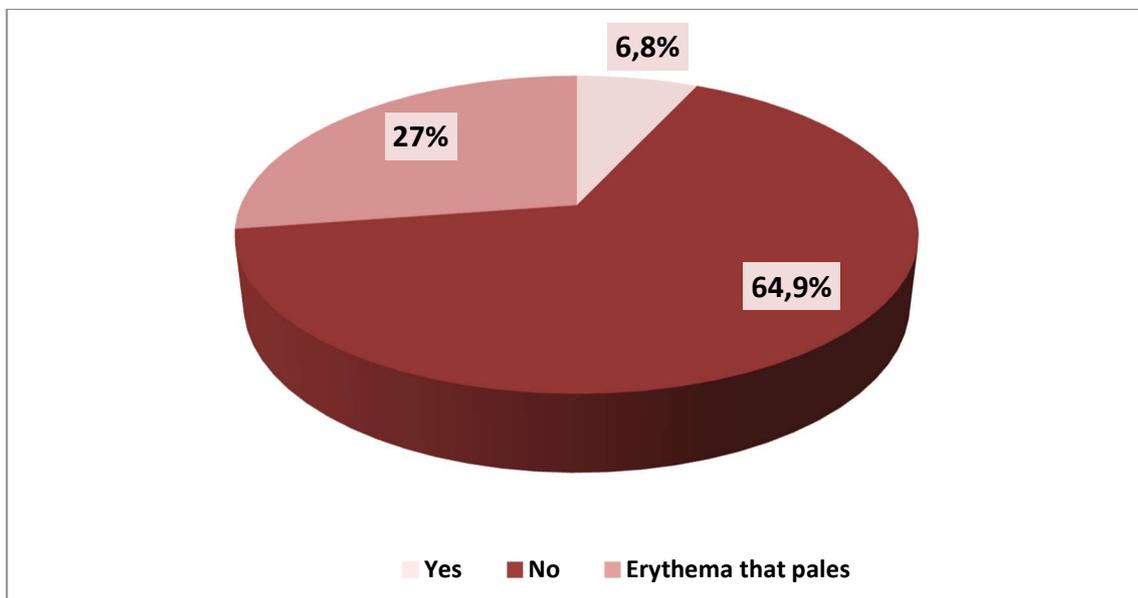
The patients presented symptoms prior to the revision such as pain (22.6%), itching (7.1%), coexisting pain and itching (7.1%) and no symptoms (60%) (Graph 2) appearing these symptoms from the placement of the splint until the third day (41.7%), second (29.2%) and first (16.7%).

**Graph 2: Symptoms associated with immobilization**



In the total sample, ulcer appeared in 6.8%, full skin in 64.9% and erythema that pales 27% (Graph 3) mostly in the calcaneus area (79.2%) and upper heel (8.3%). The category of the ulcer was first grade (71.4%) and second (14.3%) and 14.3% not documented. None of the patients included in the study presented third or fourth degree ulcers. The care applied according to the degree of ulcer was: hyperoxygenated fatty acids (AGH) (69.2%), hydrocolloid patch (30.8%) depending on the type of ulcer. 100% of the ulcers evolved favorably in successive revisions.

**Graph 3: Appearance of iatrogenic ulcer**



Among the patients not included in the study who attended on their own initiative before the appearance of alarm signs when carrying the splint, a total of 12 patients were registered, 69.2% of whom had an ulcer, 8.3% of the entire skin ulcer and 16.7% Erythema was evident that pales under pressure. Among the ulcers, 66.7% of grade I, 11.1% grade III and 11.1% grade IV were observed that were treated with AGH in 30%

of cases, hydrocolloid patch in 60% and surgical debridement in 10% depending on the degree of ulcer.

The  $X^2$  test was applied for the variables of the polymer patch application and the appearance of ulcer considering erythema that pales as an absence of ulcer, obtaining as a result  $X^2 = 0.135$  with  $p=0.713$ , therefore there is no statistical significance between the application of polymer patch and appearance of pressure ulcers. In a second analysis of  $X^2$  the presence of erythema that pales as a potential ulcer was considered and added to the values of ulcer evidenced, obtaining a value of  $X^2 = 0.451$  with  $p = 0.502$ , which establishes non-significant values for any contrast of the variables analyzed.

## DISCUSSION

The descriptive results on the total of the 74 patients in the sample offer an ulcer rate of 4.1% ( $n = 3$ ) in the experimental group and 2.74% ( $n = 2$ ) in the control group, although we do not start with preliminary data on incidence of iatrogenic ulcers caused by plaster splint in the emergency department itself, previous studies estimate around 15% the appearance of ulcers<sup>(3,4)</sup>, so our results are well below these studies. Regarding other similar studies, which use preventive polymer patch, there are large differences with a value of 3.6% of ulcers in experimental group (with patch) and 42.9% in control group (without patch)<sup>(19)</sup>, but it must be specified that In these investigations the sample is constituted by cancer patients with risk factors to develop pressure ulcers, and therefore it is a different sample from ours.

There are other similar studies with a similar objective to our study, but there are differences regarding the characteristics of the sample and the preventive technique used. In this sense, Difazio manages to reduce a 0.136% rate of skin complications in the pre-intervention group to 0.066% in the post-intervention group through the application of a cotton patch in children with closed plaster<sup>(13)</sup>. Balch et al obtained a 0.61% rate of ulcers in the first phase and 0.3% in the second phase with the application of training strategies in plaster placement among nurses<sup>(2)</sup>. Torra obtains 3.3% of ulcers in the experimental group and 44% in the control group by applying the patch to diabetic patients without plaster cast<sup>(17)</sup>.

The inferential analysis was used determining an  $X^2=0.135$  with  $p = 0.713$  for the categories of the ulcer appearance and polymer patch application variables. In this way, no statistical significance is obtained between the variables and we cannot affirm that the application of the polymeric patch is a protective preventive element. On the other hand, the statistical analysis was completed with the determination of  $X^2$  taking into account the erythema value that pales from the variable ulcer appearance as a potential sign of ulceration obtaining  $X^2=0.962$  ( $p = 0.327$ ), and therefore there is no relationship Statistically significant among the variables grouping these categories.

The high percentage of “non-therapeutic adherence” to the indications of splint care (19.2%) is sometimes noted, sometimes with the impaired state of immobilization (34.8%), so the influence of therapeutic adherence to the preventive measures of ulceration together with the appearance of ulcer offered by the nurses. In this sense, an  $X^2 = 0.098$  was obtained with a  $p = 0.952$ . Just as an  $X^2 = 0.929$  ( $p = 0.035$ ) for the splint deterioration and ulcer appearance variables, therefore there is no statistical

significance or relationship between all these variables. No scientific literature has been found to compare these values under similar research conditions.

Statistical significance is found only between the signs of splint deterioration and therapeutic adherence ( $X^2 = 26.36$ ,  $p = 0.0000$ ), which indicates that a splint detriment is linked to a poor therapeutic follow-up of preventive measures by the patient, and may be an early indicator to detect possible iatrogenic ulcers.

A relatively small sample size could be found as a limitation of the study. Among the potential, the study has a standardization in the technique of plaster cast as well as the randomization of the sample to designate the control and experimental group. This study does not present a conflict of interest.

## CONCLUSIONS

The results obtained do not allow us to affirm the hypothesis, since it is not possible to establish a direct relationship between the prevention of pressure ulcers in immobilized children with plaster splint in the lower limb and the application of polymeric protective patch according to the results of the statistical contrasts performed. Therefore, with respect to the objective of the study, it is proven that the polymeric patch is not effective in the prevention of iatrogenic ulcers by immobilization with plaster splint.

Nursing needs to continue investigating the prevention of pressure ulcers in its different variants, such as different types of padding or different forms of splint placement, as it constitutes a quality element of nursing care that provides lower morbidity for patients, Lower healthcare costs and greater patient and professional satisfaction.

Finally, we consider that the appearance of pressure ulcers is a multifactorial phenomenon, but in this specific case, we must make special mention of the importance as nurses of performing a health education for the care and maintenance of the splint to children and families in order to avoid complications.

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