Prevention's pressure ulcers heel with transparent polyurethane film

Prevenção de úlceras por pressão no calcanhar com filme transparente de poliuretano

Thaís Sanglard de Souza[1]
Mitzy Tannia Reichembach Danski[2]
Derdried Athanasio Johann[2]
Luciana Souza Marques De Lazzari[3]
Priscila Mingorance[2]

Keywords
Nursing; Pressure ulcer; Clinical nursing research; Nursing care; Clinical trial; Polyurethanes; Bandages

Descritores
Enfermagem; Úlcera por pressão; Pesquisa em enfermagem clínica; Cuidados de enfermagem; Ensaio clínico; Poliuretanos; Bandagens

Submitted
June 20, 2013

Accepted
August 2, 2013

Abstract

Objective: Evaluate the effectiveness of transparent polyurethane film in prevention of pressure ulcer of the calcaneus.

Methods: A sample of 100 patients enrolled in a non-randomized controlled trialreceived a paired analysis of both calcaneus areas; each received the experimental intervention on the left heel and the control intervention on the right heel (clinical guideline only), constituting a total of 200 heel sites for analysis.

Results: The incidence of pressure ulcers was 32%, with 6% occurring in the experimental intervention, 18% in the control intervention, and 8% bilaterally, with significant incidence in the first 15 days of hospitalization. The length of time without pressure ulcers occurrence with the experimental intervention was 19.2 days, with a 95% confidence interval.

Conclusion: It was concluded that the transparent polyurethane film associated with the pressure ulcers clinical guideline was effective in the prevention of heel pressure ulcer.

Resumo

Objetivo: Avaliar a efetividade do filme transparente de poliuretano na prevenção de úlceras por pressão no calcâneo.

Métodos: Uma amostra de 100 pacientes inscritos em um ensaio controlado não-randomizado recebeu uma análise pareada de ambas as áreas do calcâneo; cada um deles recebeu a intervenção experimental (filme transparente poliuretano) no calcanhar esquerdo e a intervenção controle no calcanhar direito (somente diretrizes clínicas), constituindo um total de 200 áreas de calcanhar para análise.

Resultados: A incidência de úlceras por pressão foi de 32%, com 6% ocorrendo na intervenção experimental, 18% na intervenção de controle e 8% bilateralmente, com incidência significante nos primeiros 15 dias de hospitalização. A duração de tempo sem ocorrências de úlceras por pressão na intervenção experimental foi de 19,2 dias, com um intervalo de confiança de 95%.

Conclusão: Foi concluído que o filme transparente de poliuretano associado às diretrizes clínicas das úlceras por pressão foi efetivo na prevenção da úlcera por pressão no calcanhar.

Clinical Trials Registry: REQ: 284

Corresponding author
Mitzy Tannia Reichembach Danski
XV de Novembro street, 1299, Curitiba, PR, Brazil. Zip Code: 80.060-000
profa.mitzy@ufpr.br

[1]Hospital Infantil Waldemar Monastier, Campo Largo, PR, Brazil.
[2]Universidade Federal do Paraná, Curitiba, PR, Brazil.
[3]Hospital de Clínicas, Universidade Federal do Paraná, Curitiba, PR, Brazil.

Conflicts of interest: the authors declare no conflict of interest.

Introduction

Pressure ulcers (PU) are ulcers caused by the lack of pressure relief, resulting in damage to underlying tissues due to interruption of blood supply.[1] They are a focus of increasing attention during the hospitalization period, as they generate costs for health care institutions, and discomfort and health risks to patients who suffer from them.[2]

The scientific literature highlights diverse therapeutic technologies for the management of pressure ulcers, however technologies for the treatment of pressure ulcers cost significantly more to institutions in financial terms than would the acquisition of preventive materials to avoid the development of these cutaneous ulcers.[3]

In Brazil, studies of pressure ulcers in the intensive care units (ICU) of university and public hospitals identified incidences that ranged between 19.2% and 44%.[4-6] Research conducted in the U.S. in sectors such as medical clinics, surgical, neurological, rehabilitation and intensive care units areas showed an overall incidence ranging from 3.5% to 33%.[7]

This finding highlights the importance of scientific evidence on the effectiveness of prophylactic options such as transparent polyurethane film (TPF), from a perspective of evidence-based practice (EBP), since this technology is indicated for such use, despite the fact that studies about this technology are still scarce and no strong evidence exists to ensure an evidence-based, minimally invasive practice with a lower iatrogenic effect on hospitalized patients.

Pressure ulcers are also known as pressure sores and decubitus ulcers, and can be described as localized areas of necrotic tissue, which develop when the tissue is compressed between a bony prominence and an external surface for a prolonged period of time.[8] The emergence of a pressure ulcers is principally related to a combination of factors extrinsic and intrinsic to patients. The extrinsic factors involved in the development of pressure ulcers are essentially pressure, friction and shearing.[8]

Pressure is the most relevant factor for the development of pressure ulcers. When the body's soft tissue is compressed between a bony prominence and a hard surface causing higher pressure than the capillary pressure, a localized ischemia occurs. The capillary pressure generally is described as being approximately 32 mmHg. Persistent pressure without relief for long periods of time is followed by tissue necrosis.[8]

In the United States, the National Pressure Ulcer Advisory Panel[9] developed a classification to categorize the degree of tissue ulcer. This classification was later adopted by the European Pressure Ulcer Advisory Panel.[1] Thus, in accordance with the EPUAP classification (2008), staging of pressure ulcers is according to the degree of tissue damage.

Transparent polyurethane film consists of a synthetic, adhesive, and hypoallergenic material. It is not inactive in the presence of moisture, since it has a gas exchange system, similar to healthy skin, which allows the diffusion of gases such as oxygen and vapors. It has an elastic quality which allows it to be applied to numerous body parts, and has resistance to friction and shearing forces.[9,10]

Another feature of transparent polyurethane film is its impermeability to fluids, secretions andbacteria. The permeability of transparent polyurethane film is measured by a variable called Moisture Vapor Transmission Rate[1] (MVTR – represents the amount that passes through the covering membrane for a given period of time. The higher the MVTR, the more effectively moisture is removed, preventing the accumulation of fluid beneath the membrane). The traditional transparent polyurethane film have a transmission rate between 400 to 800g/m^2/day, so those with high permeability of approximately MVTR 3000g/m^2/day are indicated for use at intravenous sites.[11]

In an attempt to provide preventive care to patients at risk for developing pressure ulcers, efforts have been directed toward evaluating the effectiveness of available prophylactic resources, to determine the usefulness of these interventional technologies in patient care. Pressure ulcer prevention seems a legitimate area of interest for determining suitability of prophylactic applications, since these are already being used clinically in our country. However, this use occurs despite the scarcity of scientific studies to prove effectiveness, which

would therefore support evidence-based practice. The transparent polyurethane film hase been demonstrated to be an important technology, and has been indicated for the prevention of pressure ulcers in intact skin. However, a search of the databases LILACS, MEDLINE, SciELO, PubMed, and Evidence Portal found no literature involving national or international clinical studies with transparent polyurethane film for the prevention of pressure ulcers of the calcaneus region. This finding supports the relevance of this study, and reflects the need for clinical studies that have methodological rigor and can contribute to the achievement of evidence-based practice in nursing.

Based on the insufficient scientific evidence on the subject, the objective this research was evaluate the effectiveness of transparent polyurethane film in prevention of pressure ulcer of the calcaneus.

Methods

The research design was a clinical, controlled, open, non-randomized trial involving patients in a Brazilian university teaching hospital. The study was conducted between January and June 2010. The study sample consisted of hospitalized adult patients (18 years or older) in an adult intensive care unit who met the following inclusion criteria: Assessed using the Braden Scale and presented as high, moderate or low risk for pressure ulcer development; Assessed within 48 hours after admission; Had uncompromised skin integrity of both calcaneal regions. Exclusion criteria for participants were: refusal to participate; discharge from the unit; or death during the period of study.

Patients who met the inclusion criteria constituted a single group to receive two simultaneous interventions: experimental intervention and control intervention, using a paired analysis of the cutaneous regions of bilateral heel regions. For analysis of the sites, all right heels were used as the control intervention sites (receiving intervention based on a clinical guideline for the prevention of pressure ulcer), and all left heels were used as the experimental intervention sites (receiving the transparent polyurethane film application in addition to the clinical guideline for the prevention of pressure ulcer).

The choice of the heel region for the study was justified by studies on the prevalence and incidence of PUs, since these sites as were among those most susceptible to the development of pressure ulcer.[12,13] The material under study - transparent polyurethane film - was not applied to the sacral region, due to the fact that this region is a singular site and therefore it would be impossible to analyze it simultaneously in the same patient during the period intended for this study. The transparent polyurethane film was not applied on other skin sites mentioned in the literature as likely to develop pressure ulcer due to the fact that we did not want to expose a very large body area of the patient to the application of the material.

The subjects' heels were assessed daily from the time of admission to the intensive care units, until any emergence of pressure ulcer, hospital discharge, patient withdrawal, or death (end points). During the evaluations, the transparent polyurethane film was only replaced when necessary, in situations such as full detachment from the skin or a localized skin reaction.

Between November 2009 and June 2010, 100 patients were enrolled in the study for a total of 200 calcaneal sites. Each patient was assessed daily, until the day of withdrawal from the study, be it by death, request to be excluded from the study, discharge, or an incidence of pressure ulcer, either on one or both calcaneal sites.

The method of statistical analysis used was comparative. To evaluate the incidence of pressure ulcer in the two interventions (clinical application of the guideline along with the transparent polyurethane film, and use of clinical guideline alone) the chi-square test was utilized. For the primary outcome, development of pressure ulcer, we calculated the time free from pressure ulcer and presented this using the Kaplan-Meier curves. To estimate the mean time free from pressure ulcer, we constructed confidence intervals of 95%. P-values <0.05 were considered statistically significant. For comparison of the incidence of pressure ulcer using the two simultaneous interventions, a

binomial test was used. Data were organized into an Excel spreadsheet and analyzed using the computer program, *Statistica v.8.0*. The results obtained in the study were expressed using means, standard deviations, frequencies and percentages. This research received approval from the Ethics Committee of the University Hospital and attended the national e international standards of ethics in research involving human beings.

Results

The study included 100 patients, which resulted in 200 heel sites.

The patients presented with identical baseline characteristics for both the experimental and control intervention, since this analysis was paired and consisted of a unique study group. The average age of participants was 53.3 years, and consisted of equal percentages of females and males (50%). The predominant race was white (85%). With regard to comorbidities, 15% were diabetic and 13% were hypertensive. Patients used vasoactive drugs and sedatives at the rates of 50% and 72%, respectively. The Braden Scale was used to evaluate the risk of patients developing pressure ulcers, with risk indexes ranging from 11 to 12 points.

An assessment of the incidence of pressure ulcers in the experimental and control interventions demonstrated that the period of patient monitoring during the days of hospitalization did not exceed 24 days, except for two patients, who were hospitalized 42 and 58 days, respectively, both for reasons other than the incidence of pressure ulcers.

Based on results like these, the pressure ulcers incidence rates have been described in the national and international literature. In order to calculate incidence, the length of observation time for the incidence of new cases has to be specified. The present study used the number of new cases of people with PU developed in a given period, in a population at risk, transformed into a percentage.

Table 1 presents the results obtained in the study, based on the days of patient monitoring. The follow-up period of patients in the study from the time of enrollment until the end point (onset of pressure ulcers – control, experimental or both) lasted on average 24 days. By the 15th day of follow-up, a significant number of patients (n = 18) developed a pressure ulcers, which was strong evidence that the incidence of PU was significant in this period. Pressure ulcers were observed in patients for both interventions in the study, with the percentage of incidence being significantly different between them. The amount of pressure ulcers in the experimental, control and bilateral interventions, as well as the days of higher incidence, were calculated.

Results regarding the presence or absence of pressure ulcer, based on the experimental and control interventions, are shown in table 2. Pressure ulcers occurred in 32% of patients, excluding those who were removed due to death, a withdrawal request or hospital discharge.With regard to the cases with an incidence of pressure ulcer during the monitoring period (n = 32), we adopted the classification of bilateral ulcer, pressure ulcer in the experimental intervention and pressure ulcer in the control intervention. Using this classification, we tested the null hypothesis that there would be no difference in the incidence of pressure ulcer in sites receiving the experimental intervention and control intervention.

It was observed that the percentage of pressure ulcer incidence was 8% bilaterally; 6% occurred in the experimental intervention, 18% in the control intervention, for a total overall incidence of 32% of the calcaneal sites. The statistical results indicated the rejection of the null hypothesis at a significance level of 5% (p <0, 001). Thus, it was inferred that the distribution of pressure ulcer was not uniform, with a higher frequency of cases in the control intervention. It should be noted that cases with bilateral pressure ulcer do not provide comparative information of the experimental intervention with the control, due to occurrence with both interventions. Thus, it is possible to conclude that, even though the patient may develop a pressure ulcer, the probability of this event happening with the control intervention is significantly higher than the probability of this event happening with the experimental intervention.

Table 1. Evaluation of the incidence of pressure ulcers in experimental and control interventions

Day	Day of initiation	Reason for exit		Day of exit	Pressure ulcers		
		Pressure ulcers	Other		Experimental site n(%)	Control site n(%)	Bilateral n(%)
0				100	0(0.0)	0(0.0)	0(0.0)
1	100	4	4	92	1(1.0)	3(3.0)	0(0.0)
2	92	8	5	79	1(1.1)	5(5.4)	2(2.2)
3	79	3	9	67	1(1.3)	0(0.0)	2(2.5)
4	67	2	6	59	0(0.0)	1(1.5)	1(1.5)
5	59	2	5	52	0(0.0)	1(1.7)	1(1.7)
6	52	2	5	45	0(0.0)	1(1.9)	1(1.9)
7	45	3	3	39	1(2.2)	1(2.2)	1(2.2)
8	39	2	2	35	1(2.6)	1(2.6)	0(0.0)
9	35	1	4	30	1(2.9)	0(0.0)	0(0.0)
10	30	0	2	28	0(0.0)	0(0.0)	0(0.0)
11	28	1	2	25	0(0.0)	1(3.6)	0(0.0)
12	25	1	2	22	0(0.0)	1(4.0)	0(0.0)
13	22	1	0	21	0(0.0)	1(4.5)	0(0.0)
14	21	0	3	18	0(0.0)	0(0.0)	0(0.0)
15	18	2	2	14	0(0.0)	2(11.1)	0(0.0)
16	14	0	4	10	0(0.0)	0(0.0)	0(0.0)
17	10	0	3	7	0(0.0)	0(0.0)	0(0.0)
18	7	0	2	5	0(0.0)	0(0.0)	0(0.0)
19	5	0	1	4	0(0.0)	0(0.0)	0(0.0)
20	4	0	0	4	0(0.0)	0(0.0)	0(0.0)
21	4	0	0	4	0(0.0)	0(0.0)	0(0.0)
22	4	0	1	3	0(0.0)	0(0.0)	0(0.0)
23	3	0	1	2	0(0.0)	0(0.0)	0(0.0)
24	2	0	0	2	0(0.0)	0(0.0)	0(0.0)

Legend: Two cases were followed for more than 24 days, one for 42 and the other for 58 days; they left the study for a reason other than a pressure ulcer

Table 2. Comparison of experimental and control interventions on the simultaneous incidence of pressure ulcer

Pressure ulcer	Frequency (%)
Bilateral	8(25.0)
Experimental intervention	6(18.8)
Control intervention	18(56.3)
Total cases with PU	32

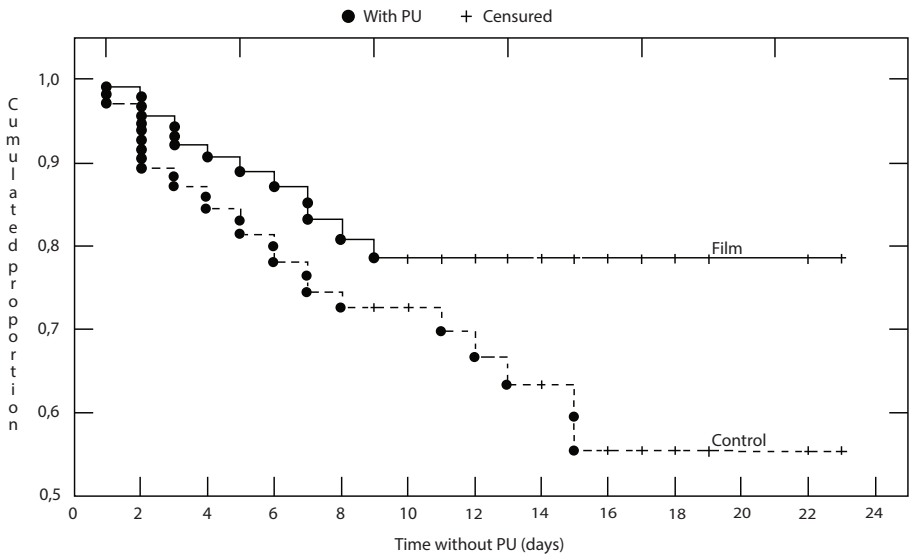

Figure 1. Time without pressure ulcer in experimental intervention and control groups

It was verified that the probability of increased pressure ulcer incidence occured with the control intervention; a second analysis involving the time free from pressure ulcer in the experimental and the control interventions also proved relevant. Figure 1 presents the curve corresponding to the time without pressure ulcer for the experimental and control interventions. Patients affected by pressure ulcer were considered "cases" and patients who died, left the study voluntarily or were discharged were removed from the study.It can be seen in figure 1 that there was a higher incidence of pressure ulcer in the first five days of monitoring, and especially in the first 48 hours. The mean time without development of pressure ulcer on the heel sites in those sites that received the experimental intervention was estimated at 19.2 days, with 95% confidence between 17.3 to 21.0 days.

Discussion

As discussed, the occurrence of pressure ulcer is a theme of great importance, and is especially relevant within hospitals, as incidence leads repercussions that generate increased costs for health facilities, and provide discomfort to patients affected by these ulcers.[14] A study by predicted an average annual cost of USD $13 million related to pressure ulcers.[15] In the United States, the Joint Commission on the Accreditation of Healthcare Organization estimated that treatment of pressure ulcers generated approximately (USD) $5,000 to $40,000 per patient, depending on the severity of the ulcer stage.[15]

The present study showed a calcaneal pressure ulcer incidence of 32% in patients admitted to the intensive care units of a public hospital, corroborating previous studies with reported incidences betwen 23,1% and 42.4%.[2,6,16,17] Another study of patients that were submeted a elective surgery the indices of pressure ulcer was 18,1%.[17]

In terms of the days in which there was a greater incidence of pressure ulcer , results found a tendency toward development of pressure ulcer in the first two weeks of hospitalization, with higher incidence occurringbetween days 1-15, especially with in the first five days, with highest incidence in the first 48 hours.These findings were consistent with previous study results.[4,5,18] Other study showed that development of pressure ulcer ranged from 11 to 20 days of hospitalization.[19] During a prospective cohort study conducted in a neurosurgical intensive care units in a São Paulo hospital over a three month period, observed that pressure ulcers

were developed between days 1-12, with a predominance occuring between postoperative days 4 –8.[20] In this study we found a statistically significant association between length of stay in intensive care units and the development of pressure ulcers.

Studies evaluating the incidence of pressure ulcer in patients undergoing transparent polyurethane film application in the literature are scarce. There is a disadvantage in use of transparent polyurethane film when the pressure ulcer presents infection and exudates.[21] In contrast, another study evaluated the incidence of pressure ulcer in patients with transparent polyurethane film applied on the sacral region.[22]

The current research holds clinical significance because it identified that the likelihood of pressure ulcer occuring in patients who do not use transparent polyurethane film is significantly higher than in those who do.

There is a need to expand optional resources for the prevention of pressure ulcer in order to reduce the discomfort and pain they cause in hospitalized individuals, as well as to lower costs for the treatment of these ulcers that in most cases are preventable.This study of transparent polyurethane film as an intervention for pressure ulcer prevention validates current clinical use with pressure ulcer as a secondary dressing, and it is well accepted both by professionals who apply it and patients receiving the treatment. Additionally, it is easy to implement, requiring only a skilled professional to apply the transparent polyurethane film and educate patients on the film's duration and required handling care.

This research points to strong scientific evidence that the transparent polyurethane film is effective in preventing pressure ulcers of the calcaneal region. We reject the null hypothesis that there will be no difference in the incidence of pressure ulcer in sites receiving the experimental intervention and control intervention.The results were also relevant because they reinforced the need for the connection between theory and practice for the conduct of nursing research, to provide strong scientific evidence for practice. The transparent polyurethane film was demonstrated to be a successful technological intervention for the prevention of pressure ulcer. This supports the current widespread use of transparent polyurethane film in practice, since results confirm its effectiveness, especially as prevention for critically ill patients admitted to intensive care units.There is also a need for training of nurses for clinical research, so that they may be able to answer practical questions.

We suggest additional, similar clinical studies using transparent polyurethane film on other body regions, especially the sacral region, since this is the region with the highest incidence of pressure ulcer. For generalization across distinct demographic populations, there is need for stratification of risk factors to be compared, in order to obtain similar baseline variables between samples.It should be noted that this was unprecedented clinical research study evaluating the effectiveness of transparent polyurethane film prevention of the incidence of calcaneal pressure ulcer.

Conclusion

The transparent polyurethane film associated with the pressure ulcer clinical guideline was effective in the prevention of heel pressure ulcer.

Collaborations

Souza TS e Danski MTR colaboraram com a concepção do projeto, análise e interpretação dos dados; redação do artigo, revisão crítica relevante do conteúdo intelectual e aprovação final da versão a ser publicada. Johann DA; De Lazzari LSM e Mingorance P contribuíram com a coleta de dados, redação do artigo, revisão crítica relevante do conteúdo intelectual e aprovação final da versão a ser publicada.

References

1. European Pressure Ulcer Advisory Panel and National Pressure Ulcer Advisory Panel (EPUAP). Prevention and treatment of pressure ulcers: quick reference guide [Internet]. Washington DC: National Pressure Ulcer Advisory Panel-2009. 2009. [cited 2012 July 5]. Available from: http://www.npuap.org/wpcontent/uploads/Final_Quick_Prevention_for_web_2010.pdf
2. Fernandes NC,Torres GV. Incidência e fatores de risco de úlceras de pressão em unidades de terapia intensiva. Ciência Cuid Saúde. 2008;7(3):304-10.
3. Joint Commission on the Accreditation of Health Care Organizations

(JCAHO). National patient safety goals. 2007. [Internet]. 2007. [cited 2011 Oct 11]. Available from: http:// www.jointcommission.org/ patientsafety/nationalpatientsafetygoals

4. Blanes L, Duarte IS, Calil JA, Ferriera LM. Clinical and epidemiological assessment of pressure ulcers in patients admitted to Sao Paulo Hospital. Rev Assoc Médica Bras. 2004;50(2):182-7.

5. Paranhos, WY, Santos VLCG. Avaliação de risco para úlceras por pressão por meio da escala de braden na língua portuguesa. Rev Esc Enferm USP, 33(n.esp):1-231,1999.

6. Rogenski NM, Santos VL. [Study on the incidence of pressure ulcers in a university hospital]. Rev Latinoam Enferm. 2005;13(4):474-80. Portuguese.

7. Anthony D, Reynolds T, Russel L. The role of hospital acquired pressure ulcer in the length of stay. Clin Effectiv Nurs. 2004;8(1):4-10.

8. Dealey C. Caring for wounds: a guide for nurses. 3a ed. São Paulo: Atheneu; 2008.

9. National Pressure Ulcer Advisory Panel (NPUAP). International Pressure Ulcer Guidelines for Prevention and Treatment -2007.[Internet]. 2007. [cited 2012 July 5]. Available from: http://www.npuap.org/wp-content/ uploads/2010/02/Final_Quick_Prevention_for_web_2010.pdf

10. Cockbill SME, Turner TD. The development of wound management products. In: Krasner DL, Rodeheaver GT, Sibbald RG. Chronic wound care: a clinical source book for healthcare professionals. 4th ed. Malvern, PA: HMP Communications; 2007. p. 233-48.

11. Rostald BS, Ovington LG. Principles of wound management. In: Bryant RA, NIX DP. eds. Acute and Chronic Wounds: current management concepts. 3th ed. New York: Mosby; 2007. p. 391-426.

12. Chacon JM , Blanes L., Hochman B, Ferreira LM. Prevalence of pressure ulcers among the elderly living in long – stay institutions in São Paulo. São Paulo Med J. 2009;127(4):211-5.

13. Enoch S, Grey JE, Harding KG. ABC of wound healing. Non-surgical and drug treatments. BMJ. 2006;332(7546):900-3. Review.

14. Johnson M. Pressure ulcer prevention: bringing it home to the perianesthesia world. J Perianesth Nurs. 2010;25(2):104-7.

15. Banks MD, Gaves N, Bauer JD, Ash S. The costs arising from pressure ulcers attributable to malnutrition. Clin Nutr. 2010;29(2):180-6.

16. Rogenski NM, Kurcgant P. The incidence of pressure ulcers after the implementation of a prevention protocol. Rev Latinoam Enferm. 2012;20(2): 333-9.

17. Ursi ES, Galvão CM. Ocorrência de úlcera por pressão em pacientes submetidos a cirurgias eletivas. Acta Paul Enferm. 2012;25(5):653-9.

18. Costa, IG, Caliri, MHL., Incidencia de úlcera de pressão em centro de terapia intensiva de um hospital universitário e fatores de risco relacionados. Rev Esc Enferm USP. 2004,3(23):202-7.

19. Sousa PR, Sousa MF, Barros IC, Bezerra MG, Sousa JE, Luz MH. [Analyze the risk factors for developing pressure ulcer among hospitalized patients in the intensive care unit]. Rev Enferm UFPI. 2013;2(1):9-15. Portuguese.

20. Diccini S, Camaduro C, Lida LI. Incidence of pressure ulcers in neurosurgical patients in a university hospital. Acta Paul Enferm. 2009;22(2):205-9.

21. Smaniotto PH, Ferreira MC, Issac C, Galli R. Sistematização de curativos para o tratamento clínico das feridas. Rev Bras Cir Plast. 2012; 27(4):623-6.

22. Imanishi K, Morita K, Matsuoka M, Hayashi H, Furukama S, Terashita F, et al. Prevention of postoperative pressure ulcers by a polyurethane film patch. J Dermatol. 2006;33(3):236-7.