

# Incontinence-associated dermatitis: a cohort study in critically ill patients

*Dermatite associada à incontinência: estudo de coorte em pacientes críticos*

*Dermatitis asociada con incontinencia: estudio de cohorte en pacientes críticos*



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## How to cite this article:

Chianca TCM, Gonçalves PC, Salgado PO, Machado BO, Amorim GL, Alcoforado CLGC. Incontinence-associated dermatitis: a cohort study in critically ill patients. Rev Gaúcha Enferm. 2016;37(spe):e68075. doi: <http://dx.doi.org/10.1590/1983-1447.2016.esp.68075>.

doi: <http://dx.doi.org/10.1590/1983-1447.2016.esp.68075>

## ABSTRACT

**Objectives:** Estimate incidence, determine risk factors and propose a prediction model for the development of incontinence-associated dermatitis critically ill adult patients.

**Method:** Concurrent cohort study with 157 critically ill patients. Data collection was daily performed between February and July 2015, at a public teaching hospital of Belo Horizonte, Minas Gerais. Data was entered in a database and subjected to descriptive, survival and multivariate analysis.

**Results:** An overall incidence of 20.4% was obtained. Nineteen (19) risk factors significantly associated with the disorder were found. The variables identified in the risk prediction model were male, trauma, use of hypnotics/sedatives, lactulose, nutritional support, loose stools and complaints of burning.

**Conclusion:** The results showed that dermatitis is a common clinical finding in critically ill adult patients and requires special attention from the nursing staff.

**Keywords:** Diaper rash. Intensive care units. Nursing. Nursing diagnosis.

## RESUMO

**Objetivos:** Estimar incidência, determinar fatores de risco e propor modelo de predição de risco para desenvolvimento de dermatite associada a incontinência em pacientes adultos críticos.

**Método:** Trata-se de um estudo de coorte concorrente realizado com 157 pacientes críticos. A coleta de dados foi conduzida diariamente entre fevereiro e julho de 2015 em hospital público e de ensino de Belo Horizonte, MG. Os dados foram lançados em banco de dados, submetidos a análise descritiva de sobrevida e multivariada.

**Resultados:** Obteve-se uma incidência global de 20,4%. Foram encontrados 19 fatores de risco que apresentaram associação significativa com o problema. As variáveis encontradas no modelo de predição de risco foram: sexo masculino, trauma, uso de hipnótico/sedativos, lactulona, suporte nutricional, fezes pastosas e queixa de ardência (local).

**Conclusão:** Os resultados mostraram que a dermatite é um achado clínico comum em pacientes adultos críticos e merece atenção especial para maior qualidade da assistência de enfermagem.

**Palavras-chave:** Dermatite das fraldas. Unidades de terapia intensiva. Enfermagem. Diagnóstico de enfermagem.

## RESUMEN

**Objetivos:** Estimar incidencia, determinar factores de riesgo y proponer modelo de predicción de riesgo para el desarrollo de la dermatitis asociada a la incontinencia en pacientes adultos críticos.

**Método:** Se trata de un estudio de cohorte concorrente de 157 pacientes críticamente enfermos. La recolección de datos se realizó diariamente entre febrero y julio de 2015, en un hospital público y de enseñanza de Belo Horizonte-MG. Los datos se introdujeron en la base de datos, sometidos a análisis descriptivo, de supervivencia y multivariada.

**Resultados:** Se obtuvo una incidencia global del 20,4%. Se encontraron 19 factores de riesgo asociados significativamente con el problema. Las variables identificadas en el modelo de predicción de riesgo fueron: sexo masculino, trauma, uso de hipnóticos/sedantes, lactulona, soporte nutricional, heces sueltas y queja de ardor (local).

**Conclusión:** Los resultados mostraron que la dermatitis es un hallazgo clínico frecuente en pacientes adultos críticos y merece una atención especial para una mayor calidad de los cuidados de enfermería.

**Palabras clave:** Dermatitis del pañal. Unidades de cuidados intensivos. Enfermería. Diagnóstico de enfermería.

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## ■ INTRODUCTION

The Intensive Care Unit (ICU) is a place where critically ill patients are admitted and receive continuous medical and nursing care. Regarding the care provided to critical patients, skin care deserves special attention from the nursing staff, representing a considerable challenge in daily practice. The issue is considered a very sensitive quality indicator, and is also related to patient safety<sup>(1-2)</sup>. Therefore, it is extremely important that care provided in the prevention and treatment of skin lesions is based on scientific evidence.

During ICU admission, patients may suffer skin damage due to exposure to various internal and external factors such as age, inadequate nutrition, use of invasive devices, and mechanical forces and moisture. The latter deserves special attention because of the so-called Moisture-associated Skin Damage (MASD). The "MASD" associated with incontinence-associated dermatitis (IAD), also known as rash, is the most common skin lesion<sup>(3)</sup>.

DAI is characterized by inflammation and erythema, with or without swelling of the skin, affecting an area larger than the perineum, such as genitalia, buttocks, thighs and upper abdomen. It results from a combination of factors such as excessive moisture caused by urinary and/or fecal incontinence, pH changes, friction, colonization by microorganisms, etc<sup>(2,4)</sup>.

Incontinence is common in hospitalized patients. A study conducted in an Australian hospital with 376 individuals (mean age of 62 years) found a prevalence of 24% of incontinence, significantly higher among women (10%) ( $p = 0.035$ ). DAI was observed in 10% (38/376) of the sample, and the prevalence of incontinent hospitalized patients was 42% (38/91)<sup>(5)</sup>. Another study identified a prevalence of 33% of fecal incontinence in adult ICU patients (6). Thus, it has been demonstrated that critically ill patients who need specific care, because of their serious condition are at high risk of developing urinary and/or fecal incontinence, and this problem is associated with skin damage in the perineal region<sup>(1-2,7)</sup>.

At the ICU, patients are given continuous given specialized nursing care for the prevention and treatment of pressure ulcers. However, IAD prevention includes the availability of special care targeted to incontinent patients wearing diapers. It should also be mentioned that some health professionals cannot properly identify IAD, which is many times mistaken with pressure ulcers (PU) in their early stages<sup>(8-9)</sup>.

Many patients admitted to ICU (the site where this study was conducted) wear diapers and therefore are

more likely to develop IAD-related complications, providing a justification for the present study. In addition to damaging the skin and causing itching and pain, IAD is considered a gateway to infections such as those of the urinary tract and skin, as well as a risk factor for the emergence of pressure ulcers<sup>(9)</sup>. Thus, this study aimed to estimate the incidence, determine the risk factors and propose a model for the prediction of risk for the development of incontinence associated dermatitis in critically ill adult patients.

## ■ METHODS

It is a concurrent cohort study conducted in two ICU's (UTI – I and UTI – III) with 10 beds each, intended for hospitalized adult patients in a public teaching hospital considered a reference for urgent care in the capital and Metropolitan region of Belo Horizonte – MG.

For sample size calculation, the population of two intensive care units was considered: ICU – I, with an average of 384 admissions per year and ICU – III, with an average of 360 admissions per year, in a total population of 744 patients. The calculation was based on an average incidence of 14% of IAD, according to the literature<sup>(7)</sup>. A minimum sample of 149 patients was obtained with confidence level of 95% and an error margin of 5%.

The study included patients who met the following criteria: 18 years old, not affected by dermatitis and sacral pressure ulcer and surrounding tissue at the time of admission; the patient should be wearing diapers and admitted to ICU for at least 24 hours. Patients from other ICUs were excluded because of their exposure to risk factors associated with those units.

Prior to data collection, five examiners selected from among nursing students ( $N = 3$ ) and students at the graduate nursing program ( $N = 2$ ) were trained. This training was conducted by an enterostomal therapy nurse specialized in skin lesions. Such therapy was considered in this study as the "gold standard". The training consisted of theoretical and practical activities on skin assessment and identification of signs and symptoms of IAD and reading of articles and texts on the subject. After the training, the examiners assessed the ICU patients independently, examiners who did not communicate among themselves to ensure the secrecy of the process. Then the collected data was recorded and individually printed by each examiner. In the assessment of inter-rater reliability Kappa statistic was used to describe and test the levels of agreement of the assessments<sup>(10)</sup>. The Kappa values obtained in patient assessment showed

agreement between the two raters (examiner A and examiner B) against the gold standard, with respectively, 1.00 and 0.87 (almost perfect reliability)<sup>(10)</sup>. The other examiners did not reach almost perfect agreement and were not selected for data collection.

Data collection was conducted from February to July 2015. The patients who met the inclusion criteria were followed daily, from admission to discharge/death/transfer or development of the study outcome (development of IAD).

Patients eligible for the study were assessed using a data collection instrument containing essential information<sup>(2,7,11)</sup> (sociodemographic factors, current and past history, clinical data, risk factors and examination of the perineal region for the identification of signs and symptoms of dermatitis).

Examination of the perineal region was performed during bathing and/ or diaper change with the patient lying in the bed. The information obtained was subsequently recorded in the data collection instrument.

The data collected was entered in Epi Info software, version 3.5.1, subjected to the double entry process in order to reduce typing errors, and statistical analysis using SPSS software (Statistical Package for Social Science) – version 19 and Stata – version 10. Descriptive analysis (simple frequencies, measures of central tendency and variability) was used in the analysis of sociodemographic and clinical data.

For the identification of the factors that obtained association with the time of IAD development survival analysis represented by contingency tables was used, as well as Cox regression models. For the determination of the relationships between the variables and the time elapsed between admission until the occurrence of IAD multivariate analysis using Cox regression model was performed. All variables with  $p$ -value  $\leq 0.25$  in bivariate analysis were included in the multivariate analysis, which was used to create a predictive model. Forward and backward stepwise regression with 0.25 significance level was used. The variables selected with stepwise regression were assessed for a level of significance of 5%, in such a way that if the  $p$  value was greater than 0.05, the variable was removed from the model until all the characteristics reached a  $p$  value less than 0.05.

Finally, the strength of the association between the variables that significantly impacted the outcome was calculated through hazard ratio (HR) and their respective intervals with 95% confidence.

This study was approved by the Research Ethics Committee of the hospital where the study was conducted and of the Federal University of Minas Gerais,

under statement No. 903520, and CAAE protocol number 37462214.8.0000.5149.

## ■ RESULTS

Of the 157 patients who participated in the study, 32 had IAD. The overall incidence of IAD was 20.4%. The average period of development of the condition was nine days (SD  $\pm$  9), median of six days and variability of two to 37 days. The incidence density was 2.5 cases per 100 persons/day, ranging from 1.7 to 3.5 cases per 100 persons/day, with a 95% confidence index.

Most patients were male (85 -54.1%) and mean age 60  $\pm$  17 years. There was a predominance of white male individuals (83-5 2.9%), with medical diagnosis of lung disease at the time of admission (51-32.5%). The risk factors for the development of IAD found in the study are shown in Table 1.

Of all the analyzed variables, those that composed the risk prediction model (multivariate analysis) were gender, admission for trauma, previous neoplasia, use of hypnotic /sedative and lactulose, need for nutritional support (oral, enteral or parenteral), loose stools and perineum burning sensation. These variables had a significant impact on the time elapsed until the development of IAD (Table 2).

Upon admission to ICU, the patients with medical diagnosis of trauma were at a risk of developing IAD 16.11 times higher than those who were not diagnosed with trauma. This risk was 13.47 times higher in patients who complained of burning and 12.97 times higher in the patients diagnosed with cancer compared with those who were not diagnosed with cancer.

## ■ DISCUSSION

The present study aimed to identify the prevalence rate of IAD in adults and elderly patients admitted to intensive care unit, in order to determine the extent of this problem in a public hospital. The risk factors for the event were also identified.

The overall incidence of dermatitis was 20.4% and the incidence density rate was 2.5% per 100 patient-days. A study on the development of IAD in adult ICU patients also found an incidence of 16/45 (35.5%). However, the small sample size makes comparison with the results of this study difficult<sup>(2)</sup>.

The average time taken to develop the problem was nine days in this study. In a study of adult ICU patients an average of four days (ranging from one to six days) was

**Table 1** – Risk factors associated with the development of IAD. Belo Horizonte, MG, Brazil, 2015

Variable		IAD		HR (95% CI)*	P-value
		No	Yes		
		N (%)			
Gender	Male	52 (41.6)	20 (62.5)	0.25 (0.12 – 0.56)	<0.001
Race	Black	35 (28.0)	5 (15.6)	0.28 (0.10-0.79)	0.016
Medication	Hypnotic / Sedative	78 (62.4)	18 (56.3)	0.26 (0.12-0.55)	<0.001
	Antipsychotic drugs	40 (32.0)	9 (28.1)	0.32 (0.14-0.71)	0.005
	Beta blocker drug	12 (9.6)	2 (6.3)	0.21 (0.04-0.97)	0.046
Loose/liquid stool	No	61 (48.8)	13 (40.6)	0.36 (0.17-0.76)	0.008
	Yes	64 (51.2)	19 (59.4)		
Isolation/Contact	No	94 (75.2)	23 (71.9)	0.33 (0.15-0.76)	0.009
	Yes	31 (24.8)	9 (28.1)		
Age	Mean	58 (17)	66 (16)	1.03 (1.00 – 1.05)	0.015
Comorbidities	Previous Neoplasia	2 (1.6)	3 (9.4)	5.93 (1.73-20.3)	0,005
Number of episodes of fecal incontinence	One	32 (45.7)	2 (6.3)	5.8 (1.3-25.5)	0.018
	Two	24 (34.3)	16 (50.0)		
	Three	13 (18.6)	11 (34.4)		
	Four	1 (1.4)	2 (6.3)		
	Five	0 (0.0)	1 (3.1)		
Number of diaper changes / 24 hours	Three	11 (8.8)	11 (34.4)	2.720 (1.29-5.69)	0.008
Burning	No	125 (100)	28 (87.5)	7.19 (2.46-20.99)	<0.001
	Yes	0 (0.0)	4 (12.5)		
Itching	No	125 (100)	30 (93.8)	4.41 (1.04-16.70)	0.044
	Yes	0 (0.0)	2 (6.3)		
Pain	No	125 (100)	30 (93.8)	14.24 (3.14-64.4)	0.001
	Yes	0 (0.0)	2 (6.3)		
Erythema response	No	125 (100)	23 (71.9)	3.91 (1.76 – 8.68)	0.001
	Yes	0 (0.00)	9 (28.1)		
Erythema and erosion	No	125 (100)	12 (37.5)	13.79 (6.38- 29.80)	<0.001
	Yes	0 (0.0)	20 (62.5)		
Erosion and fungi	No	125 (100)	31 (96.9)	8.99 (1.16- 69.37)	0.035
	Yes	0 (0.0)	1 (3.1)		

Source: Research data, in 2015.

\* HR: hazard ratio; HR = 1.0 (there is no association between exposure and effect); HR> 1.0 (risk association); HR <1.0 (protective association).

found for the development of dermatitis<sup>(2)</sup>. However, there are few studies on the relationship between the time of exposure to moisture and the onset of IAD symptoms<sup>(11)</sup>. The time required to the development of the problem of the condition is an important variable to be considered in

critically ill patients, since it is directly related to increased exposure to their risk factors<sup>(5)</sup>.

With aging the skin tends to become drier, thinner and less elastic, which may result in wrinkling and sagging due to decrease in collagen and elastin fibers<sup>(12)</sup>. In this study,

**Table 2** – Risk prediction model for IAD. Belo Horizonte, MG, Brazil, in 2015.

Variables	Group	HR (95%)*	P-value
Gender	Female		
	Male	0.15 (0.06-0.38)	<b>&lt;0.001</b>
Trauma admission	No		
	Yes	16.11 (1.63-158.53)	<b>0.017</b>
Previous Neoplasia	No		
	Yes	12.97 (2.94-57.22)	<b>0.001</b>
Using Hypnotic / Sedative	No		
	Yes	0.37 (0.16-0.84)	<b>0.018</b>
Use of Lactulose	No		
	Yes	0.35 (0.13-0.95)	<b>0.040</b>
Needs nutritional support	No		
	Yes	0.14 (0.02-0.73)	<b>0.020</b>
Loose stools	No		
	Yes	0.28 (0.11-0.72)	<b>0.009</b>
Burning	No		
	Yes	13.42 (3.90-46.49)	<b>&lt;0.001</b>

Source: Research data, 2015.

\* HR: hazard ratio; HR = 1.0 (there is no association between exposure and effect); HR > 1.0 (risk association); HR < 1.0 (protective association).

the average age of the 157 patients monitored was 60 years, considered elderly and more likely to develop incontinence. Thus, incontinence and IAD are recognized as signs and symptoms of geriatric syndromes<sup>(5)</sup>.

A predominance of white individuals (83 to 52.9%) was identified among the patients. IAD was found to affect individuals of both genders and all races<sup>(11)</sup>. However, the results of this study corroborate the findings of another study that identified (39-87%) of white patients who developed DAI<sup>(2)</sup>.

Bivariate analysis showed variables significantly associated with both higher and lower risk of developing the dermatitis. However, some risk factors differed from factors identified in the literature that found other variables with statistical significance not detected in the present study<sup>(2,8,13)</sup>.

The factors significantly associated with higher or lower risk of IAD were age, trauma admission, previous cancer, large volume of stools, number of daily diaper changes, burning, itching, pain, erythema response, erythema and erosion, erosion and fungi, male gender, black race, use of hypnotics/sedatives, antipsychotic medications, beta-blocker drugs, loose stools and isolation. Statistically significant risk factors such as fecal incontinence, frequent episodes of incontinence, pain, impaired oxygenation, fever, mobility impairment, double incontinence, mechanical stress, chronic diseases, need for nutritional support, reduced perfusion and oxygenation, skin disorders, symptoms, perfusion state, decreased cognitive status, liquid stools, age, hypoalbuminemia were found in other studies<sup>(2,13)</sup>.

In the present study, the variables that obtained significant associations of higher risk of developing IAD were age, trauma admission, previous cancer, large volume of stools and three diaper changes per day.

Trauma patients are usually more dependent on nursing care, and may be restricted to a specific position, being at higher risk of friction and shear and other factors that increase the risk for IAD. This result corroborates the findings of another study that also identified these factors related to the risk of pressure ulcer in patients with spinal cord injury<sup>(14)</sup>.

A high risk of IAD was also found in patients with previous neoplasia admitted to ICU. It is known that most of these patients are often malnourished, with their immune system affected by radiation therapy and/or chemotherapy, and may experience mouth sores, diarrhea, fatigue, and other factors associated to measures used to control advanced cancer, contributing to the development of IAD<sup>(13)</sup>.

Regarding the variable number episodes of fecal incontinence, it was found that the greater the number of daily episodes of fecal incontinence, the higher the risk of developing IAD. Thus, patients who had five episodes of fecal incontinence in 24 hours were at a risk 39 times higher of developing IAD than those who had only one episode of fecal incontinence. Additionally, patients whose diapers were changed three times per day were at a higher risk of A multicenter prevalence study with 3,713 adult and elderly patients in hospitals or nursing homes of Europe identified a strong association between the development of IAD and patients with fecal incontinence (OR 1.70; 95% CI 1:14 to 2:55) and patients exposed to friction and shear of the skin in the perineal area (OR 0.65; 95% CI 0.51-0.81) (15). It should be stressed that there was no availability of

skin and wound care products to protect skin from IAD in any of the ICUs of the study.

The variables that showed statistical significance and were related to lower risk of IAD were male gender, black race, loose stools, use of lactulose and need for nutritional support.

When urinary incontinence occurs during bed rest, women are more susceptible to IAD, especially the area exposed to urine from the perineum through the coccyx to the sacrum, due to their anatomical structure<sup>(16)</sup>. On the other hand, the variable black race was identified, in the present study, as a factor of lower risk for development of IAD. It is known that the stratum corneum of black individuals is more compact, with a greater number of layers compared to white individuals and lower absorption capacity due to lower permeability to chemical compounds<sup>(17)</sup>. Thus, black skin contributes to increased resistance to IAD risk factors.

Loose stools, variable of lower risk for the development of IAD (HR 0.28) is consistent with literature findings<sup>(2)</sup>. On the other hand, liquid stools, compared to loose stools, come into contact with a larger skin surface and, in addition to their greater amount of irritants (bile salts and pancreatic lipases), their effects are increased in the presence of alkaline pH, causes lysis of the stratum corneum keratin structure, favoring the development of IAD<sup>(5)</sup>.

Regarding the factors isolation, use of hypnotics/sedatives, antipsychotic and beta-blocker drugs for which were found to be of lower risk for the condition, contrast with literature data<sup>(2)</sup>. These factors increase the risk of development of IAD, since patients who use beta-blockers and sedatives have reduced cognitive state and hence are more likely to develop IAD compared to patients who do not use sedatives. However, a study that measured the time of nursing care devoted to patients in intensive care found that patients in isolation who are given hypnotics/sedatives, antipsychotic and beta-blocker drugs require more care time<sup>(18)</sup>. This may justify the results found, since it is assumed that the longer time spent by the nursing staff stays with these patients will result in the provision of more care related to the maintenance of the integrity of the skin of these patients.

The variable use of lactulose found in the predictive model deserves attention and should be further investigated, as the literature suggests that drugs that make stools liquid, such as laxatives and some antibiotics, are related to the development of IAD<sup>(19)</sup>.

Patients who received nutritional support had a lower risk of IAD, a fact corroborated by the literature. Critical

patients may have hypermetabolism, which increases loss of nutrition. Therefore, preventive additional nutritional support minimizes this problem<sup>(20)</sup>.

Incontinence-associated dermatitis is a significant problem that affects patients with urinary and/or fecal incontinence. Although the risk factors that lead to the development of DAI have been identified, the number of people affected by the condition is not yet known in many countries. This is explained by the difficulties in recognizing this condition that sometimes is mistaken with pressure ulcer in its early stages. Therefore, IAD remains a challenge for the nursing staff.

The incidence of IAD found, the lack of studies on the issue, and particularly in Brazil, the lack of studies on the relationship between time of exposure to moisture and development of IAD, the fact that the greater the number of episodes of fecal incontinence, the higher the risk of development of IAD, the importance of nurses' awareness of the need for care in handling patient positions to avoid friction and shear, of early identification of patients at higher risk of loose stools, whose diapers are changed more frequently, and who have burning complaints, are strong evidence that indicated the need the development and implementation of a new clinical protocol of care for incontinent ICU patients. The construction of this protocol was recommended and will certainly contribute to change care practices in the ICUs where the study was conducted and possibly in multiple health care settings.

## ■ CONCLUSION

IAD is a preventable condition when properly treated. Thus, the use of preventive measures is a priority. Patient wellbeing is essential, and the nursing staff must be prepared to provide adequate care. This study may contribute to the prevention of IAD in adult ICU patients, as well as to high quality nursing care.

In the present study, of the 157 patients that composed the sample, 32 had IAD (an overall incidence of 20.4%), and incidence density was 2.5 cases per 100 person-days. The risk factors for the development of IAD were age, trauma admission, previous cancer, large number of episodes of fecal incontinence, number of diaper changes per day, burning complaint, itching, pain, presence of erythema response, erythema and erosion, erosion and fungi. The factors related to lower risk of IAD were male gender, black race, loose stools, isolation, use of hypnotics/sedatives, antipsychotic and beta-blocker drugs.

The variables obtained in the final risk model were as follows: male gender, trauma admission, previous cancer, use of hypnotics/sedatives, lactulose, nutritional support, loose stools and burning sensation in the perineal area. The identified risk factors are relevant since some of them have not yet been reported in the literature. So, multicenter studies with larger samples are needed, involving the administration of a risk prediction scale validated specifically for use in bedridden critically ill patients exposed to IAD development, to determine the statistical significance of the risk factors identified here.

The incidence of IAD and the risk factors identified in this study are directly related to the profile of the subjects: bedridden critically ill patients dependent on nursing care. Thus, the risk for IAD should be identified early for prevention measures to be adopted.

Thus, the elaboration of a protocol of care for incontinent patients is recommended to minimize the incidence of IAD detected. According to the results of this study, this protocol should include the description of proper skin care with products that do not lower pH, skin drying, standardization of diapers with greater absorbent capacity and use of barrier creams that protect skin from the uric acid in the urine and digestive acids in fecal matter.

In addition to the implementation of the protocol, in the treatment of patients predisposed to IAD, nurses must have knowledge on the best scientific evidence regarding the proper identification of this problem, preventive measures and treatment, in order to be able to adopt an appropriate care.

Since the study was conducted to address a common clinical issue, the results provide valuable evidence for the implementation of a new protocol care adapted for use in ICU incontinent patients, which will certainly have a positive impact on the care setting where the study was conducted and in many other health settings.

Also, further clinical studies aimed to investigate nursing care to patients with urinary and/or fecal incontinence are suggested.

A major limitation of this study was the difficulty in performing daily patient assessment, which involves constant handling these patients who are often in critical condition, for the observation of the perineal area.

Another limitation is related to the variables of statistical significance, since they are associated with a small percentage of the study subjects who were exposed to these risks. Thus, studies with a larger number of patients exposed to these risk factors are needed.

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Received: 09.21.2016

Approved: 02. 01.2017