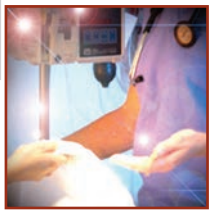

Effectiveness of Nursing Interventions to Prevent Dry Eye in Critically Ill Patients

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Background Critically ill patients are susceptible to the development of dry eye. Few studies have been conducted on how to best prevent and treat this condition.
Objective To compare the effectiveness of 2 nursing interventions in preventing dry eye in adult intensive care unit patients: liquid artificial tears (Lacribell; Latinofarma) and artificial tears gel (Vidisic Gel; Bausch and Lomb).
Methods In this randomized controlled trial, 140 participants were randomly assigned to 1 of 2 treatment groups: a liquid artificial tears group (n=70) and an artificial tears gel group (n=70). The study inclusion criteria were as follows: admission to the intensive care unit, age of 18 years or older, no diagnosis of dry eye at admission, receipt of mechanical ventilation, blink rate of less than 5 times per minute, and a score of 7 or less on the Glasgow Coma Scale. On 5 consecutive days, a single researcher who was unaware of the treatment assignment assessed the participants' eyes using the fluorescein eye stain test and the Schirmer test for dry eye.
Results Dry eye developed in 21% of participants who received liquid artificial tears versus 9% of participants who received artificial tears gel (P=.04).
Conclusions In this study, artificial tears gel was superior to liquid artificial tears in preventing the development of dry eye. These results may help nurses deliver evidence-based eye care aimed at reducing the risk of dry eye in critically ill patients. (*American Journal of Critical Care.* 2019;28:299-306)

doi:https://doi.org/10.4037/ajcc2019360

Intensive care unit (ICU) patients often have conditions leading to compromised physiological mechanisms of eye protection. These conditions include being unconscious or comatose; taking several medications such as diuretics, sedatives, and β-blockers; receiving mechanical ventilation; and being exposed to air conditioning and low air humidity.[1-4] Consequently, these patients are susceptible to the development of dry eye and other ocular surface disorders.[4-7]

Clinical guidelines that have been developed for eye care in the ICU refer to a variety of interventions designed to reduce the prevalence and incidence of ocular surface alterations in critically ill patients, such as corneal ulcerations and keratitis. These interventions include ointments, liquid eyewashes, gels, moist gauze, paraffin gauze, hydrogel, and polyethylene film.[6-8]

Dry eye has been defined as a multifactorial change in tears and the ocular surface that results in discomfort, visual disturbances, and tear film instability, with potential damage of the ocular surface.[9] In nursing, the diagnosis of "risk for dry eye" is applied to patients who are "vulnerable to eye discomfort or damage to the cornea and conjunctiva due to reduced quantity or quality of tears to moisten the eye, which may compromise health."[10(p387)]

Fifty-three percent of adult patients admitted to intensive care units have dry eye.

A recent study in Brazil showed that dry eye is a common problem in patients admitted to ICUs, with an incidence of 53%.[5] Intensive care unit patients have a higher probability of dry eye developing than do other hospitalized patients because of a variety of internal and external risk factors.[1-3,5] Dry eye can be chronic and progressive, imposing limitations on patients' ability to perform activities of daily living and negatively affecting their quality of life. Therefore, a preventive approach that includes appropriate eye care is crucial to minimize the risk of dry eye and avert possible complications.

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Because nurses are the frontline health care providers in hospitals, they have an important role to play in reducing the risk of dry eye in critically ill patients through effective nursing interventions. A study reported in 2011 compared the effectiveness of 2 nursing interventions—polyethylene film and carbomer drops—in the prevention of dry eye among 18 adult ICU patients.[2] The polyethylene film was found to prevent dry eye in all of the cases, while the carbomer drops were effective in only 17% of the patients ($P < .001$).[2] However, large studies of polyethylene film for the prevention of dry eye have not yet been conducted. Moreover, more research is needed on evidence-based nursing interventions that result in less discomfort for patients and can be more easily applied by nurses than polyethylene film. Therefore, this study was conducted to compare the effectiveness of 2 nursing interventions in preventing dry eye in adult patients admitted to an ICU: liquid artificial tears (Lacribell; Latinofarma) and artificial tears gel (Vidisic Gel; Bausch and Lomb).

Methods

This study was registered in ClinicalTrials.gov (Identifier: NCT02767258) and in the Brazilian Clinical Trials Registry (ReBec) (Identifier: RBR-5r8syp). Ethical approval was obtained from the institutional review board of the Universidade Federal de Minas Gerais before the study was begun. We followed the Consolidated Standards of Reporting Trials (CONSORT) guidelines for nonpharmacological interventions.[11] Written informed consent was obtained from each patient's family member or next of kin before recruitment.

Design

This was a double-blind (patients, outcome assessor) randomized controlled trial with 2 parallel groups. The data reported here were collected between January 14, 2016, and March 14, 2017, in a 10-bed ICU at a large tertiary care, nonprofit hospital in Brazil.

Patients recruited for the study met the following inclusion criteria: age of 18 years or older, no diagnosis of dry eye at ICU admission, receipt of mechanical ventilation, blink rate of less than 5

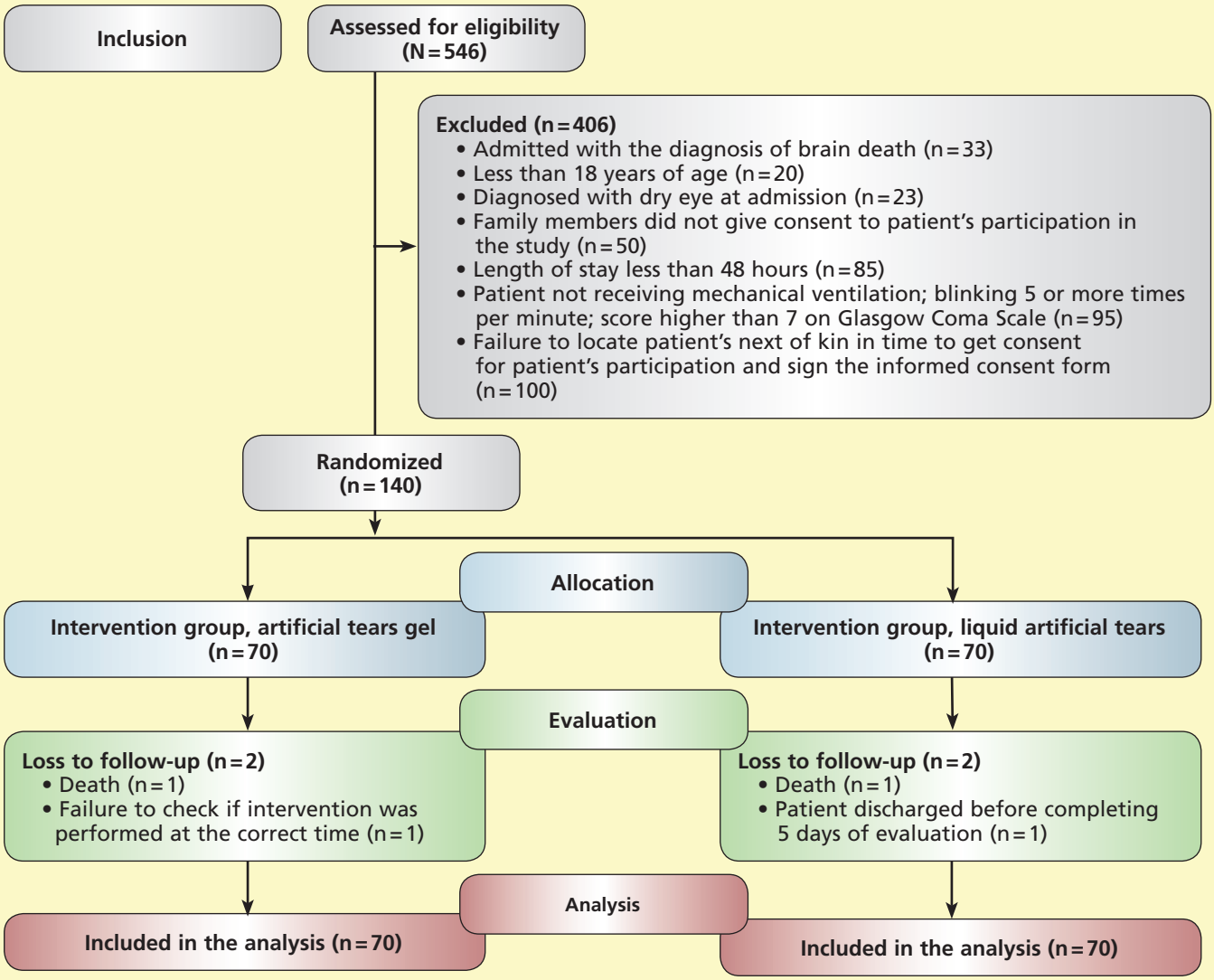

Figure Flowchart illustrating the 4 phases of the study, following the Consolidated Standards of Reporting Trials (CONSORT) recommendations for nonpharmacological interventions.

times per minute, and a Glasgow Coma Scale score of 7 or lower.[2] Patients were excluded if they had an ICU stay of less than 48 hours or were admitted to the unit with a diagnosis of brain death. Failure to document the delivery of nursing interventions (liquid artificial tears or artificial tears gel) at the correct time resulted in the participant's exclusion from the study and discontinuation of treatment.

Sample Size and Randomization

We performed a pilot study involving 30 patients between November and December 2015, with 10 patients allocated to each of 3 groups (liquid artificial tears, artificial tears gel, and 0.9% sodium chloride solution), to estimate sample size. In the pilot study, 40% of the patients treated with liquid artificial tears had dry eye develop, compared with 10% of those treated with artificial tears gel ($P = .01$). Power analysis using the proportion of unfavorable results in the pilot study (40%), a significance level of .05, power of 80%, and a relative risk (RR) of 0.5 in favor of artificial tears gel (or RR reduction of 20%) resulted in an estimated sample size of 134 patients: 67 patients for each of the 2 intervention groups. If any participants were lost during the study, more would be recruited until at least 67 patients were allocated to each group.

The initial study population consisted of 546 medical or surgical patients who had been admitted to the ICU of the target hospital. Of the 546 patients assessed for eligibility, 406 were excluded according to the inclusion and exclusion criteria. The resulting final sample consisted of 140 patients, 70 in each group (see Figure).

Despite allocation to a third group in the pilot study, we decided not to treat patients with 0.9%

sodium chloride solution in this study. The results of the pilot study showed that 60% of patients allocated to this intervention group had dry eye develop. The findings of previous studies support our decision not to use 0.9% sodium chloride solution as a study intervention.[1,12]

A statistician performed block randomization of patients using the computer software R-3.2.3. The randomized list was subdivided every 10 patients into 2 groups in a 1:1 ratio. The list was sent directly to the research coordinator of the study (T.C.M.C.) and to 2 undergraduate research assistants (D.V.A.S., C.A.O.R.) who were responsible for the allocation of the patients.

Two lubricant eye drops were used as interventions: liquid artificial tears (Lacribell) and artificial tears gel (Visidic Gel).

Interventions

Two types of lubricating eye drops—liquid artificial tears (Lacribell) and artificial tears gel (Vidisic Gel)—were used as the study interventions. After a patient was recruited for the study, the ICU nurses were notified through an information center which of the 2 interventions would be used for that patient. The intervention was prepared by a nurse and stored in a brown envelope. The ICU's nursing technicians delivered the intervention twice a day (at 8:00 AM and 8:00 PM) for 5 consecutive days. The nursing technicians followed a protocol for cleaning the patient's eyes with 0.9% sodium chloride before administering 2 drops of the predetermined intervention to each eye.

Before the study was begun, we trained the nursing team in the study protocols and procedures. The training consisted of an explanation of the study problem; an overview of the study methods; description of the inclusion and exclusion criteria; instruction on when to discontinue the interventions; explanation of informed consent, its importance, and how to obtain it; and the techniques for application of each intervention. To increase the chances of recruiting participants, nurses were given the responsibility for obtaining informed consent because of the study personnel's inability to be present on the unit for 24 consecutive hours.

The ocular assessment consisted of the Schirmer test and the fluorescein test.

Outcome

The study outcome was the development of dry eye. Potentially confounding variables included in the data analysis were age, sex, unit of origin, Nursing Activities Score, Acute Physiology and Chronic Health Evaluation II score; patient type (medical condition only or postsurgical), death, length of stay, referral unit, medical diagnosis at admission, sedation, Ramsay Sedation Scale score, Glasgow Coma Scale score, intubation, tracheostomy, mechanical ventilation, days of mechanical ventilation, mode of mechanical ventilation, fraction of inspired oxygen, positive end-expiratory pressure, other ventilatory assistance device, blink rate per minute, ocular surface exposure, edema, severity of corneal ulcer, medications, and positioning (degree of head elevation).

Data Collection

On 5 consecutive days, one of the researchers (D.D.A.) collected data and performed ocular assessment for each participant included in the sample. This 5-day period was established on the basis of the reported mean time of 3.5 days for development of dry eye in critically ill patients.[5] Before ocular assessment, the nursing technicians cleaned the patient's eyes with 0.9% sodium chloride solution to remove any traces of the intervention substances, ensuring that the researcher remained unaware of the treatment allocation of each patient.

The ocular assessment consisted of the Schirmer test and the fluorescein eye stain test. The Schirmer test was used to analyze tear volume. This test involved placing a strip of Whatman filter paper grade 41 or 50 measuring 5 mm wide and 35 mm long with the tip folded (about 5 mm) in the bottom of the lower conjunctival sac in the temporal region (outer corner of the lower eyelid). After 5 minutes, the strip was removed and the moistened part was measured and the result documented.[13] The fluorescein eye stain test was used to evaluate the cornea for possible abnormalities. A drop of fluorescein was placed in each of the patient's eyes; after 1 to 2 minutes, under low-light conditions, the cornea was examined using an ophthalmoscope with a cobalt blue light filter and a magnifying glass.[13]

Data Analysis

Two of the researchers (C.A.O.R., P.O.S.) independently entered the data into the Epi Info software program, version 3.5.1. The data entered were checked for consistency and then extracted and analyzed in the R-3.2.3 software. Frequency, central tendency (average), and standard deviation were measured. Categorical variables in the 2 intervention

Table 1
Risk scores, demographic variables, and baseline comorbidities by group

Variable	Liquid artificial tears	Artificial tears gel	*P*[a]
Continuous	**Mean (SD)**		
Age, y	52.8 (19.8) (n=70)	52.8 (19.9) (n=70)	.98
APACHE II score	22.2 (8.9) (n=70)	21.5 (7.6) (n=70)	.94
Score on Ramsay Sedation Scale	5.9 (0.3) (n=59)	5.9 (0.3) (n=63)	.24
Score on Glasgow Coma Scale	0.1 (0.3) (n=11)	0 (0) (n=7)	.49
Schirmer test result, mm	13.6 (3.9) (n=70)	12.9 (3.7) (n=70)	.19
Categorical	**No. (%) of 70 patients in each group**		
Female sex	30 (43)	24 (34)	.38
Heart disease	0 (0)	4 (6)	.12
Vascular disease	12 (17)	13 (19)	>.99
Neurologic disease	5 (7)	9 (13)	.40
Pneumonia	3 (4)	4 (6)	>.99
Trauma	22 (31)	16 (23)	.34
Gastric disease	3 (4)	9 (13)	.13
Metabolic disease	2 (3)	2 (3)	>.99
Neoplasm	1 (1)	5 (7)	.21
Patient sedated	60 (86)	63 (90)	.61

Abbreviation: APACHE II, Acute Physiology and Chronic Health Evaluation II.
[a] Mann-Whitney test was used to compare continuous variables; Fisher exact test was used to compare categorical variables. For both tests, $P \le .05$ was considered significant.

groups were compared using the Fisher exact test. Continuous variables were compared using the Mann-Whitney test. The assumption that the distribution of the continuous variables was normal was tested using the Shapiro-Wilk test. The incidence of dry eye and the effect of the nursing interventions were analyzed using the Fisher exact test. The results were presented with a 95% CI. Poisson regression was used to present the results, with the model adjusted for potential confounders (the risk factors of age, sex, and ocular surface exposure). Statistical significance was set at $P \le .05$.

Results

Participants

In total, 140 patients were included and randomized in the study. No statistically significant differences were found between the 2 groups at baseline ($P \le .05$; Tables 1 and 2), confirming that randomization was sufficient to match the groups. The fluorescein eye test indicated the presence of corneal ulceration in 1 participant treated with liquid artificial tears and 2 participants treated with artificial tears gel (Table 2; $P > .99$).

Development of Dry Eye

Table 3 shows the incidence of the primary outcome (dry eye) during the 5-day evaluation period. On the fifth day of hospitalization, dry eye was present in 21% of patients (incidence rate of 4.28 per 100 patient-days) in the liquid artificial tears group and 9% of patients (incidence rate of 1.72 per 100 patient-days) in the artificial tears gel group.

The RR estimated for the effect of the intervention was 0.400 (95% CI, 0.166-0.964; $P = .04$; Table 4), indicating that the chance of dry eye developing was twice as high in the liquid artificial tears group as in the artificial tears gel group. The effect of the artificial tears gel intervention remained statistically significant ($P = .04$) after model adjustment for the risk factors (age, sex, and ocular surface exposure) identified in the sample (Table 4).

> The nursing team should identify risk factors for dry eye as soon as a patient is admitted to the ICU and then implement the needed interventions, such as artificial tears gel.

Discussion

Most studies conducted to date on eye care practices for hospitalized patients focus on the prevention of corneal ulcers and associated risk factors. Little attention has been given to the problem of dry eye, especially among patients admitted to ICUs. Yet dry eye, if not adequately treated, can lead to corneal ulcers.[9,13]

Our results showed that artificial tears gel is more effective than liquid artificial tears (RR = 0.400; 95% CI, 0.166-0.964; $P = .04$) in preventing dry eye in adult ICU patients. We found no other published studies comparing these 2 interventions. Ezra et al[14] compared artificial tears gel and hydrogel in the prevention of exposure keratopathy among critically ill

Table 2
Characteristics of hospitalization, baseline lesions, and use of medications by group

Characteristic	No. (%) of 70 patients in each group		P[a]
	Liquid artificial tears	Artificial tears gel	
Unit of origin			.25
Emergency unit	10 (14)	19 (27)	
Emergency department	1 (1)	3 (4)	
Medical unit	17 (24)	14 (20)	
Other institution	3 (4)	1 (1)	
Surgical unit	39 (56)	33 (47)	
Patient type, surgical	42 (60)	33 (47)	.18
Ocular surface exposure	5 (7)	7 (10)	.76
Type of lesion (corneal ulcer)	1 (1)	2 (3)	>.99
Analgesic	42 (60)	45 (64)	.73
Antibiotic	48 (69)	51 (73)	.71
Anticoagulant	34 (49)	25 (36)	.17
Antiepileptic	14 (20)	21 (30)	.24
Antihelminthic	4 (6)	4 (6)	>.99
Antiemetic	18 (26)	17 (24)	>.99
Antihypertensive	14 (20)	10 (14)	.50
Antiprotozoal	1 (1)	3 (4)	.62
Bronchodilator	5 (7)	7 (10)	.76
Corticosteroid	10 (14)	7 (10)	.61
Diuretic	26 (37)	29 (41)	.73
Vasodilator	50 (71)	53 (76)	.70
Hypnotics	58 (83)	63 (90)	.32
Hypolipid	8 (11)	3 (4)	.21
Hormone	1 (1)	1 (1)	>.99
Gastric bypass inhibitor	57 (81)	59 (84)	.82
Insulin	30 (43)	26 (37)	.60

[a] Fisher exact test was used to compare variables. $P \leq .05$ was considered significant.

Table 3
Incidence of dry eye during 5-day evaluation period by group

Hospital day	No. (%) of cases of dry eye		P[a]
	Liquid artificial tears	Artificial tears gel	
2	1/70 (1)	2/70 (3)	>.99
3	2/69 (3)	5/68 (7)	.27
4	4/68 (6)	5/68 (7)	>.99
5	15/70 (21)	6/70 (9)	.04

[a] Fisher exact test was used to compare groups. $P \leq .05$ was considered significant.

patients. They found that exposure keratopathy developed in 15% of patients in the artificial tears gel group, compared with 90% of patients treated with hydrogel ($P = .04$). In Brazil, hydrogel is approved as a dressing for the treatment of lesions or cutaneous wounds, but it has not been approved for use in ophthalmology.

Zhou et al[15] conducted a meta-analysis on the prevention of corneal alterations among critically ill patients; they found no statistically significant differences in effectiveness between moisture chambers and lubricating gel (RR = 0.81; 95% CI, 0.51-1.29; $P = .38$). The authors also examined studies that tested polyethylene film versus lubricating eye drops, but those studies were of lower quality.[15] In other studies,[16-18] polyethylene film was more effective in preventing corneal ulcers than liquid artificial tears and ocular gel, although the differences were not statistically significant.

The incidence of dry eye during the 5-day evaluation period in our study was from 1% to 21% in the liquid artificial tears group and from 3% to 9% in the artificial tears gel group. The development of dry eye was assessed for a relatively short time. However, this assessment period is supported by a study conducted in Brazil,[5] where researchers found a mean time of 3.5 days for the development of dry eye among the same target population. Although the patients were exposed to internal and external risk factors related to a decrease in production of tears or an increase in their evaporation, the present study showed that after the fourth day of hospitalization, the artificial tears gel intervention was more likely than the liquid artificial tears intervention to prevent dry eye.

The use of block randomization for allocation of participants to either the artificial tears gel group or the liquid artificial tears group ensured an even distribution of participants between the groups within the established data collection time frame. This type of randomization is preferred over individual patient randomization to avoid the risk of having a smaller number of participants in one of the study groups in the event of premature completion of data collection due to unforeseen reasons.

Because nursing professionals provide uninterrupted care to patients admitted to ICUs, they are well positioned to help reduce the risk of dry eye in these patients through appropriate eye care practices. Dry eye is a precursor to more serious eye changes that can result in severe harm to patients. Therefore, the nursing team must be knowledgeable about this condition and follow eye care practices designed to prevent or minimize damage to the ocular surface and resulting visual impairment. Once a patient is admitted to the ICU, the nursing team should assess the patient's ocular surface and identify possible risk

Table 4
Regression model adjusted for age, sex, and ocular surface exposure

Intervention	Incidence, %	Relative risk	95% CI	*P*
Unadjusted				.04
Liquid artificial tears	21.4	1.000		
Artificial tears gel	8.6	0.400	0.166-0.964	
Adjusted for age and sex				.07
Liquid artificial tears	21.4	1.000		
Artificial tears gel	8.6	0.418	0.163-1.070	
Adjusted for age, sex, and ocular surface exposure				.04
Liquid artificial tears	21.4	1.000		
Artificial tears gel	8.6	0.367	0.140-0.963	

factors for dry eye, implementing necessary interventions such as artificial tears gel as early as possible.

Liquid artificial tears or artificial tears gel cannot directly prevent the evaporation of tear film in patients with lagophthalmos. However, in the present study we observed that the artificial tears gel could keep the upper and lower eyelids adhered, in addition to forming a thin film in the palpebral space, increasing its retention time on the ocular surface. This mechanism might facilitate lid closure and thus help prevent complications. Nonetheless, polyethylene film is the preferred intervention to prevent corneal ulceration in patients with lagophthalmos. In covering the eye area, it creates a moisture chamber that prevents evaporation of tears.[2,14,16,19] If corneal ulceration is identified during ocular assessment, an ophthalmologist should be consulted.

This study has a few limitations, which may have affected the findings. The sample consisted only of patients admitted to an ICU, and the interventions were delivered twice a day (to suit the study site routine), whereas it is generally recommended to administer treatment whenever necessary. We did not test polyethylene film or other interventions that have been described in clinical guidelines developed to prevent eye diseases. Moreover, although it is unlikely, it is possible that the protocol of cleaning the patient's eyes with 0.9% sodium chloride solution did not completely remove all traces of the intervention substances applied.

In this study, patients with a Glasgow Coma Scale score of 7 or lower were under sedation for 5 days, which may not accurately represent sedation practices outside of Brazil or other developing countries. Future studies on prevention of dry eye should recruit a sample that is representative of the range of sedation practices. The protocols used for application of the interventions and ocular assessment for the development of dry eye were designed to enhance the rigor of the study and may not be applicable in clinical practice. However, the artificial tears gel intervention can be delivered by nurses on schedules different from the one in this study, including its use as a preventive measure at intervals of up to 12 hours.

Conclusion

This study showed that artificial tears gel is more effective than liquid artificial tears in the prevention of dry eye in critically ill patients. It is paramount that nurses identify possible risk factors for dry eye when performing a physical examination or reviewing a patient's medical record. In addition, nurses should implement early interventions that can prevent or minimize dry eye as well as complications of this condition that may negatively affect the patient's life. Teaching health professionals how to perform an ocular assessment is an essential measure in the prevention of dry eye in patients admitted to the ICU.

> Artificial tears gel is more effective than liquid artificial tears for preventing dry eye.

ACKNOWLEDGMENTS
This work was performed at the Universidade Estadual de Montes Claros, Montes Claros, Brazil.

FINANCIAL DISCLOSURES
This research was supported by the National Council for Scientific and Technological Development, Brazil (grant number 441971/2014-8). The contents of this article are the sole responsibility of the authors and do not necessarily represent the official views of the Council.

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