Ocular surface injuries at an intensive care unit: a self-paired clinical trial

Lesão de superfície ocular em unidade de terapia intensiva: ensaio clinico auto-pareado

Lesiones de la superficie ocular en unidad de cuidados intensivos: ensayo clínico autocontrolado

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Abstract

Objective: To analyze the occurrence of ocular surface injuries at an intensive care unit in patients who were sedated or unable to blink.

Methods: Self-paired clinical trial carried out at the intensive care unit of a hospital in the northwest region of the state of Paraná, Brazil, between July 2016 and January 2017. Twenty-seven patients who did not have previous ocular injuries, submitted to bilateral eye cleaning with 0.9% salt solution and occlusion of the right eye with transparent polyurethane film, participated in the study. The association of occurrence of ocular injuries with demographic, clinical, care, and environmental variables was investigated by applying Fisher's exact test, and a comparison of the injury-free time (in days) with and without using the eyeshield was performed by using Wilcoxon test.

Results: Ocular injuries were associated with fasting (p=0.0039), lower risk of death (p=0.0056), and longer hospital stay (p=0.0088). The occlusion of the right eye with transparent polyurethane film was considered a protection factor (p=0.0019) and was associated with a longer injury-free time in the right eye (4.1 days) in comparison with the result obtained for the left eye (2.4 days) (p=0.00222).

Conclusion: In the analyzed intensive care unit, ocular occlusion proved effective in protecting the eye, especially in patients who were fasting, had a higher probability of surviving, and went through a longer hospital stay.

Resumo

Objetivo: Analisar a ocorrência de lesão de superfície ocular em Unidade de Terapia Intensiva, entre pacientes sedados e/ou incapazes de piscar.

Métodos: Ensaio Clínico Auto-pareado, realizado na Unidade de Terapia Intensiva de um Hospital da região noroeste do Paraná, Brasil, entre julho/2016 e janeiro/2017. Participaram 27 pacientes sem lesões oculares prévias, submetidos à limpeza ocular bilateral, com solução fisiológica 0,9% e oclusão do olho direito com filme transparente de poliuretano. Testou-se associação da ocorrência de lesão ocular com variáveis demográficas, clínicas, assistenciais e ambientais, por meio do Teste Exato de Fischer e; comparação do tempo livre de lesão (dias), com e sem uso da cobertura para proteção ocular, por meio do Teste de *Wilcoxon*.

Resultados: A lesão ocular associou-se com jejum (p=0,0039), menor risco de morte (p=0,0056) e; maior tempo de internação (p=0,0088). A oclusão com filme transparente de poliuretano no olho direito foi considerada fator de proteção (p=0,0019), com maior tempo livre de lesão no olho direito (4,1 dias) se comparado ao olho esquerdo (2,4 dias) (p=0,00222).

Conclusão: Na UTI investigada, a oclusão ocular apresentou-se efetiva à proteção dos olhos, especialmente entre pacientes em jejum, com maior chance de sobrevivência e tempo de internação prolongada.

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Conflicts of interest: nothing to declare.

Resumen

Objetivo: Analizar los episodios de lesión de la superficie ocular en Unidad de Cuidados Intensivos, entre pacientes sedados o incapaces de pestañear.

Métodos: Ensayo clínico autocontrolado, realizado en la Unidad de Cuidados Intensivos de un hospital de la región noroeste del estado de Paraná, Brasil, entre julio de 2016 y enero de 2017. Participaron 27 pacientes sin lesiones oculares previas, sometidos a una limpieza ocular bilateral, con solución fisiológica 0,9% y oclusión del ojo derecho con apósito transparente de poliuretano. Se examinó la relación de los episodios de lesión ocular con variables demográficas, clínicas, asistenciales y ambientales, por medio de la Prueba exacta de Fisher, y la comparación del tiempo sin lesión (días), con y sin uso de la cobertura para protección ocular, por medio de la Prueba de Wilcoxon.

Resultados: La lesión ocular se asoció con ayuno (p=0,0039), menor riesgo de muerte (p=0,0056) y mayor tiempo de internación (p=0,0088). La oclusión con apósito transparente de poliuretano en el ojo derecho fue considerada factor de protección (p=0,0019), con un mayor tiempo sin lesión en el ojo derecho (4,1 días) comparado con el ojo izquierdo (2,4 días) (p=0,00222).

Conclusión: En la UCI investigada, la oclusión ocular se mostró efectiva para la protección de los ojos, especialmente en pacientes en ayuno, con mayor chance de supervivencia y tiempo de internación prolongado.

Introduction

Technological progress and the ease to disseminate knowledge have provided debates and improvements in health services by applying universalization and standardization of care conducts, which culminate in higher patient safety and higher assistance quality.[1] Most of the efforts by hospital institutions, driven by specific regulations, have been oriented toward implementing basic protocols aligned with international patient safety goals.[2]

However, it is recognized that patient safety is not developed exclusively by improving the areas in health care that have more problems. Especially in complex environments, where errors can occur, an important challenge in the patient safety field is preventing harm resulting from the provided care, prioritizing all and each one of the patients.[3]

Intensive care units (ICUs) stand out among the environments with the highest care complexity. They are a setting where the standardization of conducts has been based on therapeutic guidelines that warn about the clinical handling of conditions and worsenings that have a high impact on patients' mortality.[4,5] One example is the establishment of measures to prevent pneumonia associated with mechanical ventilation, hydroelectrolytic disorders, and the imminence of shock, among other emerging pathologies.[6]

Despite containing cross-sectoral and multiprofessional actions, based on the best available evidence, clinical practice guidelines are useful tools to provide the best care to patients because they help, essentially, the medical decision-making.[7] Consequently, activities related strictly to the nursing area, such as care oriented toward eye protection, stay in the background and usually are not included in ICU protocols,[6] because of lack of knowledge of nurses and the multidisciplinary team of either anatomy and physiology or the proper way to carry out ocular evaluation and the care to be implemented.[8,9]

Intensive care unit patients usually are exposed to risk of corneal injuries as a consequence of sedation, coma, mechanical ventilation, and use of medications.[9-13] In these conditions, the incomplete eyelid closure causes drying of the surface mucosa and of all the epithelial tissues in the cornea, resulting in ulceration or exposure keratopathy,[8,10,14,15] whose incidence can reach up to 83.3%.[8]

In the global scenario, different interventions have been implemented to prevent this harm with the objective to decrease the incidence and prevalence of alterations in the ocular surface in critical patients. To achieve that, varied types of covers, eye drops, and ointments have been used.[16-18]

Among the resources used to prevent ocular surface injuries at ICUs, the application of polyethylene covers has shown a discrete superiority when compared to other products for eye protection.[18,19] However, films made of this polymer have not been approved as a health product in Brazil yet. As a similar alternative, transparent polyurethane films with ethylene polymers are available in the country for topical application in human beings.[20]

Regarding the Brazilian reality, ocular care procedures during nursing assistance are limited because, according to the literature, there is a lack of consensus and standardization.[21] Consequently, nursing actions are still oriented by individual experiences and adapted to local contexts.

It is important to deepen the knowledge of risk factors for the occurrence of ocular injuries, in addition to developing studies on the technologies for their prevention, to guarantee the safety of the nursing care provided at ICUs. The objective of the present study was to analyze the occurrence of ocular surface injuries at ICUs in patients who were sedated and/or unable to blink.

Methods

Self-paired clinical trial referring to the prevention of ocular surface injuries by occlusion using transparent polyurethane film, carried out between July 2016 and January 2017, at the ICU of a hospital located in the northwest region of the state of Paraná, Brazil. This ICU had seven inpatient beds and was certified for referred services to patients of the Brazilian Unified Health System. The hospital also met private and health insurance plan operators' demands.

A non-probability sampling was carried out, with evaluation of the eligibility of all the patients admitted to the ICU, including those who met the following criteria: being at least 14 years old and showing a score in the Richmond Agitation-Sedation Scale (RASS) lower than or equal to -4 points or absence of the blink reflex from the moment of admission to the ICU. Exclusion criteria were: existence of anatomical differences between the eyes previous to the admission to the ICU; ocular extirpation; presence of alterations that indicate ocular surface injury (eye stroke, ulceration, hyperemia, edema, secretion, papules, and/or corneal opacification) confirmed through clinical examination and the test with sodium fluorescein; analysis of ocular secretion with culture; impossibility of visualizing and evaluating the ocular surface (marked eyelid/periorbital edema); and formal non-acceptance of the relative or legal representative for participating in the study.

Among the 143 eligible patients, 116 were excluded (92 for not meeting at least one inclusion criterion, five for not signing the free and informed consent form, 18 for showing ocular injury during the initial evaluation, and one whose ocular secretion culture test was positive). Consequently, the sample had 27 participants, who were submitted to the daily cleaning of both eyes with 0.9% saline solution and sterile gauze, as well as occlusion of the right eye only with a piece of transparent polyurethane film (Tegaderm™, non-sterile transparent film roll, 15 cm x 10 m, 3M, Brazil).

Values and data regarding the demographic and clinical characterization at the moment of inclusion of the participants and the daily clinical evolution, ocular evaluation, and information about the environment and the nursing care were complied, treated electronically, and submitted to descriptive and inferential statistical analysis.

The participants who developed an ocular surface injury in one or both eyes were allocated into one group (n=13) and those who did not develop ocular surface injury (n=14) made up another group.

To compare the groups with and without ocular surface injury, Fisher's exact test was performed using the Epiinfo[â] software, with a level of confidence established at 5%, considering the following variables: gender; age (cutoff equal to 50 years); duration of the stay at the ICU (cutoff equal to seven days); average score obtained in the Acute Physiology and Chronic Health Evaluation II (APACHE II); average score obtained in the RASS; average score obtained in the Sequential Organ Failure Assessment (SOFA); positive-end expiratory pressure (PEEP); cardiac, neurological, pulmonary, renal, and endocrine involvement; sepsis; ventilation mode; use of analgesia and sedation, and vasoactive drugs; fasting; condition at discharge; injury in the right eye; and relative humidity and room temperature.

Wilcoxon test (n=27x2) was run using the SPSS[â] Statistics 21[â] software, with a level of significance established at 5%, to compare the injury-free time (in days) in the right and left eyes.

It is necessary to stress that all the ethical and legal requirements[20,22] were met and, over the execution of the study, the detected ocular alterations were immediately reported to the intensivist in charge so the diagnosis could be confirmed and the therapeutic process initiated. The present

study was registered as per Favorable Report no. 1,601,549/2016 of the ethics committee of the Ingá College, in Maringá, state of Paraná, Brazil, and as per Brazilian Clinical Trials Registry no. UTN U1111-1191-2395.

Results

Among the 27 participants, 18 (66.7%) were women and 9 (33.3%) were men. The ages of the people in the sample ranged from 22 to 101 years, with an average of 72.3 years (standard deviation of 15.6 years). Thirteen (48.1%) were allocated in the ocular surface injury group and 14 (51.9%) in the ocular surface injury-free group.

It is important to emphasize that all the patients who had ocular surface injury showed some sign of impairment, even if initial, of the left eye, and only six patients (46.2%) of the right eye, which was protected with a patch of transparent polyurethane film.

The demographic (gender, age, skin color) and ventilatory (ventilation mode, PEEP) variables and those related to the involvement of organic systems (cardiac, neurological, pulmonary, renal, endocrine) and to the use of drugs (analgesia and sedation, vasoactive drug) did not show a significant association with the development of ocular surface injury. The other tested variables are shown in Table 1.

Data on the comparison of the injury-free time (in days) between the right eye (occluded with transparent polyurethane film) and left eye (without protection occlusion) are shown in Table 2.

Table 1. Association of variables with the development of ocular surface injury in ICU inpatients.

Variables	With injury n(%)	Without injury n(%)	*p-value*
Gender			
Female	9(69.2)	9(64.3)	
Male	4(30.8)	5(35.7)	0.5545
Age (years)			
< 50	2(15.4)	2(14.2)	
≥ 50	11(84.6)	12(85.8)	0.6733
Sepsis			
Yes	8(61.5)	9(64.3)	
No	5(38.5)	5(35.7)	0.5982
Fasting			
Yes	13(100)	7(50)	
No	-	7(50)	0.0039
RASS (score)			
> -2.7	8(61.5)	7(50)	
≤-2,7	5(38.5)	7(50)	0.4788
APACHE II (score)			
< 35.8	10(76.9)	6(42.9)	
≥ 35.8	3(23.1)	8(57.1)	0.0789
Risk of death* (%)			
< 70.4	10(76.9)	3(21.4)	
≥70,4	3(23.1)	11(78.6)	0.0056
SOFA (score)			
< 10.0	8(61.5)	4(28.6)	
≥10,0	5(38.5)	10(71.4)	0.0906
Duration of the stay at the ICU (days)			
< 7	1(7.7)	8(57.1)	
≥ 7	12(92.3)	6(42.9)	0.0088
Room temperature at the moment (ºC)			
< 22.9	5(38.5)	9(64.3)	
≥22,9	8(61.5)	5(35.7)	0.1697
Relative humidity at the moment (%)			
< 55.8	9(69.2)	9(64.3)	
≥55,8	4(30.8)	5(35.7)	0.5545
Condition at discharge			
Survivor	7(53.8)	3(21.4)	
Non-survivor	6(46.2)	11(78.6)	0.0891
Injury in the right eye**			
Yes	7(53.8)	-	
No	6(46.2)	14(100)	0.0019

*Risk of death estimated by the APACHE II; **Eye occluded with transparent polyurethane film to prevent ocular surface injury.

Table 2. Comparison of the injury-free time (in days) between the right and left eyes in ICU inpatients.

Injury-free days	n	Average	Standard deviation	Minimum	Maximum	*p-value*
Right eye*	27	4.1	3.2	1.0	12.0	0.00222
Left eye	27	2.4	1.0	1.0	6.0	

*Eye occluded with transparent polyurethane film to prevent ocular surface injury.

Discussion

The present study was limited to a local reality, with evaluation of a single protective intervention, with rigor in the control of patient-related variables. The evaluation was determined by the methodology of allocation for intervention of the primary study.

It is expected that studies like the present one, which deepens the knowledge about risk factors and prevention strategies of ocular surface injuries in ICU inpatients, may contribute to the development and implementation of care protocols oriented toward precautions with the eyes, to guarantee patient safety and quality in the provided care. Additionally, the results described in the paper may offer resources for managers and professionals to

make decisions about the incorporation of transparent polyurethane films to protect the eyes of patients who are sedated or unable to blink and mechanically ventilated. Promoting discussions on the subject in the fields of education and health practice should also be considered.

Sedation, coma, mechanical ventilation, and medication are known risk factors for the development of ocular surface injuries in ICU inpatients.[10-14,22] In that regard, both the ventilation modality (synchronized or controlled) and the RASS score (-4 or -5 points) correspond to different levels of response of the patients and may reflect the capacity to blink. In these cases, the level of impairment shown by the patients were not associated with the development of ocular surface injuries (Table 1).

Although fasting showed an association with the development of ocular surface injuries (p=0.0039) because the provision of nutrients is essential to keep tissue integrity and viability,[23,24] the isolated influence of none of the organic systems (cardiac, neurological, pulmonary, renal, and endocrine) on the perfusion and/or maintenance of ocular integrity was detected. The functioning of the human body is complex and the organic systems interact with each other. Additionally, although lack of oxygen is usually related to kidney, liver, pulmonary, and cardiocirculatory failure, it is also necessary to consider the relationship involving two other organic systems which are dynamic and interdependent, the endothelial and the blood ones.[25]

It is noteworthy that both the risk of death estimated by applying the APACHE II (p=0.0056) and the ICU stay length (p=0.0088) were associated with the development of ocular surface injuries (Table 1), corroborating the findings described in similar studies.[8,10,26] Patients with a lower risk of death (n=10, 76.9%) and a longer ICU stay (n=12, 92.3%) showed a higher proportion of ocular surface injuries (Table 1); survival and an extended stay in the ICU promoted an increase in the time of exposure to intrinsic and extrinsic factors, contributing to the development of this type of injury.

Examination of Table 1 indicates that the right eye was associated with the non-occurrence of ocular surface injuries (p=0.0019). It is important to emphasize that the right eye of all the patients in the sample was protected by applying occlusion with transparent polyurethane film, which contributed to the injury-free time's being nearly twice compared with the result obtained for the left eye, which was not protected (p=0.00222) (Table 2).

Taking into account that the design of the present primary study (self-paired clinical trial) ensured the control of patient-related variables, with reduction of intrinsic bias, the identified ocular protection was attributed to the use of occlusion with transparent polyurethane film. The authors considered that the applied cover helps to mechanically keep the humidity of the eyes and prevent drying by external/environmental factors, similar to what is observed for transparent polyethylene covers, which has been internationally pointed out as an effective strategy to protect against ocular surface injuries at ICUs.[8, 26,27]

It is known that environmental factors, such as temperature and relative humidity, may influence the characteristics of the tear film and tear evaporation rate, because prolonged exposure to adverse temperatures might result in dry eye symptoms and, eventually, alterations in the ocular surface.[28,29]

In the present study, the average room temperature at collection time (22.9 °C) and the average relative humidity of the air at collection time (55.8%) were not associated with the development of ocular surface injuries. That occurred because the environmental conditions of the study location were kept in accordance with the standards for comfort and hygrothermal control conditions at ICUs, with a refrigeration system to guarantee the maintenance of temperature and relative humidity between 21 °C and 24 °C and 40% and 60%, respectively.[30] This reinforces the assumption that, regardless of temperature and relative humidity, it was the exposure to the environment (left eye) or not (right eye) that influenced the development of ocular surface injuries.

Therefore, it is considered that implementing eye protection with the use of transparent polyurethane film is a nursing care strategy suitable for ICUs, which contributes to reducing this type of worsening and associated complications. To achieve

that, it is fundamental to invest in training of the teams and obtain resources that ensure eye protection by occlusion with transparent polyurethane film as part of ICU care protocols.

Conclusion

The stratification of recognized risk factors for the development of ocular surface injuries in patients who are sedated or have an impaired blink function and are mechanically ventilated at ICUs is not significant when these factors are analyzed in isolation. Despite this fact, the results of the present result showed that the use of transparent polyurethane film proved to be an effective strategy to protect the eyes of ICU patients, especially those kept under fasting, with a higher probability of surviving, and longer ICU stay.

Collaborations

Hayakawa LY, Matsuda LM, Inoue KC, Oyamaguchi EK, and Ribeiro E contributed to the study conception, data analysis and interpretation, writing of the manuscript, critical review of its intellectual content, and final approval of the version to be published.

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