

Prevention of lesions on the eye surface by eye occlusion: an auto-paired clinical trial

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Abstract — Eye care is a basic nursing procedure and it is essential to prevent eye complications in Intensive Care Unit patients. In order to evaluate the effectiveness of eye occlusion by transparent polyurethane film for the prevention of lesions on the eye surface in Intensive Care Unit patients, an auto-paired clinical trial have been undertaken between July 2016 and January 2017 in the adult Intensive Care Unit of the Hospital Memorial de Maringá, Brazil. Sample comprised 27 patients who attended to the study's inclusion criteria, involving the left eye in the control group (daily cleaning of the eye region with saline solution 0.9%) and the right eye in the intervention group (daily cleaning of the eye region with saline solution 0.9%, plus application of a transparent polyurethane film). The transparent polyurethane film prevented the development of lesions on the eye surface, regardless of demographic, environmental, physiological and clinical variables and was an effectiveness strategy for eye protection in seriously ill patients, and warranted a longer lesion-free time for occluded eyes.

Index Terms — Dry Eye Syndrome, Eye Injuries, Intensive Care Units, Nursing Care, Polyurethanes, Prevention, Therapeutic use.

1 INTRODUCTION

The eye surface comprises the cornea, conjunctiva and limbo, with the production of elements of the lacrimal films throughout its epithelial extension. Conditions that alter production, composition or distribution of the lacrimal film cause damage symptoms in the eye surface's structure [1].

Critically ill patients may be at risks for eye surface lesion due to low consciousness level, insufficient closing of the eyelids, reduction of intermittent reflexes and exposure increase to pathogenic microorganisms [2], [3], [4]. The main eye complications in Intensive Care Unit (ICU) patients are conjunctivitis, chemosis, lagophthalmos, corneal abrasion, exposure keratopathy, dry eye, microbial keratitis, and endophthalmitis [5].

Eye care is not usually focused upon in ICUs due to exclusive focus on the controlling of the organic dysfunctions of the critically ill patient [2],[6]. However, emphasis should be given on the importance of the implementation of care regime for the prevention of eye surface lesions as part of ICU routine [3], [5], [7]. Eye care and ocular evaluation are relevant in nursing for ICU patients since prevention measures, early diagnosis and effective treatment may contribute towards decrease in eye complications and loss of sight [3], [2], [5], [6]. For instance, the occurrence of cornea exposure decreased when protocols and educational programs on eye care were introduced[7], [8].

Dry eye, with worldwide prevalence between 6 and 34% [9], is a multi-factor disease involving lacrimation and ocular surface, causing unstableness of the lacrimal film with possible damage to the eye surface. Acknowledgement of eye complications and eye care in ICUs in different geographic regions will surely contribute towards better practice within several contexts. In fact, the latter may be significantly different according to countries [5]. There has been an increase in research work on the theme in Brazil, although most investigation merely identifies occurrence, risk factors and review of the literature [4], [10], [11], [12], [13], [14].

Several care methods have shown scientific evidence for the prevention of dry eyes related to eye occlusion and lubrica-

tion. However, further studies are required to robustly foreground such evidence [15]. The above is highly relevant since no prevention strategies for eye protection are established in many ICUs. Frequently, strategies are merely restricted to eye hygiene [16], [5].

1.1 Relevance of the study

Provide scientific evidence to foreground the introduction of methods for the prevention of lesions of the eye surface so that care in ICUs may be safer and of a better quality. This is especially true for developing countries, renowned for their lack of standardization in eye care and for scarcity in aid resources.

We hypothesized that eye hygiene with normal saline solution followed by eye occlusion with transparent polyurethane film is more effective than eye hygiene with saline solution only for the prevention of lesions on the eye surface in ICU patients, under deep sedation or in comatose conditions, and breathing by artificial ventilation.

1.2 Study aim

To find out the effectiveness of eye occlusion with transparent polyurethane film for the prevention of lesions on the eye surface in ICU patients.

1.3 Research Question

What is the effectiveness of transparent polyurethane film in the prevention of lesions on the eye surface?

2 DESIGN AND METHODS

2.1 Study design

Auto-paired clinical trial (Fig. 1).

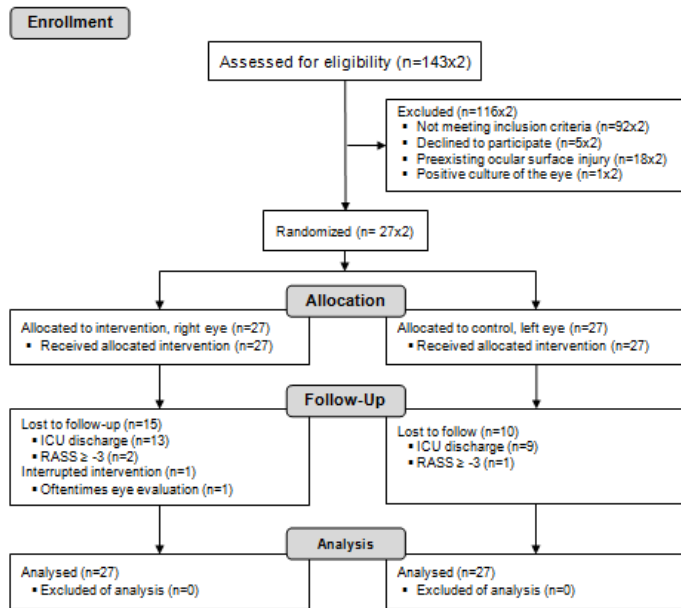


Fig.1 Study design. Maringá PR Brazil, 2018.

2.2 Setting and sample

Current study was conducted at the adult ICU of the Hospital Memorial de Maringá, Maringá PR Brazil, between July 2016 and January 2017. All patients were assessed with regard to eligibility at the moment of admittance to ICU. Only patients who attended to inclusion criteria were admitted. Criteria comprised people age 14 years old or above; with Richmond Agitation-Sedation Scale less than or equal to -4 points (minus 4) or without any blinking reaction; formal acceptance by the patient's family or the patient's legal representative to participate in the research. In the case of initial refusal to participate or prohibition to opening of the eye, there was always the possibility of admittance or return to participate in the research during the days after initial evaluation in so far as inclusion criteria were complied with.

Exclusion criteria included asymmetry or eye extirpation; changes that reveal lesion of the eye surface confirmed by clinical exams or by fluorescein sodium tests; analysis of eye secretion with positive culture; impossibility of visualization and evaluation of the eye surface.

2.3 Data collection

Patients fulfilling criteria were either assigned to the intervention (right eye) or control group (left eye). The ocular region of patients in the two groups was cleaned daily with normal saline solution and sterile gauze, and eyelids were closed after hygiene. Further, a 7.5 cm x 7.5 cm transparent polyurethane film (Tegaderm™ non sterile transparent film roll, 15 cm x 10 m, 3M, Brazil), with round edges, was fixed to the peri-orbital region of the intervention group, with closed eyelids, to guarantee total occlusion of the ocular region's concave section.

Data on demographic and clinical trails were collected, coupled to information on daily clinical evolution, therapeutic support, environmental variables and evaluation of the eye. After eye evaluation for the visual inspection of local changes,

the fluorescein test (Fluorescein Sodium ophthalmic solution 1%, 3mL, Allergan) was performed by applying one drop in each eye of the patient, plus normal saline solution and cornea reading with blue light to evaluate the integrity of the cornea-conjunctiva epithelium. A sample from the internal section of the bilateral lower eyelid was collected by swab for collection and transport with Stuart medium (sterile) acquired from the laboratory of clinical analyses of the hospital. Analyses featured processing and report on culture and anti-biogram of the material, according to sanitary requirements [17], [18]. Follow-up ended by RASS equal to or greater than -3 points, discharge of the patient from ICU, quittance from research, lesion of the eye surface.

2.4 Data analysis

Descriptive statistics of variables characterizing the agents were done by Statistica Single User 13.2. Wilcoxon test was employed to compare lesion-free days between IG and CG, and McNemar test compared qualitative variables between IG and CG. Survival curve was obtained by Kaplan-Meier non-parametric estimator, followed by log-rank test for the comparison of survival curves. Since multivariate modeling was impossible due to the variable dichotomy lesion in the right eye and in the left eye, a univariate analysis was performed by Mantel-Haenszel's χ^2 test, at 5% significance.

2.5 Pilot Study

The data-collecting instrument was analyzed by four ICU nurses, with three or more years' experience in ICUs, and by three researchers, till an agreement was reached on the presentation and text of the questions/variables. The instrument was tested by a pilot-test, during 18 days, with ten patients at the same ICU, aided by an ophthalmologist who guided the researchers with regard to eye evaluation standard used in current study. Time was determined till one of the patients complied with inclusion and non-inclusion criteria and could be followed to the end.

2.6 Ethical approval of research

Ethical and legal requirements were complied with and the project was submitted to the Brazilian Register of Clinical Assays (ReBEC) number UTN U1111-1191-2395. It was approved by the Committee for Ethics of the Faculdade Ingá, Maringá PR Brazil, number 54794316.5.0000.5220 (CAAE).

3 FINDINGS

Table 1 shows the characteristics of the 27 participants in current research.

Table 1. Characterization of patients. Maringá PR Brazil, 2018.

Characteristics	n (%)
Sex	
Male	9 (33.3)
Female	18 (66.7)
Age * (years)	68.6 (19.8)
ICU Length of stay * (days)	1.7 (2.1)
Period in ICU till allocation * (days)	1.5 (2.0)
Period in ICU * (days)	12.3 (13.4)
RASS * (scores)	-2.7 (1.7)
APACHE II * (scores)	35.7 (4.7)
SOFA * (scores)	10.0 (37.1)
Outcome conditions from ICU	
Survival	10 (37.1)
Non survival	17 (62.9)

* Means (standard deviation).

Table 2 shows that Control Group (CG) had a higher rate of fluorescein test with positive result ($p=0.0218$), while Intervention Group (IG) had more follow-up loss by spontaneous ocular opening ($p=0.0094$) and continuous neurological evaluation ($p=0.0026$).

Table 2. Comparison of evaluated qualitative variables, according to allocation of groups. Maringá PR Brazil, 2018.

Variables	IG		CG		p
	n	%	n	%	
Lesion					
Lesion	7	25.9	13	48.1	0.1904
Without lesion	20	74.1	14	51.9	
Fluorescein test					
Positive	4	14.8	12	44.4	0.0218*
Negative	23	85.2	15	55.6	
Loss					
No loss	11	40.7	17	63.0	Reference
Death	13	48.1	9	33.3	0.8231
Spontaneous ocular opening	2	7.4	1	3.7	0.0094*
Continuous neurological evaluation	1	3.7	-	-	0.0026*

* McNemar test significant at 5%.

Thirteen (48.1%) participants had eye surface lesion, or rather, the left eye was compromised by lesion in six patients (control group) and both eyes were compromised in seven (25.9%) patients, with greater occurrence time on the eye closed with transparent polyurethane film (Fig. 2).

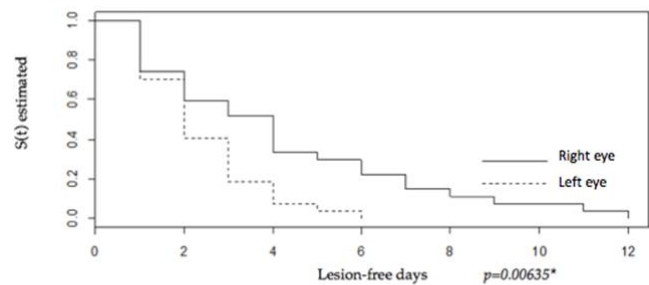


Fig 2. Kaplan-Meier's curve comparing lesion-free days, for right and left eyes. Maringá PR Brazil, 2018.

* log-rank test.

It should be underscored that mean lesion-free period lasted 4.1 ± 3.2 days in IG and 2.4 ± 1.3 days in CG. However, no variable (sex, age, days of hospitalization, period in ICU) had any significant relationship with the period, till the occurrence of eye lesion.

4 DISCUSSION

Participants were elderly people, featuring negative RASS (an inclusion criterion), with admittance to ICU due to their serious condition (mean APACHE II higher than 20 scores), with several organic dysfunctions (mean SOFA equal to 10 scores) throughout hospitalization (Table 1). The above factor contributed towards clinical emergence, worsening and development of eye lesion [9], [19].

Although the need for organic dysfunction management may have justified, until some years thence, negligence to eye care in ICU [2], [6], it should be emphasized that, even in the wake of daily care, ocular lesions occurred in CG ($n=13$) and IG ($n=7$) (Table 2). Multifactor etiology, particularly intrinsic conditions, must be underscored [9], since both eyes were jeopardized (descriptive data) in patients with eye lesion in the IG. Further, we would like to insist on the importance of evaluating and implementing effectiveness strategies for the prevention of eye lesions in ICUs. In spite of the several technologies to prevent eye lesions, such as humidity chamber, polyethylene cap, lanoline ointment and carbomer drops [20], [21], [22], they are not always available or accessible equally in all countries or regions. Normal saline solution has been widely used in eye care, due to low costs and availability. This fact has been reported in research work on sight and nursing practices in ICUs in Turkey and Palestine [5]. However, Davoodabady, Rezaei and Rezaei (2018) [23] has reported that the use of normal saline for eye care in patients hospitalized in ICUs may increase the incidence and severity of exposure keratopathy and, thus, not recommended.

We should insist that eye hygiene with saline solution followed by ocular occlusion with transparent polyurethane film had better results than ocular hygiene alone for the prevention of ocular surface lesions, with significant differences between IG and CG ($p=0.00635$) (Fig. 2). These results corroborate with Esra et al. (2009) and Sivasankar et al. (2006)'s studies [24], [25]

in which ocular protectors were employed to maintain eye lubrication. They were more effective than when such technology was discarded. Polyethylene eye caps, very similar to transparent polyurethane film caps (composed of a fraction of polyethylene) used in current assay, have proved to be effective to prevent eye dryness in ICU patients in China [20], [21], Turkey [22] and Iran [26].

Mean times for the appearance of lesions on the cornea in CG and IG were respectively 2.4 ± 1.3 and 4.1 ± 3.2 days (descriptive data). Lesion-free days were statistically less in CG when compared to those in IG, corroborating studies in Turkey [22] and in Brazil [4]. The former authors compared the effectiveness of polyethylene and carbomer drops in the prevention of dry eye syndrome in critically sick patients and detected that approximately 3 days were required for lesion occurrence. The latter author reported a mean period of 3.5 days for the occurrence of dry eyes among the 230 patients analyzed in ICUs. However, these results may be countered by Werli-Alvarenga et al. (2011) [10] who analyzed 254 adults in an ICU and reported the occurrence of lesions on the cornea after an average of 8.9 days.

Current authors would like to underscore that only one type of technology was employed with patients in serious organic dysfunction conditions (high APACHE and SOFA scores). Our results show that individual characteristics for each care (hospital infrastructure, team training and type of clients) should be taken into account.

5 CONCLUSIONS

The occurrence of surface lesion on the eye was associated to intrinsic risk factors regardless of demographic, environmental, physiological and clinical variables. Despite the development of lesion in both eyes, the use of transparent polyurethane film in eye cover was an effectiveness strategy for eye protection in seriously ill patients, with artificial ventilation, in ICU, because it warranted a longer lesion-free time for occluded eyes.

Further research should be undertaken with more patients and for longer periods for more in-depth technical and scientific conclusions. Decision-taking by managers and health agents on the incorporation of transparent polyurethane film to prevent ocular lesion would be facilitated. It would also enhance discussions and activities on the prevention of cornea lesions in nurses' learning and practice.

ACKNOWLEDGMENTS

The authors would like to thank the multi-professional team at the ICU of the Hospital Memorial in Maringá and the Centro Universitário Ingá (UNINGÁ) for their support in carrying out current study.

REFERENCES

[1] RAUZ, S.; KOAY, S.Y.; FOOT, B.; KAYE, S.B.; FIGUEIREDO, F.; BURDON, M.A.; DANCEY, E.; CHANDRASEKAR, A.; LOMAS, R. The Royal College of Ophthalmologists guidelines

on serum eye drops for the treatment of severe ocular surface disease: executive summary. *Eye (Lond)*. doi: 10.1038/eye.2017.208. [Epub ahead of print]

[2] GRIXTI, A.; SADRI, M.; EDGAR, J.; DATTA, A. V. Common ocular surface disorders in patients in intensive care unit. *Ocul Surf.*, v. 10, n. 1, p. 26-42, 2012.

[3] MASOUDI, A. N.; SHARIFITABAR, Z.; SHAERI, M.; ADIB HAJBAGHERY, M. An audit of eye dryness and corneal abrasion in ICU patients in Iran. *Nurs Crit Care.*, v. 19, n. 2, p. 73-77, 2014.

[4] DE-ARAÚJO, D.; RIBEIRO, N.; ALEIXO-SILVA, P.; REZENDE-MACIEIRA, T.; DA-SILVA, P.; MACHADO-CHIANCA, T. Dry eye in critically ill patients: integrative review *Olho seco em pacientes críticos: revisão integrativa*. *Revista de Pesquisa: Cuidado é Fundamental Online*, v. 9, n. 4, p. 907-916, 2017.

[5] GÜLER, E. K.; ESER, I.; FASHAFSHEH, I.H.D. Intensive Care Nurses' Views and Practices for Eye Care: An International Comparison. *Clin Nurs Research*, v. 26, n. 4, p. 504-524, 2016.

[6] ALANSARI, M. A.; HIJAZI, M. H.; MAGHRABI, K. A. Making a difference in eye care of the critically ill patients. *J Intensive Care Med.*, v. 30, n. 6, p. 311-317, 2015.

[7] KURUVILLA, S.; PETER, J.; DAVID, S.; PREMKUMAR, P. S.; RAMAKRISHNA, K.; THOMAS, L.; VEDAKUMAR, M.; PETER, J. V. Incidence and risk factor evaluation of exposure keratopathy in critically ill patients: a cohort study. *J Crit Care.*, v. 30, n. 2, p. 400-404, 2015.

[8] DEMIREL, S.; CUMURCU, T.; PENPEGÜL, F., et al. Effective management of exposure keratopathy developed in intensive care units: The impact of an evidence based eye care education program. *Intensive Crit Care Nurs.*, v. 30, n. 1, p. 38-44, 2014.

[9] VALIM, V.; TREVISANI, V.F.M.; DE SOUSA, J.M.; VILELA, V.S.; BELFORT, J.R.R. Current Approach to Dry Eye Disease. *Clinic Rev Allerg Immunol.* v. 49, n.1, p. 288-297, 2015.

[10] WERLI-ALVARENGA, A.; ERCOLE, F. F.; BOTONI, F. A.; OLIVEIRA, J. A. D. M. M.; CHIANCA, T. C. M. Lesões na córnea: incidência e fatores de risco em Unidade de Terapia Intensiva. *Rev. Latino-Am. Enfermagem.*, v. 19, n. 5, p. 1088-1095, 2011.

[11] DE ARAÚJO, D.D.; ALMEIDA, N.G.; SILVA, P.M.A.; RIBEIRO, N.S.; WERLI-ALVARENGA, A.; CHIANCA, T.C.M. Predição de risco e incidência de olho seco em pacientes críticos. *Rev. Latino-Am. Enfermagem*, v. 24: e2689, 2016.

[12] ARAÚJO, J.N.M.; FERNANDES, A.P.N.L.; BOTARELLI, F.R.; CÂMARA, V.G.N.; FERREIRA-JÚNIOR, M.A.; VITOR, A.F. Dry eye syndrome in an intensive care unit: a cross-sectional study. *Online braz j nurs.* v. 14, n. 0, p.396-399, 2015.

[13] BOTARELLI, F.R.; FERNANDES, A.P.N.L.; ARAÚJO, J.N.M.; BARRETO, V.P.; FERREIRA-JUNIOR, M.A.; VITOR, A.F. Analysis of nursing diagnosis "risk of dry eye": a cohort study. *Online braz j nurs* v. 14, n. 0, p.389-391, 2015.

[14] OLIVEIRA, R.; FERNANDES, A.; BOTARELLI, F.; ARAÚJO, J.; BARRETO, V.; VITOR, A. Risk factors for injury in the cornea in critical patients in intensive care: an integrative review. *Revista de Pesquisa: Cuidado é Fundamental Online*, v. 8, n. 2, p. 4423-4434, 2016.

[15] DE FRANÇA, C.S.F.M. et al. Evidence of interventions for the risk of dry eye in critically ill patients: An integrative review. *Appl. Nurs. Res.*, v.29, n.1, p. e14-e17, 2016.

- [16] CARRILLO, E.R.L.; FLORES, R.O.I.; DÍAZ, P.M.J.A.; NERI, M.R.; PALACIOS C.A. et al. Protección ocular en los enfermos internados en la Unidad de Terapia Intensiva: Una propuesta de mejora de calidad y seguridad. *Rev. Asoc. Mex. Med. Crít. Ter. Intensiva*, v. 30, n. 1, p. 17-24, 2017.
- [17] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Descrição dos Meios de Cultura Empregados nos Exames Microbiológicos. Módulo IV, p.3-4, 2004.
- [18] AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA. Procedimentos laboratoriais: da requisição do exame à análise microbiológica. v.1, n. 1, p.1-43, 2004.
- [19] PAIVA, C.S. Effects of Aging in Dry Eye. *Intern. Ophthalmology Clinics*, v. 57, n. 2, p. 47-64, 2017.
- [20] SHAN, H.; MIN, D. Prevention of exposure keratopathy in intensive care unit. *Int J Ophthalmol.*, v. 3, n. 4, p. 346-348, 2010.
- [21] SO, H. M.; LEE, C. C.; LEUNG, A. K.; LIM, J. M.; CHAN, C. S.; YAN, W. W. Comparing the effectiveness of polyethylene covers (Gladwrap) with lanolin (Duratears) eye ointment to prevent corneal abrasions in critically ill patients: a randomized controlled study. *Int J Nurs Stud.*, v. 45, n. 11, p. 1565-1571, 2008.
- [22] GÜLER, E. K.; ESER, I.; EGRILMEZ, S. Effectiveness of polyethylene covers versus carbomer drops (Viscotears®) to prevent dry eye syndrome in the critically ill. *J Clin Nurs.*, v. 20, p. 1916-1922, 2011.
- [23] DAVOODABADY, Z.; REZAEI, K.; REZAEI, R. The Impact of Normal Saline on the Incidence of Exposure Keratopathy in Patients Hospitalized in Intensive Care Units. *Iranian Journal of Nursing and Midwifery Research*. v.23, n.1, p.57-60, 2018.
- [24] EZRA, D. G.; CHAN, M. P.; SOLEBO, L.; et al. Randomised trial comparing ocular lubricants and polyacrylamide hydrogel dressings in the prevention of exposure keratopathy in the critically ill. *Intensive Care Med.*, v. 35, n. 5, p. 455-461, 2009.
- [25] SIVASANKAR, S.; JASPER, S.; SIMON, S.; JACOB, P.; GEORGE, J.; RAJU, R. Eyecare in ICU. *Indian J Crit Care Med*, v. 10, n. 1, p. 11-14, 2006.
- [26] KALHORI, R. P.; EHSANI, S.; DANESHGAR, F.; ASHTARIAN, H.; REZAEI, M. Different Nursing Care Methods for Prevention of Keratopathy Among Intensive Care Unit Patients. *Glob J Health Sci*, v. 8, n. 7, p. 212-217, 2016.