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Efficacy of Liquid Artificial Tears versus Gel Artificial Tears to Prevent Dry Eye among Critically Ill Patients in Intensive Care Units - A Randomized Control Trial

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Abstract: ***This study investigates the relative efficacy of liquid and gel artificial tears in preventing dry eye among critically ill patients in intensive care units ICUs. Conducted as a randomized control trial with 90 ICU patients, the research divided participants into two groups: Group A received gel artificial tears, and Group B received liquid artificial tears. The treatment was administered twice daily for five days, with outcomes measured using Schirmers test. The findings indicated that while there was no significant statistical difference in the efficacy of the two treatments, a notable clinical difference was observed, suggesting potential implications for ICU nursing practices.***

Keywords: eye dryness, liquid artificial tears, gel artificial tears, corneal ulcer, intensive care unit

1. Introduction

Patients who are admitted to Intensive Care Units (ICUs) are usually very critical and most of the time are in a state of sedation, coma, mechanical ventilation, intake of several medications and compromised ocular protection mechanisms.[1] The ocular surface is usually protected by tears, blinking and closing eyes during rest and sleep. All of these mechanisms can be disrupted in the population who are critically ill and admitted in ICUs, increasing the risk of developing ocular surface disease. The ICU patients experiencing dry eyes for a long period are at high risk of developing complications like eye infection, direct injury to the cornea, exposure keratopathy, chemosis, corneal ulcer, microbial conjunctivitis and keratitis.[2] According to a systemic literature review, there are indications that corneal abrasions can occur in ICU patients within a relatively short time, ranging from 48 hours to one week. In three randomized control trials, the incidence of such abrasions in the ICU population ranged from 3.33% to 22%. Another study reported that corneal abrasions were detected in 42% of ICU patients mostly within the first week of admission.[3]

It is an important aspect in the management of critically ill patient to care for their eyes along with many other cares provided, as the mechanism of eyes are compromised involved in protecting them from infection and injury. It is quite common among the intensive care population that they develop ocular surface disease, among which 20–42% of those patients develop corneal epithelial defects.[3, 4] The use of muscle relaxants and sedation in critically ill patients admitted in ICU predisposes to poor eyelid closure and eye disorders. ICU staffs are primarily concerned with life threatening conditions; therefore, the ocular signs and symptoms may be missed leading to serious ocular complications[4, 5]. Hence, early diagnosis and effective treatment will help prevent corneal abrasions, microbial keratitis and visual loss. Moreover, the ICUs consider and favour cardiovascular, respiratory and neurological systems more vital, important and assistance rather than eyes.[6,7] Therefore, this is a study with good novelty that can be vital for bridging the gap in knowledge as well as practice. The study aims to compare the efficacy of liquid artificial tears versus gel artificial tears in the prevention of dry eyes in critically ill patients in ICUs.

2. Literature Survey

Araujo et al in 2019 conducted a randomized control trial on 140 patients which aimed to compare the effectiveness of 2 nursing interventions in preventing dry eye in adult intensive care unit patients: liquid artificial tears (Lacribell) and artificial tears gel (Vidisic Gel). In this study, 21% of participants developed dryness of eye who received liquid artificial tears whereas only 9% among participants who received artificial tears gel. Hence, the study revealed that artificial tears gel was superior to liquid artificial tears in the prevention of dry eye.[32]

Problem Definition

- **Dryness of eyes**
  Dryness of eyes in this study refers to the condition which occurs when the eyes are unable to produce adequate tears for the lubrication of the eyeballs.
- **Efficacy**
  In this study, efficacy refers to the effectiveness of the two interventions given to the ICU patients in comparison to each other for the prevention of dry eyes during their admission period.
- **Liquid artificial tears**
  In this study, liquid artificial tears (Hydroxypropyl methylcellulose 0.3% ophthalmic solution) is an eye lubricant or eye drop to relieve the dryness of the eye.
- **Gel artificial tears**
  In this study, gel artificial tears (Hydroxypropyl methylcellulose 2% ocular lubricant) is an eye lubricant in gel form to prevent the dryness of the eyes.
- **Critically ill patients**
  Critically ill patients in this study are those patients admitted in the ICUs whose GCS is less than or equal to 7 (GCS ≤7) and with Mechanical Ventilation.

3. Methodology

A randomized control trial was conducted to compare the efficacy of liquid artificial tears versus gel artificial tears to prevent dry eyes among critically ill patients in ICUs, Tertiary care hospital, Puducherry. The study was approved by JIPMER Nursing Research Monitoring Committee Reg. no. JIP/CON/NRMC/M. Sc/2019/MSN/4, and the Institute ethical committee (Human studies) Reg. no. JIP/CON/IEC/M. Sc/2019/MSN/4. The study is also registered in Clinical Trial Registry - India (CTRI) with CTRI Reg. no CTRI/2020/07/026847. Data collection was done from 01/12/2020 to 31/01/2021. Consolidated Standards of Reporting Trials (CONSORT; Figure 1) was followed for the study. Informed consent has obtained from the legally authorized/acceptable representative of study participants. The study was conducted in ICUs of Neurology, Neurosurgery, Neurotrauma and Cardiovascular and thoracic surgery, the total bed of 24 capacities. Sample size calculation based on considering a difference of 3mm in the production of tears between the liquid artificial tears and gel artificial tears with standard deviation of 5 mm and type I error of 5% and 80 % power, the sample size is estimated as 90 (45 in each group). Block randomization technique was used for the present study. The list for block randomization was generated through computer in the website sealedenvelop. com and the patients were randomized into two groups by opaque open label sealed envelope. Inclusion criteria for the study both gender above 18 years, without diagnosis of dry eye during admission, patient on mechanical ventilator, Glasgow Coma Scale (GCS) score of 7 or lower. Exclusion criteria, the patients who were an ICU stay of less than 48 hours, admitted with a diagnosis of brain death, GCS improves during the time of study, patients with severe eye disease or injury. The study withdrawal criteria were death, patient discharged or shifted out before completing 5 days of intervention. The instruments used in the study consists of Part 1 socio - demographic and clinical variables include patient's age, sex, department, date of admission, date of enrolment and clinical variables included the diagnosis, co - morbidities, sedatives, duration of illness and duration of ICU stay. Part 2 Schirmer's test consist of use of Schirmer's strip (size 5×35mm) or Whatman filter paper no.41. The eyes were gently dried of excess tears before performing the Schirmer's test. The strip was folded 5mm from one end and kept in the lower fornix at the junction of lateral 1/3 and medial 2/3 (do not touch cornea or lashes) and the eyes of the patient were then closed. Tears in the conjunctival sac had caused progressive wetting of the paper strip. After five minutes, the strip was removed and the distance between the leading edge of wetness and the initial fold is measured is recorded a millimetre. There is no scoring for demographic and clinical variables. Part 2 Schirmer's test for tears production is a scale measuring from 0 - 35mm. In this score, measurement less than 4 indicate severe eye dryness, 4 - 8 mm indicate moderate eye dryness, 9 - 14 mm indicate mild eye dryness and measurement ≥15 mm indicates normal aqueous tear production. Tear production measured after 5 minutes. Demographic proforma were developed by the investigator with expert opinion. Reliability of the tool for assessing the dryness of eyes was assessed by the test - retest method. The value was found to be 0.84.

The study participants were selected according to the inclusion criteria and assessed for dryness of eyes using Schirmer's Test before initiating the procedure. The eligible patients are randomly allocated to Group A and Group B by block randomization method and before starting the procedure, the eyes of the patients are bathed before applying the lubricants with warm water/0.9% sodium chloride to remove dried ointment or any secretions. A number of 45 patients in Group A were administered artificial tears gel (hydroxypropyl methylcellulose eye gel lubricant; Lacryl PF) in both the eyes surface by pulling the lower eyelid down with a finger and inserts the ointment over the top of the lower lid into the gap between the lid and the conjunctiva. The outside of the eye must be free of the tear gel and manual closure of the eyes or tape the eyes shut with micropore horizontally across the lids to seal them properly (Picture - 1). And 45 patients in Group B were given liquid artificial tears (hydroxypropyl methylcellulose eye drops; Genteal, which is a standard treatment in the hospital) in both the eyes surface by pulling the lower eyelid down with a finger and administer two drops of the liquid tears. The outside of the eye must be free of any liquid tears discharge and manual closure of the eyes or tape the eyes shut with micropore horizontally across the lids to seal them properly (Picture - 2). The intervention was delivered twice daily (at 8: 00 AM and 8: 00 PM) for 5 consecutive days and the outcome variables were assessed after five days of intervention for both the groups using Schirmer's test. The study independent variables were age, gender, duration of ICU stay, duration of illness, diagnosis, sedation, co - morbidity, liquid artificial tears, gel artificial tears and outcome variable was tears production.

4. Result

Age of patients are well distributed in both group A and B with standard deviation 47.20 (15.28) and 47.27 (13.98) respectively. In Group A, 14 (31.1%) belong to the age - group of 46 - 60 and 10 (22.2%) comes from age group of

both 18 - 30 and >60; whereas in Group B, 21 (46.7%) belongs to 31 - 45 age group and 4 (8.9%) to 18 - 30 years. In terms of gender, male and female participants are equally distributed in both the group with 30 (66.7%) male and 15 (33.3%) females respectively. As regard to the department, majority of the participants are from Neurotrauma ICU in both Group A and B with 25 (55.6%) and 29 (64.4%) respectively and the least from CTVS ICU with distribution 1 (2.2%).

The table 1 shows the distribution of samples according to diagnosis, both in group A and group B belongs majority 18 (40%) and 19 (42.2%) to RTA.

The table 2 shows the distribution of samples according to comorbiditiessedatives, duration of illness and duration of ICU stay among patients in gel artificial tears (Group A) and liquid artificial tears (Group B).

The table 3 reveals that there is no statistically significant difference ($p<0.05$) in the median scores of both the eyes between gel artificial tears and liquid artificial tears in prevention of dryness of eyes.

The table 4 shows that Level of dryness of right and left eyes in gel artificial tears versus liquid artificial tears.

The association of demographic variables with development of dryness of eyes is at the right eye of both group A and B. It revealed that there is no association between age, gender, ICU departments and development of dry eyes at the 5% level of significance. There is an association between the diagnosis (0.007) and dryness of eyes in right eye, the sedatives are associated to the development of dryness of eyes (0.052 and 0.005) in both right eye and left eye respectively of the critically ill patients; whereas no significant association between comorbidities and development of dryness of eyes were seen in both right and left eye at the 5% level of significance. Statistical analysis Kruskal - Wallis H shows that the duration of ICU stay of the patients are found associated to the development of dryness of eyes (0.042 and 0.035) in both right and left eyes respectively, whereas no significant association between duration of illness and development of dryness were seen in both right and left eye at the 5% level of significance.

5. Discussion

The emergence of dry eye is estimated at a relatively small - time interval between 24 hours. Thus, once the patient is admitted to the ICU, the nurse should evaluate eyes for any ocular conditions and every possible intervention should be performed to prevent complications that may have negative impact on the lives of the patients during and after hospitalization.7 The age distribution in current study shows that most of the participants in Group A and Group B belonged to age group 46 - 60 years 14 (31.1%) and 31 - 45 years 21 (46.7%) respectively. With regard to the gender distribution, majority of the participants 30 (66.7%) in group A and 30 (66.7%) in group B were males. Considering the department of ICU, majority of the participants were from Neurotrauma ICU in both Group A and B with 25 (55.6%) and 29 (64.4%) respectively. Regarding the diagnosis of patients, the majority of both in Group A 18 (40%) and Group B 19 (42.2%) were admitted due to RTA. The distribution of samples according to comorbidities in group A 14 (31.1%) has hypertension, 8 (17.8%) diabetic, 1 (2.2%) hypothyroidism, 1 (2.2%) rheumatoid arthritis, 1 (2.2%) pulmonary tuberculosis and 0% CAD. In group B, 14 (31.1%) have hypertension, 7 (15.6%) diabetic, 0% hypothyroidism, rheumatoid arthritis, pulmonary tuberculosis and 1 (2.2%) CAD. With regard to sedatives out of 45 samples, in group A 10 (22.2%) received fentanyl and midaz, 1 (2.2%) midaz, 0% fentanyl and 34 (75.6%) received no sedatives. In group B, 8 (17.8%) received fentanyl and midaz, 2 (4.4%) midaz, 1 (2.2%) fentanyl and 34 (75.6%) received no sedatives. Considering the duration of illness, 31 (84.4%) in group A and 31 (84.4%) in group B were having 1 - 20 days duration. The majority of the patients 42 (93.3%) and 43 (95.6%) in group A and B respectively were admitted in ICU for 1 - 10 days.

The study showed that there is no statistically significant difference ($p<0.05$) in the effectiveness between gel artificial tears and liquid artificial tears in prevention of dryness of eyes. The right eye score difference of group A and group B showed the median (IQR) of 3 (2, 5) and 2 (1.5, 4) respectively and left eye score difference of group A and group B showed median (IQR) of 3 (1.5, 6.5) and 4 (2, 5) respectively. The variables were compared using Mann Whitney U test and in right eye score difference resulted value 844.5 ($p=0.170$) and in left eye score difference 1008.5 ($p=0.971$), which is not significant at 5% level of significance (Table 3).

The result of this study revealed that incidence of dryness of eyes were observed more in the group who received liquid artificial tears (Group B) in comparison to gel artificial tears (Group A). In both right and left eye scoring, gel artificial tears showed majority normal aqueous tear production with 28 (62.2%) and 32 (71.1%) respectively. Majority mild dryness of eye belonged to liquid artificial tears 20 (44.4%) and 20 (44.4%) in both right and left eyes respectively and majority moderate dry eye 5 (11.1%) and 5 (11.1%) belong to liquid artificial tears in both right and left eyes, showing a total incidence of 25 (55.5%) dryness of eyes in right eye and 25 (55.5%) dryness of eyes in left eye among 90 sample of participants. It is revealed by the comparison of both right and left eye scoring that incidence of dryness of eyes is observed more in patients who were administered liquid artificial tears than patients receiving gel artificial tears. No patients with severe dry eyes were observed in both gel artificial tears and liquid artificial tears (Table 4). The analysis of the study shows that even though there is no significant statistical difference in the efficacy of two interventions - gel artificial tears and liquid artificial tears in prevention of dryness eyes, a clinical difference in the efficacy of the two interventions have been noticed. In this study, in right eye findings 55.5% of the patients had developed dryness of eyes who received liquid artificial tears whereas only 31.67% developed dry eyes among patients who received gel artificial tears. Similarly, in left eye findings 55.5% of the patients had developed dryness of eyes who received liquid artificial tears whereas only 28.9% developed dry eyes among patients who received gel artificial tears.

The study supported by the following study findings one similar randomized control study was conducted in Brazil by Araujo et al. on 140 patients which compared liquid artificial tears (Lacribell) and artificial tears gel (Vidisic Gel) for its effectiveness in preventing dry eye in adult ICU patients. The result of this study showed that 21% of participants who received liquid artificial tears developed dryness of eye whereas only 9% among participants who received artificial tears gel. Hence, study revealed that artificial tears gel was superior to liquid artificial tears in the prevention of dry eye.8Kalhori et al**.** in his clinical trial on 96 patients aimed to compare effect of three eye care techniques (polyethylene cover, liposic ointment and artificial tear drop) in prevention of keratopathy in the patients hospitalized in ICU. The study found that polyethylene cover (0.59±0.665) was significantly more effective as a non - aggressive and non - pharmaceutical nursing and therapeutic method whereas no statistically significant difference was seen between liposic ointment and artificial tear drop (P=0.844). The result though showed liposic ointment more effective (1.13±0.751) than artificial tear drop (1.59±0.875) in prevention of corneal abrasion (P<0.001).9Another study conducted by Bron et al. on 179 patients which aimed to compare the efficacy and safety of two eye gels in the treatment of dry eyes: Lacrinorm and Viscotears showed that improvements in both treatment groups were significant ($p < 0.001$), with no significant differences between the two treatment groups. Thus, concluded that Lacrinorm eye gel was as effective and safe as Viscotears/Lacrigel in the treatment of dry eye.1[0]Ahmadinejad et al. in his clinical trial on 152 patients compared three eye care methods i. e. Simple Eye Ointment, Polyethylene Cover, and Eyelid Taping to prevent ocular surface disorders (OSDs) in ICU patients found that polyethylene cover followed by eyelid taping and simple eye ointment were the most effective methods in preventing OSD.[11]

The association between the clinical variables and development of dryness of eyes shows that in right eye assessment of the patients, there was significant association between the diagnosis of patients (0.007), sedatives (0.052), duration of ICU stay (0.042) and development of dryness of eyes in critically ill patients. In left eye assessment findings, there was a significant association between sedatives (0.005), duration of ICU stays (0.035) and the development of the dryness of eyes of critically ill patients. Other demographic variables such as age, gender, department of ICU, comorbidities and duration of illness showed no association with development of dryness of eyes. It is seen in many studies conducted on dryness of eyes that condition or the risk for developing dry eyes increases with increase in age. In a study conducted by Shanti et al., dry eye disorder (DED) was found significantly associated with female gender $p =$ (0.001) and older age $p =$ (0.001). According to a report on epidemiology on dry eye by Smith et al. it is stated that dry eye affects general elderly population by approximately 5–30%, and commonly affects more women than men.1[2] But in this study, there was no association found between age, gender and dryness of eyes. The result may be affected due to smaller number of sample size.

6. Conclusion

The study concludes that both liquid and gel artificial tears are effective in preventing dry eye in critically ill ICU patients. However, the incidence of dry eye was found to be lower in patients treated with gel artificial tears compared to those treated with liquid artificial tears. These findings underscore the importance of selecting appropriate eye care interventions in ICU settings to enhance patient comfort and prevent ocular complications.

7. Future Scope

Considering the current findings of the study, a similar kind of study can be conducted in future with large sample size to make generalizations and also a comparative study could be conducted with other non - pharmacological measures. Limitation of the study were generalization of the study limited on sample only from one hospital, the interventions were administered only twice daily, whereas it is recommended to administer whenever necessary and the sample size of the study may not be sufficient to generalize on a larger population.

Figures and Tables:

Table 1: Diagnosis among patients in gel artificial tears (Group A) and liquid artificial tears (Group B)

Diagnosis	Gel artificial tears (Group A) n=45	Liquid artificial tears (Group B) n=45
	n (%)	**n (%)**
Acute intestinal obstruction	1 (2.2)	0
RTA	18 (40)	19 (42.2)
Accidental fall	1 (2.2)	0
Head injury	2 (4.4)	3 (6.7)
Right frontal glioma	0	2 (4.4)
TBI	4 (8.9)	8 (17.8)
C - spine injury	1 (2.2)	0
Right temporal glioma	0	1 (2.2)
Craniopharyngioma	1 (2.2)	0
SDH	6 (13.3)	4 (8.9)
Ca rectum	0	1 (2.2)
Post traumatic hydrocephalus	1 (2.2)	0
Frontal ICSOL	1 (2.2)	0
Stroke	1 (2.2)	1 (2.2)
Left GC bleed	0	1 (2.2)

Aneurysm	2 (4.4)	1 (2.2)
Meningioma	0	2 (4.4)
Contusion	4 (8.9)	0
Aortic stenosis	1 (2.2)	1 (2.2)
ICH	1 (2.2)	0 (0.1)
Ruptured DACA	0	1 (2.2)

Abbreviations: RTA, Road Traffic Accident; TBI, Traumatic Brain Injury; SDH, Subdural Hematoma; ICSOL, Intra - cranial space occupying lesion; ICH, Intracerebral hemorrhage; DACA, Distal Anterior Cerebral Artery.

Table 2: Comorbidities, sedatives, duration of illness and duration of ICU stay among patients in gel artificial tears (Group A) and liquid artificial tears (Group B)

Clinical parameters		Gel artificial tears Group A (n=45)	Liquid artificial tears Group B (n=45)
		n (%)	n (%)
HTN	Present	14 (31.1)	14 (31.1)
	Absent	31 (68.9)	31 (68.9)
DM	Present	8 (17.8)	7 (15.6)
	Absent	37 (82.2)	38 (84.4)
Hypothyroidism	Present	1 (2.2)	0
	Absent	44 (97.8)	45 (100)
Rheumatoid arthritis	Present	1 (2.2)	0
	Absent	44 (97.8)	45 (100)
Pulmonary tuberculosis	Present	1 (2.2)	0
	Absent	44 (97.8)	45 (100)
CAD	Present	0	1 (2.2)
	Absent	45 (100)	44 (97.8)
Sedatives	Fentanyl and Midaz	10 (22.2)	8 (17.8)
	Midaz	1 (2.2)	2 (4.4)
	Fentanyl	0	1 (2.2)
	Nil	34 (75.6)	34 (75.6)
Duration of illness (in days)	1 - 20	31 (84.4)	31 (84.4)
	21 - 40	4 (8.9)	4 (8.9)
	>40	3 (6.7)	3 (6.7)
Duration of ICU stay (in days)	1 - 10	42 (93.3)	43 (95.6)
	11 - 20	3 (6.7)	2 (4.4)

Abbrebiations: HTN, Hypertension; DM, Diabetes Mellitus; CAD, Coronary Artery Disease

Table 3: Tear production score difference among patients in gel artificial tears (Group A) and liquid artificial tears (Group B)

Tear production score difference	Median (IQR)		Mann Whitney U	P value
	Gel artificial tears (n=45)	Liquid artificial tears (n=45)		
Right eye	3 (2, 5)	2 (1.5, 4)	844.5	0.170
Left eye	3 (1.5, 6.5)	4 (2, 5)	1008.5	0.971

Table 4: Incidence of dryness of right and left eyes in gel artificial tears versus liquid artificial tears (N=90)

Level of tear production	Cases of dry eye in gel artificial		Cases of dry eye in liquid artificial	
	Right eye n (%)	Left eye n (%)	Right eye n (%)	Left eye n (%)
Normal aqueous tear production	28 (62.2%)	32 (71.1%)	20 (44.4%)	20 (44.4%)
Mild eye dryness	14 (31.1%)	12 (26.7%)	20 (44.4%)	20 (44.4%)
Moderate eye dryness	3 (6.7%)	1 (2.2%)	5 (11.1%)	5 (11.1%)

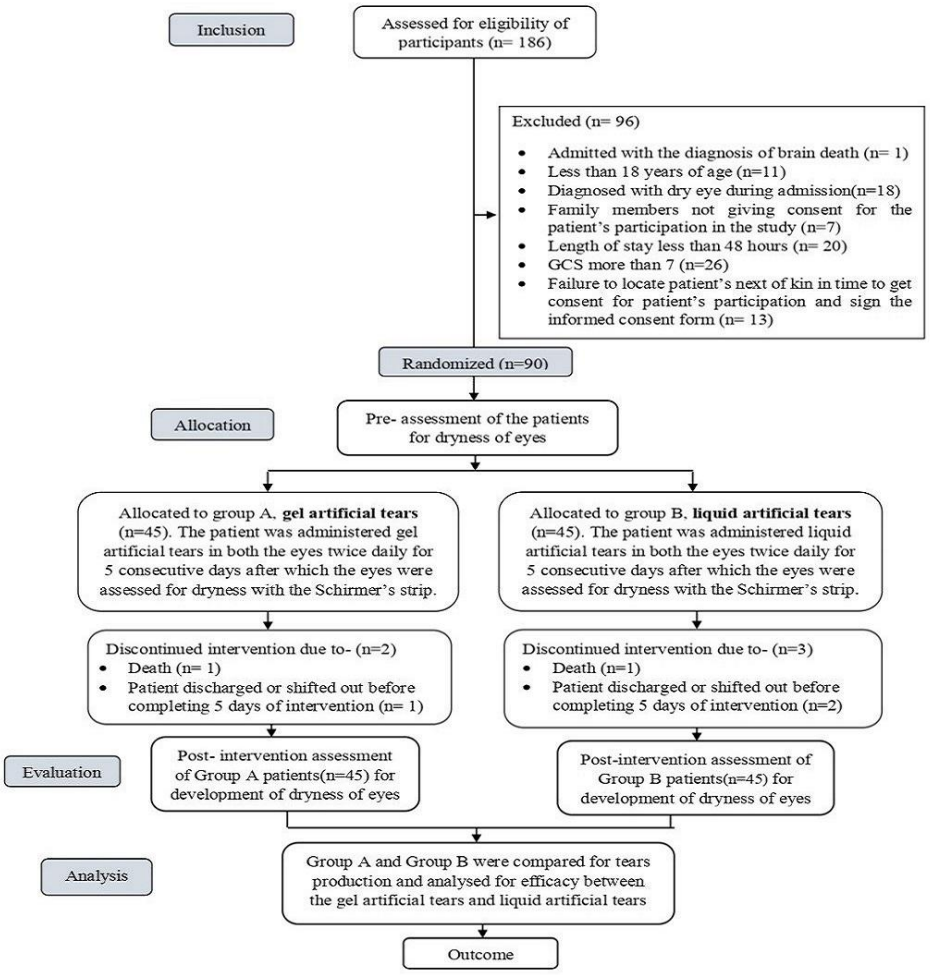
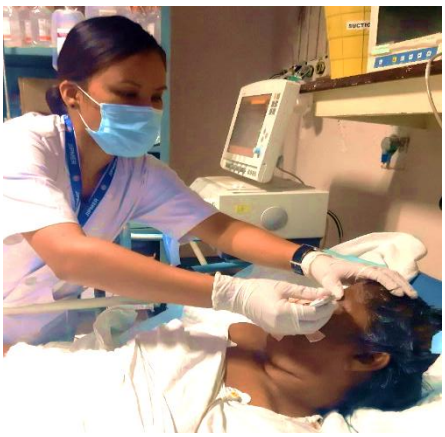


Figure 1: Consort Diagram of the Study



Picture 1: GEL Artificial Tears (Group A)

Picture 2: Liquid Artificial Tears (Group B)

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