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Predictors of treatment success in corneal surface disorder: A comparative analysis of amniotic membrane grafting and medical management

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ABSTRACT

Aim: The aim of the study was to determine the predictors of treatment success in corneal surface disorders.
Materials and Methods: The study included a total of 40 patients who were divided into two groups: Group A underwent Amniotic Membrane Grafting, while Group B received Conventional Medical Management. The patients were followed for a duration of 8 weeks after treatment. At the end of the 8-week period, visual acuity was measured using the Snellen chart, and any remaining symptoms were assessed.
Result: The study included 40 cases of corneal ulcer, with 23 (57.5%) being male and 17 (42.5%) female. Ocular surface disorders observed in the cases included persistent epithelial defect (55%), impending perforated corneal ulcer (25%), symblepharon due to chemical injury (10%) and perforated corneal ulcer (10%). Relief from symptoms such as pain levels (n=1), photophobia (n=1), foreign body (FB) sensation (n=0), eye watering (n=1), redness (n=1), and discharge (n=0) was observed earlier (4th week) in Group B compared to Group A (8th week). The majority of patients in Group B experienced relief from these symptoms by the end of the follow-up period. The success rate of the AMG-treated group was higher (85%) compared to the conventional medical management group (60%). Baseline uncorrected visual acuity (UCVA) improved from 2.67 logMAR to 1.03 logMAR within 1 to 4 weeks after surgery and to 0.76 logMAR at the last follow-up in Group B, while it improved from +2.67 to +0.85 at the last follow-up in Group A.
Conclusion: Amniotic membrane grafting is an effective treatment choice for promoting healing in corneal wounds that do not respond to conventional treatment.

1. Introduction

The initial event that leads to the development of a corneal epithelial defect and subsequent ulceration can be attributed to the breakdown of corneal epithelial surface.[1,2] This breakdown can occur due to various factors such as ocular xerosis, infection,chemical burns from external sources, or trauma, or conditions like exposure keratitis, neurotrophic keratitis, keratomalacia, or recurrent corneal erosions from internal sources.[3] Excessive inflammation or a lack of appropriate healing response can lead to the development of a persistent corneal ulcer, which carries a substantial potential for permanent vision loss.[4] Therefore, early diagnosis as well as appropriate medical intervention are critical, considering the diverse causes of corneal ulcers.[1]

Early detection and appropriate medical intervention are essential due to the various causes of corneal ulcers.[3] In cases where local medical treatments are insufficient, additional measures like bandage contact lenses,[5] conjunctival flaps,[6] or tarsorraphy[7] can be employed

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to promote epithelial healing. In certain situations, systemic immunosuppressive or immunomodulatory treatment may also be considered.[8] These established treatment options provide alternatives to manage refractory corneal ulcers and support the healing process. The transplantation of amniotic membranes (AMTX) has emerged as a promising surgical procedure for reconstructing the ocular surface and facilitating corneal epithelialization. This technique has shown positive results in supporting the healing process of the cornea.[9,10]

The application of amniotic membrane transplantation (AMTX) in the treatment of ocular surface conditions was first introduced by de Rötth and Sorsby.[11,12] Subsequently, Kim and Tseng[13] devised a technique in 1995 that involved preserving amniotic membranes through the use of glycerine. Since then, amniotic membrane has been widely employed for the treatment of various ophthalmic diseases.[14] The amniotic membrane (AM), which is the innermost layer of the fetal membrane, possesses biological factors such as cytokines, growth factors, and neurotrophins, making it highly valuable for corneal surgery. The AM aids in epithelialization by promoting migration, reinforcing adhesion, facilitating epithelial differentiation, and modulating fibroblast proliferation in the cornea, conjunctiva, and limbal region. Moreover, the AM exhibits anti-apoptotic, antimicrobial, anti-scarring, anti-inflammatory, and anti-neovascularization properties.[15–17] One of the advantages of amniotic membrane transplants (AMTs) is that the cornea typically does not mount significant immunological responses against the AM, despite the expression of HLA I and HLA II by fibroblasts, mesenchymal cells, and the amniotic epithelium.[18]

For the treatment of small to medium-sized perforations, corneal melting, and leaking descemetoceles, options such as AMTs, anterior lamellar keratoplasties, and tectonic corneal patch grafting (PG) can be considered. However, total penetrating keratoplasty, penetrating keratoplasty (PK), and sclerokeratoplasty are typically reserved for larger perforations accompanied by extensive melting, tissue destruction, and significant necrosis.[19–21]

The objective of this study was to identify the predictors of treatment success in corneal surface disorders when comparing amniotic membrane grafting with medical management.

2. Materials and Methods

2.1. Procedure

This is a retrospective study conducted at the Department of Ophthalmology. Mayo Institute of Medical Sciences, Barabanki, (U.P.), India.

Patients presenting with corneal ulcer, corneal perforation, dry eye, bullous keratopathy, exposure keratitis, neurotrophic keratopathy, recurrent corneal erosions, Corneal injury (chemical/mechanical) were screened and those who were suitable for AMG and for medical management were selected. A total of 40 patients with corneal surface disorders were included in the study. These patients were selected randomly and divided equally into two groups, with 20 patients in each group A and group B. Group A consist of patients underwent AMG application whereas patients in group B were selected for medical management. Patient were followed for 8 weeks or full resolution (whichever came earlier & the outcome measures were evaluated). At the end of 8 weeks, visual acuity and residual symptoms were measured.

2.2. Treatment

Group A patient was treated with topical drugs for respective etiology. Topical medication were Antibiotic (Moxifloxacin), antifungal (Natamycin, Fluconazole), Antiviral (Aciclovir eye ointment), cycloplegics & lubricants. Group B patient were treated with AMG application. Oral medication given to both group were Systemic antibiotic (Cefixime, ofloxacin) Analgesic (ibuprofen, paracetamol), PPI (Pantoprazol) & CAI (Acetazolamide).

2.3. Application of AM

Freeze-dried amniotic membranes wqere used in the study to assess the effectiveness of AMG (amniotic membrane grafting) in providing relief from symptoms, promoting corneal re-epithelialization, and improving visual acuity. The surgical procedure was predominantly performed under topical anesthesia, although some cases were conducted under general anesthesia depending on patient preference. During the surgical procedure, the first step involved placing an amniotic membrane with the epithelium facing up over the corneal epithelial defect. This membrane was secured in place using 10-0 sutures of interrupted nylon. Next, a second AM with the epithelium facing down was positioned to overlap first layer and cover the entire cornea. It was attached to the conjunctiva using a continuous nylon 10-0 suture.

To finalize the surgical process, over both AM, a therapeutic contact lens was placed. Following surgery, the patients were administered preservative-free antibiotic drops and topical artificial tears for treatment. The suture were removed upon the dissolution of upper AM layer. The individual sutures of the deeper AM and the contact lens were removed based on the occurrence of integration, resorption, or loss of the deeper AM layer, as well as complete re-epithelialization of the cornea.

2.4. Treatment success/ Failure

All patients were admitted for 1–3 days after operation and were followed up at 1^{st}, 4^{th} and 8^{th} week. Complete

resolution of corneal lesion with healed epithelium, minimum to absent infiltration, was regarded as successful treatment whereas persistence of any above signs excessive thinning of cornea leading to desmatocele formation were labeled as treatment failure.

2.5. Statistical analysis

Descriptive statistics were used to calculate the means as well as standard deviations (SDs) of the data. Visual acuity was measured using Snellen's chart and recorded using the LogMAR scale. Statistical analysis was conducted using IBM SPSS Statistics (Version 26). A significance level of $P < 0.05$ was used to determine statistical significance.

3. Result

Eyes of 40 patients (20 each in group A and B) with corneal ulcer were operated with the AMT and medical management techniques.

In both Group A and Group B, the majority of participants were male, accounting for 60% and 55% respectively, while females constituted 40% and 45% of the respective groups. The age distribution of participants in both groups predominantly fell within the range of 20 to 60 years. Regarding socioeconomic status, approximately 55% of participants in both groups belonged to the middle class. The lower class represented 30% of participants in Group A, whereas the upper class accounted for 15%. In contrast, in Group B, only 20% of participants were from the lower class, while the upper class comprised only 2% (Table 1).

All participants in the study presented with corneal disorders. Table 2 shows that the majority of participants (55%) had persistent epithelial defects. Impending perforated corneal ulcers were observed in 25% of the participants, while perforated corneal ulcers and symblepharon due to chemical injury were present in 10% of participants each. Among the patients, 45% had Grade-4 corneal defects, which encompassed more than 75% of the corneal area. Additionally, the majority of these defects (65%) affected the central area of the cornea.

Prior to the surgery, a significant number of patients experienced severe symptoms. Among the patients, 50% reported severe pain. Additionally, severe symptoms of photophobia were observed in 45% of participants, foreign body sensation in 47.5%, eye watering in 52.5%, redness in 50%, and decreased overall visual acuity (DOV) in 70% of patients. Mild discharge was reported by 52.5% of the participants (Table 3).

llustrates the duration of relief from post-operative symptoms during the follow-up period for both groups. The majority of participants in group A experienced painrelief in the 8th week (n=8), whereas in group B, patients found relief in the 4th week (n=12). Likewise, symptoms such as photophobia, foreign body (FB) sensation, watering, and redness of the eye were also reduced by the 4th week in group B, whereas patients in group A experienced relief from these symptoms in the 8th week. Both groups saw a reduction in eye discharge during the 1st week, but group B had a higher frequency (n=13) compared to group A (n=8). It was also observed that most participants in group A did not experience a reduction in post-operative symptoms, including pain levels (n=4), photophobia (n=3), FB sensation (n=2), eye watering (n=3), redness (n=2), and discharge (n=3). Conversely, most participants in group B found relief from these symptoms within the follow-up period, with only a few experiencing pain (n=1), photophobia (n=1), FB sensation (n=0), eye watering (n=1), redness (n=1), and no discharge (n=0).

The final treatment outcomes for both groups are presented in Table 5. The application of AMG showed a significantly higher success rate compared to group A ($P<0.05$). In group B, 17 individuals (85%) were successfully treated, whereas in group A, only 12 individuals (60%) achieved success. The rate of treatment failure was higher in group A, with 8 individuals experiencing failure, while in group B, only 3 individuals faced treatment failure.

The average logMAR visual acuity for both groups is presented in Table 6. Prior to the surgery, the median logMAR visual acuity was +2.67 in group A and +2.79 in group B, which corresponds to approximately 20/4000 on the Snellen chart. After the first week of treatment, an improvement in logMAR visual acuity was observed in group B (+1.30, 20/400 on the Snellen chart), whereas in group A, the improvement was less significant (+2.10, 20/2000 on the Snellen chart). This trend continued in the fourth week, with group B showing further improvement (+1.03, 20/200 on the Snellen chart) compared to group A (+1.15, 20/240 on the Snellen chart). By the eighth week of follow-up, group B exhibited a logMAR visual acuity of +0.76 (20/80 on the Snellen chart), while group A had a logMAR visual acuity of +0.85 (20/120 on the Snellen chart).

4. Discussion

The history of corneal disorders and their management dates back to ancient times. The conventional approach to managing these disorders involves promoting natural wound healing through the use of local medications and providing rest to the affected eye. However, the unique avascular nature of the cornea sets it apart from other tissues in terms of wound healing. As a result, various methods have been explored to manage corneal disorders that do not respond to conventional treatments. These methods include conjunctival flap surgery, human amniotic membrane grafting, therapeutic penetrating keratoplasty, vasculo-epithelioplasty, and stem cell transplantation.

Table 1: Demographic details

Parametrs		Group A		Group B	
		No. of patients	Percentage (%)	No. of patients	Percentage (%)
Age (yrs)	0-20	3	15	3	15
	20-40	7	35	7	35
	40-60	7	35	8	40
	>60	3	15	2	10
Gender	Male	12	60	11	55
	Female	8	40	9	45
Socio-economic status	Lower Class	6	30	4	20
	Middle Class	11	55	11	55
	Upper Class	3	15	5	25

Table 2: Frequency of studied cases

Parameters		No. of patients	Percentage (%)
Corneal Disorder	Persistent Epithelial Defect	11	55
	Impending perforated Corneal ulcer	5	25
	Symblepharon due to chemical injury	2	10
	Perforated Corneal ulcer	2	10
Site of Corneal	Central	13	65
	Paracentral	4	20
	Peripheral	3	15
Extent of Corneal Involvement	<25%	2	10
	25-50%	4	20
	50-75%	5	25
	>75%	9	45

Table 3: Preoperative severity of symptoms

Symptoms	Mild	Moderate	Severe
Pain	4 (10%)	16 (40%)	20 (50%)
Photophobia	6 (15%)	16 (40%)	18 (45%)
F.B. Sensation	6 (15%)	15 (37.5%)	19 (47.5%)
Watering	7 (17.5%)	12 (30%)	21 (52.5%)
Redness	8 (20%)	12 (30%)	20 (50%)
Discharge	21 (52.5%)	10 (25%)	9 (22.5%)
DOV	2 (5%)	10 (25%)	28 (70%)

The use of freeze-dried amniotic membrane grafts for managing corneal surface disorders has gained attention among ophthalmologists in recent years. Interestingly, the use of amniotic membrane in the treatment of corneal disorders had disappeared from the literature for a period of time, and it has been reintroduced.

The objective of the current study was to identify predictors of treatment success in corneal surface disorders. The study included 40 patients with corneal surface disorders who were divided into two groups. Group A received traditional medical management, while Group B underwent amniotic membrane grafting at Nehru Hospital, which is affiliated with B.R.D. Medical College in Gorakhpur. The majority of the patients were between 40 and 60 years old. Among the patients, males accounted for 57.5% of the cases, outnumbering females (42.5%) with a ratio of 1.35:1.

A separate study conducted by Dogru et al., (2002) at the Department of Ophthalmology in Turkey involved the application of preserved amniotic membrane grafts in 10 patients (3 females, 97 males) aged between 25 and 76 years (54.5 ± 16.5 years). The amniotic membrane grafts were utilized in the treatment of persistent corneal epithelial defects accompanied by stromal ulceration. The study findings indicated that the use of amniotic membrane grafts showed potential benefits in managing epithelial defects and stromal ulcers.[22]

The case studies included a diverse range of corneal disorders. Among the patients, 11 (55%) had persistent epithelial defects, 5 (25%) had impending perforated corneal ulcers with controlled infection and inflammation, 2 (10%) had corneal perforations resulting from corneal ulcers and trauma, and 2 (10%) had symblepharon caused by chemical injuries with denuded epithelium. The majority

Table 4: Relief from postoperative symptoms in both the group A and group B

Groups	Follow up (after week)			
	1 Week.	4 Week.	8 Week.	Not relieved
Relive of pain				
Group A	2	6	8	4
Group B	5	12	2	1
Relief of photophobia				
Group A	3	2	12	3
Group B	1	11	7	1
Relief of f.b. sensation				
Group A	3	7	8	2
Group B	8	9	3	0
Relief of watering				
Group A	2	8	7	3
Group B	4	10	5	1
Relief of redness				
Group A	1	8	9	2
Group B	6	11	2	1
Relief of disharge				
Group A	8	5	4	3
Group B	14	5	1	0

Table 5: Final outcome of treatment

Final outcome	Number of Patients		P Value
	Group A	Group B	
Success	12 (60%)	17 (85%)	
Failure	8 (40%)	3 (15%)	0.039
Total	20	20	

Table 6: Uncorrected visual acuity

Follow Up (After Weeks)	Number of Patients	
	Group A	Group B
At Presentation	+2. 6773	+2. 7970
One	+2. 1055	+1. 3041
Four	+1. 1506	+1. 0379
Eight	+0. 8559	+0. 7687

of the patients (36%) had Grade-4 corneal defects, involving more than 75% of the corneal area, with a significant proportion affecting the papillary area. Many patients sought medical attention after a considerable delay from the onset of symptoms.

The clinical presentation was similar across all cases, with patients experiencing symptoms such as pain, foreign body sensation, photophobia, discharge, watering, redness, and diminished vision. In most cases, the symptoms were severe. Our postoperative results revealed that relief from these symptoms was observed in the fourth week of follow-up in Group A and in the eighth week in Group B. It was also noted that a higher proportion of patients in Group B experienced relief from postoperative symptoms compared to those in Group A. Similar findings were reported by Hamza and Ullah (2009),[23] who observed remarkable improvement in ocular irritation symptoms in over 90% of cases after amniotic membrane transplantation (AMT).

In our study, the success rate in the group treated with AM was 85%, whereas the non-AM-treated group had a success rate of only 60%. Similar results were reported by Casalita et al. (2020),[24] where successful outcomes were observed in 90% of cases with moderate severity and 70% of cases with severe severity. Another study conducted by Schuerch et al. (2020)[25] demonstrated a treatment success rate of 70% in all patients.

In our study, the preoperative median of logMAR visual acuity was +2.67 in Group A and +2.79 in Group B, equivalent to 20/4000 on the Snellen chart. By the last week of follow-up (8th week), the logMAR visual acuity improved to +0.85 in Group A and +0.76 in Group B, which corresponds to 20/120 and 20/80 on the Snellen chart, respectively. Similar results were reported by Ferreira et al. (2020),[26] where the median preoperative logMAR visual

acuity was 1.30 (approximately 20/400 on Snellen chart), and the median postoperative logMAR visual acuity was 1.0 (approximately 20/200 on Snellen chart) with a significant median improvement of three lines of visual acuity. Another study by Abouhussein et al. (2020)[27] observed a mean preoperative logMAR visual acuity of 1.87 ± 0.31, which improved to a mean logMAR visual acuity of 0.67 ± 0.17 at the 6-month follow-up. Complete retinal reattachment with macular hole closure was achieved in all patients. Casalita et al. (2020)[24] also reported improvement in visual acuity, with baseline uncorrected visual acuity (UCVA) improving from 2.48 logMAR to 1.30 logMAR within 3-4 weeks postoperatively and further improving to 0.94 logMAR at the last follow-up.

The use of amniotic membrane grafting in corneal disease has shown excellent results, surpassing those obtained with conventional medical management.

5. Conclusion

In conclusion, our study highlights the effectiveness of amniotic membrane grafting (AMG) as a surgical intervention for corneal disease. The use of AMG has demonstrated significant improvements in corneal healing and symptom relief in patients with corneal surface disorders. These findings support the growing recognition of AMG as a valuable technique in ophthalmology. However, further research is warranted to investigate the long-term outcomes and potential benefits of AMG in a larger patient population. Studies with standardized follow-up protocols are needed to provide more comprehensive insights into the healing process of the cornea after AMG. Additionally, future studies should aim to elucidate the broader applications and advantages of amniotic membrane grafting in various corneal pathologies. Continued research and advancements in this field will likely enhance our understanding and utilization of this tissue in ophthalmic surgery.

6. Source of Funding

None.

7. Conflict of Interest

None.

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