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Evaluation of Post-Surgical Astigmatism in Patients with Recurrent Pterygium Managed by Amniotic Membrane Graft.

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Abstract:

Background: Pterygium surgeries always give some amount of astigmatism to the eyes. The pathogenesis of pterygia is strongly correlated with UV light exposure, although environmental insults such as exposure to dust, wind, or other irritants causing chronic ocular inflammation may also be considered as factors.

Until progressing on to the cornea, recurrence will first be observed in the conjunctiva. Repeat surgery, which is difficult, is associated with further scarring, and is prevented by treating the recurrent pterygium before the cornea gets involved. The operation of a recurrent pterygium should be stopped before it progresses to true recurrence to prevent repeated surgery.In this study we have managed the recurrent pterygium by Amniotic Membrane Graft and evaluated the amount of astigmatism in it. Similar study has not been conducted in the past.

Objectives: To evaluate astigmatism pre-operatively, post-operatively, compare the pre-operative and post- operative astigmatism in recurrent pterygium managed by amniotic membrane graft, to evaluate and assess any post-surgical complications in recurrent pterygium surgeries and to compare astigmatism post-operatively in patients with temporal and nasal pterygium.

Methodology: After considering the inclusion and exclusion criteria, the study subjects in the case group will undergo ophthalmological examination which would include Lacrimal

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Sac syringing, Best Corrected Visual Acuity estimation, Slit lamp examination, Corneal Topography, Auto Refractometer and Subjective Refraction. The patients would be operated with Amniotic Membrane Graft and would be given Dexamethasone, Moxifloxacin and Carboxy Methyl Cellulose eye drops in the post-operative period. Patient follow-up will be conducted for astigmatism estimation on postoperative day 1, day 15, day 30 and day 60.

ExpectedResults: The use of Amniotic Membrane Graft should reduce the incidence of astigmatism in recurrent pterygium.

Keywords: Pterygium, Amniotic Membrane Graft, Astigmatism.

INTRODUCTION

A Pterygiais a wing- shaped degenerative condition involving sub-conjunctival and fibrovascular tissue that encroaches upon the cornea.[1]With proximity to the equator, the incidence of pterygia gradually increases, and the disease is more prevalent in men than women, in people aged 20-30 years (the most common age range for the onset of pterygia), and in people who work outside.UponHistopathology, it showsbasophilicdegenerationof the elastoticfibres that invades the superficial cornea, which is preceded by dissolution of the Bowman layer.Apigmentediron line(Stockerline)mightbeseeninthecornea,anteriorto the edge of the pterygium. A pterygium must be distinguished from a Pseudopterygium,whichmayoccuraftertraumaorchemicalburnsorsecondary to an inflammatory cornealdisease.There are population-based surveys conducted in several countries which shows world-wide prevalence of pterygium ranging from 0.3% to 37.46%.6,23 The prevalenceofpterygiainIndianswas9.5%.24MarmamulaSetalin 2013 observed prevalence of pterygium in Andhra Pradesh was11.7% [2]

Recurrent pterygia is characterized as any re-development of any fibrovascular growth extending at the site of surgical excision through the limbus to the cornea, the fibrovascular recurrence reaching the same degree of corneal invasion as the original lesion, or re-growth to the cornea exceeding 1 mm.It is more common in younger patients with thick aggressive primary pterygium and are more aggressive in their growth characteristics and are more difficult to treat. A more aggressive, fibrovascular growth pattern is displayed by recurrent pterygium and is therefore more likely to trigger significant amounts of

1) conjunctival inflammation that results in restriction of symblepharon and motility,
2) scarring of the cornea, and
3) deficiency of limbal stem cells (LSCD), making it difficult and risky to conduct repetitive surgery.

For these factors, the failure rate for recurrent pterygium surgery is normally much greater. [3].In pterygia, the overlying epithelium may exhibit mild squamous metaplasia, for example, loss of goblet cells and surface keratinization. Some studies have demonstrated that there is abnormal expression of Ki-67; dysregulation of tumour suppressor genes, such as p53and p63, and other genes that helps in DNA repair; proliferation of cells, migration of cells, and angiogenesis; loss of heterozygosity; and microsatellite instability. When conjunctival squamous neoplasia arises, it often occurs overlying an area of pre- existing elastotic degeneration.

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Grading of Pterygium

Grade 1 applies to the cornea by less than 2mm. A deposit of iron (Stocker line) may be seen in the corneal epithelium anterior to the advancing head of the pterygium.

Grade 2 requires up to 4 mm of cornea, which after surgery can be primary or recurrent. They can interfere with and induce astigmatism from the precorneal tear film.

Grade 3- Invades the cornea by more than 4 mm. Extensive lesions can be associated with fornice-spread subconjunctival fibrosis, particularly if chronic, which may often cause restrictions on mild eye motility.

Grade 4.Invades the pupillary region and the visual axis. [4]

Recurrence will first be found in the conjunctiva before spreading to the cornea. By treating the persistent pterygium until the cornea gets involved, repeat surgery, which is difficult and is associated with more scarring, is avoided. In order to avoid recurrent surgery, the procedure of a chronic pterygium should be stopped before it leads to true recurrence.

A review of the ophthalmic literature shows that de Rotth first mooted the principle of using amniotic membrane as a graft in ocular surface disease in 1940. He used live fetal membrane, containing both amnion and chorion, for conjunctival surface reconstruction. Kim and Tseng reported the effectiveness of using preserved Amniotic Membrane as a substrate to reconstruct rabbit corneas with limbal stem cell deficiency in 1995. There has also been a surge in interest in the use of amniotic membrane as an ophthalmic surgical procedure for ocular surface repair following advances in the process of amniotic membrane preparation and preservation.

- The advantages of using Amniotic Membrane grafts include:
- Less pain (as no donor site is injured)
- Shorter period of surgical time
- Quicker recovery of patients
- Capable of covering a larger defect
- Better result for cosmetics [5]

Astigmatism is a common vision condition that causes blurred vision. When the cornea is irregularly shaped or sometimes due to the curvature of the lens inside the eye, this occurs. A typical topographic picture of a cornea without astigmatism reveals a relatively uniform color pattern centrally at the periphery with natural flattening. With-the-rule corneal astigmatism on the hemi-meridional side of the pterygium is usually caused by the pterygium. The extension of the pterygium to the cornea and the amount of induced astigmatism are substantially associated. [6]

Regular astigmatism is a uniform steepening along a single corneal meridian with a cylindrical lens that can be completely corrected. A symmetric "bow-tie" pattern around a single meridian with a straight axis on both sides of the middle is demonstrated by topographic imaging of natural astigmatism. The bow-tie pattern on topographical maps is an

artifact of Placido-based imaging because at the central measurement point the Placido picture does not feel curvature, the corneal meridional steepening appears to vanish centrally and worsen as the image travels away from the Centre.

Irregular astigmatism is non-uniform corneal steepening from a number of causes that may not be reversed by cylindrical lenses. The best corrected visual acuity (BCVA; also called corrected distance visual acuity, CDVA) is decreased by irregular astigmatism and, depending on the degree of irregularity, may decrease contrast sensitivity and increase visual aberrations. By bridging the irregular corneal surface and the contact lens with the tear film, rigid gas-permeable and hard contact lenses may restore visual acuity reductions arising from corneal irregular astigmatism.

Despite its higher cost, amniotic membrane transplantation has been introduced as an alternative to conjunctival autografting. It is composed of a simple epithelium basement membrane and an avascular stromal layer. It has been shown that the basement membrane of the amniotic membrane promotes epithelial adhesion, growth and differentiation. The tissue also has anti-inflammatory properties: it has been shown to facilitate activated apoptosis of inflammatory cells, promote phagocytosis and increase the expression of anti-inflammatory cytokines, such as IL-10.
In addition, the tissue has been shown to inhibit myofibroblast proliferation and differentiation and to assist the eye's anti-scarring efforts by suppressing TGF-beta signaling. It has also been shown that the transformation of pterygial fibroblasts into an invasive phenotype may be caused by an inflammatory insult. Therefore, by reducing inflammation and amniotic membrane scarring, we can lower the risk of pterygium recurrence. Theoretically, during pterygium surgery, these properties make it an excellent alternative for a tissue graft.

In 2012, Arain MA et all and Monero Lopez R concluded in 2004 that the use of the amniotic membrane tended to be healthy and safe and associated with lower rates of recurrence compared to the bare sclera technique. [7, 8]

Recurrent Pterygium Excisionneeds skillful dissection because of extensive fibrosis of the pterygium to the sclera and cornea, distortion of tissue planes and normal anatomy, and symblepharon formation. For Wallend M. in their research on the effects of recurrent pterygium on corneal topography in 1994, et al concluded that recurrent pterygia is considered to cause higher levels of astigmatism than its primary counterparts. [9]

Complications of pterygium surgery include recurrence of the pterygium, conjunctival granuloma, subconjunctivalhaemorrhage, corneoscleraldellen, epithelial inclusion cysts, graft retraction or necrosis, corneal or scleral melt with the use of antimetabolites or beta radiation, and conjunctival fibrosis. Few of the related studies were reported [10-12].

Rationale: We are carrying this study because in rural areas as the main occupation is farming there is a lot of exposure to UV rays which is the most implicated cause of pterygium

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and it is managed by the conventional bare sclera technique. By this we support that more cases of recurrent pterygium should be managed by amniotic membrane graft whenindicated.

OBJECTIVES

-To evaluate astigmatism pre-operatively in recurrent pterygium
-To evaluate astigmatism post-operatively in recurrent pterygium managed by amniotic membrane graft
-To compare the pre-operative and post-operativeastigmatism
-To evaluate and assess any post-surgical complications in recurrent pterygium surgeries
-To compare astigmatism post-operatively in patients with temporal and nasal pterygium

MATERIAL

SETTINGS: The study will be conducted at the Ophthalmology Department, AVB Rural Hospital, Wardha.

RESEARCH DESIGN: This is a hospital oriented Cross-sectional interventional Study.

STUDY DURATION: This would be a two yearlong study from September, 2020 to September, 2022.

PARTICIPANTS: All the patients, attending the Ophthalmology OPD at Acharya Vinoba Bhave Rural Hospital will be selected for the study after taking the inclusion and exclusion criteria into consideration.

INCLUSION CRITERIA

- Patients of more than 18 years of age of bothsexes up to 50 years of age.
- Patients with all grades of recurrent Pterygium.
- Patients consenting for the study.

EXCLUSION CRITERIA

- Patients with dacryocystitis, conjunctivitis, keratitis and other ocular or adnexal infectiveconditions.
- Patient with corneal degenerative conditions like keratoconus and keratoglobus.
- Patients with ocularttrauma.
- Patients who have previously undergone any ocular surgeries other than pterygium surgery.
- Patients with any pathologies of lens and posterior segment.
- Patients with di-headed pterygium.

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Sample size:

Sampling would be done by single blinded randomized control trial. MarmamulaSetalin 2013 observed prevalence of pterygium in Andhra Pradesh was11.7% [02]

Using sample size formula with desired error of margin

$$n = \frac{Z^2 \ \alpha/2 * P * (1-P)}{d^2}$$

Where

Zα/2 is the level of significance at 5 % i.e. 95 % confidence interval =1.96
P=Prevalence of Recurrent Pterygium= 11.70% =0.1170
D=Desired error of margin=7%=0.07

$$n = \frac{1.96^2 \text{x } 0.1170 \text{ x } (1-0.1170)}{0.07^2}$$

=72.06
n=75
75 eyes would be taken for evaluation of Astigmatism in recurrent Pterygium that has been managed by Amniotic Membrane Graft.

METHODS

An informed consent would be obtained. A proforma would be prepared meeting the demands of the study.

Patient Data collection: After enrollment, patients would be interviewed for the demographicdatasuchasage,sex,occupation.Patientswouldbeaskedaboutthe complaints and detailed history was taken regarding symptomatology and duration of recurrent pterygium. All the findings would be documented in a predesigned and pretested proforma (AnnexureI).

PRE-OPERATIVE EVALUATION: The patient would be explained about the procedure & would have the right to withdraw consent at any given time during the period of the study.

Ocular examination of the patients:

A. VISUALACUITY

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The presenting distant UCVA and BCVA of all the subjects would be measured by Snellen's visual acuity chart or illiterate C chart under standard conditions for Right followed by the Left eye.

B. ANTERIOR SEGMENTEXAMINATION

Slit lampexamination

Externaleyeexaminationwould be performed for adnexal abnormalities and conditions like enophthalmos, exophthalmos, buphthalmos, phthisis, presence of squint and nystagmus. Lid examination would be done which would include ectropion, entropion and any other lidabnormality. Detailed anterior segment examination would be done under slit lamp for the diagnosis of pterygium. The recurrent status would be known by history. The pterygium which were encroaching on the cornea would be measured from limbus with the beam of the slit lamp. The location of pterygium would be recorded and grading would be done.

C. INVESTIGATIONS:

Lacrimal Sac syringing, BCVA, Slit lamp exam, Corneal Topography, Auto-Refractometer and Subjective Refraction.

SURGICAL METHOD:

The eye undergoing surgery would be prepped and draped. The head of the pterigia would be undermined and dissected at the limbus after anesthesia which would be either local, subconjunctival, or peribulbar anesthesia, and dissected with Westcott scissors into the central cornea.An additional 1 to 2 mm margin of conjunctival tissue would be dissected after excising the head and most of the body, thereby revealing the bare sclera and creating a possible amniotic membrane room. There will be minimal cautery that would be applied.It would eliminate residual attachments of the Tenon fascia and conjunctiva and would be utilized to smoothen the peripheral cornea and limbus by scraping the region with a beaver blade and/or diamond-dusted burr on a high frequency drill.

The amniotic membrane will be cut to the required size inside its surgical packaging. There is a basement membrane surface in the amniotic membrane and it would be essential to leave the basement membrane on top, away from the sclera.The basement membrane side is on the upper surface opposite the cellulose paper on which the amnion is placed in the packaged frozen wet-form. MMC must be positioned in the subconjunctival space prior to the application of the amniotic membrane to prevent pterygium growth from recurring. Bare sclera air contamination can be avoided.

The amniotic membrane would be secured into position with sutures. However, fibrin glue can also be used in conjunction with the amniotic membrane.

FOR FIBRIN GLUE: The 2 Tisseel VH fibrin sealant components are prepared by the surgical assistant while the pterygium is removed by the surgeon. In order to shape the fibrin clot in 2 ways, the substance may be transferred to the eye surface. The first technique could

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be the use of the Duploject syringe of the Tisseel VH pack, and the second technique might be the direct placement of the fibrinogen solution drop on the scleral bed.

At the end, the speculum would be removed and the eye would be checked to make sure the graft is in place safely. The eye would be sealed over the ocular surface and an antibiotic-steroid ointment would be added. [5]

POST-OPERATIVE CARE: Steroid eye drop(dexamethasone)wouldbegiven4timesadayinitiallyandtaperedover45 days,whileantibioticeyedrop(moxifloxacin)wouldbeadministratedfourtimes adayfor15days. It will be treated for 30 days by lubrication eye drop 4 times a day (carboxy methyl cellulose 0.5%).

FOLLOW UP: All patients should be followed up periodically on day 1, day 15, day 30 and day 60 of postoperative surgery.

The following outcome variables will be measured for patients: Best Corrected Visual Acuity, Slit Lamp Evaluation, Corneal Topography, Auto Refractometer (for astigmatism assessment) and Subjective Refraction.

Statistical methods: It will be carried out using descriptive and inferential statistics using Pearson's chi-square test and version SPSS 24.0 and version GraphPad Prism 7.0 will be the software used in the analysis. It is believed that the statistical significance will be $p<0.05$.

Expected Outcomes: In this study we expect to see reduction in astigmatism post-surgery with Amniotic Membrane Graft.

DISCUSSION

The results obtained after appropriate statistical analysis will be discussed along the lines of similar or related studies done previously and conclusions from the findings will be drawn from the same.

LIMITATIONS

-This study has a cross-sectional studydesign.
- The sample size is small, and to validate these findings, further larger studies are needed.

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