Original Research Article

Comparison between suturless and glue free aminotic membrane graft versus suturless limbal conjunctival autograft in primary pterygium

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Abstract

Aim: To compare the outcome of primary pterigium excision with amniotic membrane and conjunctival auto graft. **Methods:** This study was carried out in the premises of rural-based tertiary hospital, A comparative prospective study was performed in 150 patients (150 eyes) with primary Nasal and Temporal pterigium, these were randomized to undergo pterigium surgery using!0-0 vicry suture (50 eyes) with autologus blood to attach amniotic membrane graft(100 eyes) from October 2014 to 2016 mean follow up was 18 months. Outcome measure were duration of surgery, complications, postoperative discomfort and recurrence of pterigium. **Result:** Average operative time was 24±5.64 minutes in group one and 28.64±6.45 minutes in group 2, symptoms such as pain, photophobia, foreign body sensation, watering, chemosis were significantly less in subject treated with aminotic membrane. **Conclusion:** The use of amniotic membrane graph in pterigium surgery significantly reduces operative time and patients symptoms of pain and discomfort.
Key word: conjunctival excision amniotic membrane graph pterigium.

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INTRODUCTION

Peterygium (derived from pterygion, ancient Greek for wing) is common ocular disease seen mostly in tropical and subtropical areas between the latitudes 30 north and south of the equator. Pterygium is an abnormal overgrowth of fibrovascular tissue arising from the subconjunctiva toward the cornea, almost always in the palpebral fissure and thought to be cause by increased light exposure, dust, dryness, heat and wind. Although it can be easily excised, it has a high rate of recurrence ranging from 24% to 89%. Recently, with the popularity of conjunctival autograft and use of antimetabolities such as mitomycin C and 5-Fluorouracil the incidence of recurrence has been greatly reduced up to 12%. The role of carbon dioxide and eximer lasers in pterygium surgery remains uncertain. Additionally, the relative benefit s and risks are debatable of physiochemical methods to prevent recurrence. For example possible complication of mitomycin C and beta-irradiation include aseptic necrosis of the sclera and cornea, cataract, persistent epithelial defects and visual loss. Therefore, simple surgical procedure that can reduce the recurrence rate to an acceptable level with minimal complications and without the use of potentially toxic drugs or radiotherapy would be ideal for the management of pterygim. Recent reports favor the use of fibrin glue above sutures. The use of

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fibrin glue has been reported to improve comfort, decrease surgical time, reducee complications and recurrence rates. Suture-related complications include infection, prolonged operating time, postoperative discomfort, suture abscesses, buttonholes, and pyogenic granuloma which usually require a second surgery for removal and chronic inflammation. Plasma-derived fibrin glue has the potentional risk of prion disease transmission and anaphylaxis in susceptible individuals. Sutureless grafting has been used successfully in gingival grafts and represents a similar mucosal membrance tissue environment to the conjunctiva of the eye. In this study, we compare and evaluate the safety and efficacy of sutureless glue free limbal conjunctival autograft and conventional sutured autograft for the management of primary peterygium.

MATERIAL AND METHODS

The study sample was comprised of 150 eyes of 150 patients with primary peterygium. The patients complained of conjunctival injection, tearing, rapid growth with cosmetic concerns and encroachment of the papillary area threatening the visual axis or blurred vision from induced astigmatism. Exclusion criteria were inability to complete the two year follow up period, atrophic pterygium, pseudopterygium, ocular surface pathology, infection, previous limbal surgery or double head pterygium. The study adhered to the tenets of the Declaration of Helsinki for research in humans and informed written consent was obtained from all patients. All patients underwent a comprehensive ophthalmologic examination including visual acuity, refraction, slit lamp biomicroscopy, measurement of intraocular pressure, extraocular muscle movements and dilated funduscopy. Anterior segment photography was perfomed for documentation of pterygium size and morphology. The patients were randomly assigned into one of two groups :- group 1 underwent sutureless and glue less aminotic membraine graft (n=100 eyes) and group 2 underwent free limbar conjectival autograft with suturing (n=50 eyes). The technique used in our study is simple randomization technique. This technique maintains randomization of patient assignment to particular group. The most common and basic method of simple randomization is a coin toss for example with the two treatment group (group 1 Versus group 2), each side of the coin determine the assignment of each patient to a group. The goals of pterygium surgery were to remove the pterygium restore the conjunctival anatomy leave the cornea as smooth and clear as possible and prevent recurrence. Simple pterygium excision was perfomed under local anasthesia with topical paracain drops and 2% xylocaine gelly applied over pterygium. 1 cc of 2% xylocaine injection in belley of conjunctiva for anesthesia and for ballooning of the pterygium to separate it from the sclera. Excision consisted of detachment of the pterygium head using a crescent knife and dissection the body from the overlying conjunctiva in smooth clear plane as possible using blunt and sharp dissection. Subsequently, the subconjuctival pterygium tissue and the thickened segment of conjunctiva and adjacent. Tenoris capsule were excised leaving bare sclera. Then the size of bare sclera was measured with calipers and the area documented in mm^2.

Group 1: Hemostasis was allowed to occur spontaneously without use of cautery to privde autojonius fibril to glue the aminotic memrene. 2 mm larger than bare sclara area was taken from prepacked human aminotic memrene graft, graft is held in position for 5 minute by application of gentle pressure over graft with fine non toothed forceps. The stabilization of the graft was conturmed with edge on corneal side. The eye was bandage for 48 hrs. In group 2 for harvesting the conjunctival autograft. The globe rotated downward by asking patient to look down. Superior formix was injected with 1 cc of local anesthetics (Xylocaine 2%) to facilate separation of the conjectiva from Tenons capsula than a marker was use to mark the four corner of the conjunctiva limbal graft created 2 mm larger in width and length than recipient bed. A small opening was created and careful blunt dissection with wescott scissors was performed until the entire graft was free from Tenons reaching the limbus to include limbal stem cells that act as a barrier to the conjunctiva cells migrating on to the corneal surface, subsequently the edge of the graft were cut by vannas scissor, forceps is used to gently slide the graft to the recipient bed with the epithelial side up and keeping the limbal edge towards the limbal. The graft was sutue in position with 10/0 nylon. First the two limbal corners were sutured in the episcleara and than into the conectiva keeping the limbal edge of the graft in gentle streach then the posterior corners of the graft were sutured to the bulbar conjunctiva. Both group received subconjunctiva injection of corticosteroid and antibiotics at the end of procedure. Post-operatively a pressure eye patch was applied. Analgesia was prescribed two times daily. Post-opersative medication included Predforte eye drops (Allergen Inc., Irvine, CA, USA) four times daily, Tobradex ointment (Alcon Inc., Fort Worth, TX, USA) three times daily was used for 1 week then gradual tapering for 3 weeks and liberal use of topical lubricating eye drops four times daily for 4 weeks. The patients were instructed to avoid rubbing their eyes and avoid dust, heat, direct sun exposure. The patients were also advised to wear sun glasses to reduce UVB exposure. All patients were followed up after 48 h, weekly for one month then

for 3, 6, 9, 12 and 24 months postoperatively. Patients completed a questionnaire at each follow-up visit, especially during the visits for the first post-operative month (3 days, 1 week, 2 weeks and 3 weeks) grading pain, foreign body (F.B) sensation, photophobia, hyperemia and chemosis into four grades according to the intensity. The questionnaire was scored from (0 to 3) 0 = nothing; 1 = mild; 2 = moderate; 3 = severe. Additionally, the overall satisfaction with the pro-cedure 3 weeks post-operatively was recorded as four grades 0 = unsatisfied; 1 = low satisfaction; 2 = moderate satisfac-tion and; 3 = highly satisfied. The data were collected as mean scores and recorded. The two groups were compared for ocular signs and symptoms, and overall satisfaction. • The main postoperative outcomes noted were the recur-rence rate which was defined as fibrovascular proliferation invading the cornea more than 1.5 mm at the-site of previ-ously excised pterygium, graft dehiscence, graft retraction and the gain in uncorrected visual acuity (UCVA). The second-ary outcomes were duration of surgery, postoperative pain, foreign body sensation, photophobia, hyperemia, chemosis, overall satisfaction and the complications as, persistent epi-thelial defect, dellen, inclusion cyst, pyogenic granuloma, conjunctival edema, corneo-scleral necrosis, infective scleri-tis, keratitis and endophthalmitis.

Statistical analysis: Data are expressed as mean ± SD. Snellen acuity was con-verted to Log MAR for statistical analysis. Statistical analysis was performed using one-way ANOVA. SPSS 16 for Windows (IBM Corp., New York, NY, USA) was used for statistical anal-ysis. P-values less than 0.05 were considered statistically significant.

RESULTS

The pterygia were located nasally in all eyes' for both groups. Patient age in both groups ranged from 24 to 74 years. (mean, 49 ± 12 years). (Table I). There were 100 males and 50 females enrolled in this study. In 85 eyes, pterygia were present in the right eye and 65 in the left eye. F-,• present the data for group 1 and group 2, respectively). There was no statistically difference in age between groups (P> 0.05). The two groups were clinically similar regarding the size of the pterygium. Table 2 presents the main and secondary postoperative outcomes. The. recurrence rate was 6% (3 eyes) in group 1. All cases of recurrence in group 1 occurred after 3 months. The recurrence rate was 8% (8 eyes) in group 2. All cases of recurrence in group 2 occurred after 6 months. Graft dehis-cence occurred in 8% (4 eyes) in group 1 and there were no cases of graft dehiscence in group 2. In one patient graft dehiscence developed with eye trauma on the third post-operative day. In another patient it occurred following vigor-ous rubbing of the eye on the fourth postoperative day. In two patients it occurred due to inclusion of Tenons capsule leading to lack of adhesion, graft edema and thickening, which was seen on the fifth post-operative day in one patient and the seventh post-operative day in the other patient. All four patients were treated by suturing the same graft with (10/0 nylon sutures). Early graft retraction with exposure of sclera! bed occurred in 6 eyes (12%) in group 1 and in 6 eyes (6%) in group 2 within the first postoperative week due to conjuncti-val edema and chemosis. All cases were resolved with conser-vative management except one patient from group 1 who was managed with (10/0 nylon) sutures. The gain in uncorrected visual acuity (UCVA) occurred 3 months post operatively and ranged from 0.2 to 0.5 Log MAR in 10 eyes. Four eyes (8%) were from group 1 and 6 eyes (6%) were in group 2. All cases with a gain.in UCVA were due to clearance of visual axis occupied by pterygium pre-operatively. Conjunctival edema occurred in 8 eyes (16%) in group 1 and in 6 eyes (6%) in group 2. Most- cases of conjunctival edema resolved gradually within the first post-operative week. Faint corneal nebula occurred in two eyes (4%) in group 1 and in 4 eyes (4%) in group 2. Conjunctival granu-loma (Fig. 4) occurred only in group 2 in three eyes (3%), two of them treated by surgical excision within the first post-operative month and the other one resolved by conser-vative management. Conjunctival cyst and dellen each of them occurred in one eye (1%) in group 2. There are no anes-thetic complications, graft necrosis, symblepharon, sclera! necrosis or thinning, excessive bleeding, globe perforation or injury to medial rectus in all of patient groups. Figs. 5A—B and FA—B show a clinically significant differ-ence between groups in the postoperative mean score for signs and symptoms on visits day 3, 1 week, 2 weeks and 3 weeks post-operatively. The mean scores were statistically significant lower for group 1 for each factor graded, ($P < 0.05$). At 3 weeks post-operatively, the mean overall patients' satisfaction score was significantly higher for the group 1 ($P < 0.002$).

DISCUSSION

Surgical techniques for the management of pterygium vary, but high recurrence rates after successful excision remain a challenge. The aim of pterygium surgery is to excise the pterygium and prevent its recurrence. However, there are very few clinical guidelines for optimal treatment that lower recurrence and complication rates. The variety of techniques, range from the bare sclera procedure to more complex approaches, such as amniotic membrane transplantation and lamellar keratoplasty, including conjunctival autograft, and limbal

conjunctival transplant, conjunctival flap, conjunc-tival rotation autograft surgery, cultivated conjunctival trans-plant (ex-vivo expanded conjunctival epithelial sheet) and use of fibrin glue. Adjunctive therapies include Beta irradiation, Thiotepa, 5-Fluorouracil, Daunorubiciri, and mitomycin C (MMC).' Bare sclera excision (BSE) has an unacceptably high recur-rence rate (40-60%) and has become obsolete. BSE with per-ioperative MMC, ' preoperative subconjunctival injection, intraoperative application and postoperative drops had yielded better outcomes, but the risk of complications has made this procedure less favorable. BSE with beta irradia-tion/5 has resulted in encouraging outcomes (13% recur-rence); however it has toxic and serious complications. Pterygium excision with limbal conjunctival autograft, has been reported to be more effective with low recurrence. but it may compromise the corneal stem cell population. Additionally, adjunctive use of amniotic membrane graft results in low recurrence but costly. Fibrin glue has been used as an alternative to sutures for securing the conjunctival grafts. A study has reported recur-rence rate of 5.3% for glue versus 13.5% for sutures and sug-gested that immediate adherence of the graft and lack of postoperative inflammation may inhibit fibroblast ingrowth and reduce the recurrence. - The main issue in using com, mercial fibrin glue, despite viral inactivation techniques, is the transmission of infectious agents such as parvovirus B19 (HPV B19) and prions/ Furthermore, anaphylactic reaction has been reported after the use of (TISSEEL) fibrin sealant which was due to bovine protein aprotining Foroutan *et al*. prepared autologous fibrin glue, though much safer but it is not yet used widely because of the duration it takes to pro-cure the fibrin and lack of laboratory facilities at all centers. Fibrinogen compounds may be susceptible to inactivation by iodine preparations used for conjunctival disinfection before pterygium surgery. In our study we compared the two techniques of suture-less and glue free conjunctival limbal autograft (groupl) with the conventional sutured conjunctival limbal autograft (group2) in primary pterygium surgery. The recurrence rate (6%) in group 1 was comparable to group 2 (8%). Massaoutis *et al*. stated that the concept of surgical success in pterygium surgery can be defined as the provision of a.white cosmetic conjunctiva, with no persis-tent symptoms and a low recurrence rate (less than 10%). The recurrence rate in our study agrees with The Massaoutis *et al*.'s criteria. The recurrence rate.is also similar to Malik *et al*.' who reported recurrence rate of 2.5% using a similar procedure of sutureless and glue free graft. Graft dehiscence is a recognized complication of tech-niques using Froutan *et al*. reported 13.33% rate of graft dehiscence using autologous fibrin and attributed this to a low concentration of thrombin and fibrinogen in autologous glue compared to a commercial preparation. In our study graft dehiscence occurred in 4 eyes (8%) in group 1, and did not occur in group 2. The four cases in group 1, were due to either eye trauma, or a patient rubbing his eye vigorously and inclusion of Tenons capsule with the graft. Hence, we instruct, patients to use a protective shell, and not to rub the eye in the 1st week post-operatively. Addition-ally, meticulous dissections of thin donor limbal conjunctival autograft free of Tenons capsule are mandatory for success-ful graft uptake. Graft retraction was reported by Tan who advocated sub-conjuctival fibrosis and recommended meticulous dissec-tion of sub-epithelial graft tissue. Foroutan *et al*.'" reported 20% of cases with graft retraction, in our study graft retrac-tion occurred in 6 eyes out of 50 (1`)/0) eyes in group 1 and 6 eyes (6%) in group 2. All the cases of graft retraction were due to conjunctival chemosis and edema and were resolved with conservative treatment except one case in group 1 which progressed to graft dehiscence and was sutured with 10/0 nylon. In comparison, Wit *et al*. reported no graft dis-placement and postulated that sutureless and glue free graft. resulted in even tension across the whole graft interface and no direct tension on the free edges resulting in reduced stim-ulus for sub-conjunctival scar.formation. Wit *et al*.' also pro-posed that the opposition of the eye lids to the bulbar conjunctiva provides a natural biological dressing, compres-sion, and a smooth frictionless surface. Pyogenic granuloma occurred in 3 eyes out of 100 (3%) eyes in group 2 and did not occur in group 1, cyst formation occurred in one eye (1%) in group 2 and dellen also occurred in one eye (1%) in group 2. These outcomes indicate that complications related to sutures are more common in group 2 despite using 10/0 nylon which induces minimal reaction and were removed after 2 weeks with some discomfort and foreign body sensation post-operatively. WE noted that some patients were not co-operative at the slit lamp during suture removal. Conjuctival edema occurred in our study in 8 eyes (16%) in group 1 and (6%) in group 2, using interrupted 10/0 nylon suture in group 2 which allows for any fluid build up to escape through the intervening spaces rather than precipitating a minimal reaction. Most of the cases resolved spontaneously with conservative treatment. The mean operative time. in group 1 was 24 (±5.64) min and 28.64 (±6.45) min in group 2. These times are compara-ble however' they are longer than other studies: 2 using fibrin glue which reported average operative time of 16 min (range 14-16) and 20 min (range 20-29) in suture group and reported 14 (±1.4) min in suture-less and glue free con-junctival autograft. Although, our study was conducted over a two-year duration, we believe it was

worthwhile to provide the patients with the benefits of suture-less and glue free conjunctival limbal autograft. Our results confirmed significantly lower post-operative signs and symptoms including pain, FB sensation, photopho-bia, hyperemia and chemosis at all visits in the first post-operative month as well as significantly higher overall patient satisfaction in group 1 compared to group 2. None of our patients developed serious complications such as sclera' necrosis, sclera thinning, graft necrosis, symblepharon, excessive bleeding, medial rectus muscle injury, or globe perforation.

CONCLUSION

Suture-less and glue free Amniotic Membrane graft is safe, effective, economical, and its surgical outcomes following primary pterygium surgery are comparable to conventional suture limbal conjunctival autograft with lower post-operative suture related complications, less patient discomfort and greater patient satisfaction.

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