THE EFFICACY OF FIBRIN GLUE Vs SUTURES FOR ATTACHING CONJUNCTIVAL AUTOGRAFTS AFTER PTERYGIUM EXCISION: A RANDOMIZED CLINICAL TRIAL

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ABSTRACT

BACKGROUND AND OBJECTIVE

Fibrin glues have been used in an array of ophthalmic procedures such as conjunctival closure in strabismus, vitreoretinal and glaucoma surgery. The present study was undertaken to assess the efficacy of fibrin glue versus suture in patients undergoing conjunctival autografting and also to compare operative time and post-operative complications.

METHODS

This one year randomized controlled trial on 44 patients with primary pterygium was conducted at Department of Ophthalmology, Santhiram Medical College, Nandyal, during the period of March 2010 to December 2010. Based on the computer generated randomization, these patients were divided into two groups namely, Group 1 (Fibrin glue group: n=22) and Group 2 (Suture group: n=22).

RESULTS

In the present study, equal distribution of sex (50%) was seen in Group 1 and in Group 2. Female preponderance was seen with male-to-female ratio of 1:2.14. The mean age in Group 1 was 51.74±13.65 years and in Group 2 it was ±13.75 years. All the patients in both groups presented with fleshy mass.

Most of the patients (77.27%) in both the groups had Grade 2 pterygium. Majority of the patients (95.45% in Group 1 and 100% in Group 2) had progressive type of pterygium. Among the majority of patients (86.36%) in Group 1, the surgical time was significantly less (21 to 30 minutes) compared to Group 2 where 86.36%.

KEYWORDS

Pterygium, Autograft, Fibrin Glue

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INTRODUCTION

Pterygium has been described as a triangular wing shaped encroachment of the bulbar conjunctival tissue onto the cornea.¹ It can vary from small, atrophic quiescent to large, aggressive, rapidly growing fibrovascular degenerative lesions that can distort the corneal topography. In advanced cases, it can obscure the optical center of the cornea causing visual disturbances.²

Pterygium is a common disorder in many parts of the world with reported prevalence rates ranging from 0.3 to 29%.³ Epidemiological studies^{4,5} suggest an association with chronic exposure to sunlight with an increased geographical prevalence within a peri-equatorial 'pterygium belt' of latitudes of 378 North and South of the equator.

The risk factors for pterygium include areas with more ultraviolet radiation,⁶ hot, dry, windy, dusty and smoky environments.^{4,7} There is also a hereditary factor.⁸

Limbal stem cells are indispensable for maintenance of healthy ocular surface and are thought to create a barrier against the growth of conjunctival fibrovascular tissue into the cornea and thus play a role in pathogenesis of pterygium.

When deeper parts of the limbal epithelium is damaged or removed, an abnormal corneal surface is produced. The characteristic changes are conjunctival epithelial in growth, vascularization and inflammation as seen in pterygia.⁹

Anti-inflammatory drugs and lubricants have an important role in minimising the patient's discomfort, but do not cure the disease. Hence, surgical removal is the treatment of choice.⁹

The various treatments for pterygium are aimed at reducing recurrence of the lesion. Over the years, many surgical procedures to excise this recurrent disorder have been described.¹⁰

Earlier methods of pterygium excision like bare sclera technique or McReynolds operation were associated with high recurrence. Many techniques have been suggested as adjunct therapies such as β radiation, thiotepa, 5-FU and mitomycin C. High recurrence rates are weighted against eye threatening postoperative complications.¹¹

There have been many attempts to optimise pterygium surgery. Autologous conjunctival grafting is reported to be the best method, giving both low recurrence rate and few

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complications.¹²⁻¹⁴ Sutures have been used traditionally to attach the autograft. However, it requires higher surgical expertise and is associated with several disadvantages including prolonged operating time, postoperative discomfort and potential for suture related complications such as buttonholes, dellens ulcer, suture abscesses, symblepharon, granuloma formation, tissue necrosis and graft dehiscence.¹⁵

Hence, it is reasonable to try to replace the use of sutures with a tissue adhesive that can be applied to the eye surface. In effect, attempts have been made to attach the autograft in pterygium surgery with a fibrin solution to avoid sutures.¹⁶

Fibrin glues have been used in an array of ophthalmic procedures such as conjunctival closure in strabismus, vitreoretinal and glaucoma surgery.¹⁷ Because of its biological and biodegradable properties, fibrin-based adhesives may be used to attach the conjunctival autograft without inducing inflammation. Tissue adhesives of different types had been used in previous studies to attach conjunctival grafts and compared with the use of sutures were associated with a shorter operative time and reduced postoperative complaints.^{9,18-21} To date, only few studies.¹⁷⁻²¹ have reported efficacy of fibrin glue for attaching conjunctival autograft in pterygium study in Indian context and the results are inconsistent.

Hence, the present study was undertaken to assess the efficacy of fibrin glue versus sutures in patients undergoing conjunctival autografting and also to compare operative time and postoperative complications.

OBJECTIVES

The objectives of the present study were:

Primary

1. To study the efficacy of fibrin glue versus sutures.

Secondary

1. To study the operating time in the two groups.
2. To study the postoperative complications in the two groups.

REVIEW OF LITERATURE

The term pterygium comes from the ancient Greek word πτερυξ (Pteryx)=wing and πτερυγιον (Pterygion)=fin. Pterygium is characterized by a triangular portion of the bulbar conjunctiva encroaching onto the cornea.⁹ usually within the interpalpebral fissure and most often from the nasal side. It is a fibrovascular growth originating from subconjunctival tissue and encroaches the cornea involving the Bowman's layer and superficial stroma.

Histopathologically, it shows signs of elastotic degeneration of the conjunctiva. If not treated, it may encroach the entire pupillary axis and thus cause significant disturbances in the visual acuity. The contractile forces of pterygium on peripheral cornea leads to significant flattening of the horizontal meridian (with the rule astigmatism), which is proportional to the size of the pterygium.²²

Historical Aspects

Pterygium was also mentioned by Hippocrates around 400 B.C. He treated it with eye drops made of lead, zinc, copper, iron, bile juices, urine and maternal milk. Celsus (25 BC) and

Galenus (129 AD) also advocated complex topical solutions. Avicenna (1000 AD) proposed cutting the pterygium with scissors.²²

The next recorded study is of Celsus (Rome 50 AD), where he passes a needle and thread beneath the pterygium and with a sawing motion separates the tissue. It was then described by Vegabhatt (India 300 AD), Paul Aegineta (Greece-7th Century), Al Rhazes (Arabia-932 AD), Avicenna (Greece 980-1036 AD) and Chakradatta (India-1060 AD).²³

Pterygium was also described by Sushruta (India), the world's first surgeon ophthalmologist before 1000 AD. In Sushruta Samhita he describes: "With the patient recumbent on an operation table, the pterygium is loosened and disturbed by sprinkling powdered salt into the eye. With the patient looking laterally, a sharp hook is used to secure the growth at its loosened upturned part and is held up with a toothed forceps or a threaded needle is to be passed from below the part which would be held up with the thread. The pterygium is then scratched with a sharp round-topped instrument.

The root of the pterygium should be pushed as under from the black outline (Cornea) of the eye to the medial canthus and then excised and removed. Any remnant of the pterygium should be removed with a scarifying ointment to prevent recurrences.²²" In the nineteenth century Scarpa, Travers, Desmarres, Knapp, Klein, Prince, Boeckman, Wright, Hobby, Alt, Mackenzie and others have all suggested various methods for the treatment of pterygium.²²

For more than thirty centuries, man has tried to conquer this little growth. It has been incised, removed, split, transplanted, excised, cauterized, galvanized, heated, inverted, dissected, rotated, coagulated, repositioned, irradiated, excimer lasered, stripped and grafted. Despite the best techniques in the hands of the greatest surgeons, there have been recurrences and when the pterygium recurs it is much more aggressive.²²

METHODOLOGY

The present study was conducted in the Department of Ophthalmology, Santhiram Medical College, Nandyal, during the period of March 2010 to December 2010.

Study Design

One year randomized controlled trial.

Place

This study was carried out at Department of Ophthalmology, Santhiram Medical College, Nandyal.

Source of Data

Patients with primary pterygium attending Ophthalmology Outpatient Department at Santhiram Medical College, Nandyal.

Study Period

March 2010 to December 2010.

Sample Size

A total of 44 patients divided into two groups of 22 each were studied.

RESULTS

The present one-year randomized controlled trial on 44 patients with primary pterygium attending Department of Ophthalmology, Santhiram Medical College, Nandyal, was conducted during the period of March 2010 to December

2010.

Based on the computer generated randomization, these patients were divided into two groups as below:

- Group 1; Fibrin glue group: n=22.
- Group 2; Suture group: n=22.

The data was coded and compiled on Microsoft Excel spreadsheet. The data was analysed and results obtained are tabulated as below.

DISCUSSION

A number of surgical adjunct therapies have been advocated for management of pterygium, but an ideal procedure to minimize the postoperative inflammation and recurrence is not yet established. Conjunctival autograft is a simple and safe modality for the management of pterygium.

Graft suturing has the disadvantage of a relatively long surgical time and sutures may not participate in wound healing, thus causing additional trauma to graft tissue and risk of granuloma formation. Sutures might also act as nidus for inflammation, hence allowing infectious agents to enter along the suture tract.

More recently use of conjunctival autograft with fibrin glue application is gaining its popularity with varied outcomes. Fibrin glue is safe and effective method for conjunctival autografting in primary pterygium excision. The use of fibrin glue to attach the autografts is not only as stable as those secured with sutures, but also produce significantly less inflammation, better patient comfort, less operative time. Hence, the present study was planned to assess the efficacy of fibrin glue versus suture in patients undergoing conjunctival autografting and also to compare operative time and postoperative complications.

This one year randomized controlled trial on 44 patients with primary pterygium was conducted at Department of Ophthalmology, Santhiram Medical College, Nandyal, during the period of March 2010 to December 2010. Based on the computer generated randomization, these patients were divided into two groups namely, Group 1 (Fibrin glue group: n=22) and Group 2 (Suture group: n=22).

In the present study, equal distribution of sex (50%) was seen in Group 1 (male-to-female ratio 1:1). In Group 2, female preponderance (68.18%) was seen with male-to-female ratio of 1:2.14.

Similar pattern of sex distribution was reported in a study at Turkey. A prospective, randomized, hospital-based comparative study from India reported 22 females and 25 males out of 47 patients. Though the literature documents male preponderance, our study showed female preponderance in the second group and an equal prevalence in the first group which may be due to the fact that quite majority of patients come with cosmetic disfigurement and treatment. Also, as most of the women in our study came from rural areas and were exposed more to 'chullah' smoke, it may point towards one of the aetiological factors in development of pterygium.

CONCLUSION

The present study showed better efficacy of fibrin glue in conjunctival autografting among the patients undergoing pterygium excision in terms of pain, foreign body sensation, lacrimation and discomfort during blinking. Also, it

significantly reduced the surgical time with fewer postoperative complications.

SUMMARY

Fibrin glues have been used in an array of ophthalmic procedures such as conjunctival closure in strabismus, vitreoretinal and glaucoma surgery. Because of its biological and biodegradable properties, fibrin-based adhesives may be used to attach the conjunctival autograft without inducing inflammation. The present study was undertaken to assess the efficacy of fibrin glue versus suture in patients undergoing conjunctival autografting and also to compare operative time and postoperative complications.

This one-year randomized controlled trial on 44 patients with primary pterygium was conducted at Department of Ophthalmology, Santhiram Medical College, Nandyal, during the period of March 2010 to December 2010. Based on the computer generated randomization, these patients were divided into two groups namely, Group 1 (Fibrin glue group: n=22) and Group 2 (Suture group: n=22).

In the present study, equal distribution of sex (50%) was seen in Group 1 and in Group 2 female preponderance was seen with male-to-female ratio of 1:2.14. The mean age in Group 1 was 51.74±13.65 years and in Group 2 it was ±13.75 years. All the patients in both groups presented with fleshy mass.

Most of the patients (77.27%) in both the groups had Grade 2 pterygium. Majority of the patients (95.45% in Group 1 and 100% in Group 2) had progressive type of pterygium. Among the majority of patients (86.36%) in Group 1, the surgical time was significantly less (21 to 30 minutes) compared to Group 2, where 86.36% required 31 to 40 minutes. The mean surgical time in Group 1 was significantly less compared to Group 2 (25.83±6.23 vs 34.70±7.96 minutes).

The present study showed better efficacy of fibrin glue in conjunctival autografting among the patients undergoing pterygium excision in terms of pain, foreign body sensation, lacrimation and discomfort during blinking. Also, it significantly reduced the surgical time with fewer postoperative complications.

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