Clinical Outcome of Fibrin Glue versus Sutures in Conjunctival Autografts in Patients Undergoing Pterygium Excision - A Prospective Study from Kalaburagi, Karnataka

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ABSTRACT

BACKGROUND

Pterygium removal is prone for recurrence. Use of conjunctival autografting is considered the most suitable approach that can lower the recurrence. Traditionally, the conjunctival autograft (CAG) is attached to the sclera by suturing. Recently fibrin glue has been used as an alternative to suturing. Advantages being shortened operating time, improved postoperative comfort and absence of suture related complications. Fibrin glue (Baxter TISSEEL kit) is a biological tissue which has a fibrinogen component and a thrombin component prepared by processing plasma. On activation of human fibrinogen by thrombin it imitates the final stage of the coagulation cascade and acts as a tissue adhesive. Fibrin glue is absorbable, relatively easy to use and can be kept at room temperature or in a refrigerator. We wanted to compare the postoperative outcomes in patients undergoing pterygium surgery with conjunctival autografting using fibrin glue (fibrin glue group) in comparison to suturing with 10 - 0 nylon (suture group).

METHODS

This was a prospective study carried out at M.R. Medical College, Kalaburgi, in the Department of Ophthalmology. Patients with pterygium were enrolled into the study after taking informed and written consent. Clinical grading of pterygium was done as Grade 1 - < 2 mm onto cornea, Grade 2 – 2 to 4 mm onto the cornea, Grade 3 - > 4 mm onto the cornea. 100 subjects were randomly divided into 2 groups of 50 patients each undergoing pterygium surgery between Nov 2018 and Oct 2019. Group 1: Conjunctival autograft with 10 0 nylon suture. Group 2: Conjunctival autograft with fibrin glue. A post-operative comfort scale was used to assess pain, foreign body sensation and lacrimation. These patients were followed up on postoperative day 1, one week, 1 month for postoperative signs and symptoms and 6 months for any recurrence of pterygium.

RESULTS

Patients in the fibrin glue group experienced significantly less pain, foreign body sensation and lacrimation on day-one, 1 week and at 1 month after surgery, compared to those in the suture group. Other complications like graft oedema, graft retraction, corneal scarring, sub graft haemorrhage were noted in both the groups. At the end of 6 months follow up, no recurrence was noticed in both the groups.

CONCLUSIONS

The use of fibrin glue for attaching autografts in pterygium surgery is an effective method with global autograft success, less post-operative discomfort like pain, foreign body sensation, lacrimation and less chance of recurrence.

KEYWORDS

Pterygium, Conjunctival Autograft, Suture, Fibrin Glue

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BACKGROUND

Pterygium is a wing-shaped fibrovascular tissue that has proliferated onto the cornea.[1-3] Surgical removal is the treatment of choice and pterygium removal with conjunctival autografting has been considered the best and most suitable approach that can lower the recurrence rate of pterygium.[4] Traditionally, the conjunctival autograft (CAG) is attached to the sclera by suturing; however, with the advent of tissue adhesives in the ophthalmic armamentarium, fibrin glue usage gained momentum due to several of its advantages, including shortened operating time, improved postoperative comfort, and absence of suture-related complications.[5]

Indications for surgical excision of pterygium include visual loss due to extension close to the visual axis or induced astigmatism, restriction of eye movements, ocular surface irritation, potential future vision impairment, to enable accurate biometry before cataract surgery, or cosmetic concerns.[6] Fibrin glue is a blood-derived product that is absorbable, relatively easy to use, and can be kept at room temperature or in a refrigerator.[7] Fibrin glue (Baxter TISSEEL kit) is a biological tissue which has a fibrinogen component and a thrombin component prepared by processing plasma. On activation of human fibrinogen by thrombin, it imitates the final stage of the coagulation cascade and acts as a tissue adhesive.[8] None of the authors have any commercial interest related to materials or techniques described in this study.

Objectives

1. To compare the postoperative outcomes in patients undergoing pterygium surgery between the fibrin glue group and suture group.
2. To compare the recurrence rates between the fibrin glue and suture group.

METHODS

It is a Prospective study carried out in the Department of Ophthalmology, M. R. Medical College, Kalaburagi from November 2018 to December 2019. Institution ethics committee approval was taken. All clinically diagnosed cases of pterygium undergoing surgery were asked to participate in the study. Patients were followed up postoperatively on day 1, 1 week and at 1 month for any signs and symptoms and at 6 months for any recurrence of pterygium.

Inclusion Criteria

Patients with pterygium encroaching > 2 mm of cornea.

Exclusion Criteria

- Recurrent pterygium type.
- Pre-existing glaucoma.
- Patients on anticoagulants.
- History suggestive of any hypersensitivity to human blood products.
- Immune system, eyelid or ocular surface disease.
- History of previous ocular trauma.

Sample Size Estimation

Sample size was calculated using the formula

$$n = \frac{2(z\alpha + z\beta)2 \times p \times (100 - p)}{(\mathrm{p0} - \mathrm{p1})2}$$

Where,
Zα = 1.96
Zβ = 0.84
P = (p0 - p1)2
p0 = efficacy in 1st group (sutures)
p1 = efficacy in 2nd group (autologous fibrin-blood)
p0 - p1 = effect size
Group 1: Suture group (N = 50); Group 2: fibrin glue group (N = 50)

All patients fulfilling the inclusion criteria were explained about the nature of the study and its implications and a written informed consent was obtained before enrolment. Ocular examination included recording visual acuity with Snellen's chart (in patients with visual acuity less than 6 / 60, acuity was recorded as counting fingers at particular distance or hand movements or perception of light or projection of rays). Detailed anterior segment examination was done under slit lamp for the diagnosis of pterygium and characteristics such as grade, type and site were recorded. Routine investigations prior to pterygium surgery as a part of preoperative workup included CBC, ESR, RBS, HIV, HBsAg, Urine Routine & Microscopy, Bleeding Time, Clotting Time.

Surgical Technique

- Peribulbar anaesthesia was given
- Cleaning and draping of the surgical field with 5 % povidone iodine solution followed by a wash in the conjunctival cul de sac.
- All surgeries were performed under operating microscope.
- Under aseptic precautions, a wire speculum was placed to separate the lids. A superior rectus bridle suture was taken using 4 - 0 silk and was clipped to the drapes.
- The body of the pterygium with the involved Tenon's capsule was excised without damaging underlying medial rectus muscle and the overlying conjunctiva.
- The abnormal tissue at the limbal end of the pterygium was resected.
- The size of the conjunctival graft required to resurface the exposed sclera was determined using calipers in three directions - extent across the limbus, maximum circumferential extent across the bed, and maximum distance from limbus.

- A bridle suture was then used to rotate the globe downwards exposing the superior limbus and conjunctival surface
- Using a Westcott scissors, the graft was excised starting at the forniceal end.
- Care was taken to obtain the graft as thin as possible without button holing. Once the limbus was reached, the graft was flipped over on to the cornea and the Tenon's attachment at the limbus was meticulously dissected. The flap was then excised including the limbal tissue.

Group 1

After excising the graft, the conjunctival-limbal graft was slid onto the cornea. Without lifting the tissue off the cornea, it was rotated and moved onto its scleral bed with fine non-toothed forceps.

A limbal-limbal orientation was maintained. The graft was smoothened out in its bed and the position of the graft was secured using interrupted 10 - 0 nylon sutures. The superior rectus bridle suture was removed. Two drops of antibiotic drops were instilled in the conjunctival cul de sac and the eyes were firmly patched.

Group 2

After excising the graft, the conjunctival-limbal graft was slid onto the cornea. Without lifting the tissue off the cornea, it was rotated and moved onto its scleral bed with fine non-toothed forceps.

Using Baxter TISSEEL kit, a drop of fibrinogen and a drop of thrombin was placed on the bare sclera. The graft was placed on the bare sclera in such a way so as to maintain the original orientation of the juxta-limbal border towards the cornea.

The scleral bed was viewed through the transparent conjunctiva to ensure that the residual bleeding does not lift the graft. The free graft was held in position by application of gentle pressure over it. Small central haemorrhages were tamponade with direct compression.

Postoperative Advice

In both the groups post operatively topical antibiotic-steroid eye drops were used for six times a day for 1 week and then tapered to 4 times for 1 week, 3 times for 1 week, twice for 1 week and once daily for 1 week and then stopped. Lubricating drops were used for four times / day for six weeks.

Post-Operative Follow Up

All patients were followed up on 1st day, 1st week, 1 month. All eyes were examined on slit lamp for any complications and recurrence of pterygium. At every visit patient were assessed for the following outcome variables

1. Pain
2. Foreign body sensation
3. Lacrimation

The assessment of outcome variables was done using a questionnaire and the responses were graded on a scale of 0 - 3 as:

0 = absent - no symptoms

1 = Mild - Patient had tolerable symptoms which were present occasionally

2 = Moderate - Tolerable symptoms present throughout the day or intolerable symptoms present occasionally

3 = Severe - Intolerable symptoms present throughout the day. The operated eye was evaluated for the presence or absence of hemorrhage and displacement of graft. The overall appearance of the eye was assessed and graded as red or quiet. Further other complications such as graft edema, graft extrusion, graft dehiscence, graft retraction, granuloma formation were assessed and noted.

Statistical Analysis

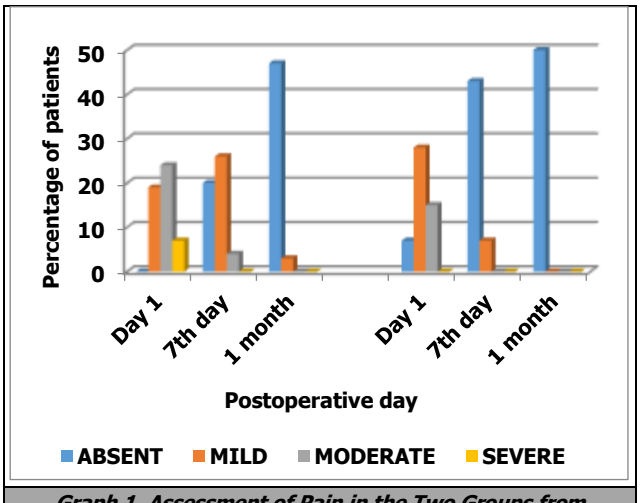
Statistical data was analysed by using SPSS 20.0 version software for qualitative data analysis. X2 (chi-square) test was applied for statistical significance.

RESULTS

In our study, most of the patients had grade 2 pterygium with 84 % in group 1 and 80 % in group 2. 16 % of patients had grade 3 in group 1 and 20 % in group 2.

		Group 1	Percentage	Group 2	Percentage
POD 1	Absent	0	0 %	7	14 %
	Mild	19	38 %	28	56 %
	Moderate	24	48 %	15	30 %
	Severe	7	14 %	0	0 %
				P=0.001	
1 Week	Absent	20	40 %	43	86 %
	Mild	26	52 %	7	14 %
	Moderate	4	8 %	0	0 %
	Severe	0	0 %	0	0 %
				P=0.001	
1 Month	Absent	47	94 %	50	100 %
	Mild	3	6 %	0	0 %
	Moderate	0	0 %	0	0 %
	Severe	0	0 %	0	0 %
				P=0.24	

Table 1. Assessment of Pain in the Two Groups from Postoperative Day 1 to 1 Month

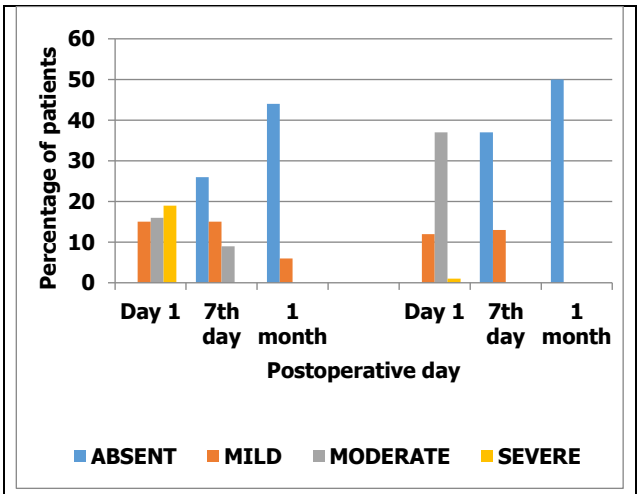


Graph 1. Assessment of Pain in the Two Groups from Postoperative Day 1 to 1 Month

In this study on post-operative day one, 38 % patients in group 1 experienced mild pain, 48 % moderate pain and 14 % severe pain, while 56 % patients in group 2 experienced mild pain and 30 % moderate pain. At 1 week 52 % patients had mild pain, 8 % had moderate pain in Group 1 and 14 % in group 2 had mild pain. During further follow up at 1 month 6 % of the patients in group 1 reported pain and none of patients in group 2 had pain. The pain was statistically significant between the two groups at day 1 and 1 week and comparable at 1 month.

		Group 1	Percentage	Group 2	Percentage
POD1	Absent	0	0 %	0	0 %
	Mild	15	30 %	12	24 %
	Moderate	16	32 %	37	74 %
	Severe	19	38 %	1	2 %
				P = 0.001	
1 Week	Absent	26	32 %	37	74 %
	Mild	15	30 %	13	26 %
	Moderate	9	18 %	0	0 %
	Severe	0	0 %	0	0 %
				P = 0.002	
1 Month	Absent	44	88 %	50	100 %
	Mild	6	12 %	0	0 %
	Moderate	0	0 %	0	0 %
	Severe	0	0 %	0	0 %
				P = 0.027	

Table 2. Assessment of Lacrimation in the Two Groups from Postoperative Day 1 to 1 Month



Graph 2. Assessment of Lacrimation in the Two Groups from Postoperative Day 1 to 1 Month

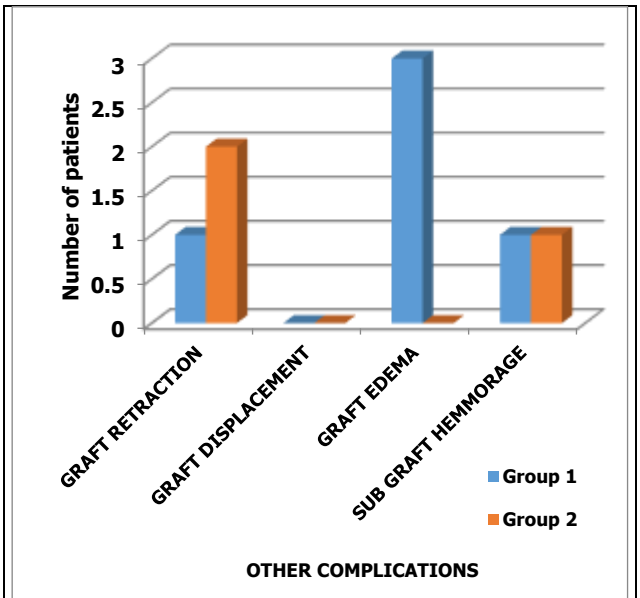
In this study it was found that on post-op day 1, 30 % patients had mild lacrimation, 32 % had moderate and 38 % had severe lacrimation in group 1, whereas 24 % had mild lacrimation, 74 % had moderate lacrimation and 2 % had severe lacrimation in group 2. On follow up at week 1 30 % had mild lacrimation and 18 % had moderate lacrimation in group 1 and 26 % had mild lacrimation in group 2.

At 1 month 12 % had mild lacrimation in group 1 and none in group 2. The results were statistically significant between the two groups at day 1, 1 week and at 1 month follow up. In this study, it was found that 28 % patients in group 1 had mild foreign body sensation, 72 % had moderate foreign body sensation on Postop day 1. Whereas 52 % had mild foreign body sensation and 16 % had moderate foreign body sensation in group 2. On follow up at 1 week 42 % had mild foreign body sensation and 28 % had moderate foreign body sensation in group 1.

While none of the patients reported foreign body sensation in group 2. At 1 month follow up, 12 % of them in group 1 had mild foreign body sensation and none in group 2. The results were statistically significant (P value = 0.001) between the two groups at Postop day 1 and 1 week.

Other Complications	Group 1	Group 2	Total
Graft retraction	1	2	3
Graft displacement	0	0	0
Graft oedema	3	0	3
Sub graft haemorrhage	1	1	2

Table 3. Assessment of Other Complications in the Two Groups



Graph 3. Assessment of Other Complications in the Two Groups

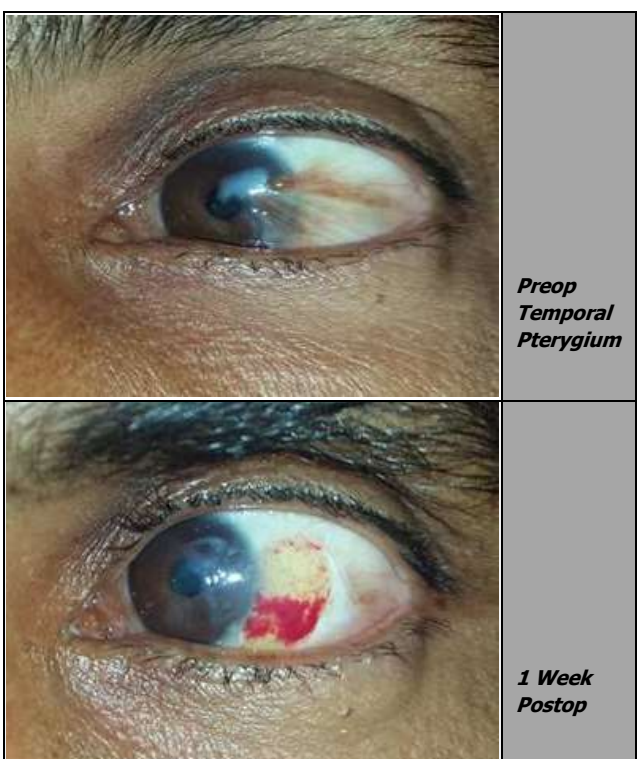


Figure 1. Preop and Postop Photographs of Temporal Pterygium Using Fibrin Glue Preop Temporal Pterygium

In this study, 45 patients in group 1 had no complications in the postoperative period against 47 patients in Group 2. 1 patient in group 1 had graft retraction, 3 patients had graft oedema, 1 patient had sub graft haemorrhage. 2 patients in Group 2 had graft retraction and 1 patient had sub graft haemorrhage.

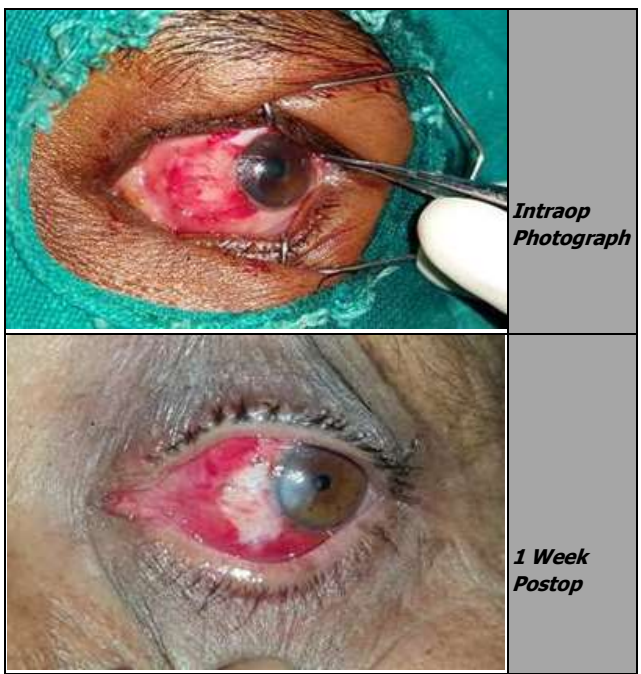


Figure 2. Preop and Postop Photographs of Nasal Pterygium Using Suture

DISCUSSION

Conjunctival autograft is a simple and safe modality for management of pterygium. Graft suturing has its own hindrances of long operating time, additional trauma to the graft tissue and suture granuloma. Sutures may also act as nidus to infection along the suture tract. Fibrin glue is safe and effective method for conjunctival autografting in pterygium excision. The glue provides not only the stability as provided by sutures but also produces significantly less inflammation, better patient comfort, less operating time. In this study most of the patients in both the groups had grade 2 pterygium being 84 % in group 1 and 80 % in group 2. 16 % of patients had grade 3 in group 1 and 20 % in group 2. Grade 1 pterygium patients were not included in the study.

In the present study we did not encounter any serious intra operative or post-operative complications. In none of the patient's button holing of the graft occurred during harvesting of the graft.

Pain

In this study on post-operative day one 36 % patients in group 1 experienced mild pain, 48 % moderate pain and 14 % severe pain, while 56 % patients in group 2 experienced mild pain and 30 % moderate pain.

At 1 week, 52 % patients had mild pain, 8 % had moderate pain in group 1 and 14 % in group 2 had mild pain. During further follow up at 1 month 6 % of the patients in group 1 reported pain and none of patients in group 2 had pain. A similar study noted that on a 10 - point numerical rating scale, both the fibrin adhesive and suture group had low median pain scores.[9] However, the pain scores immediately post-surgery and at 1-week post-surgery were significantly lower in the fibrin adhesive group ($P > 0.05$).

Foreign Body Sensation

In this study it was found that 28 % patients in group 1 had mild foreign body sensation, 72 % had moderate foreign body sensation on post op. day 1 where as 52 % had mild foreign body sensation and 16 % had moderate foreign body sensation in group 2 on post op. day 1. On follow up at week 1, 42 % patients reported mild foreign body sensation and 28 % moderate foreign body sensation in Group 1, while none of the patients had foreign body sensation in group 2. At 1 month follow up 12 % in Group 1 had mild foreign body sensation and none in group 2. The foreign body sensation was statistically significant between the two groups at 1 week and comparable at other follow up. Ratnalingam V et al. reported that post-operative foreign body sensation of mild and moderate grade was seen in 54. 54 % and 36.36 % of eyes respectively with adhesive glue. Compared to this in suture group, 100 % patients had severe foreign body sensation on day 1 ($P < 0.001$).

Lacrimation

In this study it was found that on post op. day 1, 15 % patients had mild lacrimation and 32 % had moderate lacrimation and 38 % had severe lacrimation in group 1, whereas 24 % had mild lacrimation and 74 % had moderate lacrimation and 2 % had severe lacrimation in group 2. On follow up at week 1, 30 % had mild lacrimation and 18 % had moderate lacrimation in group 1 and 26 % had mild lacrimation in group 2. At 1 month 12 % had mild lacrimation in group 1 and none in group 2. A study from Philippines concluded that subjective symptoms of lacrimation were fewer and disappeared more rapidly in the fibrin adhesive group than the suture group.

Graft Displacement

It was noted that the no graft got displaced in either of the two groups at any follow up visit which showed that both the groups were comparable. An Indian study reported, that in suture group all the patients had well placed graft on immediate post-operative day.

Graft Retraction

In this study, 1 patient in group 1 and 2 patients in group 2 had graft retraction. The patients were closely followed, and re epithelialization of the conjunctival defect occurred within 2 weeks. A study from Spain also reported mild graft

retraction which required no intervention for a complete secondary reepithelialization.[10] Graft oedema was noted in 3 patients (6 %) in group 1 and none in group 2. The oedema gradually subsided over a period of 10 days. Starck et al.[11] in their study pointed out towards the possibility of graft oedema in early post-operative period due to limbal - fornix disorientation of the graft. However, in our study, limbal - fornix disorientation did not occur in any eye. In this study, 1 patient (2 %) had sub graft haemorrhage in each group on all the follow up visits beginning from post op. day 1 to 1 month. A study done in Canada found no significant difference in the degree of sub-conjunctival haemorrhage between the two groups at any point during the follow up period.[12]

Recurrence

All eyes were followed up for a period of 6 months. None of the eyes in our study showed any recurrence. Chen et al. reported the mean time to recurrence from 3 to 4.8 months and only 6 % were noted after the sixth post- operative month.[13] O Gris et al. in their study on 7 patients with recurrent pterygium found that there was no recurrence after a follow up period of 14 months.[14]

CONCLUSIONS

Our study showed lower incidence of pain as well as post-operative foreign body sensation on postop day 1 and 7 with the use of fibrin glue which was statistically significant. Post-operative lacrimation was also significantly lower with the use of fibrin glue at post-operative day 1, 7 and 30. Other post-operative complications like graft oedema, graft retraction, sub graft haemorrhage and recurrence were not statistically significant between the two groups. Although the cost of fibrin glue is relatively higher, the decreased incidence of post-operative outcome makes it more preferable.

Data sharing statement provided by the authors is available with the full text of this article at jebmh.com.
Financial or other competing interests: None.
Disclosure forms provided by the authors are available with the full text of this article at jebmh.com.

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