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Intraoperative Injection of Triamcinolone Acetonide in External Dacryocystorhinostomy

Research Article

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Abstract

Aim: A prospective and interventional study to known the efficacy and complications of intraoperative triamcinolone acetonide (TMA) 40mg/ml injection in primary external dacrycystorhinostomy (EXDCR)

Material and Methods: Clinically confirmed 38 cases of primary acquired nasolacrimal duct obstruction (PANDO) are randomly grouped as A (Study group) with 20 cases and B (Control group) with 18 cases. Both group underwent primary EXDCR with silicone tube(ST) intubation. Group A cases received 0.5 ml of TMA 40mg/ml and group B 0.5 ml of Gentamycin 40mg/ml injection intraoperatively. Resolution of symptoms and complications of TMA injection are evaluated at 6 months follow up.

Result: Mean age, gender and laterality of the eye involvement are not different between two group. The success rate in group A is 90%(18/20) and group B 88.9% (16/18), the difference is very small (P=1.0). Raised IOP (Intraocular pressure) of > 18mmHg observed in 10% (2/20) cases of group A. Group A cases had minimal post operative wound inflammation 80%(16/20) compare to 44% (8/18) cases in group B.(P= 0.04). Early resolution with cosmetically good scar seen in 90% (18/20) in group A compare to 55.5% (10/18) cases in group B (P=0.02).

Discussion: Intraoperative TMA injection does not improve the success rate of primary EXDCR in PANDO. But significantly reduces the immediate postoperative wound inflammation and facilitates early resolution of the wound scar. Raised IOP is a concern in TMA injection group.

Keywords: Benefits; Complications; EXDCR; Triamcinolone.

Introduction

Epiphora, discharge and painless swelling in the medial canthal area are the common presentations of primary acquired nasolacrimal duct obstruction (PANDO) [1, 2]. The gold standard treatment for PANDO is external dacryocystorhinostomy (EXDCR) with success rate of 59% - 99% [3-6].

Various factors have been blamed for the failure of EXDCR. Absence of adequate size flaps in anastomosis, reduced size of osteotomy opening, fibrotic closing of the common canalicular opening, intra nasal synechia, narrowing or the closure of the osteal opening, abnormal position of the lacrimal sac wall and nasal mucosal anastomosis, granuloma formation at the inner opening of the anastomosis, exposed bony margin facilitating granula-

tion tissue formation and racial people with higher melanin in the body [2, 5, 7-11].

Many modalities and modifications have been studied to overcome these predisposing factors. Altering the number of dacry-cystorhinostomy (DCR) flaps and increasing the size of osteotomy [8, 12], intraoperative use of Mansoura T tube [13], silicone tube intubation [3, 4, 14], use of antifibrotic agents like Mitomy-cin C (MMC), 5-Flurouracil and depot steroids [9-11, 15].

Depot steroid, Triamcinolone acetonide (TMA) has been widely used in many ophthalmic diseases and procedures. As intralesional injection in medical management of chalazion [16, 17], as retobulbar injection in management of non responding dysthyroid proptosis [18], in management of diabetic macular oedema [19], for visualizing Vitreous during vitrectomy [20], and in treatment

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periocular scars [21]. Considering its anti inflammatory and antifbrotic action a hypothesis was made that intra operative depot steroid TMA may reduce the post operative inflammation related complications and improve the success rate of EXDCR in PANDO.

Material and Method

This is a prospective, comparative and interventional study done in the District Hospital Chamarajanagara in Karnataka state. This study was carried from August 2017 to July 2019. The study was approved by the review and ethical committee of the hospital. All patients were informed about the merits and demerits of the study and written consent was taken. The study adhered to declaration of Helsinki 1975. Two group were made, Group A (study group) undergoing EXDCR + silicone tube intubation with intraoperative 0.50 ml of undiluted TMA 40mg/ml depot steroid injection (Aurocort, Aurolab, Madurai, India) and Group B (control group) undergoing EXCDR + silicone tube intubation with intraoperative 0.50 ml of Gentamycin 40mg/ml injection. (Gentalab, Laborate Pharmaceutical India Ltd. Patna Sahib, India).

All enrolled patients' demography and detailed history was recorded. All patients under went comprehensive eye examination. Lacrimal duct system related diagnostic probe test, syringing, Fluorescein Dye Disappearance(FDD) test are done. For tear function Schirmer test and Break Up Time(BUT) were also done. Based on probe test, syringing and FDD test PANDO was confirmed. Patients were randomly allotted into study group and control group. Exclusion criteria are acquired secondary nasolacrimal duct block, punctual stenosis, trichiasis, entropion, ectropion, lag ophthalmos, chronic blapheritis, dry eye, corneal surface disorder. Patients with comorbid systemic diseases, nasal pathology and age group below 18 years were excluded from study.

All Patients were operated from single surgeon .Surgical steps of EXDCR are as described by Dupuy - Dutemps and Bourget modified with only single anterior flap in lacrimal sac and nasal mucosa [8, 12]. Under sterile condition surgical area infiltrated with 2:1 ratio mixtured of 2% lidocaine and 0.5% bupivacaine. Nasal pack done with 1.25cm size ribbon gauze soaked in 30 ml 4% xylocaine with 2 ampule of adrenaline 1:10000 and left till the time of silicone stenting. A curved 10-12 mm size incision 8-10 mm from medial canthus taken all along the direction of anterior lacrimal crest starting from middle point of the medial palpebral ligament. Layer by layer skin, subcutaneous tissue, orbicularis oculi were separated to expose the medial end of medial palpebral ligament. The Medial palpebral ligament disinserted. Lamina papyracea was gently perforated with bone rongue. Around 10 -15 mm diameter size osteotomy done with serial sized bone rounge. With the Bowmans probe 00 medial wall of lacrimal sac tented and single large anterior flap was made .Same size anterior flap made in nasal mucousa. A bicanalicular Silicone tube (Aurolacfrom Aurolab, Madurai, India) intubated through upper and lower pucta, retrieved through common canaliculi, osteotomy and into nasal cavity. Two ends of the tube were tied in such way that there is no snaring effect on punctae, unnecessary looping into medial fornix or hanging out of the nostril. Tied end of the tube left free in the nasal cavity at the inferior turbinate level. Both the flap were trimmed as per the requirement and joined together with 6 0 vicryl. At this point undiluted 0.50 ml of TMA 40mg/

ml injection in group A and 0.50 ml of Gentamycin(GM) 40mg/ml injection in group B was injected. Injection of 0.30 -0.40 ml was given all around the bony opening between nasal mucosa and bone endostium and 0.1 to 0.2 ml to fill the empty space above the anastomosis. Palpebral ligament refixed, orbicularis muscle and skin were closed. For all suturing 6-0 vicryl used . Fresh nasal pack and pad bandage applied.

Post operatively all patients received oral Dcilofenac +paracetamol, cefixime 200 mg twice daily for 5 days. Topically antibiotic drops five times daily in group A and antibiotic steroid drops five times daily in group B. Antibiotic ointment application over the wound two times daily in both group. Follow up done on 1 day,1 week, 4 week and monthly for 6 months. Nasal pack was removed on first post operative day, skin sutures on 10th day and silicone tube was removed between 12 – 24 weeks post operatively. During each visit patients were evaluated for the success and complications of the procedure. Success of the procedure was considered when both subjective and objective resolution of PANDO. Subjectively resolution of epiphora, discharge or swelling. Objectively by anatomical and functional patency of anastomosis by syringing and FDD test respectively.

The results are analyzed by NCSS 2020 Statistical Software (2020). NCSS, LLC. Kaysville, Utah, USA and The results are presented with group mean compared with two tailed Fishers exact test and statically significance by actual *P* value.

Results

There were 38 eyes from 38 patients . Mean age of the patients is 48.8+/-.15.4~(20-72) yrs. Female male ratio is 1.5:1. Right eye was involved in 47.4%(18/38) patients and left eye in 52.6% (20/38) patients and difference is very narrow ($P\!=\!0.35)$. Common presentation was epiphora in 73.6% (28/38) patients, mucopurulent discharge in 18.4% (7/38) and mucocele in 8% (3/38) patients .Mean duration of presentation is 9.2 (13 – 38) months.

Around 89.5% (34/38) patients were having both subjective and objective resolution of symptoms (epiphora/discharge/mucocele) at the end of 6 months. Only 10.5% (4/38) patients had no resolution of the symptoms both subjectively and objectively. In 5.3% (2/38) patients IOP was raised > 15 mmHg from base line reading during the follow up period.

There were 20 patients in group A and 18 patients in group B. Mean age of group A patients was 46.5+/- 15.3 and appears to be younger than mean age of group B patients 51.6+/-15.6 yrs, but the difference is very small and not relevant (P=0.35) There is no much difference in the gender affection female: male ratio was 1.5:1 and 1.6:1(P=1.00), laterality of the affected eye R/E: L/E 11:9 and 7:11 (P=0.35) respectively between group A and B. There is no difference in the Presenting symptoms and duration of symptoms between two groups. (P=0.71). (Table 1). On comparing the success rate between two group, in group A 90% (18/20) cases and in group B 88.9% (16/18) cases were having subjective and objective resolution of symptoms at the end 6 months and the difference is to small (P=1.00).

There were 10% (2/20) cases of failure in group A. Both after the removal of the stent at 4^{th} month follow up and underwent

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	Total (n=38)	Group A (n=20)	Group B (n =18)	<i>P</i> value
Age (years) standard deviation	48.3 +/- 16.4	46.6 +/-15.3	51.6 +/-15.6	P= 0.31
Female /Male	23/15	12/8	11/7	P = 1.00
Right eye/Left eye	20/18	11/9	9/9	P = 0.35
Epiphora	28	14	14	P=0.35
Discharge/ Mucocele	10	6	4	P=0.35
Duration of Swantons	9.2 months	9.2 months	8.8 months	D = 1.00

(4-14)

(4-14)

Table 1. Demographic details of patients, Eye involvement, presenting symptoms and duration of Symptoms.

re-intubation of the stent. In group B the procedure was failed in 11.1% (2/18) cases. These two cases had adhesion in the nasal cavity with the stent in situ on 3rd month follow up. Both the cases received 0.50 ml of TMA 40mg/ml injection and both cases had resolution of symptoms. All These 4 cases were treated as failed cases.

Duration of Synptoms

In group A 10% (2/20) cases had raised IOP. One case on 2nd month follow up period. Applanation IOP was >15 mmHg more than base line IOP and controlled with topical Beta blocker, after 6 weeks treatment IOP stabilized to <21 mmHg. Another patient on 3rd month follow up. The raise was > 22 mm of Hg from base line IOP and controlled with Beta blocker and alpha agonist to < 21 mm Hg and patient converted to steroid induced glaucoma.

Other observations we have observed in this study was minimal post operative inflammation around the incision wound in 80% (16/20) cases in group A compare to group B 44% (8/18) with wide difference between two groups (P=0.04). It is to be remembered that we have not used topical steroid drop in group A patients for 6 weeks and the local anti-inflammatory effect was taken care by depot steroid. Regarding the wound related scar it was cosmetically invisible in 90% (18/20) cases in group A and 56% (10/18) in group B and the difference is large. (P=0.02).(Table .2) (Composite Figure .1)

Discussion

Depot steroid, TMA is a synthetic corticosteroid having 5 times anti-inflammatory action compare to hydrocortisone. It is a long acting anti-inflammatory, Anti Vascular endothelial growth factor (VEGF) and antifibrotic agent. Mode of action is on chemical mediators by inhibiting phospholipase A2 which in turn prevents the synthesis of thormbaxane A, prostaglandins and leukotrenes. Also it is a inhibitor of inflammatory cells, inhibitor of VEGF gene and reduces the capillary permeability. These functions reduces exudation of plasma fluids, controls the fibroblast proliferation and regulates collagen deposit [21, 22]. An assumption was made that intraoperative depot steroid may reduces the inflammation, prevents granulation tissue formation, minimizes the fibrosis and scar formation after EXDCR in cases of PANDO.

The mean age of the patients was 48.8 (20-72) yrs. This study had more younger patients compare to previous report of mean age of 56 yrs [8, 13] and the difference is small (P=0.25) Majority of our patients were from rural area and farmers. Constant exposure to irritants like sun light, pollens, animal hairs and dust particles are known to alter the chemical composition of tear and nasal

secretion. These altered composition cause anatomical changes in mucosal lining of the lacrimal drainage system and nasal mucosal epithelium. These factors indirectly affect the cavernous plexus as follows: descending inflammation from the eye or ascending inflammation from the region of the nose may initiate malfunctions in the cavernous body with reactive hyperemia, swelling of the mucous membrane, and temporary occlusion of the lacrimal passage. Then, repeated isolated episodes of dacryocystitis may lead to structural epithelial and subepithelial changes. Loss of typical goblet and epithelial cells, which plays an important role in the tear-outflow mechanism, as well as fibrosis of the helical system of connective tissue fibers in the area of the lacrimal sac and nasolacrimal duct. Addition to this there is reduction and destruction of specialized blood vessels of the cavernous body leading to malfunctions of the tear-outflow mechanism and the vicious circle continues [1, 2]. This may be the reason for more number of younger patients developing PANDO in our study. On gender involvement female - male ratio was 1.5:1 and this is comparable to earlier observation of PANDO is more common in females [3, 4]. This study did not find any difference in the right eye and Left eye involvement of PANDO 52.64% (20/38) and 47.36% (18/38) respectively (P=0.35).

P = 1.00

(5-14)

Epiphora was the common symptoms in our study 73.68% (28/38 cases) this is in concordance with earlier reports [3, 4, 13]. The observed success rate of 89.47% (34/38) in our study is comparable with previous reports [4, 5, 13].

The mean age, gender involvement, laterality of the eye involvement and duration of symptoms are not different between two group (Table.1).

With the available literature common factors for failed EXDCR are fibrotic block of the common canalicular opening, adhesion in the nasal cavity and closure of the osteal opening by granulation tissue [1, 2]. Depot steroid TMA is known to reduce the inflammation, granulation tissue formation and fibrotic tissue [9]. The assumption in the beginning of this study was the depot steroid should improve the success rate of EXDCR in TMA received group compare to GM injection received group.

The success rate in study group was 90 % (18/20)compare to control group 89% (16/18) with small difference (P=1.0). This success rate of 90% (18/20) is comparable to previous study report [11]. Aerin et al., [11] in their prospective study, 45 patients with PANDO underwent endonasal DCR. During the follow up period various type of granuloma developed at various location of the ostium. They were treated with intralesional injection of

Table 2. Postoperative results, IOP, wound inflammation and scar resolution.

Results	Total (n= 38)	Group A (n =20)	Group B (n =18)	P Value
Success	34	18	16	P = 1.00
Failed	4	2	2	
Raised IOP > 15 mm Hg				
Yes	2	2	0	P = 0.48
No	36	20	16	F = 0.46
First post operative wound inflammation				
Minimal	25	16	8	P = 0.04
Moderate	13	4	10	$\Gamma = 0.04$
Scar resolution				
< 6 weeks	31	18	10	P = 0.02
> 6 weeks	7	2	8	F = 0.02

Composite Figure 1.



a . Positive regurgitation test in Right eye PANDOb. Positive FDD test in Left eye PANDO.

c. Left eye minimal wound inflammation on first post operative day in a group A patient.
d. Right eye moderate wound inflammation on first post operative day in a group B patient
e. Right eye Cosmetically invisible scar at 6 weeks follow up in a group A patient.
f. Left eye cosmetically visible and blemish scar at 6 weeks follow up in a group B patient

0.3ml of TMA 40mg/ml and the final success rate was 75.55 % (34/45 cases). In their study steroid was injected during the follow up period and in endonasal DCR osteotomy size relatively small and mucosal flaps are resected without anastomosis. These factors may be the reason for more number of failed cases in their study. It has been observed that depot steroid is more beneficial during the initial period of inflammation in reducing the fibrosis, scar formation and granulation tissue development [22]. Another explanation may be that we have used silicone stent in both the group. The stent it self has many positive out come on EXDCR. It enhances the lacrimal pump action, well opposes the puncta which improves the lacrimal flow during the closing phase of blinking, increased capillary function of canaliculi, prevents granuloma formation, by delaying the fibrosis, reduces the scarring and adhesion around the osteal opening [5, 12, 14]. However

this difference is minimal (P=0.31).

Where as in a retrospective study Lee et al., [15] 15 eyes of PAN-DO 5 cases received introperative TMA and 100% (5/5) had complete resolution of PANDO. Even thou Lee et al., [15]. reported success rate is more than our success rate of 90% (18/20) the difference is not significant (P=1.0). Moreover Lee et al., [15] patients were on systemic immunosuppressive agents for sarcoidosis, this may be reason for higher success rate.

Two patients in study group had raised IOP of more than 15 mm Hg during the follow up period. In general population 5-6 % will have raised IOP of more than 15 mm Hg for local and periocular steroid preparation and this will be 29 -30 % in primary open angle glaucoma patients [23]. We suggest that comprehensive

glaucoma evaluation to be done before using the depot steroid in EXDCR patients.

We have noticed the following benefits in depot steroid received group. There was no requirement of topical steroid drops, post operative minimal inflammation around the incision wound and early resolution of wound scar. In a prospective study by Tanushree et al., [21] Nine patients had post DCR hypertropic scar and each received 0.2-0.4 ml of TMA 40mg/ml 2-3 injections into the scar at 6 weekly interval. All the patients had resolution of hypertrophic scar. In our study 0.3-0.4 ml depot steroid was injected around osteotomy and 0.1-0.2 ml was pooled over the flap anastomoses before skin - muscle layers closed. This might have had positive outcome on scar development.

Even thou our study has failed to prove the assumption of intra operative injection of TMA will improve the positive outcome of EXDCR (P=1.00). It has shown other non studied benefits like reduced postoperative inflammation, omission of topical steroid and early resolution of scar. Only concern is raised IOP in susceptible patients and converting to steroid induced glaucoma. Comprehensive glaucoma eye examination to be a manadatory in patients receiving TMA injection in EXDCR procedure. Lacunae in our study is small sample size.

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