A prospective randomised double blinded study to compare the efficacy of a combination of dexamethasone and lignocaine with lignocaine in external dacryocystorhinostomy

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Introduction

External Dacryocystorhinostomy (DCR) was first described by Toti in 1904 and subsequently modified by Dupuy Dutemps and Bourguet in 1921.(1) It can be performed under local or general anaesthesia.

Local anaesthesia in DCR is safe and comfortable when proper anatomical approach to nerve blocks is performed. Local anaesthesia in patients undergoing external DCR is a good alternative because it is cost-effective and it eliminates the complications of general anaesthesia.(2)

DCR surgeries can be associated with significant pain and oedema in post-operative period. Dexamethasone is a high potency, long acting glucocorticoid with little mineralocorticoid effect. Glucocorticoids have been used to reduce inflammation and for prevention of postoperative nausea and vomiting; they are also effective in reducing postoperative pain.(3) Dexamethasone (as a corticosteroid) was reported to attenuate C-fiber responses. More recent publications indicate that 8 mg dexamethasone added to perineural local anesthetic injections augment the duration of peripheral nerve block analgesia.(4)

Materials and Methods

The study was conducted at a tertiary center eye hospital from October 2015 to May 2016. Ethics committee approval was taken prior to commencing the study. 200 patients scheduled for External DCR at our hospital were included in the study. The patients belonged to American Society of Anaesthesiology (ASA) I or II. They were randomly assigned to 2 groups of 100 each. Group 1 (n=100) received local anaesthetic concoction of dexamethasone sodium phosphate 2ml of 4mg/ml, 30 ml of 2% lignocaine hydrochloride with adrenaline 0.005mg (1:200,000) and hyaluronidase 1500 IU. Group 2(n=100) received 30ml of 2% lignocaine hydrochloride with adrenaline 0.005mg (1:200,000) and hyaluronidase 1500 IU. Reconstitution of the agents was done under complete aseptic precaution under laminar flow. Date and time of reconstitution was labelled on the bottle.

Inclusion criteria were:

- Patients aged between 20 -70 years and scheduled for external DCR under local anaesthesia.
- Patients willing to consent for the procedure.

Exclusion criteria were

- Patients with a history of hypersensitivity to dexamethasone, hyaluronidase or lignocaine.
- Patients with coagulation disorders or patients on anticoagulant therapy.
- Patients requiring additional oral steroids post operatively (as in repeat DCR or common canalicular block).
- Patients with psychiatric disorders.

Pre-operative and pre anaesthetic evaluation, including –haemoglobin, haematocrit, coagulation profile, serology for HIV and Hepatitis B was undertaken along with vital parameters –pulse, blood pressure and ECG. Lignocaine test dose given to all patients 45 minutes prior to the surgery.

No premedication were given.

Study group cocktail was reconstituted prior to injection and time of reconstitution labelled on the bottle.

Local anaesthetic was administered in supine position by the operating surgeon, who was blinded to the drug being administrated.

Using a 26-gauge needle, approximately 4 mL infiltrate was placed around the proximal lacrimal system, 2ml of which was placed along the incision line (tear trough incision), in the subcutaneous and supraperiosteal levels. Supra trochlear and inferior orbital nerve block, 1 ml each, was administered.

The patients were assessed for the appearance of pain in the post-operative period 1hr, 4 hrs and 24 hrs using a universal pain assessment tool, the Visual Analogue Scale (VAS). VAS with values ranging from 0-10 [0=no pain 1-2= mild, 3-6 = moderate, and 7-10 = severe pain] was used. Post-operative rescue analgesia, oral (Tablet Paracetamol 500 mg) or parenteral (Injection Diclofenac Sodium 25mg/ml) and the time of request was noted.

Post-operative oedema was assessed after 24 hours, by three observers of which two were ophthalmologists and another a non-medical personnel. The observers were not related to the study and blinded to the drug injected for the anaesthesia

Post op oedema was assessed by following grading, 0= no oedema, 1=minimal, 2= moderate and 3= severe.

Statistical Analysis: Descriptive statistics were presented for demographic factors. Independent sampled t-test was used to compare between two treatment groups (dexamethasone and without dexamethasone) for all continuous variables. Chi-sqaure test or Fisher's exact test was used for categorical data analysis as appropriate. Agreement between independent observers was assessed by using the weighted Kappa statistics. A two-sided p-value <0.05 was considered to be statistically significant. SPSS version 19.0 (SPSS Inc., Chicago, IL, USA) was used for data analysis.

Results

200 patients were enrolled in the study, the two groups were comparable with respect to patients' demographic data such as age and gender distribution with p = 0.073 and p = 0.128 respectively (Table 1). Patients in group 2 had more pain when compared to patients in group 1 at 1, 4 hrs and 24 hrs hour postoperatively, with p values of 0.0032, 0.017 and 0.001 respectively which was statistically significant(significant p value <0.05). Majority (88%; n = 88) of the patients in group 2 required more analgesia either oral or parenteral and was statistically significant with p < 0.0001. However, the time of request for analgesia was less in group1 (2.5 Vs 3.0hrs) in comparison with group2 but was not significant (p = 0.144) (Table 3).

Table 1: Demographic details of the patients treated for External DCR

Characteristics	Group 1	Group 2	P value
Age (years)	61.9 ± 12.5	58.4 ± 14.5	0.073
Gender (M/F)	37/63	26/74	0.128

Table 2: Pain assessment at 1 hour, 4hours and 24 hours by group 1 and group 2

Table for pain grading								
	Group I-N=100				Group II-N=100			
Time	No pain	Mild pain	Moderate pain	Severe pain	No pain	Mild pain	Moderate pain	Severe pain
1hr	0	73	27	0	O	61	34	5
4hr	0	55	40	5	6	35	59	6
24 hr	94	6	0	0	76	24	0	0
Statistically significant P value <0.05 P value 1 hr = 0.032, 4 hrs =0.017 and 24 hrs =0.001								

Table 3: Postoperative Analgesia oral or parenteral and time of request in the groups

	Group1 N = 100	Group2 N = 100	P value
Analgesia oral or parenteral (Yes/No) (% Yes)	45/55 (45.0%)	88/12 (88.0%)	<0.0001
Time of request (hours)	2.5 ± 1.9 (n = 45)	3.0 ± 1.7 (n = 88)	0.144

There was significant oedema at the operated site, postoperatively in patients treated without dexamethasone i.e. group 2 compared to patients treated with dexamethasone i.e. group1, with p value of <0.0001 as noted by the 3 observers. There was an excellent agreement between observer 1 and observer 2 in grading the oedema in patients operated in group 1 (Weighted Kappa = 0.80). And a moderate agreement between observer 2 and observer 3 and observer 1 and 3 in group 2 (weighted Kappa = 0.60 and 0.64 respectively). However, in grading oedema in group 1 patients, the agreement was moderate (Weighted Kappa = 0.54) between observers and 1 and 2 but the agreement was poor between observer 2 and 3 (Weighted Kappa = 0.28) and observer 1 and 3 (Weighted Kappa = 0.17) (Table 6).

Table 4: Post-operative oedema graded by independent observers 1, 2 and 3 in group 1 and 2

Table for Edema								
	Group I-N=100				Group II-N=100			
Observer	No edema	Mild edema	Moderate edema	Severe edema	No edema	Mild edema	Moderate edema	Severe edema
1	27	54	15	4	8	25	51	16
2	32	47	18	3	8	26	52	14
3	40	48	10	2	9	29	46	16
Statistically significant P value <0.05 P value for all the 3 observers was <0.0001								

Table 5: Weighted Kappa statistics between observers in grading the post oedema

Group	Weighted Kappa		
	Observer 1 Vs 2	Observer 2 Vs 3	Observer 1 Vs 3
Group 1 (N = 100)	0.54	0.28	0.17
Group 2 (N = 100)	0.80	0.60	0.64

Discussion

Ours was a prospective, double blinded, randomised study. Primary outcome was the efficacy of dexamethasone in reducing postoperative pain and oedema. Corticosteroids have been used routinely for treatment of cancer pain as a coanalgesic to opioids.[5] Dexamethasone has been used extensively in ophthalmology for varied reasons. Some include, as an intravitreal implant when treating macular oedema in retinal vein occlusions[6] and posterior uveitis,[7] as a posterior subtenon injection in uveitis[8] and as an intra lesional injection in thyroid orbitopathy and idiopathic inflammatory orbital disease.[9] It has also been used as a co adjuvant to lignocaine and bupivacine in peribulbar blocks. It has been found to increase the duration of post-operative analgesia and akinesia following the block.[10]

In our study we aimed to show the efficacy of dexamethasone in terms of pain and post-operative oedema with respect to regional block in External DCR.

The results of our study are in accordance with other reports studying the effects of preoperative administration of dexamethasone and other glucocorticoids. Some of the studies where it has been used as an adjuvant to local anaesthetics are, for peripheral nerve block-axillary brachial plexus blockade,[11] epidural analgesia[12] and in tooth extraction.[13]

Mohammed et al in their study, dexamethasone bupivacaine versus bupivacaine in peribulbar block for posterior segment surgeries, found that addition of dexamethasone to bupivacaine led to prolonged duration of lid and globe akinesia. In their study the time of request of rescue analgesia was delayed with prolonged post-operative analgesia. The inflammatory response to surgery was assessed postoperatively by measuring the level C reactive proteins, which was significantly less in the group with dexamethasone (p value of <0.05).[10]

Vieira et al found that dexamethasone with bupivacaine increases duration of analgesia in ultrasound-guided interscalene brachial plexus blockade. Median patient satisfaction scores were not significantly different between the two groups at 48 h (9.5 vs. 8.0, dexamethasone vs. control, respectively) in their study.[14] Shrestha et al found that dexamethasone with local anaesthetic prolongs post-operative analgesia significantly than tramadol when used to local anaesthetic in brachial plexus block in upper extremities.[15]

It was also found that, dexamethasone added to bupivacaine prolonged the duration of epidural analgesia in abdominal and thoracic surgery as studied by Naghipour B.[12]

Conclusion

From our study we conclude that dexamethasone is a useful adjuvant to local anaesthetic in regional anaesthesia, for External DCR. It provides a prolonged analgesia, reduces the postoperative oedema, and also decreases the requirement of post-operative rescue analgesia.

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