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Assessing The Efficacy of Single Inferomedial Peribulbar Injection in Lacrimal Intubation Surgery in Adult Patients: A Randomized Clinical Trial

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ABSTRACT

Background: Inferomedial injection has been suggested as a more comfortable alternative to medial peribulbar block.
Aim: We aimed to explore inferomedial injection technique efficacy in minimizing pain during injection as well as intubation compared to the classic medial canthal injection technique during peribulbar block.
Methods: This randomized, controlled trial included adult (18 to 70 year-old) patients scheduled for lacrimal intubation surgery. Eligible patients were divided in a random way into two groups. Group 1 (n=24) received inferomedial peribulbar injection using a 25G/ 1" length needle to inject 3 ml of lidocaine: bupivacaine (1: 1) with 30 IU hyaluronidase enzyme to improve the infiltration of the small volume of the local anesthetic drugs. The classic medial canthus injection was applied in Group 2 (n=24) using the same types and amounts of local anesthesia (LA) and the same needle length. The pain was assessed during local anesthetics injection and intubation using the verbal rating scale.
Results: In group 1 a low pain score was more frequent than in group 2 (83.3% vs. 16.7%). The median pain score at the LA injection was significantly lower in group 1 (1.0: IQR=1.0-1.0) than in group 2 (2.0: IQR=2.0-2.5). Alternatively, a comparison of the Verbal Rating Scale at intubation revealed comparable results between groups 1 and 2, with no significant differences ($p>0.05$).
Conclusions: Inferomedial LA injection technique is feasible and less painful than the medial canthal injection. Otherwise, both techniques provided adequate intraoperative analgesia during lacrimal intubation and comparable surgeon satisfaction.
Keywords: lacrimal intubation surgery, peribulbar anesthesia, inferomedial injection, medial canthus injection, pain score.

INTRODUCTION

Obstruction of lacrimal drainage is one of the common lacrimal disorders. Intubation using a silicone tube has been adopted for the successful treatment of both canalicular and nasolacrimal duct stenosis in adults. Nasolacrimal stents maintain the patency of the passages where it is present and thereby improve the drainage of tears from the lacrimal gland [(1, 2)].

Lacrimal intubation surgeries in adults are typically performed under general anesthesia, which increases their cost and significantly decreases the practice of these procedures. Alternatively, lacrimal tubes can be successfully placed as a simple day-case surgery under local anesthesia (LA) [(3)].

The peribulbar block technique is useful for patients willing to stay for a short time in the hospital. It has many advantages including a low incidence of cough and emesis during the immediate postoperative period [(4)].

The peribulbar block involves the injection of LA into the peribulbar space, and it produces globe akinesia and anesthesia [(5)]. Medial peribulbar block through the classic medial canthal injection site has some disadvantages, such as pain during the LA injection as well as puffiness and false tracking which may occur at the injection site [(6, 7)].

In cataract surgeries, the percutaneous ocular peribulbar anesthesia with the single injection technique using a short needle can provide adequate akinesia and analgesia. The efficacy of this technique has been previously reported. B-scan ultrasonography has been used to ascertain the distribution pattern of the injectate in peribulbar anesthesia [(8-10)]. We named it inferomedial injection in our study after its anatomical site to facilitate the description throughout this manuscript.

Inferomedial injection has been suggested as an alternative, more comfortable technique both for the patient and the surgeon. The aim of this study was to evaluate the efficacy of the inferomedial injection technique in minimizing pain during injection as well as intubation compared to the classic medial canthal injection technique during performing the peribulbar block.

PATIENTS AND METHODS

Ethical considerations

This work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans. The current study obtained approval from the IRB of the Research Institute of Ophthalmology, Egypt, and informed consents were obtained from all patients. The authors preserved the confidentiality of the participants' data. This trial was registered at ClinicalTrials.gov (ID: NCT04859049, Date: April 26, 2021).

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Study design, setting, and date

This was a randomized, clinical trial. It was conducted at the Research Institute of Ophthalmology, Egypt between September 2021 and August 2022.

Randomization and allocation concealment

Forty-eight children were randomly allocated to two groups. Each group comprised 24 patients. Randomization and allocation concealment were accomplished using the sequentially numbered, opaque, sealed envelopes method [(11)]. Each patient was first assessed and enrolled based on the eligibility criteria of the study. Then, the corresponding envelope was opened to allocate the intervention. Only the study participants were masked.

Eligibility criteria

We included adult patients aged 18-70 years of both sexes who were scheduled for lacrimal intubation surgery with American Society of Anesthesiologists (ASA) physical status I, II, or III and had axial eye length between 22 and 28 mm.

We excluded patients aged less than 18 or more than 70 years, with ASA IV, coagulation disorders, high myopia (axial length more than 28 mm), medial staphylomas, or communication difficulties that might prevent reliable pain assessment.

Study procedures

In the operating room, the patients were cannulated and fully monitored with the pulse oximeter, non-invasive blood pressure, and ECG. A nasal cannula was connected to the patient to deliver oxygen at 3 liters per minute. Then, appropriate surface anesthesia of the operative eye was performed by instillation of benoxinate hydrochloride 0.4% eye drops.

Interventions

We allocated the patients randomly into two groups. Group 1 (n=24) had the inferomedial peribulbar injection using a 25G/1" length needle to inject 3 ml of lidocaine: bupivacaine (1: 1) with 30 IU hyaluronidase enzyme (it helps the diffusion of Local anesthetics), using the single injection technique. The injection was accomplished according to **Rizzo *et al*.** [(10)]. The classic medial canthus injection was applied in Group 2 (n=24) using the same types and amounts of LA and the same needle length.

Outcomes

The primary outcomes included pain assessment during the LA injection and the intubation procedure. This was carried out using the Verbal Rating Scale (from 0 up to 3 that represents no pain or discomfort up to severe pain).

The secondary outcomes included evaluation of the surgeon's satisfaction regarding the easiness of the technique in addition to the frequency of false track occurrence during intubation.

Statistical analysis

Data were tabulated and analyzed using the SPSS, version 26 for Windows (IBM Corp., Armonk, N.Y., USA). Shapiro-Wilk test was used to check numerical variables. Normally distributed variables were expressed as mean ± standard deviation (SD), and associations were tested by the Independent T-test. Abnormally distributed variables were presented as the median and interquartile range (IQR), and the Mann-Whitney U test was applied. Categorical variables were expressed as frequencies and percentages, and the X^2 tests (Pearson's Chi-square for independence or Fisher Exact Tests as appropriate) were used to examine the associations between variables. A p-value of < 0.05 was considered statistically significant.

RESULTS

This study included 48 eligible patients who underwent lacrimal intubation surgery. They were randomly allocated into either group 1 (n=24) in which peribulbar anesthesia was performed using percutaneous inferomedial LA injection or group 2 (n=24) where the classic medial canthal injection was applied. All patients were assessed and included in the statistical analysis (Figure 1).

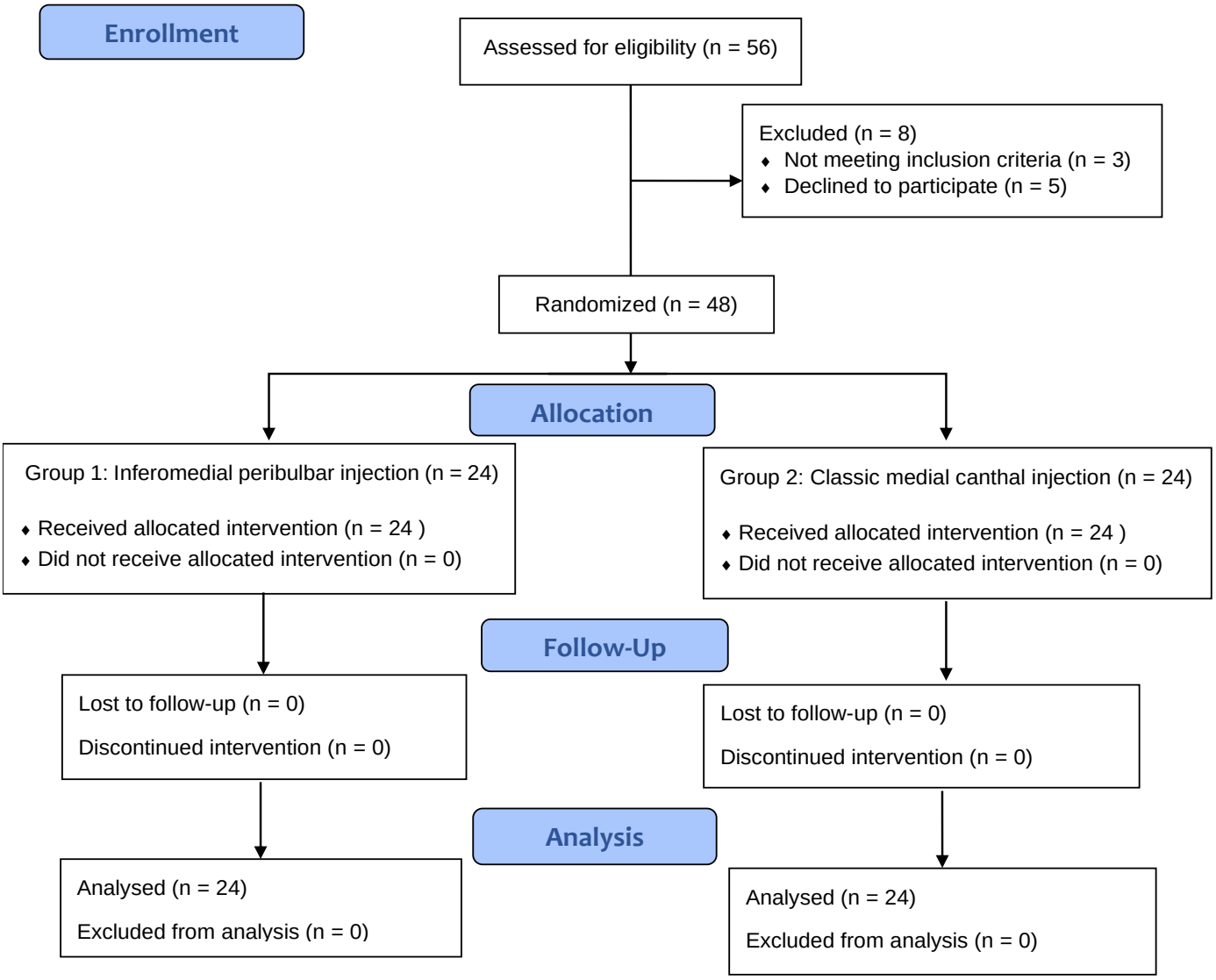

Figure 1. CONSORT flow chart of the trial.

Table 1 shows no significant differences between the two groups regarding sex and age (all p > 0.05).

Table 1. Baseline demographic characteristics of the studied groups

			Group 1 (Inferomedial peribulbar injection), n=24	Group 2 (Medial canthus peribulbar injection), n=24	P-Value
Sex	Female	n	12	12	1.00[a]
		%	50.0	50.0	
	Male	n	12	12	
		%	50.0	50.0	
Age, year	Mean ± SD		49.08±13.96	41.67±11.75	0.052[b]

n: number; SD: standard deviation; [a] Chi-Square test; [b] Independent T-test

Assessment of pain at the LA injection site revealed significant differences between both groups (p < 0.001). In group 1 low pain score was more frequent and the frequency of severe pain was lower than in group 2 (83.3% vs.16.7% and 0.0% vs. 25.0%, respectively). As well, the median Verbal Rating Scale at the LA injection site was significantly lower in group 1 (1.0: IQR = 1.0-1.0) than in group 2 (2.0: IQR = 2.0-2.5). Alternatively, a comparison of the Verbal Rating Scale at intubation revealed no significant differences between the two groups with (all p > 0.05). Furthermore, the frequency of false track occurrence during intubation was 8.3% in group 1 compared to 4.2% in group 2, with no significant difference. Both groups exhibited comparable surgeon satisfaction during the procedure (87.5% vs 79.2%), with no significant differences (p = 0.701) (Table 2).

Table 2. Pain verbal rating scale during injection and intubation, frequency of false track during intubation, and surgeon satisfaction in the studied groups

		Group 1 (Inferomedial peribulbar injection), n=24		Group 2 (Medial canthus peribulbar injection), n=24		P-Value
VRS at LA injection	Low pain, n, %	20	83.3%	4	16.7%	<0.001*[a]
	Moderate pain, n, %	4	16.7%	14	58.3%	
	Severe pain, n, %	0	0.0%	6	25.0%	
	Median (IQR)	1.0 (1.0-1.0)		2.0 (2.0-2.5)		<0.001*[b]
VRS at intubation	No pain, n, %	13	54.2%	10	41.7%	0.694 [a]
	Low pain, n, %	8	33.3%	8	33.3%	
	Moderate pain, n, %	2	8.3%	4	16.7%	
	Severe pain, n, %	1	4.2%	2	8.3%	
	Median (IQR)	0.0 (0.0-1.0)		1.0 (0.0-1.5)		0.283[b]
False track during intubation, n, %	No	22	91.7%	23	95.8%	1.00 [a]
	Yes	2	8.3%	1	4.2%	
Surgeon satisfaction, n, %	No	3	12.5%	5	20.8%	0.701[a]
	Yes	21	87.5%	19	79.2%	

n: number; IQR: interquartile range; VRS: Verbal Rating Scale; LA: local anesthetic; [a] Fisher Exact test; [b] Mann-Whitney U test; * Significant at $p < 0.05$

DISCUSSION

Satisfactory anesthesia plays a crucial role in the success of ophthalmologic surgeries. The key requirements of any regional anesthetic block are patient comfort, safety, and effectiveness [(12)].

Several intraocular, as well as extraocular procedures, are performed using peribulbar anesthesia. However, the classic medial canthal injection technique of peribulbar anesthesia is painful [(13)]. Therefore, this study suggested using the inferomedial injection site as an alternative, less painful procedure. We assessed pain scores during the administration of anesthesia as well as intubation for both the inferomedial and the classic medial canthal injection techniques.

This study revealed that percutaneous inferomedial LA injection was less painful than the classic medial canthal injection in patients who underwent peribulbar anesthesia for lacrimal intubation surgery. Assessment of pain during the LA injection revealed a significantly lower median pain score with the inferomedial injection compared to the classic medial canthal technique. Again, patients who were given the LA via the inferomedial site showed a significantly high frequency of low pain scores. Alternatively, both techniques exhibited equal efficacy regarding intraoperative pain control with comparable pain scores at the time of intubation. The intubation was painless in 54.2% and 41.7% of patients who underwent the inferomedial and the classic medial canthal injections, respectively. As well, the frequencies of low, moderate, and severe pain scores were comparable in both techniques, with no significant differences. Furthermore, a false track was recorded in two patients (8.3%) who received the inferomedial injection compared to one patient (4.2%) in the classic medial canthus injection group, with no significant difference. Both techniques also showed comparable surgeons' satisfaction throughout the procedure.

The circumferential diffusion of the LA with the addition of hyaluronidase enzyme that may facilitate the spread of LA blocks the ciliary nerves, as well as cranial nerves III and VI [(14)]. This might explain the observed adequate intraoperative analgesia with both the inferomedial and the classic medial canthus injection techniques. However, a Cochrane review reported inconsistent results regarding the efficacy of hyaluronidase addition in reducing the incidence of intraoperative pain [(15)].

Strengths and limitations

This randomized clinical trial is the first to evaluate the inferomedial LA injection technique as a new alternative to the classic medial canthal injection for performing more comfortable peribulbar anesthesia. However, the study was a single-center experience with a small sample size. Further bigger multicenter studies are needed before the generalization of the less painful inferomedial peribulbar anesthetic technique.

CONCLUSIONS

The results in the present study indicate that the inferomedial LA injection technique is feasible and less painful than the medial canthal injection. Otherwise, both techniques provided adequate intraoperative analgesia during lacrimal intubation and comparable surgeon satisfaction.

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