

The Effect of Adding Fentanyl to Peribulbar Block on Muscle Traction during Squint and Buckle Surgeries in Adult Patients: A Randomized Controlled Trial

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ABSTRACT

Background: In squint and buckle surgeries, the intraoperative pain of muscle traction might not be completely prevented by local anesthetic (LA) drugs. Adding fentanyl to LA can avoid systemic opioids side effects.

Objectives: The aim of the current work was to evaluate the safety and efficacy of adding fentanyl to peribulbar block to abolish or decrease muscle traction pain during squint or buckle operations.

Patients and methods: This randomized clinical trial study included a total of 60 adult patients (18–65-year-old) of both genders booked for either squint or scleral buckle surgeries, attending at Research Institute of Ophthalmology, Giza, Egypt. Patients were allocated randomly into two groups (30 patients each); fentanyl group and control group. Intraoperative pain was the primary outcome, whereas secondary outcomes included the onset of complete akinesia and patient satisfaction.

Results: The median pain score was 1 for both groups. Two patients of the fentanyl group and 5 patients of the control group required general anesthesia. The mean time to achieving complete akinesia was shorter in the fentanyl group with a significant statistical difference (134.2 ± 35.8 vs. 156.3 ± 34.7 , $p = 0.018$). The patient satisfaction was more with fentanyl use but with no statistical significance.

Conclusions: It could be concluded that fentanyl added to the local anesthesia mixture of peribulbar block in squint and scleral buckle surgeries shorten the time needed to achieve complete akinesia. However, it does not improve the intraoperative pain resulting from muscle traction. Also, it does not affect the need for general anesthesia or postoperative patient satisfaction.

Keywords: Strabismus, squint, scleral buckling, peribulbar block, intraoperative pain, muscle traction, fentanyl.

INTRODUCTION

Surgical procedures for strabismus include adjustable suture surgery, minitotomy, and miniplication. Scleral buckling is performed to repair rhegmatogenous retinal detachments.

In squint and buckle surgeries, muscle traction causes intraoperative discomfort. In addition, the postoperative period is marked by significant pain and postoperative nausea and vomiting ^(1, 2).

Selecting the appropriate anesthetic technique and agents guided by the required level of analgesia and akinesia has crucial implications. In ocular surgeries, general anesthesia is suitable for patients of all ages especially the pediatric group, patients undergoing bilateral eye surgeries, and in long surgeries ⁽³⁾. Another option is topical anesthesia, but it would not provide akinesia. When akinesia is required, regional blocks can be used. Regional anesthesia shortens hospital stay, helps patients recover faster with less incidence of complications as hemodynamic instability, cardiorespiratory depression, nausea, vomiting, and emergence agitation ⁽⁴⁾. Sub-Tenon's, retrobulbar, and peribulbar blocks are three popular regional procedures ⁽²⁾.

Compared to retrobulbar blocks, the peribulbar technique is rarely associated with serious complications like ocular perforation ^(5, 6). The efficacy of peribulbar

anesthesia in ophthalmic surgeries has been reported in various studies ⁽⁷⁻¹⁰⁾. An ideal local anesthetic agent should act rapidly for an adequate duration. It should provide suitable analgesia intraoperatively and postoperatively. Commonly, a mixture of local anesthetics is used for peribulbar anesthesia. Frequently, bupivacaine 0.5% is combined with lidocaine 2% or mepivacaine 2%, and usually hyaluronidase is added to ease the diffusion of the anesthetics in the peribulbar space ⁽¹⁰⁾. However, the pain of muscle traction is not blocked by only local anesthetic drugs. In addition, one of the intraoperative drawbacks of these blocks is their limited duration of action ⁽¹¹⁾.

Fentanyl is a synthetic opioid, and its action is characterized by having a rapid onset and a short duration ⁽¹²⁾. The use of intravenous opioids for perioperative analgesia in ophthalmic surgeries decreased recently after variable studies reporting lack of advantage for intravenous opioids over other options as intravenous nonsteroidal anti-inflammatory drugs ⁽¹³⁻¹⁸⁾.

Several adjuvants have been used with regional anesthesia to enhance block features. Fentanyl has been added to local anesthetics used for regional anesthesia to improve analgesia ⁽¹⁹⁻²⁴⁾. This practice has been taken to reduce complications of systemic opioids, for example cardiorespiratory depression, drowsiness, and postoperative nausea and vomiting ^(11, 25-27).

Our study was conducted to assess the safety and efficacy of fentanyl added to the local anesthetic combination during peribulbar block to abolish or decrease muscle traction-induced pain and discomfort during squint or buckle surgery.

PATIENTS AND METHODS

This randomized clinical trial study included a total of 60 adult patients of both genders (18–65-year-old) booked for either squint or scleral buckle surgeries, attending at Research Institute of Ophthalmology, Giza, Egypt. This study was conducted between September 2022 and November 2022.

Inclusion criteria: Eligible participants were adults between 18 and 70 years of both sexes who were scheduled for either squint or buckle surgeries, with American Society of Anesthesiologists (ASA) I, II, or III and axial eye length ranging between 22 and 28 mm.

Exclusion criteria: Patients aged less than 18 or more than 70 years as well as patients with ASA IV, infection at the injection site, previously operated eye, coagulation disorders, sensitivity to any drug used in this study, communication difficulties preventing reliable assessment, high myopia (axial length more than 28 mm), or staphylocomas.

The patients were allocated randomly into two groups (30 patients each); **Group F (fentanyl):** patients were subjected to peribulbar block using a local anesthetic mixture composed of 9 ml of lidocaine: bupivacaine (2:7) with 60 IU of hyaluronidase plus 50 µg (1 ml) of fentanyl, and **Group C (control):** patients were received 10 ml of lidocaine: bupivacaine (2:7) with 60 IU hyaluronidase. All patients were assessed for all outcomes and were included in the final analysis (**Figure 1**).

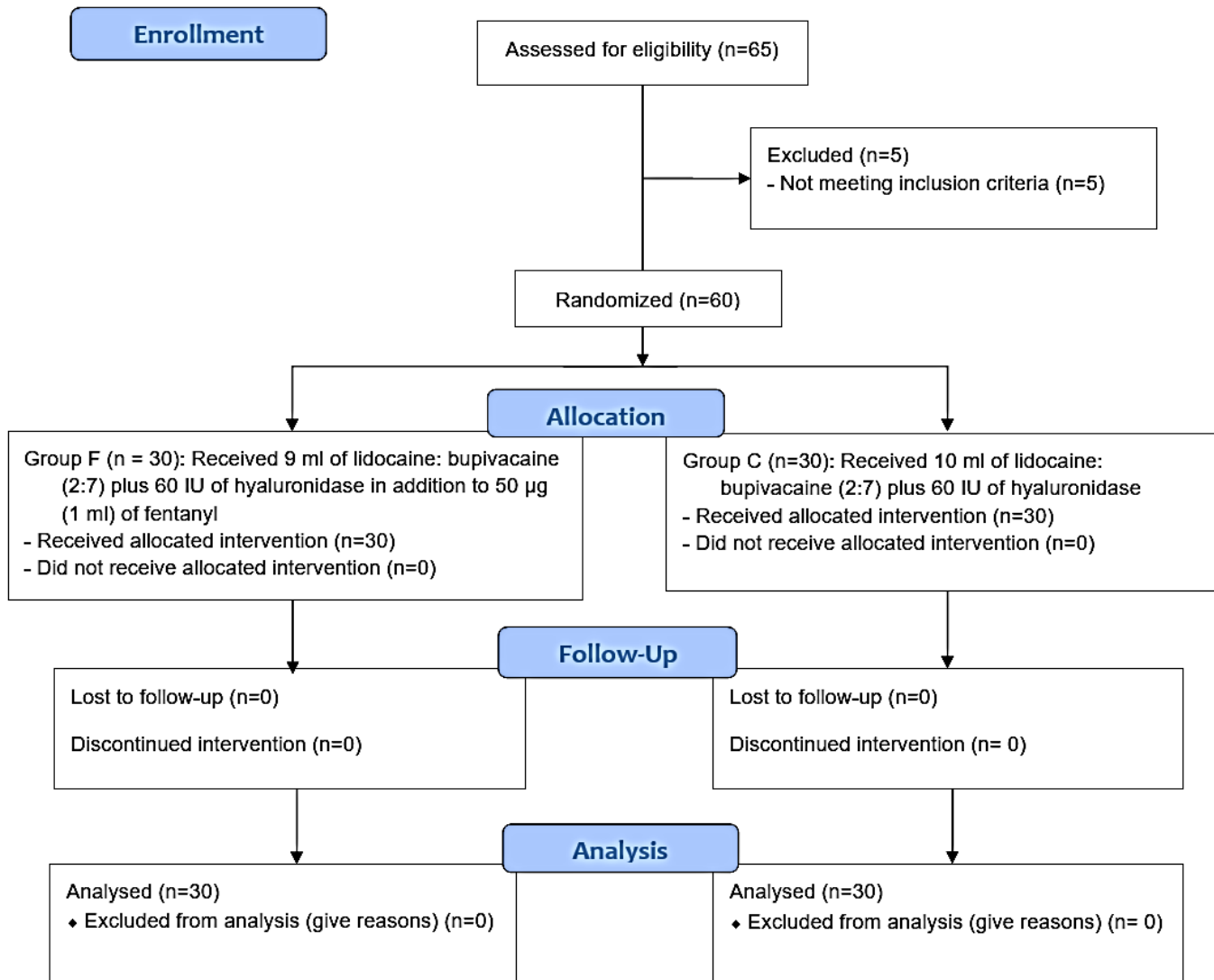


Figure 1. The CONSORT flow diagram of the trial.

The intervention

After entering the operating room, the patients were cannulated and fully monitored. They were then randomly assigned to two groups (30 patients each). In the fentanyl group (group F), peribulbar block was carried out using a 25 gauge/ 1” length needle to inject 9 ml of lidocaine: bupivacaine (2:7) with 60 IU of hyaluronidase, in addition to 50 µg (1 ml) of fentanyl at 3 points; infratemporal (4 ml), supra nasal (3 ml), and medial canthal (3 ml). Compression was done for 30 sec after each injection. In the control group (group C), a 25 G/ 1” length needle was used to inject 10 ml of lidocaine: bupivacaine (2:7) with 60 IU of hyaluronidase the same way as the previous group.

Study outcomes

The primary outcome was intraoperative assessment of pain by verbal rating scale during the steps of muscle traction. It is a 4-point scale where no pain is expressed as 0, while 3 means unbearable pain.

Mild to Moderate pain was managed using a sedative dose of midazolam and 50 µg of fentanyl. If pain continued or became not tolerated (score 3), we proceeded to general anesthesia using propofol for induction and laryngeal mask airway connected to a Bain breathing circuit (spontaneous ventilation) until surgery is finished. If the patient experienced severe pain from the beginning, we proceeded directly to general anesthesia as mentioned before.

Additional analyses were done for the secondary outcomes. Onset of complete akinesia was assessed using a 3-point scale where 0 indicates complete akinesia, 1 indicates limited akinesia, and 2 indicates normal movement. Postoperative patient satisfaction regarding the technique was also assessed.

Randomization, allocation concealment, and blinding

For randomization and allocation concealment the sealed envelopes method was used. Participants were assessed for eligibility, and eligible patients were assigned to either the intervention or the control group. Only the participants were blinded to treatment allocation.

Ethical considerations

This work has been executed according to The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies including humans. The research protocol gained approval from the Ethics Committee of the Research Institute of Ophthalmology, Egypt. Each patient gave an informed, written consent. The investigators were responsible for keeping the participants’ privacy and security of the data. This had a registration at the clinicalTrials.gov (NCT05539911).

Statistical analysis

The Statistical Package for the Social Sciences for Windows, Version 22.0. (Chicago, SPSS Inc, USA) was used. Categorical data were presented as numbers and percentages, and Chi-Square or Fisher’s Exact tests were applied to investigate the association between categorical variables as appropriate (when 25% of cells or more have an expected count less than 5).

We used Shapiro-Wilk test to test continuous data for normality. Normally distributed continuous data were expressed as means ± standard deviations and were compared using the Independent Samples Student’s T test. The non-normally distributed data were expressed as medians and interquartile ranges and were compared using the Mann-Whitney U test. Statistical significance was set at P < 0.05.

RESULTS

The two groups were comparable regarding age, sex, or type of planned surgery (All p-values > 0.05). The patients’ mean age was 36.6±12.4 years for the fentanyl group and 36.5±11.6 years for the control group. In each group, 22 patients had squint surgeries, and eight patients had scleral buckle surgeries (Table 1).

Table 1. Basic characteristics of the participants (n=60)

		Group F (n=30)	Group C (n=30)	p-value	
Age (years)	Mean ± SD	36.6±12.4	36.5±11.6	0.966	
Sex	Female	N	17	15	0.605
		%	56.7%	50.0%	
	Male	N	13	15	
		%	43.3%	50.0%	
Type of surgery	Squint	N	22	22	1.00
		%	73.3%	73.3%	
	Buckle	N	8	8	
		%	26.7%	26.7%	

Table 2 shows that the block characteristics were comparable in both groups except for the onset of complete akinesia. The median pain score assessed during muscle traction using the verbal rating scale was 1 for both groups without significant difference (p = 0.082). There was a lack of significant difference between the number of patients experiencing different pain scores (p = 0.085). Only two patients (6.7%) in the fentanyl group had unbearable pain during muscle traction that required general anesthesia compared to 5 patients (16.7%) in group C. The need for general anesthesia was comparable in the two groups (p = 0.424). The mean time to the onset

of complete akinesia was significantly shorter in group F (134.2±35.8 seconds) compared to group C (156.3±34.7 seconds) (p = 0.018). Overall, the number of patients satisfied with the procedure was 21 (70%) in group F and 20 (60.7%) in the other group with no significant difference (p = 0.781).

Table 2. Pain score during muscle traction, onset of complete akinesia, requiring general anesthesia, and patient satisfaction (n=60)

		Group F (n=30)	Group C (n=30)	p-value
Pain during muscle traction (measured by verbal rate scale)	Median	1.0	1.0	0.082
	IQR	.0-2.0	1.0-2.0	
	Mean rank	26.75	34.25	
Pain scores during muscle traction (Measured by verbal rate scale)	No	13 (43.3%)	5 (16.7%)	0.085
	Mild	8 (26.7%)	14 (46.7%)	
	Moderate	7 (23.3%)	6 (20.0%)	
	Severe	2 (6.7%)	5 (16.7%)	
Onset of complete akinesia, seconds	Mean± SD	134.2±35.8	156.3±34.7	0.018*
General anesthesia, n (%)	No	28 (93.3%)	25 (83.3%)	0.424
	Yes	2 (6.7%)	5 (16.7%)	
Patient satisfaction, n (%)	No	9 (30.0%)	10 (33.3%)	0.781
	Yes	21 (70.0%)	20 (66.7%)	

*Significant

DISCUSSION

Our study revealed no advantage for adding fentanyl to the local anesthetic combination used for peribulbar block in squint and scleral buckle surgeries in terms of intraoperative pain resulting from muscle traction, need for general anesthesia, or postoperative patient satisfaction. The time needed to achieve complete akinesia was the only block characteristic significantly affected by adding fentanyl.

Opioids are the most common adjuvants for local anesthetics (28). The theoretical basis of fentanyl as an adjuvant for potentiation of the analgesic effect of local

anesthetics could be explained by antinociception initiation due to activation of peripheral opioid receptors. Opioids can activate opioid receptors centrally and peripherally as well (29).

Opioids increase potassium conductance while local anesthetics act by inhibition of sodium channels. The combined action would lead to hyperpolarization of the nerve cell membrane. In addition, fentanyl added to local anesthesia can act centrally after peripheral absorption to the systemic circulation (23). Fentanyl has shown its efficacy in producing longer and more powerful pain control when added to local anesthetic mixtures of regional blocks (19-24).

Wulff *et al.* (27) added fentanyl to the local anesthetics of peribulbar block in 70 adult cataract patients. The drug had favorable outcomes as shortening of the latency of the anesthetic and providing greater postoperative analgesia without interfering with the degree of akinesia. It is worth mentioning that in that trial, the researchers excluded the patients in whom the anesthetic technique was changed because of insufficient analgesia or even the patients who needed intraoperative intravenous analgesics. Shortening the time needed to achieve complete akinesia as demonstrated in our study was also shared by Abo El Enin *et al.* (25) and Nehra *et al.* (26) who reported that fentanyl enhanced the onset and prolonged the duration of akinesia along with the postoperative pain control. Reports about the effect of using fentanyl with peribulbar block on intraoperative pain caused by muscle traction are lacking.

Youssef *et al.* (11) reported absence of significant differences in intraoperative as well as postoperative comfort between patients who received fentanyl in the anesthetic mixture and those who did not. The study was conducted on 90 patients scheduled for cataract surgeries with peribulbar block. They compared the effects of adding fentanyl and clonidine to bupivacaine. The researchers reported that fentanyl significantly accelerated and prolonged both globe anesthesia and akinesia and improved postoperative analgesia.

CONCLUSION

It could be concluded that fentanyl added to the local anesthesia mixture of peribulbar block in squint and scleral buckle surgeries shorten the time needed to achieve complete akinesia. However, it does not improve the intraoperative pain resulting from muscle traction. Also, it does not affect the need for general anesthesia or postoperative patient satisfaction.

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