International Journal of Research and Review
Vol.7; Issue: 10; October 2020
Website: www.ijrrjournal.com
Original Research Article *E-ISSN: 2349-9788; P-ISSN: 2454-2237*

Patient Pain during Intravitreal Injection under Modified Topical Anesthesia - A Comparative Study

Ishfaq Ahmad Sofi[1], Bipul Kumar Singh[2]

[1]MS. Lecturer, Postgraduate Department of Ophthalmology, Government Medical College, Jammu.
[2]MBBS. Postgraduate Resident, Department of Hospital Administration, Armed Force Medical College, Pune.

Corresponding Author: Ishfaq Ahmad Sofi

ABSTRACT

Purpose: To compare the pain experienced by the patients during intravitreal injection under two different techniques of topical anesthesia.
Materials and Methods: Total ninety-four, treatment-naive, female patients, receiving intravitreal injections (Ranibizumab/ Bevacizumab) were included in this prospective study. They were randomized to either of the techniques of anesthesia. Group A (n=47) 0.5% proparacaine eye drops. Group B (n=47) 0.5% proparacaine eye drops plus proparacaine-soaked cotton bud. Immediately after the injection, each patient was given a visual analog scale (VAS) to rate their pain experienced during the injection between 0 (no pain) and 10 (worst-pain, unbearable).
Results: Mean VAS pain score was 2.32 ±2.20 in group A and 2.11 ±3.42 in group B, with no statistically significant difference (p = 0.170) between the two groups. Surgeon satisfaction was significantly better in Group B (7.06 ±0.89 in Group A and 8.58 ±0.62 in Group B, p=0.04).
Conclusion: Although there was no significant difference in VAS pain scores between the groups but surgeon satisfaction was significantly higher in group B using proparacaine soaked cotton bud at the injection site in addition to proparacaine eye drops.

Keywords: Pain, Visual Analog Scale, Intravitreal Injection, Topical Anesthesia.

INTRODUCTION

Intravitreal injection has become one of the most common treatment procedures in vitreoretinal practice nowadays. The safety and efficacy of intravitreal injection (IVI) of anti-vascular endothelial growth factor (Anti-VEGF) agents in the management of diabetic macular edema (DME), neovascular age-related macular degeneration (nAMD) and macular edema secondary to retinal vascular occlusions (RVOs) were shown in multiple studies. [1-4] Patient comfort and pain experienced during injection is an important factor in compliance and satisfaction. A variety of anesthetic agents and different techniques had been tried to minimize the pain and discomfort associated with IVI procedure. [5-9] All these methods of anesthesia are found to be effective without any significant difference in terms of pain scores during injection. [10, 11] The aim of this study was to compare the pain experienced by the patients during intravitreal injection under same anesthetic agent applied with two different techniques.

MATERIAL AND METHODS

This was a prospective, randomized, double-blinded, comparative study carried out at Ophthalmology department of a tertiary care centre in northern India between March 2019 to February 2020. A total 94 consecutive female patients scheduled to receive an intravitreal Anti-VEGF (Ranibizumab/Bevacizumab) injection for the first time (treatment Naive) and who were ready to participate in the study were included in the study. Informed consent was obtained from all the patients. The study was performed in accordance with the Declaration of Helsinki and was approved by institutional ethical committee

(IEC/GMC/2019/026). All the injection procedures were performed by the same surgeon. Patients were randomized into two groups (A and B) using 1:1 block permuted randomization (47 patients in each group). Group A received 0.5% proparacaine eye drops while as in Group B proparacaine soaked cotton bud was applied at the injection site for 1 minute in addition to 0.5% proparacaine eye drops.

All the patients included in the study received a drop of 0.5% proparacaine followed by 5% Povidone-iodine solution. The periocular area was cleaned with 10% Povidone-iodine. Procedures were performed under all aseptic precautions in an operating room. A wire speculum was placed. One more drop of 0.5% proparacaine and 5% Povidone-iodine was instilled in the conjunctival sac in all the patients. In addition to this, in Group B patients a sterile cotton bud soaked with 0.5% proparacaine was applied at the injection site and pressed for 1 minute. 0.05 ml of the drug (Bevacizumab/Ranibizumab) was injected, using 30G needle, into the vitreous cavity through the pars plana in superotemporal/inferotemporal quadrant, 3.5 mm to 4mm posterior to the limbus (3.5mm in pseudophakic and 4mm in phakic). Mild pressure was applied with a sterile cotton bud over the injection site to reduce vitreous reflux. 5% Povidone-iodine was instilled in the conjunctival sac at the end of injection. An adhesive tape was applied to close the eyelids for 2 hours in all the patients. Immediately following the injection, a staff nurse explained the 10 mm visual analog scale (VAS) for pain. Patients were asked to rate their pain experienced during the injection between 0 (no pain) and 10 (worst pain, unbearable) on VAS. The mean of these scores was used for statistical analysis. The level of surgeon's satisfaction was also rated from 0 to 10. The patient, Staff nurse and the statistician all were masked to the group randomization and the type of anesthesia technique used.

Statistical Analysis:

All the data was entered into Microsoft excel and subsequently analyzed with the help of IBM SPSS (SPSS for Windows Version 22, Chicago, IL, USA). Mean (±Standard Deviation) VAS pain score, surgeon satisfaction score and age were estimated for both the groups and statistical significance between the two groups was assessed with the help of Mann–Whitney U-test. P-values less than 0.05 were considered as statistically significant.

RESULTS

The mean age was 64.19±11.30 in Group A and 62.50 ±13.21 in group B (p=0.34). There was no statistically significant difference in age between the groups. Diabetic macular edema was the most common indication for intravitreal anti-VEGF injection (44.68% in Group A and 36.17% in Group B), followed by neovascular age related macular degeneration (31.91% in Group A and 29.78% in Group B) and macular edema secondary to retinal vein occlusions (23.40% in Group A and 34.04% in Group B). Mean VAS pain score was 2.32 ±2.20 in group A and 2.11 ±3.42 in group B, with no statistically significant difference (p = 0.170) in the mean pain score of patients between the two groups. [Table 1] There was statistically significant difference in mean Surgeon's satisfaction between the two groups done under different techniques of topical anesthesia using the same anesthetic agent (7.06 ±0.89 in Group A and 8.58 ±0.62 in Group B, p=0.04). [Table1]

Table1: Comparison between two groups regarding Age, Indications, Mean Pain Score Surgeon satisfaction.

		Group A	Group B	p-value
Age (years) mean±SD		64.19 ±11.30	62.50 ±13.21	0.34
Indication for injection, n(%)	DME	21(44.68)	17(36.17)	
	nAMD	15(31.91)	14(29.78)	
	RVO	11(23.40)	16(34.04)	
VAS Pain score (mean±SD)		2.32 ±2.20	2.11 ±3.42	0.17
Surgeon satisfaction score (mean±SD)		7.06 ±0.89	8.58 ±0.62	0.04

DISCUSSION

With the widespread use of different intravitreal injections and many patients requiring multiple injections, pain and discomfort experienced during the procedure directly affects the patient care as well as management of the disease. Therefore it is important for the treatment success to consider the pain during the procedure. Since pain is a subjective concept influenced by many factors, it has been difficult to assess its severity. A visual analog scale is used to measure subjective experiences or attitudes that may be difficult to assess when there are no fixed boundaries for comparison. [12] Visual Analog Scale (VAS) has been used to evaluate pain and other symptoms in most of the studies including ophthalmological studies and shown to be valid and reliable. [13-18] In our study, we also used the VAS as a method of assessing pain. We had selected patients of one gender only (females) in our study in order to remove bias associated with the gender of the participants as was elicited by Bilgin B et al [19] in their study showing that there was a significant difference for average VAS pain scores between male and female groups (P = 0.001) while comparing VAS Scores in all males verses females (VAS pain scores in male and female patients were 2.87 ± 1.81 and 4.83 ± 2.67, respectively). A number of studies had assessed patient pain score during intravitreal injections using different agents and different anesthetic methods. In most of these studies it was found that all of these methods were effective. [10, 11, 17, 20] Most of these studies have shown no significant difference in pain score between pledget, subconjunctival injection, or topical drops. [6, 10, 11, 21, 22] Blaha et al. compared the effectiveness of proparacaine, tetracaine, lidocaine pledget, and subconjunctival injection of lidocaine. They found no statistical difference in injection or total procedure pain scores between these methods. [10] Davis et al. also evaluated the difference in anesthetic effect between topical proparacaine drops, 4% lidocaine-applied cotton tipped swabs, or 3.5% lidocaine gel. After the injection they asked the patients to grade the discomfort associated with 3 components of the injection procedure: (1) the lid speculum; (2) the needle insertion; and (3) the burning sensation from the 5%povidone-iodine solution. They did not find any difference between the groups in any of the factors that might cause discomfort during the injection. [6] However, there are also a few studies claiming that there was difference between the anesthesia methods. LaHood et al. compared the anesthetic effectiveness of topical gel, subconjunctival and combination of topical gel, and subconjunctival anesthesia for intravitreal injection in 120 consecutive patients. Their results showed that the group receiving topical gel anesthetic produced significantly higher pain scores compared to both of the other groups. [18] Blaha et al. did not find statistically significant difference between topical proparacaine drops, pledget of 4% lidocaine, and subconjunctival injection of 2% lidocaine. But they reported that proparacaine drops had the lowest average combined with pain score. [23] In the present study we used same anesthetic agent (proparacaine 0.5%) used with two different methods (eye drops only and eye drops plus proparacaine soaked cotton bud applied at injection site), we found that there was no statistical difference in mean VAS pain score between the two groups, However there was a significantly better surgeon satisfaction score in the second group in which proparacaine-soaked cotton bud was pressed at the injection site for 1minute. A limitation of our study arises from the fact that pain experienced by the patient is subjective assessment and cannot be measured directly or quantitatively.

CONCLUSION

Although there was no significant difference in VAS pain scores between the groups but surgeon satisfaction was significantly higher in group B using proparacaine soaked cotton bud at the

injection site in addition to proparacaine eye drops.

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How to cite this article: Sofi IA, Singh BK. Patient pain during intravitreal injection under modified topical anesthesia - a comparative study. International Journal of Research and Review. 2020; 7(10): 253-257.

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