Original Research

Single versus Double site Peribulbar Anaesthesia for Cataract Surgery- A Prospective comparative study

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Abstract

Background: Today,Cataract surgery is always performed under regional or local anaesthesia, unless medically contraindicated.

AIM: To compare the efficacy and safety of single injection technique of Peribulbar anesthesia with that of double site injection technique for cataract surgery.

Material and Methods: This was a single-centre, hospital based, prospective observational study involving 192 patients (96 patients in each group) conducted over a period of 18 months. Patients undergoing elective cataract surgery were divided into two groups- **Group S**: Single site injection for peribulbar anaesthesia and **Group D:** Double site injection for peribulbar anaesthesia. We measured and recorded: akinesia, analgesia and complications. **Results:**The difference in grade of akinesia was statistically insignificant ($p>0.05$) between the two groups at 5-, 10-, and 15 minutes after the injection. The mean time for onset of analgesia among the participants in the single and the double injection group was 7.8 and 6.2 minutes, respectively, however, this difference was statistically insignificant ($p=0.086$). The mean total duration of analgesia among the participants in the single and double injection group was 103 and 118 minutes respectively, however, the difference is statistically insignificant ($p=0.094$). A total of 48 participants had subconjunctival hemorrhage: 19 (19.7%) in single injection group and 29 (30.2%) in double injection group ($p=0.058$). In the present study only 56 participants had chemosis: 23 (23.96%) in the single and 33 (34.38%) in the double injection group ($p=0.112$).

Conclusion: When compared to double-site peribulbar anaesthesia, the single-site injection of peribulbar anaesthesia is the recommended procedure because it lowers the risk of complications.

INTRODUCTION

A Cataract is the pathological condition in which the natural lens of the eye loses its transparency and becomes opaque, thus hindering the entry of light in the eye thereby obstructing/diminishing normal vision(1). Cataracts commonly result in impaired or diminished vision, but they can also produce additional signs and symptoms including glare, haloes, elevated myopia, and monocular diplopia. Age-related cataracts are often progressive, and if left untreated, they can limit everyday activities and independence(2). Poor eyesight in the elderly affects both physical and cognitive performance and is linked to a lower quality of life(3). The National Blindness and Visual Impairment Survey was done in India between 2015 and 2019 reported that the prevalence of blindness among individuals aged 50 and older was 1.99%(4). In addition, the highest prevalence of blindness was seen among those aged 80 and above (11.6%), followed by those aged 70-79 (4.1%), 60-69 (1.6%), and 50-59 (0.5%). Collectively, cataracts were the leading cause of blindness (66.2%), severe visual impairment (80.7%), and moderate visual impairment (70%) in the general population(4). In addition, cataract-related surgical complications were responsible for 7.2% of instances of blindness. As there are no well-documented, effective ways of preventing age-related cataract, all efforts are directed toward providing surgery to those who need it(1,5,6). Currently, surgery is the only option for treating cataracts that is both successful and advised. Cataract surgery is often performed under regional or local anaesthesia, unless medically contraindicated. Retrobulbar blocks, which carry anaesthetic into the

muscle cone, and peribulbar blocks, which injects the anaesthetic into the extraconal area, are two sharp needle procedures for administering local anaesthesia(7,8). In spite of sub-tenons and topical or intracameral applications of local anaesthesia for cataract surgery becoming more and more popular, peribulbar or retrobulbar anaesthesia is still the method of choice in many areas of the world including both developed and developing countries. Retrobulbar anaesthesia (RB) is given by precisely delivering the local anaesthetic agent into the space behind the eye (7,8). Peribulbar anaesthesia (PB) is given by delivering the local anaesthetic agent outside the muscle cone. Like the retrobulbar approach, peribulbar anaesthesia aims to ensure ocular akinesia (eye stability) and anaesthesia during surgery; it is considered by some to be safer than retrobulbar anaesthesia. A Cochrane Systematic review by Alhassan MB et al., (2015) showed that pain control and paralysis of the eye muscles to produce akinesia were similar for the two types of anaesthesia(7). The need for additional injections of local anaesthetic was higher with peribulbar anaesthesia. However, retrobulbar haemorrhage cases were seen only with retrobulbar anaesthesia(9). It is acknowledged that using the retrobulbar method might result in substantial eye injury when a needle is blindly inserted into the intraconal area. Scleral perforation, oculocardiac reflex stimulation, and anaesthetic drug injection into the perioptic meningeal area are among the hazards(7). In recent years, peribulbar anaesthesia has gained popularity due to its relative efficacy in generating ocular akinesia and anaesthesia with a reduced risk of consequences such as optic nerve damage and globe perforation. Peribulbar anaesthesia may be administered by injecting the anaesthetic substance at two separate locations (Double injection method) or at a single site (single injection technique)(10). Although complications such as subconjunctival haemorrhage (SCH), conjunctival chemosis, and injury to intra-orbital structures are reduced with the double injection technique of peribulbar anaesthesia, the injection site in the superior orbital quadrant is regarded as a potential source of globe perforation(10). The single-injection technique of percutaneous peribulbar anaesthesia utilising less volume of local anaesthetic agent with a short needle is as effective, simple, and easy to perform as the multi-injection technique, causes less pain to the patient, and produces satisfactory anaesthesia and akinesia. These potential benefits prompted us to compare the efficacy and safety of single-site vs double-site peribulbar anaesthetic injection techniques for cataract surgery. The present study was designed with an aim to compare the safety and effectiveness of single site injection versus double site injection technique of peribulbar anaesthesia for cataract surgery.

MATERIAL AND METHODS

Study Design: Prospective Observational study.
Study Setting: Department of Ophthalmology, Laxmi Narayan Medical College, and JK hospital, Bhopal, Madhya Pradesh.
Study Duration: 18 months **Study Outcomes:** Akinesia: Degree and Grade; Analgesia: Onset and Duration; Complications

COMPARATIVE GROUPS

1. **Group S**: Single site injection for peribulbar anaesthesia
2. **Group D:** Double site injection for peribulbar anaesthesia

a) Inclusion: Patients aged >= 18 years; Patients of all genders; Patients consenting to participate in the study.

b) Exclusion Criteria: Allergic to anesthetic agent; Pre-existing ocular muscle paresis, neurological deficit; Co-existing inflammatory conditions of eye; Complicated cataracts; Previously operated eyes; A patient refused to take part in the study.

Sample Size: The minimum required sample size for the study was calculated using the formula recommended by Zhong B (2019) for a prospective comparison study. Using the formula for randomised control trial, the minimum sample size was calculated as 192 participants: with 96 participants in each of the two groups. **Informed Consent:** Everyone who participated was provided with a copy of the consent form to read. Following that, the contents of the permission form were explained to every potential participant in easy-to-understand language. It was made clear to the participants, both verbally and in writing, that they are free to discontinue their participation in the research at any moment. After that, those participants who were willing to take part were asked to sign the consent form. **Sampling:** We employed non-random, purposive, convenience sampling methodology for recruiting participants for the study. All participants posted for cataract surgery were approached for enrolment in the present study one day prior to surgery. Those agreeing to participate in the study and fulfilling selection criteria were enrolled in the present study. **Data Collection:** The data were collected in a paper-based questionnaire. The questionnaire was approved by the ethical committee before starting data collection.

PLAN AND PROCEDURE:

a) A detailed history and a thorough clinical examination of every patient were completed by the surgical team. Appropriate laboratory and radiological investigations were conducted. A detailed pre-anaesthetic evaluation was completed one day before the surgery.

b) The preoperative examination included best corrective visual acuity, slit lamp examination, fundus evaluation, intraocular pressure, lacrimal

syringing and intraocular lens power calculation followed by necessary investigations such as blood sugar levels, HIV, HBsAg and ECG.

c) On arrival in the operating room, the identity of the participant and the consent were verified again; the preoperative assessment was reviewed and updated. Various monitors were attached to measure the multiple vital parameters viz. pulse rate, non-invasive blood pressure, pulse oximetry, cardiac rhythm, and body temperature during the peri-operative period.

Technique of peribulbar anesthesia

a. Single site injection, patient were explained about the procedure and was asked to look in primary gaze. Using a 24 gauge disposable needle mounted on 5ml syringe injection was given inferior temporally at the junction of lateral 1/3rd and medial 2/3rd of lower orbital margin and 5ml of anesthetic drug was injected after cautious aspiration to rule out intra-vascular needle placement.

b. In double site injection, patient were explained about the procedure and was asked to look in primary gaze. Using a 24 gauge disposable needle injection was given inferior-temporally at the junction of lateral 1/3rd and medial 2/3rd of lower orbital margin and 3.5ml of anesthetic drug was injected. The other injection was given on supero-nasal margin of orbit at the junction of medial 1/3rd and lateral 2/3rd and 3.5ml of anesthetic drug was injected after cautious aspiration to rule out intra-vascular needle placement.

i. All cataract surgeries were performed under peri-bulbar anaesthesia by a single experienced surgeon. Subjects underwent standard small incision cataract surgery technique using in the bag one-piece polymethyl Methacrylate (PMMA) posterior chamber intraocular lens implantation.

ii. After the participants were shifted to the postoperative room, their condition was monitored by the hospital staff for any adverse events or complications. The occurrence of any adverse event during the postoperative period was recorded.

Statistical Analysis Plan: The primary outcome was the difference in the degree of akinesia and analgesia among the participants given single site and double site injection for the peribulbar anaesthesia for cataract surgery. We aimed to assess whether data supplied evidence for the superiority of two site injection over the one site injection technique. In addition, we also aimed to assess whether data supplied evidence for any significant difference in the occurrence of side effects among the two study groups. All the data were collected in a paper-based data collection form. Thereafter, the data were coded and entered in Microsoft Excel. The coded data were imported into Stata 17.1 version for analysis. A comparison of continuous variables with baseline values was analysed using a student's t-test in each group. Categorical variables were analysed using chi-square (χ^2) tests. A *P*-value < 0.05 was considered statistically significant. **Funding:** The present study did not receive any financial support. The researchers did not provide the participants with any financial compensation, presents, or other forms of compensation.

RESULTS

The mean age of the participants in the single and double injection group was almost same (59.7 versus 60.8 years; p-value =0.463). Further, most of the participants in both single as well as double injection group were more than 60 years of age. Among the 192 participants; 51.6% were female and remaining 48.4% of participants were male (p=0.664). In the present study, the degree or grade of akinesia among the participants in the single and double injection group was assessed at 5-, 10-, and 15 minutes after injection. After 5 minutes after injection among the single and double injection group 28.1% and 31.3% participants had score 0 i.e., no movements. After 15 minutes after injection among the single and double injection group 56.3% and 55.2% participants had score 0 i.e., no movements. The difference in grade of akinesia was statistically insignificant (p>0.05) between the two groups at 5-, 10-, and 15 minutes after the injection. The mean time for onset of analgesia among the participants in the single and the double injection group was 7.8 and 6.2 minutes, respectively, however, this difference was statistically insignificant (p=0.074). The mean total duration of analgesia among the participants in the single and double injection group was 103 and 118 minutes respectively, however, the difference is statistically insignificant (p=0.094). A total of 64.5% and 67.7% participants in the single and double injection group had analgesia for 90-120 minutes. A total of only 8.3% and 5.2% participants in the single and double injection group required supplementary injection (p=0.566). In the single injection group, 43.8% and 56.3% rated their experience as good and fair respectively. In comparison among double injection group, 51.04% and 48.96% rated their experience as good and fair respectively (p=0.311).

Table 1: Grading of Akinesia

Grade	Group					
	5 Minutes		10 Minutes		15 Minutes	
	Single	Double	Single	Double	Single	Double
Score 0: No movement	27	30	51	53	54	53

	28.1	**31.3**	**53.1**	**55.2**	**56.3**	**55.2**
Score 1: Reduced Movement	61	60	40	39	40	40
	63.5	**62.5**	**41.7**	**40.6**	**41.7**	**41.7**
Score 2: Normal Movement	8	6	5	4	2	3
	8.3	**6.3**	**5.2**	**4.1**	**2.1**	**3.1**
P-value	0.798		0.92		0.148	

A total of 48 participants had subconjunctival hemorrhage: 19 (19.7%) in single injection group and 29 (30.2%) in double injection group (p=0.058). In the present study, most participants in both single and double injection group had SCH either in 1 or 2 quadrants. In the present study only 56 participants had chemosis: 23 (23.96%) in the single and 33 (34.38%) in the double injection group (p=0.112). In the present study, most participants in both single and double injection group had chemosis either in 3 or more quadrants. In the present study only 14 participants had ecchymosis: 4 (4.17%) in the single and 10 (10.42%) in the double injection group (p=0.112). In the present study only 2 participants (both in double injection group) had lid hemorrhage. In the present study only 2 participants (both in double injection group) had retrobulbar hemorrhage.

Table 2: Onset of action of Analgesia (n=192)

Onset of Analgesia	**Group**	
	Single	**Double**
Mean	7.8	6.2
0-5 Minutes	26(27.1%)	31 (32.3%)
6-10 Minutes	50 (52.1%)	54 (56.3%)
11-15 Minutes	14 (14.6%)	11 (11.5%)
>15 minutes	6 (6.3%)	0 (0.0%)

Table 3: Complications among participants in the two groups (n=192)

Side Effects	**Group**		
	Single	**Double**	**P-value**
Chemosis	23 (24.0%)	33 (34.4%)	0.058
Sub-Conjunctival Hemorrhage	19 (19.7%)	29 (30.2%)	0.112
Ecchymosis	4 (4.2%)	10 (10.4%)	0.087
Lid Hemorrhage	0 (0.0%)	2 (2.1%)	0.1551
Retrobulbar Hemorrhage	0 (0.0%)	2 (2.1%)	0.1551

DISCUSSION

In the present study degree or grade of akinesia among the participants in the single and double injection group was assessed at 5-, 10-, and 15 minutes after injection. In the present study, 5 minutes after injection, in the single and double injection group 28.1% and 31.3% participants had score 0 akinesia i.e., no movements. Further, after 5 minutes of injection, 8.3% and 6.3% of participants had normal eye movement. However, after 5 minutes of giving injection the difference in the degree of akinesia was statistically insignificant between the participants given single and double injection peribulbar block for cataract surgery. **Anneshi RC et al.** found that in the single injection group, 5 minutes after injection, 8.2% of patients had full movements, 62% had decreased motions, and 29.8% of patients had no movements(11). This is quite comparable to our findings. A total of 31.6% of participants in the two fold injection group experienced whole akinesia, 7% had full movements, and 61.4% had decreased movements (P=0.073). Additionally, **Deruddre S et al.** observed that after five minutes, there was no discernible change in akinesia ratings between the single and double injection groups(12). At 15 minutes after injection among the single and double injection group 56.3% and 55.2% participants had score 0 i.e., no movements. In addition, 2.1% and 3.1% of participants in the single and double injection group had normal eye movement after 15 minutes. **Anneshi RC et al.** found that in the single injection group, 15 minutes after injection, 4.7% of patients had full movements, 41.5% had decreased motions, and 53.8% of patients had no movements(11). This is consistent with our findings. 2.9% of those who received two injections had full motion, 41.4% had limited motion, and 55.6% had entire akinesia (P=0.061). **Deruddre S et al.** also noted that after fifteen minutes, there was no discernible difference between the two groups' akinesia ratings. After 15 minutes of administration, the akinesia scores in the groups receiving a single injection and a double injection were equal (0.2)(12). After 15 minutes of injection, **Kollaritis et al.** found that 82% of patients receiving peribulbar anaesthesia were completely akinesic(13). According to a research by **Ghali AM et al,** the effectiveness of the single injection method and the traditional double injection techniques was comparable after 15 min (93% vs. 84%) in the groups receiving the single injection and the double injection, respectively(14).Contrary to our

findings, **El Said TM et al.** stated that double injection classic peribulbar anaesthesia was superior than single injection peribulbar anaesthesia in terms of globe akinesia and globe anaesthesia, although the differences were not statistically significant(15). Another work by **Mahfouz et** al. shown that a sufficient block may be obtained with a single peribulbar injection administered either medially or infero-temporally (the traditional approach) (single percutaneous technique)(16). This supports the claim that a single injection is just as effective as a double injection approach for providing enough akinesia and analgesia during cataract surgery.The mean time for onset of analgesia among the participants in the single and the double injection group was 7.8 and 6.2 minutes, respectively, however, this difference was statistically insignificant (p=0.086). According to **Abdul Rahman et al.,** both the single and double injection groups had satisfactory analgesia after 10 minutes of administration(17). According to **Aneeshi RC et al.,** in the single injection group, 30.4% of patents required 0–5 minutes for the medication to take effect, 52.6% of patients took 0–10 minutes, and 16.8% took 0–15 minutes. 31.6% of patients in the double injection group took 0–5 minutes, 55.6% took 5–10 minutes, and 11.7% took 15–20 minutes (P=0.053)(11). The average time for the onset of analgesia in the single and double injection blocks was 10.05 and 10.40 minutes, respectively, according to **Deruddre et al**(12)**. El Said TM et al.** revealed that although the double injection classic peribulbar anaesthesia group had a greater rate of globe anaesthesia onset than the single peribulbar injection group, the differences were not statistically significant(18).The mean total duration of analgesia among the participants in the single and double injection group was 103 and 118 minutes respectively, however, the difference is statistically insignificant (p=0.094). According to **Anneshi RC.,** who studied 171 patients in the single injection group, the duration of analgesia was as follows: 10 patients' aesthetic action lasted for 30–60 minutes, 35 patients' action lasted for 60–90 minutes, 110 actions lost for 90–120 minutes, and 16 patients' action lost for more than 120 minutes. These results are similar to the findings of the current study(11). The difference in action time between the 2 groups was similarly not statistically significant (P=0.051).About 8.3% and 5.2% of the participants in the present study research needed an additional injection of local anaesthetic to complete the procedure (p=0.566). Nine patients (18%) in both the single and double peribulbar injection techniques required one additional injection to create the proper circumstances for surgery, according to **Abdulrahman AA et al**(17)**.** Similar to this, **Deruddre S et al.** observed that in order to provide favourable circumstances for surgery, the necessity for supplemental injection was equivalent across individuals given single and double peribulbar injection techniques(12). Similar to this, **Budd et al.** observed that both the single and double peribulbar injection techniques required one supplemental injection from volunteers in order to provide the ideal circumstances for surgery(19). **Ghali et al.,** in contrast to our findings, reported that 16% of participants in the double injection group and 7% of those in the single injection group, respectively, required supplemental injection (p0.05)(14). In the present study, 48 patients experienced subconjunctival haemorrhage, with 19 (19.7%) patients receiving a single injection and 29 (30.2%) patients receiving a double injection (p=0.058). Out of 171 patients in the single injection group, **Anneshi RC et al.** found that 136 (79.5%) had no SCH, 20 (11.6%) had SCH in one quadrant, 15 (8.7%) had SCH in two quadrants, and 3 (1.5%) had SCH in three or more quadrants(11). Similar to our findings, the double injection group had a higher rate of sub-conjunctival haemorrhage, however this difference was not statistically significant. Similar to our study, **Abdulrahman et al.** reported that only one patient in the double injection group had SCH and no patients in the single injection group had SCH. However, the difference between the two groups' rates of incidence of SCH was statistically insignificant (p=0.99)(17). In contrast to our findings, **Ghali and Hafez found** that the single injection group had a greater frequency of subconjunctival haemorrhage, which they ascribed to the restriction of bleeding to the anterior region of the orbit(14). According to **Mahfouz et al.,** the incidence of subconjunctival haemorrhage was 18% greater in the group receiving superficial peribulbar anaesthesia than it was in the group receiving traditional peribulbar block (0.5%; P 0.001)(16). **Stan and colleagues (1997**) reported subconjunctival haemorrhage in 56% of cases, compared to **Wasee and colleagues (2006)** who recorded it in 23% of patients(20,21).Of the 56 patients in the current study, 23 (23.96%) who received a single injection and 33 (34.38%) received a double injection developed chemosis (p=0.112). Chemosis was noted in 14 patients in the double injection group and none in the single injection group, according to **Abdulrahman et al.** (P=0.0001)(17). The single injection group, however, had a greater frequency of chemosis which **Ghali and Hafez** ascribed to the restriction of bleeding to the front region of the orbit(14). In comparison, only four patients developed chemosis that did not interfere with surgery were documented by Rizzo et al (22). **Anneshi RC et al.,** reported that overall, double injection group had higher chemosis than single injection group, although this difference was not statistically significant(11). They concluded that when an anaesthetic agent was administered during surgery, the single injection approach was more pleasant for the patient since problems including SCH and chemosis were less common than with the double injection technique. In contrast to our findings, **Ghali and Hafez** found that the single injection group had a greater frequency of chemosis which they

ascribed to the restriction of bleeding to the anterior region of the orbit(14).

LIMITATIONS

This was an observational study, thus, the distribution of the patient related confounding variables such as age, weight, type of cataract could not be controlled for the in the single and double injection group.

CONCLUSION

When compared to double-site peribulbar anaesthesia, the single-site injection of peribulbar anaesthesia is the recommended procedure since it causes less discomfort during administration. Because both the amount of the injection and the number of injection sites are increased in a double-site injection, the risk of complications such as chemosis and subconjunctival haemorrhage is higher than in a single-site injection. It is recommended to use the single site injection technique of peribulbar anaesthesia because it lowers the risk of complications caused by the additional injection that is administered during the double injection technique of peribulbar anaesthesia.

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