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Original Research Article

A comparative study of clinical outcome following topical versus peribulbar anesthesia in phacoemulsification surgery

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ABSTRACT

Objective: The objective of our study was to evaluate and compare clinical outcomes, patients and surgeon's satisfaction following topical versus peribulbar anesthesia in phacoemulsification surgery.
Materials and Methods: A hospital based Randomized Prospective interventional Comparative Study done between November 2017 to May 2019. A total of 200 patients included in the study, ocular examination, biometry were done. Patients were randomly distributed into group1 TA (topical anesthesia) and group 2 PA (Peribulbar anesthesia), they underwent phacoemulsification with intraocular lens implantation, postoperative visual outcome and inflammation on day1 and after 1 week, VAS (Visual Analogue scale) pain scale used to analyse patients comfort and pain postoperatively. The Statistical analysis was performed by STATA 11.2 (College Station TX USA).
Results: In our study 200 participated, it was found in PA group, 60.47 ± 11.86 yrs and in TA group 59.01 ± 11.29yrs as mean age, majority were male. PA group had few complications during anesthesia and in both groups majority had no intraoperative complications. Log Mar visual acuity postoperative day 1, PA group was 0.65±0.40 and in TA was 0.49±0.32, post operative visual recovery was better in TA group patients and had less pain and more comfortable than PA. Surgeon had difficulty more with TA group patients.
Conclusion: It was found, postoperative visual recovery was faster and better in patients with topical group with less postoperative inflammation and complications. Topical anesthesia being a non invasive procedure can be considered better than peribulbar when compared in terms of patients comfort and postoperative recovery.

1. Introduction

Cataract forms the second most prevalent treatable cause of blindness in world. From cataract extraction by sushruthas couching to Charles Kelmans Phacoemulsification, there has been phenomenal progression. Success of cataract surgery, decided by earliest and best visual rehabilitation, but hurdle is postoperative astigmatism, it depends on incision. Phacoemulsification being NO SUTURE and clear corneal incision technique, nullifies postoperative astigmatism and helps in quick rehabilitation. [1]

In India, National survey on blindness 2001-2002 shows prevalence of blindness in general population is 1.1%, cataract about 62.6%, every year nearly 3.8 million persons become blind in India. The National Programme for Control of Blindness was launched in 1976 with emphasis on gradual shift from camp surgeries to institutional surgeries, improvement in equipment, training, advancements in surgical procedure, there has been change in anesthesia too. [2,3]

General anesthesia limited to paediatric cases, mentally challenged individuals. In regional anesthesia, Retrobulbar block, Peribulbar anesthesia, perilimbal anesthesia, facial blocks, sub tenon's anesthesia and non-invasive

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topical anesthesia. Peribulbar anesthesia provides excellent analgesia and akinesia, and is safer than retrobulbar anesthesia. Peribulbar anesthesia associated with complications of chemosis, raised IOP, retrobulbar hemorrhage, optic nerve injury, globe perforation, ptosis. Facial blocks, for paralysis of orbicularis muscles, to be given with peribulbar or retrobulbar block. Topical anesthesia, for phacoemulsification where complete akinesis not required, being non-invasive,is patients friendly too. Hence study needs to be done to compare safety, efficacy, advantages and disadvantages of topical anesthesia versus peribulbar anesthesia.

2. Materials and Methods

Study was done in patients undergoing phacoemulsification surgery at our institute. It was Hospital based Randomized, Prospective, interventional Comparative Study done between November 2017 to May 2019.Ethical committee clearance was obtained.

Patients willing to give written informed consent with visually significant Presenile and Senile cataract with normal range Intraocular pressure, with well controlled comorbidities willing for phacoemulsification surgery. Patients excluded are one with any posterior segment pathologies like diabetic retinopathy, HTN retinopathy, glaucoma etc., and patients with complicated cataract , excessive anxiety, dementia, hearing impairment.

Patients were randomly assigned to group using the sealed envelope method after the patient was in the anesthesia room.

Group 1: Topical anesthesia patients.

Group 2: Peribulbar anesthesia patients.

Demographic data (age, gender, address, occupation), history, concomitant medications, physical examination, clinical examination including recording of vital signs and details of drug prescription by the treating physician, detailed ocular examination recorded in the study proforma. Preoperative visual acuity by Log mar visual acuity chart, anterior segment evaluation by slit lamp biomicroscopy, preoperative refraction, A SCAN Biometry, Keratometry and intraocular pressure measured by applanation tonometry. For TA group, one drop of proparacaine hydrochloride 0.5% was instilled 4 to 6 times with an interval of 5minutes.TA was instilled soon after dilating pupil before start of surgery and intraoperative intracameral lignocaine injection 1%, 0.1ml given after forming side port. For PA group, 5ml of 2% lignocaine with 1:10000 adrenaline was injected using 24G needle. Needle was inserted at the junction of middle and outer third of inferior orbital margin and directed towards floor of the orbit, the eyelids were closed and applied pressure on the eye for 5min. A 2.8mm sized incision in the clear cornea was created for the phaco port, and two side ports were created of 0.8mm each. Methylcellulose was inserted in the anterior chamber and an anterior continuous curvilinear capsulorhexis was performed with cystome, hydrodissection, hydrodelineation, phacoemulsification, aspiration of residual cortical lens matter and implantation of intraocular lens in capsular bag performed. At the end of surgery wound margins were hydrated, self-sealing wound was checked for leakage by gentle compression with sponge. Postoperative treatment was similar in both groups; Antibiotics and steroids combination eye drops used at hourly interval slowly tapered off. Patients' level of discomfort and pain during anesthesia, during surgery, 1hr to 4hours and 24hr after surgery is assessed by Visual Analogue Scale (VAS), which consists of scale of 10cm with zero being no pain to 10cm being severe pain. Patients were briefed about the use of this pain scale to rate the level of pain, were asked to report pain intensity by placing a line perpendicular to the VAS line at the point that represents their pain intensity. Using a ruler, the score is determined by measuring the distance (cm) on 10cm line between the "no pain" anchor and the patients' mark, providing a range of score from 0-10.

Score interpretation is done as:

No pain= 0mm

3. Pain=0 to 5mm

Moderate pain= 5mm to 7mm

Severe pain=7mm to 10mm. Patient is given less than 1minute to complete VAS.[4]

Duration of surgery compared in both groups. Visual acuity, status of cornea, status of wound compared between two groups, 4hrs and 24hrs and 1week after surgery. Complications during anesthesia and during surgery compared between two groups. Surgeons' satisfaction level assessed by difficulty encountered during the procedure is graded as

Not difficult =Grade 0

Slightly difficult (patient uneasy) =Grade 1

Moderately difficult (patient repeatedly squeezes eyes) =Grade 2

Extremely difficult requiring additional analgesia (unbearable pain) =Grade 3.[5]

3.1. Statistical analysis

Sample size estimated based on previous study by Srinivasan Gopal et al.[4] Patients who did not feel any pain in group 1 with Topical anesthesia was 46% and in group 2 with peribulbar anesthesia was 52 and minimum expected deviation will be 20. The sample size calculated

$$n = \frac{(Zalpha - Z1 - beta)^2 \, (P1(100 - P1) + P2(100 - P2)}{d^2}$$

$Z\alpha$ = normal deviate at a level of significance= 1.96 for 5% level of significance. Z1-β = normal deviate at 1-β% power = 0.84 at 80% power. P1= 46 ; P2=52; n=97.6=100.

n1 and n2 = sample size for Group 1 and Group 2 such that, N = n1 + n2=200.

Group1= Patients who are given Topical anesthesia.

Group 2= Patients who are given Peribulbar anesthesia

The Statistical analysis was performed by STATA 11.2 (College Station TX USA). Students t-test or Mann Whitney test was used to find the mean significant difference between the age, Log mar visual acuity, Intra ocular pressure, K1 and K2, axial length, IOL power, duration of procedure and visual analogue score, in both groups and its expressed as mean and standard deviation. Chi square test for goodness of fit was used to measure the association between the age, gender, Diabetes, hypertension, ischemic heart disease, visual acuity, intra operative complications and grade of visual analogue score with groups and it expressed as frequency and percentage.

4. Results

During the study period between November 2017– May 2019, a total of 200 patients with cataract were evaluated, 100 patients in each group. Most of the patients in both the groups belonged in age group between 51 to 60years of age (36.3%) and least age was 30yrs. In both the groups it was found majority were males, in Group1 60%(60) and in Group2, 51%(51). In both groups nearly 30%(60) had Diabetes mellitus and 40%(80) had hypertension and 10%(20) had IHD.

On detailed ocular examination and slit lamp evaluation it was found that in group 1, 34(68%) patients presented with nuclear sclerosis Grade 2 and posterior subcapsular cataract. In group 2, 41(82%) presented with posterior subcapsular cataract. Mean preoperative vision in group 1 was log mar visual acuity 1.6 ± 0.66 and in group 2 1.89 ± 0.70. Mean IOP in group 1 was 12.84 ± 2.44mmHg and group 2 was 12.97 ± 1.96 mmHg. Ocular biometrics was done, mean keratometry values in Group 1 were 44.03 ± 1.5D and 44.84 ± 1.66D; In group 2, 44.08 ± 1.48D and 45.92 ± 1.87D, vertical and horizontal keratometry respectively. Axial length mean value in group1 being 23.14 ± 0.88mm and in group 2 being 23.09 ± 0.97mm. Mean IOL power of both groups were 21.09 ± 2.22D and 21.23 ± 2.79D respectively, nearly 10(5%) patients had axial length more than 24mm, myopic. Complications during anesthesia were noted, among group 2, 15(15%) had chemosis, 6(6%) had raised Intraocular pressure, 14(14%) had subconjunctival hemorrhage and 3(3%) had retrobulbar hemorrhage which were managed well and 62(62%) were uneventful. Patients underwent Phacoemulsification surgery, average duration of procedure for group 1 was 10.84 ± 2.55 minutes and group2 7.27 ± 0.95minutes with P value being (<0.001) significant. Intraoperative complications were notedTable 1.

After the procedure, postoperative day 1, ocular findings and vision were compared in both the groups (Figure 1) P value being 0.042, nonsignificant.

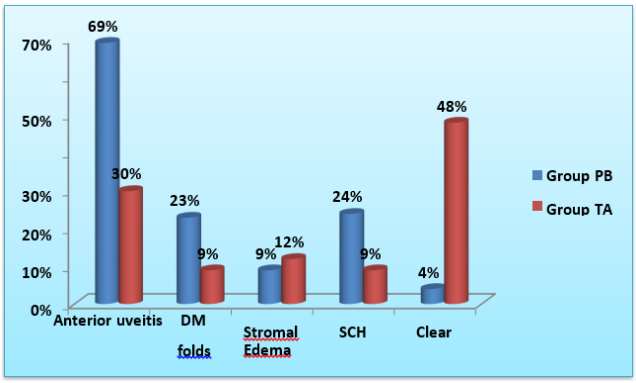

Fig. 1: Postoperative day 1 ocular findings

Log mar visual acuity on postoperative day 1 was compared, and was significant P value (0.001).

Patients were questioned about extent of postoperative pain and noted using Visual analogue scale, which consists of scale of 10cm with zero being no pain to 10cm being severe pain. And response was tabulatedTable 3. And compared between 2 groups showed significant difference P value (<0.001).

5. Discussion

Cataract affects 20million worldwide which is expected to increase to 50 million by 2020.[6] An ideal anesthetic is the one which permits painless surgery with very few systemic or local complications. Peribulbar anesthesia being blind insertion of needle in retrobulbar space associated with few sight and few life threatening complications.[7] Topical anesthesia(TA), being noninvasive procedure, is believed to have advantages over peribulbar anesthesia(PA) in terms of safety, pain free, rapid onset and recovery, free of injection related complications,[7] rapid visual recoverybut it also has disadvantages of increase anxiety, discomfort and inadvertent eye movements for both patient and surgeon.[8] Many studies have been done to compare peribulbar and topical anesthesia, but being a government teaching institute catering to much of rural population, patients being excessively anxious, comparatively uncooperative, exhibit suboptimal cognition, cataract surgeries were always done under peribulbar anesthesia for all. With proper counselling we started doing phacoemulsification under topical anesthesia and comparison with peribulbar was done. In present study it was found that, most of the patients in both the groups were in the age group of 51 to 60 years of age (36.3%). Mean age of patients in Group 1, 59.01 ± 11.29yrs and in Group 2, 60.47 ± 11.86 yrs., nearly 2% of pediatric which were of 12yrs and 14yrs old for whom peribulbar anesthesia was only given and 2 premature senile cataract cases. In both the groups, majority were males,

Table 1: Intraoperative complications during surgery

	Group PB	Group TA	Total	P-Value
Argentina flag of CCC	1	1	2	
Chemosis	0	2	2	
PC Rent	2	0	2	
SCH	0	4	4	0.149
Stromal edema	1	2	3	
Zonular Dehiscense	1	0	1	
None	95	91	186	
Total	100	100	200	

Table 2: Postoperative visual acuity

	Group PB	Group TA	P-Value
	Mean ± SD	Mean ± SD	
Postoperative			
Day 1	0.65 ± 0.40	0.49 ± 0.32	0.001
One Week	0.22 ± 0.24	0.14 ± 0.21	0.010

Table 3: Visual analogue pain scale

	Group PB (in cm)	Group TA (in cm)	P-Value
	Mean ± SD	Mean ± SD	
Anesthesia	7.60 ± 1.36	0.16 ± 1.16	<0.001
Surgery	0.87 ± 1.44	2.65 ± 2.00	<0.001
4 hours	3.62 ± 1.72	3.43 ± 2.67	0.541
24 hours	3.38 ± 1.75	0.31 ± 0.94	<0.001

in Group 1, 60% and in Group 2, 51%. In both groups nearly 30%(60) had Diabetes mellitus and 40%(80) had hypertension and 10%(20) had IHD, patients with IHD, Hypertension requires minimal anesthetic monitoring when done under peribulbar as compared to topical anesthesia with minimal tissue handling, not require anesthetic monitoring as found in study by Faincham et aland other studies[9–11] vital parameters of patients undergoing topical phacoemulsification was stable throughout procedure. Hence topical anesthesia is better over peribulbar in such patients.

On detailed ocular examination and slit lamp evaluation, patients presented with all grades of nuclear sclerosis, with cortical cataract, with posterior subcapsular cataract, senile hypermature cataract, among all these it was found that in group1, 34(68%) patients presented with Nuclear sclerosis Grade2 and posterior subcapsular cataract. In group 2, 41(82%) presented with posterior subcapsular cataract, mean IOP being 12mmHg, mean Keratometry being 44.03 ± 1.50 in group 1 and 44.08 ± 1.48 in group 2. Mean Axial length being 23.14 ± 0.88mm in group 1 and 23.09 ± 0.97mm in group 2. Among the patients, some 10 had axial length skewed towards Myopia, being more than 24mm, and 2 had high Myopia with axial length being 28mm. Hence patients with high myopia have high risk of globe perforation during peribulbar injection, which can be prevented when done under topical anesthesia. Peribulbar anesthesia being a blind procedure, there are few possible complications like chemosis, subconjunctival hemorrhage, retrobulbar hemorrhage, globe perforation, occulo cardiac reflex leading to cardiac arrest as compared to noninvasive topical. In group 2, 15(15%) had chemosis, 6(6%) had raised Intraocular pressure, 14(14%) had subconjunctival hemorrhage, which causes discomfort to both patient and surgeon and 3(3%) had retrobulbar hemorrhage which were managed well and 62(62%) were uneventful. Hence was statistically significant difference.

In our study intraoperative complications found were Argentina flag sign (1%) in each group, subconjunctival hemorrhage 4(4%), chemosis 2(2%) in TA group because any ocular movements during wound construction can pose difficulty to create clear corneal wound and part of conjunctiva at limbus may get involved causing chemosis, posterior capsular rent 2% in PA group but in both the cases posterior chamber IOL could be placed as rent was small, stromal edema 4% in each group, zonular dehiscence 1% in PA group. Majority of the surgeries went uneventful, P value being 0.149, no difference between two groups as compared to Zulfikar-ud-din et al[8] study where intraoperative complications were more with TA group,[8] under topical anesthesia, due to excessive ocular movements during surgery may result in intraoperative complications, but an experienced surgeon and cooperative patient[12] can overcome such complications. Stupp et al.[13] noted that the rate of intraoperative complications were minimal in both groups, however, older age of the patient posed a higher

risk of complications in the TA group. When examined on postoperative day1, inflammatory reaction was 69% in PA and 30% in TA group patients than PA, P value (<0.001) statistically significant as compared to Dole K et al[14] study where postop day 1 complications were more in TA group. No any postop cystoid macular edema noted. Postop vision noted at 24hrs and 1week after the surgery, it was found that in group 1, postop day 1 vision was 0.49±0.32 and after 1 week was 0.14±0.21 and in group 2, post op day1 vision was 0.65±0.40 and after 1 week was 0.22±0.2. Hence postoperative visual recovery was found better in topical anesthesia group on day 1 than peribulbar group, which was statistically significant same as found in study by Naik P et al.[14] But after 1 week there was no much difference in visual recovery in both the groups.

Postoperatively patients in both the groups were asked to grade their extent of pain on visual analogue scale which consisted of 10cm scale, in group 1, topical anesthesia being noninvasive procedure patients were comfortable during anesthesia, and experienced mild pain during surgery (2.65±2.00mm), 4hrs postop (3.43±2.67mm) and 24hrs later (0.31±0.94mm) but in group 2, peribulbar anesthesia being invasive procedure patients experienced maximum pain nearly 70% (mean 7.60±1.36mm) during injection and had mild pain after 4hrs(mean 3.62±1.72mm) and 24hrs(3.38±1.75mm) of surgery, because of injection site pain, even after 24hrs patients had discomfort, but were comfortable during surgery (0.87±1.44mm) as compared to study of Ahmad N et al.[15] in which peribulbar anesthesia better patient satisfaction then topical anesthesia. Hence there was statistically significant difference between both the groups in terms of patients' comfort level, during anesthesia (group 1 comfortable, P value <0.001), during surgery (group 2 comfortable, P value <0.001) and 24hrs after surgery (group 1 comfortable, P value < 0.001). This was in contradiction to the observations of Pablo et al.[16] and Sauder et al.[17] that pain during and after surgery between groups was not significantly different.

In present study, surgeon was questioned regarding the satisfaction level for each patient and graded accordingly, it was found, surgeon had no difficulty during the procedure in group 2 patients, majority of group 2 were graded 0(63%), only few were graded as 1 and 2. Surgeon had difficulty when operating on group 1 patients, majority of them were graded 2 (71%) and only few were graded as grade 0(11%), grade 1(11%) and grade 3(7%). P value being <0.001.

6. Limitation of our study

Since patients were randomly distributed between 2 groups the intraoperative complications caused may be influenced by type of cataract itself, as hypermature cataract prone for Argentina flag sign of capsulorrhexis.

7. Conclusion

In our study we found that there was no difference between 2 groups in terms of age of presentation, sex distribution, associated co morbidities, and also in terms of intraoperative complications during surgery. But it was found postoperative visual recovery was faster and better in patients with topical group with less postoperative inflammation and complications. As per Visual analogue pain scale patients in TA group were more comfortable and more satisfied than peribulbar group and it was stastistically significant.

Proper patient couselling and gaining confidence, knowledge about patient preferences and satisfaction can help surgeon for correct approach towards better outcomes.

8. Source of Funding

None.

9. Conflict of Interest

None.

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