

Clinical Evaluation and Outcomes of Topical versus Retrobulbar Anesthesia in Cataract surgery by Phacoemelsification

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ABSTRACT

The objective of this study is to assess and compare the degrees of pain and problems experienced by patients undergoing phacoemulsification and implantation of foldable intraocular lenses. The study will specifically focus on patients with senile cataract who receive either topical or retrobulbar anaesthesia. An experimental study was conducted over a 10-month period at Al-Basir Ophthalmic Centre in Hawler, Iraq, using random assignment and control groups. We examined the eyes of 200 patients, totaling 200 in number. Phacoemulsification was performed on 100 eyes using retrobulbar anaesthesia, while another 100 eyes were treated with topical anaesthesia. The overall intra operative complication were capsular tear in 2.5%, zonular tear in 3.5% for, vitreous loss 2.5%, and iris prolapse occurred in 3% of patients. Chemosis was observed in 4% of the participants in the retrobulbar group, whereas none of the participants in the topical group exhibited chemosis. No significant disparity in intraoperative and early postoperative problems was detected. The retrobulbar group had a 4% incidence of subconjunctival haemorrhage and a 2% incidence of periorbital hematoma. Within the retrobulbar group, 92% of individuals reported a pain score of 0-1, whereas the remaining 8% reported a pain score of 2. Within the topical group, 80% of participants reported a pain score of 0-1, whereas the remaining 20% reported a pain score of 2. The topical approach achieved a patient satisfaction rate of 90%, while the retrobulbar procedure achieved a rate of 82%. There were no patients in either group who experienced a pain level of 3 (extremely severe intolerable pain). The incidence of surgical complications was comparable between the two anaesthesia procedures. Overall, topical anaesthesia provides a safe and efficient substitute for retrobulbar anaesthesia in cataract surgery that involves phacoemulsification and IOL folded lenses, particularly for proficient surgeons.

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1. INTRODUCTION

Cataract is defined as the irreversible loss of transparency of the lens leading to visual impairment. It represents one of the common reversible causes of blindness. The etiology is diverse, however, aging is considered the most common cause(1).

Cataract surgery is the most common intervention among the elderly population. Cataract surgery has proven to be a highly cost-effective intervention. At the same time, patients demand the most advanced surgical techniques to obtain the best results. To achieve surgical success, it is known that the surgeon's skill, correct planning of the surgical technique, and its possible modifications in different circumstances are essential (2–4)

Despite the fact that aging is the most common cause of cataracts, but there are also other risk factors such as trauma that causes damage to the continuity of the capsule - Congenital due to having a family history with cataracts, poor diabetes control, eye injury due to surgery or radiation treatments in the upper trunk of the body, injury from ultraviolet rays, the use of certain medications such as corticosteroids can cause early cataract formation. Smoking can increases the risk, High blood pressure, drinking alcohol in excess produces direct oxidative stress in the lens. Female gender has a higher risk of developing cataract (1,5,6). Currently, all over the world, cataracts are a widespread eye disease and one of the main causes of decreased vision and blindness, in this regard, one of the priorities put forward by World Health Organization (WHO) is the elimination of blindness due to cataracts. Globally, the prevalence of cataract blindness remains high. It is estimated that 2.2 billion people have visual impairment. Of these cases, approximately 1 billion visual impairments could have been prevented or treated (4,7). In Iraq, cataract represent one of the commonest cause of visual impairment and blindness, where it contributes for almost 26% and 76% of visual impairment and blindness cases, respectively (8,9).

Surgical treatment of patients with cataracts has now reached a high level of perfection. (10). In recent years, cataract surgery has undergone considerable evolution in terms of surgical techniques. (11,12).

Phacoemulsification is employed in many countries as as the gold standard in cataract surgery. Within the scope of the advantages of phacoemulsification, is the lower risk trauma

to the corneal endothelium, less time required for healing of smaller incisions, the risk of endophthalmitis is reduced and the visual prognosis is improved. (13). The fact that all cataract surgeries have to be performed under anesthesia, different anesthetic techniques are currently available and applied in many centers worldwide. The administration of anaesthetic drugs through a retrobulbar injection has been extensively employed for over a hundred years in cataract surgery. Although there have been numerous improvements made over the years to minimise the possible dangers of harming structures within the eye socket, blindly inserting a needle into the space behind the eyeball has never been entirely without serious consequences that can result in loss of vision or even death. (14,15)

Topical anaesthesia has been suggested as a favourable substitute for the conventional practice of injecting local anaesthetic drugs. This approach leads to quicker visual recovery and greater patient contentment. Topical anaesthesia offers several benefits, including its simple application, minimal to no discomfort during administration, quick onset of anaesthesia, and most importantly, reduced risks associated with retrobulbar or peribulbar injection. This technique is also cost-effective, avoids unwanted cosmetic side effects, and allows for immediate visual recovery (15). We aimed in this study to compare topical versus retrobulbar anesthesia in Iraqi patients undergone cataract surgery by phacoemelsification with regard to the levels pain that the patients did have, any complication during cataract surgery by phacoemulsification and implantation of foldable intraocular lenses under topical or retrobulbar anesthesia and further to assess the safety of noninvasive topical anesthesia as another way of local anesthesia.

2. METHODOLOGY

This was a prospective, randomized, controlled clinical trial carried out, at Al-Basir eye hospital in Erbil from during a period of 10 months. Comparing retro bulbar with topical anesthesia in patients with senile cataracts undergoing pahcoemulsification and foldable intraocular lens (IOL) implantation. A total of 200 patients aged 45 years and above were randomly assigned for either topical or retrobulbar anesthesia.

Inclusion criteria

Patients with senile cataract of both genders aged 45 years or above undergone cataract surgery by Phacoemulsification Those aged 45 years and above were eligible for inclusion.

Exclusion criteria

Patients with allergy to lidocaine were excluded and also patients with complex anterior segment pathological features.

Patients with hearing impairment, excessive anxiety or poor fixation due to nystagmous were also excluded.

1. Preoperative protocol

- Patients were well prepared prior to anesthesia.
- No oral sedation before operation or injection was administered in all patients.
- Patients were fasting and used their routine drugs for treatment of any associated systemic disease.

• All our patients were day care cases and were admitted at 4 P.M. in the afternoon of the operation.

- Vital signs were measured using standard methods and reported.
- On the table, the patients were connected to pulse oximetry, and nasal or oral catheter for oxygen at a rate of 3-5 LPM.

2. Administration of anesthesia.

- Patients in the retrobulbar anesthesia group received one injection of 3 ml lidocaine 2% (Indian made) in to the infero temporal orbital area (junction of lateral one third medial two third) using a 25 gauge 31 mm syringe.
- The plunger is withdrawn to assess for mal injection.
- Intermittent ocular compression for 5-10 minutes was achieved by manual compression.
- Prior to surgery, the surgeon assessed the effectiveness of the block by observing ocular motility, pain threshold and the occurrence of any complication.

• Patients in the topical anesthesia group received one drop of tetracaine 0.5% (Sena darn Iranian made) in the eye 15 minutes before surgery, one drop into the lower conjuctivai sac repeated frequently, the last two doses given while the patient is lying on the bed and the final dose just before starting phacoemulsification.

3. Pain assessment: Pain was assessed on a scale of 4 points as follows: No pain = 0

Mild pain = 1 (tolerated pain), Moderate pain = 2 (needs help or interference like more anesthetic or analgesic) and severe pain=3 (extreme pain non tolerable). Assessment of pain and scoring was done depending on the (1) direct questioning of the patient upon completion of the operation (2) verbal expression of pain or motor reflex that patients made during operation. (3) Direct questioning of the patient after 24 hours (if the patient likes to have the same procedures or type of anesthesia in the other eye in the future).

The same question was posed to the surgeon and the results were recorded.

4. Assessment of akinesia: movement of the eye ball during surgery was graded as follow:

- Score 0 = no akinesia (full range movement)
- Score 1= partial akinesia (partially moving)
- Score 2 = full akinesia (no movement)

5. Surgeons' comment during surgery which was recorded as follows:

- No difficulty
- Slightly difficult
- Moderate difficult
- Extremely difficult

6. Intra ocular pressure (I.O.P)

Base line I.O.P checking was recorded before surgery with an applanation tonometer (HAAG STRIET), a 24 hr post operatively the tension were checked to assess any increase in I.O.P. An increase of intra ocular tension

more than 21 mmHg regarded as elevated tension (in the absence of preexisting ocular hypertension or glaucoma).

7. Surgical technique:

All surgical procedures were performed in Al-Basir Ophthalmic Center in Erbil by one surgeon. He used a scleral incision phacoemulsification (Everest machine) and implantation of IOL. The globe was immobilized by asking the patient to look to the light or by a forceps; cautery was used for all of the cases.

One side port paracentesis, at 4 or 8 o'clock was performed.

Viscoelastic injection (Healon), continuous curvilinear capsulorhexis, hydrodissection, hydrodelineation, phacoemulsification, bimanual aspiration of the remaining

cortical lens material, and finally in the bag implantation of the foldable IOL was performed.

The pupil was dilated with (iris retraction hooks in some difficult cases) followed by IOL implantation and removal of the viscoelastic substance.

Postoperative treatments were similar in both groups. In both groups we used subconjunctival injection of gentamycin and decadron via an insulin syringe.

Further drug administration Chloramphenicol eye drop q.i.d, Betamethasone eye drop t.i.d were used for three weeks.

8. Outcome measures:

Outcome measures were the number of complications and adverse events arising preoperatively, intraoperatively and within 24 hours postoperatively.

9. Ethical issues:

were approved by the authors and consent was obtained before surgery from patients or their relatives.

10. Statistical analysis:

Collected data were entered in a data base using Microsoft Excel. Variables in the two groups were compared using Chi square test. P. value ≤ 0.05 indicated statistical significance.

3. RESULTS

Two hundred eyes have belong to 200 patients were studied; 100 eyes received retrobulbar anesthesia namely (R.B.A group) and the other 100 eyes received topical anesthesia, namely, (Topical A group) . No significant differences were found between both groups in their baseline characteristics for age and sex, (P>0.05). The highest percentage of patients were in the age group (61-70) who contributted for 32% and 36% of R.B.A and Topical A groups, resepectively. In total, among the 200 patients, 114 there were males (57%) and 86 (43%) females. (**Table 1**).

Regarding the postoperative pain, 45% of patients in R.B.A group and 24% in Topical A group had no pain (score 0). Mild pain (score 1) reported in 47% and 56% of patients in R.B.A group and Topical A group, resepctively. Moderate (score 2) pain reported in 8% of R.B.A group and 20% of the topical A group. In both groups none of the cases had extremely severe (non tolerable) pain(score 3), the difference in the reported postoperative pain was statistically insignifciant (P>0.05), (**Table 2**)

For akinesia, in R.B.A group, none had grade 0 (no akinesia, full range of movement), 20% with grade 1(partial akinesia) and 80% had grade 2 (full akinesia, no movement). In the topical A group all patients were at grade 0 (no akinesia, full range of movement), (**Table 3**). At the 24 hours postoperatively, the IOP rise within a range of (10-15) mmHg, this was observed in about 74% of patients received R.B.A and in 60% of patients with Topical A, however, the difference was statistically insignificant, (P>0.05). In R.B.A group, posterior capsular rupture occurred in 2%, vitreous loss 2%, iris prolapse 2%, zonular tear 3%, chemosis 4% and sub conjunctival hemorrhage in 4%, in the topical A group capsular rupture occurred in 3%, vitreous loss 3%, iris prolapse 4%, Zonular tear 4%, none for chemosis and sub conjunctival hemorrhage, however, comparisons of these complications revealed no statistically significant difference between both group, (P>0.05).

Surgeon's comment during surgery about difficulty of procedures revealed no difficulty (G1), sligh (G2) difficulty, moderately difficult (G3) and extremely difficult (G4) in 50%, 40%, 10% and 0% for R.B.A group, G1 and G2 contributted for 90%. In the second group (Topical A), G1, G2 and G3 reported in 20%, 60% and 20%, respectively and none with G4. In this group, G1-2 contributted for 80%, the differences in the surgeon's comment during surgery were statistically insignificant between the studied groups, (P>0.05). Furthermore, in R.B.A group, 70% of patients experienced anxiety, compared to only 2% in topical group during application of anesthesia with high significant difference, (P<0.001). Additionally, 24% of R.B.A patients showed discomfort during application of anesthesia while only 10% of topical anesthesia patients did have with significant difference, (P<0.05). More over, 18 patients in RBA group and 10 patients in topical A group were preferring other type of anesthesia, and they were not significantly different, (P>0.05), these findings are shown in (**Table 4**).

	R.B.A		Topical A		Ρ.
Variable	No.	%	No.	%	value
41 - 50	16	16.0	4	4.0	
51 - 60	16	16.0	28	28.0	0.445
61 - 70	32	32.0	36	36.0	0.115 ns
71-80	30	30.0	22	22.0	115
> 80	6	6.0	10	10.0	
Male	58	58.0	56	50.0	0.886
Female	42	42.0	44	44.0	ns

Table 1. Age and sex distribution of the studied groups

ns: not significant

	R.B.A		Topical A	
Pain score	No.	%	No.	%
0	45	45.0	24	24.0
1	47	47.0	56	56.0
2	8	8.0	20	20.0
3	0	0.0	0	0.00
P. value = 0.235,	not significant			·

 Table 2. Comparison of postoperative pain between the studied groups

Table 3. Distribution of Akinesia in both studied groups

	R.B.A		Topical A		
Akinesia	No.	%	No.	%	
Grade 0 (NO)	0	0.0	100	100.0	
Partial (Grade 1)	20	20.0	0	0.0	
Full (Grade 2)	80	80.0	0	0.0	
P. value = 0.001, significant					

Outcome	R.B.A		Topical A		Duralua
Outcome	No.	%	No.	%	P. value
Raised I.O.P	74	74.0	60.00	60.0	0.350 ns
Capsular rapture	2	2.0	3	3.0	0.234 ns
Vitreous loss	2	2.0	3	3.0	0.234 ns
Iris prolapse	2	2.0	4	4.0	0.211 ns
Zonular tear	3	3.0	4	4.0	0.312 ns
Chemosis	4	4.0	0	0.0	0.129 ns
Sub conj. hemorrhage	4	4.0	0	0.0	0.129 ns
Surgeon's comfort (No to slightly difficult)	90	90.0	80	80.0	0.074 ns
Patient's opinion and satisfaction	76	76.0	82.0	82.0	0.385 ns
Anxiety on application	70	70.0	2.0	2.0	<0.001 sig
Patients discomfort during application	24	24.0	10.0	10.0	0.008 sig
Patient prefers other type of Anesthesia	18	18.0	10.0	10.0	0.153 ns

Table 4. Outcomes after receiving anesthesia in both studied	groups

ns: not significant , sig: significant

4. DISCUSSION

During surgery, the pain score of 0-1 was found in 92% of R.B.A group and 80% of patients in topical anesthesia group, our findings close to that reported by Munir et al. from Pakistan who found that 90% of cases who received R.B.A and 100% of those with topical anesthesia had no or mild postoperative pain (16), conversely, Zhao et al. (17) showed that postoperative pain score was significantly higher in topical anesthesia group, (P<0.05), another study conducted in Qatar b Said et al. (18) found that pain scores of 0-1 in 75% in RBA group and 90% in topical A group. In our study we documented that 20% of topical A group had a pain score of 2 and they required supplemental anesthesia, supplementation with tetracaine drop only without injection, compared to 8% of patients in R.B.A groups these values are higher than what found in another study in which only 1.3% of topical and

0.8% of R.B.A group required supplemental anesthesia (15). Variability of pain scores among studies may be related to patient's pain threshold, type and number of anesthetics used, and whether the patient is pre medicated prior to surgery.

Akinesia of the globe will not be achieved with topical anesthesia, which affects only the nerve endings of trigeminal nerve in cornea and conjunctiva, that's why there's no akinesia in topical anesthesia group, there were variable grades in R.B.A group, 20% of patients showed partial akinesia while 80% of them developed total akinesia, these figures are similar with another study (15) in which partial akinesia was found in 11% of cases and full found in 89% of cases. The lack of akinesia among topical anesthesia patients was not clinically significant since supplemental paraocular anesthesia was not required in any patient to continue surgery.

Checking for I.O.P 24 hours after surgery showed some variations, our routine for follow up of our patients were 24 hours, one week and three weeks post operatively. Elevation of IOP found in 74% of patients in the R.B.A group and 60% of patients in the topical anesthesia group. The IOP was elevated up to 30-35 mm; however it was transient and did not require medical or surgical intervention. This finding is consistent to the results published by Willerscheidt et al. (19), but disagree figures obtained by Chambless et al. (20) who found that a pressure raise of 58% for R.B.A group and 67% for topical group... The higher incidence of pressure change among retrobulbar group may be explained by increase in the volume inside the muscle cone and hence increase of the whole I.O.P, where as in both groups, a retained viscoelastic agents may be a factor. In addition to the type of tonometry used for checking I.O.P. The data showing an incidence of 2% in R.B.A groupand 3% in topical anesthesia group with an average of 2.5%. Other study conducted by Norregaard et al. (21) reported values of 1.5% for R.B.A and 1.9% for topical group. The higher incidence of capsular rupture among topical group patients, although not significant statistically, may be attributed to excessive contraction of extraocular muscles yielding high vitreous pressure which followed by rapture of the capsule. However, Chitkara and Smerdon (22)found an equal incidence of (1%) capsular rapture in both groups. In this study the higher incidence of zonular tear was observed among topical anesthesia group patients which was 4%, while in R.B.A group, it was 3% with the overall incidence of 3.5%. This difference was not clinically

significant. These values are in concordance with another study which showed figures of 3% zonular tear in topical anesthesia group and 2.5% in R.B.A group (23). Our results can be explained by the presence of zonular weakness among a number of cases prior to the surgery; also it may be developed accidentally during the surgical procedure. The incidence of iris prolapse through the incision tunnel was 2% among R.B.A group and 4% among topical group, with the overall incidences of 3%. Similar studies found an incidence of 1.7% iris prolapse in topical group while it was 0.4% In R.B.A group (22), another study reported values of 1% among topical and 0.5% among R.B.A group (18). In this study the difference was statistically not significant, however iris prolapse mostly occur in eyes with increase I.O.P, especially hyperopic eyes, also in anxious patients with higher chance of extra ocular muscle contraction which mostly occurs in topical anesthesia without motor blockade. Another explanation is that in R.B.A, ocular compression done routinely to counter act possible pressure increase during surgery, but this maneuver is not applicable in topical anesthesia group. In this study the Incidence of VL among patient groups was 2% in R.B.A and 3% in topical group, with the overall incidence of 2.5% among all patients. Values of 1.5% in R.B.A and 1% in topical group had been reported by Norregaard et al. (21) and were significantly lower in topical group.

In our study it appears that vitreous loss however it was statistically not significant but it is higher in topical group, possibly because of increasing intra ocular pressure due to contraction of extra ocular muscle in case of topical anesthesia group that had led to loss of vitreous through a ruptured capsule. The above signs were exclusively found in retrobulbar group their incidences were (4%, 4%, and 2%) successively, they were of no clinical significanceat all and never led to delaying or canceling of the operation. Unlike ourstudy results observed by Davis and Mandel were (2.5%, 1.7%, and 0.8%) successively in a retrobulbar group only (24). This is probably attributed to the technique of injection we had used. In 80% of topical A. group and 90% of R.B.A group, the surgeon's grading for difficulty was between 0-1 (i.e. no difficulty-slightly difficult) whereas grade 2 difficulty (moderately difficult) was 10% in R.B.A groupand 20% in topical group.These readings slightly differ from what have been found in a study reported that, in topical group 90% and in R.B.A group 88%

the surgeon's difficulty grading was from(0-I) and grade 2 difficulty was 14 % in topical and 8 % in R.B.A (25).

Overall surgical conditions assessed by the surgeon favored the use of retrobulbar anesthesia. However, the difference in surgeon's assessment between the two groups was not statistically significant. In 70% of R.B.A and 2% of topical group were anxious during application of anesthesia, this is in concordance with a similar study by Jose Gulherme (26) which found anxiety in 65% of patients with R.B.A group and 4% with topical group, a vaiying figures of 23% in R.B.A and 0% in topical group was reported by by Learning D. (27). These figures are expected as injection into around the eye makes the patients apprehensive. Topical anesthesia administration was significantly less painful than the administration of retrobulbar anesthesia (in the retrobulbar group 24% reported some discomfort while only 10 % in the topical anesthesia group felt burning sensation). However, the results that have been reported by NG et al. (28) who found that 17% of R.B.A groupand 2% of topical anesthesia patients experienced discomfort. Higher data's have been encountered in a study done by Jose Gulherme (26) who found 53% of R.B.A group and 2 % of topical group became discomfort. 10 % of topical anesthesia patients preferred another type of anesthesia compared to 18 % of R.B.A group that preferred anesthesia other than R.B.A. This means that 90% of our patients were satisfied with topical and 82% of patients were satisfied with R.B.A. The result shows a statistically significant difference between both groups in regard to patient's satisfaction to the type of anesthesia. Close figures found in a study which reported that (91%) of patients were satisfied from topical and (62%) from R.B.A (25).

5. CONCLUSIONS

Topical anesthesia is a safe and an effective alternative to retrobulbar anesthesia in cataract surgery using phacoemulsification and IOL folded lenses for experienced surgeons. Hence we recommend, that surgical training and good patient preparation is required for safe use of topical anesthesia. Reassurance of patients before his entry to the operation room assists the patient a lot to tolerate any pain or discomfort during operation, this is especially important in topical anesthesia group. Various measures present to alleviate patient discomfort associated with intra ocular manipulation include adequate papillary dilatation with mydriatic agents to minimize stretching of zonules and the ciliary muscle, or lowering the irrigation solution bottle to minimize the intra ocular hydrostatic pressure. Verbal contact with the patient throughout the surgical procedure is extremely helpful if not crucial for a comfortable and safe cataract procedure under topical anesthesia. The speed of phacoemulsification must be high andextra caution during intra ocular manipulation is very important.

Ethical Approval:

All ethical issues were approved by the author. Data collection and patients enrollment were in accordance with Declaration of Helsinki of World Medical Association, 2013 for the ethical principles of researches involving human. Signed informed consent was obtained from each participant and data were kept confidentially.

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