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A COMPARISM BETWEEN A FENTANYLE ALONE OR FENTANYLE AND PROPOFOL IN CONSCIOUS SEDATION IN EYE SURGERY UNDER REGIONAL ANAESTHESIA

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Abstract:

Background: Regional anesthesia is popular and offers several benefits to the patient and anesthetist. Sedation is part of the general management of a patient receiving a regional block and being awake during the whole surgical procedure.
Objective of study: To evaluate the comparison between the clinical efficacy and sedative effect of fentanyl alone and combination of propofol and fentanyl in cataract surgery.
Patients and methods
A prospective clinical trial study was conducted in ALdiwanyia teaching hospital from 1st January to 1st September 2021 at the ophthalmology department. It was enrolled 80 patients from those scheduled to undergo cataract surgery at the ophthalmology department. The patients were allocated into two groups of 40 according to type of drug that used in sedation. Group one patients received only fentanyl and second group had been received propofol and fentanyl, IN both group surgery had been done under RA.
Result
The study enrolled eighty patients with mean age 66.9±5.3 years. Mean age for first group was 67.1±4.8 and for second group was 66.3±6.2. Male were constituted 51.3% while female was 48.7%. The systolic and diastolic mean was lower in group of fentanyl and propofol (2nd group) drugs during and after surgery. Although the decrement was seen in both groups but group two much lower than group of only fentanyl (group 1) which are statistically difference. The patient's satisfaction was higher in fentanyl and propofol group than fentanyl group. Where is the surgeon satisfaction was not significantly differing.
Conclusion: - The combination of fentanyl and propofol was superior to fentanyl alone in hemodynamic evaluation and patient satisfaction.

Keywords: T1DM, thyroid disorder, GADA-Ab, ZNT8-Ab and IA-2ic-Ab

INTRODUCTION:

Regional anaesthesia is popular and offers several benefits to the patient. The top three from the patient's point of view are being awake postoperatively, early family contact, and early food intake [(1)]. For the anaesthetist, cardiovascular and respiratory stability, rapid postoperative recovery, and preservation of protective airway reflexes are the most important advantages of regional anaesthesia[(2)]. Many obstacles related to this procedure and its technique for example pain that happened in site of puncture, panic from needle and remember of operation. These factors stress the importance of sedation that offers analgesia, anxiolysis, and amnesia [(3)].

Conscious sedation is define as a procedure by which uses of medications to produce a state of CNS depression permitting management to be achieved, but during which verbal contact with the patient is maintained through out the period of sedation[(4)] .

During regional anesthesia the sedation considers a corner part in general treatment of this patient receiving anesthesia, whose stay awake alongside of surgical operation. These measures aim to keep patients comfort with little of amnesia for operation and regional block procedure, lead to more safety and increase patient preference[(5)] .

Numerous study reported patient's satisfaction during regional block are elevated by use of sedation, which is result in increase patient acceptance for these types of procedures. On other hand, uses of sedation during regional anesthesia are valuable thing to make surgeon and anesthetist convenient [(6)].

The ASA classified sedation into three levels[(7)] : Minimal sedation : drug induced state where the patient responeds normaly to verbal commandes , cognitive function and physical co – ordination can be impaired but airway reflexes and ventilatery and cardiovascular functions are maintained

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Moderate sedation : patient responeds purposefully to verbal stimuli which may be accompained with light tactile stimulation this equate to conscious sedation
Deep sedation : patients responed only to repeated or painfull stimulation, can be associated with significant ventilatory depression .
Cataract is one of most common type of ophthalmic surgeries that performed world wide. More over, various anesthetic regimes are introduces in cataract operation, such as general anesthesia, regional, topical and some times combination of these methods [8].
Pain is frequently reported complication with regional anesthesia due to pierce of needle, for lighten this pain, different sedation methods are used for example opioid, propofol, benzodiazepine and combination of drugs, to enhance patient's compliance to procedure and reduce anxiety[9] .
Choice of these drugs depend on its characters, proper sedative should have rapid action and short duration in addition to have few side effects [10].
A lot of papers appear the effectiveness of various combination of drugs to perform conscious sedation for cataract under regional anesthesia [5].
Fentanyl is a highly lipid-soluble opioid commonly used for analgesia . It has no anti-anxiety and anti-amnesia effects. Due to the mentioned characteristics and quick passage across the blood-brain barrier, it has a rapid onset and short duration of action , have minimal direct effect on heart , does not depress cardiac contractility when given alone , it causes decrease in arterial blood pressure as a result of opioid induced bradycardia , venodilation and decreased sympathetic reflexes[11] . Fentanyl depresses ventilation particularly respiratory rate , rapid administration of large doses of fentanyl can induce chest wall rigidity . IT decreases cerebral oxygen consumption , CBF , CBV , and intracranial pressure but to much lesser extent than propofol . Stimulation of medullary chemoreceptor trigger zone is responsible for opioid induced nausea and vomiting , it may cause miosis and pruritus , the bolus dose of fentanyl **0.25 – 0.5** microgram per kg repeated every 5 to 10 minutes , onset of action 3-5 min ,duration of action 30 min. Depth of analgesia is dose related and can be adjusted to the pain level of surgical procedure assessted by neumerical rating scale . IT is not a sedative but have a synergistic effect with sedative drugs **[12].**
Propofol is a substituted isopropyle phenol that is administered intravenously as 1% solution in an aqueous solution of 10% soya been oil, 2.25% glycerol , and 1.2 % purified egg phosphatide , pka 11 , it acts as a sedative- hyponotics , distribution half life is 1-2 minutes and elimination half life 1-5 minutes, metabolized in the liver and excreted by renal, there are no active metabolites . Thus recovery is rapid with minimal residual effects, making it particularly suited to short cases [13].
Pain on injection is common , it may be reduced by prior injection of lidocaine , administration of opioid or injecting into a large vein . Hypotension is common whether caused by direct myocardial depression , reduced systemic vascular resistance or both . Normo or bradycardia is common , antanalgesia has not been reported , has anti emeting effect , involuntary movement have been reported following propofol , reduces CBF , ICP and IOP . Reflex sneezing appear to be more likely in patient who are sedated with propofol , bolus sedative doses of propofol 0.25- 0.5 mg / kg IV followed by 10-20 mg incremental boluses[13] .
Cataract surgery is one of the most common operations performed worldwide. Modern techniques, such as phacoemulsification and small-incision extracapsular surgery, have resulted in a significant reduction in surgical duration as well as an increased turnover of patients in the operating room, leading to improved efficiency [14].
Improved efficiency should not be at the expense of the individual patient's safety and comfort, with a great probability of success, but with a minor risk of overwhelming complication [13].
The select of anaesthesia method is deepened up on the preferences of patient, anaesthetist and surgeon, the complexity of the procedures, resource and the healthcare delivery system. There is no gold standard and management should be determined on an individual basis. Whatever the choice, the goals are to be safe, painless, efficient and effective[12].
Many risk factors increase possibility of pain during operation such as young age, dominant eye surgery, previous surgery for cataract or myopia, long duration operation, sudden changes in intra-ocular pressure; and accidental stimulation of the iris with surgical instruments.
Patients are more likely to have pain during second eye surgery, which may be related to higher pre-operative anxiety . Other intra-operative factors that influence pain include: choroidal effusion; suprachoroidal haemorrhage; and aqueous misdirection syndrome. Pain during surgery will generally affect patient satisfaction but can usually be controlled with additional measures for example use of eye drop anesthetic or intracameral injection, reassurance and sedation[13].
Patient's anxiety is reported by many patients listed for cataract surgery pre operatively in spite of knowing in advance about surgical process. Those who accept regional anaesthetic technique may worry about pain or discomfort during the procedure, or an inability to remain still [15].
Unintentional patient movement induced by pain or anxiety will negatively influence surgical outcomes. Sedation/ analgesia minimises patient anxiety and

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discomfort and should help patients remain immobile for the procedure, as well as improve patient satisfaction. Opioids such as fentanyl have often been used as analgesic adjuncts or sole agents during the performance of eye blocks, as well as topical anaesthesia.

Determining the exact dose needed for a specific level of sedation is a unique challenge due to wide variability in patient response [13].

Understanding the pharmacokinetics and synergistic effects of various agents, as well as incremental dosing, is critical. The decision to provide sedation/ analgesia and the agents selected can vary, and is usually based on the needs of the patient or surgeon and the duration of the procedure [16].

Marked individual variations in pharmacokinetics as well as pharmacodynamics sensitivity to sedatives and analgesics can make it difficult to provide the optimum degree of sedation. Therefore, patients may drift into unintended deeper levels of sedation. This can result in airway obstruction and respiratory depression, which may lead to life threatening hypoxaemia [15] .

Cardiovascular depression causes hypotension and cardiac arrhythmias. Furthermore, impaired protective airway reflexes may increase the risk of aspiration of gastric contents. Excessive sedation can impair the patient's ability to communicate verbally, reduce compliance and increase patient movement. It has been reported that, although cataract surgery is a safe procedure with a low risk of complications [16].

Several measures have been suggested to reduce the risk of adverse events during cataract surgery. Pre-operative patient information and education regarding anaesthesia and surgery are considered useful. A low ambient noise level, reduced lighting in the procedure room, maintaining a comfortable temperature for the patient and appropriate selection of anaesthesia or sedation/analgesia technique, are all important. The patient's vital signs should be monitored (pulse oximetry, NIBP and ECG) anaesthetic assistant must be well trained all equipments of general anaesthesia should be available including ETT , laryngoscopy , ambu bag , oxygen source and suction apparatus [17].

AIM OF THE STUDY :

To evaluate the comparison between the clinical efficacy and sedative effect of fantenyl alone and combined of propofol and fentanyl in cataract surgery.

PATIENTS AND METHODS:

Study design: - a prospective clinical trial study, which was conducted in ALdiwanyia teaching hospital from 1st January to 1st September 2021 at the ophthalmology department, the clinical trial was recorded after patient consent was written and approval of scientific council of anesthesia and intensive care, It was enrolled 80 patients from those scheduled to undergo cataract surgery at the ophthalmology department

Inclusion criteria were:

1. Age between 60- 90 years old.
2. ASA classification II –III.
3. The Exclusion criteria included;
4. Patients on aspirin or anticoagulant
5. Uncontrolled hypertension
6. Hyperthyroidism
7. Frequent cough
8. Drug abuse
9. Impaired hearing
10. Neurological or psychological disorders

There was three dropped cases with partial and failed block

Data collection

A complete history and clinical examination was done, Full investigation had been done in preoperative periods.

The patients were assigned into two clusters of forty according to type of drugs that used in sedation. Group one patients received only fentanyl and second group had been received propofol and fentanyl.

Procedures:

All patients were not give any drugs and were reserved fasting for four to six hour before operation. Measurements of hemodynamic status were done before, during and after operation. In addition to, record the adverse effects, patients and surgeon satisfaction were assessed.

Prior to giving of sedation and every five minute there are measurement and documentation of systolic and diastolic blood pressure. Others parameters such as Heart rate, and blood oxygen saturation (SpO2) was continually recorded by pulse oximetry .

Before sedation was given IV access was done to the patient and nasal cannula with O2 source was available for all patients with ECG monitor.

In the first group the patients received 0.25 – 0.5 μg/kg of fentanyle 5 minutes prior to regional anaesthesia was given. We start with lowest dose then increase accordingly (antiemetic metclopromide 10 mg iv slowly was given with fentanyle).

In the propofol and fentanyle group (second group) propofol titrated at a dose of 0.25-0.5 mg/kg as bolus and incremental dose was 10-20 mg, until reaching the satisfactory level of sedation (2-3 on Ramsay Sedation Scale).

The safe and effective sedation level in the present study was defined as patient's ability to maintain consciousness/responsiveness throughout the surgery. Sedation level was measured using the Ramsay sedation scale classified 1 – 6[13]

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0	awake, orientated
1	agitated, anxious
2	awake, cooperative
3	sleeping, but cooperative
4	deep sedation, quick reaction to pain stimuli
5	deep sedation, slow reaction to pain stimuli
6	deep sedation, no reaction to pain stimuli

The study goal was to achieve a sedation level of 2 -3 based on Ramsay sedation scale.
Anesthetic complications including bradycardia, tachycardia, hypotension, hypertension, hypoxemia, apnea, involuntary movement , SpO2 less than 90%, agitation, and postoperative nausea were recorded and treated.
The interval between the end of the procedure and meeting the criteria to be discharged from the postanesthesia care unit (the recovery time) was recorded.

The recovery of the patients was evaluated using a modified Aldrete score[13]. It was determined by scoring from 0 to 10, according to the patient's activity, oxygen saturation, consciousness, respiration, and circulation. Patients with an Aldrete score ≥ 9 were discharged from the post anesthesia care unit.

Parameters	Description of the patient	Score
Activity level	Moves all extremities voluntarily/on command	2
	Moves 2 extremities	1
	Cannot move extremities	0
Respiration	Breathes deeply and coughs freely	2
	Is dyspneic, with shallow, limited breathing	1
	Is apneic	0
Circulation (blood pressure)	Is 20 mmHg > preanesthetic level	2
	Is 20 to 50 mmHg > preanesthetic level	1
	Is 50 mmHg > preanesthetic level	0
Consciousness	Is fully awake	2
	Is arousable on calling	1
	Is not responding	0
Oxygen saturation as determined by pulse oximetry	Has level > 90% when breathing room air	2
	Requires supplemental oxygen to maintain level > 90%	1
	Has level < 90% with oxygen supplementation	0

*Maximum total score is 10; a score of ≥9 is required for discharge.

Bradycardia/tachycardia: Decrease or increase of heart rate by 20% of basal values, Hypotension/hypertension: Decrease or increase of the blood pressure by 20% of baseline during intra- and postoperative period, Hypoxemia (SpO2 < 90%), Apnea: Complete cessation of breathing for 10 seconds or more.
At the end of the surgery (after full recovery) or before discharge, the patients' and surgeons' satisfaction were evaluated and recorded by the anesthesiologist using a five-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neither agree nor disagree, 4 = agree, 5 = strongly agree).
Ethical consideration
Oral consent from participants was considered and brief explanation about purpose of study and benefits, furthermore any question raise by patients should have clear responded. In addition, the permission from health directorate in governorate was taken.

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STATISTICAL ANALYSIS

SPSS Software (version 23.0 for Linux) was used to perform statistical analysis of the study data. Qualitative data are presented as numbers and percentages, while continuous numerical data are presented as mean + standard deviation. Comparison of study groups was carried out using chi-square test for categorical data, P value of <0.05 was considered statistically significant.

RESULTS

The study enrolled eighty patients with mean age 66.9±5.3 years. Mean age for first group was 67.1±4.8 and for second group was 66.3±6.2. The mean weight for first and second group was 77.1±10.8 and 80.2±9.8 respectively. Male were constituted 51.3% while female were 48.7%. As shown in table 1.

Table1: Patient's characters.

		Group 1	Group 2	p-value
Age		67.1±4.8	66.3±6.2	0.4
Height		170.3±13.5	169.7±15.2	0.2
Weight		77.1±10.8	80.2±9.8	0.6
Gender	**Male**	17	24	0.1
	female	23	16	

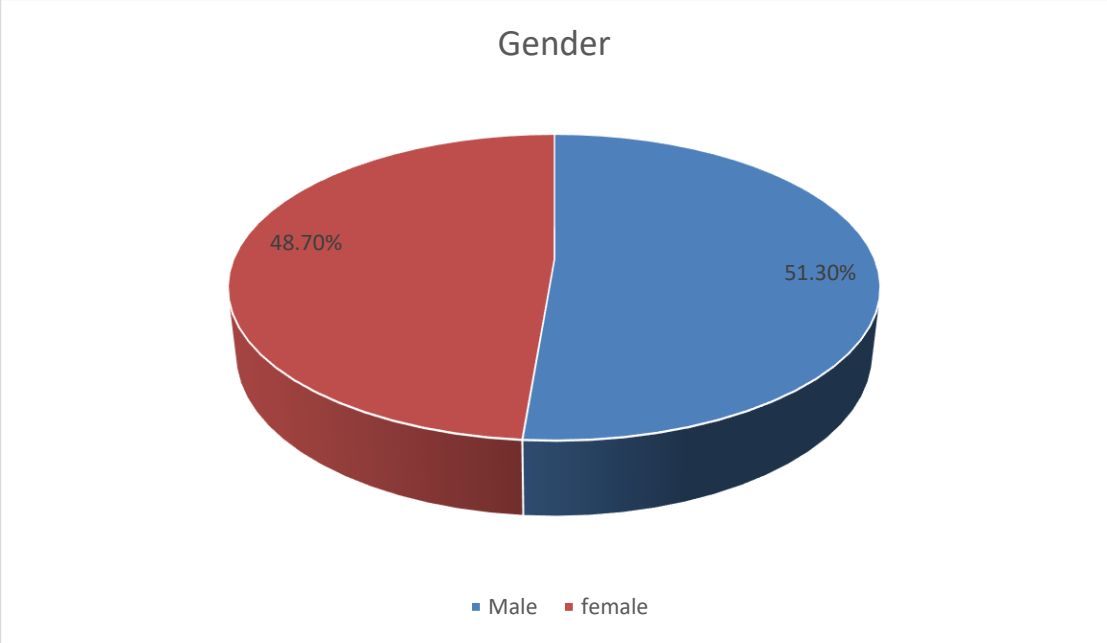

Figure 1: Gender distribution.

Hemodynamic criteria of patients were recorded before the beginning of surgery which are not statistical different between two group. After launch of operation the blood pressure was significantly differs between two groups with p value less than 0.001. The systolic and diastolic mean was lower in group of both fentanyl and propofol drugs during and after surgery. Although the decrement was seen in both group but group two much lower than group of only fentanyl. On other hand there were no difference in statistical view in heart rate and oxygen saturation during surgery. These are presented in table 2.

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Table 2: Hemodynamic readings.

TIME	Groups	BP/ systolic	Diastolic	HR	SPo2	
Five minute	Group 1	154.7±15.1	89.1±6.3	77.2±3.3	97.3±3.4	
	Group 2	153.6±18.3	86.4±9.2	76.1±6.4	96.4±2.5	
p-value		0.3	0.1	0.5	0.6	
Ten minute	Group 1	157.2±20.1	90.4±11.2	70.1±4.2	97.3±2.8	
	Group 2	142.6±10.2	83.1±8.4	71.2±5.3	96.1±2.1	
p-value		0.001	0.001	0.4	0.7	
15 minute	Group 1	133.6±17.1	81.4±7.2	64.2±6.1	97.3±2.6	
	Group 2	124.3±15.8	72.4±9.1	67.1±2.3	97.2±2.4	
p-value		0.001	0.001	0.3	0.5	
20 minute	Group 1	145.5±13.5	82.4±9.2	63.2±9.3	98.7±3.7	
	Group 2	134.2±11.3	78.1±6.4	62.1±8.2	98.1±3.4	
p-value		0.001	0.009	0.8	0.7	

In according to Ramsy score there was insignificantly difference between the groups (p-value =0.7). The score 2 was highly prevalent in both samples. The frequency of score 2 and 3 were 92.5% in group one and 97.5% in group two. As shown in table 3.

Table 3: Show the Ramsy score.

Ramsay score	**Group 1**	**Group 2**	**p-value**
1	1	0	0.7
2	28	29	
3	9	10	
4	1	1	

There was significant difference in patients score regarding the comparison between groups. Where as the surgeon score was not significantly differs. The patients score was higher in fentanyl and propofol group than fentanyl group as in table 4. And figure

Table 4: Patients and surgeon satisfaction score.

Satisfaction score	**Group 1**	**Group 2**	**p-value**
Patients	4.1±0.3	4.9±0.7	0.01
Surgeon	4±0.4	4.1±0.3	0.2

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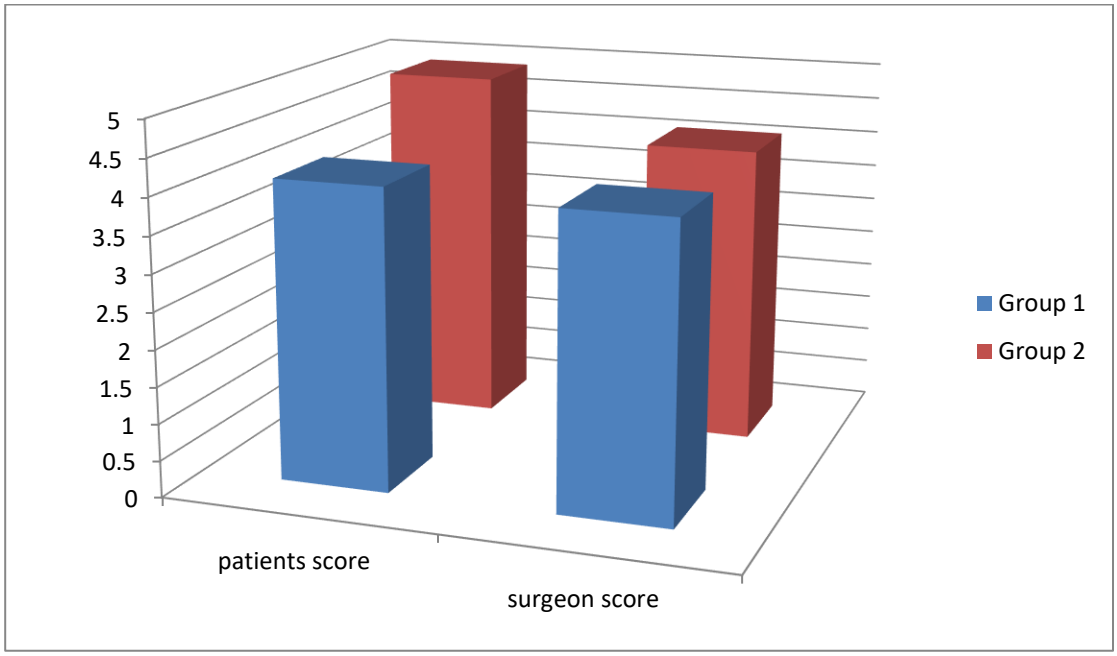

Figure 2: the patients' and surgeons' mean score of satisfaction.

Regarding anesthetic complication, there were low numbers of patients experience complications and the difference not significant. As shown in table 5.

Table 5: It shows prevalent of anesthetic complication in sample.

Anesthetic complications	**Group 1**	**Group 2**
Dizziness	1	1
Restlessness	2	1
Vomiting	1	0
Nausea	3	1
Hypoxemia	1	2
Bradycardia	4	2
Tachycardia	1	1
Hypotension	4	4

DISCUSSION:

Phacoemulsification is the most commonly used minimally invasive cataract surgery pr0cedure, which has become a routine cataract extraction technique in all developed and most developing countries [18]. In addition, considering that most of the patients are elderly cases with other concomitant diseases such as cardiovascular or respiratory disorders, they need a higher dose of analgesics [19]. Thus, appropriate pain control is considered the most important care for this group of patients[19].

During regional anesthesia, patients often sensing light and color, and they even see the surgeon's hands and surgery tools, and sense pain when manipulating the iris, stretch of the globe, and inserting the lens. Therefore, sedation or supplemental analgesia is often required during surgery [18].

In order to optimize the efficacy of phacoemulsifcation cataract surgery and reducing the postoperative pain

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and some reported complications introducing of an appropriate anesthetic protocol for this procedure would be more favorable [20].

Actually, many agents were used to provide sedation and anxiolysis during operations under regional anesthesia such as midazolam, α2 agonists (clonidine or dexmedetomidine), ketamine, sevoflurane, and remifentanil [1].

The mean age of our study sample was 66.9±5.3 years. Mean age for first group was 67.1±4.8 and for second group was 66.3±6.2. The mean weight for first and second group was 77.1±10.8 and 80.2±9.8 respectively. Male were constituted 51.3% while female were 48.7%. It is close to the result of study by Adinehmehr L et al. who enrolled 58% male and 42% female and mean age of the studied population was 69.68± 12.0 years. They reported no significant differences among the groups in terms of mean of age, weight, and height of the patients (P > 0.05) [13].

Shetabi, et al presented mean age of the studied population was 66.26 ±12.79. Mean age, weight, height, and body mass index of the patients in the two groups were not statistically different (*P* > 0.1). Two groups
were comparable in terms of gender distribution (*P* > 0.1) [18].

Hussien and Ibrahim study were included 47 males and 53 females with a mean age 60.1 ±8.2 years in the first group and 58.9 ± 7.4 years in the second group [22].

In this study we compared the effect of fentanyl and propofol together in comparison to effect of fentanyl alone in cataract surgery under regional anesthesia, these drugs used for sedation. The comparison documented by hemodynamic monitoring of patients. Hemodynamic criteria of patient were recorded before of beginning of surgery which is not statistically different between two groups. After launch of operation the blood pressure was significantly different between two groups with p value less than 0.001.

The mean of blood pressure in term of systolic and diastolic data was lesser in patients with combination of fentanyl and propofol drugs during and after operation. Although the decrement was seen in both group but group two much lower than group of only fentanyl.

However, there was no difference between mean of heart rate and oxygen saturation during operation. These parameters decrease may be attributed to the relief of anxiety and over activity of sympathetic pathway which aggravated by fear from surgery before onset[23].

On other hand, this decrease in heart rate and MABP was not significant clinically as it was less than 20% of pre-sedation values [23].

Adinehmehr L et al was showed the hemodynamic evaluation at baseline in their study did not show any significant differences between the studied groups, but during and after surgery, the mean systolic and diastolic blood pressure and mean arterial blood pressure were significantly decrease [13].

Aghadavoudi et al, study was conducted to evaluation the value of sedation by compare the effect of etomidate infusion against fentanyl midazolam ketamine combination during cataract operation, the result appeared that the hemodynamic changes and the pulse rate increased significantly after recovery [11].

Current study reported results were vary from outcome for study of Choi et al [24] and Vinson and Bradbury[25]. These variations in results between studies back up to different protocol, dosages, surgery duration and bolus or infusion route of administration of sedation [1].

Another finding, the inter group comparison reported no clear difference in arterial saturation during surgery.In the study of Aghadavoudi et al., the oxygen saturation percentage was significantly higher in the etomidate-fentanyl group, especially after recovery, than that of the fentanyl-midazolam-ketamine group, which was not coordinated with the result of the current study [10].

There was no report of any sedation related adverse effects in present study groups. The finding were consistent to previous studies that recorded no related adverse events in cataract surgery with sedation for example aspiration, laryngospasm, need for intubation, hospital admission, or death from fentanyl or propofol complications [27].

There were no significant differences between groups regarding different anesthetic complications.

The most common reported complication in the two groups was hypotension. However it was not statistically different.

In present study not appears difference in study groups in regard to surgeon satisfaction mean score which is consistent to results by Adinehmehr L et al study [13]. More over, in operation of colonoscopy Banihashem et al [6] was as showed same mean satisfaction score between the propofol-fentanyl and etomidate-fentanyl groups in elective situation. The present study result is consider similar to finding reported by Aghadavoudi et al. [10], and Vinson and Bradbury [25]. Some studies demonstrated that the method of sedation had no significant impact on the surgeon's or patients' satisfaction [28, 29].

Regarding patients' mean score of satisfaction, the present study finding showed the score of the fentanyl propofol groups were considerably upper than that of the fentanyl group. Aghadavoudi et al. [11] and Lee-Jayaram et al [12] were

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studied the efficiency of etomidate fentanyl versus ketamine midazolam in procedural sedations for cataract surgeries. The two trials reported the patient satisfaction mean score was greater in the ketamine-midazolam group than that of the etomidate-fentanyl group.
In the previous study, though the difference was not significant, patients' satisfication score was higher in the midazolam group than the etomidate group. It is suggested that the pain caused by the etomidate injection could explain lower satisfaction score of the patients [(12)].

CONCLUSION

1- The quality of sedation was acceptable in both groups
2-the combination of fentanyl and propofol was superior to fentanyl alone in hemodynamic evaluation and patient satisfaction.
3-The study was reported no significant complication in both groups.

RECOMMENDATION

1-The combination of fentanyl and propofol are more suitable for performance of conscious sedation for cataract surgery.
2-Continous monitoring of patients during cataract surgery by anesthetic to observe any hemodynamic changes and modified the sedative doses.

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