

Comparison of sedative effect of Fentanyl and Remifentanyl during Phacoemulsification with local anesthesia

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Abstract: Nowadays, Phacoemulsification surgery is mostly carried out under local anesthesia. In this type of anesthesia the patient needs to be sedated. Because of painful intracameral injection, an Intravenous (IV) analgesia is also required using bolus dose of Fentanyl or Remifentanyl. Our main purpose was the comparison of the sedative effects of 2 models of Intravenous local analgesia during Phacoemulsification in cataract patients. Moreover, to investigate the patient, surgeon satisfaction and complication rate in two groups. Material and methods: This Clinical Trial study was carried out on 64 patients with cataract who underwent phacoemulsification surgery in Baqiyatallah hospital in second half of year 2013. Patients with American Society of Anesthesiologists (ASA) Physical Status classification system; ASA class I & II were chosen and randomly divided into two groups. The level of sedation was assessed using the Ramsay sedation (RS) scale. Moreover, along with sedative effect, patient, surgeon satisfaction, Vital signs, rate of pain and complication rate were recorded and compared in two groups. Results: Thirty six patients were in Fentanyl group with mean age of 64.71 ± 8.21 years and 28 in Remifentanyl group with mean age of 65.2 ± 12.43 . RS in Fentanyl group was significantly higher than Remifentanyl group (2.02 ± 1.08 versus 1.42 ± 1.19 , $p < .05$). Rate of satisfaction of patients and surgeons was significantly higher in Fentanyl group in comparison with Remifentanyl group ($p < .05$). Side effects in Fentanyl group was also significantly less than Remifentanyl ($p < .05$). There was no significant difference in vital signs of patients in two groups neither before surgery nor after that. Conclusion: Results of this study show that, Fentanyl has fewer side effects, more sedation effect and more patient and surgeon satisfaction in comparison with Remifentanyl. The administration of fentanyl appears to be a better choice as an analgesic with local anesthesia in cataract surgery

Keywords: Fentanyl, Remifentanyl, Cataract, Phacoemulsification, Sedation, Local Anesthesia

1. Introduction

Nowadays, Phacoemulsification surgery is mostly carried out under local anesthesia due to speed and ease of administration, rapid visual recovery postoperatively and the lack of block-related complications.[1] In this type of anesthesia the patient needs to be sedated. The advantage of local anesthesia is that it have no potential side effect such as retrobulbar bleeding, temporary blinding and pre-orbital echimosis. The local anesthesia side effects during

phacoemulsification include rising patient anxiety and uncomfortable emotion because of the light of microscope, thus it is necessary to use an IV sedative drug for patient, which for this purpose bolus dose of Fentanyl and Remifentanyl with propofol is used for sedation maintenance. [2,3]

Fentanyl is an artificial opium agonist that is 75 – 125 time stronger than morphine. Higher potency and sooner

effect of Fentanil than morphine indicate the more ability of solvency in the fat which facilitates its iteration from the blood- brain barrier. Because the Fentanil has spread quickly in the inactive tissue like fat and muscle , during multiple IV dose or IV infusion usage , a continuous saturation happens yielding to slowly reduction of plasma density that causes lengthening the sedation and respiratory suppression effect. Clinically it is used in low dose ($1 - 2 \mu\text{g} / \text{kg}$ for IV infusion) for sedation and high dose ($50 - 150 \mu\text{g} / \text{kg}$ for IV infusion) for anesthesia. [4,5,6,7,8]

Remifentanil, a selective opiate agonist with potency of sedating as like as Fentanil , has an individual structure causing hydrolyzation via plasma and tissue esterase and because of this have some trait such as quickly starting effect, non aggregation effect and quick awakening after holding IV infusion. The clinical usage of Remifentanil is for temporary effect and deep sedation. Remifentanil is used as part of sedating in general anesthesia with ($0.05 - 2 \mu\text{g} / \text{kg}$ dosage). [9,10,11,12,13,14,15,16,17] Furthermore, because intracameral injection is painful, an Intravenous (IV) analgesia is also required using bolus dose of Fentanil or Remifentanil.[18,19] The goal of this study was to compare the sedative effects of 2 models of Intravenous local analgesia during Phacoemulsification in cataractus patients.

2. Methods

This clinical trial study comprised 64 cataractus patients which underwent cataract surgery in the second term of 2013 in Baqiyatallah Hospital, Tehran, Iran. The study was approved from the Institutional Review Board and written consent of patients and guardians was obtained. Patients scheduled for phacoemulsification underwent an informed consent procedure that explained the surgery and the study in detail. All of the patients were oriented about this study by the coordinator. Patient with ASA class 1 & 2 randomly selected and classified into two groups. After admission in the hospital , one night before the surgery, tablet of diazepam 5 mg p.os was given to all patient. They were Non per os (NPO) for 8 hours before the surgery. Vital signs were monitored and recorded throughout the study. After entering to operation room, they were under cardiac monitoring, pulse oximetry, and vital signs. Standard monitoring included ECG, blood pressure, and pulse oximetry. Then IV line fixed using angiocat number 22 and normal saline was infused. Oxygen was given through nasal prong; $8 - 10 \text{ L} / \text{min}$. Then, in the first group ,Fentanil with $1 / 5 \mu\text{g} / \text{kg}$ dosage and in the second group , Remifentanil with $0/25 \mu\text{g} / \text{kg}$ dosage during 30 second was given and at the same time propofol with dosage of $25 \mu\text{g} / \text{kg} / \text{min}$ was started. Local anesthesia performed with 0/5 cc Lidocaine 2 % and 0/5 cc adrenaline with 4CC distilled water as diluents administered as intracameral anesthesia. Moreover, tetracaine 0.5 % as topical anesthesia was used for patients. Vital sign was

checked every 2 minutes in operation room , in the recovery and 2 hours after the procedure. In the recovery also, one anesthesiologist who was blinded to the patient group evaluated emergence agitation and postoperative nausea and vomiting along with adverse events . The patient sedation was checked according to Ramsey score which classified from 0 – 5(0 = anxious , 1 = calm , 2 = lethargic , 3 = confuse but responding to conversation , 4 = no response to speaking , 5 = no response to painful stimulation) . If the patient was not responding to speaking , the infusion propofol has been holded. Patient with SPo2 less than 90 % have been encouraged to breathe more ,however during more than 90 % SPo2 , they were ventilated with mask. For patients who vomit in the recovery room, ondansetron 4 mg IV infusion in 30 second was used. Duration of anesthesia using Fentanil and Remifentanil until perfect awareness and duration of operation have been recorded. The surgeon satisfaction was recorded immediately postoperatively.

Also , in the recovery room the patient have been asked regarding their satisfaction from operation , the pain quantity according to the visual analogue scale and the side effect such as vomiting. Patient who complained from pain, received pethedine $0/25 \mu\text{g} / \text{kg}$ IV infusion. The result of study without name of patient exposed to others. The data with normal distribution were expressed as mean \pm standard deviation. The continuous variables were compared between two groups by using the independent *t*-test. Categorical variables were compared using the chi-square test . Statistical analysis was performed using SPSS 18.0 (SPSS Inc., Chicago, IL, USA). P values less than 0.05 were considered statistically significant.

3. Results

This study evaluated 64 cataractus patients(nucleus sclerosis grade 2 to 3) with mean age of 64.91 ± 9.21 years [range 44 to 88] who were candidate for phacoemulsification surgery between June 2013 and December 2013 at Baqiyatallah hospital ,Tehran, Iran. Thirty six patients were in Fentanil group with mean age of 64.71 ± 8.21 years and 28 in Remifentanil group with mean age of 65.2 ± 12.43 . 17 patients in Fentanil group were male and 19 patients were female and in the Remifentanil group , 11 patients were male and 17 patients were female. There was no statistically significant difference in the demographic data. The average grade of pain during the operation in Fentanil group was recorded $0/91 \pm 0/1273$ and in the Remifentanil group was $1/82 \pm 1/88$ after questioning in recovery room. A significant difference was found between 2 groups regarding pain intensity ($P = 0/034$). The mean Ramsey score in Fentanil group was $2/02 \pm 1/081$ and $1/42 \pm 1/199$ in Remifentanil group. The vital sign index is shown in the table 1 & 2 . There was no significant difference between two groups regarding vital sign ($P > 0/05$).

Table 1. Vital sign index in two groups before drug infusion

Index	Fentanyl	Remifentanyl	P value
H.R(before drug infusion)	68/17 ± 13/190	70/04 ±12/699*	0/574
SBP (before drug infusion)	159/00 ±24/927	150/93 ±24/799	0/207
DBP (before drug infusion)	89/52±15/329	86/55 ±14/412	0/438
SPo2 (before drug infusion)	95/86 ±3/728	95/63 ±2/633	0/784

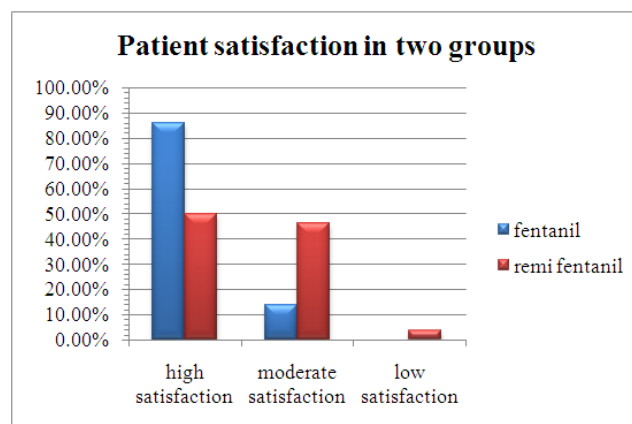
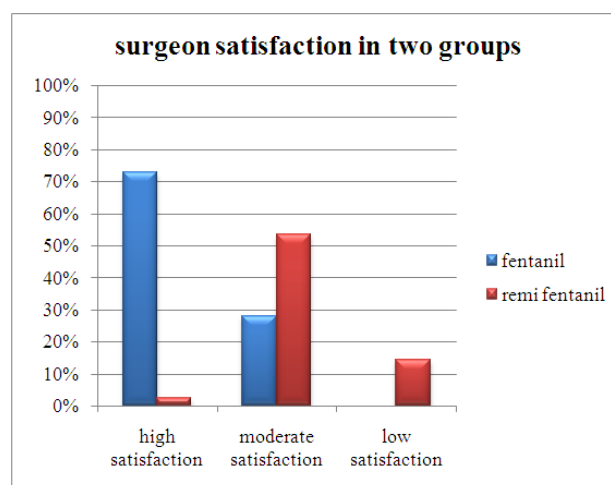
*Average ± standard deviation

Table 2. Vital sign index in two groups after drug infusion

Index	Fentanyl	Remifentanyl	P value
H.R(5 min before drug infusion)	70/00± 12/802	66/89±11/729	0/322
H.R(10 min before drug infusion)	69/83 ± 11/542	67/36 ± 12/099	0/408
SBP (5 min after drug infusion)	153/83 ±23/606	152/32± 26/410	0/810
SBP (10 min after drug infusion)	144/42± 22/083	149/29±28/635	0/445
DBP (5 min after drug infusion)	84/19 ±13/330	83/07 ±11/563	0/725
DBP (10 min after drug infusion)	83/30 ±12/932	83/92 ±10/831	0/838
SPo2 (5 min after drug infusion)	96/94 ±3/488	97/14 ±2/519	0/801
SP o2(10 min after drug infusion)	97/22±3/950	97/00 ±2/494	0/222

*Average ± standard deviation

In Fentanyl group , 5 patients had moderate satisfaction (13/9 %) and 31 patient had high satisfaction (86/1 %). In Remifentanyl group 1 patient had low satisfaction (3/6 %) and 13 patients had moderate satisfaction (46/4 %) and 14 patients had high satisfaction (50 %). A significant difference was found about patients satisfaction between two groups(P =0/003). [Figure 1] While , moderate satisfaction of surgeon (27/8%) was demonstrated in Fentanyl group in 10 cases and high satisfaction (72/2%) in 26 cases, in Remifentanyl group in 4 cases low satisfaction (14/3 %), in 15 cases moderate satisfaction (53/6%) and in 9 cases high satisfaction (32/1 %) was demonstrated. There was significant difference about surgeon satisfaction between two groups (P= 0/001). [Figure 2]

**Figure 1.** patient satisfaction in two group**Figure 2.** Surgeon satisfaction in two group

In Fentanyl group only 1 patient experienced xerostomia (2/8 %) and 35 patients were not experienced any complication (97/2%). In Remifentanyl group, 8 patients(28/6%) experienced complications such as coughing during the surgery , blood pressure rising , nausea and vomiting and 20 patients(71/4 %) had not experienced any complication . A significant difference was found between two groups in term of complications (P = 0/001) .

4. Discussion

In this clinical trial study, sedative effects, side effects and the surgeon and patients satisfaction of 2 models of Intravenous local analgesia during Phacoemulsification in cataractus patients were investigated. More sedation effect ,more patient and surgeon satisfaction and fewer side effects was found in Fentanyl group in comparison with Remifentanyl group.

In a study comparing Remifentanyl with alfentanil , lower levels of sedation was shown in remifentanyl[8] that is in accordance to our study. Moreover, Rate of satisfaction of patients and surgeons was evaluated Previously. For instance, high level of satisfaction with Fentanyl was found in study by Aydin et al.(2002) when

sedation with fentanyl in phacoemulsification under topical anesthesia was assessed.[20] Furthermore, in a study conducted at the University of Delhi's Lady Harding recovery, discharge, and patient satisfaction was higher in the Fentanyl group. [21] Similarly, we found higher level of Patients and Surgeons satisfaction in Fentanyl group in comparison with Remifentanyl group. In addition, they demonstrated significantly better rate of the pain intensity and relaxation in Fentanyl group than Remifentanyl group.

The rate of adverse effects in this study was significantly lower in the Fentanyl than Remifentanyl. Likewise, Low complication rates of Fentanyl have been reported in other studies. [8,23,24]

The vital sign were not significantly different between the two groups before surgery in our study. It seems that Remifentanyl is generally the upper side compared with alfentanil. Similar to our study, in a study by the University of Ardebil, shown that in Remifentanyl group, there was higher nausea and vomiting after surgery and delay in the return of spontaneous respiration. [22]

Our study has some limitations including difference in time-to-peak effect of these medications, an aspect that has not been taken into consideration in the present study, single center study and the small sample size. Future investigations should be designed to assess this different effect.

5. Conclusion

In summary, Results of this study show that administration of Fentanyl as an analgesic with local anesthesia appears to be a better choice in cataract surgery due to fewer side effects, more sedation effect and more patient and surgeon satisfaction in comparison with Remifentanyl.

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