RESEARCH ARTICLE

Comparison of Paracetamol and Fentanyl for Postoperative Pain and Perioperative Events in Phacoemulsification Cataract Surgery

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Background: We administered paracetamol and fentanyl at the beginning of phacoemulsification cataract surgery. We think that paracetamol administered alone is as effective as fentanyl in treating pain after cataract surgery with fewer side effects during operation and in post anesthesia care unit (PACU). The goal of this study was to compare to the postoperative pain relief effect of paracetamol and fentanyl and to assess their side effects in PACU.

Methods: This study was a randomized double-blinded clinical trial comprising 160 patients aged 50-80 year old undergoing cataract surgery using phacoemulsification method by local anesthesia and sedation. The patients were randomized to two groups; patients who received 1 gr paracetamol (P group) and who received 1µg/kg fentanyl (F group) at the beginning of operation. The pain, sedation, patients' satisfaction and complications during surgery and recovery time were assessed.

Results: The mean scores for intraoperative and postoperative pain on the visual analog scale showed no statistically significant differences (P=0.445). The scores of anxiety and pain were not significantly different comparing two groups after the surgery (P =0.574). The mean score of satisfaction was (8.84± 1.096) in P group and (9.48 ± 8.03) in F group (p=0.04). The mean arterial blood pressure in group P was lower comparing with group F (P=0.011). Nausea and vomiting, apnea and arrhythmia did not occur in P group, while 3(3.8%) of patients in group F had apnea and arrhythmia, 4(5%) had nausea, and 3(3.8%) had vomiting. While these differences were clinically significant, only nausea showed statistically significant difference between two groups (P=0.043).

Conclusion: Paracetamol is an effective analgesic for postsurgical pain in patients undergoing cataract surgery and it is safe with no important side effects.

Keywords: paracetamol; fentanyl; Phacoemulsification; pain

The surgery of cataracts by phacoemulsification method is one of the most common eye surgeries in the old age group [1]. Most patients report a mild to moderate pain after surgery. Phacoemulsification is done using topical anesthesia. Benefits of topical anesthesia include ease of use, effectiveness, fast recovery, and lack of complications of retrobulbar or peribulbar block and general anesthesia [2-3]. Adequate analgesia and sedation with narcotics and alternative adjuvants drugs are supposed to prevent stress-induced reactions such as hyper metabolism, hypertension, tachycardia and altered wound healing and to optimize patient comfort [4].

A study of Cochrane assessed other studies and concluded that paracetamol is an effective analgesic drug in half of patients with acute pain during 4 hours after surgery. Pre-emptive analgesia decreases the pain severity during and post operation phase and lowers the demand for more analgesic [5].

The mechanism of analgesic action of paracetamol is not clearly known; there are many manifestations of central antinociceptive effects and it works by inhibiting cyclooxygenase 2 (cox-2) in central nervous system (CNS) and inhibition of a putative central cyclooxygenase 'COX-3' that is selectively susceptible to paracetamol [6]. The intravenous paracetamol is an effective analgesic agent for mild to moderate pain with high level of safety, and there are no side effects in analgesic dosage [7]. Paracetamol is not addictive and its analgesic property is basically derived from inhibiting the cyclooxygenase enzyme and probably has indirect effects on serotonergic system in CNS [5].

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Paracetamol easily diffuses the blood brain barrier (BBB) [5]. Paracetamol has also been shown to prevent prostaglandin production at the cellular transcriptional level, independent of cyclooxygenase activity [8]. Paracetamol is therefore an effective postoperative analgesic, with potency slightly less than a standard dose of morphine or the NSAIDs [9]. In general, the incidence of side effects after intravenous administration of paracetamol was relatively small [10].

Narcotics have a limited usage for sedation because they have known side effects such as coughing, apnea, nausea and vomiting. The ideal sedative drug would be one with no dangerous side effects such as respiratory depression or hemodynamic instability. It should also produce sedation and amnesia for the short time required to perform the phacoemulsification cataract surgery without over sedation [8]. To our search and knowledge, there is no published literature about the effects of paracetamol in cataract operation. The aim of our study was comparison of analgesic effect of paracetamol and fentanyl and assessing perioperative complications and side effects in phacoemulsification cataract surgery.

Methods

This study was confirmed by ethics committee of Tehran University of Medical Sciences and was registered in Iran clinical trial website with registration ID number IRCT2012120511676N1. All patients accepted to enter this study and signed the written informed concern. 160 patients were entered to our study with 50-80 years old and ASA class I or II, who were being operated for first time in outpatient surgery with local anesthesia and sedation. The patients were excluded if they had history of addiction, psychotic or neurologic diseases, severe anxiety, and previous pain, recent use of sedative drugs, severe allergic diseases, or uncontrolled comorbidities (e.g. liver disease, renal disease, heart disease, and diabetes mellitus). The patients were randomly divided into 2 groups by block randomization methods: paracetamol (P) group and fentanyl (F) group.

After IV catheter fixed, all patients received 250 ml ringer serum and also 0.015 mg/kg midazolam for sedation before the operation. Tetracaine eye drop (2 droplets) was prescribed in each eye and repeated 5 minutes later. In P group paracetamol 1gr/100cc normal saline was infused over 20 minutes and in F group, fentanyl 1µg/kg in 100cc normal saline was infused in 20 minutes. In both groups, if there was pain during operation, fentanyl 1 µg/kg IV was administered again until verbal analogue scale <3 (VAS: 0-10; 0: no pain, 10: worst pain imaginable) and its dosage recorded. Surgical team had no information about the drug`s prescription. The drugs labeled with mark 1 and 2 and the study was double blinded. The demographic data including sex, age, and weight were recorded. Also, VAS score, heart rate, and the mean arterial blood pressure 0, 5, 10, and 15 minutes after start of local anesthesia and in recovery room were evaluated between two groups. Sedation score before and 5 minutes after operation, and in recovery room was evaluated based on the demeanor of the patient using a 3-point scale as follows [3]: very calm and calm (0); slightly anxious (1); very anxious (2). Satisfaction score (Satisfaction score: 0-10; 0: no satisfaction, 1-3: mild satisfaction, 4-6: moderate satisfaction, 7-10: good satisfaction) and side effects during and after surgery in recovery have been evaluated and the dose of supplementary consumption of fentanyl and propofol were recorded and analyzed.

Data were given as mean ± standard deviation for continuous variables. The chi-square test was used to compare binary variables between two groups. Continues variables were compared using independent sample t test. Non-parametric tests (Man-Whitney U test and Wilcoxon test) were used for comparison of scale variables. P value less than 0.05 considered as statistically significant in all tests.

Results

Demographic data of patients does not differ in two groups (Table 1). Mean age of patients was 60.95±14.18 year in P group and 66.08±10.67 year in F group (P=0.059). Male/Female Ratio in P group (%38.8 to %61.2) and F group (%43.8 to %56.3) was the same (P=0.512).

The incidence of anxiety, pain and heart rate in perioperative period does not differ in both groups. The mean scores for intraoperative and postoperative pain on the visual analog scale showed no statistically significant differences in intraoperative or postoperative pain (P=0.445). The scores of anxiety and pain were not significantly different comparing two groups after the surgery (P =0.574). All patients were hemodynamically stable during the surgery. In PACU the pulse rates of patients were within normal range and there was not statistically difference between two groups (P=0.425). The mean of arterial blood pressure of recovery was (100.54± 16.16) in P group and (103.64± 19.45) in F group. The mean arterial blood pressure in group P was lower comparing with group F (P=0.011). Mean satisfaction score of patients after operation in group p (8.84±1.096) and group F (9.48±8.03) showed significant difference between two groups (P=0.040) (Table 2).

Administration of rescue analgesic in paracetamol group was as follow: 21 patients needed 1ml and one patient needed 2ml of supplementary fentanyl. But in fentanyl group as: 12 patients needed 1ml, 5 patients needed 2 ml, and one patient needed 3 ml of rescue fentanyl. There were no statistically significant differences (p value= 0.814). Paracetamol group did not need supplementary propofol but in fentanyl group one patient needed 40 mg supplementary propofol.

Apnea, arrhythmia, nausea and vomiting were not seen in group P, but in group F apnea, arrhythmia and vomiting occurred in 3(3.8%) (p= 0.082), and nausea in 4(5%) patients (p= 0.043).

Table1- The comparison of demographic date between two groups

	P group	F group	P value
Sex			
Men	31 (38.8 %)	35 (43.8%)	0.512
Women	49 (61.1%)	45 (56.3%)	
Age (years)	60.95± 14.18	66.03 ± 10.67	0.059

Table2- Comparison of perioperative characteristics between two groups in PACU

	Paracetamol group	Fentanyl group	P value
Anxiety			
Calm	75(%93.8)	75(%93.5)	
Moderate anxiety	5(%6.3)	4(%5)	
Severe anxiety	0(%0)	1(%1.3)	0.574
VAS score	0.04±0.19	0.11±0.48	0.445
Heart rate (beat/min)	72.84±11.48	74.05±14.83	0.429
Mean Blood Pressure (mmHg)	100.54±16.16	103.64±19.45	0.011
Patient Satisfaction	9.48±8.03	8.84±1.10	0.040

Discussion

Cataract surgery is one of the most common operations in elderly populations. The incidence of cataract will increase in every decade of age after 40 years; therefore, approximately the most old people have been involved [1]. Thus surveys about this problem, especially about postoperative pain, are useful for all societies.

In our study patients' basic demographic data were the same in two groups. Pre-operation evaluation including anxiety level, pain score, heart rate and mean arterial blood pressure were also equal in both groups. Hemodynamic status was not different in two groups during the operation. The VAS score of paracetamol and fentanyl groups was not significantly different, therefore the analgesic effect of both groups were comparable. Vomiting, apnea and arrhythmia incidence in fentanyl group were higher than the paracetamol group and paracetamol patients had no side effect in the standard dose of 1gr which indicates the safety of this drug. Among mentioned side effects, only nausea showed statistically significant difference, whereas the difference in vomiting, apnea and arrhythmia incidence were only clinically significant. In PACU, patients' satisfaction score in fentanyl group was more than in paracetamol group, but patients' satisfaction level in both groups was acceptable.

The ideal sedative drug should be one with no dangerous side effects and patient would be hemodynamically stable without respiratory depression [11]. Various agents have been investigated with the aim of reducing the postoperative pain with variable outcomes. Usual combination of midazolam and fentanyl, for decrease pain has a synergistic effect on respiratory depression side effect [12]. Koay and colleagues, studied patients for cataract surgery and concluded that 55% of patients had no pain, 32% had mild complications, 8% had mild pain and only 5% had moderate to severe pain after the cataract surgery [3]. In a review study in Cochran bank data information with 4186 patients, the frequency of reported side effects between 1g acetaminophen and placebo was not significantly different [5]. kaluzny and colleagues studied patients for cataract surgery by phacoemulsification method and concluded that, 1g oral acetaminophen consumption before the surgery is more beneficial than placebo in terms of pre and post operation pain decrease, safety, easy usage and costs. These conclusions are related to our study [7]. Viadeanu and colleagues conducted a study about paracetamol prevention effect on pan retinal photocoagulation (PRP) post operation pain decrease, in patients that received paracetamol 48 hours before the surgery. They concluded that paracetamol has no significant effect on PRP post operation pain levels, but post operation pain level increase in paracetamol group was significantly less than control group [13]. We think that in PRP operation pain is severe and paracetamol isn't a good choice.

Nissman and colleagues compared gabapentin and oxycodone/acetaminophen effects on pain reduction after photorefractive keratectomy surgery. Results showed that, ultimately there is no significant difference in reported post operation pain levels in two groups. The reason for this insignificant difference was because of pain severity. They concluded that acetaminophen was effective for mild to moderate pain when analgesics and narcotics usage were standardized for moderate to severe pain(s) [14]. We concluded that paracetamol showed fewer side effects than fentanyl; therefore, it seems safer than fentanyl. Therefore, paracetamol is an effective analgesic for postsurgical pain in patients undergoing cataract surgery and it is safe with no important side effects.

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