International Journal of Current Research in Medical Sciences

ISSN: 2454-5716

www.ijcrims.com

Volume: 1- Issue: 1 July 2015

Research Article

Comparison of recovery profile and adverse effects with two different formulations of propofol given in ENT surgeries

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Abstract

In Iran propofol 1% Provive™ (Claris) and Propofol 1% MCT/LCT Fresenius®(Fresenius-Kabi) are two common formulation of propofol in clinic. We compared adverse effects of these formulations of propofol in recovery room until 4 hours after operation in those operations which need to administration a relatively high dose of propofol for control the blood pressure in a low level to reduce bleeding (rhinoplasty and functional endoscopic sinus surgery). In a double blind clinical trial patients were divided randomly into two groups. One group was anesthetized with Provive™ formulation and the other received Fresenius®. Type of adverse effects and their incidence, loss of consciousness time and recovery time were compared in both groups.Both groups were match in demographic characteristics and two formulation didn't have any significant difference about observed adverse effects, loss of consciousness time and recovery time.

Keywords: propofol, anaesthesia, formulation, adverse effects, recovery, consciousness.

Introduction

Propofol has become the most common used intravenous (i.v.) anaesthetic(1, 2). Because of its favourable pharmacokinetic characteristics (rapid onset and rapid recovery) and a reduced incidence of post-operative nausea and vomiting it is used widely both in induction and maintenance of anesthesia (3-5).Controlled hypotension is commonly used to provide a bloodless and dry operative field to have a successful surgery in some ENT operations like rhinoplasty and FESS (Functional Endoscopic Sinus Surgery)(6).Apnea, bradycardia, pain in injection area and hypotention, especially in patients whit low levels of body fluid volume are common side effects of propofol. Nausea and vomiting after surgery, allergy and hypersensitivity reactions occur rarely with propofol whileallergic complications, which may include bronchospasm, have been reported with some formulations formulation(7, 8). Hypotension induced by propofolisa dose dependent effect. Reducing vascular resistance, decreasing cardiac output and vascular

smooth muscle relaxation are the cardiovascular effects of propofol (9).In Iran different formulations of propofol are available for clinical uses that two common of them are propofol 1% Provive™ (Claris) and Propofol 1% MCT/LCT Fresenius® (Fresenius-Kabi). Many questions remain about the real clinical equivalence, recovery profile and adverse effects between these brands.

These formulations are oil in water emulsions but contain different ingredients, so this difference may influences the pharmacological effects of drug (10).The aim of this study is to compare adverse effects of two more useful formulations of propofol in recovery in those operations which need to administration a relatively high dose of propofol for control the blood pressure in a low level to reduce bleeding.

Materials and Methods

After obtaining approval by the local ethics committee of Ahvaz Jundishapur University of Medical Sciences, 26 patients (aged 15-55 years) with American Society of Anaesthesiologists physical status class I or II scheduled to undergo rhinoplasty or functional endoscopic sinus surgeries. They gave written inform consent to participate in study. In a randomized, double blind pilot study patients were divided in to two groups (n1=14, n2=12). Patients with cardiovascular, neurologic, metabolic diseases, impaired renal or hepatic function or a positive pregnancy test and history of drug abuse, egg lecithin and soybean allergies were excluded from participating in the study. Before anesthetic induction, standard monitoring including electrocardiogram, pulse oximetry and noninvasive blood pressure monitoring was applied for all patients in operating room. In addition, a BIS monitor recorded BIS values continuously during surgery (each minutes to 30 minutes after consciousness).The anaesthetic technique was standardized, using midazolam 0.03 mg/kg, fentanyl 2µg/kg and propofol 2 mg/kg for induction. They were paralyzed with atracurium. Thereafter patients were intubated and mechanically ventilated. After induction, patients were randomized to receive propofol as 1 % MCT/LCT Freseninus® formulation or the commercially available provive ™ 1 % formulation with 30-100 µg/kg/min rate with infusion pump. During surgery, propofol infusion continued and about 10 minutes before the end of surgery, the infusion was stopped. During surgery, remifentanil (0.1-1 µg/kg/min) or sufentanil (0.5-1.5 µg/kg/h) infusion as analgesic drugs was established. During infusion of propofol, patients with hemodynamic instability and hypotension or bradycardia who need to be cut so that the infusion, were excluded from the study. Loss of consciusness time (from the beginning of propofol injection until patient became unconscious) and recovery time (since the infusion stopped until the opening of the eye) were measured in both groups. All probable adverse effects and complications of anaesthesia monitored untill four hours after the surgery with a questionnaire. Our sample size was not big and our data didn't have normal distribution so the data of the patients were compared using the Mann-Witney U test for the continues and ordinal variables and Fisher's exact test for the categorical variables. A p-value<0.05 was considered significant.

Results

Both groups were match with together in demographic parameters contain age, weight, height, sex and BMI. They didn't have any significant difference in mean of age (pvalue=0.57), weight (pvalue=0.59), height (pvalue=0.66), BMI (pvalue=0.82) and sex (pvalue=0.71) (Table 1). Operation type was match in both groups too (pvalue=0.71).Both formulations didn't have any significant difference in loss of consciousness (pvalue= 0.07) and recovery time (pvalue= 0.46) (Table1).

Any type of heart arrhythmia, any respiratory disorder such as stridor, laryngospasm and bronchospasm, irritability, itching, hypotension, hypertension, vertigo, lethargy and hallucination didn't observed in any patients of both

groups. One case in the Fresenius® group was agitated until one hour after surgery and one case in this group had vomiting once in first 4 hours after surgery. One case in Provive ™ group and two cases in Fresenius® group reported headache with low incidence. 6 patients in Provive™ group and 5 patients in Fresenius® group had shivering after awakening that 3 in Provive ™ and 2 in Fresenius® group had high incidence. But both groups didn't have any significant difference (p value=0.17). All patients were satisfied from anaesthesia and none of them heard any voice in operation room.

Table 1. Comparison of demographic characteristics and recovery profile in two groups

	Treatment										
	Fresenius®					Provive ™					
	Count	Mean	Minimum	Maximum	SE	Count	Mean	Minimum	Maximum	SE	p-value
Age (year)	14	30.77	18	51	11.12	12	29	16	50	10.9	0.57
Weight (kg)	14	66.71	48	91	12.3	12	69.75	58	85	10.5	0.59
Height(cm)	14	167.1	150	184	9.4	12	169.33	158	185	9	0.66
BMI	14	23.81	18.06	31.1	3.35	12	24.37	20.1	32	3.6	0.82
Loss of consciousness (s)	14	20.7	10	30	6.15	12	28.33	10	60	12.6	0.07
Recovery time	14	19.3	6	35	8.85	12	17.08	4	33	8.53	0.46

Discussion and Conclusion

The operation time in patient who had vomiting was longer than others (245min) and she received high dose of propofol (1.16g). She had a rhinoplasty surgery and a lot of blood was entered to stomach. Postanesthetic shivering (PAS) occurs frequently postoperatively and may be very distressing for patients (11). It seems to be more common in males and after longer surgeries.4 patients in Provive ™ group and 4 patients in Fresenius® group who had postanaesthesia shivering were male and duration of operation in all of them was longer than 100 minutes.In our study observed adverse effects and incidence of reported adverse effects within 4 hour after operation were low and did not have significant difference between two groups.The adverse effects after anaesthesia and recovery profile with Fresenius® and Provive ™ formulations, the two common commercial propofol formulations in clinic, for anaesthesia in rhinoplasty and FESS operations didn't have any significant difference between two formulations.

Acknowledgements

This paper is issued from thesis of Niloufar Goudarzi and financial support was provided by Ahvaz Jundishapur University of Medical Sciences. We are indebted to all physicians, staff and patients who participated in this study.

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