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Effect of ketofol in reducing cough caused by fentanyl in patients undergoing general anesthesia

Efecto del ketofol en la reducción de la tos causada por el fentanilo en pacientes sometidos a anestesia general

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ABSTRACT

Fentanyl is now widely used for anesthetic and pain relief. Fentanyl with the 80-fold antinociceptive effect of morphine was introduced in the 1960s as an intravenous anesthetic in medicine. The incidence of fentanyl-related cough is reported to be about 80-28% and is an undesirable side effect of anesthesia. Its main application is as an analgesic and sedative pre-anesthetic in the operating room. The aim of this study was to evaluate the effect of ketofol on couched induced fentanyl in patients undergoing general anesthesia. The is a randomized, double-blind clinical trial that has been done on 124 patients candidate for general anesthesia in age range 16-60 years which hospitalized in Fatemi and Imam hospitals in Ardabil city in year 2018. Checklist included demographic and clinical data collected for all patients. The first group received ketamine 2 cc, the second group received propofol 2 cc (10 mg), the third group received ketofol 2 cc(propofol 10 mg + ketamine 10 mg 1: 1), and the fourth group received normal saline 2 cc by orally. Then fentanyl (2 μg / kg) was administered to each of the 4 groups. Coughing, severity and time of onset of it were recorded in time intervals per second in each of the four groups. Finally, all the data entered the statistical analysis program and analyzed by statistical methods in SPSS version 20. In this study, couch rate was 22.6%, 32.3%, 6.5% and 61.3% in ketamine, Propofol, ketofol and control group respectively. The highest cough delay was observed in the recipients of ketofol and propofol, and the highest premature cough was observed in the control group. Also, none of the prescribed drugs did significantly change the blood pressure, heart rate, and MAP in the control group. It was observed that ketofol, ketamine and propofol significantly reduced the cough rate compared with the control group. The results of this study showed that ketofol had the most fentanyl-induced cough suppressant compared to placebo and propofol, and it can be used a good medication for patients.

Keywords: Ketofol, Ketamine, Propofol, Fentanyl-induced cough, General anesthesia, Ardabil.

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RESUMEN

El fentanilo ahora se usa ampliamente para la anestesia y el alivio del dolor. El fentanilo con el efecto antinociceptivo 80 veces mayor de la morfina se introdujo en la década de 1960 como un anestésico intravenoso en medicina. Se informa que la incidencia de tos relacionada con el fentanilo es de aproximadamente 80-28% y es un efecto secundario indeseable de la anestesia. Su aplicación principal es como preanestésico analgésico y sedante en quirófano. El objetivo de este estudio fue evaluar el efecto del ketofol sobre el fentanilo inducido en pacientes sometidos a anestesia general. El es un ensayo clínico aleatorizado, doble ciego que se realizó en 124 pacientes candidatos a anestesia general en un rango de edad de 16 a 60 años que se hospitalizó en los hospitales Fatemi e Imam en la ciudad de Ardabil en el año 2018. La lista de verificación incluyó datos demográficos y clínicos recopilados para todos los pacientes El primer grupo recibió ketamina 2 cc, el segundo grupo recibió propofol 2 cc (10 mg), el tercer grupo recibió ketofol 2 cc (propofol 10 mg + ketamina 10 mg 1: 1), y el cuarto grupo recibió 2 cc de solución salina normal por oralmente. Luego se administró fentanilo (2 μg / kg) a cada uno de los 4 grupos. La tos, la gravedad y el tiempo de aparición se registraron en intervalos de tiempo por segundo en cada uno de los cuatro grupos. Finalmente, todos los datos ingresaron al programa de análisis estadístico y se analizaron por métodos estadísticos en SPSS versión 20. En este estudio, la tasa de cobertura fue de 22.6%, 32.3%, 6.5% y 61.3% en ketamina, Propofol, ketofol y grupo de control respectivamente. El mayor retraso de la tos se observó en los receptores de ketofol y propofol, y la mayor tos prematura se observó en el grupo de control. Además, ninguno de los medicamentos recetados cambió significativamente la presión arterial, la frecuencia cardíaca y la PAM en el grupo de control. Se observó que el ketofol, la ketamina y el propofol redujeron significativamente la tasa de tos en comparación con el grupo control. Los resultados de este estudio mostraron que el ketofol tenía el supresor de la tos más inducido por el fentanilo en comparación con el placebo y el propofol, y puede usarse como un buen medicamento para los pacientes.

Palabras clave: Ketofol, Ketamina, Propofol, Tos inducida por fentanilo, Anestesia general, Ardabil

RESUMO

O fentanil é agora amplamente utilizado para anestesia e alívio da dor. O fentanil com o efeito antinociceptivo de 80 vezes da morfina foi introduzido na década de 1960 como um anestésico intravenoso em medicina. A incidência de tosse relacionada ao fentanil é relatada como sendo cerca de 80-28% e é um efeito colateral indesejável da anestesia. Sua principal aplicação é como um anestésico analgésico e sedativo na sala de cirurgia. O objetivo deste estudo foi avaliar o efeito do cetofol sobre o fentanil induzido em pacientes submetidos à anestesia geral. Trata-se de um ensaio clínico randomizado e duplo-cego que foi realizado em 124 pacientes candidatos a anestesia geral na faixa etária de 16 a 60 anos que hospitalizaram em Fatemi e Imam na cidade de Ardabil no ano de 2018. A lista de verificação incluiu dados demográficos e clínicos coletados para todos os pacientes. O primeiro grupo recebeu cetamina 2 cc, o segundo grupo recebeu propofol 2 cc (10 mg), o terceiro grupo recebeu cetofol 2 cc (propofol 10 mg + cetamina 10 mg 1: 1) e o quarto grupo recebeu solução salina normal 2 cc por oralmente. Em seguida, fentanil (2 mg / kg) foi administrado a cada um dos 4 grupos. Tosse, gravidade e tempo de início foram registrados em intervalos de tempo por segundo em cada um dos quatro grupos. Por fim, todos os dados entraram no programa de análise estatística e analisados por métodos estatísticos no SPSS versão 20. Neste estudo, a taxa de sofá foi de 22,6%, 32,3%, 6,5% e 61,3% em cetamina, propofol, cetofol e grupo controle, respectivamente. O maior atraso na tosse foi observado nos receptores de cetofol e propofol, e a maior tosse prematura foi observada no grupo controle. Além disso, nenhum dos medicamentos prescritos alterou significativamente a pressão arterial, freqüência cardíaca e MAP no grupo controle. Observou-se que o cetofol, cetamina e propofol reduziram significativamente a taxa de tosse em comparação com o grupo controle. Os resultados deste estudo mostraram que o cetofol teve o supressor da tosse mais induzido pelo fentanil comparado ao placebo e ao propofol, e pode ser usado um bom medicamento para os pacientes.

Palavras-chave: Cetofol, Cetamina, Propofol, Tosse induzida por fentanil, Anestesia geral, Ardabil

Introduction

Fentanyl is one of the most common intravenous opioids that is used in the operating room for premedication in patients undergoing general anesthetic or as a sedaytiv drug (1). Fentanyl has high efficacy rate in comparison to other opioids, which leads to relaxation, reduction of anxiety and analgesia and the least cardiovascular depression in patients and the release of histamine is minimal (2). Complications of fentanyl are reflux cough that usually benign, transient and self limiting but in some times is spasmodic and explosive that requires to immediate treatment (3,4). The incidence of fentanyl-related cough is reported to be about 28%-80% and is one of the undesirable side effect especially in patients with diseases such as increased brain pressure (ICP), cerebral aneurysms, trauma and brain hernia , aortic aneurysm dissociation, open eye injury, respiratory system diseases, and pneumothorax (5-7). To reduce the incidence of fentanyl related cough we

used a receptor agonist for β^2, ephedrine, lidocaine , ketamine , clonidine , dexamethasone , dexmedetomidine, N-methyl D-aspartate antagonist, benzodiazepines , propofol and huffing manoeuvre (8-6). Ketamine and propofol have been used as a combination anesthetic for surgery sine 1990 and in compare to fentanyl and alfentanil are safer. The effect of Ketofol , including analgesia , sodasiuom with sustained hemodynamics and preservation of airway reflexes is very popular in short-term painful surgery. Combination of ketamine with propofol causes higher procedural sedation and analgesia (PSA), reduced surgical complications such as nausea , early discharge of patients from the hospital and increased patient satisfaction and treatment staff. The aim of this study was to determine the effect of ketofol on decreasing fentanyl-related cough in patients candidate for general anesthesia.

Materials and methods:

This clinical trial study was performed on 124 patients with aged 18-60 years who admitted in Fatemi and Imam Khomeini hospitals of Ardabil in 2018 and candidate for general anesthesia. All patients signed the consent form and patients with asthma, COPD, heart failure, chemical waste, history of chest surgery, renal and hepatic dysfunction, upper respiratory infection in the last 4 weeks, smoking, steroid use, antihistamines and histamine inhibitors in the last 4 weeks excluded from the study. A checklist containing clinical and demographic information such as type of surgery, blood pressure and median arterial pressure, heart rate, incidence and duration of onset of the cough were completed for all patients. Patients were divided into four groups using simple sampling method and 8 random blocks (AABBCCDD). The first group received ketamine 0.015 mg / kg, the second group propofol 1.05 mg / kg and the third group ketofol 1.05 mg / kg both of which were 1: 1 and the fourth group received normal saline. Fentanyl was administered as 2 µg / kg for each of the four groups and all oral medications were discontinued 8 hours before surgery. Operating room temperature and other influencing factors such as sex and age were identical and then the incidence of coughing severity and start time were recorded at different time intervals. The severity of coughing was recorded at intervals of 0-5-10 seconds in each group and coughing was less than 5 seconds defined as early cough and after 10 seconds before induction as a late cough . Then patients underwent general anesthesia with propofol and loosener . Data were analyzed using descriptive and analytical statistical methods in SPSS version 20. P value less than 5% was considered significant .

Results:

In this study, the average age of patients in the ketamine group was 30.35 ± 10.17, propofol group was 34.54 ± 13.07 the ketoffol group was 35.12 ± 88.9 and the control group was 36.64 ± 15.26(P=0.220). There was no significant difference between sexes and age groups among the studied groups (Table 1). The lowest and highest levels of cough were in the ketoffol and control groups(P=0.001). The type of cough among the groups was statistically significant (P=0.004). The highest levels of severe cough were seen in the control group (22.6%) and the lowest mild cough were seen in ketamine and ketofol groups (6.5%). The highest percentage of early cough (less than 5 seconds) and late cough (after 10 seconds) were seen in the control group (22.7%) which was statistically significant. There were no significant differences in heart rate, systolic and diastolic blood pressure and arterial pressure in patients before and after fentanyl injection, but the difference between systolic blood pressure and arterial pressure at the beginning and the end of the study was statistically significant. The highest reduction of cough was observed in the ketoffol group and the highest increase was seen in the propofol group (Table 2). The results showed that in the study groups, ketofol significantly decreased cough rates compared to propofol (p=0.001) and control groups (P=0.037) but there was no significant difference between ketamine and ketophorol. In comparison propofol and ketamine results showed that the severity of cough in these two groups in compared to the control group was statistically significant. In terms of severity of cough ketofol significantly reduced the severity of severe cough in compared to the control group and propofol (P=0.005).

Table 1: Demographic and clinical characteristics of patients based on study group

Variables n		Ketamine		Propofol		Ketoffol		Control		p-value
		%	n	%	n	%	n	%		
Age	<20	8	25.8	2	6.5	2	6.5	3	9.7	0.312
	30-21	8	25.8	13	41.9	9	29	12	38.7	
	40-31	7	22.6	7	22.6	9	29	3	9.7	
	>40	8	25.8	9	29	11	35.5	13	41.93	
Sex	Male	17	13.7	12	9.7	10	8.1	13	10.5	0.3
	Female	14	11.3	19	15.3	21	16.9	18	14.5	
ASA	Calss1	28	22.6	28	22.6	22	17.7	26	21	0.01
	Class2	3	2.4	3	2.4	9	7.2	5	4.1	
Type of cough	No cough	24	77.4	21	67.7	29	93.5	12	38.5	0.004
	Mild cough	2	6.5	3	9.7	2	6.5	7	22.6	
	Moderate cough	2	6.5	3	9.7	0	0	5	16.1	
	Severe cough	3	9.7	4	12.9	0	0	7	22.6	
Duration of cough	<5s	1	3.2	4	12.9	0	0	7	22.6	0.002
	10-6s	4	12.9	2	6.5	1	3.2	5	16.1	
	>10s	2	6.5	4	12.9	1	3.2	7	22.6	

Table 2: Clinical characteristics of patients in terms of heart rate and blood pressure before and after fentanyl injection by study groups

Clinical characteristics	Group	Time	Mean	SD	p-value
Pulse rate	Ketamine	Before	91.22	19.08	0.728
		After	92.83	17.21	
	Propoffol	Before	89.93	19.81	0.630
		After	87.58	18.41	
	Ketoffol	Before	92.74	18.46	0.519
		After	95.77	18.32	
	Normal saline	Before	93.77	22.98	0.773
		After	92.19	19.93	
Systolic blood pressure	Ketamine	Before	125.87	11.81	0.673
		After	127.32	14.93	
	Propoffol	Before	129.87	15.09	0.415
		After	126.58	16.47	
	Ketoffol	Before	130.77	12.30	0.443
		After	133.48	15.19	
	Normal saline	Before	132.29	16.38	0.618
		After	130.03	19.03	

Diastolic blood pressure	Ketamine	Before	78.51	11.28	0.510
		After	80.29	9.74	
	Propoffol	Before	79.16	7.36	0.222
		After	76.22	11	
	Ketoffol	Before	80.7	12.48	0.502
		After	82.83	12.33	
	Normal saline	Before	80.09	10.55	0.972
		After	80	10.74	

Discussion:

In this study the incidence of cough after fentanyl injection was 22.6% in the ketamine group and 61.3% in the control group . In the study of Yeh et al, the incidence of cough after fentanyl injection was 2.7% in the recipients of ketamine and 21.6% in the placebo group which was lower than that in the present study (9). In the study of Saleh et al, the incidence of cough after receiving fentanyl was 20% in the ketamine and 53% in the placebo group which was lower than the current study (2). In the present study, the most severe incidence of cough was seen in the control group (22.6%) and the lowest mild cough in ketofol and ketamine groups (6.5%) but in the study of Yeh and Saleh and colleagues the severity of mild cough in the ketamine group was 69% and 50% which higher than the current study (2,9). In a study by Tang et al, comparing the incidence of cough in different doses of propofol after fentanyl injection it was observed that the incidence of cough was 40% in the dose of 1 mg / kg propofol, at a dose of 1.5 mg / kg was 6.7% , at a dose of 2 mg/ kg was 3.3% and at 1.5 and 2 mg / kg, all of patients had only mild cough (10). In the present study, the incidence of cough after injection of 2 mg / kg propofol was 32.3% and 12.9% of patients had severe cough and 9.7% had mild to moderate cough. In the study of Sadeghi-nejad et al, the incidence of cough in the receiving group of propofol with fentanyl was 25.6% and, in the placebo, group was 74.4% and the severity of cough in the propofol group was 90% mild and 10% moderate. In the present study, the incidence of cough after injection of propofol was 9.7% for mild and moderate cough and 12.9% for severe cough which was lower than that of Sadeghi Nejad and colleagues study (11).

By comparison of propofol and placebo in reducing the incidence of cough in the study by Firouzan et al, it was observed that the incidence of cough in the propofol group was 9.2% and, in the placebo, group was 40.4% that this amount was 32.3% in the propofol group and 61.3% in the control group (12). The results of this study showed that the incidence of cough in the ketamine and propofol groups was lower than other studies but the severity of coughs was lower which could be due to the injected fentanyl dose, the quality of injected drugs and the genotype of liver enzymes in patients in different populations . Also, the results of other studies similar to those of the present study showed that ketofol is a very good drug for reducing cough in patients receiving fentanyl and can significantly reduce the incidence of cough . In the recent study, the highest incidence of delayed onset of coughing was observed in propofol and control groups and the highest premature cough was observed in the control group . In Saleh et al, the average cough time in the control group was 15.7 seconds in the ketamine group 18.6 and in the ketamine-dexmedetomidine group was 25.8 seconds and as a result, the incidence of cough in the Ketodex group was significantly delayed which not in line with the present study (2). In the present study, none of the prescribed drugs did not significantly change the blood pressure, heart rate and MAP in the control group. In the study of Yeh et al before and after fentanyl injection systolic and diastolic blood pressure as well as heart rate had no significant difference in compare to the control group (9). In the study of Firozan et al, observed that systolic blood pressure , diastolic blood pressure, average arterial pressure and heart rate in propofol and placebo recipients before and after fentanyl were not significantly different and administration of propofol did not result in significant changes in hemodynamics in patients after fentanyl injection (12).

Studies have shown that administration of propofol, ketamine and ketofol does not have a significant effect on hemodynamics in patients and this study was in line with other studies. In this study, it was observed that ketofol reduced the level of cough compared to propofol and control but no significant correlation was found between ketamine and ketofol. In comparison propofol and ketamine also showed that the severity of cough in these two groups was statistically significant compared to the control group. A study by Saleh et al, found that Ketodox was able to reduce the incidence of coughing over doses of dexmedotomidine and ketamine in patients. In the study of Sadeghi-Nejad et al, the efficacy of propofol was demonstrated and found that the drug could significantly reduce the incidence of cough (11,2). In a study by Yousef et al, it was reported that ketofol could significantly decrease the incidence of cough

compared to propofol which was similar to the present study(13). Another study by Sun et al, found that the administration of dezocin reduced the level of cough after fentanyl in the control group from 70% to 0 % in the case group (14). In the study of Guler et al, Ketamine was able to reduce the cough rate after fentanyl injection significantly compared to the control group and lidocaine (15). Finding a low-grade drug and having the least effect on hemodynamics of patients who can reduce fentanyl induced cough has a significant impact on the satisfaction of patients and anesthesiologists with the anesthetic and treatment process . The study also found that ketofol had the most suppression in fentanyl induced cough and regarding the non-significant effect on hemodynamics of patients it can be a good drug for patients .

Conclusion:

Finding a solution to reduce the complications of anesthetic drugs is one of the main goals of the study that is being done in this area . The results of this study showed that ketofol had the highest fentanyl induced cough suppression compared to placebo and propofol but did not have a significant superiority to ketamine and due to the less effect on hemodynamics of patients it can be a good drug for patients. Ketamine and propofol also delayed the onset of coughing which was in line with other studies.

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