



Оценка боли при применении комбинации фентанил-пропофол: два уровня дозировки

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РЕЗЮМЕ

Актуальность. Пропофол широко используется в качестве средства для вводной анестезии. Однако частым побочным эффектом является боль при его инъекции, которая может привести к дискомфорту у пациентов. Были исследованы различные стратегии предотвращения или облегчения этой боли, учитывая наличие опиоидных рецепторов в первичных афферентных нервных окончаниях периферических тканей, что позволяет предположить потенциальную роль опиоидов в смягчении боли, вызванной пропофолом. Было обнаружено, что фентанил, чистый опиоидный агонист короткого действия, обычно используемый для системной анальгезии во время интраоперационного и послеоперационного периодов, обладает периферически опосредованными анальгетическими свойствами в пределах его клинической дозировки. Таким образом, задачей данного исследования было оценить эффективность низкой дозы фентанила в комбинации «фентанил–пропофол» для уменьшения боли при инъекции пропофола.

Цель – оценить и сравнить эффективность двух различных доз фентанила в облегчении боли, связанной с инъекцией пропофола.

Материалы и методы. В исследовании приняли участие 90 пациентов, имеющих риск по шкале ASA I–II, которым была назначена плановая операция. Исследование длилось более 4 месяцев с ноября 2022 г. по апрель 2023 г. и включало пациентов в возрасте от 19 до 65 лет. Пациенты были разделены на 3 группы, каждая из которых состояла из 30 пациентов. Контрольная группа получала только 5 мл (50 мг) пропофола. 1 группа получала только 5 мл смеси фентанила и пропофола, приготовленной из 20 мл (200 мг) пропофола и 2 мл (100 мкг) фентанила, в то время как 2 группа получала только 5 мл смеси фентанила и пропофола, приготовленной из 20 мл (200 мг) пропофола и 4 мл (200 мкг) фентанила со скоростью инъекции 0,5 мл/с. После 10 секунд введения препарата пациентам задавали стандартный вопрос о комфортности инъекции и словесную оценочную шкалу (VRS).

Результаты. Было установлено, что статистически значимых различий между пациентами этих групп не было, т. е. группы были однородны. В контрольной группе частота возникновения сильной боли при инъекции пропофола составила 46,7%, тогда как в 1 и 2 группах она составила 0% ($p < 0,05$).

Вывод. Было показано, что комбинация фентанила и пропофола эффективно снижает частоту возникновения боли при инъекции пропофола. Интересно, что в этом исследовании не наблюдалось существенной разницы между 2 различными дозами фентанила, использованными в смеси. Это говорит о том, что низкой дозы фентанила может быть достаточно для купирования боли во время введения пропофола, тем самым предлагая экономически эффективный подход в клинической практике.

Ключевые слова: боль, пропофол, оценка, общая анестезия, фентанил

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Pain assessment in fentanyl-propofol combination: two dosage levels

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ABSTRACT

Background. In the field of intravenous anesthesia, propofol is widely utilized as an induction agent. However, Propofol injection pain is a frequent adverse event that may result in discomfort for patients. Various strategies have been investigated to prevent or alleviate this pain, considering the presence of opioid receptors in the primary afferent nerve endings of peripheral tissues, which suggests a potential role of opioids in mitigating propofol-induced pain. Fentanyl, a short-acting pure opioid agonist commonly used for systemic analgesia during intraoperative and postoperative periods, has been found to possess peripherally mediated analgesic properties within its clinical dosage range. Therefore, the objective of this study was to evaluate the efficacy of a low dose of fentanyl in the fentanyl-propofol combination for reducing propofol injection pain.

The objective of our study was to evaluate and compare the efficacy of two distinct doses of fentanyl in mitigating the pain associated with propofol injection.

Materials and methods. The study enrolled 90 patients classified as ASA I–II who were scheduled for elective surgery. The study spanned over 4 months, from November 2022 to April 2023, and included patients aged 19 to 65 years. Patients were divided into three groups, each comprising 30 patients. The control group received only 5 ml (50 mg) of propofol. The group M1 received only 5 ml of a mixture of fentanyl and propofol, prepared with 20 ml (200 mg) of propofol and 2 ml (100 µg) of fentanyl, while the group M2 received only 5 ml of a mixture of fentanyl and propofol, prepared with 20 ml (200 mg) of propofol and 4 ml (200 µg) of fentanyl, at an injection speed of 0.5 ml/s. After 10 seconds of medication, patients were asked a standard question about the comfort of the injection, and a verbal rating scale (VRS) was used to assess propofol injection pain. Anesthesia induction was then continued following standard protocols. Statistical significance was set at $p < 0.05$ for all analyses.

Results. The three groups were found to be similar in terms of patient characteristics. In the control group, the incidence of severe pain upon propofol injection was 46.7%, whereas it was 0% in both groups M1 and M2 ($p < 0.05$).

Conclusion. The combination of fentanyl and propofol has been shown to effectively reduce the incidence of propofol injection pain. Interestingly, in this study, no significant difference was observed between the two different doses of fentanyl used in the mixture. This suggests that a low dose of fentanyl may be sufficient in achieving a pain-free environment during propofol induction, thereby offering a cost-effective approach in clinical practice.

Key words: pain, propofol, assessment, general anesthesia, fentanyl

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Introduction

Propofol, an intravenous anesthetic, is commonly used in Monitored Anesthesia Care (MAC) procedures, general anesthesia induction, or procedural sedation [15, 19]. However, propofol injection pain, also known as Pain on Propofol Injection (POPI), is a significant concern, with reported incidence rates ranging from 28% to 90% [10]. This is in contrast to other intravenous anesthetics such as thiopentone, which has a much lower incidence of discomfort following induction at around 7% [17]. Despite being an optimal intravenous anesthetic, propofol-induced discomfort during injection remains an ongoing issue, and patient satisfaction with perioperative care has become increasingly important [12, 20].

Various techniques have been explored to minimize propofol injection pain, counting adding lidocaine, adjusting temperature, diluting the propofol solution, injecting into a larger vein, or using pre-injection medications such as ephedrine, ondansetron, metoclopramide, opioids, thiopental, or ketamine [7, 13, 16]. However, each approach has its limitations and outcomes. Despite numerous formulations and clinical studies, no single treatment has been universally successful in managing all patients [13, 16].

Fentanyl, a short-acting pure opioid agonist with rapid onset of action, is commonly used for systemic analgesia before and after surgery, and it exhibits peripherally mediated analgesic activity within the therapeutic dose range [3, 11, 12]. The objective of our research is to compare the effectiveness of different doses of fentanyl in reducing propofol injection pain during anesthesia induction. By evaluating the impact of fentanyl in combination with propofol, this study aims to contribute to the understanding of optimal pain management strategies during anesthesia induction, potentially improving patient comfort and satisfaction in the perioperative period.

Materials and methods

The study was conducted at Al-Sader Teaching Hospital in Najaf, Iraq, between November 2022 and April 2023, after obtaining ethical approval from the Al-Najaf health director's ethical committee. A total of 90 patients with American Society of Anesthesia (ASA) I or II physical status, who provided oral consent, were included in the study. These patients aged 19 to 65 years were scheduled for various surgeries under general anesthesia.

Inclusion criteria required patients to have ASA I–II physical status, no previous use of opioids or antipsychotics, and be scheduled for elective surgeries

under anesthesia. Exclusion criteria included patients with ASA III or IV physical status, communication difficulties, patient rejection, children (due to difficulties in pain expression), psychiatric and neurological disorders, history of allergy or contraindication to study drugs, and use of analgesics or sedative drugs within 24 hours before surgery.

The study followed a prospective, randomized single-blind design. Patients were randomly assigned to one of three groups using an Excel-generated randomization table. Before anesthesia induction, patients were informed that they would receive intravenous anesthetics in their forearms, which might cause pain. A 20-gauge cannula was inserted into a vein on the dorsum of the patient's non-dominant hand. A preload of 10 ml/kg of isotonic saline solution was administered before induction of anesthesia. All study drugs were prepared preoperatively at room temperature.

Patients in the control group (group C) received only 5 ml of propofol. Patients in the group M1 received only 5 ml of a mixture of fentanyl and propofol, which was prepared using 20 ml (200 mg) of propofol and 2 ml (100 µg) of fentanyl. Patients in the group M2 received only 5 ml of a mixture of fentanyl and propofol, which was prepared using 20 ml (200 mg) of propofol and 4 ml (200 µg) of fentanyl, at an injection speed of 0.5 ml/s. Ten seconds after the medication was administered, patients were asked a standard question regarding the comfort of the injection. The severity of pain due to the propofol injection was evaluated using a verbal rating scale (VRS), which ranged from 0 (no pain) to III (severe pain with a strong vocal response or facial grimacing, arm withdrawal, or tears).

All patients were able to respond to the question about injection comfort, and thereafter anesthesia induction was continued. Demographic data and statistical analysis were recorded on a specifically designed questionnaire, collected, entered into the computer, and analyzed using IBM SPSS (Statistical Package for Social Sciences) version 26. All data were normally distributed within three groups (control, M1, and M2) using Shapiro-Wilk Test, and *p*-values were greater than 0.05. Results were compared among patients with different variables using ANOVA and Chi-square tests, with a statistical significance level of < 0.05. The findings were presented in tables and figures as rates, ratios, frequencies, and percentages.

Results

Ninety patients were enrolled in the study, with 28 (31%) males and 62 (69%) females. The mean±standard deviation (SD) of age and weight of patients were 35±11 and 71±11, respectively. There were no

Table 1. Association between study groups and pain score

Study group	Pain score				Total
	Pain-free	Slight pain	Moderate discomfort	Intense pain	
Control	13.3%	13.3%	26.7%	46.7%	100%
	4	4	8	14	30
M1	40.0%	40%	20%	0%	100%
	12	12	6	0	30
M2	46.7%	33.3%	20%	0%	100%
	14	10	6	0	30
Total	33.3%	28.9%	22.2%	15.6%	100%
	30	26	20	14	90

Table 2. No pain as compared in three study groups

Pain score	Groups	N (%)	P-value
No pain	Control	4/30 (13.3%)	0.026
	M1	12/30 (40%)	
No pain	Control	4/30 (13.3%)	0.006
	M2	14/30 (46.7%)	
No pain	M1	12/30 (40%)	0.573
	M2	14/30 (46.7%)	

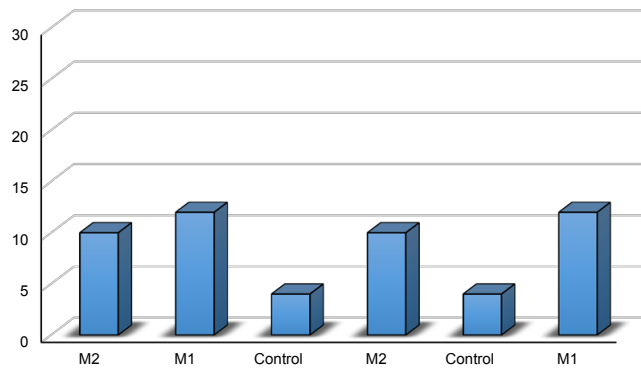


Fig. 1. Incidence of no pain as compared in three study groups

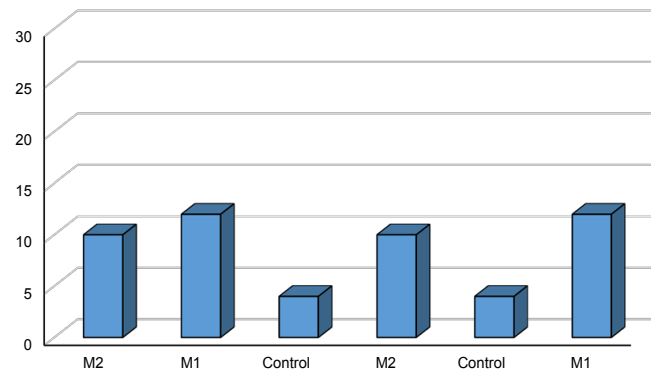


Fig. 2. Incidence of mild pain as compared in three study groups

Table 3. Incidence of mild pain as compared in three study groups

Pain score	Groups	N (%)	P-value
Mild pain	Control	4/30 (13.3%)	0.023
	M1	12/30 (40%)	
Mild pain	Control	4/30 (13.3%)	0.08
	M2	10/30 (33.3%)	
Mild pain	M1	12/30 (40%)	0.564
	M2	10/30 (33.3%)	

statistically significant associations between different study groups with both the age and weight of patients (p -values > 0.05).

The overall incidence of no pain was 13.3% (4/30) in the control group, while it was 40% (12/30) in the group M1 and 46.7% (14/30) in the group M2. The overall incidence of severe pain was 46.7% (14/30) in the control group, while none of patients in both groups M1 and M2 experienced severe pain (table 3).

Pain-free. In the control group, 13.3% (4/30) of patients reported no pain during propofol injection. In contrast, in the group M1, 40% (12/30) of patients, and in the group M2, 46.7% (14/30) of patients reported no pain. The incidence of no pain was significantly higher

in both groups M1 and M2 compared to the control group (p -value < 0.05), indicating that the addition of fentanyl to propofol may reduce pain during injection. Furthermore, there was no significant difference in the incidence of no pain among groups M1 and M2 (p -value: 0.573), suggesting that the two different doses of fentanyl used in the mixture did not result in differential pain reduction. These findings suggest that the use of the fentanyl-propofol combination may effectively reduce the incidence of pain during propofol injection, regardless of the dosage of fentanyl used.

Incidence of mild pain. In the control group, a total of 13.3% of patients (4 out of 30) reported experiencing mild pain during propofol injections. In contrast, in the group

Table 4. Incidence of moderate pain as compared in three study groups

Pain score	Groups	N (%)	P-value
Moderate pain	Control M1	8/30 (26.7%) 6/30 (20%)	0.542
Moderate pain	Control M2	8/30 (26.7%) 6/30 (20%)	0.542
Moderate pain	M1 M2	6/30 (20%) 6/30 (20%)	1

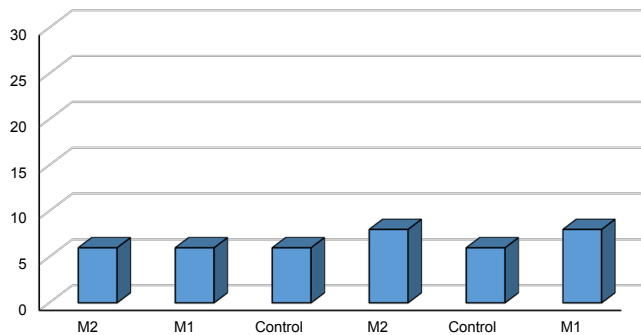


Fig. 3. Incidence of moderate pain as compared in three study groups

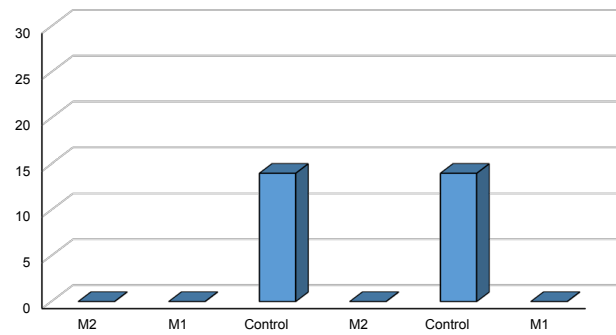


Fig. 4. Incidence of severe pain as compared in three study groups

Table 5. Incidence of severe pain as compared in three study groups

Pain score	Groups	N (%)	P-value
Severe pain	Control M1	14/30 (46.7%) 0/30 (0%)	0.0
Severe pain	Control M2	14/30 (46.7%) 0/30 (0%)	0.0
Severe pain	M1 M2	0/30 (0%) 0/30 (0%)	1

M1, 40% of patients (12 out of 30), and in the group M2, 33.3% (10 out of 30) reported experiencing mild pain. The incidence of mild pain was found to be significantly higher in both groups M1 and M2 compared to the control group (p -value < 0.05). However, no significant difference was observed between groups M1 and M2 in terms of mild pain (p -value: 0.564) (p -value: 0.573), indicating that the two fentanyl dosage groups did not differ significantly in reports of mild pain incidence.

Incidence of moderate pain. The incidence of moderate pain was comparable between groups M1 and M2, with both groups exhibiting a 20% of incidence (6 out of 30 patients). Notably, this incidence was lower than that observed in the group C, where the incidence of moderate pain was 26.7% (9 out of 30 patients), but the difference did not reach statistical significance (p -value: 0.564).

Incidence of severe pain. In the control group, 46.7% of patients (14/30) experienced severe pain, whereas no patients did in groups M1 and M2 (statistically significant (p -value: 0.0).

Discussion

Due to its unique pharmacological characteristics, notably its rapid onset and short duration, propofol is now one of the most widely utilized anesthetic drugs for sedation, induction, and maintenance of anesthesia [15]. The most frequent adverse effect of injections is

discomfort. To lessen the discomfort during the injection of propofol, several trials have been conducted. In this study, we examined the effectiveness of a modest dosage of fentanyl to lessen the discomfort caused by propofol. In our study, the overall incidence of no pain during injection of propofol in the control group was 13.3% compared with 40% in the group M1, 46.7% in the group M2. It was found that there was a significant difference in the incidence of no pain in the control group in comparison to both groups who received propofol-fentanyl mixture (p < 0.05).

No patient (0%) in either group receiving the fentanyl-propofol combination experienced severe pain, whereas 14 patients (46.7%) in the control group experienced (p -value: 0.000). This study found that the fentanyl-propofol combination reduced pain severity when compared to the control group, and there was no difference between the two fentanyl doses.

Our results show a significant decrease in propofol injection pain in both groups who received the mixture compared to the control group and there was no difference between the doses of fentanyl in reducing propofol injection pain, proving that a low dose of fentanyl is preferable to avoid side effects and increase the cost.

N. Kizilcik et al. (2015) reported that fentanyl mixed with propofol reduced injection pain significantly compared with the control and fentanyl pretreatment groups that goes with our study and in addition, our study shows

no difference between two doses of fentanyl when mixed with propofol [8]. M. Eriksson et al. (1997) [5] reported that decreasing the pH of propofol resulted in a lower concentration of propofol in the aqueous phase, which goes with our study. J. H. Helmer et al. (1990) [6] reported a significant decrease in the incidence of propofol injection pain, from 40 to 16%. In our study, the incidence of severe pain was 46.7% in the control group and 0% in both groups who received 2 ml and 4 ml of fentanyl in the fentanyl-propofol combination. J. T. Stewart et al. (2000) show that propofol and fentanyl were compatible when mixed, which goes with our study that showed that no precipitation was seen in the syringe [18].

In conclusion, fentanyl mixed with propofol reduced propofol injection pain significantly compared with the control groups and there was no difference between fentanyl doses.

There are other methods of decreasing the pain of propofol injection: ondansetron pretreatment to alleviate pain on propofol injection [1]; ephedrine reduces the pain from propofol injection [4]; small-dose ketamine reduces the pain of propofol injection [9]; effect of prior administration of cold saline on pain during propofol injection [2].

Conclusions

Our research demonstrated that there was no change in fentanyl dosages and that the incidence of pain after

propofol injection was decreased by the fentanyl-propofol combination. Nobody in the two groups who got the fentanyl-propofol combination had significant pain.

Recommendations

We advise that patients getting the fentanyl-propofol combination receive low-dose fentanyl instead of higher dose since it is more cost-effective and pleasant for the patient. More research is needed to determine the effects of low-dose fentanyl in the fentanyl-propofol combination.

Limitation. The limitations of the present study were that the ASA physical status is limited to classes I and II and we didn't examine how gender or age affected outcomes. Patients under the age of 18 were not included in this research, because they are frequently having poor coordination during clinical procedures [14].

Ethics approval and consent to participate. The ethical code for this study (227 on 25/10/2022) was provided by Al-Najaf health director for doing the research in the operation room of elective surgery on the first and second floors in Al-Sader Teaching Hospital, Najaf, Iraq.

Availability of data and material. The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Conflict of Interests. The authors state that they have no conflict of interests.

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