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A Study on Pain and Hemodynamic Parameters in Minor Gynecological Procedures: Propofol – Fentanyl Vs. Ketamine – Midazolam

Dena Sameer Najeeb (MBChB)[1], Bnar Halko Ahmed (FICMS, FIPP)[2]

[1] Raparin Children Hospital , Erbil, Iraq
[2] Rizgary Teaching Hospital, Erbil, Iraq

Abstract

Background: One of the minor obstitrical procedures is dilation and curettage; pain usually occurs during it. Consequently, an anesthetic drug desires sufficient analgesia, brisk onset, and recovery.

Objective: To evaluate two groups of drug combinations {midazolam 0.08mg/kg – ketamine (0.5mg/kg)} and propofol with (1mg/kg) –fentanyl dose (1mcg /kg)}, in hemodynamic parameters, pain scoring and recovery characteristics thus finding the optimal combination which can be applied all along the operation.

Patients and Methods: It was taken100 patients weregoing through dilatation & curettage of approximately 15-30 min. Duration was enrolled after ethical committee approval in Erbil in 2022, and it was divided into two groups of 50 each. Baseline anesthesia was maintained, and the patients were haphazardly selected to get propofol 1mg/kg with 1 mcg/kg fentanyl (First group), midazolam 0.08mg/kg with 0.5 mg/kg ketamine (Second group) as a bolus to induce anesthesia and for maintenance. Then. pain scores, Aldrete scores, and hemodynamic signs were assessed during and after the procedure. Finally, the results were arranged and inspected statistically with the Student's unpaired t-test and chi-square test.

Results: BP (systolic, diastolic) and PR were significantly higher in Group 2 compared with Group 1. No significant difference was found in the two groups regarding the parameters: the sedative level at 3-5 minutes ($p = 0.499$) and the duration of the operation ($p = 0.105$).

Conclusion: group (propofol -fentanyl) was superior to group (midazolam–ketamine) and may be a good option in uterine dilation, and curettage (propofol –fentanyl) provides sufficient analgesia for the minor surgical intervention with accurate recovery characteristics like awakening time and response to verbal commands.

Keywords: Fentanyl, Propofol, Ketamine, Midazolam, Uterine Dilation & Curettage , Aldrete scores

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Correspondence Address: Dena Sameer Najeeb
Raparin Children Hospital ,Erbil, Iraq
Email: dena.sameer63@yahoo.com

Website: https://djm.uodiyala.edu.iq/index.php/djm

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Introduction

Dilation and curettage is a general and short-lasting procedure in obstetrics and gynecology [1]. "Dilation" indicates the opening of the cervix."Curettage" means the aspiration or evacuation of tissue within the uterus by an instrument named a curette. This procedure is performed as a treatment for miscarriage, retained placenta after vaginal delivery (postpartum), and molar pregnancy. During treatment, there may be a pain. Hence, the drugs were introduced to administer brisk, tolerable necessary anesthetic depth with a brief recovery duration [2].

Both propofol -fentanyl and ketamine/midazolam combinations are probably the principal technique of induction of anesthesia for D &C at present, which provides reliable and effective hypnosis and analgesia [3].

Propofol(2, 6 diisopropyl phenol) and its properties is a potent intravenous hypnotic drug with a short duration of action (t half‰ distribution 2± 4 min) and consequently a more rapid recovery time for the patient (10±20 min drug that is used for induction and maintenance of sedation and general anesthesia. It exerts its effects by potentiating the inhibitory neurotransmitter c-amino butyric acid (GABA) at the GABA receptor. The main reactions of propofol administration relate to alterations in cardiopulmonary physiology and loss of airway reflexes—the low occurrence of postoperative nausea and vomiting (PONV). In addition, there is some experience of pain on injection, and Propofol should only be administered by practitioners trained and experienced in providing general anesthesia. [4]. Propofol is mainly utilized for sedation and anesthesia for most types of surgery and is suitable for daytime anesthesia, but it requires a strong analgesic effect; hence, best joined with an analgesic such as Fentanyl. This has been reported to be a fairly secure combination, despite some considerations indicate that opioids provokes the respiratory depressant effects of Propofol.

Fentanyl and its properties are potent synthetic agents and lipophilic molecules. It affects through two distinctive synergistic components. The first is a powerless opioid agonistic impact by affecting mü –opioid receptors, and the second is reuptake blockade of noradrenaline & serotonin also binds to kappa- and delta-type receptors. Fentanyl has a large volume of distribution and high total body clearance, a dose of 1–2-µg/kg i.v. It expends a peak effect of 5 minutes and adds adequate painkillers for approximately 30 minutes. The reactions of Fentanyl are dose-related by briskly overpassing the blood-brain barrier, such as respiratory abjection. Its expressed through a reduction in the responsiveness of the respiratory center to CO_2 (mainly through prolongation of expiratory time), leading to a reduction in respiratory rate and tidal volume. Also, Fentanyl causes dose-related respiratory depression. It also provides cardiovascular stability.

Midazolam (Dormicum) and its proprieties is propriety a new water soluble benzodiazepine. The drug possesses properties similar to those of other benzodiazepines (sedative, anxiolytic, anticonvulsant, muscle-relaxant) and is of low toxicity; it is chosen because it has

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potent amnestic properties, some anxiolytic effect, and a short elimination half-life, However, sometimes could not provide adequate patient comfort during more sophisticated interventional procedures. Recent data suggest synergism between ketamine such that a dose reduction of ketamine can be achieved. Midazolam. and Benzodiazepines have been found to be the most acceptable adjuvants in decreasing the emergence problem.

Ketamine (Ketalar, CI-581) and its properties: an (NMDA) receptor disability drug and a disintegrative anesthetic with neurostimulator reactions. It could be utilized as a particular anesthetic in short procedures, as an induction agent, or as an additive to other small potency anesthetic drugs; it keeps an extensive margin of assurance, preservation of pharyngeal and laryngeal reflexes with least dejection of respiration, and benign incitement of the cardiovascular system such as elevated blood pressure and increased heart rates, however, be a deprivation in a patient with hypertension disease or any cardiac decompensation. Other detriments are the absence of muscle loosening and an almost grateful incidence of postoperative psychological reactions. And it became apparent that there was an unacceptably high incidence of delirium and unpleasant dreams during the recovery period. This can be distressing for both patients and attendants[5].

This study evaluated two groups of TIVA using Propofol–Fentanyl with midazolam-ketamine by studying introduction and maintenance, and recovery characteristics following anesthesia with these groups. It compares hemodynamics and respiratory effects (as a primary outcome), pain scores during a procedure, and recovery period (as a secondary outcome) following the process of both propofol- fentanyl and ketamine/midazolam. It was chosen group 1 and group 2 because it would investigate the effects of the agents on participators being sedated.

Patients and Methods

Study protocol

The prospective study was carried out at Hawler Maternity and Children's Teaching Hospital. The sample size is about one hundred patients programmed for a D&C procedure and divided into two groups. Each group includes fifty patients joined in this randomized study.

The patients who are fulfilled with the indicative and therapeutic convention of dilatation and curettage as they are diagnosed by applicable laboratory checking and imaging exploration and based on clinical affections have surgical consecrations and a grade I or II of the American Society of Anesthesiologists (ASA) are comprised.

Patients who do not give consent, aged under 18 years, those with a history of serious organs diseases such as hepatic, renal and cardiovascular, neurological disease and with uncontrolled fluctuating blood pressure, malignant tumors or blood diseases, disease-related with the musculoskeletal system, those using calcium-channel blockers, anticoagulants, antidepressants and anti-psychotics, those with alcohol or drug addiction, and past allergic reactions to any of the study drugs, or took anticoagulation a week preoperation have been excluded.

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Study design

The detailed information of patients has been documented from patient files and anesthesia follow-up forms. The patients were prepared to fast at best 8-6 hours, and sedative premedication was not given before the surgery. Perioperative standard heart rate (HR), monitored non-invasive blood pressure (BP) at 5-minute intervals, and pulse oximetry for oxygen saturation was tested for all patients. An IV. a cannula was added, and a 10mL/kg/h 0.9% standard saline infusion started. Patients will impulsively breathe, with a supporting 4 L/min of oxygen inclined by a face mask throughout the procedure. Two groups were established, and there were 50 patients per group; the patients in group one induce with 1mg/kg Propofol IV . and 1 -µcg /kg fentanyl, and Group 2 patients were induced with 0.08 mg/kg midazolam IV bolus with a dose of ketamine 0.5 mg /kg. During the process, the speculum is established in the vagina; the tissue lining the uterus is removed using a curette and sent to a laboratory for histopathological evaluation.

Observational indexes

The patients' discomfort has been determined according to body movements. Another dose of propofol, 0.5 mg/ kg for the first group and midazolam 0.01mg/kg for the second group, were given when the patient expressed ache during the procedure. Also, if the analgesic effect is insufficient, additional analgesia is introduced, and the patients' ages and weights are noted. These bp diastolic and systolic blood pressure pr spo2 are documented by an anesthetist before, drug application baseline at the end of the introduction of anesthesia 5 minutes and 10 minutes after that. In addition, the Ramsey sedation scale is a commonly used scale for determining when surgical patients can be safely processed for the operation,(level 1, awake group, distressed or fearful, or both, level 2, coordinated, calm,logical and tranquil, level 3 responding to commands only, level 4 appears a sleep with a speedy response to a stimulant, level 5 inactive determined response to a loud audible stimulus or rigid glabellar tap, level 6 no response to painful stimulation) and the digital rating pain scale(0 no pain ,4-6 moderate pain,10 worst pain) these scales were recorded at the procedures beginning 5th min and end also the Aldrete recovery score a famous post-anesthesia recovery score was assessed 5 and 10 min after the completion of the course besides that any drug reaction was documented such as nausea or vomiting and the period of the surgical operation.

Statistical Analysis

The input were processed applying the arithmetical Package for Social Sciences (SPSS, version 25), and the measurement data were expressed as mean ± standard deviation (SD) or n, where appropriate. Chi-square test was expressed to measure proportions. Fisher's test was applied when the expected frequency was fewer than 5 of more than 20% of the table's cells. The Student's t-test of two independent samples (unpaired t-test) was used and employed to analyze parametric continuous variables to compare means of two pieces. The counting data were expressed by the X2 test. A P-amount of fewer than 0.05 is recognized statistically significant.

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Results

A hundred patients participated in the study; 50 took propofol and fentanyl (PF group), and 50 took midazolam and ketamine (MK group). The most significant proportion (52%) of the sample were aged 30-39 years, but there was no significant difference in the age distributions of the two groups (p = 0.665). None of the patients had a past medical history, while 53% had past surgical history. No significant difference was found between the combinations of drugs (p = 0.548). None of the patients had a past drug history Table (1).

Table (1): Basic characteristics of the study groups

	Propofol and fentanyl	Midazolam and ketamine	Total	
	No. (%)	No. (%)	No. (%)	P*
Age (years)				
< 30	15 (30.0)	14 (28.0)	29 (29.0)	
30-39	24 (48.0)	28 (56.0)	52 (52.0)	
≥ 40	11 (22.0)	8 (16.0)	19 (19.0)	0.665
Mean (SD)	33.2 (5.9)	32.5 (6.5)	32.9 (6.2)	
Past medical history				
No	50 (100.0)	50 (100.0)	100 (100.0)	NA
Past surgical history				
Yes	25 (50.0)	28 (56.0)	53 (53.0)	
No	25 (50.0)	22 (44.0)	47 (47.0)	0.548
Past drug history				
No	50 (100.0)	50 (100.0)	100 (100.0)	NA
Total	50 (100.0)	50 (100.0)	100 (100.0)	

*By Chi square test. NA: Not applicable

In the pre-operative time, no significant differences were detected between the two study groups regarding the following means: SpO2 (p = 0.322), DBP (p = 0.412), and PR (p = 0.844). The mean of the SBP of the MK group (131.16 mmHg) was significantly (p = 0.029) higher than the mean of the PF group (127.6 mmHg).

During the operation, the SpO_2 of both groups, at 5 and 10 minutes, was higher than 99 (but the differences were significant between the two groups). Regarding the SBP at 5 minutes, it was significantly (p < 0.001) higher in the MK group (124.4 mmHg) than in the PF group (116.5 mmHg). It was also significantly (p = 0.012) higher at the 10th minute in the MK group than in the PF group (125.4 mmHg vs. 122.28 mmHg, respectively). No significant differences were detected between the groups in the DBP at 5 minutes (p = 0.057) and at 10 minutes (p = 0.529). The mean PR at 5 minutes was 78.5 beat/minute in the MK group compared with 76.8 beat/minute in the PF group (p = 0.322), but at 10 minutes, the mean PR was significantly (p = 0.003) higher in the MK group than the PF group (82.3 vs. 77.2 respectively). In the postoperative period, the mean SpO2 of the PF group was 100 compared with 99.44 in the MK group (p < 0.001). The mean SBP of the MK group (125.8 mmHg) was significantly (p = 0.013) higher than the mean of the PF group (122.3 mmHg). No significant differences were detected between the two groups regarding the means of DBP and PR Table (2).

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Table (2): Means of the parameters of the two study groups before, during, and after the operation

	Propofol and fentanyl		Midazolam and ketamine		
	Mean	(SD)	Mean	(SD)	
Pre-operative					
SpO_2	99.98	(0.14)	100.00	(0.00)	0.322
SBP	127.66	(8.83)	131.16	(6.86)	0.029
DBP	78.36	(9.14)	79.84	(8.83)	0.412
PR	85.80	(9.52)	85.42	(9.80)	0.844
Intra operative					
SpO_2 5 min	99.48	(0.79)	99.04	(0.40)	0.001
SpO_2 10 min.	99.34	(0.56)	99.80	(0.57)	< 0.001
SBP 5 min.	116.50	(9.67)	124.40	(7.02)	< 0.001
SBP 10 min.	122.28	(4.94)	125.40	(7.06)	0.012
DBP 5 min.	76.22	(7.75)	72.98	(9.00)	0.057
DBP 10 min	76.66	(11.04)	78.06	(11.13)	0.529
PR 5 min.	76.86	(7.55)	78.52	(9.06)	0.322
PR 10 min.	77.22	(7.64)	82.34	(9.20)	0.003
Post-operative					
SpO_2	100.00	(0.00)	99.44	(0.50)	< 0.001
SBP	122.30	(4.03)	125.84	(8.89)	0.013
DBP	79.28	(10.30)	79.66	(17.33)	0.894
PR	84.78	(9.17)	82.42	(7.69)	0.166

SBP: systolic blood pressure. DBP: diastolic blood pressure. PR: pulse rate

It is evident in Table (3) that the majority of the PF group (84%) had no response, compared with 6% in the MK group ($p < 0.001$). Around half (44%) of patients of the MK group had moderate pain in 5 minutes, while none of the patients of the PF group had pain ($p < 0.001$). One-fifth (20%) of the MK group had moderate pain in 10 minutes, compared with 2% in the PF group ($p = 0.004$). Almost all (96%) of the patients in the PF group were ready for discharge, compared with 0% of patients in the MK group ($p < 0.001$). No significant differences were detected between the two groups regarding the parameters: the sedative level at 3-5 minutes ($p = 0.499$) and the duration of the operation ($p = 0.105$).

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Table (3): Outcomes of the two study groups

	Propofol and fentanyl	Midazolam and ketamine	Total	
	No. (%)	No. (%)	No. (%)	P
Sedative level				
Cooperative	4 (8.0)	10 (20.0)	14 (14.0)	
Agitated	0 (0.0)	1 (2.0)	1 (1.0)	
Drowsy, respond to verbal stimuli	1 (2.0)	8 (16.0)	9 (9.0)	
Quick response to tapping	3 (6.0)	3 (6.0)	6 (6.0)	
Sluggish response	0 (0.0)	25 (50.0)	25 (25.0)	
No response	42 (84.0)	3 (6.0)	45 (45.0)	< 0.001*
Sedative level at 3-5 min.				
Sluggish response	2 (4.0)	0 (0.0)	2 (2.2)	
No response	48 (96.0)	41 (100.0)	89 (97.8)	0.499*
Pain score at 5 min.				
No pain	50 (100.0)	28 (56.0)	78 (78.0)	
Moderate pain	0 (0.0)	22 (44.0)	22 (100.0)	< 0.001†
Pain score at 10 min.				
No pain	49 (98.0)	40 (80.0)	89 (89.0)	
Moderate pain	1 (2.0)	10 (20.0)	11 (11.0)	0.004†
Duration of operation				
Diagnostic D & C 10-15 min.	25 (50.0)	17 (34.0)	42 (42.0)	
Therapeutic D & C 15-30.	25 (50.0)	33 (66.0)	58 (58.0)	0.105†
Aldrete score 5				
6-8 Needs further follow-up	2 (4.0)	50 (100.0)	52 (52.0)	
9-10 Ready for discharge	48 (96.0)	0 (0.0)	48 (48.0)	< 0.001†
Total	50 (100.0)	50 (100.0)	100 (100.0)	

*By Fisher's exact test. †By Chi square test

Discussion

The patients who will undergo D & C do not have aches and do not remember following an operation, which is a convenient condition. Formerly, a double-blinded analysis was examined to analyze the adequacy of ketamine and tramadol in preventing discomfort in patients undergoing termination of pregnancy in daycare surgery [5]. We have experienced the effects of agents (propofol-fentanyl) and (midazolam - ketamine) on hemodynamic parameters, pain, and recovery scores. We used Propofol, the most famous intravenous hypnotic agent, for the first group. It is significant, specially in painful, shortened interferences such as dilatation and curettage [4]. All the same, Propofol is marked as the most suitable anesthetic agent for TIVA due to its ideal sedation, short duration of action, minimal side effects, and rapid recovery profile. It requires additional analgesics, as Propofol has no analgesic properties, so narcotic agents such as Fentanyl, alfentanil, and remifentanil should be used. In a multicenter study, using TIVA with Propofol and Fentanyl proved safe, tolerable, and practical, with a considerable degree of acceptance by the patients. It was found that postoperative pain was reduced with the TIVA technique, and there were also reduced analgesic requirements [6].

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Ideally, choosing an analgesic drug is not to affect respiration in brief-durable procedures, to have a rapid onset of action and shorter emergency characteristics, and to be more hemodynamically stable, choosing Fentanyl as a centrally acting synthetic agent. Fentanyl is less able to suppress respiratory mechanisms. In the second group, we used midazolam, which has sedative and amnesic effects but also needs analgesic agents such as ketamine, which provides dissociation of the thalamus from the limbic. Ketamine is a unique drug due to its dose-dependent nature of producing pain-free, blackout, loss of consciousness, and akinesia. It does not have acute side effects on respiration and the cardiac system. In the group(propofol –fentanyl), the hemodynamics was more balanced and no hypoventilation to be found, while in group 2 (midazolam-ketamine), the heartbeat rate following the procedure slightly increased, to support this situation. Systolic blood pressure at the time of induction of group midazolam ketamine was substantially higher. In addition for patients who use propofol-fentanyl, sedation is superficial. These have shown that group 1 builds a positive latitude during brisk surgical procedures, but its side effects include nausea or vomiting. We haven't encountered any side effects. This study demonstrates that 1mcg/kg of fentanyl or ketamine 0.5 mg/kg is effective intravenous analgesia for pain management in patients managing from dilatation or a curettage procedure, but despite the excellent sedation and analgesia, less respiratory depression and side effects during the use of group ketamine with midazolam, but we outfaced some delay in onset of action, also in the recovery profile in our study appeared the patients of group 2 had long-lasting recovery period as compared to patients of group 1 had recovered quickly and comfortably from anesthesia.

Conclusions

Midazolam –ketamine and propofol–fentanyl groups outcome intact anesthesia with minor reactions and lesser hemodynamic variations. Ketamine and fentanyl are analogous in terms of analgesic efficiency. When patient safety is considered, fentanyl can be more recommended than ketamine, with fewer events on vital parameters and speedy emergency.

Recommendations

It was recommended propofol –fentanyl used for daycare procedures where the minor reactions and initial recovery are applicable. It was recommended further studying with many more educational programs that are required for more steady opinions regarding this study.

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Ethical clearance: The study is allowed by the medical ethics committee of our hospital, and written informed approval is achieved from the patients before the procedure.

Conflict of interest: Nil

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دراسة عن الألم والبارامترات الديناميكية الدموية في الإجراءات النسائية البسيطة: (البروبوفول-الفنتانيل) ضد (الميدازولام- الكيتامين)

دينا سمير نجيب [١] ، د. بنار هلكو احمد [٢]

الملخص

خلفية الدراسة: واحدة من إجراءات التوليد البسيطة هي التمدد والكشط. الألم يحدث عادة خلاله. وبالتالي ، فإن الدواء المخدر يرغب في تسكين كاف ، بداية سريعة ، والشفاء.

اهداف الدراسة: لتقييم مجموعتين من تركيبات الأدوية {ميدازولام ٠,٠٨ ملغم/كغ - كيتامين (٠,٥ مغ/كغ)} وبروبوفول مع (١ مغ/كغ) – جرعة الفنتانيل (١ مغ/كغ)}، في المعلمات الديناميكية الدموية، وتسجيل الألم وخصائص الانتعاش وبالتالي إيجاد المزيج الأمثل الذي يمكن تطبيقه طوال العملية.

المرضى والطرائق: تم إحصاء ١٠٠ مريض يمرون بالتوسع والكشط لمدة ١٥-٣٠ دقيقة تقريبا. المدة وتم تسجيلهم بعد موافقة اللجنة الأخلاقية - أربيل في عام ٢٠٢٢ ، مقسمة إلى مجموعتين من ٥٠ لكل منهما. تم الحفاظ على التخدير الأساسي ، وتم اختيار المرضى بشكل عشوائي للحصول على البروبوفول ١ ملغ / كغ مع ١ ميكروغرام / كغ فنتانيل (المجموعة الأولى) ، ميدازولام ٠,٠٨ ملغ / كغ مع ٠,٥ ملغ / كغ من الكيتامين (المجموعة الثانية) كبلعة للحث على التخدير وللصيانة. ثم. تم تقييم درجات الألم ودرجات Aldrete وعلامات الدورة الدموية أثناء العملية وبعدها. وأخيرا ، تم ترتيب النتائج وفحصها إحصائيا باستخدام اختبار t غير المقترن للطالب واختبار chi-square.

النتائج: كان ضغط الدم (ضغط الدم الانقباضي ، الانبساطي) والعلاقات العامة أعلى بشكل ملحوظ في المجموعة ٢ مقارنة بالمجموعة ١. لم يتم العثور على فرق معنوي في المجموعتين فيما يتعلق بالمعايير: المستوى المهدئ عند ٣-٥ دقائق (ع = ٠,٤٩٩) و مدة العملية (ع = ٠,١٠٥).

الاستنتاجات: كانت المجموعة (بروبوفول - الفنتانيل) متفوقة على المجموعة (ميدازولام - كيتامين) وقد تكون خيارا جيدا في تمدد الرحم ، ويوفر الكشط (بروبوفول - الفنتانيل) تسكينا كافيا للتدخل الجراحي البسيط مع خصائص استرداد دقيقة مثل وقت الاستيقاظ والاستجابة للأوامر اللفظية.

الكلمات المفتاحية: الفنتانيل ، البروبوفول ، الكيتامين ، الميدازولام ، توسيع الرحم والكشط ، درجات ألدريت

البريد الالكتروني: dena.sameer63@yahoo.com

تاريخ استلام البحث: ٢٢ حزيران ٢٠٢٢

تاريخ قبول البحث: ٢١ أب ٢٠٢٢

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[١] مستشفى رابرين للاطفال التعليمي - أربيل - العراق

[٢] مستشفى رزكاري التعليمي – قسم علاج الآلام المزمنة - اربيل - العراق