Section: Anaesthesia

Original Research Article

COMPARATIVE STUDY BETWEEN PROPOFOL-FENTANYL AND PROPOFOL-MIDAZOLAM FOR SEDATIVE EFFECT IN SHORT GYNECOLOGICAL PROCEDURES

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ABSTRACT

Background: Sedation is essential in short gynecological procedures to ensure patient comfort and cooperation. This study compares the sedative efficacy and safety profiles of two sedation regimens: propofol-fentanyl and propofol-midazolam. **Aim:** To compare the sedative effects, onset of action, recovery time, haemodynamics and safety profiles of propofol-fentanyl and propofol-midazolam during short gynecological procedures.
Material and Methods: A randomized trial with 100 patients undergoing short gynecological surgeries was conducted. Patients were divided into two groups: Group M received propofol with midazolam, while Group F received propofol with fentanyl. Key parameters measured included heart rate, mean arterial pressure (MAP), oxygen saturation perioperatively and pain by VAS, sedation by RSS and awareness assessed post operatively.
Results: The group M exhibited more stable haemodynamics, in compared to group F The group M achieved higher Ramsay Sedation Scale (RSS) scores postoperatively indicating deeper sedation. Group F demonstrated superior pain management with lower Visual Analog Scale (VAS) scores and faster onset and recovery.
Conclusion: Both regimens are effective for short gynecological procedures. Propofol-fentanyl allows for faster onset and recovery, preferred in patients with comorbidities and Propofol-midazolam is preferred in anxious patients.
Keywords: Propofol, Fentanyl, Midazolam, Sedation, Short gynecological procedures, Procedural sedation, Analgesia.

INTRODUCTION

Procedural sedation is used to alleviate discomfort, anxiety, and awareness during short medical procedures. Procedural sedation allows patients to be sedated making it suitable for outpatient gynecological procedures such as dilation and curettage (D&C), hysteroscopy, and dilation and evacuation (D&E). This study evaluates the efficacy and safety of two sedation regimens: propofol-fentanyl and propofol-midazolam.

Propofol is a commonly used intravenous anesthetic agent for sedation and general anesthesia. It works by promoting GABA (gamma-aminobutyric acid) activity, leading to a depressant effect on the central nervous system.

Fentanyl is a potent opioid analgesic commonly used in combination with other sedatives to provide additional analgesia. Fentanyl acts on opioid receptors, blocking pain transmission and offering additional comfort during procedures.

The combination of Propofol and Fentanyl is generally used for more painful procedures, as the opioid enhances analgesia, reducing the need for additional pain management.

Midazolam is a benzodiazepine that has anxiolytic, amnestic, and sedative properties. It enhances the effects of GABA in the central nervous system,

leading to calming and sedative effects. The combination of Propofol and Midazolam is typically induces less analgesia and moderate sedation.

Although both combinations are routinely used, their comparative effects on hemodynamic stability, anxiolysis, amnesia and analgesia are well established for short gynecological procedures. Both the combinations are known to establish awareness amnesia, preventing patients from forming conscious memories during procedures."

Aim and Objectives

The aim of this study is to compare the sedative efficacy, onset of action, recovery time, and safety profiles of propofol-fentanyl and propofol-midazolam. The objectives include:

- Evaluating hemodynamic stability during procedure
- Evaluating patient awareness and amnesia peri operatively
- Measuring pain severity by VAS SCORE post operatively
- Measuring sedation depth using the Ramsay Sedation Scale (RSS) post operatively
- Comparing recovery time
- Documenting adverse effects, including nausea, vomiting, respiratory depression.

MATERIALS AND METHODS

Study Design

A randomized controlled trial was conducted on 100 female patients, aged 18–60 years, undergoing short gynecological surgeries. Inclusion criteria were patients classified as ASA I or II. Exclusion criteria included known allergies to study drug history of substance abuse, significant cardiovascular, respiratory, or neurological disorders, and ASA class III or higher.

Preoperative assessment was conducted a day before surgery and included a review of medical and surgical history, physical examination, systemic examination and necessary lab tests. Special attention was given to co-morbidities like hypertension, diabetes, and respiratory diseases. Cardiovascular and respiratory evaluations were emphasized, and all patients were classified as ASA I or II. Airway assessment was performed to anticipate any intubation or ventilation challenges.

Written informed consent of patient and relative was taken after explaining about anaesthesia and its risks

Method

After confirming NBM status, patients were taken to the operating theatre, where IV access was secured, iv fluids were started and baseline vitals (HR, MAP, SpO_2) were attached and recorded . Continuous monitoring included ECG, NIBP, pulse oximetry, and capnography. For anesthesia induction, in Group M, midazolam 0.05 mg/kg administered followed by propofol 1.5-2.0 mg/kg was administered intravenously. In Group F, fentanyl at 1.0 µg/kg followed by propofol 1.5-2.0 mg/kg. The goal in both groups was to maintain hemodynamic stability and prevent excessive sedation or awareness.

The study measured several parameters, including heart rate (HR) and Blood pressure which was recorded at baseline and then at 1,2,3, 5, 10, 15, 20,25 and 30 minutes post-induction. Mean arterial pressure (MAP) was also measured at the same intervals as HR. Oxygen saturation (SpO2) was continuously monitored throughout the procedure

Duration and pattern of recovery was also observed as per the recovery criteria.

Ramsay Sedation Scale is calculated by observing the patient's response to stimuli and assigning a score from 1 to 6, where 1 = anxious/agitated, 2–4 = increasing sedation, and 5–6 = deep sedation with no response to stimuli. Postoperative pain was assessed using the Visual Analog Scale (VAS), where patients rated their pain on a scale of 0 to 10, with 0 indicating no pain and 10 representing severe pain.

RESULTS

The comparative analysis between Group F and Group M in short gynecological procedures highlights key differences in terms of Haemodynamic stability, recovery, analgesia and amnesia.

Demographics

Age, sex: No statistically significant difference was observed between the two groups.

ASA grading also doesnt show any significance.

Hemodynamics

The tables compare physiological data for two groups, M and F, following drug administration. Key parameters measured include heart rate, systolic and diastolic blood pressure, mean arterial pressure, oxygen saturation (SpO2), and respiratory rate (RR). These vital signs were monitored over a 30-minute period to assess the drugs' effects.

GROUP M

Table 1: Demographic and Baseline Characteristics of Study Participants (n = 50)

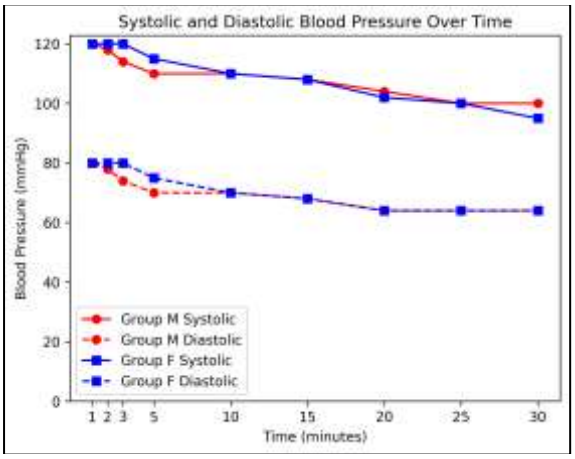
Time	Mean HR (bpm)	Mean Systolic BP (mmHg)	Mean Diastolic BP (mmHg)	MAP (mmHg)	SpO2 (%)	RR (breaths/min)
1	80	120	80	93.33	99	15
2	78	118	78	91.33	99	15
3	75	114	74	87.33	99	15
5	75	110	70	83.33	99	15
10	70	110	70	83.33	99	15

15	65	108	68	81.33	99	13
20	65	104	64	77.33	99	13
25	64	100	64	73	99	12
30	62	100	64	72.33	99	11

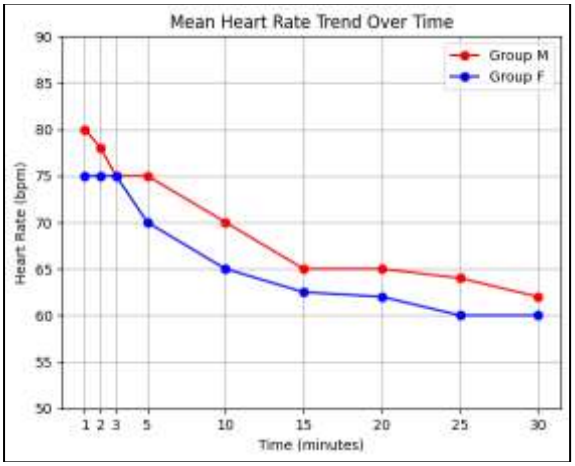
GROUP F

Table 2: ?

Time	Mean HR (bpm)	Mean Systolic BP (mmHg)	Mean Diastolic BP (mmHg)	MAP (mmHg)	SpO2 (%)	RR (breaths/min)
1	75	120	80	93.33	99	15
2	75	120	80	91.33	99	15
3	75	120	80	87.33	99	15
5	70	115	75	83.33	99	15
10	65	110	70	83.33	99	15
15	62.5	108	68	81.33	99	13
20	62	102	64	75.33	99	13
25	60	100	64	73	99	12
30	60	95	64	71.33	99	11

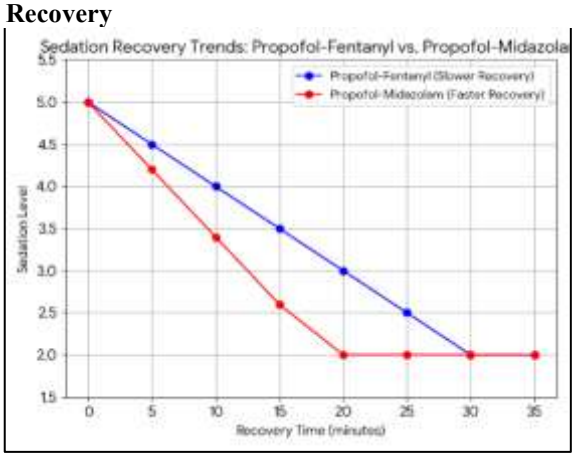


The above graph illustrates the systolic and diastolic blood pressure trends for patients



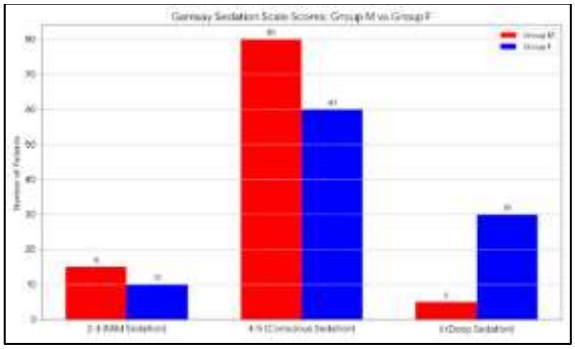
The graph indicates a comparable effect on cardiac chronotropy by both groups over 30 minutes .Group F caused more reduction in heart rate and blood pressure following administration in comparison to Group M.

Recovery



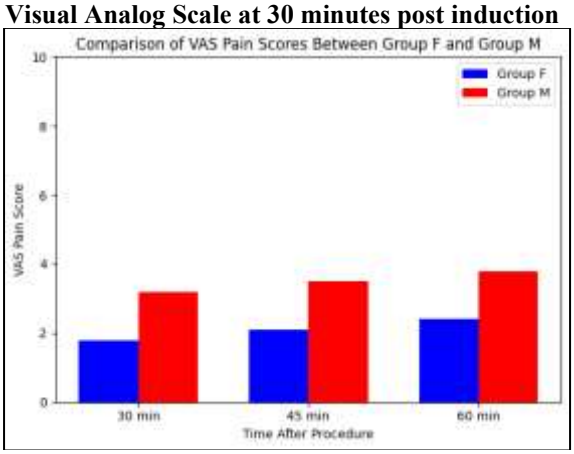
Group M shows a faster recovery from sedation, characterized by earlier eye-opening and quicker responses to verbal commands post-procedure while the Group F shows a slower, more gradual recovery.

Ramsay Sedation Scale (RSS) at 30 minutes post induction



The Group F group experienced significantly deeper sedation than the group M. The most notable difference was that 30% of patients in the Group F reached deep sedation, compared to only 5% in the Group M The study also confirmed that the Ramsay Sedation Scale was a reliable tool for measuring these sedation

Visual Analog Scale at 30 minutes post induction



The Group F offers superior pain relief , reflected in lower VAS pain scores of approximately 1.5 to 2.5, and provides a faster slower recovery. . Conversely, Group M provides good sedation, faster recovery but it is less effective for pain, resulting in higher VAS scores around 3.0 to 4.0.

DISCUSSION

Procedural sedation is a cornerstone of modern medicine, especially in short surgical procedures . The goal is to provide a state of reduced consciousness and pain, allowing for patient comfort, cooperation, and safety. This approach is invaluable in alleviating the anxiety and discomfort associated with procedures.

Drugs Used in Procedural Sedation

Beyond the drugs investigated in this study, a range of pharmacological agents can be used for procedural sedation. These include:

Ketamine, Dexmedetomidine, Nitrous Oxide (Entonox), Etomidate, Remifentanil, Sevoflurane,

Benzodiazepines

This study specifically compared two common sedation regimens, each built on a foundation of propofol:

Propofol is a widely used intravenous anesthetic agent that facilitates both the induction and maintenance of general anesthesia and procedural sedation. Its mechanism of action involves enhancing the inhibitory effects of gamma-aminobutyric acid (GABA) by binding to and activating GABA-A receptors in the central nervous system. This potentiation of GABA activity leads to a rapid depressant effect, characterized by quick onset and a short duration of action. These properties make it ideal for outpatient procedures where a fast recovery is desired. However, propofol can also cause significant side effects, including hypotension and respiratory depression, particularly at higher doses, necessitating close monitoring of the patient's vital signs.

Midazolam is a short-acting benzodiazepine that is primarily used for its anxiolytic, sedative, and amnestic effects. Its mechanism of action is similar to propofol in that it also enhances GABA-A receptor activity. This leads to a calming and sedative effect, and most importantly, provides strong anterograde amnesia, preventing the patient from forming conscious memories of the procedure. midazolam has minimal analgesic properties. Midazolam directly depresses the central respiratory drive in the brainstem, which can lead to respiratory depression. Midazolam typically has a minimal effect on heart rate While it is generally considered hemodynamically stable. Overall propofol-midazolam combination is particularly beneficial for highly anxious patient.

Fentanyl is a highly potent synthetic opioid that primarily acts on mu-opioid receptors. In the central nervous system, it provides powerful analgesia, sedation, and a sense of euphoria by blocking pain signals and increasing dopamine. Its most dangerous effects are on the respiratory system, where it causes dose-dependent respiratory depression by directly suppressing the brain's breathing centers. On the cardiovascular system, fentanyl can cause a decrease in heart rate (bradycardia) and a drop in blood pressure (hypotension), although it generally maintains more stable hemodynamics than some other opioids and has minimal effect on the heart's contractility.

sed on the provided data, here is a detailed discussion of the two sedation regimens, including their hemodynamic stability, analgesia, amnesia, Ramsay Sedation Scale (RSS) and Visual Analog Scale (VAS) scores, and recovery

Hemodynamic Stability

Hemodynamic stability refers to the body's ability to maintain stable heart rate and blood pressure, which is crucial for patient safety during sedation. The data shows a clear difference in trends between the two regimens. The Propofol-Midazolam regimen offered superior blood pressure stability. Midazolam, by itself, typically causes a mild dose-dependent decrease in mean arterial pressure (MAP) by reducing systemic vascular resistance. This effect is generally When combined with propofol, which also causes hypotension through vasodilation, the overall effect is still stable and manageable compared to the Propofol-Fentanyl combination.

In contrast, the Propofol-Fentanyl was more prone to mild reduction in blood pressure (hypotension). Fentanyl, especially when administered rapidly, can cause hypotension by reducing sympathetic nervous system activity and causing vasodilation. This effect is compounded by propofol's own hypotensive properties, creating a higher risk of a significant and decrease in blood pressure that requires vigilant monitoring and intervention.

The Propofol-Midazolam group associated with a lower incidence of bradycardia (slow heart rate). Midazolam has a minimal effect on heart rate,

Conversely, the Propofol-Fentanyl group was linked to a higher incidence of bradycardia. Fentanyl directly stimulates the vagus nerve in the brainstem, which increases parasympathetic activity and causes the heart rate to slow. This effect is dose-dependent

and can be particularly dangerous when combined with propofol. This combined action requires careful monitoring of the patient's heart rate to prevent severe bradycardia.

Amnesia and Sedation

Propofol-Midazolam provided a stronger amnesic effect, which is primarily due to the potent amnestic properties of midazolam. The RSS scores also revealed a difference in sedation depth. In the propofol-midazolam group, the majority of patients (80%) were in the conscious sedation range (RSS 4-5), with only 5% achieving deep sedation (RSS 6). In contrast, the propofol-fentanyl group demonstrated a higher incidence of deep sedation, with 30% of patients reaching RSS 6. This difference was statistically significant ($P = 0.022$), suggesting that the combination of propofol and fentanyl induces deeper sedation than propofol and midazolam. The concordance between RSS scores and other sedation measures was strong in both groups, supporting RSS as a reliable tool for monitoring sedation

Analgesia and the Visual Analog Scale (VAS)

Analgesia refers to the relief of pain without causing loss of consciousness. The Visual Analog Scale (VAS) is a common tool used to quantify a patient's pain level on a scale, typically from 0 (no pain) to 10 (severe pain)

Propofol-Fentanyl

The Propofol-Fentanyl regimen provides superior analgesia primarily due to the inclusion of fentanyl. Fentanyl is a powerful synthetic opioid that acts as a potent analgesic. This action directly reduces the perception of pain, even during and after a procedure. patients in this group reported lower VAS scores, ranging from approximately 1.5 to 2.5. These low scores indicate minimal pain and discomfort, making this combination highly effective

Propofol-Midazolam

In contrast, the Propofol-Midazolam regimen offers significantly less effective pain relief because midazolam has minimal to no analgesic properties. Midazolam's primary role is to provide sedation and amnesia, not to block pain. While propofol can have some minor analgesic effects, the combination lacks a strong, dedicated pain-relieving component.

As a result, patients in this group reported higher VAS scores, ranging from 3.0 to 4.0. These scores suggest a moderate level of pain that often necessitates the use of additional pain medication after the procedure.

Recovery

Recovery time was calculated from the time of drug administration until the patient regained full orientation, which was determined by criteria such as eye-opening and the ability to respond to verbal commands.

The Propofol-Midazolam combination allows for a quicker return to normal, as patients demonstrate earlier eye-opening and a faster response to verbal commands. In contrast, the Propofol-Fentanyl combination can result in slight discomfort and a slower recovery, as fentanyl's effects tend to linger longer.

Overall, Propofol-Fentanyl is more effective for pain management, ensuring better analgesia, while Propofol-Midazolam is more suitable when sedation and amnesia are the primary concerns, in addition to its faster recovery. Therefore, Propofol-Fentanyl is the preferred combination for procedures requiring effective pain control, while Propofol-Midazolam is better suited for procedures where sedation and amnesia are the main goals and faster recovery is desired.

Parameter	Fentanyl + Propofol	Midazolam + Propofol
Hemodynamic Stability	Fentanyl can cause bradycardia, hypotension, and respiratory depression in higher doses.	Midazolam may cause mild hypotension and respiratory depression, but typically less pronounced than fentanyl.
	- Careful monitoring is necessary for maintaining hemodynamic stability.	- Overall, hemodynamic changes are stable
Sedation level	Deep sedation can be achieved with propofol and fentanyl combination.	Midazolam contributes to a lighter sedation level compared to fentanyl.
	- Good control over the depth of sedation	- Provides anxiolysis but does not offer the same depth of sedation as fentanyl.
Amnesia	Propofol provides amnesia, but fentanyl does not contribute significantly to amnesia.	Midazolam has strong amnesic properties, which contribute to the absence of recall of the procedure.
	- Patients typically do not recall the procedure.	- Provides a deeper amnesic effect than fentanyl.
Recovery time	fentanyl's prolonged effect may result in delayed recovery in cases.	Recovery might be faster due to its less profound sedation
		-
Analgesia	Fentanyl is a potent opioid analgesic, providing effective pain relief during surgery.	Midazolam is primarily an anxiolytic and sedative, with minimal analgesic properties.
	- Analgesia is well-maintained throughout the procedure.	- Analgesia is typically weaker than fentanyl, and additional analgesics might be needed.
Side effects	Potential for opioid-related side effects (nausea, vomiting, respiratory depression).	Midazolam may cause paradoxical reactions (e.g., agitation in some patients), though less common.
	- Requires careful monitoring of the airway and vital signs.	- Typically, fewer opioid-related side effects compared to fentanyl.

CONCLUSION

Both propofol-fentanyl and propofol-midazolam regimens are effective for sedation in short gynecological procedures. Propofol-fentanyl offers advantages in effective pain relief and preferred in patients with comorbidities while propofol-midazolam provides greater stability in heart rate and blood pressure, anxiolysis and amnesia.

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