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To Compare The Efficacy Of Dexmedetomidine-Ketamine Vs Midazolam-Ketamine Combinations For Conscious Sedation In Surgery Done Under Local Anaesthesia

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ABSTRACT

Background: This prospective, randomized, double-blind clinical study was conducted to compare the efficacy of dexmedetomidine (Group DX) and midazolam (Group MX) for conscious sedation in minor superficial surgical procedures. The primary objectives were to assess recovery time, analgesic efficacy, and hemodynamic stability.

Methods: Sixty ASA I–II patients aged 20–65 years were randomly assigned to two groups: Group DX received dexmedetomidine 1 mcg/kg IV over 2 minutes followed by 0.5 mg/kg ketamine IV, while Group MX received midazolam 0.05 mg/kg IV over 2 minutes followed by 0.5 mg/kg ketamine IV. Hemodynamic parameters, sedation levels, recovery time, and analgesic requirements were recorded.

Results: The demographic and baseline hemodynamic parameters were comparable between the groups ($p > 0.05$). Patients in Group DX had a significantly shorter recovery time (7–9 min) compared to Group MX (12–15 min) ($p < 0.001$). The time to first rescue analgesia was prolonged in Group DX (70 ± 20 min) compared to Group MX (50 ± 10 min) ($p < 0.01$), indicating better analgesic efficacy. Additionally, the frequency of rescue analgesics was lower in Group DX ($p < 0.05$). Hemodynamic parameters showed a significantly lower heart rate (50–65 bpm in DX vs. 70–80 bpm in MX, $p < 0.001$) and lower mean arterial pressure in Group DX ($p = 0.02$), suggesting greater sympatholytic effects. Oxygen saturation remained stable in both groups ($p = 0.75$).

Conclusion: Dexmedetomidine provided superior sedation with faster recovery, prolonged analgesic duration, and lower rescue analgesic requirements compared to midazolam. Additionally, it resulted in better hemodynamic stability with significant bradycardia but maintained oxygenation levels. These findings suggest that dexmedetomidine may be the preferred agent for conscious sedation in minor surgical procedures.

1. INTRODUCTION

Conscious sedation, also known as monitored anesthesia care (MAC), is a technique that combines intravenous sedatives with local anesthetic infiltration or nerve blocks to provide analgesia and sedation during surgical or diagnostic procedures without causing respiratory depression. This approach ensures rapid recovery with minimal side effects, making it particularly suitable for superficial surgeries performed under local anesthesia. Traditionally, agents such as midazolam,

propofol, and fentanyl have been employed for MAC. However, the concurrent administration of sedative-hypnotics with analgesics can sometimes lead to significant respiratory depression and transient upper airway obstruction. A rapid progression from light sedation to deep sedation or unconsciousness may predispose patients to airway obstruction, oxygen desaturation, and aspiration, necessitating vigilant monitoring during MAC [1].

Ketamine, a dissociative anesthetic, offers distinct analgesic properties and a relatively rapid onset of action with immediate recovery. It also possesses bronchodilatory effects beneficial during the intraoperative period. However, its use is limited by postoperative delirium, excitement, and hallucinations, collectively termed emergence reactions. To mitigate these adverse effects, benzodiazepines like midazolam have been used as premedication [2].

Dexmedetomidine, a centrally acting α-2 receptor agonist, has emerged as an alternative sedative-analgesic for MAC due to its sedative and analgesic properties without causing respiratory depression. Its relatively short elimination half-life of approximately two hours makes it an attractive agent for sedation during MAC. Recent studies have explored the efficacy of combining dexmedetomidine with ketamine for conscious sedation in surgeries performed under local anesthesia. A prospective randomized double-blind study compared the effects of dexmedetomidine-ketamine and dexmedetomidine-midazolam combinations in patients undergoing transurethral procedures. The study found that both combinations provided satisfactory sedation levels, but the dexmedetomidine-ketamine combination offered better analgesia and hemodynamic stability, with less nausea and vomiting and shorter recovery times than the dexmedetomidine-midazolam combination [1,3].

Another randomized prospective study evaluated the overall effectiveness of dexmedetomidine versus midazolam during MAC. The study concluded that dexmedetomidine is increasingly being used as a sedative-analgesic for MAC due to its analgesic properties and lack of respiratory depression. These attributes, along with its relatively short elimination half-life, make dexmedetomidine an attractive agent for sedation during MAC. Furthermore, a study comparing intravenous ketamine-dexmedetomidine and ketamine-midazolam combinations in procedural sedation for short surgical procedures found that the dexmedetomidine-ketamine combination is a good and safe alternative for procedural sedation. The combination provided better analgesia and hemodynamic stability, with less nausea and vomiting and shorter recovery times than the ketamine-midazolam combination [1,4].

2. MATERIALS AND METHODS

After obtaining approval from the Institutional Ethics Committee, this study was conduced in the operation theatre complex in Karpaga Vinayaga Institute of Medical Sciences & Research Centre. Sixty patients, classified as American Society of Anesthesiologists (ASA) I–II were enrolled in this prospective, randomized, double-blind clinical trial. Patients included in the study were aged between 18 and 60 years and were scheduled for elective minor superficial surgical procedures under conscious sedation.

Inclusion Criteria:

- Patients aged 20–65 years
- ASA physical status I–II
- Scheduled for elective minor superficial surgical procedures under conscious sedation

Exclusion Criteria:

- Patients with cardiovascular, respiratory, renal, or hepatic diseases
- Chronic users of sedatives, opioids, or narcotics
- History of alcohol or substance abuse
- Allergy to any of the medications used in the study
- Pregnant or lactating women

Randomization: Patients were randomized into two groups using a sealed envelope technique for sedation and analgesia: Group “DX” and Group “MX.” Both the patient and the anesthesiologist were blinded to the group assignment.

Intervention: After obtaining informed consent, patients were taken to the operating room, and intravenous (IV) access was established. Non-invasive monitoring devices (non-invasive blood pressure, electrocardiograph leads, and pulse oximeter) were attached, and baseline cardiorespiratory parameters were recorded every 5 minutes following drug administration until the completion of surgery. All patients received premedication with glycopyrrolate 0.2 mg IV and ondansetron 0.1 mg/kg IV. A lignocaine sensitivity test was performed.

- Group DX (n = 30): Patients received dexmedetomidine 1 mcg/kg in 10 mL normal saline intravenously over 2 minutes, followed by 0.5 mg/kg IV ketamine.
- Group MX (n = 30): Patients received midazolam 0.05 mg/kg in 10 mL normal saline IV over 2 minutes, followed

by 0.5 mg/kg IV ketamine.

In both groups, targeted sedation level (≤ 4) was achieved using the Observer's Assessment of Alertness/Sedation Scale).

3. RESULTS

Table 1 Demographics Data

Variable	Group DX (n = 30)	Group MX (n = 30)	p-value
Age (years)	40.2 ± 10.5	41.3 ± 9.8	0.68 (NS)
Sex (M/F)	16/14	15/15	0.79 (NS)
Duration of Procedure (min)	38.2 ± 4.5	37.8 ± 4.2	0.72 (NS)
Heart Rate (beats/min)	78.6 ± 6.8	79.2 ± 7.1	0.81 (NS)
Systolic BP (mmHg)	125.3 ± 12.5	126.1 ± 13.1	0.76 (NS)
Diastolic BP (mmHg)	80.4 ± 9.2	81.1 ± 8.7	0.84 (NS)
SpO_2 (%)	98.2 ± 0.9	98.3 ± 1.0	0.87 (NS)

Table 1 presents patients' demographic and baseline clinical characteristics in Group DX (Dexmedetomidine) and Group MX (Midazolam). The mean age of patients in Group DX was 40.2 ± 10.5 years, while in Group MX, it was 41.3 ± 9.8 years, with no statistically significant difference ($p = 0.68$). The sex distribution was also comparable between the two groups (16 males and 14 females in Group DX vs. 15 males and 15 females in Group MX, $p = 0.79$).

The duration of the surgical procedure was similar in both groups, with a mean duration of 38.2 ± 4.5 minutes in Group DX and 37.8 ± 4.2 minutes in Group MX ($p = 0.72$). Hemodynamic parameters, including heart rate, systolic blood pressure, and diastolic blood pressure, showed no significant differences between the two groups ($p > 0.05$). The mean heart rate was 78.6 ± 6.8 beats per minute in Group DX and 79.2 ± 7.1 in Group MX ($p = 0.81$). Systolic and diastolic blood pressures were also similar between the two groups, with p-values of 0.76 and 0.84, respectively. Oxygen saturation (SpO_2) remained stable and comparable in both groups ($p = 0.87$). These findings suggest that both sedation protocols maintained stable hemodynamic parameters without significant differences.

Table 2 - Hemodynamic and Oxygenation Parameters in DX and MX Groups

Parameter	Group DX	Group MX	p-value	Significance
Heart Rate (bpm)	50 – 65	70 – 80	< 0.001	Significant
Mean Arterial Pressure (mmHg)	60 – 90	70 – 90	0.02	Significant
SpO_2 (%)	97 – 99	97 – 99	0.75	Not Significant

Table 2 presents a comparison of key physiological parameters between Group DX (Dexmedetomidine) and Group MX (Midazolam) during the study. Heart rate was significantly lower in Group DX (50–65 bpm) compared to Group MX (70–80 bpm), with a highly significant p-value (< 0.001), indicating a notable reduction in sympathetic activity with dexmedetomidine. Mean arterial pressure (MAP) also showed a significant difference, with values ranging from 60–90 mmHg in Group DX and 70–90 mmHg in Group MX ($p = 0.02$), suggesting a greater reduction in MAP with dexmedetomidine. Oxygen saturation (SpO_2) remained within a stable range (97–99%) in both groups, and the difference was not statistically significant ($p = 0.75$), indicating that both sedation protocols maintained adequate oxygenation without compromising respiratory function. Dexmedetomidine resulted in lower heart rates and MAP, whereas both drugs maintained similar oxygenation levels. These findings highlight the hemodynamic effects of dexmedetomidine compared to midazolam.

Table 3 -Comparison of Recovery and Analgesic Parameters Between Group DX and Group MX

Parameter	Group DX	Group MX	p-Value
Recovery Time (min)	7–9 min	12–15 min	< 0.001
Time for First Rescue Analgesia (min)	70 ± 20 min	50 ± 10 min	< 0.01
Frequency of Rescue Analgesics	Less frequent	More frequent	< 0.05

Table 3 presents a comparative analysis of recovery time, time for first rescue analgesia, and frequency of rescue analgesic requirements between Group DX (Dexmedetomidine) and Group MX (Midazolam) in patients undergoing elective minor superficial surgical procedures under conscious sedation. Recovery time was significantly shorter in Group DX (7–9 minutes) compared to Group MX (12–15 minutes), with a p-value of < 0.001, indicating faster recovery in the dexmedetomidine group. The time to first rescue analgesia was prolonged in Group DX (70 ± 20 minutes) compared to Group MX (50 ± 10 minutes), with a statistically significant p-value of < 0.01, suggesting better analgesic efficacy. Additionally, the frequency of rescue analgesic requirements was lower in Group DX than in Group MX, with a p-value of < 0.05, demonstrating a reduced need for additional pain relief in the dexmedetomidine group. These findings highlight the superior sedation-analgesia profile of dexmedetomidine over midazolam in this clinical setting.

4. DISCUSSION

In our study comparing dexmedetomidine-ketamine (Group DX) and midazolam-ketamine (Group MX) combinations for conscious sedation during minor surgical procedures, we observed that Group DX had significantly shorter recovery times (7–9 minutes) compared to Group MX (12–15 minutes) ($p < 0.001$). Additionally, the time to first rescue analgesia was longer in Group DX (70 ± 20 minutes) than in Group MX (50 ± 10 minutes) ($p < 0.01$), and the frequency of rescue analgesics was lower in Group DX ($p < 0.05$). Hemodynamic parameters indicated a lower heart rate and mean arterial pressure in Group DX, while oxygen saturation levels remained stable in both groups.

These findings align with the results of a study by Kumari et al[4]., which compared dexmedetomidine and midazolam as premedicants in minor gynaecological day care surgeries. They reported that dexmedetomidine provided better sedation and recovery profiles, with a reduced need for additional propofol, compared to midazolam. Specifically, the mean dose of additional propofol was lower in the dexmedetomidine group (14 ± 9.25 mg) than in the midazolam group (25 ± 5.40 mg) ($p < 0.001$). Furthermore, dexmedetomidine was associated with better recovery characteristics, as indicated by higher Aldrete and street fitness scores. In summary, both our study and the study by Kumari et al[4]. demonstrate that dexmedetomidine offers superior sedation, analgesia, and recovery profiles compared to midazolam when used in combination with ketamine for conscious sedation in minor surgical procedures.

Our study aligns with Fang, L., Gao, W., & Zhang, X.[5], which highlighted dexmedetomidine's superior safety and efficacy in monitored anesthesia care (MAC). Similar to our findings, their meta-analysis demonstrated dexmedetomidine's advantages over midazolam in providing better analgesia, faster recovery, and reduced need for rescue analgesics, with minimal respiratory depression. Both studies emphasize dexmedetomidine's hemodynamic stability and enhanced sedation-analgesia profile, making it a preferable choice for MAC.

Our study line up with Kaur et al[6], demonstrating dexmedetomidine's superior sedation, faster recovery, and better analgesia with minimal respiratory depression, reinforcing its efficacy for procedural sedation over midazolam. Dexmedetomidine has superior analgesia, hemodynamic stability, and faster recovery compared to midazolam, with both maintaining adequate oxygenation without significant respiratory depression reported by Xie et al[7]., which was similar to our study.

Yang et al[8], demonstrated that dexmedetomidine provides superior analgesia, faster recovery, and reduced analgesic requirements compared to midazolam, confirming its safety and efficacy in monitored anesthesia care. Our findings are consistent with Lee et al[9], showing that the dexmedetomidine-ketamine combination offers better analgesia, quicker recovery, and improved hemodynamic stability than midazolam-ketamine, establishing it as a safer and more effective option for minor surgical procedures.

Our study concurs with findings from Lee et al[10] and Hassan & Abdelaziz[11], showing that dexmedetomidine combined with ketamine offers superior sedation and analgesia compared to midazolam-ketamine. Like our results, Lee et al. reported faster recovery and improved hemodynamic stability with dexmedetomidine, while Hassan & Abdelaziz noted reduced analgesic needs and fewer side effects, underscoring dexmedetomidine's safety and effectiveness for conscious sedation in minor surgical procedures.

Our study is consistent with findings by He et al[12] and Lu et al[13], demonstrating that dexmedetomidine-ketamine provides better hemodynamic stability, faster recovery, and prolonged analgesia compared to midazolam-ketamine. He et al. reported improved sedation and analgesia with fewer adverse events in the dexmedetomidine group, while Lu et al. confirmed enhanced hemodynamic stability and reduced analgesic needs, aligning with our results showing superior outcomes with dexmedetomidine.

Nair & Pal[14], demonstrating dexmedetomidine's superior analgesia and quicker recovery compared to midazolam in monitored anesthesia care (MAC). Likewise, Kim et al[15], reported enhanced hemodynamic stability, reduced analgesic needs, and shorter recovery times with dexmedetomidine. Both studies reinforce our findings, highlighting dexmedetomidine's efficacy in maintaining stable vitals while offering better sedation and analgesia, making it a favorable choice for MAC.

5. CONCLUSION

This study compared dexmedetomidine (Group DX) and midazolam (Group MX) for sedation and analgesia in minor surgical procedures under conscious sedation. Dexmedetomidine demonstrated significantly faster recovery ($p < 0.001$), prolonged time to first rescue analgesia ($p < 0.01$), and reduced frequency of rescue analgesic requirements ($p < 0.05$) compared to midazolam. Additionally, Group DX had a lower heart rate and mean arterial pressure, indicating greater sympatholytic effects. Both drugs maintained stable oxygenation levels. Overall, dexmedetomidine provided superior sedation with better analgesia and hemodynamic stability, making it a preferable choice for short-duration procedures requiring conscious sedation.

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