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Research Article

Assessing the Effect of Intranasal Sedation with Midazolam on Reducing Anxiety in Patients Undergoing Mandibular Third Molar Surgery

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Abstract

Aims: The present study aimed to evaluate the efficacy of intranasal sedation with Midazolam on reducing anxiety in patients undergoing surgical removal of impacted mandibular third molars.

Materials and Methods: Thirty healthy individuals of both genders were included in this study of both genders; their ages ranged between 18-40 years, who were looking for surgical removal of impacted mandibular third molars under local anesthesia, and they possessed moderate to severe grades of anxiety. Patients were randomly assigned to two groups: the Midazolam group included fifteen patients who were premedicated with intranasal Midazolam using a nasal spray in a concentration of 0.2 mg/kg body weight ten minutes before surgery; the Placebo group included fifteen patients who received an oral Placebo of glucose powder capsules one hour before surgery. The following parameters were assessed: systolic blood pressure, diastolic blood pressure, and anxiety score.

Results: Regarding systolic blood pressure measurements, there was a statistically significant difference between the Midazolam and Placebo groups after drug administration. There was a highly significant difference between the Midazolam and Placebo groups during the surgical procedure, as well as at the end of the surgical procedure**.** Regarding diastolic blood pressure measurements, there was a highly statistically significant difference between the Midazolam and Placebo groups after drug administration, during the surgical procedure, and at the end of the surgical procedure. Regarding anxiety, there was a highly significant difference between the Midazolam and Placebo groups post-operatively.

Conclusion: Intranasal administration of Midazolam is recommended as a safe, reliable, and effective conscious sedation for anxious patients during the surgical removal of impacted mandibular third molars.

Keywords: Anxiety, Intranasal, Midazolam, Sedation, Molars.

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INTRODUCTION

Removal of third molars is a popular surgical procedure carried out in oral and maxillofacial surgery. Patients with extractions of wisdom teeth have the highest levels of dental anxiety. Dental treatment under sedation can notably lower the adverse effects of anxiety. In the meantime, novel techniques have been presented in dentistry for sedation (1-3).

Moderate conscious sedation is defined as the use of a drug or drugs that result in a formal depression of the central nervous system whilst also enhancing the patient's safety, psychological control, and the capability to control behavior and anxiety, which aids to continue the treatment. Nevertheless, verbal communication with the patient is maintained throughout the sedation. It can be produced by different routes of administration, for instance, inhalation, oral, intravenous, intranasal (IN) spray, and intramuscular routes (3-6). In this study, patients were selected for IN administration of Midazolam.

Midazolam is a member of the benzodiazepine family, which has amnesic, anxiolytic, and the highest lipid-soluble characteristics correlated with short-acting sedation and few side effects. The exclusive characteristics of Midazolam, comprising its effects on episodic memory, its wide margin of safety, and its anxiolytic properties, have made it a drug of choice in conscious sedation (4,7-9).

Intra-nasal Midazolam has obtained a lot of acceptance by patients who cannot cooperate with intravenous cannulation. It can be absorbed quickly into the systemic circulation as a result of the high vascularity of the nasal mucosa. The essential benefit of this method is that its onset is three times quicker than oral sedation as a result of its fast absorption (10-12).

MATERIALS AND METHODS

Study design and sample

This prospective randomized control study was carried out in the Oral and Maxillofacial Surgery Department, College of Dentistry, University of Mosul, and at

Right-Sided Specialized Dental Center, Mosul, Iraq. The sample involved dental patients who required surgical removal of impacted mandibular third molars (IMTM) under local anesthesia. According to the applicable guidelines, the research was approved by the local scientific committee and by the research ethics committee **(UoM.Dent/ H.66/ 22)** of the College of Dentistry/ University of Mosul.

A total of 30 IMTMs were collected from 30 patients, including 15 males and 15 females. Patients' ages ranged from 18 to 40 years, who met the qualification criteria for surgical removal of IMTM. Informed consent was obtained from all participants. The participants in the current study gave their verbal and written agreement. The research goal was explained to the participants, and they were assured of the privacy and confidentiality of their data.

Group allocation

The patients were randomly distributed into two groups:

Midazolam group (study group): fifteen patients premedicated with IN Midazolam using a nasal spray in a concentration of 0.2 mg/kg body weight ten mins before surgical removal of IMTM (13) in order to obtain the peak plasma levels of the nasally given sedatives at the time of procedure, as shown in Figure (1).

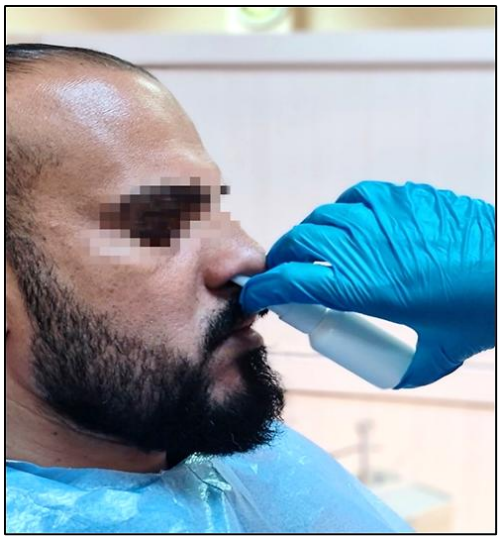

Figure (1): The nasal spray tip was inserted into the nostril.

Placebo group (control group): fifteen patients received an oral placebo of a glucose powder capsule one hour before the surgical removal of IMTM.

Blood pressure assessment

Systolic and diastolic blood pressure levels were measured and recorded using a non-invasive blood pressure monitor in mmHg at the following intervals:

1. At baseline.
2. Ten mins after drug administration in the Midazolam group and 60 mins after drug administration in the Placebo group.
3. During the surgical procedure (mean was taken).
4. At the end of the surgical procedure.

Anxiety assessment

Preoperative anxiety was evaluated in all the patients who participated in the study using Corah's Dental Anxiety Scale (DAS) (14), as shown in Table (1) to define their anxiety level before the surgical procedure.

Post-operative anxiety was assessed after full recovery by the end of surgery and before discharging the patients using the same Corah's DAS to verify whether the sedation technique that was used had been efficient in controlling the anxiety of the patients or not.

Table (1): Corah's Dental Anxiety Scale (14).

If you had to go to the dentist tomorrow for a check-up, how would you feel about it? 1. I would look forward to it as a reasonably enjoyable experience. 2. I wouldn't care one way or the other. 3. I would be a little uneasy about it. 4. I would be afraid that it would be unpleasant and painful. 5. I would be very frightened of what the dentist would do.
When you are waiting in the dentist's office for your turn in the chair, how do you feel? 1. Relaxed. 2. A little uneasy. 3. Tense. 4. Anxious. 5. So anxious that I sometimes break out in a sweat or almost feel physically sick.
When you are in the dentist's chair waiting while the dentist gets the drill ready to begin working on your teeth, how do you feel?

1. Relaxed. 2. A little uneasy. 3. Tense. 4. Anxious. 5. So anxious that I sometimes break out in a sweat or almost feel physically sick.
Imagine you are in the dentist's chair to have your teeth cleaned. While you are waiting and the dentist or hygienist is getting out the instruments that will be used to scrape your teeth around the gums, how do you feel? 1. Relaxed. 2. A little uneasy. 3. Tense. 4. Anxious. 5. So anxious that I sometimes break out in a sweat or almost feel physically sick.

This scale ranges from 4 to 20 points, with a score of less than 11 points denoting a low anxiety level, 11 to 15 points denoting a moderate anxiety level, and more than 15 points denoting a severe anxiety level (15).

Data analysis

The Statistical Package for Social Science (SPSS) version 22 was used for statistical analysis of the study data. The Shapiro-Wilk test was used to test the normal distribution of our study data. The test *p*-value was <0.05, which means that the null hypothesis of normal distribution of data was rejected, and our data were not-normally distributed; therefore, Median and Interquartile range (IQR) were used to present the data, and non-parametric tests were used for statistical comparisons. As regard to the study data with finite numbers, including Corah's DAS, which is a qualitative scale and its scores are numerically bounded at both ends of their range of values (categorized as ordinal/rank-order data), hence, they are presented as Median and IQR, and non-parametric tests were used for statistical comparisons. Significance was set at *p*-value ≤ 0.05

Blood pressure

Table (2): Descriptive statistics of systolic blood pressure and diastolic blood pressure measurements in each group at the scheduled intervals.

Group	Parameter	Measurement Intervals			
		At baseline	After drug administration	During the surgical procedure	At the end of the surgical procedure
Midazolam	SBP (mm Hg)	12.8	12.4	12.7	12.3
	DBP (mm Hg)	8	7.7	8	7.7
Placebo	SBP (mm Hg)	12.8	12.9	14.8	13.7
	DBP (mm Hg)	8.1	8.3	8.9	8.3

Note: Data presented as Median. Abbreviations: DBP, diastolic blood pressure; SBP, systolic blood pressure.

-Anxiety

Table (3): Descriptive statistics of anxiety score in each group pre- and post-operatively.

Group	Preoperative anxiety	Postoperative anxiety
Midazolam	14 (2)	8 (2)
Placebo	14 (2)	13 (3)

Note: Data presented as Median and IQR.

Comparisons of statistics between the groups

-Systolic blood pressure

The Mann-Whitney U test was used to compare systolic blood pressure measurements between the Midazolam and Placebo groups at the scheduled intervals, as shown in Table (4).

Table (4): Comparisons of systolic blood pressure measurements between the groups at the scheduled intervals.

Groups	At baseline	After drug administration	During the surgical procedure	At the end of the surgical procedure
Midazolam Vs Placebo	0.868^{NS}	0.013^{*}	0.000^{***}	0.001^{**}

The Mann-Whitney U test was used for comparisons. NS: Non-Significant, *= $p< 0.05$, **= $p<0.01$, ***=$p<0.001$. SBP: systolic blood pressure.

-Diastolic blood pressure

The Mann-Whitney U test was used to compare diastolic blood pressure measurements between the Midazolam and Placebo groups at the scheduled intervals, as shown in Table (5).

Table (5): Comparisons of diastolic blood pressure measurements between the groups at the scheduled intervals.

Groups	At baseline	After drug administration	During the surgical procedure	At the end of the surgical procedure
Midazolam Vs Placebo	0.901^{NS}	0.002^{**}	0.000^{***}	0.003^{**}

The Mann-Whitney U test was used for comparisons. NS: Non-Significant, *= $p< 0.05$, **= $p<0.01$, ***= $p<0.001$. DBP: diastolic blood pressure.

-Anxiety

The Mann-Whitney U test was used to compare anxiety scores between the Midazolam and Placebo groups pre-operatively and post-operatively.

Table (6): Comparisons of anxiety score between the groups pre and postoperatively .

Groups	Pre operatively	Post operatively
Midazolam vs Placebo	0.232^{NS}	0.000^{***}

The Mann-Whitney U test was used for comparisons. NS: Non-Significant, ***= $p<0.001$

DISCUSSION

Third molar extraction is related to dental anxiety and is stated to be the most anxiety-inducing procedure in oral surgery. Anxiety can influence the physiology of the patient and cause changes in the systolic and diastolic blood pressures. Another important factor is pain sensitivity, which appears as a reaction to a physical or psychological negative stimulus, thus eliciting stress in human bodies and leading to hemodynamic changes. The reduction of dental anxiety is essential for both patients and surgeons because surgical removal of IMTM under local anesthesia is more

difficult in patients with high dental anxiety, thus increasing patient discomfort and prolonging operating time. Anxiolytic treatments are associated with a slower heart rate, lower systolic and diastolic blood pressure, and better patient cooperation (16,17-20)

-Blood pressure

Pain and anxiety can increase the release of endogenous catecholamines, an increasing blood pressure (21). Yamashita *et al*. stated that lessening a patient's dental anxiety can significantly inhibit sympathetic activities and thus decrease their blood pressure (22). Consistent with this explication, the current study showed that systolic and diastolic blood pressure values in the Midazolam group were significantly decreased after drug administration, during and at the end of the surgical procedure, as compared to the baseline time.

The present study shows that systolic and diastolic blood pressure decreased significantly after administration of IN Midazolam and persisted at a lower level than the initial levels until the end of the surgical procedure. This finding agrees with those reported by Kiran *et al*. (23) and Kunusoth *et al*. (6), who mentioned that there was a significant decrease in systolic and diastolic blood pressure after administration of IN Midazolam, which was used for sedation of patients undergoing surgical removal of IMTM (6,23).

Göktay *et al*. in their study found that there was a decrease in blood pressure after IV administration of Midazolam, which is in favor of the present study results (19). In agreement with these findings, Hari Keerthy *et al*. also found that both the systolic and diastolic blood pressure were decreased following IV administration of Midazolam as compared to the baseline values, and this decreased value remained throughout the procedure (24). Watanabe *et al*. observed a reduction in systolic, diastolic, and mean arterial pressure after administration of IV Midazolam at doses of 0.2-0.3 mg/kg, a finding which may support the results of the present study (25). Li *et al*. in their study indicated that the Mean arterial pressure measurements in both Remimazolam and Midazolam groups were significantly lower at local anesthesia administration, at the

beginning of the operation, 5 mins after the start of the operation, and at the end of the operation compared to the baseline entry times (2). A finding that may support the present study concerning the reduction in blood pressure at the study interval times.

Dellovo *et al.* stated that systolic blood pressure was significantly reduced after 30 mins of administration of oral Midazolam and persisted lower than the initial level until the end of the surgical extraction of IMTM (26), a finding which is in favor of that of the current study as regards the effects of IN Midazolam on the reduction of blood pressure.

The present study shows that, though the systolic and diastolic blood pressure were reduced, they persisted within the accepted biological levels during all assessment periods. A finding which is in agreement with Drysdale, who also stated that blood pressure remained normal throughout the dental treatment among patients who received IN Midazolam (9). Furthermore, Berg *et al*. in their study stated that vital signs remained within normal ranges throughout the dental treatment among patients who received IN Midazolam (27), which also supports the same finding by the present study. Similarly, Dellovo *et al.* stated that the blood pressure levels measured among patients who were sedated with oral Midazolam for surgical extraction of IMTM, even when reduced, persisted within the accepted biological levels throughout all assessment periods (26).

The outcome of this study regarding the reduced systolic and diastolic blood pressure after IN Midazolam administration is in contrast with the outcomes of Hiwarkar *et al.* study, who found that there was a transient increase in the systolic blood pressure levels 10 minutes after administration of IN Midazolam in patients undergoing surgical removal of impacted lower third molar (13).

-Anxiety

Chen *et al*., in a systematic review, evaluated the efficiency of Midazolam in the management of anxiety for third molar removal surgery and concluded that this medication can be efficient in relieving anxiety of the patients and can be administered

safely, either alone or with other drugs (4). A conclusion that supports the results of the present study.

Michalek-Sauberer *et al*. stated that there was a reduction in anxiety scores in patients undergoing dental extraction after administration of IN Midazolam (28), which is in agreement with the present study. The present study finding is also in agreement with Kiran *et al*. (6) and Kunusoth *et al*. (23), who both used IN Midazolam for sedation of patients undergoing surgical removal of IMTM. Both studies reported that there was a significant decrease in the anxiety scores from the pre-operative to the post-operative period

Dellovo *et al*. stated that twenty-five (83.3%) of the study patients showed less anxiety when oral Midazolam was used for patients undergoing surgical removal of IMTM (26), an observation which may support the present study. The reduced post-operative Corah's DAS scores in the Midazolam group of the present study are consistent with Li *et al*., who stated that the Modified Dental Anxiety Scale scores following surgery were significantly lower in both Remimazolam and Midazolam groups than before the surgical removal of impacted teeth (2).

CONCLUSIONS

Within the limitations of the current study, it is possible to conclude that:

1. Intranasal administration of Intranasal is recommended as a safe, reliable, and effective conscious sedation for anxious patients during the surgical removal of impacted mandibular third molars.
2. Delivery of intranasal Midazolam is relatively painless, non-invasive, easy with a minimum of training, and socially acceptable.
3. Anxiolysis noticed in patients in the Midazolam group was better as compared to that observed in patients in the Placebo group.

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Authors' Contribution

Conceptualization: Al-Shamaa RS., Delemi ZH., Khudhur AS. Formal analysis: Al-Shamaa RS., Delemi ZH., Khudhur AS. Funding acquisition: Al-Shamaa RS., Delemi ZH. Investigation: Al-Shamaa RS., Delemi ZH. Methodology: Al-Shamaa RS., Delemi ZH. Project administration: Delemi ZH., Khudhur AS. Resources: Al-Shamaa RS., Delemi ZH., Khudhur AS. Software: Al-Shamaa RS. Supervision: Delemi ZH., Khudhur AS. Visualization: Al-Shamaa RS., Delemi ZH., Khudhur AS. Writing–original draft: Al-Shamaa RS. Writing–review editing: Delemi ZH., Khudhur AS. All authors have read and approved the final manuscript.

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Ethical statement: This research was conducted in compliance with ethical standards and received approval from the Research Ethics Committee and Scientific Committee of the Department of Dental Basic Science, College of Dentistry, University of Mosul, under the reference number **(UoM.Dent/ H.66/ 22).** Informed consent was obtained from all participants. The participants in the current study gave their verbal and written agreement. The research goal was explained to the participants, and they were assured of the privacy and confidentiality of their data.

Conflict of interest

The authors declare that there are no conflicts of interest regarding the publication of this manuscript

Availability of data and materials: All data generated or analyzed during this study are included in this published article and its supplementary information files.

Declaration of Generative AI and AI-assisted technologies

During the preparation of this work, the authors did not use any of the AI tools. The authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

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تقييم تأثير التخدير الأنفي باستخدام ميدازولام على تقليل القلق لدى المرضى الذين يخضعون لجراحة ضرس العقل السفلي

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الملخص

الأهداف: تهدف الدراسة الحالية إلى تقييم فعالية التخدير الأنفي بالميدازولام على الحد من القلق للمرضى الذين يخضعون للقلع الجراحي لأضراس العقل السفلية المطمورة. **المواد وطرائق العمل:** تم تضمين ثلاثين شخصا سليما في هذه الدراسة من كلا الجنسين. تراوحت أعمارهم بين (١٨-٤٠) سنة، والذين كانوا يسعون للإزالة الجراحية لأضراس العقل السفلية المطمورة تحت التخدير الموضعي وكان لديهم مستويات متوسطة إلى شديدة من القلق. تم تقسيم المرضى بشكل عشوائي إلى

مجموعتين، المجموعة الأولى: مجموعة الميدازولام (مجموعة الدراسة) تضمنت خمسة عشر مريضًا تم اعطاؤهم الميدازولام الأنفي بتركيز (٢ ،٠) ملغم / كغم من وزن الجسم قبل عشر دقائق من الإزالة الجراحية لأضراس العقل السفلية المطمورة، المجموعة الثانية: مجموعة الدواء الوهمي (المجموعة الضابطة) تضمنت خمسة عشر مريضًا تلقوا دواءً وهميًا عن طريق الفم من كبسولة مسحوق الجلوكوز قبل ساعة واحدة من الإزالة الجراحية لأضراس العقل السفلية المطمورة. تم تقييم المعايير التالية: ضغط الدم الانقباضي وضغط الدم الانبساطي ودرجة القلق. خضعت النتائج للتحليل الإحصائي والاختبارات الإحصائية لأجل المقارنة. **النتائج**: فيما يتعلق بقياسات ضغط الدم الانقباضي: كان هناك فرق كبير ذو دلالة احصائية بين مجموعتي الميدازولام والدواء الوهمي بعد تناول الدواء، وكان هناك فرق كبير للغاية ذو دلالة احصائية بين مجموعتي الميدازولام والدواء الوهمي أثناء العملية الجراحية وكذلك في نهاية العملية الجراحية. فيما يتعلق بقياسات ضغط الدم الانبساطي: كان هناك فرق كبير للغاية ذو دلالة إحصائية بين مجموعتي الميدازولام والدواء الوهمي بعد تناول الدواء، أثناء العملية الجراحية وفي نهاية العملية الجراحية. فيما يتعلق بالقلق: كان هناك فرق كبير للغاية بين مجموعتي الميدازولام والدواء الوهمي بعد الجراحة. **الاستنتاجات**: ان إعطاء الميدازولام الأنفي كتخدير واعٍ آمن، موثوق وفعال للمرضى القلقين أثناء الإزالة الجراحية لأضراس العقل السفلية المطمورة.

الكلمات المفتاحية: القلق، عن طريق الأنف، ميدازولام، التخدير، الأضراس