SHORT COMMUNICATION

Use of pre-operative Midazolam as oral sedation for anxiety reduction amongst patients scheduled for dental extractions under local anaesthesia

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Abstract

Anxiety is a common observation that warrants attention especially for patients scheduled for surgical tooth extraction. A quasi-experimental study was carried out that included sixty (60) patients, booked for surgical extraction at Baqai Dental College, Karachi, Pakistan. Baseline respiratory rate (RR), and blood pressure (BP) were recorded before the administration of the 7.5mg Midazolam (test group). The subjects waited for one hour before the commencement of the dental extraction. The BP and RR were checked again, and the level of anxiety was registered on the modified dental anxiety scale. A significant reduction in the systolic BP, diastolic BP, and RR were observed amongst the participants who were administered pre-procedure Midazolam (p-value <0.001). However, compared to controls, only diastolic BP (p=0.003) and RR (<0.001) reduced significantly in the test group with no notable change in the systolic BP (p-value=0.119).

Keywords: Midazolam; Anxiety; Dental extraction; Sedation.

DOI: https://doi.org/10.47391/JPMA.22038

Introduction

Fear and anxiety before any dental procedure is common among patients of all ages.[1] Anxiety is a complex multi-dimensional phenomenon which is dependent upon the perceived threat and danger of a surgical procedure, pain, anaesthesia, and/or the outcome of the surgery.[2,3] Despite advances in anaesthetic agents, fear of dental procedures continues to exist. Among commonly feared situations, dental anxiety has been ranked the fifth most common.[4] Behavioural problems are seen mostly in younger patients due to various elements such as immature reasoning, restricted coping skills, and anxiety/fear.[5] Although, the anxiety can be reduced with the use of anxiolytic drugs, the management of such patients is mostly challenging.

Several groups of sedatives are available, amongst which Benzodiazepines are the most commonly used.[2] Benzodiazepines are also widely used as anxiolytics prior to surgery. These anxiolytic drugs possess hypnotic, anticonvulsant, muscle relaxant, and ante grade amnesic properties.[3-5] The relatively high margin of safety compared to other sedative-hypnotic medications and the availability of an effective reversal agent (Flumazenil), makes the use of Midazolam an attractive choice for invasive dental procedure in an outpatient setting.[6]

Midazolam is a member of the Benzodiazepine family of sedatives and hypnotics. It is used as pre-anaesthetic medication and as an adjunct during surgical procedures performed under local or general anaesthesia.[4] Among available Benzodiazepines, Midazolam has a rapid onset of action, rapid recovery, and a short elimination half-life (2-4 hours); a feature which makes it potentially useful for short-acting anxiolysis. The dose dependent effects of Midazolam include sedation, relief of anxiety, anterograde amnesia, hypnotic, anti-convulsant, anaesthesia, and muscle relaxant.[4]

This study aims to compare the role of pre-operative oral Midazolam in reducing anxiety and fear among patients scheduled for surgical dental extraction.

Patients / Methods and Results

A total of 60 patients were included in this study. The duration of the study was four months, from September 2020 to January 2021. All the patients had dental extraction at the department of oral & maxillofacial surgery, Baqai Dental College, Baqai Medical University, Karachi. The protocol of this study was approved by the institutional review board (BDC/ERB/2018/012). Written informed consent was obtained from all the patients. The inclusion criteria comprised male and female patients scheduled for dental extraction for the first time. Medically compromised patients, subjects with ischaemic heart disease, asthma, impaired liver or renal function, alcohol consumption or already on Midazolam, or with

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Submission complete: 07-10-2024 **First Revision received:** 17-01-2025

Acceptance: 29-11-2025 **Last Revision received:** 28-11-2025

Table-1: Association of factors affecting anxiety in the participants using Modified Dental Anxiety Scale

No.	Question	p-value
1	If you went to your dentist for treatment tomorrow,	0.77
2	If you were sitting in the waiting room (waiting for treatment), how would you feel?	0.40
3	If you were about to have your tooth drilled, how would you feel?	0.08
4	If you were about to have your teeth scaled and polished, how would you feel?	0.31
5	If you were about to have a local anaesthesia injection into your gum, above and upper back tooth, and how would you feel?	0.19

known allergy to Midazolam, and pregnant or lactating women were excluded. The study participants were randomly assigned to the two groups (Group A and B). Group A (control) received 500mg Paracetamol and Group B (test) received 7.5mg oral Midazolam, one hour prior to dental surgery. Baseline respiratory rate (RR) and blood pressure (BP) were recorded before the administration of the pre-anaesthetic medication (7.5mg oral Midazolam), and patients were asked to wait for an hour before the start of the dental extraction. After one hour patients' BP and RR were re-examined and their level of anxiety was checked by asking them to fill-in a proforma based on the modified dental anxiety scale (MDAS). This scale comprised five questions, each with a 5-category ordinal scale where: 1= not anxious, 2= slightly anxious, 3= moderately anxious, 4= very anxious, 5= extremely anxious. The total score on the scale is a sum of all five items, ranging from 5 to 25; cut off 19 and above indicated a highly anxious patient. The data was collected by a blinded assessor using a structured proforma.

Data was analysed on SPSS version 21.0. Descriptive statistics were computed. Paired and independent sample t-test were applied to compare BP and RR within the group and between the groups, respectively. Mann-Whitney U test was applied to compare the two groups for the responses gathered using Modified Dental Anxiety Scale (MDAS).[7] The level of significance was kept at 0.05.

A total of 60 patients, 37 females and 23 males between the ages of 15-50 years were included in the study. The mean age of the participants in the test group (19 females and 11 males) was 31.3±10.6 years and the control group (18 females and 12 males) was 30.7±11.2 years, respectively. There were no statistically significant differences in the dental anxiety levels between the test and control groups assessed using the MDAS (p-value: 0.77, 0.40, 0.08, 0.31, and 0.19; Table 1). A significant reduction in the systolic BP, diastolic BP, and RR was observed within the test group before and after the administration of Midazolam (p-value <0.001). However,

Table-2: The before-after difference between the parameters with the administration of oral Midazolam (n= (60).

Variable	Test group (n=30)	Control group (n=30)	p-value*
Age of the participant (in years)	31.30±10.6	30.77±11.2	0.851
Systolic BP before Midazolam (mmHg)	138.73± 23.0	137.50±19.8	0.825
Systolic BP after Midazolam (mmHg)	129.87± 17.7	137.53±19.8	0.119
Difference: p-value**	<0.001	0.995	
Diastolic BP before Midazolam (mmHg)	83.23± 9.9	83.30±8.7	0.976
Diastolic BP after Midazolam (mmHg)	76.33± 8.7	83.20±8.8	0.003
Difference: p-value**	<0.001	0.964	
Respiratory rate before Midazolam (per minute)	18.70± 1.9	18.93±1.0	0.559
Respiratory rate after Midazolam (per minute)	14.53± 2.6	19.00±1.0	<0.001
Difference: p-value**	<0.001	0.787	

*Within the group comparison using independent sample t test
**between the group comparison using Paired t test
Bold value signifies statistical significance

between the group comparison showed that at baseline, both groups were comparable but upon one hour of administration of Midazolam, only diastolic BP (p=0.003) and RR (<0.001) reduced significantly with no notable change in the systolic BP (p-value=0.119). (Table 2)

Discussion

Encountering subjects with high levels of anxiety is not uncommon in dental practice. It's imperative to address anxiety among patients, especially if their dental procedure is scheduled under local anaesthesia and is invasive in nature. The patients, who are calm and composed, are likely to cooperate better and thus expected to get predictable outcomes of the treatment. Midazolam has been suggested as an oral pre-medication for anxiety management. It has a short half-life, a feature which makes it potentially useful as an anti-anxiety medication in a day care surgery. Other desirable features are hypnosis, sedation, amnesia, muscle relaxant, and haemodynamic stability.[4]

The present study was conducted to evaluate the role of Midazolam in reducing anxiety during dental extractions under local anaesthesia. It was observed that both respiratory rate as well as diastolic BP reduced significantly among patients who took pre-procedure Midazolam. The systolic BP also reduced but the difference was not significant. (Table 2)

Jerjes et al. observed 38 male patients who were given oral Midazolam before dental extraction under general anaesthesia.[8] They observed a drop in BP and RR but the reduction was not statistically significant. Also, the Hospital Anxiety and Depression Scale (HADS)[9] scores

showed no difference in the study groups. This study contradicts the findings of the present study as it observed a statistically significant difference between the treatment and placebo groups for the above parameters.

A study conducted by Ahmed et al. evaluated the role of oral Midazolam as pre-medication in day care surgery in adult Pakistani patients.[10] They studied 50 patients who were administered oral Midazolam one hour prior to surgery. A significant difference was noticed in the mean heart rate and BP in both the groups. The finding of this study is in agreement with the present study. McMillan et al. studied 80 children with oral Midazolam as pre-medication. They observed no significant change in the heart rate, arterial oxygen saturation, and anxiolysis.[11]

Bell showed a significant decrease in the anxiety level and higher number of sedated patients in the Midazolam group compared to placebo group.[12] Although the findings of their study is consistent with the present study, the inclusion criteria were different as only children were included in that study.[12]

The present study suggests that administration of 7.5mg oral Midazolam reduced anxiety levels in individuals undergoing dental surgery under local anaesthesia with no drug related complications observed. However, care must be taken as these patients may need peri- and post-operative ambulatory support for the next few hours to prevent fall injuries. The limitation of the current study was that it was a quasi-experimental study done at a single centre with limited sample size. Thus, the generalisability is limited. This emphasises the need for a large scale trial on the effectiveness of oral Midazolam as a premedication in patients for day care surgery.

Conclusion

A significant reduction in the blood pressure and respiratory rate was observed among individuals who received pre-operative oral Midazolam compared to placebo.

Disclaimer: None.

Conflict of Interest: None.

Source of Funding: None.

Contributions: All authors have contributed intellectually; they have read and approved the final manuscript.

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AUTHOR'S CONTRIBUTION:

HKS: Concept, design, performed the experiments, data collection and writing.

FRK: Data analysis and critical review.
WA & MC: Performed the experiments.
NB & JS: Data analysis.