

A Comparison of Preoperative Psychological Preparation with Midazolam Premedication to Reduce Anxiety in Children Undergoing Adenotonsillectomy

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Abstract

Introduction: Considering the multiplicity of adenotonsillectomy in children 2–10-year old at the paediatric surgery centres, patient anxiety leads to an increase in surgical and anaesthetic complications. Patients' unfamiliarity with surgical and anaesthetic interventions may increase their stress. Midazolam premedication reduces patient anxiety. In previous studies, psychological preparation before surgery using understandable terms to children, has reduced their anxiety. The aim of this study was to compare and study behavioural reflections among the children in two groups: the first group was prescribed oral midazolam, and the second group received psychological preparation with the booklet about anaesthesia and anaesthesia-resident explanation. **Materials and Methods:** This study is a clinical trial conducted on 48 children undergoing adenotonsillectomy. Children in the first group (midazolam group) received oral midazolam 0.5 mg/kg, 20 min before surgery. A booklet containing pictures and information about anaesthesia and the operating room was given to the second group (psychological preparation group) the night before surgery and anaesthesia resident explained the booklet to the children. The anxiety level was measured in both groups using the State-Trait Anxiety Inventory for Children questionnaire the night before surgery and on the morning of surgery (after giving midazolam to Group II). The results were analysed using SPSS. **Results:** In this study, 58.3% of the first group and 45.8% of the second group were male. The mean age of the first and second groups was 8.45 ± 1.86 and 9.12 ± 1.72 years, respectively. The anxiety in the first group significantly decreased in the morning before surgery compared to the night before operation ($P < 0.001$). The anxiety in the second group significantly decreased in the morning before surgery compared to the night before as well ($P < 0.001$). **Conclusion:** The results showed that midazolam and psychological preparation prior to surgery can reduce the anxiety of children before adenotonsillectomy.

Keywords: Adenotonsillectomy, children anxiety, midazolam, premedication, psychological preparation

INTRODUCTION

Millions of children undergo surgery every year and most of these children develop significant anxiety before surgery. About 50% of children show different reactions of anxiety during anaesthetic induction.^[1] Anxiety before surgery is aligned with clinical, behavioural and psychological side effects such as delay in recovery, the increasing need for analgesic and new behavioural disorders.^[2,3] Anxiety before surgery increases the stress hormones, leading to an increase of serum cortisol and epinephrine. These stress responses are stimulated by different stimuli such as fear, anxiety, pain, cold, infection and surgery.^[4] There are different ways to reduce children's anxiety, including sedation with various drugs, parent-child

psychological preparation before surgery and creation of a good relationship between parents, children and medical staff through group training. Methods such as psychological preparation through video, toys and books, carrying patient to surgery room by toy wagon, use of clowns and scented masks in the form of toys at induction have been used at various centres to reduce children's anxiety while waiting for surgery. Parents' presence during induction has reduced children's anxiety in some studies. However, parents' presence

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in the operating room has increased children's anxiety in other studies.^[5] Nonpharmacologic interventions before surgery on children and parents (including video training, training with an illustrated manual, hypnotherapy and acupuncture) with premedication using sedatives have been compared in several studies.^[6-8] It has been reported that many interventions are less effective or as effective as midazolam in reducing anxiety.^[9] In other studies, the presence of parents during induction with premedication using midazolam or the presence of parents throughout the procedure and premedication (midazolam) has been compared. In some studies, midazolam has been preferred to the presence of parents.^[9] Midazolam premedication has been used in the Tabriz University children's Hospital in recent years to reduce separation anxiety from parents. This study aimed at creating a psychological preparation before surgery by anaesthesiology residents and comparing children's anxiety with a group receiving midazolam premedication. The booklet in the psychological preparation group contained useful information about anaesthesia which was prepared (in accordance with the regional culture) by the anaesthesiologist in the university children's hospital and was put at the patients' and their parents' disposal.^[10]

MATERIALS AND METHODS

This study is a single-blind clinical trial in the operating room of University Children's Hospital after obtaining the approval of the medical school ethics committee and informed consent of the parents, 48 children admitted to hospital were included in the study. A sample size of 21 was calculated for each group based on the study of Lehman^[11] and using online software (<http://www.stat.ubc.ca/~rollin/stats/ssize/nz.html>) considering $\alpha = 0.05$ and power = 80%. The number of patients in each group was increased to 24 people to increase the accuracy of the study. The children were divided randomly into two groups: midazolam premedication ($n = 24$) and psychological preparation ($n = 24$) through a simple sampling method and in order of entering the operating room and using online software available at <http://graphad.com/quickcalcs/randomized.cfm>. All candidate of adenotonsillectomy who were 6 years or older and without underlying disease (ASA I or II) were included in this study. Unwillingness of parents to participate in the study, emergency surgery, children with chronic diseases, a history of hospitalization and medication and illiterate parents were exclusion criteria. Surgeries were performed under general anaesthesia for both groups. The level of anxiety in children was measured the night before surgery in both groups (before any intervention). On the day of surgery, midazolam group received 0.5 mg/kg oral midazolam (midazolam maleate - 2.5 mg/1 mL manufactured by Amsed UK) with 20–30 ml of water 20–30 min before entering the operating room. The level of anxiety in children was measured the night before surgery in the second group (psychological preparation), then they were given a booklet containing information about anaesthesia and operating room practice and psychological preparation was

provided by an anaesthesia resident. The second group of children was asked to read the booklet prepared by paediatric anaesthesiologist. The anxiety of children was measured and scored twice in both groups, once the night before surgery and the second time in the morning just before entering the operating room, using the State-Trait Anxiety Inventory for Children. The STAIC (the State-Trait Anxiety Inventory for Children) containing 20 questions, each question represent three modes. To assess children's anxiety, the questionnaire contained 20 questions that 10 was scored on the basis of direct and 10 on reverse direction of scoring (positive emotion score 1, negative emotion score 3, intermediate emotion score 2). In this way the minimum score for children was 20 and maximum score was 60. The scores equal or less than 33 represented weak anxiety, scores equal or more than 43 sever anxiety, other scores showed intermediate anxiety. The questions contained the following items: being calm, being confused, being cheerful, being nervous, being angry, being relieved, being scared, being at peace, being worried, being pleased, being threatened, being happy, being confident, feeling good, having problems, being anxious, being pleasant, being panicked, being confused and being hopeful. The questions were scored in a way that half the questions had positive scales and half the questions were reversed (positive feeling: 1, feel in between: 2 and negative feeling: 3). The minimum and maximum scores obtained were 20 and 60, respectively. Scores less than or equal to 33 indicate mild anxiety, more than or equal to 47 indicate severe anxiety and scores between 33 and 47 moderate anxiety. The resident who completed questionnaire was unaware (blind) about type of preparation. Once the data were collected and coded, SPSS 16 (SPSS Inc. Chicago, IL) was used for statistical analysis using Chi-squares and *t*-tests and in the form of tables and graphs through descriptive statistics. The significance level was considered to be $P < 0.05$ in all tests listed. All personal information of the patients was kept confidential and none of the patients' names were mentioned in the study.

RESULTS

In this study, 48 patients were equally divided into two groups. The number of male patients was 14 in the midazolam group (58.3%) and 11 (45.8%) in the psychological preparation group ($P = 0.386$). The mean age of the children in the midazolam group and the psychological preparation group was 8.45 ± 1.86 and 9.12 ± 1.72 years, respectively ($P = 0.205$).

In this study, 20 questions were asked from the children receiving the psychological preparation on the night before surgery (pre-intervention) and on the day of the surgery just before entering the operating room. At first, the impact of the booklet on the children's anxiety reduction was examined and it was found that the distress ($P = 0.034$) and fear ($P = 0.004$) before surgery were reduced and relaxation before surgery ($P = 0.003$) was increased among children in the psychological preparation group. However, other anxiety criteria in the psychological preparation group did not change significantly. The effect of

midazolam on anxiety was also examined in the midazolam group. The results showed that midazolam could only increase the relaxation before the operation in children ($P = 0.015$). It should be noted that midazolam made significant changes in the cheerfulness ($P = 0.022$), pleasure ($P = 0.009$) and panic ($P = 0.021$) in children; however, cheerfulness was reduced and panic was increased in children in the midazolam group.

The patients' anxiety level was analysed by statistical tests. The results showed that the anxiety level of children in the morning before surgery was significantly less than the night before surgery in both midazolam and psychological preparation groups ($P < 0.001$). No significant difference was seen in the level of anxiety between the two groups at the beginning of the night before surgery ($P = 0.861$), and no significant difference was observed after examining children's anxiety on the day of surgery (30 min before surgery) as well ($P = 0.193$) [Table 1].

No significant difference was observed between the two groups in terms of anxiety on the night before

surgery (pre-intervention) ($P = 0.598$) or on the morning of surgery ($P = 0.312$). The severity of anxiety was also studied in the two groups at different times. The results showed that anxiety in both groups significantly decreased on the morning of surgery (30 min before surgery) ($P < 0.001$). The children's heart rate significantly increased before surgery compared to the night before surgery in both the psychological preparation group ($P = 0.002$) and the midazolam group ($P = 0.012$). The increased heart rate difference in the midazolam group was lower than in the psychological preparation group, but the difference was not statistically significant ($P = 0.663$). No significant difference was observed between the two groups comparing the average heart rate the night before surgery and the morning of surgery ($P = 0.597$ night; $P = 0.941$ morning).

The systolic blood pressure in both groups significantly increased before surgery in the morning (30 min before the operation) compared to the night before surgery ($P < 0.001$ in both groups). Although the psychological preparation group was higher than the midazolam group, no statistically significant difference was seen between the two groups in mean systolic blood pressure ($P = 0.707$). In addition, no significant difference was observed in systolic blood pressure between the two groups on the night before surgery ($P = 0.513$) or 30 min before surgery ($P = 0.338$). Diastolic blood pressure of the patients was also examined. The diastolic blood pressure in the psychological preparation group ($P < 0.001$) and the midazolam group ($P < 0.001$) increased significantly on the morning of surgery compared to the night before surgery. The average diastolic blood pressure in both groups the night before surgery ($P < 0.001$) and 30 min before surgery ($P < 0.001$) were also examined [Tables 2 and 3].

Table 1: Comparison of the average amount of anxiety on 'The night before the surgery' and '30 min before surgery'

Group/time	Time/group	Mean anxiety±SD	P
Midazolam	Night before surgery	57.50±6.07	<0.001
	Morning before surgery	36.70±6.03	
Psychological preparation	Night before surgery	59.50±6.07	<0.001
	Morning before surgery	37±5.41	
Night before surgery	Midazolam	57.50±6.07	0.861
	Psychological preparation	59.50±6.07	
Morning before surgery	Midazolam	36.70±6.03	0.193
	Psychological preparation	37±5.41	

SD: Standard deviation

Table 2: Comparison of the mean heart rate, systolic pressure and diastolic pressure in both groups on the 'night before surgery' and '30 min before surgery'

Group/time	Time/group	Mean heart rate±SD	P	Mean systolic pressure±SD	P	Mean diastolic pressure±SD	P
Manual training	Night before surgery	107.70	0.002	115.12±9.60	<0.001	76.62±10.61	<0.001
	Morning before surgery	91.33±13.02		95.50±8.34		62.08±5.69	
Midazolam	Night before surgery	107.29±20.60	0.012	111.75±14.13	<0.001	76.41±11.17	<0.001
	Morning before surgery	93.75±18.00		95.70±10.37		60.62±9.81	
Night before surgery	Psychological preparation	107.70±16.69	0.597	115.12±9.60	0.513	76.62±10.61	0.532
	Midazolam	107.29±21.60		111.75±14.13		76.41±11.17	
Morning before surgery	Psychological preparation	91.33±13.02	0.941	95.50±8.34	0.338	62.08±5.69	0.948
	Midazolam	93.75±18.00		95.70±10.37		60.62±9.81	

SD: Standard deviation

Table 3: Comparison of the mean heart rate, systolic pressure and diastolic pressure changes between two groups

Group	Mean heart rate±SD	P	Mean systolic pressure±SD	P	Mean diastolic pressure±SD	P
Psychological preparation	16.37±6.77	0.663	17.62±13.70	0.707	14.45±9.38	0.675
Midazolam	13.54±5.39		16.04±12.12		15.79±8.99	

SD: Standard deviation

DISCUSSION

In this study, it was observed that preoperative psychological preparation through a booklet containing information on anaesthesia and the operating room practice reduced children's confusion and fear before surgery and increased preoperative relaxation; however, midazolam premedication only increased preoperative relaxation. It was also observed that the psychological preparation did not reduce children's anxiety more than midazolam premedication; anxiety decreased in both groups on the morning of surgery. A number of studies have compared psychological preparation and pharmaceutical premedication in reducing anxiety. In the study of Mohammad Olya *et al.*, it was observed that psychological preparation did not significantly reduce anxiety. Zakeri Moghaddam *et al.* showed that anxiety in a psychological preparation group was significantly less than in a control group. Li *et al.*^[12] indicated that children receiving mental practical information had less anxiety before and after their surgery. However, their anxiety after surgery showed no significant difference compared to that of the control group. In the study conducted by Guo *et al.*,^[13] preoperative psychological preparation significantly reduced children's anxiety ($P < 0.001$) and depression ($P < 0.001$). Momeni *et al.* showed that patients' anxiety decreased after the psychological preparation in both groups compared to the past. Majzoobi *et al.*^[14] study showed that children in a psychological preparation group had less preoperative anxiety compared to a control group. Bahrami *et al.*^[15] discovered that increased vital signs in the group receiving psychological preparation for reducing anxiety were lower than those found in the antianxiety treatment group; however, no significant relationship was seen in the levels of vital signs between two groups. They also observed that serum cortisol level in patients undergoing pharmaceutical treatment compared to a psychological preparation group was significantly lower ($P < 0.01$). Felder-Puig *et al.*^[16] showed that psychological preparation through a booklet could have a great impact on children's anxiety reduction before surgery; this impact and anxiety reduction were statistically significant. A study carried out by Seyedhejazi *et al.*^[17] in 2015 on children candidates for surgery and their parents showed that simultaneous psychological preparation of children and their mothers could be effective at reducing preoperation anxiety.^[20] Considering the aforementioned studies, we conclude that preoperative psychological preparation can have an impact on children's anxiety levels. However, given that a number of studies have also failed to show such a relationship, it is likely that there are many factors which increase or decrease children's anxiety. These factors may include the mother's education level, the type of underlying disease, the children's history of surgery and the type of surgery. Some other studies have also been conducted on adults in this area: a number of these studies failed to show a relationship between stress level and psychological preparation. In the Rahnmani *et al.* study,^[18] it was shown that anxiety decreased before surgery in both a psychological preparation group and an antianxiety medication

receiving group. The reduction in the psychological preparation group was higher than that seen in the pharmaceutical group; however, the difference was not statistically significant. The results of the Salzwedel *et al.* study^[6] showed that an educational video program had no significant effect in reducing patients' anxiety but the knowledge of patients in the groups watching film was higher than the control group. In the study of Díez-Álvarez *et al.*,^[19] it has been shown that the patients' anxiety when visited before surgery was 18.96 and 20.03 in the control group, and no significant difference was observed between the two groups. However, the following studies have shown this relationship. The results of Wang and Lin's^[20] study showed that anxiety level of the study group was reduced after nursing education interventions compared to the control group at a confidence level of more than 90% ($P < 0.001$). In their study, Jjala *et al.*^[21] indicated that the patients in the control group experienced more preoperative anxiety compared to that of the training group ($P < 0.001$), and that patients in the psychological preparation group were more relaxed before surgery compared to the control group ($P = 0.004$). In a study done by Nikumb *et al.*,^[22] it was observed that preoperative visiting and providing patients with training information led to anxiety reduction in 26.5% of patients.

Furthermore, some studies examined the pharmaceutical effect on patients' anxiety: Rostami *et al.* showed that 93.3% of the children in a study group (midazolam) separated from parents without crying or mild crying, and 90% of children in the control group separated with moderate and severe crying. The results of Ayatollah and Behdad's study showed that 14% of the children in the first group and 68% in the second group were calm and alert while separating from their parents 20 min after administration of midazolam drops ($P < 0.00001$). It should be noted that while the children's heart rate receiving midazolam was lower than ones receiving psychological preparation (intervention) in the present study, this difference was not statistically significant. The results of this study show that preoperative psychological preparation through a booklet as well as receiving midazolam as premedication reduced children's anxiety before adenotonsillectomy surgery. However, the difference between the two groups was not significant in terms of anxiety reduction.

CONCLUSION

It seems that both midazolam and preoperative psychological preparation decreases the anxiety level of children in the morning of surgery comparing to the night before surgery. We recommend that the pediatric age group must have preoperative preparation with the psychological preparation or midazolam or both.

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Conflicts of interest

There are no conflicts of interest.

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