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Original contribution

The effect of play distraction on anxiety before premedication administration: a randomized trial ☆

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Abstract

Study objective: The majority of children scheduled to undergo surgery experience substantial anxiety in the preoperative holding area before induction of anesthesia. Pharmacological interventions aimed at reducing perioperative anxiety are paradoxically a source of stress for children themselves. Midazolam is frequently used as premedication, and the formula of this drug in Turkey is bitter. We aimed to assess the role of distraction in the form of playing with play dough (Play-Doh) on reducing premedication anxiety in children.

Design: Prospective randomized clinical trial.

Setting: Preoperative holding area.

Patients: One hundred four healthy children aged 3 to 7 years scheduled to undergo elective surgery were enrolled into the study.

Interventions: All children routinely receive sedative premedication (oral midazolam) before anesthesia. Children were randomized to 2 groups to receive either play dough (group PD) (n = 52) or not (group C) (n = 52) before administration of oral premedication.

Measurements: Children's premedication anxiety was determined by the modified Yale Preoperative Anxiety Scale (mYPAS).

Main results: The difference in mYPAS scores between groups at T_0 (immediately after entering the preoperative holding area) was not significant ($P = .876$). Compared with group C, group PD was associated with lower mYPAS scores at T_1 and T_2 ($P < .001$). In group PD, mYPAS scores were significantly lower at both T_1 and T_2 as compared with the scores at T_0 ($P < .001$); they were similar between T_1 and T_2 ($P > .001$).

Conclusion: This study showed that distraction in the form of playing with play dough facilitated administration of oral midazolam in young children.

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1. Introduction

The majority of children scheduled to undergo surgery experience substantial anxiety in the preoperative holding area before induction of anesthesia [1,2]. Potential causes of preoperative anxiety are separation from parents, unfamiliar environments and people, and negative anticipation of surgical procedures [1]. Anxiety in the preoperative holding area may manifest itself by facial expressions of fear, trembling, panic, crying, or even combativeness. Preoperative anxiety also has been associated with difficulty in anesthetic induction [2].

Pharmacological interventions aimed at reducing perioperative anxiety are paradoxically a source of stress in children themselves. Oral administration of such drugs may cause refusal, and insistence may aggravate anxiety [3]. Anxiety, in turn, may impair cooperation and induce refusal [4]. Taste is another factor associated with drug compliance [5]. Midazolam is frequently used in premedication [6–8] and routinely used in our department. However, the oral preparation of this drug in Turkey is bitter [9]. Premedication with midazolam, therefore, may not significantly reduce preoperative anxiety but, instead, may aggravate it in some cases if refused. The use of distraction in the form of clowns, video games, and cartoons has been shown to alleviate preoperative anxiety in children [10–12]. Although some of these interventions are more frequently used, others are not due to time constraints, adverse effects, or rising health care costs. Play dough (PD) is a simple, inexpensive toy enjoyed by the majority of preschool- and elementary school–aged children.

We performed this randomized, placebo-controlled study to test the hypothesis that playing with play dough would reduce premedication anxiety in preschool children undergoing elective surgery.

2. Methods

The study took place in August and September 2013 in Ministry of Health Yildirim Beyazit Diskapi Education and Research Hospital. Children were prospectively and consecutively enrolled in the study after their parents provided written informed consent [13]. The study protocol was approved by the Institutional Ethics Committee (reference no. 4/65, 24/09/2012) and was registered in the Australian New Zealand Clinical Trial Registry prospectively (ACTRN12613000928718).

One-hundred four healthy children aged between ages 3 and 7 years and scheduled to undergo elective urogenital surgery under general anesthesia were enrolled into the study. Children with a history of previous anesthesia, chronic disease, prematurity, and growth retardation and those with an impaired vision or hearing were excluded. Children were randomized through sealed envelope method into either the PD (group PD) (n = 52) or no PD (group C) (n = 52) by the anesthesiologist. The primary end point of this study was the anxiety manifested by children at the time of premedication administration.

All operations were scheduled in the morning, and all children are accompanied by their parents. An anesthesiologist assessed all the patients' level of anxiety using the modified Yale Preoperative Anxiety Scale (mYPAS), immediately after entering the preoperative holding area (T0). After 3 minutes of waiting in the preoperative holding area, group PD received PD and allowed to play with it for 6 minutes. An anesthesiologist assessed the patients' level of anxiety using mYPAS just after playing with PD (T_1). T_2 was assessed during administrating 0.5 mg/kg oral midazolam 5 minutes after T_1.

In group C, children waited for 9 minutes in the preoperative holding area. After this 9 minutes, an anesthesiologist assessed the patients' level of anxiety using the (mYPAS) (T_1). T_2 was assessed during administrating 0.5 mg/kg oral midazolam 5 minutes after T_1. Children in the control group were rewarded with a PD after surgery.

The level of anxiety in children was assessed in the preoperative holding area using the mYPAS [14]. The mYPAS, which is an observational checklist consisting a total of 22 items in 5 domains: activity, emotional expressivity, state of arousal, vocalization, and the use of parent, is accepted as a reliable tool for assessing children's anxiety during the perioperative period. Total score varies between 22.5 and 100, and higher scores correlate with greater anxiety [14].

2.1. Statistical analysis

We used the SPSS version 11.5 (SPSS, Inc, Chicago, IL) to perform statistical analyses. We used the Shapiro-Wilk test to assess the normality of variables. Continuous variables were summarized with median (minimum-maximum) and percentage. We performed Pearson χ^2 test on categorical variables and Mann-Whitney U test, Friedman test, and Wilcoxon signed rank test on continuous variables. We also used the repeated-measures analysis of variance with the SPSS generalized linear model approach. Statistical significance was set at $P \leq .05$.

The sample size of 43 per group was determined by using 28 ± 8 as the mean ± SD values of the mYPAS scores reported for children and by assuming that a reduction of 5 U in the anxiety score would be significant at .05 (α) for type I and 0.2 (β) for type II error [14,15].

3. Results

In August and September 2013, we enrolled 109 patients to the study (54 to group PD, 55 to group C) but dismissed 4 patients because of upper airway infection and 1 family refused the operation in the preoperative holding area so the study ended with 52 patients in each group (Fig. 1).

Group PD and group C were well matched in relation to age (P = .876), sex (P = .556), and body weight (P = .926) (Table 1).

The difference in mYPAS scores between groups at T_0 was not significant (P = .876), but group PD has significantly lower scores at T_1 and T_2 than group C (P < .001, for both