



Randomized-controlled trial of parent-led exposure to anesthetic mask to prevent child preoperative anxiety

Étude randomisée contrôlée d'une exposition des enfants au masque anesthésique par un parent pour prévenir l'anxiété préopératoire des jeunes patients

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Abstract

Purpose To examine the efficacy of parent-directed anesthetic mask exposure and shaping practice to prevent child preoperative anxiety, with a specific focus on timing of exposure.

Methods This randomized-controlled trial included 110 children ages four to seven years undergoing day surgery dental procedures and their parents. Families were randomly assigned to one of three groups: 1) parent-directed mask exposure/shaping practice at least three times in the week prior to surgery (Group 1); 2) parent-directed mask exposure/shaping practice at least once on the day of surgery (Group 2); 3) no exposure prior to induction (Group 3). Child anxiety was observer-rated using the modified Yale Preoperative Anxiety Scale during the day surgery experience, and induction compliance was observer-rated using the Induction Compliance Checklist.

Results Results demonstrated significant differences in observer-rated child anxiety at anesthetic induction across groups. Group 2 demonstrated significantly lower observer-rated anxiety than Group 3 with a medium effect, $F(1, 71) = 4.524$, $P = 0.04$, $\eta_p^2 = 0.06$. A significant interaction was observed between these two groups over time (i.e., admission to anesthesia induction), $F(1, 71) = 4.365$, $P = 0.04$, $\eta_p^2 = 0.06$ (i.e., small to medium

effect). Group 2 demonstrated the best anesthesia induction compliance (i.e., significantly lower scores than Group 3, $P = 0.04$).

Conclusion Timing of the delivery of mask exposure (i.e., on the day of surgery) to address child preoperative anxiety and induction compliance in the day surgery setting may be an important consideration. The current results inform the integration of this simple, effective strategy into practice.

Résumé

Objectif Examiner l'efficacité d'une exposition au masque anesthésique menée par un parent et détermination d'une pratique visant à prévenir l'anxiété préopératoire de l'enfant en se concentrant spécifiquement sur le moment de l'exposition.

Méthodes Cette étude randomisée contrôlée a inclus 110 enfants âgés de quatre à sept ans subissant une procédure dentaire en chirurgie d'un jour et leurs parents. Après randomisation, les familles ont été assignées à l'un des trois groupes suivants : 1) exposition au masque/pratique de modelage comportemental dirigée par le parent au moins trois fois dans la semaine précédant l'intervention (Groupe 1); 2) exposition au masque/pratique de modelage comportemental dirigée par le parent au moins une fois le jour de la chirurgie (Groupe 2); 3) aucune exposition avant l'induction (Groupe 3). L'anxiété de l'enfant a été évaluée par un observateur utilisant l'échelle mYPAS (échelle modifiée d'anxiété préopératoire de Yale) au cours de l'expérience le jour de la chirurgie et la conformité de l'induction a été évaluée par un observateur utilisant l'ICC (liste de vérification de la conformité de l'induction).

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Résultats *Les résultats ont mis en évidence des différences significatives entre les groupes sur l'anxiété de l'enfant évaluée par un observateur au moment de l'induction anesthésique. Le Groupe 2 a présenté une anxiété évaluée par l'observateur significativement inférieure à celle du Groupe 3 avec un effet médian $F(1, 71) = 4,524$, $P = 0,04$, $\eta_p^2 = 0,06$. Une interaction significative a été observée entre ces deux groupes au fil du temps (c'est-à-dire entre l'admission et l'induction de l'anesthésie), $F(1, 71) = 4,365$, $P = 0,04$, $\eta_p^2 = 0,06$ (soit un effet petit à moyen). Le Groupe 2 a manifesté la meilleure conformité de l'induction de l'anesthésie (c'est-à-dire, des scores significativement inférieurs au Groupe 3, $P = 0,04$).*

Conclusion *Il peut être important de tenir compte du moment de l'exposition au masque (c'est-à-dire le jour de l'intervention) pour répondre à l'anxiété préopératoire de l'enfant et à la conformité de l'induction dans le cadre de la chirurgie d'un jour. Les résultats actuels renseignent sur l'intégration de cette stratégie simple et efficace dans la pratique.*

Researchers and clinicians have sought pharmacological and non-pharmacological interventions to prevent child preoperative anxiety (experienced in 40–60% of cases),¹ the resulting noncompliant behaviour at anesthesia induction,² (e.g., inconsolable crying, screaming and thrashing,³ requiring restraint),⁴ and development of maladaptive behaviours post-surgery.^{5,6} Presurgical anesthetic mask exposure is one non-pharmacological intervention that has demonstrated promising research support.^{7–12} Nevertheless, most studies had methodological limitations (i.e., no comparison group or standardized measure of child anxiety).^{7,8} An exception is a study by MacLaren and Kain,¹² who examined the efficacy of a brief, standardized, parent-directed anesthetic mask exposure and shaping protocol on the day of surgery against a control group who received standard care. Results demonstrated that the exposure intervention significantly decreased anxiety and improved compliance at anesthetic induction. Nevertheless, findings highlighted that the timing of the exposure intervention required further examination. The application of an anesthetic mask exposure protocol may be even more effective if initiated before the day of surgery.¹³

The present randomized-controlled trial (RCT) examined the efficacy of parent-directed exposure and shaping practice to the anesthetic mask as a stand-alone intervention for the prevention of preoperative anxiety in children (employing MacLaren and Kain's¹² anesthetic mask exposure protocol), with a specific focus on the

timing of the intervention. Our hypotheses were fourfold: 1) children in the group who received anesthesia mask exposure and shaping practice during the week prior to surgery (Group 1) would have lower observer-rated anxiety scores than children in the group who received anesthesia mask exposure and shaping practice on the day of surgery (Group 2) and children in the group who received no anesthesia mask exposure and shaping practice (Group 3) throughout the day of surgery and at induction of anesthesia; 2) children in Group 1 would have lower observer-rated anesthetic induction compliance scores (i.e., better compliance) than children in Groups 2 and 3; 3) parents of children in Group 1 would have lower self-reported state anxiety scores than parents of children in Groups 2 and 3 throughout the day of surgery; 4) observer-rated anxiety scores throughout the day of surgery for Group 2 would be similar to those reported in the benchmark study.¹² The study hypotheses were pre-registered in February 2016 through Open Science Framework (registration number: osf.io/wc4k8).

Method

Harmonized ethics approval from the Universities of Regina and Saskatchewan, and Regina Qu'Appelle and Saskatoon Health Region Research Ethics Boards was obtained in April 2016. Child participants underwent day surgery dental procedures (e.g., extractions, fillings, caps) under general anesthesia via anesthesia mask induction at a local surgical centre. Induction was standardized to inhalation by mask. The providers consisted of The Royal College of Physicians and Surgeons of Canada-certified anesthesiologists with varying levels of experience. Exclusion criteria included a history of central nervous system disease, liver disease, renal disease, cancer, neurological or cognitive impairment or disease, and participation barriers (e.g., reading and responding to questionnaires or following written instructions in English). Cases that were considered inappropriate (e.g., significant deviation from study protocol in that the anesthesiologist showed a movie or allowed the child to play a video game during anesthesia induction) were also excluded. Families who met inclusion criteria and consented to participate were randomized by the principal investigator (using a computer-generated random number table)¹⁴ into one of the three aforementioned experimental conditions following Consolidated Standards of Reporting Trials (CONSORT) guidelines.

One parent of each participating child completed a consent form, a brief child and parent demographics form, and baseline measures of parent self-reported trait anxiety

(Trait version of the State Trait Anxiety Inventory [STAI]¹⁵ and child temperament (Emotionality, Activity, Sociability, Impulsivity [EASI]¹⁶ scale) via SurveyMonkey. The measures employed are the most widely used measures in child preoperative literature. Participants in Group 1 were mailed an anesthesia mask, practice pamphlet, and practice tracker sheet and asked to practice at least three times prior to the day of surgery. Participants in Group 2 were given the anesthetic mask and practice pamphlet on the morning of surgery. Participants in Group 3 (control group) were not exposed to the anesthesia mask prior to surgery. On the day of surgery, parents filled out the measure of parent state anxiety (i.e., STAI) at admission and post-surgery. Child anxiety was observer-rated (modified Yale Preoperative Anxiety Scale [mYPAS])¹⁷ at five time points (i.e., admission, holding area, transfer to operating room (OR), anesthetic induction, and post-surgery) and induction compliance (Induction Compliance Checklist [ICC])⁶ was observer-rated at anesthetic induction by the researcher and research assistants trained as observers.

MacLaren and Kain's¹² exposure protocol was employed with the exception of the removal of two components (i.e., hairnet and adult face mask). We also did not include formal parent training of the protocol; instead, we provided the standardized exposure protocol via pamphlet to allow us to evaluate parent-delivery of the protocol without assistance. The pamphlet provided parents with instructions on how to direct the shaping procedure with their child. Instructions for the following approximations were provided sequentially: a) child holds anesthesia mask to his/her mouth; b) child breathes into anesthesia mask while holding mask over his/her mouth; c) child breathes into anesthesia mask while parent holds mask over his/her mouth; d) child breathes into anesthesia mask while holding mask over his/her mouth and nose; e) child breathes into anesthesia mask while parent holds mask over his/her mouth and nose; and f) child breathes into anesthesia mask while parent holds mask over his/her mouth and nose while lying down, imagining they are in the dentist's office.

Measures

The mYPAS¹⁷ was designed to assess observer-rated preoperative anxiety in children age two years and older in under one minute. The 27-item measure has five behavioural categories: activity, emotional expressivity, alertness and arousal, vocalizations, and interaction with parents. Total scores for each time point range from 23.33 through 100 with higher scores indicating greater

anxiety.¹⁷ In the current study, a secondary rater was present for 50% of the participants (i.e., 55 participants). Interrater reliability (via intraclass correlation) at anesthetic induction fell within the excellent range of agreement (intraclass correlation = 0.98).

The ICC⁶ is an 11-item observer-rated measure to examine cooperation at the point of anesthesia induction for children aged two to ten years. The items are rated dichotomously as present or absent, and a score of 0 is considered a "perfect" induction (i.e., no behaviours that could interfere with anesthesia induction). A secondary rater was present for 50% of the participants (i.e., 55 participants). Interrater reliability was in the excellent range (intraclass correlation = 0.98).

The EASI¹⁶ is a 20-item parent-report measure of child temperament that is comprised of four subscales: emotionality, activity, sociability, and impulsivity. Items are rated on a five-point Likert scale, with higher subscale scores indicating higher facets of that temperamental style. Scores range from 5-25 for each temperament. Internal consistency ranged from poor to acceptable: $\alpha = 0.71$ for emotionality, $\alpha = 0.63$ for activity, $\alpha = 0.52$ for sociability, and $\alpha = 0.55$ for impulsivity. This variability is consistent with the literature.¹⁸

The STAI¹⁵ is an adult self-report measure of state (STAI-S) and trait (STAI-T) anxiety. Items are rated on a four-point Likert scale with scores ranging from 20-80. Higher scores indicate greater anxiety. Internal consistency of the STAI-S was excellent at baseline ($\alpha = 0.95$), admission ($\alpha = 0.94$), and post-surgery ($\alpha = 0.95$). Internal consistency of the STAI-T was good (i.e., baseline; $\alpha = 0.88$).

Analytic procedure

Statistical analyses were performed using the Software Package for the Social Sciences (SPSS: version 22.0, IBM Corp., Armonk, NY, USA). Descriptive statistics were computed for demographic variables and measure total and subscale scores (where appropriate). Eight sets of analyses were completed: 1) univariate analysis of variances (ANOVAs) to assess group differences across demographic variables; 2) bivariate correlations between child age and mYPAS and ICC scores at anesthetic induction; 3) bivariate correlations between number of previous surgeries and mYPAS and ICC scores at anesthetic induction; 4) a *t* test between child sex and mYPAS scores; 5) a 3 (group) \times 5 (mYPAS measurement time points) repeated measures ANOVA (with post-hoc tests completed where appropriate) to examine the effect of the exposure intervention on child observer-rated anxiety;

6) a univariate ANOVA (with post-hoc tests where appropriate) to examine the effect of the exposure intervention on induction compliance; 7) a 3 (group) \times 2 (STAI-S at admission vs post-surgery) repeated measures ANOVA to examine the effect of the exposure intervention on parent self-reported anxiety; and 8) *t* tests to compare the current mYPAS scores with those of MacLaren and Kain.¹²

A sample size calculation was performed *a priori* using G*Power software.¹⁹ To conduct the main analysis to answer hypothesis 1 (a mixed design ANOVA) with a medium effect (i.e., partial eta squared of 0.06-0.13) expected, setting power (1- β) at 0.82, with three groups over five time points, the sample size required was 27 participants per group (i.e., 81 participants overall). Nevertheless, we also conducted a univariate ANOVA with fixed effects (omnibus one way) for baseline and specific group differences. Allowing for a medium to large effect (i.e., partial eta squared of 0.06-0.20), setting power (1- β) at 0.80, and having three groups, then 99 participants would be required. Therefore, the target of our data collection was 99 participants.

Results

Recruitment took place between May 2016 and May 2017. Approximately one week prior to surgery, parents of children undergoing surgery were contacted by phone and invited to participate. The principal investigator was provided contact information for potential participants from participating dental clinics, as approved by the health region's research ethics board. Figure 1 shows the CONSORT diagram and flow of participants through the study. Fifty-five parents declined participation, some of whom declined due to previous exposure to a mask (e.g., via previous surgery or administration of medications). After exclusion, 37 children in Group 1 had complete data (measured by complete mYPAS observations at anesthesia induction), 37 children in Group 2 had complete data, and 36 children in Group 3 had complete data. Descriptive statistics were computed for all child and parent demographic variables and study measures (see Tables 1 and 2). Child participants ranged in age from four to seven years to limit developmental variability in cognitive capacity and understanding.

A parent accompanied each child to the OR. No parent was so anxious or upset that he/she was not allowed to be present during anesthesia induction or asked to leave the OR by the healthcare team during anesthesia induction. No child received sedative premedication. All children were given liquid acetaminophen and ibuprofen (15 mL·kg⁻¹ presurgically to reduce postoperative pain.

Preliminary analyses

No significant associations were observed between child anxiety at anesthesia induction or compliance at anesthesia induction with child age, number of previous surgeries, sex, or ethnicity.

Examination of the effect of anesthetic mask exposure intervention

Results from the 3 \times 5 repeated measures ANOVA computed to examine the effect of the exposure intervention on observer-rated child anxiety demonstrated a significant main effect for time, $F(2.11, 225.49) = 43.06$, $P < 0.001$, $\eta_p^2 = 0.29$ (i.e., large effect). Pairwise comparisons with alpha set at 0.01 and with least significance difference post-hoc tests (i.e., equivalent to no adjustment, chosen because of the low number of tests run)^A of mYPAS scores at consecutive time points (Table 3) showed child anxiety at admission (mean (M) = 26.69, standard error (SE) = 0.65) was similar to in the holding area ($M = 25.18$, $SE = 0.38$). Anxiety at holding was significantly lower than at transfer to the OR ($M = 29.70$, $SE = 1.28$). Anxiety at transfer to the OR was significantly lower than at anesthesia induction ($M = 47.84$, $SE = 2.79$). Anxiety at anesthesia induction was significantly higher than at post-surgery ($M = 38.36$, $SE = 1.55$).

The results also demonstrated a significant main effect for group, $F(2, 107) = 3.35$, $P = 0.04$, $\eta_p^2 = 0.06$ (i.e., medium effect). The contrast between time and group was not significant, $F(4.22, 225.49) = 1.70$, $P = 0.15$, $\eta_p^2 = 0.03$. The estimated marginal mean observer-rated child anxiety score for Group 2 ($M = 30.57$, $SE = 1.55$, 99% confidence interval [CI], 26.51 to 34.62) was significantly lower than for Group 3 ($M = 36.24$, $SE = 1.57$, 99% CI, 32.13 to 40.35). The estimated marginal mean anxiety score for Group 1 ($M = 33.85$, $SE = 1.55$, 99% CI, 29.80 to 37.91) did not significantly differ from Group 3.

Visual examination of Fig. 2 suggested a significant difference in mYPAS scores across groups at anesthesia induction. The overall effect of group was not significant, $F(2, 107) = 2.55$, $P = 0.08$, $\eta_p^2 = 0.05$ (i.e., small to medium effect); nevertheless, Group 2 significantly differed from Group 3 at anesthesia induction, $t = -2.07$, 99% CI,

^A Stricter post-hoc tests such as Bonferroni value type I error over type II error. Nevertheless, no correction is recommended if the study is restricted to a small number of planned comparisons. If the results of the individual tests are important, the exact *P* values for each individual test should be quoted and discussed appropriately, and the *P* value cut-off should be adjusted appropriately, as we have adjusted it to 0.01. See Armstrong RA. When to use Bonferroni correction. *Ophthalmic & Physiological Optics* 2014; 34: 502-508.

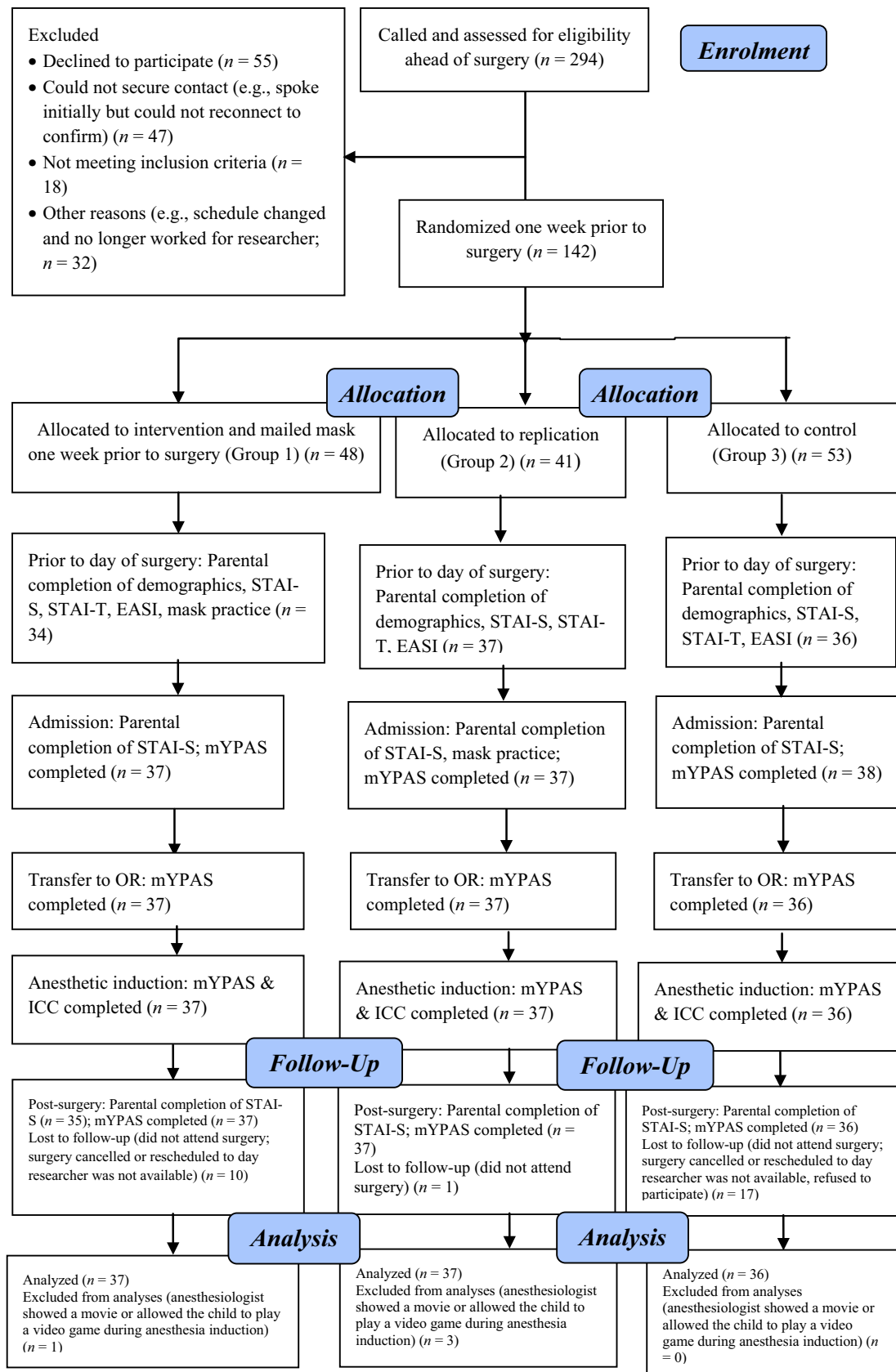


Fig. 1 Overview of participants at each study point

Table 1 Descriptive statistics for demographic variables

	Full sample	Group 1	Group 2	Group 3
Children				
Age, yr	5 (1)	5 (1)	5 (1)	5 (1)
Sex, M:F, %	55:45	54:43	53:47	58:42
Ethnicity, Caucasian	<i>n</i> = 53; 47%	<i>n</i> = 19; 51%	<i>n</i> = 22; 58%	<i>n</i> = 12; 32%
Previous surgery	<i>n</i> = 19; 17.2%	<i>n</i> = 6; 16.2%	<i>n</i> = 4; 10.5%	<i>n</i> = 9; 23.7%
No. previous surgeries, range	1-3	1-2	1	1-3
Diagnosed medical or mental health conditions	<i>n</i> = 11; 10%	<i>n</i> = 6; 16%	<i>n</i> = 2; 5%	<i>n</i> = 3; 8%
Times practiced with anesthesia mask		10 (13)	9 (7)	
Previous surgical procedures, <i>n</i>				
Dental	9	3	1	5
General	5	2	1	2
ENT	4	1	1	2
Ophthalmologic	1			1
Urologic	1		1	
Parents				
Age, yr	34 (8)	34 (8)	34 (7)	35 (10)
Sex, M:F, %	16:84	19:81	16:84	13:87
Mother accompanied only	<i>n</i> = 52; 46%	<i>n</i> = 17; 46%	<i>n</i> = 15; 40%	<i>n</i> = 20; 53%

Group 1 = children who received anesthesia mask exposure/shaping practice in the week before surgery. Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. Group 3 = children who did not receive anesthesia mask exposure/shaping practice before surgery. ENT = ear, nose and throat; M:F = male:female

Table 2 Measure subscale and total scores

Measure	Sample Range	Group 1		Group 2		Group 3	
		<i>n</i>	<i>M</i> (<i>SD</i>)	<i>n</i>	<i>M</i> (<i>SD</i>)	<i>n</i>	<i>M</i> (<i>SD</i>)
Baseline							
STAI-S	20-70	27	37.0 (10.9)	27	40.4 (12.5)	23	38.0 (11.9)
STAI-T	20-60	34	34.7 (7.3)	37	35.1 (8.5)	36	35.0 (8.1)
EASI Emotionality	5-21	34	13.4 (3.6)	37	12.1 (3.7)	38	12.4 (4.0)
EASI Activity	7-25	34	15.8 (4.1)	37	16.8 (3.9)	38	15.6 (3.9)
EASI Sociability	11-25	34	19.2 (2.8)	37	19.3 (3.2)	38	18.6 (3.1)
EASI Impulsivity	6-22	34	14.2 (3.2)	37	14.4 (3.8)	38	13.7 (3.3)
Day of surgery							
Admission STAI-S	20-64	35	36.4 (11.2)	37	37.2 (12.2)	38	38.7 (12.1)
mYPAS admission	23.3-58.3	37	25.6 (5.8)	39	26.7 (6.6)	37	27.7 (7.6)
mYPAS holding area	23.3-85.0	37	25.2 (3.9)	39	25.6 (9.9)	37	26.3 (5.6)
mYPAS transfer to OR	23.3-91.7	37	30.9 (16.6)	39	29.4 (14.2)	36	30.7 (12.3)
mYPAS induction	23.3-100.0	37	51.4 (31.8)	38	39.6 (24.3)	36	53.2 (30.9)
mYPAS post-surgery	23.3-91.7	37	36.2 (14.9)	38	35.6 (16.0)	36	43.2 (17.6)
ICC	0-9	37	2.2 (2.7)	38	1.1 (2.1)	36	2.2 (2.7)
Post-surgery STAI-S	20-71	35	29.2 (9.8)	37	35.1 (13.4)	37	35.2 (10.5)

Group 1 = children who received anesthesia mask exposure/shaping practice in the week before surgery. Group 2 = children who received anesthesia mask exposure/shaping practice on the day of surgery. Group 3 = children who did not receive anesthesia mask exposure/shaping practice. Values are rounded up to one decimal place; ICC = Induction Compliance Checklist; EASI = Emotionality, Activity, Sociability and Impulsivity Scale; M = mean; mYPAS = modified Yale Preoperative Anxiety Scale; OR = operating room; SD = standard deviation; STAI = State Trait Anxiety Inventory-State Version; STAI-T = State Trait Anxiety Inventory-Trait version

Table 3 Pairwise comparisons of mean differences in child anxiety (mYPAS) across consecutive time points

Time point 1	Time point 2	M_{diff}	99% CI
Admission	Holding area	1.5*	-0.1 to 3.2
Holding area	Transfer to OR	-4.5***	-8.0 to -1.0
Transfer to OR	Induction	-18.1***	-24.5 to -11.7
Induction	Post-surgery	9.5***	2.0 to 17.0

* $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$. CI = confidence interval; M_{diff} = mean difference; mYPAS = modified Yale Preoperative Anxiety Scale; OR = operating room

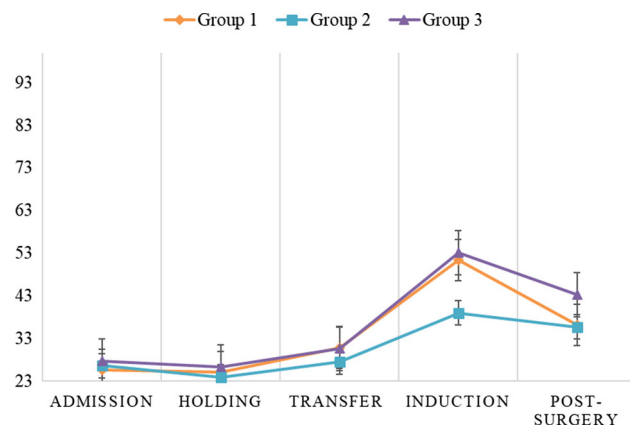


Fig. 2 Child observer-rated anxiety (via modified Yale Preoperative Anxiety Scale [mYPAS]) at the five time points (admission, holding, transfer to operating room, induction of anesthesia, post-surgery). mYPAS range = 23.3-100.00

-32.07 to 3.80, $P = 0.041$, $\eta_p^2 = 0.04$. The interaction effect between the different groups over time revealed a significant main effect for group, $F(1, 71) = 4.52$, $P = 0.04$, $\eta_p^2 = 0.06$ (i.e., medium effect). Group 2 differed significantly from Group 3 ($M_{diff} = -7.67$, $SE = 3.61$, $P = 0.04$, 99% CI, -17.22 to 1.88). Most importantly, a significant interaction was observed between time and group, $F(1, 71) = 4.37$, $P = 0.04$, $\eta_p^2 = 0.06$ (i.e., small to medium effect), demonstrating that children in Group 2 were equally anxious at admission as children in Group 3, then significantly differed in their level of anxiety at anesthesia induction, likely due to the intervention.

Results from the univariate ANOVA computed to examine the effect of the exposure intervention on induction compliance approached significance, $F(2, 107) = 2.84$, $P = 0.06$, $\eta_p^2 = 0.05$ (i.e., small to medium effect). When examining the specific contrasts, Group 1 did not significantly differ from Group 3 ($P = 0.22$, 99% CI, -0.69 to 1.90), but Group 2 significantly differed from Group 3 ($P = 0.04$, 99% CI, -2.67 to 0.34).

Results from the 3×2 repeated measures ANOVA computed to examine the effect of the exposure intervention on parent self-reported anxiety demonstrated

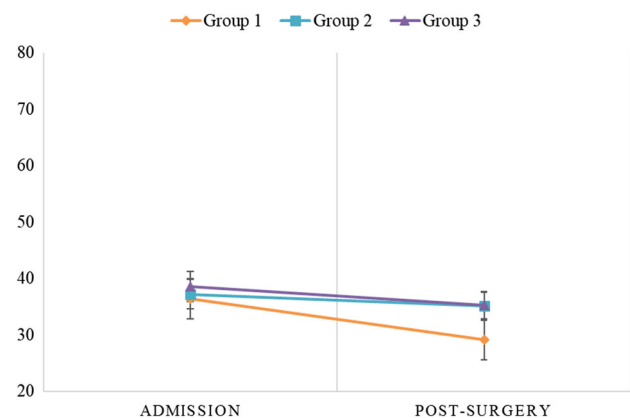


Fig. 3 Parent anxiety (via State Trait Anxiety Inventory-State Version [STAI-S]) at admission and post-surgery. STAI-S range = 20-80

a significant main effect for time, $F(1, 106) = 11.65$, $P < 0.001$, $\eta_p^2 = 0.10$ (i.e., large effect). Examination of the pairwise comparisons for time revealed a significant difference between admission and post-surgery, $M_{diff} = 4.27$, $SE = 1.25$, $P = 0.001$, 99% CI, 0.99 to 7.56 (Fig. 3). A significant main effect was not observed for group, $F(2, 106) = 1.87$, $P = 0.16$, $\eta_p^2 = 0.03$, nor was the interaction of time and group significant, $F(2, 106) = 1.44$, $P = 0.24$, $\eta_p^2 = 0.03$.

Comparison with benchmark study

Results from t tests computed between mean mYPAS ratings in the current investigation to the results of MacLaren and Kain¹² demonstrated significant differences at holding area ($t = 4.06$, 99% CI, -12.23 to -2.59, $P < 0.001$, Cohen's $d = 0.94$) and transfer to the OR ($t = 3.00$, 99% CI, -15.61 to -0.99, $P = 0.004$, Cohen's $d = 0.67$). Nevertheless, mean mYPAS ratings at anesthesia induction (the most anxiety-provoking and clinically meaningful time point) across studies were consistent ($t = 1.10$, 99% CI, -19.80 to 8.06, $P = 0.28$, Cohen's $d = 0.24$).

Discussion

The current RCT is the first of its kind to examine the efficacy of a parent-directed exposure and shaping practice with an anesthetic mask, with a novel focus on the timing, as a stand-alone intervention to prevent child preoperative anxiety. Overall, Group 2 (i.e., anesthesia mask exposure/shaping practice on the day of surgery) had significantly lower observer-rated child anxiety scores than Group 3 (i.e., no anesthesia mask exposure), while Group 1 (i.e., anesthesia mask exposure/shaping practice in the week before surgery) did not. At the most anxiety-provoking time point (i.e., anesthesia induction) parent-directed mask exposure and shaping employed on the day of surgery reduced child anxiety compared with no intervention. These results were inconsistent with existing research that indicated that children were most anxious when a preoperative preparation program was given close to surgery, and that preparation best reduced anxiety when implemented five to seven days before surgery.¹³ Children in the current investigation may have been exposed to the anesthesia mask for a sufficient amount of time on the day of surgery to allow for distributed practice, decreasing anxiety at anesthesia induction. In line with the aforementioned findings, children in Group 2 were also significantly more compliant at anesthesia induction than children in Group 3. Being less anxious on the day of surgery should improve the child's surgery experience and post-surgery outcomes and negate the potentially traumatizing effects of restraint at anesthesia induction, as well as reduce distress of parents and the healthcare team, all while maintaining timely completion of the day surgery process. Also, being conscious of their anesthesia induction and experiencing it in a neutral or positive manner may facilitate children's future positive inductions.¹

Overall, parent state anxiety decreased across the day surgery experience, but did not differ significantly by group. Our findings are inconsistent with previous research showing that preoperative interventions for children can also alleviate parent anxiety.²⁰⁻²³ Nevertheless, our findings are difficult to compare with existing research, which does not include the postoperative assessment time point.²⁴⁻²⁶ Variability across studies in terms of site of surgery (i.e., hospital vs surgical centre), type of surgery, or age of participants may represent potential explanations for differences in findings.

Children in the current investigation were significantly less anxious than children in the benchmark study¹³ in the holding area, perhaps because of a number of setting (i.e., same location used for admission and holding, small surgical centre) or process (i.e., children in setting do not separate from parents for induction) variables. Importantly,

child anxiety was not significantly different across the two studies at induction of anesthesia, which lends support to the integrity and generalizability of the exposure protocol.

Some study limitations require attention. First, we were unable to blind the first rater of the mYPAS and ICC to group allocation since the first rater was the principal investigator and a third person was not available to conduct the randomization. Secondary raters blind to the study hypotheses were utilized to address the latter. Second, many researchers monitor children's behaviour upon returning home;²⁷⁻²⁹ nevertheless, examination of postoperative behaviour was outside of the current study's purpose (i.e., examining the efficacy of anesthetic mask exposure for acute anxiety reduction at anesthesia induction). Obtaining follow-up data would have allowed us to extend our understanding of the impact of the anesthetic mask exposure intervention beyond the day of surgery. Third, the type of surgery that our participants underwent was homogenous (i.e., dental surgery) and the surgical setting employed in the current study may be different from typical hospitals (e.g., physical set-up of setting, protocol); as such, future research should replicate these findings with participants undergoing a diverse set of day surgeries in a hospital setting. Fourth, compliance with the intervention protocol for Group 1 was assessed by parent self-report only. With any self-report there is a possibility that a respondent may not be entirely forthcoming. In this case parents may not have been entirely forthcoming about their compliance with the exposure protocol, but there is no way to know this. As with most (voluntary) interventions for children, parents play a primary role, and it is at their discretion when, how, and how much an intervention should take place for their child.

In conclusion, the current findings demonstrate that providing children and their parents with an anesthesia mask and practice protocol on the day of surgery reduces child anxiety and improves compliance at anesthesia induction. The intervention requires no extra effort by members of the healthcare team, and no parent training except providing the exposure instructions and an anesthetic mask at admission. Given the limited impact on the busy day surgery setting, this exposure intervention could be easily integrated into surgical settings, representing a simple means of improving the day surgery experience for patients, families, and healthcare providers.

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