

The use of a scented face mask may facilitate the induction of anesthesia in pediatric patients: a randomized controlled trial

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Abstract

Background: Scented face masks are commonly used during the induction phase of anesthesia. The present study investigated whether the use of a scented mask improved mask acceptance before slow induction of anesthesia in pediatric patients.

Methods: This prospective, randomized controlled trial enrolled patients aged 2–10 years who were scheduled to undergo surgery under general anesthesia. Patients were randomly assigned to undergo masking with a scented (experimental group) or unscented (control group) face mask before anesthesia induction in the presence of a parent. The primary outcome was the mask acceptance score, rated on a validated 4-point from 1 point (not afraid; easily accepts the mask) to 4 points (afraid of a mask; crying or struggling). The secondary outcome was heart rate assessed by pulse oximetry in the pediatric ward before transfer to the operating room (OR), at the entrance to the OR, at the patient notification of mask fitting by the anesthesiologist, and after mask fitting.

Results: Seventy-seven patients were accessed for eligibility, with 67 enrolled in the study: 33 in the experimental group and 34 in the control group. Mask acceptance was significantly greater among patients aged 2–3 years in the experimental than in the control group ($p < 0.05$).

Conclusions: Use of scented masks can improve mask acceptance before anesthesia induction with a parental presence in pediatric patients aged 2–3 years.

Background

Inhalation of a volatile anesthetic agent via a face mask, so-called slow induction, is generally employed to reduce physical and psychological stresses in pediatric patients during the induction of general anesthesia. Satisfactory mask acceptance is important for a smooth induction process; however, some patients experience discomfort or fear of the mask and refuse mask fitting, which can complicate successful anesthesia induction. The use of a scented mask, which can disguise the odor of the mask and/or inhaled anesthetic agents, has been used for anesthesia induction in pediatric patients, as it may improve mask acceptance [1,2].

Many efforts have been made to facilitate the induction of general anesthesia in pediatric patients, such as premedication with sedative agents, such as midazolam or dexmedetomidine [3], parental presence during the induction of anesthesia [4,5], giving toys [6], video games [7], and clown doctors [8]. Showing video programs to the patient during slow induction is another resort used to facilitate anesthesia induction in pediatric patients; however, the effectiveness of audiovisual stimuli is dependent on the patient's age [9]. This result inspired us to examine whether the effectiveness of a scented mask for the induction of anesthesia in pediatric patients is dependent on age.

This study hypothesized that the use of a scented mask would facilitate the before-induction phase of general anesthesia in pediatric patients, and that mask acceptance may be age-dependent. This study,

therefore, compared acceptance of scented and unscented masks in pediatric patients categorized according to age.

Methods

This clinical trial was registered with the University Hospital Medical Information Network Clinical Trial Registry (https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000040819). The trial registration number was UMIN000037724. The full date of first registration was 19/08/2019. The study protocol was approved by the Jikei University Hospital Ethics Committee (ID number: 30-242), and written and oral informed consent were obtained from all parents and/or patients. This single-institution prospective study was performed in accordance with the Declaration of Helsinki and Clinical Trials Act established by the Japanese Ministry of Health, Labour and Welfare.

This prospective, observational, randomized controlled study included pediatric patients (age 2–10 years) who were scheduled to undergo general anesthesia from 19/08/2019 to 23/11/2020. The data were saved to a secured external storage unit on site. Patients were included if they had an American Society of Anesthesiologists (ASA) physical status of 1 or 2. Patients with intellectual disability, developmental delay, or without a documented pulse rate (PR) were excluded, as were uncooperative patients, defined as those with difficulty wearing the pulse oximeter. Patients were stratified by age into three groups: group 1, patients aged 2–3; group 2, patients aged 4–6 years; and group 3, patients aged 7–10 years [9]. Based on a preliminary study, the appropriate sample size for a power of 80% and a statistical significance of $p < 0.05$ was calculated to be eight patients per group. Allowing for dropouts and exclusions, the minimum number of patients per group was set at 10.

Patients in each age group were randomly assigned to undergo masking with a scented (strawberry, cherry, or gum) face mask (experimental group) or an unscented face mask (control group). To reduce selection bias, the envelope method was used for randomization. An anesthesiologist who did not participate in the study selected one piece of paper from the envelope for each patient. The children or their parents chose the flavor of the scented mask the day before surgery. All patients underwent preoperative fasting, and none received premedication. The primary outcome was the mask acceptance score. Mask acceptance, as evaluated by an independent observer or/and the attending anesthesiologist, was rated on a scale of 1 to 4 points, with 1 point indicating no fear of the mask and its easy acceptance; 2 points indicating a slight fear of the mask, with the patient being easy to comfort; 3 points indicating moderate fear of the mask, with the patient being difficult to calm; and 4 points indicating fear of the mask, with the patient crying or struggling [10]. Simultaneously, the behavioral score, defined as the number of distress behaviors, including crying, screaming, nonverbal resistance, and verbal resistance [11], was determined. The secondary outcome was PR, as assessed by pulse oximetry at four time points: (1) at baseline in the pediatric ward before proceeding to the operating room (OR), (2) at the entrance to the OR, (3) at patient notification of mask fitting by the anesthesiologist, and (4) after mask fitting.

Patients were accompanied by either or both of their parents from the pediatric ward to the OR and until induction of anesthesia, according to clinical practice at our hospital. Patients were shown the selected scented face mask (Ambu King Mask; Ambu A/S, Ballerup, Denmark) or an unscented face mask prior to placing it on the patient's face. At this point, only oxygen was provided so that the effect of the mask itself could be assessed by an independent anesthesiologist.

Patient demographic and baseline clinical data are expressed as mean (SD). Mask acceptance score and PR are expressed as medians (25% and 75%, respectively). Statistical analyses were performed using SigmaPlot version 13 (Systat Software, Inc, San Jose, CA, USA). The normal distribution of mask acceptance scores was determined using the Bartlett test for equal variances, followed by one-way analysis of variance and the Bonferroni multiple comparison test. The normal distribution of PR was tested using the Shapiro-Wilk test followed by analysis using repeated-measures, two-way analysis of variance. PRs in the control and experimental groups for each age category were evaluated by multiple pairwise comparisons using the Holm-Šidák method. *P* values <0.05 were considered statistically significant.

Results

Figure 1 shows a Consolidated Standards of Reporting Trials (CONSORT) flow diagram for the patients in this study from 19/08/2019 to 23/11/2020. Of the 77 patients recruited, 10 were excluded, including one patient with Down syndrome, one without a parent present during anesthesia, and eight who refused to wear a pulse oximeter before entering the OR (Figure 1). The 67 patients included 33 in the experimental group and 34 in the control group. The trial ended because the number in each group exceeded 10.

Baseline patient characteristics are summarized in Table 1. There were no statistically significant differences between the experimental and control groups. The primary outcome, the mask acceptance score, is shown in Table 2. The mask acceptance score was significantly lower in the experimental than in the control group in patient group 1 (3.0 (2.0, 4.0) vs. 1.0 (1.0, 1.0), *p* < 0.05). Similarly, the behavioral score was significantly lower in group 1 in the experimental than in the control group (*p*=0.003, Figure 2).

PR results are shown in Figure 3. Mean PR in the ward did not differ in the experimental and control groups in any age category. In group 1, PRs were significantly lower in the experimental than in the control group at mask notification (105±8 vs 132±26, *p* < 0.001) and just after mask fitting (105±8 vs. 133±28 vs.107±8, *p* < 0.001), but not at the other time points. No significant difference in PR was observed between the control and experimental groups in patient groups 2 and 3.

Discussion

This study evaluated mask acceptance scores in response to fitting with a scented or unscented face mask in pediatric patients categorized by age. The results showed that the use of a scented mask significantly improved mask acceptance at mask fitting and decreased PR in patients aged 2–3 years.

These results might suggest that the use of a scented mask could attenuate stress responses to mask fitting in these younger patients.

Various approaches to facilitate slow induction have been examined in pediatric patients. Showing a children's audiovisual program, selected by the patient or parent in advance, during slow induction was found to facilitate induction in patients aged 7–10 years [9]. Patients aged 2–3 years had difficulty paying attention to videos before and during induction, indicating that video-assisted induction was not useful for these patients. In the present study, patients or parents chose a scented mask based on scent preference on the day before surgery. An analysis of olfactory capacity in healthy preverbal children showed that, for 98% of 105 children, the first presentation of the olfactory stimulus resulted in a modification of respiratory rhythm, a fixed gaze, and a decrease in mobility [12]. In addition, 75% of the children aged ≥ 1 year held the olfactory stimulus (scented tissue) to the nose for more than 20 seconds, a finding that may explain why patients aged 2–3 years in the present study showed good mask acceptance. Improvement of mask acceptance might enhance the success of slow induction in pediatric patients.

Mask acceptance, behavioral score, and PR in patients aged 4–6 years did not differ significantly between the experimental and control groups. Social perceptiveness is thought to develop from ages 4 to 6 years [13], suggesting that patients in this age group, even those fitted with unscented masks, might easily adapt to situations without fear. Use of the Induction Compliance Checklist (ICC) [14] to determine the quality of induction and mYPAS score to measure anxiety found no difference between placebo and flavored masks in patients aged 4–12 years [15]. Although the number of highly anxious children differed in the placebo and flavor mask groups, the quality of induction was similar in patients aged 4–12 years. Similarly, the results of the present study showed no difference between the use of scented and unscented masks in children aged 4–10 years.

By contrast, the use of essential oil was found to promote induction of anesthesia in children aged 5–14 years [2]. In that study, children undergoing tooth extraction were randomly allocated to slow induction of anesthesia with or without the use of sweet orange essential oil. Children inhaling sweet orange essential oil were significantly more relaxed and cooperative during induction (72% vs. 23%, $p < 0.05$) and stated that they would prefer a similar anesthetic technique in the future (82% vs. 55%, $p < 0.05$). We expected the mask acceptance rate would improve in similarly aged patients in our study because the patients were allowed to choose a scented mask by themselves; however, there was no difference. The variety or intensity of the scents might have affected the results of our study.

Limitations

First, this study was performed in a setting where the parent(s) was present during induction. Because pediatric patients pay attention to what their parents say and their behavior, the presence of a parent might have affected the study results. However, the presence of a parent or parents during induction is generally accepted in the practice of pediatric anesthesia; hence, the results of the present study would rather reflect the real-world situation. Second, the results of our study might have been affected by

differences in the experience of attending anesthesiologists who applied the masks the attending anesthesiologists who applied the mask. It may also be difficult to evaluate stress levels using the mask acceptance score and the change in PR alone. Future studies should include measurements of mYPAS to determine anxiety.

Conclusion

The use of a scented face mask could improve mask acceptance before anesthesia induction in pediatric patients with a parent, especially in those aged 2–3 years.

Declarations

Ethics approval and consent to participate

The protocol of this study was approved by the Ethics Committee of the Jikei University (ID number: 30-242). Informed and written consent was obtained from the parents of the patients. This single-institution randomized controlled study was performed in accordance with the Declaration of Helsinki and Clinical Trials Act established by the Japanese Ministry of Health, Labour and Welfare.

Trial registration

The trial registration number was UMIN000037724.

(https://upload.umin.ac.jp/cgi-open-bin/ctr_e/ctr_view.cgi?recptno=R000040819) The full date of first registration was 19/08/2019.

Consent for publication

It was not applicable in this study.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available because the institutional rules strictly prohibit releasing the native data on the web; however, they are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

All authors approved the final version of the manuscript for publication. YA and KT conceived the idea of the study and substantially contributed to study conceptualization. KT drafted the original manuscript. YA made substantial contributions to the study concept, the data analysis, and interpretation. KT, YS, YH, EH, and AK contributed acquisition of the data. NK supervised the conduct of the study and revised the manuscript critically for important intellectual content. TT provided advice on statistical analyses, and contributed to the interpretation of the results.

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Tables

Tables 1 and 2 are available in the Supplementary Files section.

Figures

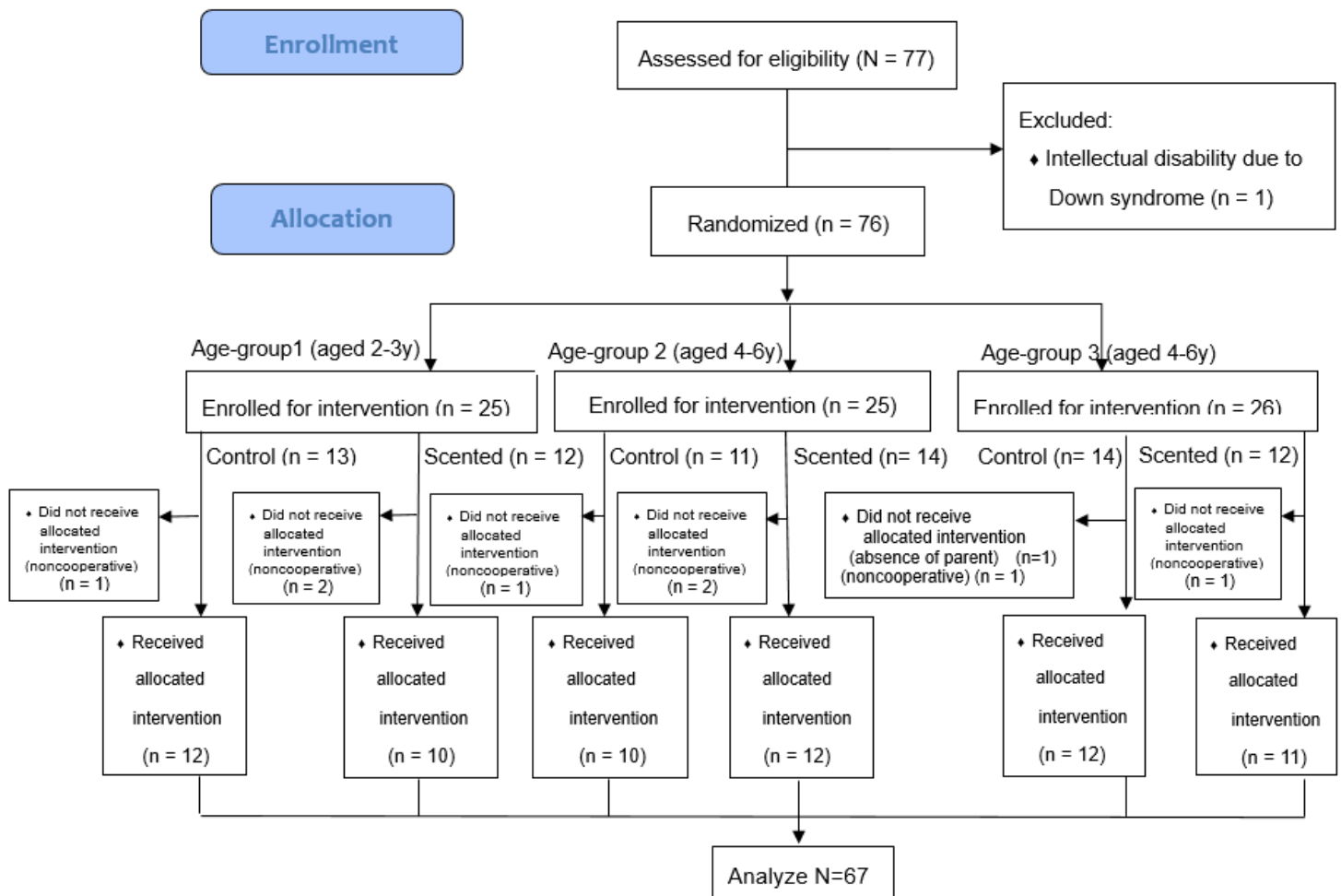


Figure 1

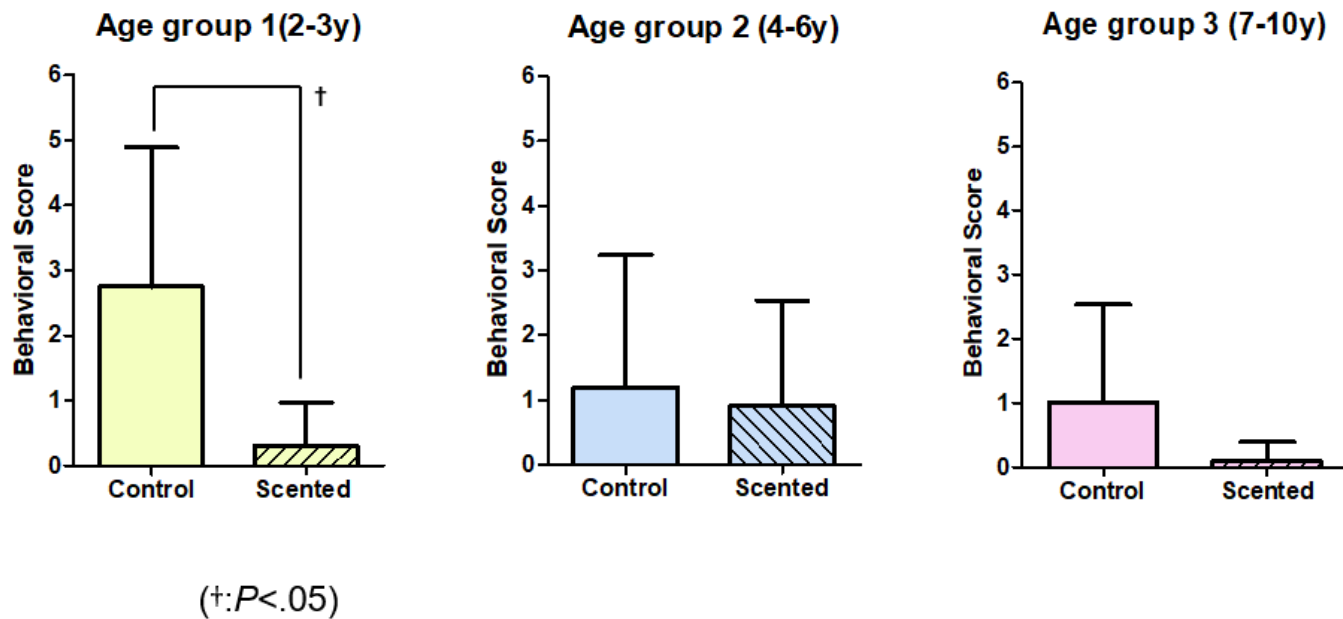


Figure 2

Behavioral scores by age group. Behavioral scores were significantly lower in patients aged 2–3 years wearing a scented than in those wearing an unscented mask.

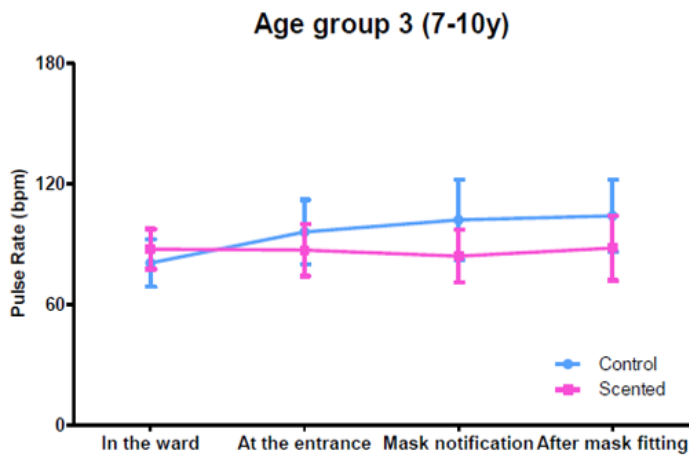
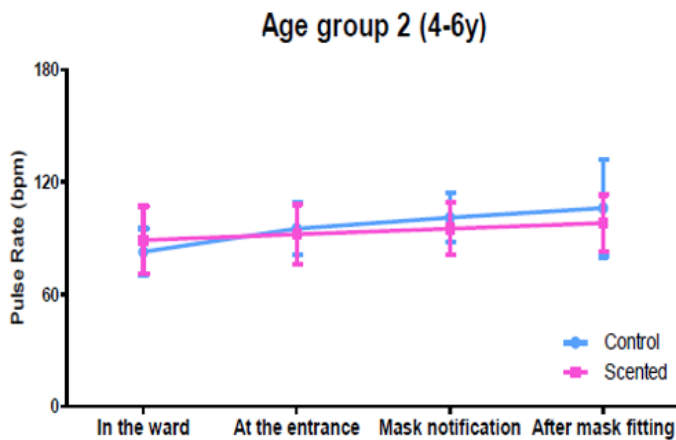
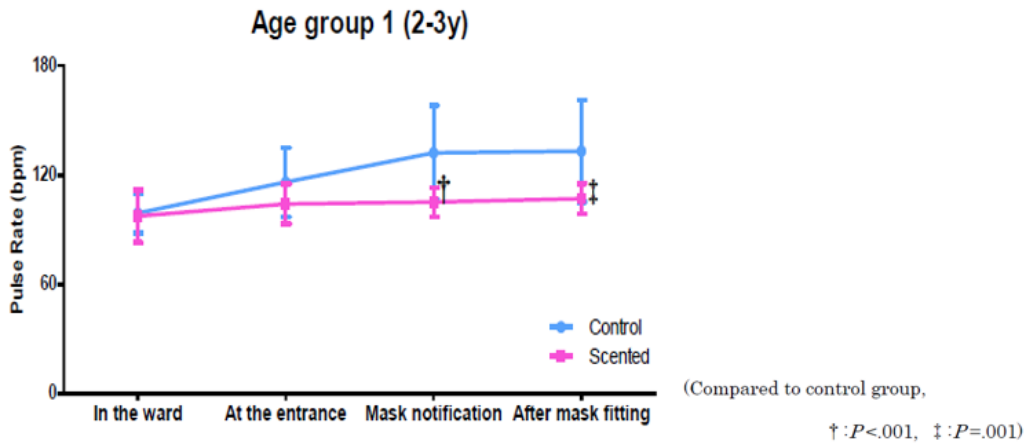


Figure 3

Pulse rate (PR) measurements by age group. PR at mask notification ($p < 0.001$) and after mask fitting ($p = 0.001$) was significantly lower in patients aged 2–3 years wearing a scented mask than in those wearing an unscented mask. *bpm*, beats per minute.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [Table1Patientcharacteristics.pdf](#)
- [Table2Maskacceptancescores.pdf](#)