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Original article**Preoperative distraction using electric ride-on cars for children undergoing elective ambulatory surgery: a randomised controlled trial**

SHORT TITLE: Distraction with ride-on cars in paediatric surgery

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ABSTRACT

Background

Preoperative anxiety occurs in 18 to 60% of children undergoing surgery and results in poor outcomes. Non-pharmacological methods of distraction are effective in alleviating peri-operative anxiety. In our institution, ride-on electric cars (ride-on e-cars) are routinely used by children undergoing ambulatory surgery as a mean of non-pharmacological distraction.

Objectives

The aim of this study is to assess the effect of preoperative distraction with ride-on e-cars on children's preoperative anxiety when undergoing elective ambulatory surgery.

Design

This was a prospective, randomised, controlled and open-label study, with two-parallel arms.

Setting

The study was carried out from September 2019 to September 2021 in the ambulatory paediatric surgery unit of our teaching hospital, in Marseille, France.

Patients

Children of both genders aged two to 10 years and weighting less than 35 kg undergoing elective ambulatory surgery were eligible. One hundred and fifteen children were included, 56 in the control group and 59 in the intervention group.

Intervention

Children in the control group were transported to the operating room (OR) using a trolley, while children in the intervention group used the ride-on e-cars, without pharmacological premedication nor parental presence.

Main outcome measures

The primary outcome was preoperative-anxiety at the end of the transport (prior going into the OR), assessed by the modified Yale Preoperative Anxiety Score Short Form (mYPAS-SF). Secondary outcomes were the anxiety levels in children over time, as well as postoperative pain and agitation assessed with the Face Legs Activity Cry Consolability (FLACC) and Paediatric Anaesthesia Emergence Delirium (PAED) scales, respectively.

Results

The mYPAS-SF anxiety scores did not differ between the control group and the intervention group (39 ± 19 vs. 37 ± 21 , $p = 0.574$). The secondary outcomes were similar between the two groups.

Conclusions

Our randomised controlled trial showed that the use of ride-on e-cars did not alter preoperative anxiety as compared with standard transport in children undergoing elective ambulatory surgery.

Trial registration

Clinicaltrials.gov identifier: NCT03961581

KEY POINTS

- Preoperative anxiety is frequent in children and results in poor outcomes.
- We assessed the effect of non-pharmacological distraction with ride-on electric cars on children's preoperative anxiety in ambulatory surgery.
- The use of ride-on e-cars did not reduce preoperative anxiety.
- Nevertheless, the use of ride-on e-cars was well accepted by both children and parents.

INTRODUCTION

Anaesthesia induction and separation from parents create fear and anxiety in children undergoing emergency or elective surgery. This occurs in a range from 18 to 60% of children and results in adverse behavioural changes during the peri-operative period.¹ Pharmaceutical anxiolysis has been widely used to prevent preoperative anxiety in children.² However, due to adverse events such as paradoxical reactions and prolonged sedation times, sedative drugs are not in line with the principles of enhanced recovery after surgery.³ Non-pharmacological methods such as active distraction are promising interventions to alleviate peri-operative anxiety. A multitude of interventions are already associated with effective distraction, such as video games,⁴ virtual reality,⁵ music therapy⁶ among others.⁷⁻⁹

In 2018, a non-profit organisation offered our department a set of three children's ride-on electric cars (ride-on e-cars), which are routinely used by the children undergoing elective ambulatory surgery. Previous studies reported that transporting children on ride-on e-cars or a hand-towed wagon was effective in reducing anxiety.^{10,11} The primary objective of our study was to assess the effect of preoperative distraction with ride-on e-cars on children's preoperative anxiety when undergoing elective ambulatory surgery. The secondary objectives were to assess the levels of child anxiety, pain, and agitation as well as parental anxiety.

METHODS

Study design

This prospective, randomised, controlled and open-label study, with two parallel arms was carried out from September 2019 to September 2021 in the ambulatory paediatric surgery unit of the Hospital Nord, a 650-bed teaching hospital, which is part of the Hôpitaux Universitaires de Marseille, Marseille, France.

Ethics

Ethical approval for this study was provided by the Comité de Protection des Personnes – Île de France II, Hôpital Universitaire Necker Enfants Malades, Paris, France (Chairperson Dr. S. Donnadieu) on March 7, 2019, under number 2019-A00531-56. The study protocol was registered with clinicaltrials.gov under number NCT03961581 on May 26, 2019. **The study protocol was declared in accordance with the National Commission on Information Technology and Civil Liberties (Commission nationale de l'informatique et des libertés - CNIL) by our local data protection officer (agreement CNIL 2018172v0 from December 20, 2016).** The patients were informed about the collection of their data, according to French law and local ethical committee guidance.¹² The methodology was based on the Consolidated Standards of Reporting Trials Statement (CONSORT).¹³

Selection criteria

Inclusion criteria were children of both genders aged two to 10 years and under 35 kg (ride-on e-car manufacturer instructions) undergoing ambulatory elective surgery (ear-nose-throat and eye surgeries). Exclusion criteria were cognitive or physical disabilities impeding the safe use of the ride-on e-cars, emergency surgery and parental refusal. All included children were affiliated with a social security regimen. An informed and written consent was obtained from parents or legal guardians for all participating children. Patient selection and consent was made during the pre-anaesthesia consultation at least 48h before surgery. Parents and children had a minimum period of 48h to decide on their consent to participate. In the control group, the children were transported to the operating room (OR) on a paediatric trolley. In the intervention group, they were transported on a ride-on e-car that could be driven by the child himself/herself or by the medical team using a remote control.

Objectives

The primary objective was to assess the effect of a ride-on e-car ride on preoperative anxiety prior to going into the OR for children undergoing elective ambulatory surgery, as compared with standard transport on a trolley. Anxiety was assessed using the modified Yale Preoperative Anxiety Score Short

Form (mYPAS-SF score).¹⁴ This score is composed of 18 items distributed over four categories (activity, arousal, vocalization and emotional status) and ranges from 23 to 100. A mYPAS-SF score < 24 defined a non-anxious child, a score between 24-30 defined anxiety, and a score > 30 defined severe anxiety. Secondary objectives were to assess preoperative anxiety in children by comparing the incidence of non-anxious, anxious, and severely anxious children with the mYPAS-SF score at three different times: upon admission to the ambulatory surgery ward, at the surgery facility and prior to going into the OR. We also evaluated the compliance with anaesthesia induction with the Induction Compliance Checklist (ICC),¹⁵ as well as the pain and agitation in the post-anaesthesia care unit (PACU) with the Face Legs Activity Cry Consolability (FLACC)¹⁶ and Paediatric Anaesthesia Emergence Delirium (PAED)¹⁷ scales, respectively.

To minimise the risk of confusion bias, the preoperative anxiety profile of children under 7 years-old using the Preschool Anxiety Scale Revised (PAS-R)¹⁸ and parental anxiety using the State-Trait Anxiety Inventory (STAI)¹⁹ were recorded before randomisation. All the scores and scales used in this study are presented under Supplemental Material 1.

General procedure

To enhance protocol compliance, avoid frustration and a contamination bias, the randomisation was not performed at an individual level, but rather on the inclusion periods. Randomisation was set up as follows: the ride-on e-cars were used for all children admitted for elective ambulatory surgery every other week. The surgery was scheduled by the surgical teams, which were blinded to the use or not of the ride-on e-cars.

The anaesthesia protocol was similar in the two groups, except for the mode of transport from the reception area of the surgical facility to the OR. In our institution, parents accompany their child until the reception area of the surgical facility, where they can meet and greet the medical team. No parental presence was allowed during transport and induction: the child is accompanied by the anaesthesiologist and/or nurse anaesthetist to the OR. Children were transported on a paediatric trolley or ride-on e-car, depending on the assigned group. The ride-on e-car was presented to the child and parents at the time of transportation to the OR. No pharmacological premedication was used. Preoperative fasting and management of recent or on-going upper respiratory tract infections were in compliance with guidelines.²⁰ In the OR, standard monitoring consisting of non-invasive blood pressure, oximetry and electrocardiogram was used. Induction was performed via a facemask using sevoflurane, without use of nitrous oxide. Anaesthesia was maintained with sevoflurane with a minimal alveolar concentration (MAC) targeted at 1.0 % (\pm 0.2). An initial 50:50 mixture of oxygen:air was adjusted according to pulse oximetry measurements of oxygen haemoglobin saturation. Pain was

controlled using sufentanil $0.2 \mu\text{g}\cdot\text{kg}^{-1}$. Airway management was left at the discretion of the anaesthesiologist in charge. To prevent postoperative pain and nausea, acetaminophen, non-steroidal inflammatory drugs, droperidol and dexamethasone were administered unless contraindicated. After surgery, the children were transferred to the paediatric PACU where they met their parents. Clear fluids were authorised as soon as children requested them. Hospital discharge was allowed ~~after 6 hours~~ if the Post Anaesthetic Discharge Scoring System (PADS-S) was ≥ 8 . In our institution, for children below 10 years-old, the anaesthetic team consist of one senior anaesthesiologist and one nurse anaesthetist. Occasionally, junior anaesthesiologist or junior nurse anaesthetist can complement this team.

Age, gender, history of prior anaesthesia and use of postoperative analgesia were recorded. The scales and scores at each point were recorded by the senior anaesthesiologist or the nurse anaesthetist in charge of the child, who received training prior to participation. The mYPAS-SF score was evaluated in the reception area of the ambulatory surgery ward, the reception area of the surgical facility and prior to going into the OR (at the end of the transport). The PAS-R and STAI scores were recorded in the reception area of the ambulatory surgery ward. The ICC was recorded just before anaesthesia induction. The FLACC and PAED scores were recorded during anaesthesia recovery in the PACU. A timeline of the study is presented in Figure 1.

Statistical analysis

Sample size calculation was based on a hypothesis formulated on the primary outcome, according to previously published data.^{21,22} To detect a significant difference between groups of 10 points (\pm standard deviation 15) on the mYPAS-SF score prior going into the OR, with a power of 90% and an alpha risk of 5%, the sample size was 98 patients. To consider 10% of missing data for the primary outcome, the final sample size was included 110 patients. The statistical analysis was carried out with SPSS statistics software (IBM™, USA) and was based on the intention-to-treat population. The level of significance was set at 5%. The scores of the different standardised questionnaires were calculated according to the algorithms provided by the scale developers.^{15-19,23} Descriptive analysis of the baseline characteristics was presented per group (age, gender, history of prior anaesthesia, use of postoperative analgesia). The means of the mYPAS-SF score prior to going into the OR (primary outcome) were compared between groups using the Student's t-test. Secondary outcomes were compared between groups according to the nature of the variable (χ^2 test or Fisher exact test for qualitative variables, Student's t-test or Mann-Whitney test for quantitative variables). The evolution of the mYPAS-SF score over time was compared between groups using a generalised linear model for repeated measures.

RESULTS

One hundred and fifteen children were included, 56 in the control group and 59 in the intervention group. The baseline characteristics (age, gender, history of prior anaesthesia, use of postoperative analgesia) are presented in Table 1. Preoperative anxiety of children under 7 years-old and parental anxiety did not differ between the control group ($n = 48$) and the intervention group ($n = 48$) (PAS-R score: 37 ± 20 vs. 43 ± 17 ; $p = 0.362$) (STAI score: 39 ± 13 vs. 41 ± 12 ; $p = 0.654$) (Table 2).

One child in the intervention group was excluded from the intent-to-treat analysis (not meeting one inclusion criteria: under two years-old). The final sample was 56 in the control group and 58 in the intervention group. The flowchart is presented in Figure 2.

Regarding the primary outcome, the mean mYPAS-SF anxiety scores did not differ between the control group and the intervention group (39 ± 19 vs. 37 ± 21 ; $p = 0.574$) (Table 2).

Regarding the secondary outcomes, no significant differences were reported between the two groups. The incidence of non-anxious, anxious, and severely anxious children did not differ at any time – in the reception area of the ambulatory surgery ward (23 (50%), 6 (13%) and 17 (37%) vs. 22 (49%), 3 (7%) and 20 (44%), respectively; $p = 0.534$), in the surgical facility (26 (46%), 6 (11%), 24 (43%) vs. 30 (52%), 3 (5%) and 25 (43%), respectively; $p = 0.53$) and prior to going into the OR (22 (39%), 5 (9%), 29 (52%) vs. 30 (53%), 3 (5%) and 24 (42%), respectively; $p = 0.334$) – (Table 2). The evolution of the mYPAS-SF score over the time did not differ between groups ($p = 0.507$) (Figure 3).

No significant differences were found between the control group and the intervention group for the PAS-R (35 ± 19 vs. 42 ± 18 ; $p = 0.078$), the ICC (1 ± 2 vs. 2 ± 3 ; $p = 0.907$), the FLACC (2 ± 3 vs. 2 ± 2 ; $p = 0.681$) and the PAED (3 ± 4 vs. 3 ± 3 ; $p = 0.398$) scores (Table 2).

DISCUSSION

Our randomised controlled trial did not find a significant effect on preoperative anxiety of preoperative distraction with ride-on e-cars in children undergoing elective ambulatory surgery. Despite the use of several scores, the intervention did not alter the outcome for children and did not significantly relieve parental anxiety. However, no harm was reported with the use of ride-on e-cars.

Peri-operative anxiety in children is a critical issue that needs to be addressed accordingly. Indeed, peri-operative anxiety is associated with adverse events such as the need for an increased sedative dose at anaesthesia induction, increased postoperative pain and cognitive dysfunction, eating and sleep disorders, regressive behaviour, and even increased surgical site infection.²⁴⁻²⁷ Preoperative administration of midazolam is the most widely used pharmacological anxiolysis in children, but this intervention was associated with paradoxical reactions, prolonged sedation times and delayed discharge.³ Wide inter-individual variability and increased nursing time to prepare, check, and administer were also described.²⁸ In our study, no children received preoperative pharmacological premedication.

Distraction is supposed to be an effective non-pharmacological strategy to alleviate peri-operative anxiety in children. Many interventions have been described and compared with the use of premedication with midazolam.⁴⁻⁹ The use of ride-on e-cars is a non-pharmacological intervention with potential advantages. Their use is easy without any learning curve for the children and the medical team. In addition, they need minimal maintenance.

Two previous randomised controlled trials evaluated the use of toy cars to reduce preoperative anxiety in children, using the mYPAS-SF anxiety score and a similar procedure of parental presence before surgery. Liu and colleagues showed that transport on a ride-on car was an effective way to reduce preoperative anxiety, as compared to transport on a trolley for children undergoing cardiac surgery for congenital heart disease (58 (interquartile range (IQR) 46 to 73) vs. 44 (IQR 27 to 47), $p < 0.001$). The use of midazolam did not affect these findings.¹⁰ Park and colleagues showed that the transport on a hand-towed wagon was also effective in reducing preoperative anxiety as compared to a transport on a trolley in non-premedicated children undergoing minor surgery (52 (IQR 37 to 83 vs. 37 (IQR 27 to 52), $p = 0.007$).¹¹

In our study, distraction with the ride-on e-cars did not result in a significant diminution of preoperative anxiety. However, our control group exhibited anxiety levels (39 ± 19) that were lower than those reported in the aforementioned studies (58 (IQR 46 to 73) and 52 (IQR 37 to 83)).^{10,11} In a French randomised controlled trial comparing midazolam premedication to tablet distraction for children undergoing ambulatory surgery, Marechal and colleagues found no differences in the mYPAS-SF score between the two groups (41 ± 19 vs. 42 ± 21 ; $p = 0.99$). Yet, they reported anxiety levels comparable with those reported in our study (39 ± 19 vs. 37 ± 21).⁹ This variability in anxiety levels across studies

might be explained by cultural and local factors like the presence of parents tardily in the process, the experience of the medical team or unmeasured variables. For example, in our institution, many other non-pharmacological distractions are routinely used like toys, songs, playing, arm carrying. The features of surgery may also affect our findings since we only included children undergoing elective ambulatory surgery, corresponding to minor procedures.

Our study has several limitations that we must acknowledge. The study may be underpowered to detect a difference in a population of children with lower anxiety scores than those expected, but the difference seems minimal after re-assessment. The age spread as inclusion criteria (to match the manufacturer instruction) is wide and could create a bias. However, the age spread observed in our population is narrow, reducing this confusion bias. Although statistically non-significant, we observed a difference in anaesthesia history and use of postoperative analgesia in the PACU between groups. Of note, we did not collect the types of surgery in each group. However, only eye and ENT ambulatory procedures were performed during this study. We also observed that the subscale of the PAS-R scale assessing separation anxiety was higher in the intervention group (9 ± 5 vs. 7 ± 5 ; $p = 0.023$) (data not shown). Those confounding factors may have impacted anxiety levels, but further evaluation will be required to assess them. Another limitation is the randomisation model, which was supposed to reduce the contamination bias. However, it could not eliminate it since the same anaesthesia team managed children from both groups. In addition, we did not consider the colours and types of our three ride-on e-cars. Finally, our results may not be transferable in all healthcare setting since our perioperative pathway does not occurs worldwide.

Nevertheless, the use of ride-on e-cars was feasible and well accepted by both children and parents. Although the differences between the two groups did not reach statistical significance, we observed a trend towards diminished anxiety for children in the intervention group, and feedback from children and parents regarding the ride-on e-cars was positive.

In conclusion, our randomised controlled trial showed that the use of ride-on e-cars neither improved nor worsened preoperative anxiety or other outcomes, as compared with standard transport for children undergoing elective ambulatory surgery.

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Conflicts of interests:

Professor LEONE reports personal fees from ASPEN, personal fees from AMOMED, personal fees from LFB, personal fees from AMBU, personal fees from GILEAD, outside the submitted work.

Professor ZIELESKIEWICZ reports personal fees from GENERAL ELECTRIC HEALTHCARE, outside the submitted work.

Dr PASTENE reports personal fees from EDWARDS LIFESCIENCES, outside the submitted work.

Dr PICLET, Dr PRAUD, Mrs GARCIA, Mrs LOUIS, Mrs SCHMIDT, Dr BOYADJIEV, Dr BOUCEKINE, Dr BAUMSTARK, Dr BEZULIER and Professor BOUVET have nothing to disclose.

Presentation:

The preliminary data for this study will be presented as an oral presentation at the upcoming Société Française d’Anesthésie et Réanimation (SFAR) meeting, 22-24 September 2022, Paris.

Data statement:

The data that support the findings of this study are available from the corresponding author, BP, upon reasonable request.

Details of authors’ contributions:

Bruno Pastene: Investigation, Writing - Original Draft

Jules Piclet: Investigation, Writing - Original Draft

Camille Praud: Investigation, Writing - Original Draft

Karine Garcia: Conceptualisation, Investigation, Data Curation

Katia Louis: Conceptualisation, Investigation, Data Curation

Claire Schmidt: Conceptualisation, Investigation, Data Curation

Ioanna Boyadjiev: Conceptualisation, Investigation

Mohamed Boucekine: Methodology, Formal analysis

Karine Baumstarck: Methodology, Formal analysis

Karine Bezulier: Methodology, Data Curation

Lionel Bouvet: Writing - Review & Editing

Laurent Zieleskiewicz: Writing - Review & Editing, Supervision

Marc Leone: Conceptualisation, Writing - Review & Editing, Supervision

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TABLES

Table 1: demographic characteristics, anaesthesia, and postoperative analgesia

Table 2: primary and secondary outcomes

LEGENDS TO FIGURES

Figure 1: timeline of the study

Figure 2: flow chart of the study

Figure 3: mYPAS-SF score evolution over time in both groups

mYPAS-SF: modified Yale Preoperative Anxiety Score Short Form

SD: standard deviation