

# Continuous Infusion of Lidocaine in Pediatric Colonoscopy: A Randomized Double-Blind Placebo-Controlled Study

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## Research article

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## Abstract

**Background:** Propofol is commonly used for providing procedural sedation during pediatric colonoscopy. Intravenous (*i.v.*) lidocaine can mitigate visceral pain and reduce propofol requirements during surgery. The aim of this study is to investigate the effect of intravenous lidocaine on perioperative propofol and sufentanil dose, pulse oxygen saturation, postoperative pain score, and recovery time during pediatric colonoscopy.

**Methods:** We designed a randomized double-blind placebo-controlled study and enrolled 80 children aged from 3 to 10 years old who underwent colonoscopy. After titration of propofol to achieve unconsciousness, the patients were given *i.v.* lidocaine (1.5 mg/kg then 2 mg/kg/h) or the same volume of saline. Sedation was standardized and combined propofol with sufentanil. The primary outcome variables were intraoperative propofol and sufentanil requirements, and the number of oxygen desaturation episodes. Secondary outcome variables were recovery time after colonoscopy and post-colonoscopy pain.

**Results:** Lidocaine infusion resulted in a significant reduction in propofol requirements: (median (quartile) 1.8 (1.5-2.0) vs. 3.0 (2.8-3.3) mg/kg respectively;  $P<0.001$ ) and sufentanil requirements: (median (quartile) 0.06 (0.05-0.08) vs. 0.1 (0.1-0.1)  $\mu$ g/kg respectively;  $P<0.001$ ). The number of subjects who experienced oxygen desaturation below 95% in the lidocaine group was also significantly less than that in the control group: 2 vs. 8 ( $P=0.04$ ). The mean (SD) recovery time was significantly shorter in the lidocaine group: (19.2 (2.6) vs. 13.3 (2.6) min respectively;  $P<0.001$ ). There was no significant difference regarding post-colonoscopy pain.

**Conclusion:** Continuous infusion of lidocaine resulted in reduction in propofol and sufentanil dose requirements, recovery time, and risk of hypoxemia during pediatric colonoscopy.

**Trial Registration:** Chinese Clinical Trials Registry, ChiCTR2000028927, January 8, 2020, prospectively registered.

## Background

Colonoscopy is commonly conducted in infants and children for the diagnosis and treatment of abdominal pain, diarrhea, weight loss, unexplained iron deficiency anemia, or unexplained hematochezia. (1, 2) Colonoscopy has been developed as a diagnostic and therapeutic tool for pediatric patients.(3) Anesthesiologists are increasingly involved in providing procedural sedation and analgesia for pediatric colonoscopy due to the lack of patients' cooperation. Midazolam, propofol, and opioids are the most commonly used anesthetics for procedural sedation and analgesia during pediatric colonoscopy.(4, 5) However, each of these anesthetics causes respiratory depression, and combining midazolam or propofol with opioids may further increase the risk for hypoxemia and apnoea during pediatric colonoscopy.(6) In order to decrease the incidence and frequency of complications during pediatric endoscopy, different methods have been tried previously. Propofol-ketamine combinations are associated with fewer

cardiopulmonary adverse effects than with propofol alone according to previous reports.(7-9) Lidocaine is an amide local anesthetic. *I.V.* lidocaine has peripheral and central actions, and involves several mechanisms.(10, 11) Previous studies have shown that it can alleviate visceral pain, reduce central or peripheral sensitization of pain, and inflammatory response through the reduction of cytokine secretion. (12-14) Thus, *i.v.* lidocaine may be another potential adjunct to propofol anesthesia, and some researchers have indicated that *i.v.* lidocaine can alleviate abdominal pain in patients.(15, 16) During colonoscopy, colonic distention and traction may cause abdominal discomfort and visceral pain potentially amenable to *i.v.* lidocaine. C. Forster et al.(17) have reported that *i.v.* lidocaine can be another adjunct to propofol sedation during adult colonoscopy and concluded that *i.v.* lidocaine resulted in a 50% reduction of propofol dose requirements. However, the application of lidocaine in pediatric colonoscopy has not been reported. We therefore conducted a clinical study to investigate whether *i.v.* lidocaine reduces propofol requirements and improves post-colonoscopy recovery during pediatric colonoscopy.

## Methods

We designed and implemented a randomized placebo-controlled double-blind trial in the operating room of Guangdong Women and Children Hospital, China. This study was approved by the Ethics Committee of Guangdong Women and Children Hospital on December 30, 2019 (identifier number 201901164) and registered with the Chinese Clinical Trials Registry ([www.chictr.org.cn](http://www.chictr.org.cn), identifier number ChiCTR2000028927, January 8, 2020, prospectively registered). After written informed consent was obtained, 80 American Society of Anesthesiologists (ASA) grades 1-2 aged from 3 to 10 children undergoing colonoscopy under sedation were included in our study from January 9, 2020 to June 30, 2020 (see **Fig. 1** for CONsolidated Standards Of Reporting Trials (CONSORT) trial profile). Inclusion criteria were: aged from 3 to 10 with normal electrocardiogram (ECG) results. Exclusion criteria were: age > 10 yr or < 3 yr, liver insufficiency, major cardiac arrhythmia, and allergy to lidocaine.

### **Study design and intervention**

Once the participants entered the operating room, their ECG and oxygen saturation (SpO<sub>2</sub>) were routinely monitored. All of the children were sedated with an *i.v.* bolus injection of propofol (Lipofen, B. Braun Melsungen AG, specifications: 20 ml: 100 mg, batch number: 17515033) 1.5 mg/kg by the same anesthesiologist (C. Y.) who was blinded to patient allocation groups. A dose of sufentanil (Sufentanil citrate injection, EuroCept BV, specifications: 1 ml: 75 ug, batch number: 180262) 0.05 ug/kg was administered via *i.v.* after loss of consciousness. Then, the children were randomly and double blindly assigned to saline group (group S) and lidocaine group (group L) using sealed envelopes. Group L was given an *i.v.* bolus of 1.5 mg/kg of lidocaine followed by a continuous infusion of 2 mg/kg/h of it, while group S was given the same volume of saline.(18) Study medications were prepared by the same anesthesiologist (J.W.) involved neither in patient sedation nor in collecting study data. In order to avoid interference with blinding, study medications were infused after loss of consciousness in both groups as the initial bolus of lidocaine may result in a specific reaction (if lidocaine had been injected first and then propofol, a sting at the injection site might disappear, which would let the researchers know that lidocaine

was given instead of a placebo). An *i.v.* bolus of 10–20 mg of propofol was administered in response to abdominal discomfort expressed by the children or evidenced by irritability or haemodynamic changes (increase in heart rate  $\geq$  20 beats/min) during colonoscopy. 0.05 µg/kg of sufentanil was added if the propofol was insufficiently effective. During colonoscopy, all children breathed spontaneously and received 4 L min<sup>-1</sup> of oxygen through a nasal catheter in order to maintain oxygen saturation > 90% during colonoscopy. Assisted ventilation via a mask or endotracheal intubation was given if the children developed respiratory depression (defined as SpO<sub>2</sub> < 90%) or arrest (defined as 10-second apnoea).

### **Outcome variables**

The primary outcome variables were intraoperative propofol and sufentanil requirements and the number of oxygen desaturation episodes (defined as peripheral capillary oxygen desaturation (SpO<sub>2</sub>) less than 95% and 90%). Secondary outcome variables were recovery time in the post-anesthesia care unit (PACU) (time between end of colonoscopy and ability for the children to blink) and post-colonoscopy pain. The pain scores were recorded using the Wong-Baker FACES Pain Rating Scale after recovery in the PACU 15 and 30 min later. The scale contains six cartoon faces showing pain ratings of 0–10, which are, from left to right, no pain (0), a little pain (2), mild pain (4), average pain (6), severe pain (8), and excruciating pain (10). Researchers involved in the assessment of these variables were blinded to patient allocation groups.

### **Statistical analysis**

The sample size was calculated on the basis of a local pilot study. The mean propofol requirement during pediatric colonoscopy was  $120 \pm 47$  mg. To detect a 30% decrease in propofol needs between groups, a power estimation analysis suggests that 36 patients per group will be required to achieve a power of 90%, when considering a bilateral type I error of 0.05. In view of a dropout rate of 10%, the sample size is estimated to be 40 per group. All statistical analyses were performed using IBM SPSS Statistics for Windows (version 23.0, IBM Corp, Chicago, IL, USA). Quantitative variables were presented as mean  $\pm$  standard deviation (SD) or median with interquartile range. Categorical data were reported as frequencies. Enumeration data and categorical variables were analyzed using the Chi square test or Fisher's exact tests as appropriate. Continuous variables were tested with Student's *t* test or the Mann Whitney U test depending on the distribution of the data which was examined by the Shapiro-Wilk normality test. Mixed model analysis of variance (ANOVA) was used to compare postoperative pain scores. A value of *P* < 0.05 was considered statistically significant.

## **Results**

A total of 120 children were screened and evaluated from January 9, 2020 to June 30, 2020 in the operating room at Guangdong Women and Children Hospital. Among which, 23 of them did not consent, 3 of them had exclusion criteria (major cardiac arrhythmia), and 14 withdrew due to a combination with gastroscopy. Finally, 80 ASA grades 1–2 aged from 3 to 10 children undergoing colonoscopy under sedation were included in this randomized placebo-controlled double-blind study (**Fig. 1**). There was no

significant difference in age, gender, weight, height, body mass index (BMI), ASA physical status, hemoglobin (Hb), iron, high sensitivity C-reactive protein (hs-CRP), reasons for colonoscopy, and duration of colonoscopy between the two groups (**Table 1**). Therefore, the data sets of the two groups were comparable.

The propofol and sufentanil consumption in group L showed a significant reduction compared with group S ( $P < 0.001$ ; **Table 2**). The recovery time of group L was shorter than that of group S ( $P < 0.001$ ; **Table 2**). The number of subjects who experienced oxygen desaturation below 95% in the lidocaine group was also significantly less than that in the control group: 2 vs 8 ( $P = 0.04$ ; **Table 2**). The number of children who experienced oxygen desaturation below 90% (1 vs. 2 subjects in the groups L and S, respectively) was similar in the two groups ( $P = 0.56$ ; **Table 2**). There was no significant difference regarding respiratory frequency between the two groups (19 (18-21) vs 20 (19-21) byte/min,  $P = 0.26$ ; **Table 2**). No endotracheal intubation or apnoea occurred in both groups. In the group L, one child reported dizziness and vomiting after recovery (**Table 2**). The pain scores after colonoscopy were also similar in the two groups [ANOVA: drug effect ( $df=1$ ,  $F=3.7$ ):  $P=0.06$ ; time effect ( $df=1$ ,  $F=74.4$ ):  $P<0.001$ ; interaction ( $df=1$ ,  $F=3.3$ ):  $P=0.071$ ] (**Fig. 2**). As shown in **Fig. 2**, there was no statistical difference in the pain scores between the two groups of children at 15 minutes and 30 minutes after recovery in the PACU.

## Discussion

Colonoscopy has developed into a diagnostic and therapeutic tool for pediatric patients. Discomfort associated with pediatric colonoscopy leading to a lack of cooperation results mainly from visceral nociception and secondary to colonic distension and tractions. Therefore, the involvement of an anesthesiologist is often required to reduce fear and anxiety in the children and make colonoscopy more comfortable for the endoscopist. Nowadays, propofol combined with opioids is one of the most common techniques used for procedural sedation and analgesia during pediatric colonoscopy.(4, 5) However, there exists risk of respiratory and hemodynamic complications when using propofol combined with opioids. (6) Different strategies have been tried to reduce the incidence and frequency of complications during pediatric endoscopy. According to previous studies, propofol-ketamine combinations showed fewer cardiopulmonary adverse effects than with propofol alone.(7, 19) Lidocaine is another potentially interesting adjunct to propofol sedation because it can alleviate visceral pain and weaken central or peripheral sensitization through different mechanisms.(12-14, 20, 21). We therefore conducted a clinical study to investigate whether *i.v.* lidocaine reduces propofol requirements and improves post-colonoscopy recovery during pediatric colonoscopy. Our study demonstrated that adding *i.v.* lidocaine could significantly reduce the propofol and sufentanil requirements for pediatric colonoscopy and at the same time, shorten the recovery time.

In our study, despite the fact that the propofol and sufentanil requirements in the lidocaine group was significantly less, all of the children successfully underwent the colonoscopy. In addition, postoperative pain after colorectal surgery was similar in both groups, and no tracheal intubation and apnoea occurred in both groups. Hypoxia and apnoea secondary to respiratory depression and airway obstruction are the

most frequent cardiopulmonary complications of propofol sedation for pediatric colonoscopy. An adjunct is administered to propofol and sufentanil partly to reduce their needs and consequently the incidence of their adverse effects. In our study, the number of subjects who experienced oxygen desaturation below 95% in the lidocaine group was significantly less than that in the control group, but there was no significant difference in age, gender, weight, height, BMI, ASA physical status Hb, iron, hs-CRP, reasons for colonoscopy, and duration of colonoscopy between the two groups. Thus, we believed that continuous infusion of lidocaine could reduce the risk of hypoxemia by reducing the use of propofol and sufentanil. Although the duration of colonoscopy in the two groups was similar, the recovery time was also shortened when adding *i.v.* lidocaine, which may also be related to reducing the dose of propofol and sufentanil.

Several studies have demonstrated that lidocaine administration as an analgesic could reduce opioids consumption(22, 23) and benefit patients with earlier airway activity, the return of bowel function, and a shorter hospital stay after an operation.(24, 25) Our study also demonstrated that adding *i.v.* lidocaine could significantly reduce the propofol and sufentanil comsumption in pediatric colonoscopy. However, lidocaine does have some adverse events, as with all other medications, such as dizziness, nausea and vomiting, transient slurred speech, perioral numbness, dry mouth etc.(13, 26) The toxicity symptoms are transient and rapidly reversible due to its short half-life. In this study, we also observed lidocaine side effects, however, the incidence of adverse effects (dizziness, vomiting) was self-limited, and did not require any medical intervention.

Several limitations of this study should be addressed. For example, recording the blood pressure might further help in detecting differences of adverse events associated with propofol. The endoscopists' working conditions were not quantified in this study. In the future, for better comparison, they can be quantified using visual analog scores. Finally, this study is a single-center clinical trial, a multi-center clinical study should be carried out for further confirmation.

In conclusion, adding *i.v.* lidocaine can significantly reduce the propofol and sufentanil consumption and risk of hypoxemia for pediatric colonoscopy, while simultaneously, shorten the recovery time without impacting working conditions for the endoscopists. The potential side effects of lidocaine *i.v.* administration should also be considered.

## Abbreviations

I.V., intravenous; CONSORT, CONsolidated Standards Of Reporting Trials; ECG, electrocardiogram; SpO<sub>2</sub>, oxygen saturation; PACU, postanesthesia care unit; SD, standard deviation; ANOVA, analysis of variance; ASA, American Society of Anesthesiologists; BMI, body mass index; Hb, hemoglobin; hs-CRP, high sensitivity C-reactive protein.

## Declarations

## ***Ethics approval and consent to participate***

This study was approved by the Ethics Committee of Guangdong Women and Children Hospital on December 30, 2019 (identifier number 201901164). Written informed consent was obtained from the participants' guardians.

## ***Consent for publication***

Not applicable.

## ***Availability of data and materials***

De-identified individual participant data (including data dictionaries) will be made available, in addition to study protocols, the statistical analysis plan, and the informed consent form. The data will be made available upon publication to researchers who provide a methodologically sound proposal for use in achieving the goals of the approved proposal. Proposals should be submitted to mzkhzrong@163.com.

## ***Competing interests***

The authors declare that they have no competing interests.

## ***Funding***

Not applicable.

## ***Authors' contributions***

CY and CW conceptualized and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. JW, NG, KL, YL, XH, and WH designed the data collection instruments, collected data, carried out the initial analyses, and reviewed and revised the manuscript. ZH conceptualized and designed the study, coordinated and supervised data collection, and critically reviewed the manuscript for important intellectual content. All authors approved the final manuscript as submitted and agree to be held accountable for all aspects of the work.

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Not applicable.

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## Tables

**Table 1.** Characteristic data and duration of colonoscopy. Data are mean (standard deviation), median (interquartile range), or number.

	Group S (n=40)	Group L (n=40)	P
Age (yr)	6 (5,8)	7 (5,9)	0.53
Gender (M/F)	21/19	18/22	0.50
Weight (kg)	24.80 ± 5.61	25.20 ± 7.27	0.78
Height (cm)	1.16 ± 0.14	1.15 ± 0.14	0.75
BMI (kg/m)	21.25 ± 3.02	21.59 ± 4.21	0.68
hs-CRP (mg/L)	3.97 ± 1.31	4.01 ± 1.36	0.89
Hb (g/L)	122.4 ± 11.6	120.8 ± 11.7	0.55
Fe <sup>2+</sup> (mumol/L)	15.34 ± 5.74	15.99 ± 6.12	0.63
Reason for colonoscopy:			
Hematochezia	9	12	0.45
Intestinal polyps	16	14	0.64
Inflammatory bowel disease	15	14	0.82
ASA physical status (1/2)	19/21	23/17	0.37
Duration of colonoscopy (min)	12.40 ± 1.65	12.35 ± 1.79	0.90

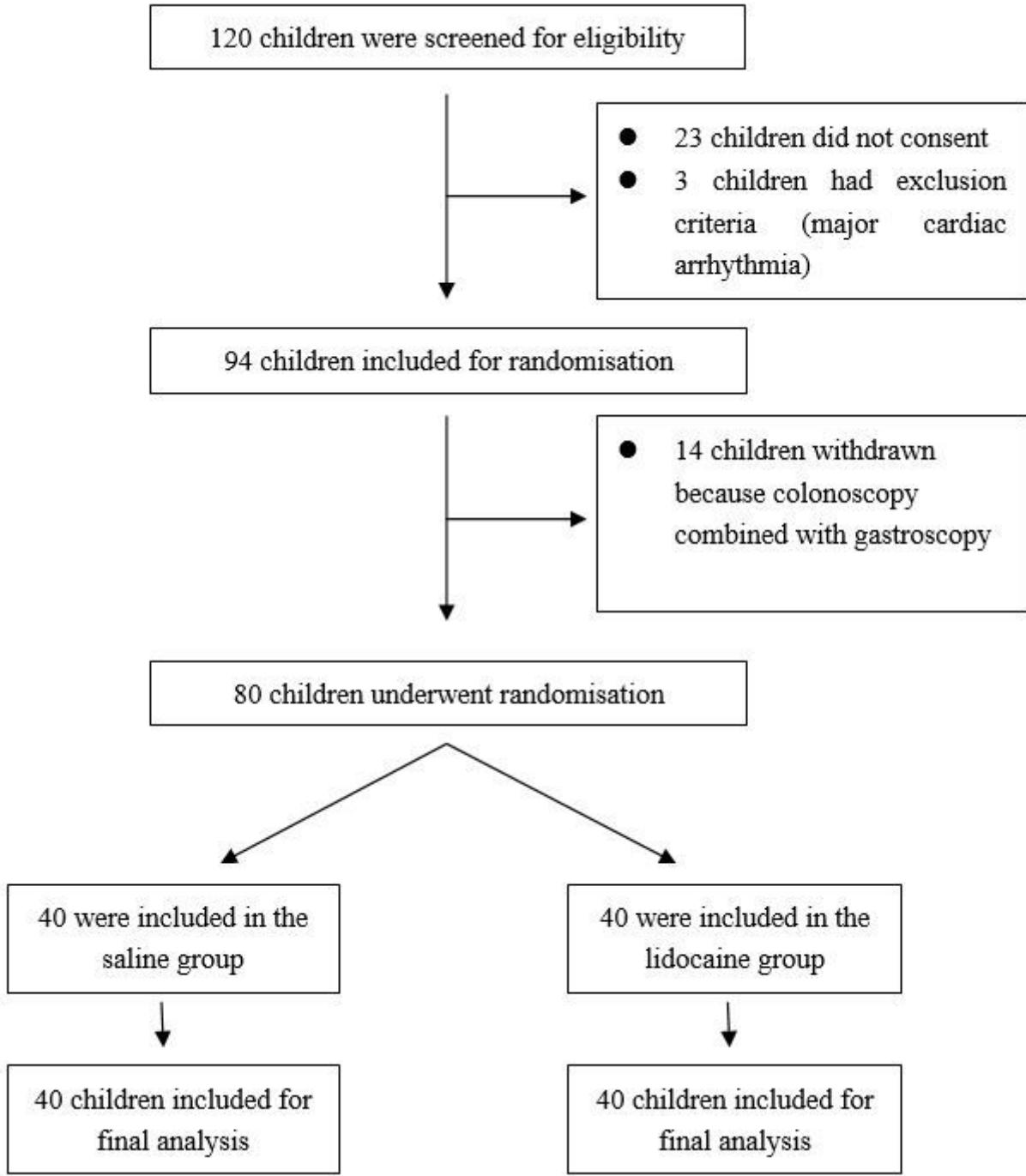
Abbreviations: BMI, body mass index; hs-CRP, high-sensitivity C-reactive protein; Hb, hemoglobin; ASA, American Society of Anesthesiologists.

**Table 2.** Result variables. Data are mean (standard deviation), median (interquartile range), or number.

	Group S (n=40)	Group L (n=40)	P
Propofol: total dose (mg/kg)	4.5 (4.3-4.9)	3.3 (3.0-3.5)	< 0.001
Propofol: induction of sedation (mg/kg)	1.5 (1.5-1.6)	1.5 (1.5-1.5)	0.07
Propofol: during infusion of study medications (mg/kg)	3.0 (2.8-3.3)	1.8 (1.5-2.0)	< 0.001
Sufentanil (μg/kg)	0.1 (0.1-0.1)	0.06 (0.05-0.08)	< 0.001
Lidocaine (mg/kg)	—	1.58 (1.56-1.61)	—
Recovery time (min)	19.2 ± 2.6	13.3 ± 2.6	< 0.001
SpO <sub>2</sub> < 95% (n)	8	2	0.04
SpO <sub>2</sub> < 90% (n)	2	1	0.56
Respiratory rate (bpm/min)	19 (18-21)	20 (19-21)	0.26
Dizziness and vomiting (n)	—	1	—

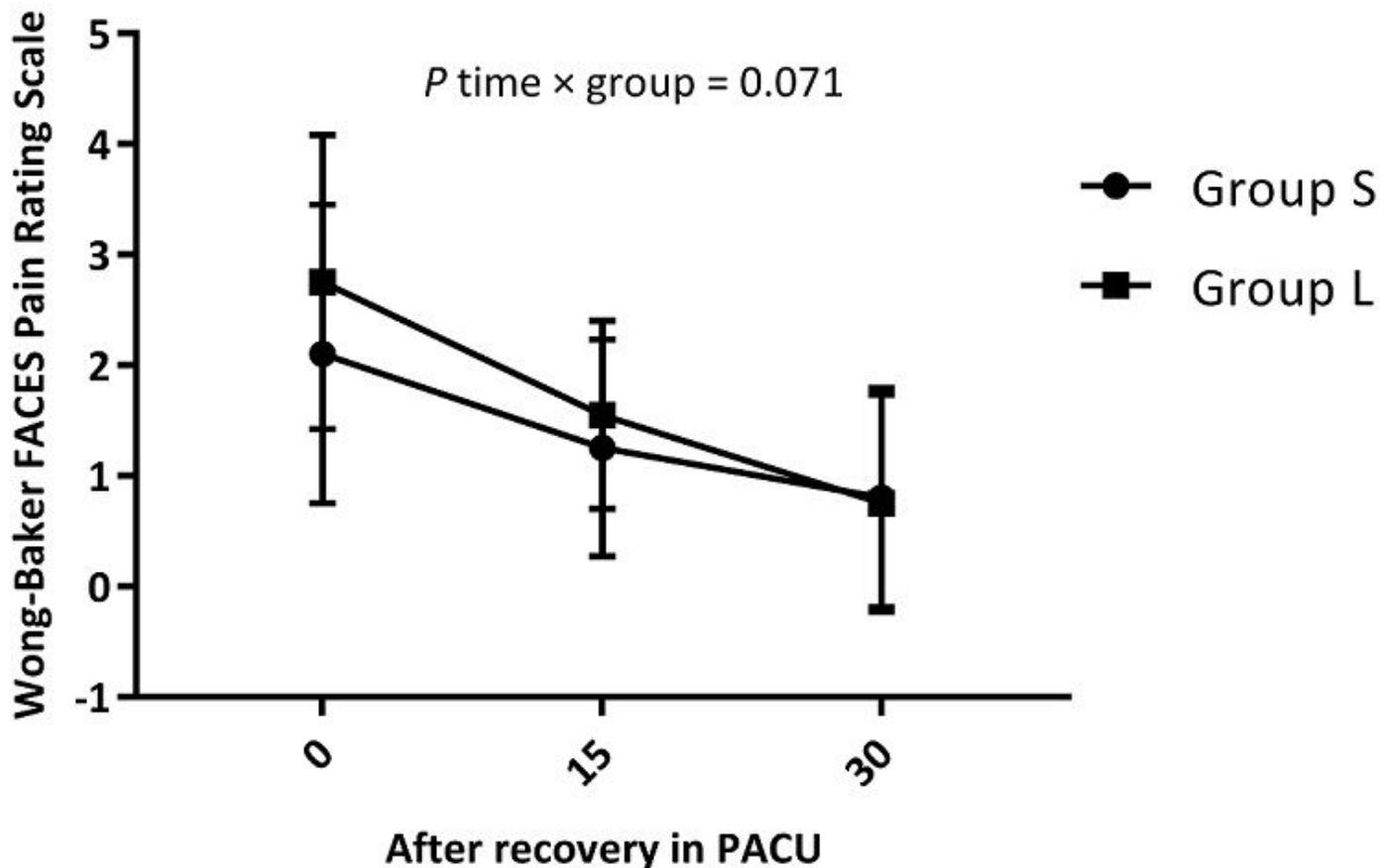
Abbreviations: SpO<sub>2</sub>, oxygen saturation.

## Figures



**Figure 1**

CONSORT 2010 Flow Diagram of this study. A total of 120 children were screened and evaluated from January 9, 2020 to June 30, 2020 in the operating room at Guangdong Women and Children Hospital. Among which, 23 of them did not consent, 3 of them had exclusion criteria (major cardiac arrhythmia), and 14 withdrew because of colonoscopy combined with gastroscopy. In total, 80 children underwent randomization.



**Figure 2**

Pain score after colonoscopy. Data are mean (SD). Pain was recorded using the Wong-Baker FACES Pain Rating Scale after recovery in the PACU 15 and 30 min later. Pain scores after colonoscopy were similar in two groups (analysis of variance:  $P=0.071$ ).

## Supplementary Files

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

- CONSORT2010Checklist.doc