

# Surgical pleth index in children younger than 24 months of age: a randomized double-blinded trial

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## Abstract

**Background:** The surgical pleth index (SPI) is a measurement of intraoperative nociception. Evidence of its usability in children is limited. Given that the autonomic nervous system is still developing during the first years of life, the performance of the SPI on small children cannot be concluded from studies carried out in older age groups.

**Methods:** Thirty children aged <2 yr, planned for elective open inguinal hernia repair or open correction of undescended testicle, were recruited. The children were randomized into two groups; the saline group received ultrasound-guided saline injection in the ilioinguinal and iliohypogastric nerve region before surgery and ropivacaine after surgery, whereas the block group received the injections in the opposite order. The SPI was recorded blinded and was analysed at the time points of intubation, incision, and when signs of inadequate anti-nociception were observed.

**Results:** There was a significant increase in the SPI after intubation ( $P=0.019$ ) and after incision in the saline group ( $P=0.048$ ), but not at the time of surgical incision in the block group ( $P=0.177$ ). An increase in the SPI was also seen at times of clinically apparent inadequate anti-nociception ( $P=0.008$ ). The between-patient variability of the SPI was large.

**Conclusions:** The SPI is reactive in small children after intubation and after surgical stimuli, but the reactivity of the SPI is rather small, and there is marked inter-individual variability in reactions. The reactivity is blunted by the use of ilioinguinal and iliohypogastric nerve block.

**Clinical trial registration:** NCT02045810.

**Key words:** monitoring, intraoperative; nociception; paediatrics

### Editor's key points

- The surgical pleth index (SPI) has been developed as a measure of nociception in adults.
- It is calculated from analysis of the heart beat interval and plethysmographic pulse wave amplitude.
- The value of the SPI in small children, in whom the sympathetic system is not fully developed, is unknown.
- The authors found that the SPI did react to noxious stimuli in children younger than 2 yr.

Nociception during general anaesthesia can elicit significant autonomic, hormonal, and metabolic changes. Marked changes in heart rate, blood pressure, or patient movement during anaesthesia are considered signs of inadequate anaesthesia. A variety of opioids are used during surgery in order to prevent these changes.<sup>1</sup> The use of opioids can lead to significant postoperative respiratory depression, especially in small children.<sup>2</sup>

Traditionally, the signs of inadequate anti-nociception have guided opioid administration. The surgical pleth index (SPI, formerly surgical stress index) was originally introduced in 2007.

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It is calculated from normalized photoplethysmographic waveform analysis and normalized analysis of the heart rate.<sup>3</sup>

The SPI has been used to study opioid administration during surgery,<sup>4–7</sup> but evidence of its efficacy in paediatric populations is scarce. Only two studies have been conducted in paediatric populations, and the children were older than 3 yr in both.<sup>8,9</sup>

Development of the nervous system continues after birth,<sup>10</sup> and heart rate is an age-dependent parameter in children.<sup>11</sup> As the heart rate is higher when compared with adults, and the scientific background on the behaviour of the plethysmographic waveform as a function of age is very limited, evidence from adult populations cannot be directly adapted to children.

In this prospective, randomized, double-blinded study, we wanted to test the performance of the SPI to detect nociception in small children at the time of intubation, surgical incision, and at signs of inadequate anti-nociception.

## Methods

The study was registered at ClinicalTrials.gov (NCT02045810). After receiving approval from the local ethics committee (ETL R13137), 30 patients were randomized into the study groups (Fig. 1). Written informed consent was obtained from both parents before enrolment. The study population consisted of children aged <2 yr, with ASA classification I–III. They were undergoing surgery for inguinal hernia repair or correction of undescended testicles. Both uni- and bilateral procedures were included. Patients with cardiac problems or known ECG disturbances were excluded.

### Randomization

Randomization information was kept in opaque, sealed, numbered envelopes. Before the patient entered the operating room, an independent nurse, who was otherwise not involved in the study, opened the envelope and labelled two syringes based on the randomization. The syringes were marked as number one or two, indicating the order of usage. The saline group (SG) was

given an injection of NaCl 0.9% into the ilioinguinal and iliohypogastric nerve region before surgery and an injection of levobupivacaine 2.5 mg ml<sup>-1</sup> (Abbvie, Helsinki, Finland) after surgery, before extubation. The block group (BG) received the injections in the opposite order. The order of the injections was blinded to the patient and the study personnel.

### Induction of general anaesthesia

Fentanyl 2 µg kg<sup>-1</sup> i.v., glycopyrrolate 5 µg kg<sup>-1</sup> i.v., and thiopental 4–5 mg kg<sup>-1</sup> i.v. were used for induction of general anaesthesia and to enhance tracheal intubation. When clinically necessary, succinylcholine 1–1.5 mg kg<sup>-1</sup> i.v. was also given.

### Delivery of local anaesthesia

Patients received an ilioinguinal and iliohypogastric nerve block under ultrasound guidance (Sonosite S-nerve; Sonosite Inc., Bothell, WA, USA) during anaesthesia, before and after surgery. One author (J.H.) performed all of the preoperative blocks and most of the postoperative blocks. A visual assessment with ultrasound was used to ensure the necessary amount of local anaesthesia to produce an effective block. However, the maximal amount of levobupivacaine (1.5 mg kg<sup>-1</sup> for children <6 months or 3 mg kg<sup>-1</sup> for children >6 months) was not exceeded.

### Maintenance of anaesthesia

Anaesthesia was continued with sevoflurane (2–5% end tidal) and additional fentanyl boluses of 0.5–1.0 µg kg<sup>-1</sup> i.v., if clinically necessary. As the concentration of sevoflurane was considered sufficient, any additional medication was at the discretion of the practising anaesthetist. In most instances, a bolus of fentanyl was given in the event of movement or a rapid 15% increase in heart rate (HR) or non-invasive blood pressure (NIBP) during a 5 min period if clinically necessary. A fentanyl bolus was not judged as mandatory treatment in all episodes of movement or changes in haemodynamics. The delivery of sevoflurane was adjusted based on clinical decision and primarily not as a reaction to the signs of inadequate anti-nociception. Tracheal extubation was performed in children aged <6 months when fully awake, and in older children after the return of spontaneous breathing. Monitoring ended in all patients upon leaving the operating theatre.

### Monitoring

The ECG and the photoplethysmography were continuously monitored. For ECG monitoring, a standard three-lead ECG was used. Measurement of the SPI was performed from a finger on the side opposite to the NIBP measurement, with a TS-PAW adhesive saturation sensor™ (GE Healthcare, Helsinki, Finland). The NIBP measurement was set to 5 min intervals. The SPI and the entropy values were kept hidden from the personnel during surgery. An anaesthesia nurse or attending anaesthetist simultaneously recorded the time points of interest and the concentrations of sevoflurane throughout the study. The numerical values of HR, NIBP, entropy, and SPI were monitored with a Carescape B850 or B650 monitor (GE Healthcare) and recorded using the S5 Collect software (GE Healthcare) at 10 s intervals. The plethysmographic waveform was continuously recorded, and the manufacturer reanalysed the curve to produce data for the components of the SPI, normalized pulse plethysmographic amplitude (PPGANorm), and normalized RR interval (RRInorm).<sup>3</sup>

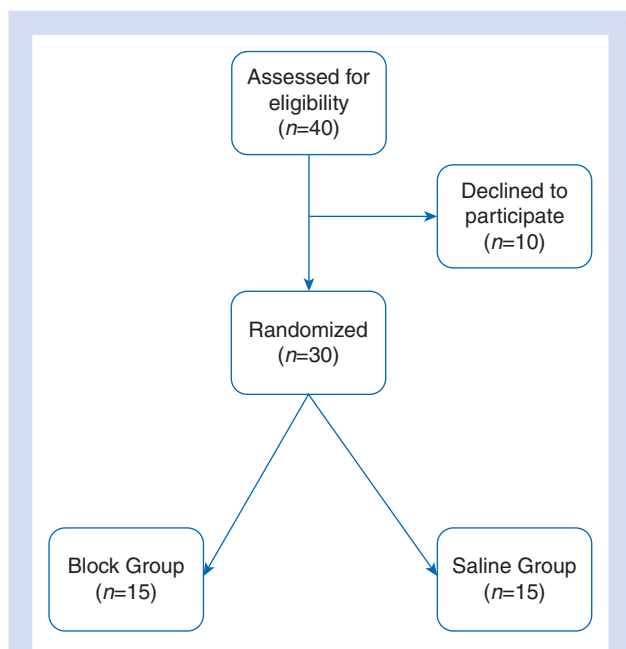


Fig 1 Flowchart.

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