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Clinical Investigation

CLINICAL INVESTIGATION

Surgical pleth index: prediction of postoperative pain in children?

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Abstract

Background. Surgical Pleth Index (SPI) is a non-invasive, dimensionless score (0–100) aimed to allow an estimate of intraoperative nociception. Thus, it may be a useful tool to guide intraoperative analgesia. However, no optimum SPI target range for the use in children has yet been defined. It was the aim of this study to define a clinically appropriate SPI target to predict moderate-severe postoperative pain in children.

Methods. After ethics approval 105 children (2–16 yr) undergoing elective sevoflurane/opioid-based anaesthesia were included. SPI was recorded directly before the end of surgery and compared with acute postoperative pain (age appropriately assessed on different pain scales in the age groups two to three yr, four to eight yr and nine to16 yr) in the postoperative acute care unit (PACU).

Results. Data of 93 children were analysed. A significant negative correlation was found between age and SPI ($r=-0.43$; $P=0.03$). The SPI cut-off value with the highest sensitivity (76%) and specificity (62%) in all children combined was 40. The negative predictive value for SPI ≤ 40 to predict the absence of moderate-severe pain in PACU was 87.5%. The commonly used SPI cut-off (50) published in all related studies had neither any clinically relevant sensitivity nor specificity to predict the presence or absence of acute pain in PACU.

Conclusions. The results suggest that a lower (≤ 40) than previously published (50) target for SPI may be more appropriate in studies investigating SPI guided anaesthesia in children, if the avoidance of moderate-severe postoperative pain is the main goal.

Clinical trial registration. ACTRN12616001139460.

Key words: children; postoperative pain; surgical pleth index

The surgical pleth index (SPI, GE Healthcare, Helsinki, Finland) is a dimensionless, normalized score (0–100) which is based on the photoplethysmographic analysis of the pulse wave and the heart beat interval.[1] Though a gold standard for the assessment of nociception does not exist, SPI scores have been reported to reflect different intraoperative stimuli and different levels of autonomous nervous system activation with some accuracy.[2–4]

Several studies in adult patients have shown that SPI-guided administration of opioids may be beneficial,[3 5 6] but only one

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Editor's key points

- Reliably measuring nociception intraoperatively to optimise analgesia could usefully improve postoperative pain in children.
- Paediatric use of the Surgical Pleth Index (SPI) to monitor nociception has not been validated.
- This study evaluates the predictive value of the SPI for moderate to severe postoperative pain.
- A lower SPI target than previously suggested is required to avoid significant postoperative pain.

trial has investigated this matter in children.[7] In contrast to the studies in adults, in children SPI guided administration of analgesics resulted in higher postoperative pain scores compared with standard intraoperative management.

Of note, all previous studies have uniformly but arbitrarily utilized a target value of SPI $\leq$ 50, though there is little or no validation of this specific cut-off value. A recent study in adult patients described a significantly lower cut-off value (SPI $\leq$ 30) as a more reliable intraoperative target to predict the presence *vs* absence of significant acute postoperative pain.[8]

Based on the latter trial in adults, we hypothesised that the SPI target of $\leq$ 50 utilized in the only available study about SPI guidance and postoperative pain in children,[7] could also have been too high. Thus, it was the aim of this study to investigate the relationship between SPI at the end of surgery and acute postoperative pain in children of three different age groups, with the goal of possibly identifying a more age-appropriate SPI target for future trials.

Methods

After registration of the protocol with the Australian New Zealand Clinical Trials Registry (ACTRN12616001139460), and approval by the Ethics Committee of the Princess Margaret Hospital for Children (EP2016085) and the University of Western Australia (RA/4/1/8634), 105 children undergoing non-emergency surgery under general anaesthesia with sevoflurane and opioids were included in the study. As the standards of assessing postoperative pain in our institution are age-specific (see below), 35 children each were recruited in one of three age groups: two to three yr, four to eight yr and nine to16 yr, respectively.

Exclusion criteria for recruitment included: age<two>16 yr, diabetes, severe peripheral or cardiac neuropathy, pacemaker, use of a surgical tourniquet (unless already deflated before time of measurements), treatment (infusion) with vasoactive medication, any pre or intraoperative treatment until after the five min observation period with ketamine, beta-receptor blockers, clonidine (as premedication, intraoperative use, or regional adjunct), beta-receptor agonists (i.e. Ventolin) or any other drug suspected to interact with the sympatho-vagal balance. Neuromuscular blocking agents antagonism using neostigmine, atropine or glycopyrrolate was only permitted after the six min observation period.

All children received a standard anaesthetic with sevoflurane and opioid (opioid dosage as per attending anaesthetist). As per clinical requirement and the attending anaesthetists' preferences, the children were permitted to receive nitrous oxide, regional/neuraxial blocks and a laryngeal mask airway or tracheal tube. After anaesthesia induction, all children received standard anaesthesia monitoring and monitoring of SPI and state entropy (SE) (both GE Healthcare, Helsinki, Finland). SE was kept between 40–60, whereas no specific target was prescribed for SPI.

At the end of surgery (defined as the time of skin closure or wound dressing), but before SE > 60, SPI was recorded six times (T0, T1, T2, T2.5, T4, T5) during a five min observation interval. The highest and the mean SPI of this series were both recorded (only the highest SPI score was used in the final analysis). Thereafter, anaesthesia was terminated and, once appropriate, the patients were discharged from the operating theatre. On arrival, and once the patient was conscious and deemed non-delirious in the postoperative acute care unit (PACU), acute postoperative pain was recorded every five min for 15 min, and the mean and the highest pain scores noted (with the highest pain score used in the final analysis). Pain was rated as per the guidelines of the Princess Margaret Hospital for Children on three different age-appropriate pain scales (all 0–10): two to three yr aged children were assessed with the FLACC (Face, Legs, Activity, Cry, and Consolability) score, the group of four to eight yr old children with the Revised Faces Pain Scale (FPS-R) and the group of nine to16 yr by means of a Numeric Rating Scale. Treatment of pain was as per our institution's PACU standards.

The primary study outcome parameter was the definition of the optimum (highest combined sensitivity and specificity, Youden's point) cut-off value for SPI to distinguish between no to mild ($\leq$ 3/10) *vs* moderate to severe (>3/10) postoperative pain in children. The secondary outcome parameter was the assessment of a potential variation in SPI in children depending on their age undergoing surgery under general anaesthesia.

Statistics

As no related study was available as guidance, we aimed to gather data from at least 30 patients in each age group in a pilot trial design. As a certain loss of data because of technical difficulties, consent withdrawal or protocol violations was expected, we included 105 patients (35 per group) in total.

All data were tested for normal distribution (K-S test). As appropriate, further analysis (IBM SPSS Statistics Version 20 [IBM Australia, ST Leonards, NSW]) of continuous data was performed via ANOVA or Mann-Whitney*U*-test, correlations were tested using Pearson correlation coefficient or Spearmans' rho, positive and negative predictive values of SPI cut offs were calculated using a χ^2 test and the predictive value (sensitivity and specificity) of SPI cut-offs for acute postoperative pain scores was computed with receiver-operating characteristics (ROC). For the description of a "best-fit" cut-off for SPI, the Youden's point (highest combined sensitivity and specificity) was used. Data are displayed as either mean (SD) or median (quartiles), as appropriate.

Results

105 patients were included in the study. However, data from 12 patients were excluded as a result of protocol violations and thus 93 complete data sets were analysed.

Patient characteristics are displayed in Table 1.

Across all age groups, SPI at the end of surgery was significantly higher when the highest pain rating in PACU was rated moderate to severe (pain score>3) *vs* nil or mild (pain score $\leq$3): 39 (31–46) *vs* 47 (40–51); P=0.009. In all children combined, the area under the ROC curve (testing whether SPI may predict