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Avoiding propofol injection pain in children: a prospective, randomized, double-blinded, placebo-controlled study

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Background. Pain on injection limits the use of propofol in children. The combination of lidocaine and propofol is widely used to reduce pain. A new solvent [medium-chain triglyceride (mct)/long-chain triglyceride (lct)] has been advocated to be less painful than standard (lct) propofol in adults, but no information is available of its usefulness in pre-school children. We designed a prospective, randomized, double-blinded, placebo-controlled study to assess injection pain with two different propofol emulsions, each given with or without lidocaine in children $<$7 yr.

Methods. A total of 160 ASA I–III children were randomly assigned to receive lct–propofol or mct/lct–propofol, 5 mg kg^{-1}, with lidocaine 10 mg ml^{-1} or saline. The site and size of venous cannulation and restlessness before injection were recorded in each patient. A pain score graded 0–6 was established based on spontaneous verbal and motor reaction during injection, each graded 0–3. Kruskall–Wallis and Mann–Whitney tests were used for statistical analysis.

Results. Median pain scores decreased in all groups compared with lct–propofol–saline ($P<0.001$) and were least in the lct/mct–propofol–lidocaine group ($P<0.001$). Painless injection (score, 0–2) occurred in 92.5% of patients in the mct/lct–propofol–lidocaine group compared with 41–77% in the others ($P<0.001$).

Conclusions. Mct/lct–propofol caused significantly less pain than lct–propofol in preschool children. Mixing of lidocaine with mct/lct–propofol resulted in a further significant decrease, virtually eliminating the pain on injection.

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Well-known advantages of propofol[1] should make it a gold standard in paediatric anaesthesia. However, pain on injection, experienced by 70% of adults[2] and in up to 85% of children,[1] prevents its use in young children. The most popular method to prevent painful injection in children is mixing lidocaine with propofol immediately before injection. Significant but heterogeneous results have been obtained in adults, but, to our knowledge, no information is available in preschool children. This knowledge is important because painful injection is particularly undesirable in paediatric population, and it is most likely to occur in these patients as a result of the size of accessible veins. Recently, a medium-chain triglyceride/long-chain triglyceride (mct/lct) emulsion has been introduced as a solvent for propofol injection. It has been advocated to reduce injection pain compared with standard (lct) propofol in both adults and teenagers.[3 4] However, neither mixing with lidocaine nor the solvent alone could eliminate pain.

We conducted a prospective, randomized, double-blinded, placebo-controlled study to assess injection pain with two different propofol emulsions, with or without lidocaine, in preschool children.

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Methods

After obtaining the approval from Institutional Review Board, all children up to 7 yr old, ASA-PS I–III, undergoing elective general anaesthesia without any contra-indication to propofol anaesthesia were approached and an informed consent was obtained from their parents.

The patients fasted for 6 h, and clear liquids were allowed up to 2 h before anaesthesia. They received midazolam 0.4 mg kg^{-1} as rectal premedication 30 min before anaesthesia. EMLA® cream was applied on the dorsum of one hand for 1 h and removed 15 min before anaesthesia. Once in the operating theatre, an i.v. cannula was inserted, an infusion line attached, and routine monitoring applied. If i.v. catheter insertion was unsuccessful or appeared difficult in the EMLA® treated zone, the patient was given N_2O 70% in O_2 as analgesia until another venous line was secured. The child was then allowed to breathe O_2 100% for at least 5 min, and total clearance of N_2O was ensured from expired gas monitoring.

We hypothesized that children would be at least as sensitive to injection pain as adults. From the information available in adults,[5 6] it was calculated that, given $\alpha=0.05$ and $\beta=0.8$, 280 patients were required to recognize a 50% decrease in injection pain. As no paediatric information was available, an intermediate analysis was performed after recruiting 100 patients to adjust the number of patients to be studied if necessary. Therefore, the α significance level was adjusted to 0.029 in the final analysis to avoid increasing type I error, as recommended by the European Medicines Agency.

For the induction of anaesthesia, patients received either lct–propofol (propofol 1%, Fresenius Kabi France) or mct/lct–propofol (Propofol-lipuro 1%, B. Braun medical), 5 mg kg^{-1}, with lidocaine or an equal volume of saline, and lct–propofol–saline was considered the control group. The patients were assigned to one of the four groups according to a computer-generated table of randomization equilibrated by series of four patients. In an adjacent room, an attendant anaesthetist nurse opened the sealed envelope and prepared either lct– or mct/lct–propofol together with lidocaine or saline (1 ml of lidocaine 1% mixed with 10 ml of propofol) to be injected within a few minutes. The attendant anaesthetist was blinded to the patient's group, and the appearance of the drug to be injected was similar in all groups. Propofol was injected over 30 s, spontaneous behaviour of the patient during injection was graded according to a specifically designed scale, and anaesthesia was then carried on as decided by the anaesthetist.

Using the specifically designed composite pain scale, the pain was graded 0–6. The score was based on the assessments of patients' motor and verbal reactions during propofol injection until loss of consciousness (Table 1). This scale had been previously used by our group and proved satisfactory for inter-observer correlation (unpublished data). Pain score >2 was considered unacceptable.

Table 1 Composite injection pain score applicable upon anaesthesia induction in preschool children

Motor events	
• No movement	0
• Slight hand withdrawal	1
• Marked withdrawal, rubbing, tring to tear off the line	2
• General restlessness	3
Verbalization scale	
• No vocalization	0
• Purposeless moaning	1
• Explicit protest	2
• Screams, cries	3
Total	0–6

Age, weight, ASA-PS, type of analgesia for i.v. cannula insertion, site and size of cannula, and restlessness of the patient immediately before injection were also recorded. Mean arterial pressure (MAP), heart rate (HR), Sp_{O_2} value, and unexpected side-effects were recorded before, during, and up to 3 min after injection.

Statistical analysis was carried out using SAS enterprise guide, version 2. The main outcome measurement was occurrence of pain score >2 and the secondary outcome measurement was pain intensity, other data were considered side-effects. Continuous data distribution was described by median and interquartile range, and categorical data were described by frequency count and percentage. Continuous data were compared by Student's *t*-test, Mann–Whitney–Wilcoxon, or Kruskal–Wallis test as appropriate. Categorical data were compared by χ^2 or Fischer's exact test as appropriate. Whenever significant discrepancies appeared, each group was compared separately with others in order to analyse the differences with Bonferroni correction when appropriate. $P<0.029$ was considered significant.

Results

In the intermediate analysis after recruiting 100 patients, 25 in each group, incidence of pain was found to be 70% in Group lct–propofol–saline and 8% in Group mct/lct–propofol–lidocaine. On the basis of these results, it was calculated that 21 patients had to be included in each group to meet our objectives. It was also found that there were a larger number of restless patients before propofol injection in mct/lct–propofol–saline group. Restlessness being a part of pain scale, validity of pain scoring could have been impaired. Therefore, it was decided to recruit 42 patients in each group in order to increase the scope of the study and to eliminate this potential confounding factor. Of the 168 patients, eight were excluded from analysis after randomization because of lack of essential data: four in the lct–propofol–saline group, one in the

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