Reviewer's report

Title: The efficacy of intravenous paracetamol versus dipyrone for postoperative analgesia after day-case lower abdominal surgery in children with spinal anesthesia: a prospective randomized double-blind study

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Reviewer: Søren Mikkelsen

Reviewer's report:

Comments regarding the paper The efficacy of intravenous paracetamol versus dipyrone for postoperative analgesia after day-case lower abdominal surgery in children with spinal anesthesia: a prospective randomized double-blind study

By
Esra CALISKAN, Mesut SENER, Aysu KOCUM, Nesrin BOZDOGAN, S. S. EZER, Anis ARIBOGAN

The paper describes a study in which 60 children scheduled for elective lower abdominal surgery were randomized to receive either intravenous paracetamol, dipyrone or placebo for postoperative pain after spinal anesthesia. Primary outcome parameter was Postoperative pain assessment by VAS scores. Secondary outcome parameters were time to first administration of rescue analgesic and cumulative pethidine requirements.

Following lower body non-orthopedic surgery of a duration of around 40 minutes, the patients were assessed at 15 and 30 minutes, 1, 2, 4, and 6 hours postoperatively.

In general, the study is interesting and the scientific principles applied seem sound.

However, some problems are evident in the paper:

The authors state that “The requirement for postoperative rescue analgesics was significantly lower for the paracetamol and dipyrone groups compared with the saline group (paracetamol vs. saline, p= 0.037; dipyrone vs. saline, p=0.02) (Fig. 2).”

Taking the results reported in table 2 into account, that statement does not seem justified: The only statistical significant difference is that fewer “patients in the actively treated groups required rescue analgesics”. The total doses of rescue analgesics are not significantly different between groups: 9,5 mg; 10 mg, 10,6 mg.
Is it so that the patients from the active groups in need of rescue analgesics needed larger doses of analgesics when needing rescue analgesics?

A major problem is that it appears that the study groups are too small. When it is not possible to discern any difference in postoperative pain in groups receiving drugs with a well-known analgesic effect in comparison to placebo, either the pain experienced is of too low a magnitude to allow for comparisons or the study groups are too small.

On what basis did the authors choose to study groups of 20 patients?

One major error applies to the application of descriptive statistics: The authors state that non-parametric statistics has been applied. However, in the text the results are presented as mean and SD. Mean and standard deviations requires results to follow a normal (Gaussian) distribution. Reporting pain scores with a mean of 1,8 with a standard deviation of 1,3 implies – given normal distribution must be assumed - that one in 21 patients could experience negative NRS-values as 95.4 % of patients should be contained within the interval: mean minus 2 X SD.

The results should be presented as median and quartiles in order to make sense and the text should be corrected in this regard as well as the tables.

A few (five or six) typographical errors or inaccurate linguistic entries should be corrected.

**Level of interest:** An article of limited interest

**Quality of written English:** Acceptable

**Statistical review:** Yes, and I have assessed the statistics in my report.

**Declaration of competing interests:**

I declare that I have no competing interests.