

# **The effect of caudal anesthesia block on perioperative pain control and reduction of the anesthetic agent in pediatric infra-umbilical surgery: A prospective randomized trial**

**Statistical analysis date 04/04/2022** IRB approval number: 123311219,

## **Study population**

The Consolidated Standards of Reporting Trials (CONSORT) checklist was used for the enrolment and allocation of patients. Children aged between two months and six years who were undergoing infra-umbilical surgeries with ASA PS I were randomly allocated to either group A (GA with CEB) or to group B (GA without CEB)., Both groups were compared based on hemodynamic stability, level of sedation, analgesia need, pain score, and parental satisfaction. Postoperative pain was evaluated by the Children's Hospital Eastern Ontario Pain Scale (CHEOPS), Faces Pain Scale-Revised (FPS-R), and Face, Legs, Activity, Cry CONSOL ability (FLACC) scales

The raw data which was collected from case report forms were entered into a Microsoft Excel Spreadsheet initially. Then, the data have been transferred to and analyzed by IBM SPSS Statistics software version 21. The categorical and numerical variables of both groups were analyzed and compared. Data are expressed as *n* (%), mean  $\pm$  standard deviation or median and interquartile range (IQR) according to distribution normality. Continuous variables were compared using the Mann-Whitney U test, and categorical variables were compared using Fisher's exact test or Pearson Chi-square test.  $P < 0.05$  was considered statistically significant. The confidence interval was set at 95%.

## Tables and Figure legends

**Table 1.** Demographic parameters of children with (group A) or without (group B) caudal block anesthesia.

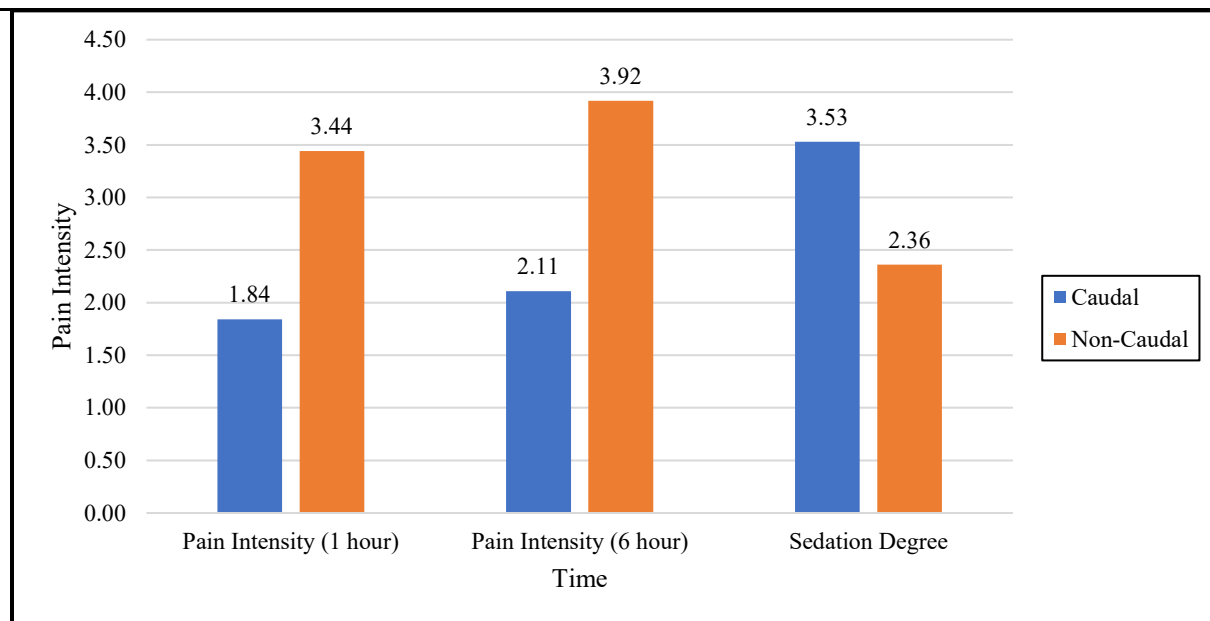
Demographic parameters	Group A (n=36)	Group B (n=36)	<i>P</i>
Age (months), mean $\pm$ SD	20.68 $\pm$ 1.7	29,688 $\pm$ 3.4	0.3
Sex    Female	16 (13%)	15 (11.25%)	0.5
Male	20 (15%)	21(15.75%)	
Heights (cm), mean $\pm$ SD	90 $\pm$ 2.08	103 $\pm$ 4,2	0.8
Weights (kg), mean $\pm$ SD	9 $\pm$ 1,05	12 $\pm$ 3,02	0.6

SD= standard deviation.

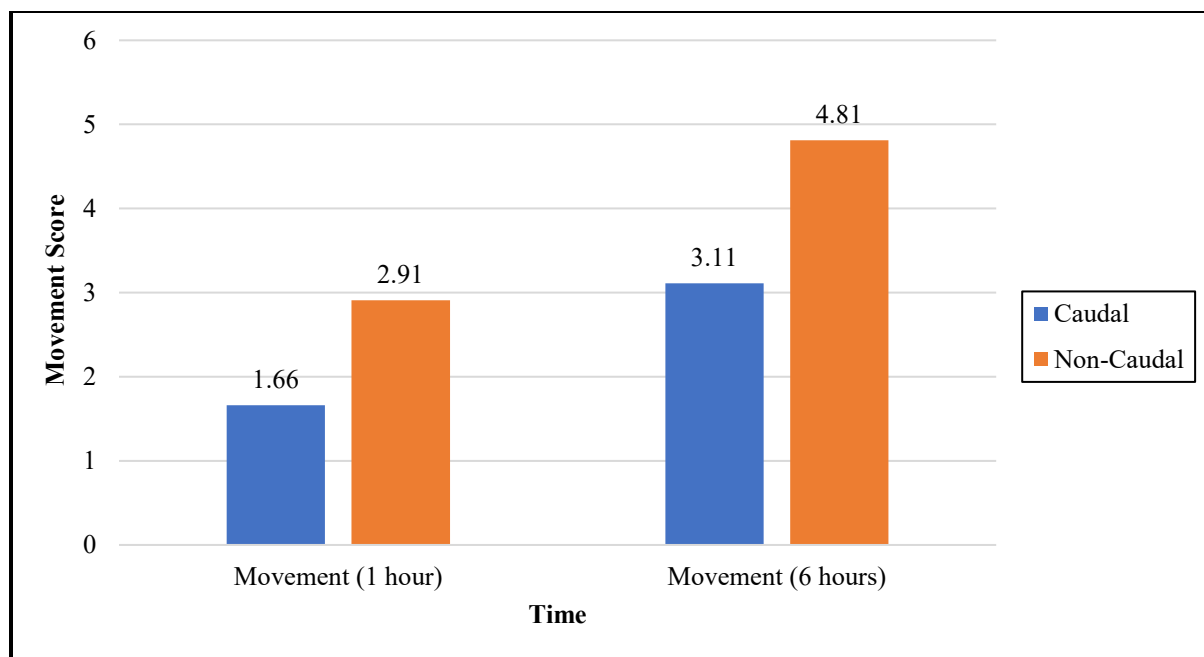
**Table 2.** Differences between children with or without caudal block anesthesia in the average pain scores at the various time points according to Children's Hospital Eastern Ontario Pain Scale (CHEOPS).

Variables	Group A (n=36)	Group B (n=36)	<i>P</i>
CHEOPS Score average	3 $\pm$ 0.11	5 $\pm$ 0.49	<0.005
At 30 minutes	2.6 $\pm$ 0.41	4 $\pm$ 0.44	<0.003
At 1 hour	2.11 $\pm$ 0.98	4 $\pm$ 0.54	<0.0001
At 2 hours	3 $\pm$ 0.44	4 $\pm$ 0.65	<0.003
At 6 hours	3.05 $\pm$ 1.53	4.80 $\pm$ 2.04	0.005

Postoperative analgesia	Yes	3.0 (8.3%)	36 (100%)	<0.001
	No	33 (91.7%)	0.0 (0.0%)	
Parental satisfaction	Good	30 (80%)	5.0 (20%)	<0.002
	Perfect	30 (80%)	5.0 (20%)	<0.001



**Figure 1.** Effect of caudal block versus non-caudal block anesthesia on pain intensity at 1 and 6 hours and the degree of sedation in children undergoing infra-umbilical surgery under general anesthesia.



**Figure 2.** Effect of caudal block versus non-caudal block anesthesia on movement score at 1 and 6 hours postoperatively in children undergoing infra-umbilical surgery under general anesthesia.