

COVER LETTER

Statistical Analysis Plan

ORIGINAL TITEL:

Comparison between the caudal block and other methods of postoperative pain relief in children undergoing circumcision: A prospective randomized study

This study was approved by the research ethics committee operates Institution Review Board number 70130623

The study conforms to the provisions of the Declaration of Helsinki in 1995 (as revised in Edinburgh 2000) and it was ethically approved by the Research Committee for Government Hospitals, Salmaniya Medical Complex, Kingdom of Bahrain (IRB number: 70130623).

Data management

The collected data were recorded then presented and statistically analyzed by computer using SPSS 27.0 for Windows (*SPSS Inc., Chicago, IL, USA*) and Prism Graphpad version 9.4.1 (*Graphpad, San Diego, USA*). A test of normality was done using the Kolmogorov-Smirnov test. Kruskal-Wallis test was used to compare between groups for numerical variables, while Chi-square and Fisher's Exact test were used for categorical variables. Linear regression analysis was used to detect the predictors of pain scale. All tests were two-sided. The accepted level of significance in this work was ($p \leq 0.05$). A p -value ≤ 0.01 was considered highly statistically significant and $p > 0.05$ was considered non-statistically significant.

Results

A total of 90 patients had participated in this current study. The study subjects were classified into 3 main groups. The first group (group A) received general anesthesia with caudal block including 29 patients. The second group (Group B) represented general anesthesia with an opioid group with a total of 33 participants, while the last group (Group C) was patients with a penile block 28 patients. Group B was significantly older in comparison with the other two groups, while Group A was the youngest age group as described in Table 1. No significant difference had been observed regarding operation duration among the three groups. Sevo Mac consumption is significantly lower in group A in comparison with the other two groups. Fentanyl consumption intra and post-operative is higher in group B followed by group C, while the lowest level of consumption with among group A patients. Participants' heart rates are shown in Figure 1. Group C significantly showed a higher mean heart rate intraoperative, 5, 10, 20, 30, and 60 minutes postoperative, while group B showed the lowest mean heart rate in the three groups ($p < 0.005$). The behavioral score is represented in figure 2 which had been measured 5, 10, 20, 30, and 60 minutes postoperative. Group C significantly demonstrated a higher percentage of severe discomfort in comparison with the other two groups in 5, 10, 20, and 30 minutes post-operative (82.1, 25.0%, 21.4%, and 3.6% respectively). The percentage of severe discomfort in group B in 5, 10, 20, and 30 minutes post-operative was 18.2, 6.1%, 3.0%, and 0.0% respectively, while only one patient expressed severe discomfort in 5, 10, and 20 minutes in group A. The pain scale was much higher among group C, while group A showed the lowest mean pain scale (Figure 3).

Table 2 represents the crying scale (5, 10, 20, 30, 60 minutes postoperative) among the studied groups. Group C showed a higher percentage of crying in comparison with the other two groups, however, the relation was non-significant.

The movement scale also was significantly different between the 3 groups in 5, 20, and 30 minutes post-operative (Table 3). Similarly, a significant difference was shown between the 3 groups in the agitation scale in 5, 10, and 30 minutes postoperative (Table 4). Table 5, demonstrated a

statistically significant difference between the 3 groups on the posture scale in 5, and 30 minutes post-operative.

Table 6 explains that the type of block, fentanyl intraoperative and postoperative was the predictor of the 5-minute pain scale, while the type of block was only the significant predictor of the 10, 20, and 30-minute pain scale. The type of block and weight of participants were the predictors of the pain scale 60 minutes postoperative

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Table 1. Demographic data of children who underwent circumcision

Demographic data of children who underwent circumcision Variables	Group A (n=29) Mean±SD	Group B (n=33) Mean±SD	Group C (n=28) Mean±SD	P-value*	Significant pairs**
Age (months)	16.0±7.5	41.8±43.3	16.3±19.7	0.002	Group A vs.s Group B AND Group B vs Group C
Weight (KG)	10.3±2.4	11.3±3.8	9.0±5.1		0.130
Operation duration (minutes)	14.6±3.5	15.1±4.6	16.3±6.1		0.523
Sevo mac	0.5±0.3	2.0±1.6	1.5±0.2	<0.001	Group A vs. Group B AND Group A vs. Group C
Fentanyl intraoperative	9.9±5.4	22.1±9.1	16.4±5.4	<0.001	Group A vs Group B Group A vs. Group C AND Group B vs. Group C
Fentanyl postoperative	4.8±3.1	10.5±4.6	5.2±2.5	<0.001	Group A vs. Group B AND Group B vs. Group C

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Table 2:

represents the crying scale (5, 10, 20, 30, 60 minutes postoperative) among the studied groups. Group C showed a higher percentage of crying in comparison with the other two groups, however, the relation was non-significant

Crying scale (5, 10, 20, 30, 60 minutes postoperative) among studied groups

Brief title: Participants' Crying Scale

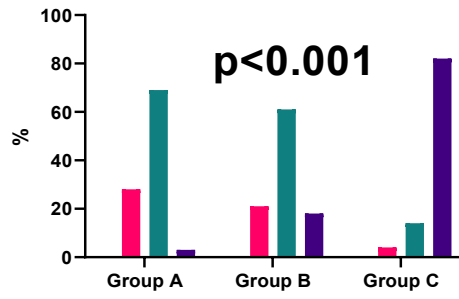
Variables	Group A (n=29) N (%)	Group B (n=33) N (%)	Group C (n=28) N (%)	<i>P</i> -value
5 minutes postoperative				
Not crying	19 (65.5)	19 (57.6)	13 (46.4)	0.344
Crying but responds to tender Loving care	10 (34.5)	14 (42.4)	15 (53.6)	
10 minutes postoperative				
Not crying	15 (51.7)	17 (51.5)	10 (35.7)	0.375
Crying but responds to tender Loving care	14 (48.3)	16 (48.5)	18 (64.3)	
20 minutes postoperative				
Not crying	19 (65.5)	16 (48.5)	12 (42.9)	0.200
Crying but responds to tender Loving care	10 (34.5)	17 (51.5)	16 (57.1)	
30 minutes postoperative				
Not crying	13 (44.8)	15 (45.5)	14 (50.0)	0.912
Crying but responds to tender Loving care	16 (55.2)	18 (54.5)	14 (50.0)	

60 minutes postoperative

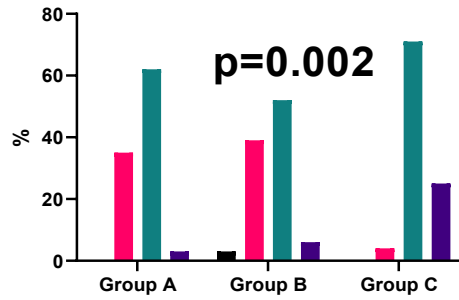
Not crying	17 (58.6)	19 (57.6)	12 (42.9)	0.407
Crying but responds to tender Loving care	12 (41.4)	14 (42.4)	16 (57.1)	

The comparison between groups was done using Chi square test (χ^2)

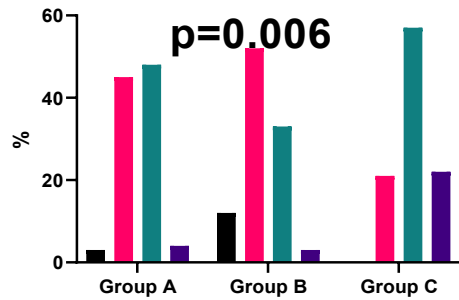
5 Minutes



10 Minutes

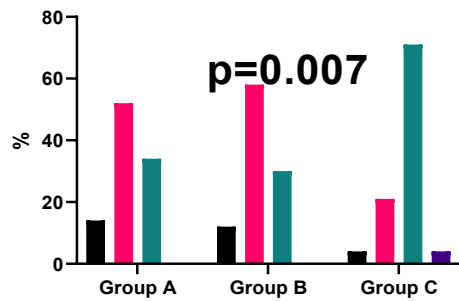


20 Minutes

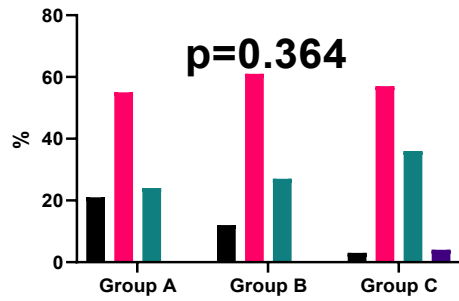


- Relaxed and comfortable
- Mild discomfort
- Moderate pain
- Severe discomfort/pain

30 Minutes



60 Minutes



Behavioral score among studied groups. *Fisher's exact test was used* FLACC scores from 0-10 , zero is analgesia, 1-3 is for mild pain, 4-6 is for moderate pain, and 7-10 is for severe pain