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Original Article

Comparison of local and intra venous dexamethasone on post operative pain and recovery after caeseream section. A randomized controlled trial

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ABSTRACT

Objective: To compare the effect of local infiltration and intravenous dexamethasone on postoperative pain and recovery after Cesarean Section (CS).
Material and methods: A Prospective, randomized study conducted on 120 pregnant women attending the labor wards. All participants were scheduled for elective CS under spinal anaesthesia and were randomly divided into 3 equal groups. Group 1 received 16 mg Dexamethasone IV drip. Group II received 16 mg Dexamethasone subcutaneous injection around the caesarean section scar after skin closure and Group III received Placebo (500 cc saline infusion). All cases were followed up for 48 h for assessment of level of pain by using a 10-cm visual analog scale (VAS). Primary outcome parameters were VAS score and the need for additional analgesics. Other parameters were hemodynamic changes and occurrence of side effects or complications.
Results: there was a highly statistically significant difference between placebo and local infiltration groups and between the placebo and IV groups regarding the needs for postoperative morphine. Comparing both interventional groups revealed statistically significant difference between local infiltration and IV groups regarding the needs for postoperative morphine.
Conclusion: Local infiltration of dexamethasone is more effective than systemic administration to decrease postoperative pain with weaker antiemetic effect.
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Introduction

Caesarean section (CS) births are described as being at epidemic levels across middle-income and high-income countries [1,2].

The risk of postpartum complications in women who received a cesarean section (CS) was higher than that in women who underwent a vaginal delivery (VD) and vaginal birth after cesarean section (VBAC) [3,4].

Patients who undergo cesarean delivery should achieve more postoperative pain relief than other surgical patients because of different factors related to the operation complications as well as maternal and neonatal wellbeing [5].

Tissue Damage causes the release of chemical mediators such as substance P, hydroxytryptophan, serotonin, bradykinin and prostaglandins, which stimulate the A (delta) and C nerve fibers and therefore cause to pain perception [6].

Currently, opioids are commonly used for relief of postoperative pain after caesarean section, either by intrathecal administration prior to section or postoperative parenteral administration [7]. But the usage of opioids are associated with many undesirable side effects such as drowsiness, nausea and vomiting [8]. There-after, there are needs for alternative analgesic drugs to reduce the amount of opioids [9].

Multimodal analgesia approaches have been suggested to manage postoperative pain. One of these is the injection of

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dexamethasone [10]. Acute inflammation induced by tissue damage has a major role in development of postoperative pain, nausea and vomiting. Therefore, dexamethasone should be useful in lowering pain, nausea and vomiting, due to its potential anti-inflammatory effect. Dexamethasone is the most powerful anti-inflammatory drug with a long half- life and its administration is considered safe for periods shorter than two weeks even in amounts above physiological doses [11].

Mechanism of action of glucocorticoids is not fully understood, however, the suggested theories include: Inhibition of production of inflammatory mediators (prostaglandin, bradykinin), preventing reduction of "pain threshold," which occurs in surgeries and reducing tissue swelling because of anti-inflammatory effects and therefore inhibit nerve compression by inflammatory tissue [12].

Both systemic administration of Dexamethasone [13,14] and local infiltration [15] can reduce postoperative pain scores and average consumption of analgesics, as well as treat postoperative nausea and vomiting.

The aim of the current study is to compare the effect of post operative local injection of dexamethasone at C.S scar and pre operative single IV administration on post operative pain and vital signs.

Material and methods

This study was a prospective single blind placebo controlled randomized study. It was conducted on 120 pregnant women attending the labor wards in Kasr Al Ainy and Fayoum maternity hospitals from May 2014 to December 2015.

The study was approved by local ethics committee. All women candidate for elective CS were approached, the nature of the study and expected values were explained and women were invited to participate. Only women signing informed consents were included in the study. All participants were scheduled for elective cesarean section under spinal anaesthesia. The exclusion criteria were women with neurological disorders, psychologically disturbed, those with uncontrolled hypertension, Diabetes Mellitus, peptic ulcer, liver cirrhosis or glaucoma. Women with systemic infections, allergy to Dexamethasone or contraindications to spinal anaesthesia were also excluded.

The 120 women candidate for elective CS with American Society of Anaesthesiologists (ASA) classes I and II were randomly divided into 3 equal groups using computer generated random numbers. Group 1 included 40 women received 16 mg Dexamethasone IV drip on 500 cc saline (dexamethasone sodium phosphate USP 8 mg/2 ml amp. EIPICO pharmaceutical,.Egypt). Group II included 40 women received 16 mg Dexamethasone subcutaneous injection around the caesarean section scar after skin closure and Group III received Placebo in the form of IV fluids 500 cc saline infusion.

The patients were subjected to history taking, including age, parity, menstrual history for verification of gestational age and medical history for confirmation of inclusion and exclusion criteria. Full general and abdominal and obstetric examinations were done. Investigations including complete blood picture, liver functions and coagulation profile to exclude those not fitting with the above listed criteria. Ultrasound was done to assess gestational age.

Patients were checked for coagulation abnormalities. Large gauge (18G) cannula was inserted in cephalic or ante cubital veins. Patients were preloaded with HAES- steril 6% (hydroxyl ethyl starch) Fresenius or with ringer's lactate 20 ml/kg [16]. Patients were positioned in the sitting position for spinal anaesthesia and sterilization of the back was done using Betadine. L3-L4 space was determined for the insertion of spinal needle. Then 25G spinal needle was used to perform a single shot spinal anaesthesia using 10 mg of 0.5% hyperbaric Bupivacaine and Fentanyl 20 μg [17].

All surgeons had close surgical skills and used the same technique transverse lower segment incision.

The procedure is then completed using traction on cord to deliver the placenta, exteriorization of uterus, closure of uterine incision in 2 layers, closure of both visceral and parietal peritoneum, closure of rectus sheath, no subcutaneous closure and finally subcuticular skin closure. Follow up for all cases for 48 h. Primary outcome parameters were VAS score and the need for additional analgesics. Other parameters were hemodynamic changes and occurrence of side effects or complications.

The visual analogue scale or visual analog scale (VAS) is a psychometric response scale which can be used in questionnaires. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two endpoints.

This continuous (or "analogue") aspect of the scale differentiates it from discrete scales such as the Likert scale. There is evidence showing that visual analogue scales have superior metrical characteristics than discrete scales, thus a wider range of statistical methods can be applied to the measurements [18].

Power analysis based on the pilot cases done prior to the study had indicated that at least 31 patients in each group will be required to demonstrate a clinically significant difference in the mean pain VAS score at 24 h of postoperative with probability = 0.05 and a power of 90%. Assuming a 5% drop out rate, at least 39 patients were required to be recruited in each trial arm.

Data was analyzed using SPSS version 16 (SPSS Inc., Chicago, IL). Results are presented as mean ± standard deviation for continues (pain severity, HR, RR, MAP and number and percent for qualitative variables as morphine. Comparison of quantitative between groups was done using ANOVA followed by post hoc test (LSD). Within group comparison at each time follow up was done using repeated measure analysis of variances (ANOVA)." Mauchly test for checking sphericity condition as a perquisite assumption was conducted. In those conditions that this assumption was not satisfied, multivariate Wilk's λ test was used. <0.05 was considered as statistically significant.

Results

Flow chart is described in Fig. 1.

Characteristics of the study groups show no significant differences between the three groups regarding age, gestational age, parity, number of cesarean sections, duration of surgery or neonatal birth weight (Table 1).

The mean blood pressure, heart rate and respiratory rate show no statistically significant difference between the three groups when measured at 30 min up to 24 h after the operation (Table 2).

A higher VAS score was detected among women in placebo group than the other two groups (Table 3 and Fig. 2).

The needs for postoperative morphine at 1 h up to 24 h after the operation was significantly higher among those in the placebo group when compared to women in the local infiltration. While that difference was significant only till only 6 h after the operation in the IV group (Table 3).

There was a statistically significant difference between local infiltration and IV groups at 4, 12 and 24 h after the operation regarding the needs for postoperative morphine (Table 3).

There was a significantly higher number of women who experienced nausea among placebo women group against those in the IV group (Table 4).

There was no significant difference between the three study groups regarding the occurrence of wound and chest infections (Table 4).