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ORIGINAL RESEARCH **OBSTETRIC ANESTHESIA**

Pre-emptive intravenous paracetamol vs. ketorolac for shoulder pain in cesarean section under spinal anesthesia: A randomized double-blind placebo-controlled trial

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Abstract

Introduction: Intraoperative shoulder pain (ISP) is a common side-effect of spinal anesthesia (SA) for cesarean sections (CS), but in most cases, it does not receive sufficient attention by the anesthesiologists. Following a randomized prospective double-blinded design, we aimed to compare the effect of ketorolac and paracetamol in prevention of the development and intensity of intraoperative ISP in patients undergoing CS under SA.

Methodology: A total of 147 parturients, American Society of Anesthesiologists (ASA) Physical status II, who were planned for elective CS under SA were randomly allocated to three groups, to receive either intravenous ketorolac 30 mg (K group, n= 50), paracetamol 1 g (P group n= 50) or normal saline (Control group, n-52). Demographic data, surgery, negative outcomes, and average severity of ISP were collected by a blinded observer. Intraoperative ISP and intensity of intraoperative and postoperative ISP were defined as primary and secondary outcomes, respectively. Hypotension, bradycardia, and request for intraoperative rescue analgesia were other secondary outcomes.

Results: The prevalence of ISP was significantly higher in the control group than in the other two groups (33.3% vs. 14% and 6.1 %, respectively, $p = 0.002$). The intensity of the pain was higher in the control group. ($p = 0.748$), and the parturients in the control group had a considerably higher demand for intraoperative analgesia (12.2 % vs. 0 % and 2 %, $p < 0.001$). We found no significant difference regarding incidences of bradycardia and hypotension between the groups ($p = 0.99$, $p = 0.854$).

Conclusion: Single shot ketorolac 30 mg and paracetamol 1 g may decline both development and intensity of intraoperative shoulder pain in C-sections under spinal anesthesia without enhancing negative events.

Key words: Ketorolac; Acetaminophen; Shoulder pain; Cesarean section

Abbreviations: ISP – intraoperative shoulder pain; CSI – combined spinal epidural anesthesia; SA – spinal anesthesia; CS – cesarean sections; NSAID – nonsteroidal anti-inflammatory analgesic; NRS – Numerical Rating Scale

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1. Introduction

Shoulder pain has often been observed after spinal anesthesia (SA) for cesarean sections (CS) in the parturients. However, it has not received its due attention. The literature is sparse regarding the true incidence and the intensity of intraoperative shoulder pain (ISP). [1] We know that ISP does happen due to SA during CS, and is usually of sharp nature in the shoulder area. Patients usually attribute its origin to deep inside the shoulder. The incidence is high in females who had CS under combined spinal epidural anesthesia (CSE).[1]

This pain has been attributed to sub-diaphragmatic clots, sub diaphragmatic air trapping, or the resultant peritoneal irritation.[2] Preventive analgesia using non-opioid analgesics is intended to decline post-surgery pain as well as preventing negative impacts of opioids.[3]

Ketorolac is a commonly used nonsteroidal anti-inflammatory analgesic (NSAID) for treating postoperative pain in combination with multimodal analgesia. Single-dose ketorolac is used in labor analgesia and is reported as a safe and effective intervention for the mother and the fetus.[4] Acetaminophen (paracetamol) is a non-narcotic analgesic that has no known adverse effect on the fetus and the parturient. Both these drugs are commonly used during perioperative period in CS under SA. Regarding this safety profile and efficacy in obstetrics as well as the opioid-sparing role, we studied ketorolac and paracetamol to assess their efficacy in declining ISP in pregnant women scheduled for CS under SA.

2. Methodology

Following a prospective randomized, double-blind, placebo-controlled design, the current study was carried out in Hafez Hospital, affiliated to Shiraz University of Medical Sciences, Shiraz, between October 2019 and January 2020.

2.1. Patients

Two hundred and thirty-six parturients were eligible to participate. The study protocol was explained to them, and written informed consent was obtained. The study was approved by the Ethical Committee of Shiraz University of Medical Sciences, code: (IR.SUMS.MED.REC.1397.358) on 21 October 2019, and registered at www.irct.ir (IRCT20180922041084N4; http://www.who.int/ictrp/en/).

A total of 152 primigravida or second gravida parturients planned for elective CS under SA (ASA II), who had singleton pregnancy at term (37 weeks of gestational age or more), and who consented to participate in the study, were enrolled (Figure 1). Exclusion criteria included allergy to the study medications, asthma, gestational diabetes, cardiovascular and hepatic disorders, renal insufficiency, chronic alcoholism, bleeding tendency, chronic pains or history of upper extremity trauma, history of peptic ulcer disease, history of abdominal surgery and previous severe preeclampsia. Any contraindication to SA and CS and failed SA excluded from the study. Parturients had a BMI 20 to 25.

2.2. Intervention

Using random drawing of sealed envelopes, parturients were randomly allocated to three groups (www.randomization.org).

Three parturients were removed following allocation process. A blinded researcher who was not a member of the research team prepared medications. Afterwards, an anesthesiology resident, who was not a member of the research team, administered the medications. All participants were evaluated before surgery, and received warmed (37°C) lactated Ringer's solution 15 ml/kg IV. Oxygen 5 L/min was administered through a Hudson mask during anesthesia. A blinded person to the study group of participants collected all data. As mentioned before, 152 subjects were randomly assigned to receive ketorolac 30 mg in 100 ml normal saline during 20 min (50 patients; Ketorolac group), or paracetamol 1000 mg in 100 ml normal saline during 20 min (50 patients, Paracetamol group), or 100 ml normal saline as placebo during 20 min (52 patients; Control group).

The patients were assisted to sit upright, and SA was applied following the midline approach in the lumbar vertebral interspace L3-L4 or L4-L5, using 25 gauge Quincke needle. After obtaining a free flow of cerebrospinal fluids, 10 mg of bupivacaine hydrochloride and 10 µg of fentanyl were injected.

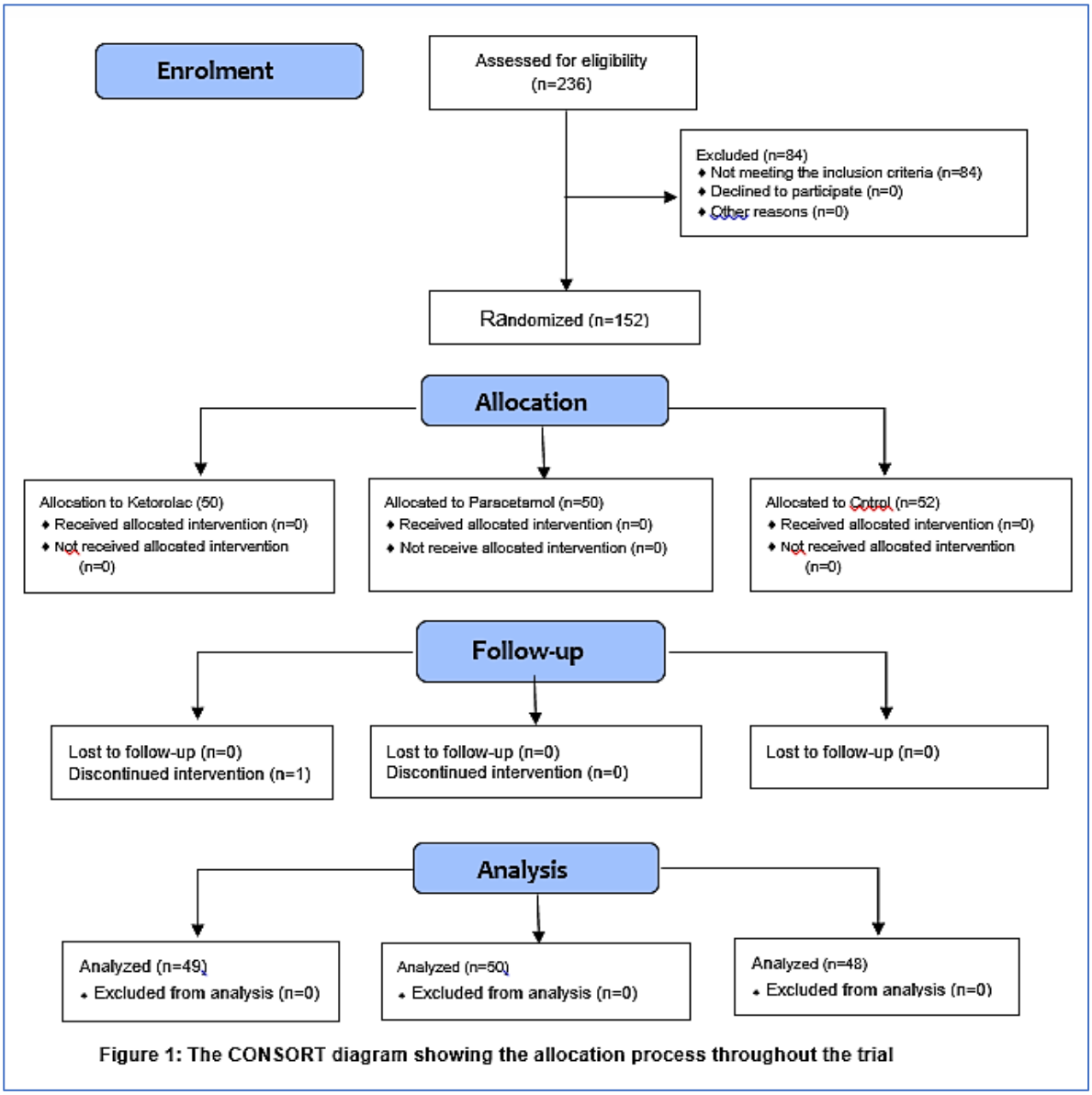

Figure 1: The CONSORT diagram showing the allocation process throughout the trial

The parturients were placed in the supine position with a 15° left lateral table tilt until delivery of the infant. SBP, the heart rate and pulse oximetry were monitored consistently before the induction of anesthesia and throughout the intraoperative period. Response to cold was tested to determine block level. After attaining block level at least to T6, the surgeons could proceed with surgery. At present, most of the

Table 1: Demographic data in study group patients

Parameter	Ketorolac Group (n=49)	Paracetamol Group (n=50)	Control Group (n=48)	p value
Age (y)	26.91 ± 5.7	26.34 ± 5.71	26.77 ± 6.08	0.876
Weight (kg)	79.02 ± 10.6	81.34 ± 10.21	76.57 ± 10.74	0.101
Height (cm)	161.06 ± 4.96	160.42 ± 5.19	160.73 ± 3.61	0.792
BMI	31.37 ± 3.86	29.31 ± 3.72	29.60 ± 3.56	0.201
Data given as Mean ± SD				

obstetricians would pull the uterus out of the abdominal cavity before suturing to check for bleeding and to prevent postpartum hemorrhage.

The investigators thoroughly explained the usage of numerical rating scale (NRS) in describing the pain to the patients and emphasized the patients to declare the pain to the anesthesiologist or the anesthesia nurse at any time during surgery and at 10 min during surgery and recovery. Oxytocin 20 IU in normal saline 500 ml was administered to all three groups after delivery.

2.3. Outcomes

The patients noted that the sharp pain was in the shoulder area or under the diaphragm. The pain was described as coming from deep within the shoulder, and in some, it radiated from the right chest. In some parturients it spread down from the upper right arm and up the right neck, which led to muscular tension and pain.

The intensity of ISP was evaluated by the verbal the 0-10 Numerical Rating Scale (NRS) and the pain was categorized for analysis into mild (NRS score 0-3), moderate (NRS score 4-7), and intense (NRS score 8-10). For cases with intense pain, analgesia was administered by fentanyl 25 µg IV and then repeated 25 µg as needed.

Hypotension (a 20% decline in systolic blood pressure from the baseline) received ephedrine 5 mg. Blood pressure was measured every 5 min. Bradycardia (HR< 60/min) was managed with atropine 0.5 mg IV. Heart rate was monitored continuously.

2.4. Data analysis

Continuous variables are described using mean and standard deviation. Categorical variables expressed using frequency and percentage. Continuous variables level was considered as a $p < 5\%$. SPSS 25.0 (SPSS Chicago, IL) was used to analyze the data. Data were analyzed by the repeated Measure test, One-way ANOVA, and Post HOC. The statistical significance to detect the incidence rate and intensity of ISP, a sample size of 90 cases (45 in each group) was calculated, with a power of 80%. According to the following formula and Abbas's study,[6] the sample size of this study was decided.

$n1 = n2 = n3 = (p1 (1-p1) + p2 (1-p2)) (z1-\alpha 2 + z1-\beta) 2 (p1-p2) 2$

$p1 = 0.08$

$p2 = 0.23$

$\alpha = 0.05$

Power = 80%

n1 = 45, n2 = 45, n3=45

3. Results

A total of 236 patients from October 2019 until January 2020 were assessed for eligibility, 152 out of them were found to be eligible. In the following scrutiny 84 parturients were excluded, as they were multiparity (32), and patients who had breech or transverse presentation (10), needed emergent surgery (20), twin pregnancy (10), active peptic ulcer disease (6), liver disease (one person) and renal disease (5). SA failed in 4 patients during study. Finally, we analyzed 147 parturients (Figure 1).

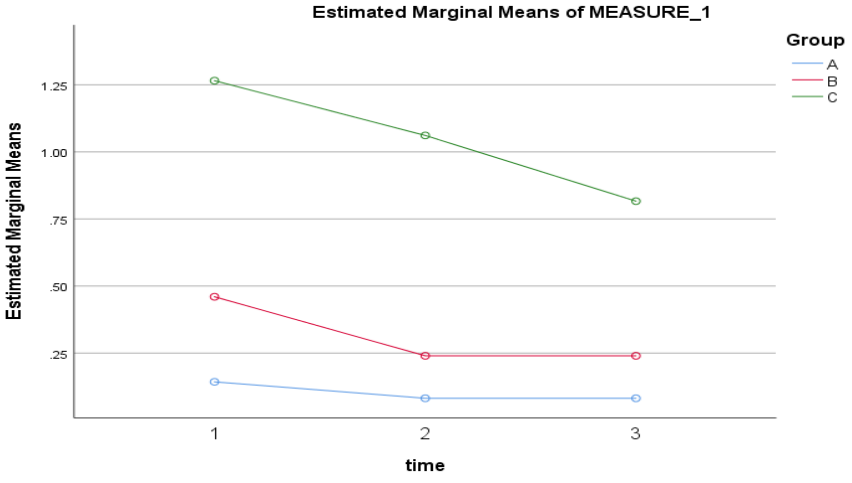

Figure 2: Comparison of the incidence of cesarean section and the rate of use of delivery helping instruments

Patients were similar in demographic characteristics regarding age, height, weight. Data related to surgery and analgesic are provided in Table 1. Those in the control group experienced a significantly higher rate of ISP than those in the ketorolac and paracetamol groups (33.3% vs.14% and 6.1

Table 2: Comparative data of the complications side-effects in three groups

Parameter		Ketorolac Group (n=49)	Paracetamol Group (n=50)	Control Group (n=48)	p value
Shoulder Pain		3 (6.1)	7 (14)	16 (33.3)	0.002
Hypotension		16 (32.7)	19 (38)	16 (33.3)	0.854
Bradycardia		3 (6.1)	4 (8)	4 (8.3)	0.99
Shoulder Pain Severity	Mild	3 (6)	5 (71.4)	10 (62.5)	0.748
	Moderate	0	2 (28.6%)	5 (31.3)	
	Severe	0	0	1 (6.3)	

Data given as n (%)

Table 3: Comparative data regarding block and analgesic scores

Parameter	Ketorolac Group (n=49)	Paracetamol Group (n=50)	Control Group (n=48)	p value
Time to reach highest block (min)	12.17 ± 2.25	11.31 ± 4.24	11.72 ± 2.11	0.344
Sensory level; median (Range)	T5 [T2-T6]	T4 [T3-T6]	T5 [T4-T6]	
Estimated blood loss (ml)	675 ± 120	740 ± 170	630 ± 220	0.457
Overall NRS Score (15 min)	2.33 ± 0.57	3.28 ± 1.25	3.87 ± 1.78	0.288
Overall NRS Score (30 min)	1.33 ± 0.57	1.71 ± 1.11	3.25 ± 1.12	0.004
Overall NRS Score (RR)	1.33 ± 0.57	1.71 ± 0.95	2.50 ± 1.09	0.102

Data given as Mean ± SD or n (%)

%, p = 0.002). There were low requests for intraoperative analgesia for intolerable ISP in the ketorolac and paracetamol groups compared to the control group (p < 0.001). The incidence of intraoperative bradycardia and hypotension were not different between the groups (p = 0.99, p = 0.854 respectively). Nevertheless, we found no significant difference among both groups concerning time to sensory block, maximum level to sensory block, and estimated blood loss.

Severity of ISP was higher (moderate to severe) in the control group than the rest, with no statistical significant difference (p = 0.748).

NRS data were examined separately using Friedman test due to the abnormal distribution of data. We found a significant difference among the study groups concerning NRS changes using repeated measurements test. Ketorolac and paracetamol group patients experienced less severe ISP than the control group, as measured by post hoc test. We found a significant difference among the ketorolac and control groups (p = 0.03) and also between the Paracetamol and control groups (p = 0.014) at 30 min after injection in terms of NRS score (Figure 2).

4. Discussion

Intraoperative shoulder pain (ISP) is a common CS complication that is usually overlooked despite being annoying. Besides, it is often neglected in clinical work and scientific studies.

Shoulder pain has been reported in patients under thoracotomy with epidural chest anesthesia,[7] which in thoracotomy patients was a referred pain involving the phrenic nerve. The presence of residual blood after manipulation of visceral organs can stimulate the diaphragm and it also affects the phrenic nerve.[8] Obstruction or a pressure on peritoneal membrane can cause severe irritation of the C5 nerve and cause referred pain in the axillary nerves.[9] Carbon dioxide trapping during laparoscopic cholecystectomy may cause pain below the diaphragm. This symptom is

usually associated with gas penetration under the diaphragm or peritoneal stimulation or diaphragm or the stretching effects of laparoscopic surgery.[10] The pain may spread through the roots of the C5 nerve to the axillary, radial, median, and musculoskeletal nerves. The nerve endings C3, C4, and C5 make up the diaphragmatic motor nerve and have sympathetic fibers.

The precise cause of pain is not identified yet, but it is attributed to sub-diaphragmatic clot, sub-diaphragmatic amniotic fluid, or sub-diaphragmatic air trapping.

Kehr's sign (referred pain) is defined as acute pain in the tip of the shoulder because of the presence of blood or other irritants in the peritoneal cavity. This pain is found to go down through the upper arm and up in the neck on the right side in some cases, which sometimes causes muscle spasm. The most common causes of ISP are accumulation of blood or amniotic fluid drained from uterus during the CS and it commonly needs a rapid intervention due to its severity.

There are other factors that may contribute to clots remaining in situ. Packing around the uterus is the ideal preventive intervention to prevent accumulation of the fluid under the diaphragm. Nevertheless, this may cause pain. Hence caution should be taken. Shoulder pain was a common complaint after caesarean section in the Phelps et al. Study.[11]

The rate of ISP after cesarean section is 39.45%.[16] The total number of cases with shoulder pain was lower in patients with SA than those with general anesthesia.[17] Tenoxicam 20 mg in 5 ml of normal saline (NS) immediately after the skin incision has been reported to produce an increase the pain severity, bradycardia, nausea, vomiting, chest tightness, and shoulder pain According to our study, intravenous single dose of ketorolac 30 mg or paracetamol 1 g before cesarean section under SA can prevent ISP in some cases and reduce the severity of it in some other cases.

General anesthesia for cesarean section is an older method for cesarean section anesthesia, but the preferred method in some cases, like hypovolemia; Coagulopathy; intractable catheter infection or needle injection site; enhanced intracranial pressure and patient dissatisfaction with spinal anesthesia.[9] Some studies like Phelps study suggest that SA is correlated with a considerable decline in the incidence and severity of shoulder pain. This decrease is mainly due to the patient's position. It seems that stimulation of the diaphragm with amniotic fluid or blood is the most important cause of shoulder pain after caesarean section. Placing patients in a Trendelenburg position may increase the aperture of the diaphragm by fluids. Therefore, diaphragmatic stimulation is more common in patients with normal drowsiness during general anesthesia than in those who are mainly in the state of Trendelenburg position under spinal anesthesia.[11]

Contrary to Phelps study, Zirak study states that postoperative shoulder pain in patients with SA has been higher than in general anesthesia, and this difference may be due to the position of the patients during and after the surgery.[10]

The duration of surgery and the amount of bleeding in Zirak study were measured as pathophysiological factors of shoulder pain.

A number of studies have shown that procedures that reduce abdominal distention and reduce stimulation of the diaphragm muscle, cause low shoulder pain after laparoscopic surgery.[7, 12-15]

The rate of shoulder pain after cesarean section is 39.45%.[16] The total number of cases with shoulder pain was lower in patients with SA than those with general anesthesia.[17]

The results of our study are in agreement with Jelinek study who showed that 30 mg of ketorolac intramuscularly before CS compared with single-dose corticosteroid had a similar effect to the same dose of opioids but less side effects.[18,19]

There are several studies of post-operative and cesarean pain management using paracetamol.[20-23] To the best of our knowledge there is no randomized study of pre-emptive paracetamol effect for prevention of ISP.

5. Limitations

The important limitations of our study are lack of pretreatment pain measurement and also this issue that analgesic requirement may vary from patient to patient. these should be mentioned as limitations of the study. Our option has a disadvantage of exposing the fetus to non-steroidal anti-inflammatory drugs (NSAID), also uterine relaxing effect of NSAID may contribute to increased blood loss.

6. Conclusion

This study demonstrated that a single shot ketorolac 30 mg and paracetamol 1 G, both reduce the incidence and intensity of intra-operative shoulder pain in C-section under spinal anesthesia without any increased negative side effects.

7. Acknowledgment

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8. Authors' contribution

LD: Supervisor, hypothesis
SA: Supervisor, hypothesis, manuscript writing
FF: Data collection, Draft writing, editing
MYK: Review, corresponding author

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