



Comparison of Intravenous Paracetamol and Intraperitoneal Instillation of 0.25% Bupivacaine with Dexamethasone for Postoperative Analgesia in Patients Undergoing Laparoscopic Sterilisation – A Randomized Clinical Trial

Authors

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Abstract

Background: Intraperitoneal instillation of local anaesthetic as a postoperative analgesia following laparoscopic sterilization is an easy technique which doesn't need expert hands or specialised equipment and can even be followed in rural centres where sterilisation is performed.

Aim: To study the efficacy and compare intravenous paracetamol with intraperitoneal instillation of 0.25% bupivacaine with dexamethasone during laparoscopic sterilisation for postoperative analgesia.

Methodology: Patients were randomly divided into 2 groups, Group 1 (n= 20) - received 100ml of intravenous Paracetamol and Group 2 (n= 20) - received 20ml of 0.25% bupivacaine with dexamethasone (8mg) for intraperitoneal instillation. Patients weighing between 50-70 kg, willing to give written informed consent and assessed under ASAPS I and II are included in this study. Outcome measures will be assessed from baseline and at 0, 1, 2, 4, 8 and 12hrs after the procedure at hospital.

Result: At 8 hours and 12 hours, the mean VAS score was high in group 1 (2.3 ± 0.94), (3 ± 0.94) followed by group 2 (0.4 ± 0.51), (1.1 ± 0.99) respectively which was statistically significant.

Conclusion: This study infers that intraperitoneal instillation of 0.25% bupivacaine with dexamethasone as postoperative analgesia following laparoscopic sterilization is effective in comparison with intravenous Paracetamol.

Keywords: Intraperitoneal instillation, laparoscopic sterilization, postoperative analgesia, intravenous paracetamol, bupivacaine, dexamethasone.

Introduction

In a developing country where population control is a priority, every effort should be made to make the family planning methods more acceptable. In India laparoscopic sterilisation is a very popular method of family planning. Laparoscopic operations outnumbered postpartum sterilisations. Yet, the fear of operation and the pain associated with operative interference deters many eligible

clients from undergoing sterilisation operations. Traditionally, opioids or NSAIDs, in various combinations, have been used for postoperative analgesia after laparoscopic sterilisation^[1]. For more than a decade, there has been world-wide interest in application of local anaesthetic to the tubes to reduce the postoperative pain.^[2-5] We decided to study the efficacy of intraperitoneal instillation of bupivacaine with dexamethasone

and intravenous paracetamol as postoperative analgesia for laparoscopic sterilisation.

Methodology

A randomized parallel group trial was conducted in the month of November and December 2021 after obtaining approval from the Institutional Ethical committee. Sample size calculations was calculated based on the previous study conducted by Goyal et al. using G-power analysis keeping the power of the study 95% and alpha error at 5%, the minimum sample size was calculated to be 36 subjects with 18 subjects in each group. Anticipating 10% attrition, the sample size was increased to 40 with 20 subjects in each group. Patients admitted in family planning ward posted for laparoscopic sterilization were selected randomly into two groups, using a computer-generated randomization schedule, to receive either 100 ml of IV Paracetamol assigned as Group 1 (n=20) or 20ml of 0.25% bupivacaine with 8mg dexamethasone assigned as Group 2 (n=20) for intraperitoneal instillation during laparoscopic sterilization. Patients weighing between 50-70 kg, willing to give written informed consent and assessed under ASAPS I and II are included in this study. All the patients received the same

premedication and induction agent but the dosage was titrated according to their weight. The patients are intubated using 3 size classical LMA and connected to closed circuit with maintenance of nitrous oxide and oxygen. After the completion of operative procedure, before removal of camera port, local anaesthetic was instilled intraperitoneally via the camera port. An independent physician, who is blinded to the treatment allocations, performed all preoperative baseline and post-procedural outcome measurements. Outcome measures were assessed from baseline and at 0, 1, 2, 4, 8 and 12hrs after the procedure at hospital. Before each procedure, the patients were instructed about the use of a 10 mm visual analogue scale (VAS) (range: no pain to unbearable pain) and if VAS ≥ 4 they will receive rescue analgesia of tramadol 50mg IM injection. No patients reported any adverse effects like perioral numbness, seizure, delayed gastric emptying, nausea and vomiting during this study. The data were entered in Microsoft excel spreadsheet and analysed using SPSS software version 21. Descriptive statistics were used. Comparison between the groups were done using Mann-Whitney U test. A p-value of <0.05 was considered significant.

Results

Table 1: Baseline characteristics of the study population

Baseline parameters	Group 1	Group 2	p-value
Age	24.82 \pm 2.1	25.16 \pm 1.9	0.654
Weight	54.25 \pm 6.14	52.25 \pm 3.14	0.45
Heart rate	78.9 \pm 5.14	76.4 \pm 6.14	0.89
Blood pressure			
Systole	126 \pm 10.32	124 \pm 12.16	0.21
Diastole	76 \pm 6.52	79 \pm 9.02	0.82

Table 1 depicts the baseline characteristics of the study population. There was no significant difference in the distribution of study population based on age, weight, heart rate and blood pressure

Table 2: Comparing the VAS scores between the two groups at different time intervals

VAS scores	Groups	N	Mean	Std. Deviation	p-value
4 hours	Group 1	10	.70	.4	0.146
	Group 2	10	.00	.00	
8 hours	Group 1	10	2.3	.91	0.001
	Group 2	10	.40	.61	
12 hours	Group 1	10	3	.92	0.001
	Group 2	10	1.10	.97	

Table 2 depicts comparing the VAS scores between the two groups at different time intervals.

Since post operative VAS of both groups at 0,1 and 2 hours was zero they are not taken up for statistical workup as it remains statistically insignificant. At 4 hours, there was no statistically significant difference between the groups. At 8 hours and 12 hours, the mean VAS score was high

in group 1 (2.3 ± 0.94), (3 ± 0.94) followed by group 2 (0.4 ± 0.51), (1.1 ± 0.99) respectively. The difference at 8 hours and 12 hours between the groups were found to be statistically significant ($p < 0.05$).

Figure 1: VAS scores of the two groups at different time intervals

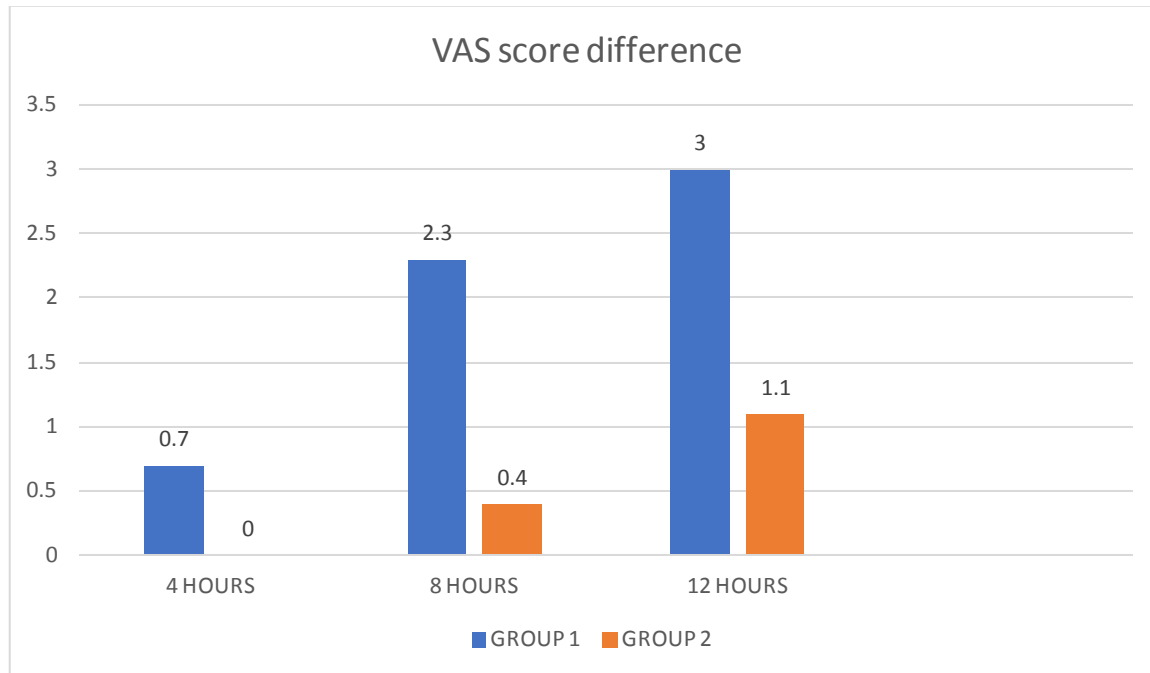


Figure 1 depicts the mean VAS score of 2 groups compared among themselves during 4,8 and 12hour postoperative period.

Discussion

Laparoscopic Sterilization (LS) is not a totally pain free procedure, with the pain being most intense on the day of surgery and on the following day. Use of intraperitoneal local anaesthetic for laparoscopic Sterilization may be a way of reducing pain.

As there was a paucity of literature assessing the efficacy of intraperitoneal instillation of bupivacaine as postoperative analgesia for laparoscopic sterilisation, a study was planned to assess the effectiveness of intravenous Paracetamol and 0.25% bupivacaine with dexamethasone for postoperative analgesia in patients undergoing laparoscopic sterilisation.

In our study there was no significant difference in

the distribution of study population based on age, weight, heart rate and blood pressure. At 0, 1, 2 and 4 hours, there was no statistically significant difference in the VAS scores between the groups. At 8 hours and 12 hours, the mean VAS score was high in group 1 (2.3 ± 0.94), (3 ± 0.94) followed by group 2 (0.4 ± 0.51), (1.1 ± 0.99) respectively. The difference at 8 hours and 12 hours between the groups were found to be statistically significant ($p < 0.05$). 0.25% bupivacaine with dexamethasone showed more effectiveness than intravenous Paracetamol alone.^[6] A study done by Anita et al., showed that intraperitoneal instillation of bupivacaine was not as effective as Ropivacaine, as it not only provides superior analgesia but also reduces the total rescue analgesic dose consumption without any significant adverse effects in an elective caesarean section. The reason for reduced VAS scores may be attributed to the addition of dexamethasone.

Conclusion

Intraperitoneal instillation of local anaesthetic following laparoscopic surgeries was proved to be an excellent technique for postoperative pain relief. This study signifies that addition of dexamethasone to intraperitoneal local anaesthetic potentiates the efficacy of post op analgesic effect.

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