Research Paper

Volume : 3 | Issue : 7 | July 2014 • ISSN No 2277 - 8179

Comparative Study of Intraperitoneal Instillation of 0.5% Bupivacaine with Adrenaline and Placebo for Postoperative Analgesia in Laparoscopic Cholecystectomy

Medical Science

KEYWORDS : bupivacaine, intraperitoneal instillation, laparoscopic cholecystectomy, Post-operative Analgesia.

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ABSTRACT

Background : This study was designed to know the analgesic effects of bupivacaine administered intraperitoneally in patients undergoing laparoscopic cholecystectomy. Methods: prospective randomized clinical study was carried out on 100 patients belonging to ASA grade I&II, age group between 18-60yrs posted for elective laparoscopic cholecystectomy. Group A(study group) received 20 ml 0.5% bupivacaine with adrenaline intraperitoneally at gall bladder bed and under right hemidiaphragm both before and at the end of surgery through laparoscope port in trendelenburgh position. Group B(placebo group) received 20 ml normal saline intraperitoneally at the same location. Vital parameters, duration of effective analgesia were recorded and compared. Statistical analysis: Repeated measure ANOVA, Student 't' test and paired 't' test was used. Results: Study group provided a substantial reduction of pain intensity during the first 4 hours postoperatively and this was found to be statistically significant. Total rescue analgesic doses required in study group was less compared to placebo group. Conclusions: Bupivacaine is effective at preventing pain at wake-up and over the first 4-8h after laparoscopic cholecystectomy when intraperitoneally instilled at the beginning and end of laparoscopy.

INTRODUCTION

In spite of several advantages of laparoscopic procedures over laparotomy it does not take away the disadvantage like the post-operative pain which results in an unpleasant experience for the patient and thereby increase the hospital stay[1,2]. Pain usually occurs on the first day following surgery and it may be a visceral, parietal or shoulder pain[3].

By evaluating the pathophysiology of pain it is shown that we can prevent or reduce pain by blocking the nociceptors before their stimulation by use of local anaesthetics[4], Bupivacaine is one such local anaesthetic which has a good safety profile, is long acting and free of side effects like gastritis due to NSAID's or nausea and vomiting and fear of drug dependence as in opioids[5,6].

The objective of this study is to compare the effect of intraperitoneal instillation of 0.5% bupivacaine with adrenaline versus saline for post-operative analgesia in laparoscopic cholecystectomy by Visual analogue scale and verbal rating scale. And to assess the need of rescue analgesics in post-operative period in both groups & observe the side effects.

METHODOLOGY:

100 adult patients admitted to department of surgery posted for elective laparoscopic cholecystectomy were selected. Approval from the ethical committee of the institution was obtained. All the patients were explained about the basis of the study and informed consent were obtained.

The study design is a Randomised clinical trial.

Patients of either sex between age group 18 to 60 years of ASA-1 and ASA-2 undergoing elective laparoscopic cholecystectomy were divided into two groups of 50 patients each randomly. Patients with ASA III&IV, with chronic pain syndrome, previous abdominal surgery, allergy to protocol drug & patients in whom conversion to open cholecystectomy is done for any reason were excluded.

Enrolled patients were explained about the use of visual analogue scale and verbal rating scale employed in this study.

All patients received alprazolam 0.5mg orally and ranitidine 150mg orally night before surgery.

All patients underwent similar general anaesthetic procedure. The laparoscopic procedure was done in standard fashion.

GROUP (A) – STUDY GROUP:

patients received 20 ml 0.5% bupivacaine with adrenaline intraperitoneally at gall bladder bed and under right hemidiaphragm both at the start and end of surgery through laparoscope port in trendelenburgh position.

GROUP (B) - PLACEBO GROUP:

patients received 20 ml normal saline intraperitoneally at the same location

After the induction of anaesthesia patients were randomly assigned to one of two groups in a double-blinded manner.

The surgeon was blinded for the nature of the solution used.

Post operatively the patients were assessed for pain using visual analogue scale (VAS) and verbal rating Prince Henry scale (VRS). The time of arrival in the postoperative ward was defined as zero hour postoperatively. Pain intensity was measured at fixed time interval. The patients were also enquired about nausea -vomiting, number of times and dose of rescue analgesia using a predesigned proforma, which were assessed at 1, 2, 4, 6, 12, 24 and 48 hour.

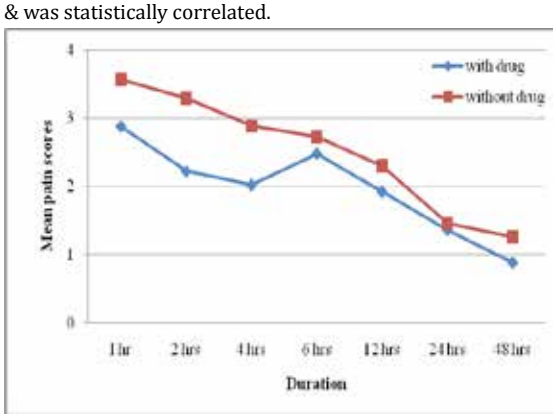
Rescue analgesics Inj.diclofenac 75mg i.m, was given when VAS was more than 6 or VRS was more than 3 postoperatively, which was given by the ward staff who were unaware of the nature of the intraoperative analgesia.

The time from the end of surgery until the first requested analgesia was recorded, and the doses of postoperative analgesia for breakthrough pain was assessed. Pain assessment was done by the investigator, who was blind to the group allocation of the patient and to any postoperative analgesia administered.

Data were collected, tabulated, coded then analyzed using Repeated measure ANOVA, Student 't' test and paired 't' test. SPSS (statistical presenting system software) for windows (version 15) software were employed for data analysis. A difference with significant level <0.05 was considered statistically significant.

OBSERVATION AND RESULTS:

The patients in both groups were similar in respect to age, sex & ASA status distribution. The mean pulse rate, blood pressure & respiratory rate was more closer to the base line in study group & was statistically correlated.



Graph 1

In VRS the mean (SD) pain score at 4 hour in study group was found to be2.02 (0.51) as compared to placebo group 2.88 (0.32) and it was found statistically significant, as can be seen in the graph the trend of pain was less in the initial period but later both showed similar pain scoring.

In VAS up to 4 hours postoperatively the mean (Std Deviation) pain score of study group was found to be 4.2 (1.03) as compared to placebo group 6.2 (0.89) and it was found to be statistically significant with p value of < 0.05, in VAS.

38 patients in study group required rescue analgesia in the initial 4 hours whereas all the 50 patients received analgesics in the first 4 hours post operatively in placebo group. The p value was 0.029 & was significant.

A total of 71 rescue analgesia was required in study group whereas a total of 185 analgesic doses was required in placebo group. In group A maximum analgesic dose taken was 3 in the initial 48 hr period of monitoring whereas group B required a maximum of 6 doses of analgesic drug.

Therefore, study group provided a substantial reduction of pain intensity during the first 4 hours postoperatively and this was found to be statistically significant.

Nausea & vomiting were comparable in both groups and was found to be statistically insignificant.

DISCUSSION

Laparoscopic cholecystectomy is the preferred surgical technique for uncomplicated cholecystectomy, because of an improved postoperative course[7]. Furthermore, the fact that laparoscopic cholecystectomy is performed on a fast-track basis, emphasizes the importance of improving early postoperative pain. Pain after laparoscopic cholecystectomy may vary in quality and localization and is reported in several trials to be incisional, intraabdominal, or referred (shoulder tip)[8]. The etiology is complex, including damage to abdominal wall structures, the induction of visceral trauma and inflammation, and peritoneal irritation because of CO2 entrapment beneath the hemidiaphragms[9,10]. Acute pain is typically associated with neuroendocrine stress response that is proportional to pain intensity, and it has been hypothesized that a reduction in surgical stress responses (endocrine, metabolic and inflammatory) will lead to a reduced incidence of postoperative organ dysfunction and thereby to an improved outcome [11,12]. The latter suggests that effective postoperative pain management is not only human but a very important aspect of postoperative care. Uncontrolled postoperative pain has an adverse sequel of delayed resumption of normal pulmonary function, restriction of mobility (thus contributing to thromboembolic complications), nausea and vomiting, increase in the systemic vascular resistance, cardiac work, and myocardial oxygen consumption through an increase in the catecholamine release induced by the stress response.

It was suggested that intraperitoneal injection of local anaesthetic may provide an effective block of postoperative visceral pain after laparoscopic cholecystectomy. Unfortunately, studies in which local anaesthetics have been used in this setting have provided conflicting results. Most of these initial studies have used small doses of bupivacaine or lidocaine. By contrast, other recent studies that have used larger doses and concentrations have demonstrated that intraperitoneal bupivacaine can be effective[13]. Bupivacaine, an amide local anaesthetic has a reduced systemic and cardiac toxicity which was evaluated by several studies in doses as large as 300–375 mg for infiltration and no clinical evidence of toxicity was observed[14,15].

The frequency of diclofenac given as rescue analgesia postoperatively was less in the bupivacaine group, meanwhile the time to first requested dose was significant between both groups. So, we believe that intraperitoneal bupivacaine administration is more effective than intraperitoneal saline in controlling postoperative abdominal pain. And we recommend its use as a part of multimodal analgesic technique for laparoscopic cholecystectomy.

CONCLUSION

To conclude, bupivacaine is effective at preventing pain at wake-up and over the first 4-8hours after laparoscopic cholecystectomy when intraperitoneally instilled at the start and end of laparoscopy. Bupivacaine is better choice because of its higher efficacy and larger safety margin. A systematic instillation is likely to be costeffective, because it decreases time in the PACU, for NSAIDS or opioid titration and resource utilization in the ward for treatment of postoperative pain .

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