Original Research Article

A double blind randomized clinical trial as preemptive and preclosure analgesia using bupivacaine in post operative pain

Shridhar Kuradagi*, Bharathkumar Bidinal

Department of General Surgery, Gadag Institute of Medical Sciences, Malasamudra, Karnataka, India

Received: 03 September 2016

Revised: 09 September 2016

Accepted: 12 September 2016

*Correspondence:

Dr. Shridhar Kuradagi,

E-mail: shridharkuradagi@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Post-operative pain management has been a constant challenge to many of the surgeons. Effective relief of pain has got physiological and psychological benefits. Because of their side effects most of the analgesic dosage is inadequate. There is need for developing newer modalities which can provide good analgesia with fewer side effects. The aim of the study was to compare preemptive and preclosure infiltration of bupivacaine in reducing post-operative pain and analgesic requirement.

Methods: Double blind randomized clinical trial was done in GIMS Hospital Gadag, Karnataka, India. Total of 40 patients, 10 undergoing open cholecystectomy, 10 undergoing laparoscopic cholecystectomy, 20 undergoing elective laparotomy were included in study. Post-operative pain measured using numerical VAS and amount of analgesic use.

Results: In the whole group comparison though the pain score was less in preemptive group but it was not significant. Requirement of rescue analgesia occurred early in preclosure group and also there was significant difference in analgesic requirement at 6th hour and at 10th hour.

Conclusions: Overall, though preemptive infiltration of bupivacaine reduces pain better than preclosure infiltration in common abdominal surgeries but it may be not significant. Preemptive infiltration of bupivacaine delays the time duration for the requirement of first analgesic dose and may also be helpful in reducing the number of analgesic doses in postoperative period when compared to preclosure infiltration in common abdominal surgeries.

Keywords: Preemptive, Preclosure analgesia, Bupivacaine, Post-operative pain

INTRODUCTION

The concept of pre-emptive analgesia was first proposed following basic scientific research that showed that the C.N.S. demonstrated plasticity and was not 'hard-wired'.¹ Noxious stimuli could induce changes in neural function such as hyper excitability or 'wind up' in the dorsal horn of the spinal cord; 'wind-up' may relate to the establishment of a subsequent pain memory.² Blocking or reducing this process before noxious stimulus might lead to reduced analgesic requirement in the acute phase of injury such as postoperative period.

The effective relief of pain is of paramount importance in patients undergoing surgery. Pain relief has significant physiological benefit and leads to a smoother postoperative course with earlier discharge from hospital and also reduces the onset of chronic pain syndromes.³ Postoperative pain is treated inadequately in about one half of people undergoing surgeries.⁴ Under treatment results in unacceptable levels of pain with tachycardia and analgesic administration above patient's requirement increases side effects such as nausea, vomiting, somnolence and dizziness.⁵

Preemptive analgesia is antinociceptive treatment that prevents establishment of altered central processing of afferent input from injuries". Preemptive interventions are many; our study is restricted to use of local anesthetic infiltration. Surgery is the clinical setting where preemptive technique is most effective since the onset of intense noxious stimuli is known. Preclosure analgesia is infiltration of local anesthetic into tissue planes before closure.⁶ Side effects most of the analgesics dose is below the optimum levels and all these side effects of opioids and NSAID's can be avoided by wound infiltration with local anesthetics.⁷

There are few clinical studies that answer the effectiveness preemptive analgesia. We need to know if the effect is clinically apparent at safe drug doses and also the efficacy of preemptive analgesia in reducing post-operative analgesic requirement has to be evaluated.

Objectives

1. To evaluate and compare preemptive and preclosure analgesia using 0.25% bupivacaine infiltration in reducing post-operative wound pain.
2. To evaluate postoperative analgesic requirement in the two groups.

METHODS

The stratified randomized double blind clinical trial was carried out in Gadag Institute of Medical Sciences Hospital, Gadag, Karnataka, India over a period of one year between May 2014 to April 2015. The study population consisted of 40 patients who met inclusion and exclusion criteria and were divided into 3 groups. Group I consisted of 10 patients undergoing open cholecystectomy, group II consisted of 10 patients undergoing laparoscopic cholecystectomy and group III consisted of 20 patients undergoing elective laparotomy. Each group was divided into two subgroups preemptive and preclosure to receive infiltration accordingly.

Exclusion criteria

Acute abdomen/peritonitis cases; preoperative use of analgesics >3 days per week for >3 months; Pediatric patients; patients having chronic pain (>3 months); History of chronic drug /alcohol abuse; epidural/spinal anesthesia; undergoing re-operation; severe hepatic, renal, CVS dysfunction.

The study population underwent stratified randomization to receive infiltration from pre-loaded syringes such that each patient received bupivacaine infiltration either preemptively i.e. pre incision or pre-closely i.e. just before closure is done.

Double blinding was done by a neutral person (pharmacologist) who was not in contact with patient. A set of 2 syringes were prepared for each patient such that

one consisted 0.25% bupivacaine and another 0.9% saline. The syringes were of 10ml each for laparoscopic cholecystectomy group. 20 ml each for open cholecystectomy and elective laparotomy group. The syringes were carried from preparation room (laboratory) to the operation theatre by sterile steel trays which were autoclaved after every use. Each syringes were coded, such that a patient received bupivacaine either pre-emptively or pre-closely. The randomization plan was obtained from computer generated randomization method and was kept secret by the pharmacologist only to be decoded once the study is over. Standard protocol was followed during infiltration of bupivacaine. Pre-emptive infiltration was given after induction of anaesthesia and painting and draping the parts. Incision was taken about 5 min after the infiltration. The timing of preemptive infiltration, the duration of surgery, its intra-operative findings and the time of pre-closure infiltration were noted.

Evaluation of pain was done post-operatively using Visual analogue score at 3rd hour, 6th hour 10th hour, 24th hour, 32nd hour and 48th hour. Patient coming out of anaesthesia was taken as '0' hour. For each patient at each interval of time pain was tested in three modalities a-incisional pain, b- pain on pressure, c-pain on movement. Patient was asked to give individual score for each of them. Analgesic used was tramadol 100 mg IV injection. It was given to patients experiencing severe pain or on demand if the patients wanted. And the time and amount of Tramadol given was noted. Throughout the post-op period vitals were monitored and noted at intervals and compared to the severity of pain. Statistical analysis was done using Mann-Whitney 'U' test. Test of proportions was used for analysis of analgesic requirement in different groups.

RESULTS

Table 1 showed there was statistically significant difference in analgesic requirement at 6th hour (P=0.03) and at 10th hour (P=0.02). In rest of the intervals there was no statistically significant difference in analgesic requirement. Though the pain scores were less in preemptive group. There was no statistically significant difference in pain scores at any interval.

DISCUSSION

The numbers of doses were more in pre-closure group. Also requirement occurred early in pre-closure group. There was statistically significant difference in analgesic requirement at 6th hour (P=0.03) and at 10th hour (P=0.02). In rest of the intervals there was no statistically significant difference in analgesic requirement.

The results of this group were comparable to previous published studies by Turner GA et al, Carr DB et al, Raymond KE et al, Judy B et al, Tverskoy M et al.⁷⁻¹¹

Table 1: Visual analogue score at 3rd hour, 6th hour 10th hour, 24th hour, 32nd hour and 48th hour in all patients.

	3 Hour	6 Hour	10 Hour	24 Hour	32 Hour	48 Hour	Average
Average pain score in PE subgroup (20 pts)	2.75	3.31	4.25	4.90	4.09	3.55	3.77
Average pain score in PC subgroup (20 pts)	3.13	3.74	4.72	4.66	4.35	3.66	4.04
P value	0.15	0.07	0.06	0.18	0.25	0.65	0.22
Statistical significance	Not significant	Not significant	Not significant	Not significant	Not significant	Not significant	Not significant
Analgesic doses in PE sample (20 pts)	-	1	4	14	3	-	-
Percentage of analgesic dosage in PE group	-	5%	20%	70%	15%	-	-
Analgesic doses in PC sample (20 pts)	-	5	10	9	3	-	-
Percentage of analgesic dosage in PC group	-	25%	50%	45%	15%	-	-
P value	-	0.03	0.02	0.05	No diff.	-	-
Statistical significance	-	Significant	Significant	Not significant	No diff.	-	-

Preemptive infiltration of bupivacaine is marginally better than preclosure infiltration in reducing postoperative pain in open cholecystectomy. It is helpful in delaying first dose of analgesic and decreasing the number of analgesic doses in first 48hrs postoperatively in open cholecystectomy.

There is no significant difference in preemptive and preclosure infiltration of bupivacaine in reducing postoperative pain in laparoscopic cholecystectomy. Preemptive infiltration is helpful in delaying first dose of analgesic as compared to preclosure infiltration in laparoscopic cholecystectomy.

Preemptive infiltration of bupivacaine is marginally better than preclosure infiltration in reducing postoperative pain in elective laparotomy. It is also helpful in delaying first dose of analgesic and decreasing the number of analgesic doses at certain intervals.

Overall, though preemptive infiltration of bupivacaine reduces pain better than preclosure infiltration in common abdominal surgeries but it may be not significant. Preemptive infiltration of bupivacaine delays the time duration for the requirement of first analgesic dose and may also be helpful in reducing the number of analgesic doses in postoperative period when compared to preclosure infiltration in common abdominal surgeries.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

REFERENCES

1. Coderre TJ, Katz J, Vaccarino AL, Melzack R. Contribution of central neuroplasticity to pathological pain: review of clinical and experimental evidence. *Pain*. 1993;52:259-85.
2. Woolf CJ. Evidence for a central component of post-injury pain hypersensitivity. *Nature*. 1983;306:686-8.
3. Rockville MD. Acute pain management: operative or medical procedures and trauma. Clinical practice, Guideline No. 1992;1:116-7.
4. Carr DB, Jacox AK, Capman CR, Ferrell B, Fields HL, Heidrich G. Clinical practice guidelines for acute pain management: operative or medical procedures and trauma. Agency for Health Care Policy and Research, DHHS. 1992; Publication no. 95:0034.
5. Kehlet H. Surgical stress: the role of pain and analgesia. *Br J Anaesth*. 1989;63(2):189-95.
6. Gottschalk A, Smith DS. New concepts in pain therapy: preemptive analgesia. *American Family Physician*. 2001;63(10):1979-85.
7. Turner GA, Chalkiadis G. Comparison of preoperative with postoperative lignocaine infiltration on postoperative analgesic requirements. *British J Anaesthesia*. 1994;72:541-3.

8. Hannibal K, Galatius H, Hansen A, Obel E, Ejlersen E. Preoperative wound infiltration with bupivacaine reduces early and late opioid requirement after hysterectomy. *Anesth Analg.* 1996;83:376-81.
9. Raymond KE, Portera SG, Bagous W, Lincon S. A randomized double-blinded trial of preemptive analgesia in laparoscopy. *The American College of Obstetricians and Gynecologists.* 1998;92(6):972-5.
10. Bourget JL, Clark J, Joy N. Comparing preincisional with post incisional bupivacaine infiltration in the post operative pain management. *Arch Surg.* 1997;132:766-9.
11. Tverskoy M, Cozacov C, Ayache M, Bradley EL, Kission I. Postoperative pain after inguinal herniorrhaphy with different types of anaesthesia. *Anaesthe Analg.* 1990;70:29-35.

Cite this article as: Kuradagi S, Bidinal B. A double blind randomized clinical trial as preemptive and preclosure analgesia using bupivacaine in post operative pain. *Int Surg J* 2016;3:1942-5.