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Research Paper

Acute Pain: A Study of Intravenous Tramadol Hydrochloride Versus Bupivacaine Hydrochloride Irrigation Through Surgical Drains

Medical Science

KEYWORDS : Acute, Post mastectomy pain, Bupivacaine,Tramadol.

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ABSTRACT

Background

Aims of the study were to determine the effects of bupivacaine irrigation in management of acute postoperative pain after radical surgery for breast cancer and to study the twenty four hour dose requirement of tramadol after bupivacaine irrigation with its safety profile.

Methods: This study was conducted in forty adult patients belonging to ASA I and II posted for elective modified radical mastectomy under general anaesthesia. They were randomly assigned into two groups of twenty each.

Group B-10 ml of 0.4% bupivacaine in each drain 8 hourly.

Group T-Intravenous infusion of tramadol at the rate of 0.25 mg/kg/hour.

Postoperative pain scores, and side effects like nausea, vomiting, sedation, urinary retention, respiratory depression, pruritus, ECG, haemodynamic changes were monitored and requirement of additional rescue analgesic doses were noted.

Results:

Bupivacaine irrigation through surgical drains is a reasonably good technique for acute postmastectomy pain relief.It is associated with reduction in tramadol requirement by one fifth.(P-0.0004) Nausea, vomiting, sedation and respiratory depression are less in B group than in T group and are statistically significant.(P<0.05) Conclusion:

Bupivacaine irrigation is a reliable method for control of acute postoperative pain after modified radical mastectomy, reduces the twenty four hour requirement of tramadol. Bupivacaine is also safe in terms of causing side effects like nausea, vomiting, sedation, respiratory depression and urinary retention associated with tramadol.

INTRODUCTION

Post operative pain is both distressing and detrimental for the patient. The management of postoperative pain involves assessment of pain in terms of intensity at rest and activity associated pain, treatment by pharmacological means as well as monitoring of induced side effects. [1]

Breast surgery is associated with mental distress and is physically painful also.In modified radical mastectomy patients, acute postoperative pain of variable intensity is mainly due to axillary dissection .It is aggravated by shoulder and arm movement. Pain is more when intercostobrachial nerve is not preserved.[2]

The introduction of multimodal analgesia including opioids[3] and non-opioids delivered through various routes[4] ,use of local anaesthetics either alone or in combination with other drugs[5] and techniques such as patient controlled analgesia[6] have greatly improved efficacy of pain control while minimizing the side effects of any one modality.

Adequate pain management in postoperative period results in patient satisfaction and techniques which reduce the dose of postoperative opioid requirement result in faster waking up of patients, more alert patients, less opioid related side effects and early discharge of patients from hospital.[7]

The alternative strategies for postoperative pain relief have been studied. In particular the treatment of postoperative pain by perfusion of surgical wound with local anaesthetics has proved effective in reducing postoperative pain, postoperative analgesic requirement and related side effects after various surgical procedures.[8,9]

This study was planned to experience the efficacy of bupivacaine irrigation through surgical drains in terms of postoperative pain relief,analgesic requirement and related untoward effects.

MATERIAL AND METHOD

This study was conducted with the permission of ethics committee of our institute and after taking informed consent from forty patients of age group of thirty to seventy years (ASA grade I and II). Screening of all patients, posted for modified radical mastectomy,was done during the preanaesthetic assessment.

Exclusion criteria included pregnancy,allergy to local anaesthestics, regular consumption of analgesics,valvular heart diseases,coronary heart disease,cardiac arrythmias,chronic obstructive pulmonary disease and hepatorenal disease.

All patients were tested for sensitivity to bupivacaine by an intradermal skin test.

Forty patients were randomly devided into two groups, twenty patients in each group. They were named Group B andGroup T.A standard anaesthetic technique was adopted.For premedi-

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cation Tab Lorazepam Hydrocloride 1 mg orally was given on the previous night of surgery.Cefuroxime 1.5 gram intravenously was given before induction as antibiotic prophylaxis. All patients were given Inj Ondansetron 4 mg intravenously before induction. Patients were induced with Inj Glycopyrrolate 0.2 mg ,Inj Fentanyl 2 µg/kg ,Inj Thiopentone Sodium 5 mg/kg intravenously and neuromuscular blockade was achieved with Inj Succinylcholine 2 mg/kg intravenously . Oral intubation was done in all patients. Anaesthesia was maintained with

Fentanyl,Vecuronium and Isoflurane in nitrous oxide and oxygen (50%) mixture.

Neuro-muscular blockade was reversed with Inj Glycopyrrolte 0.4 mg and Inj Neostigmine 0.05 mg/kg intravenously.

Intercostbrachial nerve was preserved in all the patients. At the end of surgery two drains were placed, one in axilla and one along the chest incision. After closure of the incision both drains were connected to a closed wound drainage system under negative pressure. After extubation and recovery the drains were checked for collection.

Group B patients were given 10 ml of 0.4% Bupivacaine through each drain (which were clamped after injection) and repeated 8 hourly for 24 hours under aseptic precautions. After 20 minutes the drain clamp was removed to remove the excess solution. Group T patients were given intravenous infusion of Inj Tramadol at the rate of 0.25 mg/kg/hr for 24 hour.This treatment regimen was discussed with infection control committee for its safety.

All the patients were not given Inj Ondansetron postoperatively. The patients were kept under close observation of anaesthesiologists for assessment of pain and any immediate side effects. Pulse, blood pressure, ECG changes and oxygen saturation(SpO_2) were monitored for twenty four hours period.

Evaluation of pain was done every two hourly and was recorded six hourly on a visual analogue scale(VAS) at rest and on movement for twenty four hours.

O: no pain
1-4: mild pain
5-7: moderate pain
8-10: severe pain

Movement was defined as flexion of the arm on the side of surgery. Patients were given bolus dose of 50 mg tramadol intravenously when VAS was greater than four.

Nausea, vomiting, sedation, respiratory depression, hypotension, urinary retention, pruritus and other untoward events were monitored. [Table 1] The total dose of analgesics and supplemental dose of anti-emetics administered during twenty four hours were noted. Incidences of postoperative fever and wound infection were also noted.

Table -1 - Side effects

1	Nausea	Absent/Present
2	Vomiting	Absent/Present
3	Sedation	Sedation score 0: Alert 1: Sometimes drowsy/ easily aroused 2: Often drowsy/ easily aroused 3: Often drowsy/ difficult to arouse 4: Asleep or stirs to touch
4	Urinary retention	Patient unable to pass urine despite bladder sensitivity.
5	Respiratory depression	Patient unable to maintain SpO2>90% decreased respiratory rate(<10/minute)
6	Hypotention	Blood pressure below 30% of baseline
7	Pruritus	Absent/Present

Statistical methods
A comparision in mean post treatment pain scores was done between bupivacaine and tramadol groups using "Chisquare test".

Average tramadol consumption and incidence of side effects in Group B and Group T were compared by using Student's T test. For all tests P-value less than 0.05 was considered statistically significant.Statistical analysis was carried out using software

(http://www.graphpad.com./quickcalcs/ttest).

RESULTS
The table[2] shows demographic data of patients which were almost comparable in both groups.

Table-2-Demographic data

Group	Age(years) Mean ± SD	Weight(kg) Mean ± SD	Sex Male/female
Group B	45.6 ±10.36	56.2 ± 14.73	1/19
Group Tt	50.5 ± 10.78	52.8 ± 11.53	0/20

There was no difference in pain scores of both groups immediately after extubation .Mean pain scores were also compared.We found no difference in mean pain scores at rest (P-0.88) and on movement.(P-0.91)[Table-3,4]

B group needed 26 rescue doses of tramadol 50 mg and T group needed 20 rescue doses. Total tramadol consumption in B group was 65 mg and in T group it was 316.8+50mg. (P -0.0004) Any other type of analgesics were not needed in any patient.

Comparision of side effects in both the groups was done.[Table-5] T group had more nausea (P -0.0005),vomiting(P-0.0005), sedation(P-0.008)and respiratory depression (P-0.01) and were statistically significant.Incidence of urinary retention in T group was also near to statistically significant value(P-0.07). Only one patient in tramadol group had pruritis which is not significant. No patients had hypotention, ECG changes and evidence of local infection and scar was healthy in all patients.We found no difference in date of discharge from hospital in both the groups.

Distribution of severity of postoperative pain by visual analogue scale.

Table-3-PAIN AT REST

Severity of pain	6 hours		12 hours		18 hours		24 hours	
	B N=20	T N=20	B N=20	T N=20	B N=20	T N=20	B N=20	T N=20
No pain	O8	07	11	08	12	11	12	12
Mild	05	07	05	07	03	05	05	05
Moderate	06	05	03	04	05	04	03	03
Severe	01	01	01	01	00	00	00	00
Total	20	20	20	20	20	20	20	20

Table-4-PAIN ON MOVEMENT

Severity of pain	6 hours		12 hours		18 hours		24 hours	
	B N=20	T N=20	B N=20	T N=20	B N=20	T N=20	B N=20	T N=20
No pain	O1	02	02	02	02	03	06	06
Mild	10	10	10	12	12	13	11	11
Moderate	08	07	07	05	06	04	03	03
Severe	01	01	01	01	00	00	00	00
Total	20	20	20	20	20	20	20	20

Table-5-Incidence of side effects

No.	Side effects	Group B No. of patients	Group T No. of patients	P value
1	Nausea	5	15	0.0005
2	Vomiting	5	15	0.0005
3	Urinary retention	0	2	0.07
4	Sedation	0	5	0.008
5	Respiratory depression	0	4	0.01
6	Pruritis	0	1	0.16

DISCUSSION:

An essential observation is that tissue injury and the resulting nociceptor barrage initiates a cascade of events that can alter pain perception.Blockade of this nociceptive input into central nervous system by administration of long acting local anaesthetic agent decreases the development of central hyper excitability resulting in less pain and analgesic requirement.[10]

The use of local anaesthestics for wound instillation[9] and wound infiltration[7] are gaining popularity over intravenous and intramuscular use of opioids and NSAIDs and intramuscular use of local anaesthetic[3,17] Wound irrigation with local anaesthestics through surgical drains is a newer concept. [1,5,8,13] Wound perfusion with local anaesthetics through drains or catheters has been described after cholecystectomy,[8] splenectomy,[8] abdominal hysterectomy[6] and cardiac surgery.[9]

Moiniche et al had no evidence of effect of incisional local anaesthetic in open abdominal surgeries except in inguinal herniotomy.[14] Adverse effects of local anaesthetic infilteration on wound healing are stated in a study.[15] J Padmanabhan et al did not find any reduction in postoperative opioid requirement and pain score after intermittent bupivacaine infusion.[16]

No significant difference was found between bupivacaine and tramadol groups in mean pain score at rest (P-0.88) and on movement. (P-0.91).

In our study the total tramadol consumption is 316.8 +50 mg and 65 mg in group T and group B respectively (p=0.0004).The bupivacaine irrigation decreased the 24 hours requirement of tramadol by one fifth. However in the study of Dr H. Talbot et al the morphine consumption in the study and control group was not significantly different. They put one drain in the axilla only and they stated that positioning of drain was inadequate.[5]

Intercostobrachial nerve was preserved in all cases as it reduces pain ,numbness and significant long term morbidity.[2]There is decreased sensory disrurbance with preservation of intersostobrachial nerve .[18,19,20,21]

Breast surgeries are generally performed under general anaesthesia but cervical epidural anaesthesia can be used for this surgery[22]

Nausea and vomiting are common problems after general anaesthesia.There are a number of risk factors for postoperative nausea and vomiting apart from postoperative opioid use like non-smoking, female patients,breasr surgery,nitrous oxide and neostigmine.[11]

In the study of Dr. S. J. Dolin et al the overall mean incidence of nausea was 25.2 % and of vomiting was 20.2% for all three analgesic techniques.Patient controlled analgesia using opioids was associated with the highest incidence of nausea [12]

In the present study less nausea and vomiting were found in Group B as compared to Group T. The P value for both is 0.0005 which is statistically significant.

Dr. B. L. Partridge et al had observed that the patients receiving wound infiltration with 30 ml of 0.25% bupivacaine had lower respiratory rates and significantly higher minimum SpO2%. [7]

In our study four patients of Group T had respiratory depression in terms of decreased respiratory rate to less than 10 per minute and a decreased SpO_2 to 89% or less. The P value for that is 0.01 which is statistically significant.

Five patients of Group T had sedation in our study. The P value for that is 0.008 which is statistically significant. In the study of Dr. S J. Dolin et al epidural anaesthesia was associated with lowest level of sedation while intramuscular analgesia and intravenous-patient controlled analgesia were associated with higher level of sedation and the overall incidence of urinary retention reported to be 23% with a tendency for epidural analgesia to be associated with a higher incidence of urinary retention.[12] In the present study only two patients of Group T had urinary Retention and required urinary catheterization. The p value for that is 0.07 which is nearer to statistically significant value.

In the study of Dr. S. J. Dolins[12] the overall incidence of pruritus was14.7%. The incidence of pruritus with intramuscular analgesia was lower than with either patient controlled analgesia or epidural analgesia. In the present study only one patient of Group T had pruritus and is not significant statistically (P value 0.16)

There are studies in which 80mg and 100mg bupivacaine solutions are used. So 80 mg of bupivacaine in our study is comparable to doses used by them in their studies also.[1,5]

ECG changes or hypotention were not found in any patient.

From this study we concluded that when bupivacaine is administered through surgical drains it is equally effective in controlling postoperative pain to intravenous tramadol with reduction in the dose of tramadol to one fifth.With bupivacaine administration there are significantly less side effects like nausea, vomiting, sedation,respiratory depression and urinary retention. Bupivacaine can be a good alternative to opioids for acute postoperative pain management in patients undergoing radical mastectomy for breast cancer.

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