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Efficacy and safety of Bupivacaine infiltration at the wound site for post-operative pain relief in cases of elective abdominal surgery — a randomised controlled trial

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Objectives: *The efficacy and safety of Bupivacaine infiltration at the wound site were studied for postoperative pain relief in patients undergoing elective abdominal surgery.*

Methods and Materials: *A randomized clinical trial conducted in an institution of medical education and a tertiary care centre. A total of 90 patients who were scheduled for elective abdominal surgery were randomly assigned to one of two groups. Bupivacaine infiltration was given to Group T, while sterile water was given to Group C at the incision site just before closure of the wound. The pain intensity was measured using the Visual Analogue Score (VAS) at different time intervals after surgery. The requirements for rescue analgesic, pain VAS, patient satisfaction score, and side effects were recorded over the course of 24 hours following surgery. The data was statistically analysed and expressed as a mean +/- standard deviation. The data was analysed using the Chi-square test, Mann — Whitney U test, and Wilcoxon Test of matched pairs. * $p < 0.05$ is considered statistically significant.*

Results: *The difference in VAS score after 2 hrs, 4 hrs, 8 hrs, and 24 hrs was found to be significantly higher in the control group as compared to the experimental group. At the end of 24 hrs, the mean score in the control group was 3.02 ± 0.66 , which is higher as compared to the experimental group, which was 2.33 ± 0.67 ($p < 0.05$).*

Conclusion: *Infiltration of Bupivacaine at the incision site was extremely effective for post-operative pain control with maximum patient satisfaction. This study may provide new evidence to formulate guidelines for optimum pain management in the postoperative setting for the benefit of patients with a reduced need for analgesics.*

Key words: *Bupivacaine, postoperative pain, Tramadol, rescue analgesic, Visual Analogue Score*

Introduction

Pain is a multidimensional experience, personalized for each patient. Pain perception is influenced by biological response, psychological state, individualization, and so-

cial context [1, 2]. Tissue injury associated with surgery triggers a multitude of responses in the pain matrix, from sensitization of peripheral and central pain path-

ways to feelings of fear, anxiety, and frustration during the acute phase, which if unhealed, may be measured to be chronic with an increasing requirement of analgesics [3]. Major abdominal surgeries with upper abdominal incisions resulted in unfavourable levels of pain, which is still the most common complaint among patients following surgery; in fact, pain can prolong hospitalization and lead to increased postoperative morbidity, such as pulmonary complications such as shallow breathing, atelectasis, secretion retention, and lack of cooperation during physiotherapy [4, 5, 6]. Prevention and relief of postoperative pain are the main responsibilities of healthcare professionals and have been given more importance in recent years, with considerable concurrent advancements in this regard [7, 8]. Despite this advancement, postoperative pain continues to be a challenge and often leads to patient dissatisfaction.

Even today, postoperative pain management is still based on the use of traditional opioids, nonopioids, local anaesthetics, and benzodiazepines [9, 10]. Still, more opioid administration is associated with a variety of dose-limiting side effects that range from bothersome to life-threatening adverse effects, including ventilatory depression, drowsiness and sedation, nausea and vomiting, pruritus, ileus, urinary retention, and constipation [11, 12, 13]. The literature on the possible harmful effects of combining analgesics is poorly studied, though the concept of multimodal analgesia is widely accepted. The main purpose of perioperative pain control is to provide adequate relief and acceptable side effects for patients. Numerous recent studies have not shown a consistent level of success because of the numerous variables in available data.

Surgical wound infiltration has been advocated as a simple and safe technique to minimize the pain following abdominal surgery [14, 15]. It has been suggested that pre- or post-incision wound infiltration with local anaesthetics prevents hypersensitivity of the central nervous system, reduce cytokine production, modulate inflammation and thereby lowers postoperative pain [16]. However, the results of clinical studies examining the pre-emptive effect of wound infiltration with local anaesthetics (LA) have been unsettled. Since a local anaesthetic with a longer duration of action like Bupivacaine may be more effective in preventing post-injury hypersensitivity.

Bupivacaine is a potent and long-acting amide linked to LA that promotes differential conduction blockade, mainly the inhibition of sodium influx through volt-

age-gated sodium-specific ion channels in the neuronal cell membrane, which prevents transmission of nerve impulses where local anaesthetics are applied [9, 17, 18]. A 0.25–0.5% solution injected into the epidural produces adequate analgesia without significant motor blockade. As a result, it has become very popular in obstetrics [9]. Certain preclinical studies discovered that lidocaine and bupivacaine reduce collagen production and wound breaking strength in Wistar rats and have a negative effect on wound healing in Sprague-Dawley rats, particularly at the late stages [19]. But the clinical studies in humans have a very subjective way of healing the wound and relieving postoperative pain. Uncertainties in this field can only be explained with new studies. With these objectives in mind, we planned this study to assess the efficacy and safety of local anaesthetic bupivacaine infiltration at the incision site for postoperative pain relief.

Materials and Methods

This was a randomised clinical trial conducted in an institution of medical education and a tertiary care centre in a developing country. The study was approved by the Institutional Ethics Committee for Humans and the trial has been registered under Clinical Trial Registry India (CTRI; <http://ctri.nic.in> with REF/2021/10/047909). The calculated sample size came out as 90 based on the assumption of a standard deviation of the expected difference from previous studies [20]. The patients were equally assigned to each of group's T (the test group) and C (the control group). Informed consent from all study participants was obtained and the baseline characteristics like age, sex, and body mass index (BMI) were noted for comparison. Every patient was individually randomised by Sequentially Numbered Opaque Sealed Envelopes method, and hence had an equal opportunity to be in either of the groups.

The patients undergoing elective abdominal surgery were between the age groups of 18 to 70 years old and, as per the physiological group of the American Society of Anaesthesiologists (ASA) I & II physical status, with no major systemic disease, were included in the study [21]. Patients with a history of drug allergy to any of the study drugs, chronic alcoholism, or daily intake of NSAIDs for a long time were excluded from the study. The patients were familiarized with the concept of the visual analogue scale (VAS), which ranged from 0 = no pain to 10 = the worst pain imaginable [22, 23].

Patients in Group T (Group I) received a subcutaneous infiltration of 15 ml of 0.5% Bupivacaine and

Group C (Group II) patients received subcutaneous sterile water just before closure of the wound. The total volume of infiltrated solution in the two groups was 15 ml, divided proportionally according to the length of the skin incisions. The patients were observed for 24 hours after surgery. The intensity of pain was assessed using a 10-point visual analogue score (VAS) scale at 2, 4, 6, 12, 18, and 24 hours after surgery. The pulse, blood pressure, oxygen saturation, urine output, and adverse effects (nausea, vomiting, allergic reactions, or any other) were noted. If a patient reported a VAS pain score of greater than 4, a rescue analgesic in the form of an IV tramadol 100 mg injection was given. The need for rescue analgesics was recorded for both the groups at time periods of 2, 4, 6, 12, 18 and 24 h after surgery.

The primary outcome of our study was the recording of VAS score until the first rescue analgesic request and the requirement of rescue analgesics in the form of injection tramadol over 24 hours. The secondary outcomes measured were patient satisfaction score (PSS) till rescue analgesic was given and adverse events. VAS was measured on a scale from 0 to 10 and rescue analgesic was administered at any score greater than 4. PSC was assessed using a four-point rating scale (poor = 0, fair = 1, good = 2, and excellent = 3) [24]. **Statistical analysis** was performed using SPSS 17.0 for the Windows 7 ver-

sion [25]. The mean and standard deviation (mean \pm SD) are used to express the data. Data was analysed using the Chi-square test, Mann — Whitney U test, and Wilcoxon Matched Pairs test. * $p < 0.05$ is considered statistically significant.

Results

The participants were enrolled and analysed as shown in Figure 1. (Consort flow diagram). 90 patients were identified by the surgeon and consented to the study. There were 29 males and 16 females in the control and experimental groups, respectively. Both the allocated groups were compared on a number of variables like baseline characteristics, duration of surgery, total tramadol requirement, and number of patients requiring rescue analgesics to ensure adequate randomisation; the comparisons are shown in Table 1 and did not differ significantly ($p = 0.588$; $p = 0.899$).

The comparative features of the control and experimental groups with other variables were shown in Table 2. The mean duration of surgery in experimental groups was 80.67 ± 28.93 and in the control group it was found to be 75.22 ± 28.14 . The difference was not found to be significant ($p = 0.367$). A significant of 88.89% of the control group required rescue analgesia as compared to only 26.67% in the experimental group (* $p < 0.05$).

Table 1. Comparison of control and experiment groups with demographic profile

Profile	Control group	%	Experiment group	%	Total	χ^2	P-value
Age groups							
20–29 yrs	6	13.4	5	11.11	11	0.588	0.899
30–39 yrs	9	20.00	12	26.67	21		
40–49 yrs	15	33.33	14	31.11	29		
≥ 50 yrs	15	33.33	14	31.11	29		
Mean	43.33		43.40		43.37		
SD	12.18		11.44		11.75		
Gender							
Male	29	64.44	29	64.44	58	0.000	1.000
Female	16	35.56	16	35.56	32		
Total	45	100.00	45	100.00	90		

Patient satisfaction score (PSC) till administration of rescue analgesic is represented in Table 2, which shows there is a significant difference between the groups ($p < 0.05$). In the control group, it was observed that only 4.44% scored 3, i.e., 95.56% were found to be unhappy or unsatisfied with the postoperative pain relief. But in the experimental group, 40% of patients scored 3 and 51.11% scored 2, with statistically significant results ($p < 0.05$) indicating good PSC score is appreciably higher in the experimental group when compared to the control group. In our study, no major adverse drug reactions to the drugs were noted.

Pain intensity in the form of a postoperative pain VAS score is shown in Table 3, Figure 2. The difference in VAS score after 2 hrs, 4 hrs, 8 hrs, and 24 hrs was found to be significantly higher in the control group as compared to the experimental group. At the end of 24 hrs, the mean score in the control group was 3.02 ± 0.66 , which is higher as compared to the experimental group,

which was 2.33 ± 0.67 indicating statistically significant with $p < 0.05$.

A comparison of different treatment times with post-surgery VAS scores in control and experiment groups is depicted in Table 4; Figure 2. While comparing different treatment times within the group, post-surgery pain was increased by 21–57% from 2–4 hrs and found to be significant ($p < 0.05$), but from 2–8 hrs it was observed to be 20.26% which was not significant ($p > 0.05$). There was no statistically significant difference between 2–18 hrs and 2–24 hrs in post-operative analgesic pain. However, good improvement in pain reduction was seen in the experimental group from 2–4 hrs (55% reduction in pain intensity), 2–8 hrs (66.42% reduction in pain intensity), and 2–12 hrs (57.14% reduction in pain intensity). All the comparison results between different treatment times and post-surgery VAS scores were found to be statistically significant ($p < 0.05$).

Table 2: Comparison of control and experiment groups with other variables

Profile	Control group	%	Experiment group	%	Total	Statistic	p-value
Duration of surgery (min)							
Mean	75.22		80.67		77.94	$t = -0.904$	0.367
SD	28.14		28.93		28.51		
Type of anaesthesia							
GA	19	42.22	19	42.22	38	$\chi^2 = 0.000$	1.000
Spinal	26	57.78	26	57.78	52		
Need of rescue analgesics							
No	5	11.11	33	73.33	38	$\chi^2 = 35.709$	0.0001*
Yes	40	88.89	12	26.67	52		
Patient satisfactory							
Score 0	9	20.00	1	2.22	10	$\chi^2 = 42.611$	0.0001*
Score 1	25	55.56	3	6.67	28		
Score 2	9	20.00	23	51.11	32		
Score 3	2	4.44	18	40.00	20		
Total	45	100.00	45	100.00	90		

* $p < 0.05$

Table 3. Comparison of control and experiment groups with post surgery VAS scores at different treatment times by Mann — Whitney U test

Treatment times	Control		Experiment		U-value	Z-value	P-value
	Mean	SD	Mean	SD			
2 hrs	3.40	1.90	1.00	0.00	90.00	7.440	0.0001*
4 hrs	4.13	1.41	2.22	0.70	254.50	6.112	0.0001*
8 hrs	4.09	1.26	2.98	0.92	493.00	4.188	0.0001*
12 hrs	3.33	1.04	3.69	1.02	836.50	-1.416	0.156
18 hrs	2.98	0.81	3.11	1.01	969.50	-0.343	0.731
24 hrs	3.02	0.66	2.33	0.67	530.00	3.889	0.0001*

* $p < 0.05$ **Table 4. Comparison of different treatment times with post-surgery VAS scores in control and experiment groups by Wilcoxon matched pairs test**

Groups	Times	Mean	SD	Mean Diff.	SD Diff.	% Of effect	Z-value	P-value
Control	2 hrs	3.40	1.90					
	4 hrs	4.13	1.41	-0.73	1.96	-21.57	2.108	0.035*
	2 hrs	3.40	1.90					
	8 hrs	4.09	1.26	-0.69	2.61	-20.26	1.618	0.105
	2 hrs	3.40	1.90					
	12hrs	3.33	1.04	0.07	1.70	1.96	0.491	0.623
	2 hrs	3.40	1.90					
	18 hrs	2.98	0.81	0.42	1.80	12.42	1.527	0.126
	2 hrs	3.40	1.90					
Experiment	24hrs	3.02	0.66	0.38	1.72	11.11	1.505	0.132
	2 hrs	2.22	0.70					
	4hrs	1.00	0.00	1.22	0.70	55.00	5.511	0.0001*
	2 hrs	2.98	0.92					
	8 hrs	1.00	0.00	1.98	0.92	66.42	5.776	0.0001*
	2 hrs	3.69	1.02					
	12 hrs	1.00	0.00	2.69	1.02	72.89	5.841	0.0001*
	2 hrs	3.11	1.01					
	18 hrs	1.00	0.00	2.11	1.01	67.86	5.841	0.0001*
2 hrs	2.33	0.67						
24 hrs	1.00	0.00	1.33	0.67	57.14	5.511	0.0001*	

* $p < 0.05$

Discussion

Adequate management of postoperative pain is a core determinant of the patient's achieving early ambulatory status. Various dimensions of pain experience with respect to biological, psychological, and social conditions should be considered and should be understood in order to provide optimum pain management in the postoperative setting [26, 27]. The challenges of effective pain management which can cause inadequacies in the management are as follows: first, the negative attitudes and misconceptions among some health professionals with respect to opioid analgesics and other pharmacological agents [28]. Second, technical issues potentially affecting the treatment of acute postoperative pain include difficulties with intravenous (IV) lines and patient-controlled analgesia (PCA) devices [29]. Third, pharmacokinetic and pharmacodynamic factors may influence acute post-operative analgesia; for example, the intramuscular route may be associated with delayed or inadequate pain relief due to variable and erratic absorption [30, 31].

Over the last decade, there has been a slight improvement in the treatment of patients with acute post-operative pain due to changes in pain management approaches such as individualized pain management, early postoperative ambulation and rehabilitation, and the upcoming concept of regional analgesia (central neuraxial techniques and peripheral nerve block), which has been enhanced in recent times with well-constructed randomised controlled trials demonstrating superior acuity [31]. There are several types of regional anaesthetic techniques. A few important ones are epidural, intrathecal, peripheral trunk blocks (e.g., transversus abdominis plane and rectus sheath), paravertebral, and wound infiltration [32, 33, 34]. The advantages of these techniques are that they are known to reduce pain and systemic opioid requirements in the immediate post-operative phase, reduce pulmonary, thromboembolic, cardiovascular, ileus, and surgical stress responses, and require early administration with continued use safely after operation [33, 34].

In our study, the mean time of surgery in both groups was not significantly significant, however the need for rescue analgesics was much higher in the control group than in the bupivacaine group. This suggests that Bupivacaine may lessen the requirement for traditional analgesics in the treatment of postoperative pain. The difference in VAS score almost every 2 hours was substantially higher in the control group than in the experimental group, showing that the control group's patients were

in moderate to severe pain after surgery. When comparing different treatment intervals within the group, the experimental group showed a significant improvement in pain reduction, exceeding 50%. It could be because bupivacaine is more effective at controlling pain and nociception in the postoperative period; and perhaps the anaesthetic effect of this medicine may begin right after the skin is incised, resulting in a reduced inflammatory response of the organism in the incision sites [17, 18]. In this approach, we may explain why Bupivacaine infiltration on the wound site is more effective for post-operative pain reduction in situations of elective abdominal surgery. In neither group, there were any severe side effects. We were very careful in distinguishing side effects from residual effects of anaesthesia and surgery during the evaluation of our findings pertaining to side effects.

In the case of intraperitoneal infiltration or incisional site infiltration, many studies recommend administering anaesthetic medicines before or after surgery. Liposomal bupivacaine at the surgical site, according to Hamilton TW et al., appears to minimise postoperative pain when compared to placebo. However, current evidence does not show that it is superior than bupivacaine hydrochloride [35]. Maktabi M et al. compared the effectiveness of bupivacaine and ketamine in reducing postoperative pain in patients undergoing abdominal hysterectomy, and found that higher doses of ketamine and bupivacaine single dose resulted in a significant reduction of postoperative pain in patients compared to the placebo group [36]. Following abdominal hysterectomy, Bourget et al. found that wound infiltration, either pre-incision or post-incision, had no clinically meaningful influence on pain scores or analgesic requirements [37]. Pre-emptive analgesia with a combination of lidocaine hydrochloride and bupivacaine hydrochloride did not minimise post-operative discomfort, reduce analgesic requirements, or shorten hospital stay in patients undergoing appendectomy, according to Ko et al. [38]. Local tissue infiltration has a number of benefits, including ease of use, safety, and low cost. The efficacy of this process has been explored in various research, but no clear result has been reached that demonstrates the true benefits of this technique.

In conclusion, infiltrating the incision site with long-acting anaesthetics is a highly effective treatment for post-operative pain control after elective abdominal surgery, according to our findings. More study with large sample sizes is still needed to examine Bupivacaine and its role in postoperative pain therapy in greater depth.

This study adds to the amount of knowledge available to patients, doctors, and institutions when developing post-operative pain management guidelines for the best possible postoperative pain management.

What is already know on this topic:

- Research studies Surgical wound infiltration has been recommended as a simplistic and safe way to reduce discomfort after abdominal surgery.
- It has been proposed that pre- or post-incision wound infiltration with local anaesthetics minimizes central nervous system hypersensitivity.
- Clinical investigations exploring the pre-emptive efficacy of wound infiltration with local anaesthetics (LA) have produced conflicting results.

What this study adds:

- According to our findings, infiltrating the incision site with long-acting anaesthetics is a highly effective treatment for post-operative pain control following elective abdominal surgery.

- This study expands the body of knowledge available to patients, doctors, and institutions when formulating post-operative pain management guidelines for the best possible postoperative pain management, particularly with regard to Bupivacaine and its function in postoperative pain therapy.

Competing interests: The authors declare no competing interest.

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Authors' contributions:

	Contributor 1	Contributor 2	Contributor 3
Concepts	×	×	
Design	×	×	×
Definition of intellectual content	×	×	
Literature search	×	×	
Clinical studies	×		
Experimental studies	×		
Data acquisition	×	×	
Data analysis		×	×
Statistical analysis			×
Manuscript preparation		×	×
Manuscript editing		×	
Manuscript review	×	×	×
Guarantor	×	×	×

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Ефективність і безпека інфільтрації бупівакаїну на місці рани для післяопераційного знеболення у випадках планової абдомінальної хірургії — рандомізоване контрольоване дослідження

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Мета: Вивчено ефективність і безпеку інфільтрації бупівакаїну в місці рани для полегшення післяопераційного болю у пацієнтів, які перенесли планові операції на черевній порожнині.

Методи та матеріали: рандомізоване клінічне дослідження, проведене в медичному закладі освіти та центрі третинної медичної допомоги. Загалом 90 пацієнтів, яким була призначена планова операція на черевній порожнині, були випадковим чином розподілені в одну з двох груп. Інфільтрацію бупівакаїну проводили Групі Т, тоді як Групі С давали стерильну воду в місці розрізу безпосередньо перед закриттям рани. Інтенсивність болю вимірювали за допомогою Visual Analogue Score (VAS) через різні проміжки часу після операції. Вимоги до невідкладного анальгетика, больового показника VAS, показника задоволеності пацієнта та побічних ефектів реєструвалися протягом 24 годин після операції. Дані були статистично проаналізовані та виражені як середнє \pm стандартне відхилення. Дані були статистично проаналізовані за допомогою критерію χ^2 -квадрат, U-тесту Манна-Уїтні та тесту Вілкоксона відповідних пар. $*p < 0,05$ вважається статистично значущим.

Результати: було встановлено, що різниця в показниках VAS через 2 години, 4 години, 8 годин і 24 години була значно вищою в контрольній групі порівняно з експериментальною групою. Через 24 години середній бал у контрольній групі становив $3,02 \pm 0,66$, що є вищим показником порівняно з дослідною групою, де він становив $2,33 \pm 0,67$ ($p < 0,05$).

Висновок: інфільтрація бупівакаїну в місці розрізу була надзвичайно ефективною для контролю післяопераційного болю з максимальним задоволенням пацієнта. Це дослідження може надати нові докази для формулювання рекомендацій щодо оптимального лікування болю в післяопераційному періоді на користь пацієнтів зі зниженою потребою в анальгетиках.

Ключові слова: бупівакаїн, післяопераційний біль, трамадол, невідкладний анальгетик, візуальна аналогова оцінка