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Comparison of Mean Post-Operative Pain Score with or Without Bupivacaine Infiltration at Incisional Site in Patients Undergoing Midline Laparotomy for Clean and Clean Contaminated Wound

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ABSTRACT

Background: In abdominal surgery, midline incision is most often used and it is a major contributor to postoperative pain. **Objective:** The purpose of the study was to evaluate the effect of local anesthesia by comparing mean post-operative pain scores in patients undergoing midline laparotomy for clean and clean contaminated wounds. **Study Design:** Randomized controlled trial. **Settings:** Department of Surgery, Allied Hospital, Faisalabad, Punjab, Pakistan. **Duration:** From April 6th, 2018 to October 5th, 2018. **Methods:** A total of 80 patients undergoing midline laparotomy and classified as ASA physical status I–II were randomly divided into two equal groups. Before wound closure, patients in Group A received local infiltration of 20 ml of 0.25% bupivacaine with epinephrine (maximum dose 1 mg/kg) into the skin and rectus sheath. Group B received a placebo (2 ml of normal saline). Postoperative pain was assessed using the Visual Analogue Scale (VAS) every hour for 24 hours. Analgesics were administered only when necessary and recorded. Data were analyzed using SPSS version 21. **Results:** Of the 80 patients, the mean age was 45.83 ± 9.13 years. There were 37 (46.2%) males and 43 (53.8%) females. The mean VAS pain score over 24 hours was significantly lower in the bupivacaine group (4.1 ± 1.52) compared to the placebo group (6.88 ± 1.23), with a p-value of 0.0001. **Conclusion:** Incisional site bupivacaine instillation significantly decreases the painful sensations as well as requirements for analgesia in comparison with the placebo group thus making it a simple, well-tolerated, and safe treatment in relieving pain after midline laparotomy.

Keywords: *Pain, Bupivacaine, Analgesia, Postoperative period.*

INTRODUCTION

Midline laparotomy across the surgical disciplines is a common type of operative procedure, and it is most frequently used during abdominal surgeries. Midline incision provides wide and instant access to the abdominal cavity, resulting in minimum damage to vessels, muscles, and nerves because such structures do not lie across midline.[1] The midline incision is an essential contribution to postoperative pain.[2] Postoperative pain results in tachycardia, hypertension, increased cardiac workload, nausea, vomiting, and consumption of myocardial oxygen via the increase in the release of catecholamine stimulated due to stressful response.[3] So, during the early postoperative period, comfortability of the patient and pain relief are given more importance because injecting analgesics can lead to delayed discharge. The efficacy of pain control during the early postoperative period helps to determine when to discharge the patient safely.[4] It influences the ability of the patient to return to daily life activities. Opioids are the most frequently utilized medication for post-operative pain management. However, they cause unwanted side effects, leading to longer hospitalizations and higher costs. Adverse effects due to higher dosages of opioids are a major risk factor. For the reduction of postoperative painful sensations in various surgeries, localized anesthetics are injected in the wound before incision as an effective alternative.[5] Pre-operative analgesia acts as a sensory block used as a strategy for pain control to counteract central sensitization. The purpose of pre-operative analgesia is to decrease postoperative pain via the blockade of pain pathways in the nociceptive afferent region of CNS and PNS. Infiltration of bupivacaine in the

surgical region is an easy, cost-effective, and reliable technique for injecting localized analgesia. Unfortunately, negligence towards the method is the reason it is not applicable in midline laparotomy.[6] With a half-life of 2.5 to 3.5 hours, Bupivacaine is reliable for 6 hours of pain control. The safety margins linked to bupivacaine as analgesia are wide. This study aimed to evaluate the effect of local anesthesia by comparing mean postoperative pain scores in patients undergoing midline laparotomy for clean and clean-contaminated wounds.

METHODS

This prospective, randomized placebo-controlled clinical trial was carried out at the Department of Surgery, Allied Hospital, Faisalabad, Punjab, Pakistan from April 6th, 2018 to October 5th, 2018.

By utilizing the sample size calculator of WHO for 2 means, 80 patients were enrolled in the study by applying a non-probability, consecutive sampling technique.

After obtaining permission from the ethical authorities of the hospital, patients of ages ranging from 30- 60 years including both genders undergoing midline laparotomy with clean and clean-contaminated wounds and of ASA grade I & ASA grade II enrolled in the study and consent was taken from patients after proper explanation of all entire procedure. Patients having dirty or contaminated wounds, a history of addiction, or any contraindication to bupivacaine were excluded.

Randomly, patients were separated into two equal groups (each containing 40 patients) utilization of computer-generated random number table. Group A (intervention) and Group B (placebo). With the maintenance of a similar protocol, anesthesia was injected into patients. 20ml epinephrine bupivacaine 0.25% (maximum 1 mg.kg-1). Was used to infiltrate the incision sites before suturing in group A, while in group B, 20 ml of normal saline was used. Loop surgical string proline no 1 was used applying continuous suture technique for fascia suturing. A simple interrupted technique was used for suturing skin. Post-operative pain score was assessed at one hourly interval for 24 hours. No analgesia was given unless needed, and if given, it was recorded. A record of all the information on predesigned performance was kept.

Using SPSS V-21, all collected data was analyzed. Descriptive statistics were calculated and included all variables. For calculation of standard deviation and mean of all quantitative variables, i.e., age, BMI, and post-operative pain score. For qualitative variables that are gender and ASA status calculation of frequency and percentage was done. For a comparison of postoperative pain scores between the two groups, an independent sample t-test was applied. Effect modifiers like age, gender, BMI, and ASA status were controlled via stratification. Post-stratification independent sample t-test was applied. P-value ≤ 0.05 was taken as significant.

RESULTS

80 patients undergoing midline laparotomy were included in the study and randomly divided into two groups. Group A underwent incisional site bupivacaine infiltration under the skin and rectus sheath, while group B underwent midline laparotomy without bupivacaine. Out of 80 patients, the mean age was 45.83±9.132 years. Minimal age was 30 years, whereas the maximum age was 60 years. Out of 80 patients, the mean BMI was 29.74±5.27. The minimum BMI was 20, while the maximum BMI was 40.

In group A, out of 40 patients, the mean age was 45.2±8.85 years and in group B, the mean age of the patients was 46.45±9.48 years. In group A, out of 40 patients, the mean BMI was 30.37±5.04, and in group B, the mean BMI was 29.1±5.5. Out of 80 patients, 36 (45%) patients had age between 30-45 years, and 44 (55%) patients had age between 46-60 years. In group A, out of 40 patients, 20 (50%) patients had age between 30-45 years, and 20 (50%) patients had age between 46-60 years. In group B, out of 40 patients, 16 (40%) patients had an age between 30-45 years, and 24 (60%) patients had an age between 46-60 years with p-value = 0.369.

Out of 80 patients, 43 (53.8%) patients had a BMI < 30, and 37 (46.2%) patients had a BMI ≥ 30. In group A, out of 40 patients, 18 (45%) patients had a BMI < 30, and 22 (55%) patients had a BMI ≥ 30. In group B, out of 40 patients, 25 (62.5%) patients had a BMI < 30, and 15 (27.5%) patients had a BMI ≥ 30 with p-value = 0.116. Out of 80 patients, 37(46.2%) patients were male while 43 (53.8%) were female patients. In group A, out of 40 patients, 20 (50%) patients were male, while 20 (50%) patients were female. In group B, out of 40 patients, 17 (42.5%) patients were male, while 23 (57.5%) patients were females with p-value = 0.501. Out of 80 patients, 52 (65%) patients had ASA status I, while 28 (35%) patients had ASA status II. In group A, out of 40 patients, 26 (65%) patients had ASA status I, while 14 (35%) patients had ASA status. In group B, out of 40 patients, 26 (65%) patients had ASA status I, while 14 (35%) patients had ASA status II with p-value=1.

In group A, patients had a 4.1±1.52 pain score on VAS and in group B, patients had a 6.88±1.23 pain score on VAS with p-value = 0.0001.

Tables 9, 10, 11, and 12 showed significant differences in pain scores on VAS in both groups according to stratification of age, BMI, gender, and ASA status, respectively.

Table 1: Descriptive statistics of Quantitative variables

	N	Minimum	Maximum	Mean	Std. Deviation
Age	80	30	60	45.83	9.132
BMI	80	20	40	29.74	5.265

Table 2: Descriptive statistics of Quantitative variables among both groups

Group		n	Minimum	Maximum	Mean	Std. Deviation
Group A	Age	40	30	60	45.20	8.850
	BMI	40	20	40	30.37	5.042
Group B	Age	40	30	60	46.45	9.476
	BMI	40	20	40	29.10	5.467

Table 3: Distribution of age

Age distribution	Group A		Group B		Total		Chi-square value	p-Value
	n	%	n	%	n	%		
30- 45 years	20	50.0	16	40.0	36	45	0.808	0.369
46-60 years	20	50.0	24	60.0	44	55		
Total	40	100	40	100	80	100		

Table 4: Distribution of BMI

BMI	Group A		Group B		Total		Chi-square value	p-value
	n	%	n	%	n	%		
<30	18	45.0%	25	62.5%	43	53.8%	2.464	0.116
≥ 30	22	55.0%	15	37.5%	37	46.2%		
Total	40	100	40	100	80	100		

Table 5: Distribution of Gender

Gender	Group A		Group B		Total		Chi-square value	p-value
	N	%	n	%	n	%		
Male	20	50.0%	17	42.5%	37	46.2%	2.464	0.501
Female	20	50.0%	23	57.5%	43	53.8%		
Total	40		40		80			

Table 6: Distribution of ASA status

ASA status	Group A		Group B		Total		Chi-square value	p-value
	n	%	n	%	n	%		
I	26	65.0%	26	65.0%	52	65.0%	0	1
II	14	35.0%	14	35.0%	28	35.0%		
Total	40	100	40	100	80			

Table 7: Pain score among both groups

Variable	Group		p-value
	A	B	
Pain score	4.1±1.52	6.88±1.23	0.0001

Table 8: Pain score among both groups according to age distribution

Age group	Variable	Group		p-value
		A	B	
30-45 years	Pain score	4.15±1.46	6.38±1.204	0.0001
46-60 years	Pain score	4.05±1.61	7.21±1.25	0.0001

Table 9: Pain score among both groups according to BMI

BMI	Variable	Group		p-value
		A	B	
< 30	Pain score	3.83±1.47	6.72±1.28	0.0001
≥ 30	Pain score	4.32±1.55	7.13±1.3	0.0001

Table 10: Pain score among both groups according to gender

Gender	Variable	Group		p-value
		A	B	
Male	Pain score	4.15±1.5	6.82±1.19	0.0001
Female	Pain score	4.05 ± 1.57	6.91 ± 1.38	0.0001

Table 11: Pain score among both groups according to ASA status

ASA status	Variable	Group		p-value
		A	B	
I	Pain score	4.42±1.42	6.96±1.31	0.0001
II	Pain score	3.5 ± 1.56	6.71 ± 1.27	0.0001

DISCUSSION

For open surgery, an incision of the required length was made to gain access via the abdominal wall. It gave surgeons a wide view of the entire operative field. The entrance of instruments and hands was made easy into the abdomen. The preferable incision for exposure of intra-abdominal content is a midline incision. Its benefits include quick access and ease of surgery. Various complications come with Laparotomies, like infections in wounds, wound dehiscence, and incisional hernia. An irritable complication is a pain in midline laparotomy during early postoperative hours.[6] Pain after midline laparotomy is derived from multiple origins, for example,

the abdominal wall and viscera, and from peritoneal irritation. Therefore, a single agent or pain-relieving technique is seldom enough for post-operative (POP) pain management. Thus, multimodal analgesia is usually applied. Multimodal treatment of POP pain may include non-opioid analgesics, paracetamol and nonsteroidal anti-inflammatory drugs (NSAIDs), regional blocks, and opioids.[7] The basis for the pre-emptive analgesia concept is to block pain before provocation. The pain signals are blocked due to which they are unable to reach the brain or spinal cord. Central and peripheral sensitization is carefully blocked by understanding the causative mechanism of pain therapeutically. The pre-emptive analgesia will lead to nerve blockage before incision by injecting local anesthesia into the incisional site.[8] There is some uncertainty in the pain-relieving effects of bupivacaine wound perfusion. Studies have suggested that the application of bupivacaine has reduced the dependence on opioids by reducing postoperative pain scores. Whereas, saline wound perfusion showed somewhat similar effects. Whereas, for midline wounds, a study has addressed the effectiveness of bupivacaine infusion for postoperative pain or analgesic demand.[9] The results of the study show that most of the patients were aged between 46 and 60 years with a mean age of 45.83±9.132 years. Females are more common than male patients. There is a significant difference between with and without incisional site infiltration of bupivacaine (4.1±1.52 vs 6.88±1.23 respectively) with p-value = 0.0001.[10] A study was conducted on the effect of incisional site infiltration of bupivacaine on postoperative pain and meperidine consumption after midline laparotomy. The pain score within 24 hours after laparotomy with bupivacaine was 4.83±2.8, and without bupivacaine infiltration, it was 6.4±1.8. They concluded that after midline laparotomy, infiltration of bupivacaine decreases the pain and post-operative consumption of opioids. Victory *et al* conducted a study on the effect of pre-incision versus post-incision infiltration with bupivacaine on postoperative pain. They compared no wound infiltration of bupivacaine with pre- and post-incision infiltration of bupivacaine.[11] They either found that wound infiltration, pre-incision or post-incision, and without wound infiltration, had no clinically significant effect on the pain scores or analgesic requirements. A study was conducted on rectus sheath infusion of bupivacaine to determine whether it reduces postoperative opioid requirement or not.[12] They observed that the mean pain score within 24 hours with bupivacaine was 2.24, and with normal saline, it was 1.89. They concluded that intermittent bupivacaine infusion into the rectus sheath space after midline laparotomy does not reduce postoperative opioid requirement, nor does it affect postoperative pain score. In this study, it is demonstrated an efficient and safe regime for the prevention and treatment of post-operative pain. Significant differences were found between the two studied groups, where the control group experienced more pain as compared to the intervention group. Cheong *et al* conducted their study on a randomized clinical trial of local bupivacaine perfusion versus parenteral morphine infusion for pain relief after laparotomy. They observed a significant decrease in pain scores with bupivacaine infiltration (P=0.03). They conclude that bupivacaine wound perfusion with direct continuous local technique is 0.5 times as effective as analgesia application in patients for relief of pain postoperatively after laparotomy. In comparison with parenteral opioids, it is a reliable, cost-effective, and safe alternative.[13] Considering the analysis of demographic characteristics in the present study, there were highly statistically significant differences (p=0.0001) between the two groups for the age distribution, gender, BMI, and ASA status. A similar, significantly higher number of demographic differences have been reported by other scientists that might be due to different sample sizes.[14] The small sample size is the main limitation of our study, despite our findings in favor of the analgesic efficacy of bupivacaine thus precluding us reaching from a definite conclusion.

CONCLUSION

This study concludes that Bupivacaine infiltration at the incisional site significantly decreases the pain as compared to bupivacaine infiltration in patients undergoing midline laparotomy. Thus, it is suggested that the use of Bupivacaine infiltration at incisional sites postoperatively may improve the patient's compliance significantly in relation to pain control.

LIMITATIONS

The research study was conducted at a single hospital. The findings of a single-center study might not be generalizable to other institutions with different patient demographics or surgical practices.

SUGGESTIONS / RECOMMENDATIONS

Based on the findings of the current study, it is recommended to consider adopting bupivacaine infiltration as a routine practice in midline laparotomy procedures to reduce post-operative pain for surgical wounds.

Develop further patient-specific pain management strategies that should include local anesthetics like bupivacaine, along with other multimodal analgesia techniques, for optimal outcomes.

Investigate the efficacy of bupivacaine infiltration in diverse populations, including patients with different surgical procedures, comorbidities, or varying pain thresholds.

Multi-center research studies should be conducted to validate the findings across various clinical settings and improve the generalizability of the results.

CONFLICT OF INTEREST / DISCLOSURE

There is no conflict of interest among all authors.

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