

## ROLE OF LOCAL INFILTRATION OF INJECTION BUPIVACAINE IN REDUCING EARLY POST-OPERATIVE PAIN

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### ABSTRACT:

**BACKGROUND & OBJECTIVE:** Intolerable morbidity occurs after major thoracic, orthopedic or abdominal surgeries due to post-operative pain. Inadequately controlled pain leads to patient displeasure and major morbidities like post-operative pulmonary dysfunctions and cardiac ischemic changes. Various techniques are presently used to treat this pain and opioids are the most regularly used medications by parenteral or neuraxial route. Intolerable morbidity occurs post-operatively due to inadequately controlled pain. The objective of this study was to compare the mean pain scores in patients undergoing laparotomy with and without local infiltration of injection bupivacaine at surgical incision site in post-operative period.

**METHODOLOGY:** This randomized controlled trial was conducted at surgical department Allied hospital Faisalabad from June 2017 to December 2017. Total 80 patient were included in this study that were randomly divided into two groups using random number tables. In post-operative period, patients of both groups were given treatment as per requirement of their respective diseases. They received a baseline analgesia using Inj. Toradol (ketorolac) 30mg/1ml intravenously every 8 hours, first dose given during the surgery. The study group was additionally given 10ml Inj. Bupivacaine HCl 0.5% diluted with 10ml saline injected into the subcutaneous plane around the incision immediately after the closure of skin and time was noted. No further difference in the treatment of patients of both groups required for the purpose of this study. The patients in both groups were compared for the degree of pain experienced by them in early post-operative period. This information was collected using Numeric pain scale, 10 being worst pain and 1 meaning least appreciable pain. These assessments were done 2 and 4 hours after surgery.

**RESULTS:** We recorded pain score  $3.0 \pm 0.75$  in study and  $5.2 \pm 0.72$  in control group, P-value was  $<0.001$  showing a significant difference.

**CONCLUSION:** We concluded that there is significantly lower pain in patients infiltrated with injection bupivacaine around surgical incision in early post-operative period as compared to those who had only intravenous analgesics.

**KEYWORDS:** Laparotomy, Local infiltration of injection bupivacaine, Mean post-operative score.

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## INTRODUCTION:

Midline abdominal incisions cater a number of benefits for the surgeon but one draw-back is significant pain in post-operative phase<sup>[1]</sup>. This pain is one of the most important factors in limiting early mobilization of patient, increasing requirement for post-operative analgesics and respiratory tract complications, eventually decreasing the rate of recovery<sup>[1]</sup>.

If post-operative pain is not adequately controlled it may lead to various unwanted outcomes that not only prove problematic for the patient but also increase length of hospital stay of the patient putting additional but avoidable burden on hospital resources<sup>[2]</sup>.

Various methods of post-operative pain control are practiced worldwide<sup>[3]</sup>. One of the newer methods is injecting a long acting local anesthetic like bupivacaine in the skin around the surgical incision<sup>[2]</sup>. This blocks pain signals originating at the cut edges of the skin from reaching higher centers thereby reducing the morbidity caused by pain. This injection may be repeated at appropriate intervals with comparatively low chance of complications<sup>[4]</sup>. This technique is usually coupled with continuous baseline analgesia provided by intravenous/ intramuscular injection of either an NSAID (e.g. Ketorolac, Diclofenac) or an opioid (Nalbuphine, Morphine)<sup>[5]</sup>. Combination of a centrally acting analgesic and peripheral blockage of pain sensations is theoretically more effective than individual use of these two modalities.

This method has been used in various different specialties like general surgery,<sup>3,6</sup> orthopedics,<sup>4,5</sup> gynecology<sup>2</sup> and interventional cardiology<sup>7</sup> with variable response. Most of the previous studies have found it to be an effective means of reducing post-operative pain especially in the first few hours after surgery, better than intravenous opioid analgesia alone. According to Monsef, et al<sup>[4]</sup> these effects are most pronounced at 2 and 4 hours interval after bupivacaine infusion, the effects gradually receding and becoming statistically insignificant from 6 hours onwards. These differences resulted in early mobilization, reduced requirement of post-operative analgesics, reduced overall morbidity and early discharge of the patient<sup>[2,4,6]</sup>. Patients receiving local

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infiltration of bupivacaine had pain score of  $3.33 \pm 1.65$  at closure as compared to control  $5.62 \pm 1.150$  (p-value <0.001). However, other researchers differ from these findings, stating that there is no appreciable advantage of per-incisional bupivacaine infiltration. These studies suggested that the difference in pain scores in patients with and without infiltration of bupivacaine is negligible and not statistically significant<sup>[8]</sup>.

The aim of this study was to assess pain scores in early post-operative phase of patients undergoing exploratory laparotomy using this technique for analgesia, to evaluate the efficacy of this technique, and if it proves beneficial, to establish this technique in future practice.

## METHODOLOGY:

This randomized controlled trial study was conducted at surgical department of Allied hospital Faisalabad from June 2017 to December 2017. The study has been approved by the Ethical review committee of Punjab Medical College Faisalabad. It included 80 patients which were divided into two equal groups by using random tables. Patients between 25 to 65 years of age, from both genders and undergoing laparotomy through midline abdominal incision for any indication were included in this trial while patients with any trauma to anterior abdominal wall, having neurological deficit due to spinal cord trauma, undergoing second-look laparotomy, patients with any pre-operative infective skin/ subcutaneous lesion at the site of incision, patients with disturbed renal function or gastric ulcer contraindicating use of NSAIDs i.e. InjToradol (Ketorolac), were excluded from the study.

After the approval of this study from hospital ethical review committee, all the patients admitted in our unit undergoing exploratory laparotomy for elective or emergency indications were included in the study.

Each participant of the study was informed in

detail regarding the procedure and an informed consent (written) was taken. Contact details including address and phone number were taken from each patient and recorded on individual patient's record pro-forma for the purpose of documentation.

Participants included in this study were assigned to two groups using random number tables.

In post-operative period, patients of both groups were given treatment as per requirement of their respective diseases. They received a baseline analgesia using Inj Toradol (ketorolac) 30mg/1ml intravenously every 8 hours, first dose given during the surgery. The study group was additionally given 10ml Inj bupivacaine HCl 0.5% diluted with 10ml saline injected into the subcutaneous plane around the incision immediately after the closure of skin and time was noted. No further difference in the treatment of patients of both groups required for the purpose of this study.

The patients in both groups were compared for the degree of pain experienced by them in early post-operative period. This information was collected using Numeric pain scale, 10 being worst pain and 1 meaning least appreciable pain. These assessments were done 2 and 4 hrs. after surgery.

All the data was collected with the help of a questionnaire.

The data were analyzed using SPSS version 18. For quantitative variables like age, BMI and Numeric pain scores after 4hrs, mean and standard deviation (S.D) was calculated. For qualitative variables like gender, diagnosis leading to laparotomy and the urgency of procedure, frequency and percentages were calculated. Mean pain score for both groups was compared by using independent sample t-test and P-value equal to or less than 0.05 was considered significant. Stratification done for result modifying factors like age, gender, BMI, indications for laparotomy and urgency of procedure and then independent t-test was applied.

## RESULTS:

Total 80 patients who fulfilled the inclusion and exclusion criteria were divided into two groups with 40 patients each and the mean pain scores was compared in early post-operative period between patients given local infiltration of injection bupivacaine and patients without infiltration at surgical incision site of patients undergoing laparotomy.

Age distribution of the patients revealed that 52.5% (n=21) in study and 57.5%(n=23) in control group were between 25-40 years of age whereas 47.5%(n=19) in study and 42.5%(n=23) in control group were between 41-65 years of age. Mean $\pm$ SD was calculated as 39.43 $\pm$ 8.63 years in study and 38.93 $\pm$ 8.51 years in control group.

Gender distribution manifest as 70% (n=28) in study and 75% (n=30) in control group were male whereas 30% (n=12) in study and 25% (n=10) in control group were females.

Mean BMI of the patients was recorded as 31.24 $\pm$ 4.74 in study and 32.41 $\pm$ 3.67 in control group. (Table-I)

Diagnosis leading to laparotomy categorized as 47.5%(n=19) in study and 55%(n=22) in control group had abdominal trauma. 30%(n=12) in study and 25% (n=10) in control group had small intestinal perforation whereas 22.5%(n=9) in study and 20%(n=8) in control group had abdominal infection.

Urgency of procedure was recorded in 85% (n=34) in study and 80% (n=32) in control group whereas 15% (n=6) in study and 20% (n=8) in control group had no urgency of procedure (Table-II).

Comparison of pain score were 3.0 $\pm$ 0.75 in study and 5.2 $\pm$ 0.72 in control group with p-value=0.0001 which exhibit significant difference (Table-III).

Data stratification for age, gender, BMI, indications for laparotomy and urgency of procedure was done before applying independent sample t-test. P-value  $\leq$  0.05 was considered as significant (Table- IV-VI).

**Table-I: Descriptive Information of Patients.**

Age(In years)	Study Group(40)		Control Group(40)	
	Patients #	%	Patients #	%
25-40	21	52.5	23	57.5
41-65	19	47.5	17	42.5
<b>Gender</b>				
Male	28	70	30	75
Female	12	30	10	25
<b>Total</b>	<b>40</b>	<b>100</b>	<b>40</b>	<b>100</b>
<b>Mean<math>\pm</math>SD</b>	<b>39.43<math>\pm</math>8.63</b>		<b>38.93<math>\pm</math>8.51</b>	
<b>BMI</b>	<b>Study Group (n=40)</b>		<b>Control Group (n=40)</b>	
	<b>Mean</b>	<b>SD</b>	<b>Mean</b>	<b>SD</b>
	31.24	4.74	32.41	3.67

**Table-II: Diagnosis Leading to Laparotomy and Urgency of Procedure (n=80).**

Diagnosis leading to laparotomy	Study Group		Control Group	
	No. of patients	%	No. of patients	%
Abdominal trauma	19	47.5	22	55
Small Intestinal perforation	12	30	10	25
Abdominal infection	9	22.5	8	20
<b>Urgency of Procedure</b>				
Yes	34	85	32	80
No	6	15	8	20
<b>Total</b>	<b>40</b>	<b>100</b>	<b>40</b>	<b>100</b>

**Table-III: Comparison of Mean pain Score at 4-hours after Surgery (n=80).**

Pain score	Study Group		Control Group	
	Mean	SD	Mean	SD
	3.0	0.75	5.2	0.72

P-value: 0.0001

**Table-IV: Stratification for Age & Gender of the Patients (n=80).**

Age (In Years)	Study Group (n=40)		Control Group (n=40)		P-value
	Mean	SD	Mean	SD	
25-40	3.10	0.77	5.17	0.78	0.0001
41-65	2.89	0.74	5.24	0.66	0.001
<b>Gender</b>					
<b>Male</b>	2.96	0.88	5.20	0.71	0.0001
<b>Female</b>	3.08	0.29	5.20	0.79	0.001

**Table-V: Stratification for BMI of the Patients & Urgency of Procedure (n=80).**

BMI	Study Group (n=40)		Control Group (n=40)		P-value
	Mean	SD	Mean	SD	
≤30	3.14	0.73	5.10	0.72	0.0001
>30	3.04	0.76	5.14	0.70	0.001
<b>Urgency of procedure</b>					
Yes	3.18	0.69	5.14	0.68	0.0001
No	3.09	0.66	5.05	0.67	0.0001

**Table-VI: Stratification for Diagnosis Leading to Laparotomy (n=80).**

Diagnosis leading to laparotomy	Study Group (n=40)		Control Group (n=40)		P-value
	Mean	SD	Mean	SD	
Abdominal trauma	3.21	0.71	5.10	0.74	0.0001
Small Intestinal Perforation	2.92	0.77	5.13	0.71	0.0001
Abdominal infection	3.11	0.76	5.14	0.67	0.0001

**DISCUSSION:**

Intolerable morbidity occurs after major thoracic, orthopedic or abdominal surgeries due to post-operative pain. Inadequately controlled pain leads to patient displeasure and major morbidities like post-operative pulmonary dysfunction and cardiac ischemic changes. Various techniques are presently used to treat

this pain and opioids are the most regularly used medications by parenteral route.

We planned this study to assess pain scores in early post-operative phase of patients undergoing exploratory laparotomy using this technique for analgesia. We intended to evaluate the efficacy of this technique, and if it proves beneficial, to establish this technique in our practice.

We compared our results with a previous study<sup>[4]</sup> receiving local infiltration of bupivacaine had pain score of  $3.33 \pm 1.65$  at closure as compared to control  $5.62 \pm 1.150$  ( $P$ -value  $< 0.001$ ).

The advantage of local wound infiltration was assessed with regards to diminished post-operative narcotics usage, declined VAS score and timely patient mobilization. Surprisingly only once intra-operative local wound infiltration of bupivacaine extend the time to first analgesic dose, lower the VAS score at 4th post-operative hour and diminished the first post-operative day analgesics utilization. The number of patients not in need of analgesics also increased. The results were predominantly notable during the first 24 hours post-operatively but diminished subsequently. During the succeeding time span, the constancy of analgesics usage remained the same as in the control group.

On the other hand, a study by Hariharan, *et al*<sup>[9]</sup> has proclaimed that local wound infiltration either before or even after surgical incision did not markedly reduce the post-operative pain after total abdominal hysterectomy. But uninterrupted local wound infiltration was outmatched, as compared to ones with per-operative wound infiltration as well as post-operative opioids for sustained analgesia. However, its functionality for the post-operative pain also determined by the type of surgery.

A randomized double blind study by Tauzin-Fin *et al*<sup>[10]</sup> reported a cutback in overall tramadol utilization to  $221 \pm 64.1$  mg in group receiving intravenous magnesium sulfate along with ropivacaine local wound infiltration and even to  $134 \pm 74.9$  mg in other group receiving magnesium added ropivacaine locally in wound after radical retropubic prostatectomy.

On the contrary, in another study by Berthon *et al*<sup>[11]</sup>, it was noticed that local wound infiltration with anesthetic agent was not advantageous in laparoscopic prostatectomy and recommended that it should not be consumed on regular basis. We can say the postoperative pain after minimal invasive surgeries is generally trivial to start with.

In a comparably similar randomized double blind study by Updike and colleagues<sup>[12]</sup> on 68 patients, they used placebo for control group. At incision site just before total abdominal

hysterectomy, they infiltrated the operation site either with 30ml of ropivacaine or placebo. They established similar outcome in both groups in relation to pain score and narcotic usage frequency at any time during post-operative time span.

However, contemporary studies provided evidence for better pain control and diminished opioid consumption by use of uninterrupted wound infiltration. Other beneficial consequences included lesser duration of ileus and shorter length of hospital stay with significant reduction in per patient cost<sup>[13]</sup>.

Local analgesic infiltration of surgical site is oldest and most commonly performed method however now a modality of ultrasound guided TAP block proved a better analgesic quality as compared to LAI for reducing postoperative pain<sup>[14,15]</sup>. A study by Ali, *et al* showed significant reduction in mean pain score at 12 hours post-operatively and less mean opiate requirement in patient with TAP block as compared to LAI with  $P$ -value  $< 0.05$ <sup>[16]</sup>.

Similar beneficial results of TAP block shown by Khan, *et al* for open appendectomy and inguinal hernia repair, by Sivapurapu *et al* for lower abdominal gynecological surgeries and by Patersen *et al* for laparoscopic cholecystectomy<sup>[19]</sup>.

The findings of our study revealed that "Patients infiltrated with injection bupivacaine around surgical incision experience less pain in early post-operative period in comparison to patients getting only intravenous analgesics."

## CONCLUSION:

We concluded that there is a significant decrease in pain score in patients infiltrated with injection bupivacaine around surgical incision in early post-operative period as compared to those getting only intravenous analgesics.

## CONFLICT OF INTEREST:

All authors disclose no conflict of interest.

## Grant Support & Financial Disclosures:

None.



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**Sumara Tabassam:** Data analysis, review of literature.

**Farhad Alam:** Literature search review, proof reading.

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**Mudassar Jabeen:** Write up, formatting, references, proof reading.

**Fawad Zafar:** Data collection, preparations of results, study design.

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Failures are often the results of timidity and fears;  
disappointments are the results of bashfulness; hours of leisure  
pass away like summer-clouds, therefore, do not waste  
opportunity of doing good

***Hazrat Ali (Karmulha Wajhay)***