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Comparison of Mean Post-Operative Pain Score with Pre-Incisional Versus Postoperative Injection of Bupivacaine in Patients Undergoing Elective Surgery

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ABSTRACT

The most important concern after the surgical intervention is pain which needs to be addressed for better compliance and early mobilization to avoid other complications. The need for a better analgesic and time of administration is the key to success.Objective; To compare the mean post-operative pain score with pre-incisional versus post-operative injection of bupivacaine in patients undergoing elective surgery.Study design; This Randomized controlled trial was conducted in the General surgery department, National Hospital & Medical Centre, Lahore from 24-02-20 to 24-11-20. Data was collected through Non-probability consecutive sampling. The cases of both genders with an age range of 18-60 years undergoing elective surgeries were selected. They were divided into two groups. The cases in group A were given pre-incision bupivacaine and group B with post-operative bupivacaine and were assessed 1 hour after surgery regarding pain on VAS.Results; In the present study there were a total of 64 cases with 32 in each group. The mean age in group A was 47.56±7.51 years while in group B was 49.13±8.03 years. There were 19 (59.37%) males in group A vs 18 (56.25%) in group B. The mean post-operative pain in group A was 3.07±0.67 vs 3.59±0.91 in group B on VAS with p= 0.03. Mean post-operative pain in males was 3.12±0.65 vs 3.47±0.86 and in females, it was 3.21±0.66 vs 3.53±0.90 in groups A and B with p values of 0.21 and 0.23 respectively. Mean Post-operative pain was 3.11±0.66 vs 3.44±0.83 in the age group 18-39 years and 3.08±0.68 vs 3.47±0.88 in age group 40 to 60 years in group A and B with p values of 0.25 and 0.20 respectively. There was a significant difference in terms of postoperative pain in cases undergoing open cholecystectomy where pain was 3.21±0.78 vs 3.86±1.02 in group A and B respectively with p= 0.01. Whereas no difference was seen in the rest of the variables. Conclusion; Mean post-operative pain is significantly better in cases treated with pre-incisional bupivacaine as compared to post-operative bupivacaine and this difference was also seen as significantly high in cases undergoing open cholecystectomy.

INTRODUCTION:

The most important factor related to patient discomfort after surgery is pain. Although many studies[1,2] have shown that effective analgesia reduces postoperative complications, pain is often overlooked and not adequately controlled[2]. Postoperative pain causes a significant increase in sympathetic activity and increases the heart rate and oxygen consumption and delays early mobilization. It also causes increased hospital stay and it has been reported that up to 75% of postsurgical patients suffer severe postoperative pain. Effective pain relief can cause good psychological and physical effects on the patients which can lead to better recovery[3].

Postoperative analgesia is a major component of peri-operative care and local anesthetic (LA) techniques are more effective than systemic analgesia regardless of the operation and mode of delivery. When choosing a 'procedure-specific' technique, the simplest, safest and most effective block should be employed whenever possible. Thus, the meticulous direct application of LA to each identifiable layer during a surgical procedure has considerable appeal for both surgeons and anesthetists. Local anesthetic infiltration for surgery itself has largely been confined to small superficial outpatient procedures. However, performed well, this is a logical means of preventing pain and other noxious stimuli from reaching the spinal cord[4,5]. Pre-emptive analgesia; the administration of an analgesic before a painful stimulus, is an attempt to obtain better pain relief compared with when the same analgesic intervention is used after the painful stimulus. Clinical studies have conflicting results regarding the efficacy of preemptive analgesia[6,7,8]. Khan et al.[9] (2014) in a randomized controlled trial over 44 patients reported that pre-incisional infiltration of bupivacaine was associated with significantly lower mean postoperative pain on the visual analog scale (VAS; 3.16±0.71 vs. 3.75±0.94; p=0.0013) as compared to post-operative bupivacaine confirming the advantage of pre-emptive analgesia.

The results of Khan et al.[9] are promising and pre-operative bupivacaine infiltration can thus reduce the post-operative pain and therefore the analgesic requirements with associated complications.

However, before adopting this practice in routine its worth mentioning that Fouladi et al.[10] (2013) reported significantly higher mean post-operative pain on the visual analog scale with pre-incisional infiltration of bupivacaine (2.11±1.26 vs. 1.39±1.20; p<0.001) as compared to postoperative bupivacaine claiming post-operative infiltration to be superior. A possible

explanation for this conflict among studies can be the selection bias where Khan et al.[9] included patients undergoing laparoscopic appendectomy while Fouladi et al.[10] conducted the trial on women undergoing C-sections. Due to limited and conflicting evidence on the topic, the purpose of the current study is to repeat this trial and further confirm the results. The present study will include patients undergoing various abdominal procedures and the results will be stratified to determine any confounding effect of elective procedure. The results of the present study will help in the selection of a more appropriate timing of bupivacaine infiltration for post-operative pain analgesia.

OBJECTIVES:

 To compare the mean postoperative pain score with pre-incisional versus postoperative injection of bupivacaine in patients undergoing elective surgery.

OPERATIONAL DEFINITIONS:

1. Elective Surgery: It will include patients undergoing the following procedures on the elective list.

a. Laparoscopic Cholecystectomy

b. Laparoscopic Hernioplasty

c. Laparoscopic Appendectomy

d. Open Cholecystectomy

e. Open Hernioplasty

f. Open Appendectomy

g. C-Section

2. Post-Operative Pain: It will be assessed using the Visual Analogue Scale (Appendix-I) ranging from 0 (no pain) to 10 (maximum pain) 1 hour after the application of skin stitches.

HYPOTHESIS:

There is a difference in the mean postoperative pain score with pre-incisional versus postoperative injection of bupivacaine in patients undergoing elective surgery.

MATERIAL AND METHODS:

1. Study design: It's a randomized controlled trial.

2. Settings: Surgical Department, National Hospital, Lahore.

3. Duration of study: 6 months after the approval of synopsis.

4. Sample Size: The sample size of 64 cases (32 in each group) is calculated with 80% power of test and 95% confidence interval while taking the expected mean post-operative VAS score to be 3.16±0.71 with pre-incisional and 3.75±0.94 with post-operative infiltration of bupivacaine in patients undergoing elective abdominal surgery [9].

5. Sampling Technique: Non Probability, Consecutive Sampling.

6. Sample Selection:

Inclusion criteria:

1. Patients of both genders with ages in the range of 18-60 years undergoing elective surgery as per operational definition.

2. Patients who sign written informed consent to participate in the study.

Exclusion criteria:

1. Patients having a history of allergy to bupivacaine.

2. Patients having a history of steroid intake.

3. Patients with deranged coagulation profile (PT&APTT ≥ 5 sec above control and international normalized ratio; INR ≥2.5)

4. Known hypertensive (Blood Pressure≥140/90mmHg on at least two occasions 4 hours apart), obese (BMI≥30kg/m^2) and diabetic (fasting blood sugar≥110mg/dl).

5. Patients falling under American Society of Anaesthesiologists; ASA Class ≥III

(Appendix II).

DATA COLLECTION PROCEDURE:

After approval from the Hospital's Ethical Review Board, 64 patients undergoing elective surgery at the operation theatres of National Hospital Lahore who fulfill the above criteria will be counseled and explained the details of the study. Written informed consent and detailed history will be taken from each patient. These patients will be then randomly divided into the following two groups using lottery method.

- Group A: Pre-incision Bupivacaine (10 ml of Bupivacaine infiltrated in subcutaneous tissue of marked area for incision 5 minutes before incision)

- Group-B: Post-Operative Bupivacaine (10 ml of Bupivacaine infiltrated in subcutaneous tissue around incision immediately after wound closure)

Patients in both groups will receive treatment as per group. Post-operative pain will be assessed using Visual Analogue Score 1 hour after surgery. All the pre and post-operative care and injection of bupivacaine as well as the assessment of post-operative pain will be performed by a single resident (candidate herself) to eliminate bias. Confounding variables will be controlled by exclusion. Data will be stratified to address effect modifiers.

DATA ANALYSIS PROCEDURE:

All the collected data will be entered and analyzed through SPSS version 21.

1. Numerical variables; age, duration of surgery and VAS score for postoperative pain will be presented by mean ±SD. Independent sample t-test will be used to compare the mean postoperative VAS score between the two groups taking $p \leq 0.05$ as significant.

2. Categorical variables; gender and elective procedure (laparoscopic cholecystectomy, laparoscopic hernioplasty, laparoscopic appendectomy, open cholecystectomy, open hernioplasty, open appendectomy and C-section) will be presented by frequency and percentage.

3. Data will be stratified for age, gender, elective procedure (laparoscopic cholecystectomy, laparoscopic hernioplasty, open cholecystectomy, open hernioplasty and C-section) and duration of surgery to address effect modifiers. A post-stratification independent sample test will be applied taking $p \leq 0.05$ as significant.

4. RESULTS;

In the present study, there were a total 64 cases with 32 in each group. The mean age in the group A was 47.56±7.51 years while in group B was 49.13±8.03 years as shown in table 01. The mean duration of surgery was 53.47±21.13 vs. 52.67±23.34 minutes in group A and group B respectively as displayed in table 2. There were 19 (59.37%) males in group A vs. 18 (56.25%) in group B (table 3). Table no 4 reveals various types of procedures in both groups. The mean post-operative pain in group A was 3.07±0.67 vs. 3.59±0.91 in group B on VAS with p= 0.03 as in table 05. Mean post-operative pain in males was 3.12±0.65 vs. 3.47±0.86 and in females it was 3.21±0.66 vs. 3.53±0.90 in group A and B with p values of 0.21 and 0.23 respectively (table 06). Mean post-operative pain was 3.11±0.66 vs. 3.44±0.83 in age group 18-39 years and 3.08±0.68 vs. 3.47±0.88 in age group 40 to 60 years in group A and B with p values of 0.25 and 0.20 respectively (table 07). There was significant difference in terms of postoperative pain in cases undergoing open cholecystectomy where pain was 3.21±0.78 vs. 3.86±1.02 in group A and B respectively with p= 0.01 whereas no difference was seen in rest of the variables as shown in table 08.

TABLE NO. 01: STUDY VARIABLE (AGE) n= 64 (32 in each group)

	A GE	
	Group A	Group B
Mean	47.56	49.13
Std. Deviation	7.51	8.03
Minimum	18	19
Maximum	60	60

TABLE NO. 02: DURATION OF SURGERY (MINUTES) n= 64 (32 in each group)

	Duration of surgery (minutes)	
	Group A	Group B
Mean	53.47	52.67
Std. Deviation	21.13	23.34
Minimum	30	30
Maximum	90	100

TABLE NO. 03: GENDER DISTRIBUTION IN STUDY SUBJECTS n= 64 (32 in each group)

Gender	Group	
	Group A	Group B
Male	19 (59.37%)	18 (56.25%)
Female	13 (40.63%)	14 (43.75%)
Total	32	32

TABLE NO. 04: TYPES OF ELECTIVE PROCEDURES IN STUDY SUBJECTS

Types of procedures	Group	
	Group A	Group B
Laparoscopic cholecystectomy	9 (28.1%)	7 (21.8%)
Laparoscopic hernioplasty	7 (21.8%)	8 (25%)
Laparoscopic appendectomy	7 (21.8%)	9 (28.1%)
Open cholecystectomy	5 (15.6%)	6 (18.7%)
Open hernioplasty	2 (6.2%)	1 (3.1%)
Open appendectomy	2 (6.2%)	1 (3.1%)
C section	0 (0%)	0 (0%)
Total	32	32

TABLE NO. 05: POST-OPERATIVE PAIN WITH RESPECT TO BOTH GROUPS

	GROUP		p
	A	B	
pain	3.07±0.67	3.59±0.91	0.03

TABLE NO. 06: POST-OPERATIVE PAIN IN BOTH GROUPS WITH RESPECT TO GENDER

Gender	Group		p-value
	A	B	
Male	3.12± 0.65	3.47±0.86	0.21
Female	3.21±0.66	3.53±0.90	0.23

TABLE NO. 07: POST-OPERATIVE PAIN IN BOTH GROUPS WITH RESPECT TO AGE

Age	Group		p-value
	A	B	
18-39	3.11±0.66	3.44±0.83	0.25
40-60	3.08±0.68	3.47±0.88	0.20

TABLE NO. 08: POST-OPERATIVE PAIN IN BOTH GROUPS WITH RESPECT TO THE TYPE OF PROCEDURE

Type of procedure	Group		p value
	A	B	
Laparoscopic cholecystectomy	3.13±0.67	3.41±0.81	0.23
Laparoscopic hernioplasty	3.19±0.69	3.45±0.82	0.31
Laparoscopic appendectomy	3.03±0.62	3.34±0.68	0.18
Open cholecystectomy	3.21±0.78	3.86±1.02	0.01
Open hernioplasty	3.17±0.67	3.35±0.79	0.43
Open appendectomy	3.09±0.63	3.45±0.81	0.31

DISCUSSION;

The number of both emergency and elective surgeries is on the rise in recent times and each carries its own risks and complications. Post-operative pain is one of the most common entity to be encountered and adds a great degree of concern not only for the patients, families and also has direct and indirect effect on wound healing and early mobilization to avoid further morbidity in such cases. elective surgeries have the advantage of good prior medication with analgesics as compared to the emergency ones. [191] Bupivacaine has been widely used as an analgesic associated with surgeries but majorly in patients with post-operative period. Recent time has shown its good utility as pre medication and also better efficacy in post-operative period; though the data was scarce and wide variable. Better post-operative pain can also add the extra benefit of early hospital discharge and hence reducing hospital cost and the chances of nosocomial infections. [192-93] In the present study, the mean post-operative pain in group A treated with pre-incisional bupivacaine was 3.07±0.67 as compared to 3.59±0.91 in group B treated with post-operative administration of bupivacaine on VAS with p= 0.03 in

cases undergoing for various elective surgeries. These results were closer to the findings of the past studies where this was shown that the preemptive therapy with bupivacaine has shown much better results as compared to later after the surgery. According to a study done by 88 Khan R et al it, they compared this modality in cases undergoing laparoscopic appendectomy and it was seen that the mean pain on VAS in pre vs. post-surgery was seen as 3.16±0.71 vs. 3.75±0.94 with a significant p value of 0.001. [194] In another study done by Fouladi et al similar results were seen and in their study the mean pain with much higher after the surgery where it was 2.11±1.26 in contrast to 1.39±1.20 managed with pre-incisional medication with p-value of < 0.001.[195] In this study mean post-operative pain was 3.11±0.66 vs. 3.44±0.83 in the age group 18-39 years and 3.08±0.68 vs. 3.47±0.88 in the age group 40 to 60 years in groups A and B with p values of 0.25 and 0.20 respectively. The findings of the present study were also enforced by the studies done in the past where they also did not find a significant difference. According to a study done by Abuelaish et al they found that regarding both their age groups there was no significant difference in terms of pain after the surgery with p-value of > 0.05 and similar was seen regarding sex where the difference in pain was again in significant with p= > 0.05 which was similar to the present study in terms of gender as well where mean post-operative pain in males was 3.12±0.65 vs. 3.47±0.86 and in females it was 3.21±0.66 vs. 3.53±0.90 in group A and B with p values of 0.21 and 0.23 respectively. Moreover the over all pain in pre and post-operative Bupivacaine was 3.1 vs. 3.7 with p value less than 0.05 and they also revealed that mean post-operative 89 morphine consumption was also much higher in cases where bupivacaine was given post operatively.[196] There was significant difference in terms of post-operative pain in cases undergoing open cholecystectomy where pain was 3.21±0.78 vs. 3.86±1.02 in group A and B respectively with p= 0.01 where as no difference was seen in rest of the variables. This was also seen by the study done by Sayyed et al where they also revealed that the degree of pain was much less with pre surgical use of bupivacaine and further more they found that 65% of these cases did not require any narcotic analgesics in the post-operative time.[197] This can be explained by the fact that this was the most time consuming surgery as compared to the other procedures included in this study in their form of appendectomy and hernioplasty and also , majority of the cases were those that were initially inducted in laparoscopic surgery and then converted to open surgery and led to extensive tissue manipulation which led to more degree of pain and this was better controlled with the pre incisional bupivacaine as compared to the post-operative administration. The other studies done in the past have also revealed its great efficacy in cases undergoing cholecystectomies both in the form of open and

laparoscopic procedures.[198-200] 90 There were few limitations in this study as this study did not look for the amount of other analgesics as well as the narcotics used which have been extensively studied and also had an impact on outcome. However, there were many strengthening points of this study as well as this study elaborated a number of surgeries and the most important issue of surgery i.e. post-operative pain management in surgical cases.

CONCLUSION;

Mean post-operative pain is significantly better in cases treated with preincisional bupivacaine as compared to post-operative bupivacaine and this Difference was also seen as significantly high in cases undergoing open cholecystectomy.

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PROFORMA

Comparison of Mean Post-Operative Pain Score with Pre-Incisional versus Post-Operative Injection of Bupivacaine in Patients undergoing Elective Surgery

CASE NO _____

Name of Patient: _____ S/D/W/O: _____
Hospital's Reg. #: _____ Age: _____ Gender: _____
Address: _____
_____

Elective Procedure:

- Laparoscopic Cholecystectomy ☐
- Laparoscopic Hernioplasty ☐ Open Appendectomy
- Laparoscopic Appendectomy ☐ C-Section
- Open Cholecystectomy

Open Hernioplasty ☐

Duration of Surgery: _____ minutes ☐

Study Group ☐ **Post-Operative** ☐

Pre-Incisional

☐ Post-Operative Pain? _____ VAS Score

Appendix-I: Visual Analogue Scale (VAS)

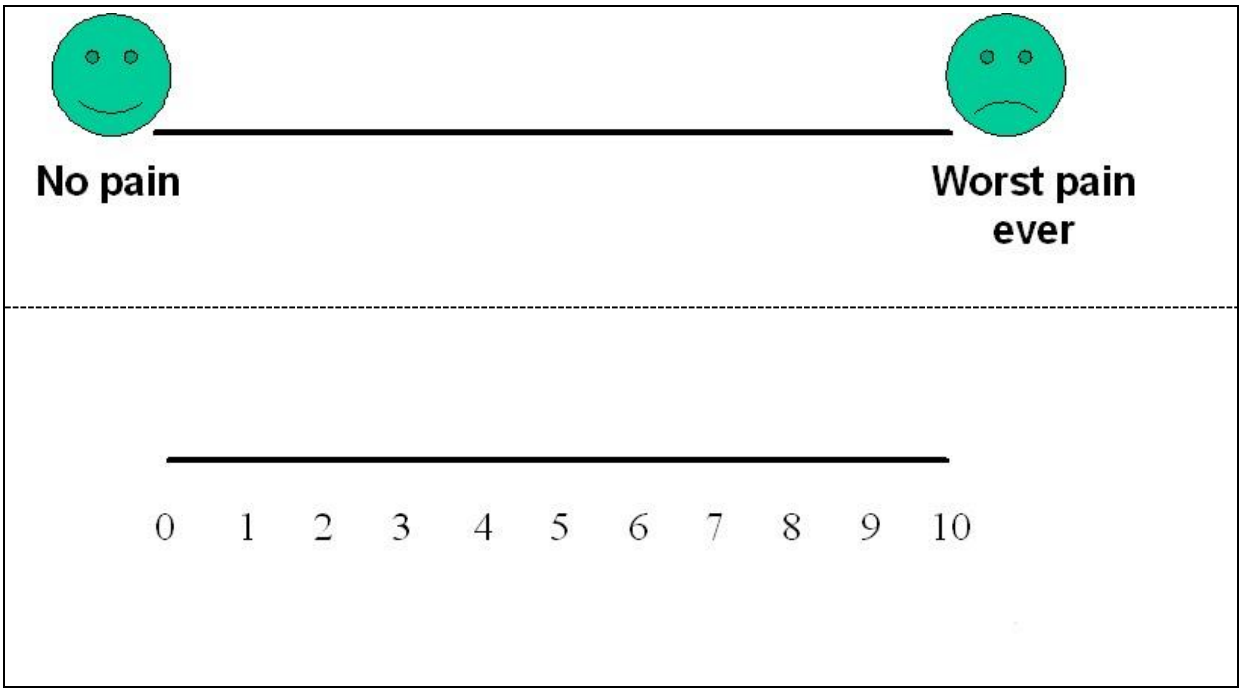

Fig. 1: Visual Analogue Scale

Appendix-II: American Society of Anaesthesiologists (ASA) Classification

These are as under

ASA Class I - A normal healthy patient

ASA Class II - A patient with mild systemic disease

ASA Class III - A patient with severe systemic disease

ASA Class IV - A patient with severe systemic disease that is a constant threat to life

ASA Class V - A moribund patient who is not expected to survive without the operation

ASA Class VI - A declared brain-dead patient whose organs are being removed for donor purposes