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Original Research Article

A Comparative Study between Intravenous Lignocaine and Intravenous Paracetamol for Postoperative Analgesia in Exploratory Laparotomy

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Conflict of interest: Nil

Abstract

Aim: The aim of the present study was to assess the impact of intravenous lignocaine and intravenous paracetamol on intra-operative hemodynamics, post-op pain scores, and post-op analgesic requirement in patients undergoing exploratory laparotomy.

Methods: This randomized single-blinded observational study was conducted in The Department of Anaesthesiology, critical care, and pain management at SRMS Institute of Medical Sciences, Bareilly, after obtaining prior approval from the ethical committee and after written, informed consent was obtained from the patient. The study was conducted from 1st Feb 21 to 31st July 22. The sample size for this study was 72 patients i.e., 36 patients in each group.

Results: The mean ± SD of age (years) in group I was 38.42 ± 10.8 and in group, II was 37.86 ± 10.62 with no significant difference between them. No significant difference was seen in weight (kg) (p value=0.448), height (cm) (p value=0.75), and body mass index (kg/m²)(p value=0.739) between group I and group II. Mean ± SD of weight (kg), height (cm), body mass index (kg/m²) in group I was 61.06 ± 5.82, 161.61 ± 7.34, 23.78 ± 2.33 respectively and in group II was 62.19 ± 6.82, 161.08 ± 6.66, 23.96 ± 2.09 respectively with no significant difference between them. No significant difference was seen in heart rate, systolic, diastolic blood pressure, VAS scores and SPO2.

Conclusion: The present study demonstrated lignocaine as a superior analgesic drug with context to paracetamol for postoperative pain relief in an exploratory laparotomy.

Keywords: lignocaine, paracetamol, intravenous, post-operative analgesia.

Introduction

General or regional anaesthesia can be appropriate for patients undergoing abdominal surgery. In common practice, for abdominal surgical procedures, balanced anaesthesia with inhalational anaesthetics, opioids, and neuromuscular blockers is used. Abdominal wall incision is the major origin of pain experienced by patients after exploratory laparotomy. [1] Postoperative pain results due to the release of inflammatory, visceral, and neuropathic mediators as a result of surgical trauma producing structural and functional changes in pain pathways resulting in hyperalgesia and central sensitization. [2,3]

Effective analgesia is the most important aspect of rehabilitation from surgery. Inadequate pain management in the postoperative period carries a wide range of unfavourable consequences, including increased morbidity, impaired physical function and quality of life, and slow recovery. [4] Post-operative pain control is an essential component of anaesthesia management which is crucial factors in an ambulatory surgical plan. Management Plan should be aimed at providing adequate pain relief and at the same time minimizing side effects like sedation. So that the patient can be safely discharged from the surgical facility without any major influence on the patient's ability to resume their normal activities of daily living.

Drugs such as non-steroidal anti-inflammatory drugs (NSAIDs), paracetamol, cyclooxygenase-2 (COX-2) inhibitors, local anaesthetics, and steroids are often used for their opioid-sparing action to reduce opioid-related side effects and hasten recovery. Paracetamol (acetaminophen; N-acetyl-p-aminophenol) is an acetanilide derivative, a safe, well-tolerated drug with proven efficacy as an analgesic. Its clinical effects arise most likely from the central action, and intravenous (IV) administration provides rapid and predictable therapeutic plasma concentration through the inhibition of p descending serotonergic inhibitory pathways. [5,6]

Intravenous administration of lidocaine in the perioperative period produces analgesia by increasing in concentration of acetylcholine in cerebrospinal fluid, leading to activation of inhibitory descending pain pathway, blocking of muscarinic receptors M3, inhibition of glycine receptors, the release of endogenous opioids, reduction of the inflammatory response to tissue ischemia, and decreased release of cytokines in response to tissue damage are some of the mechanisms proposed for the analgesic effects of lignocaine infusion. Lignocaine also causes the direct or indirect reduction of postsynaptic depolarization mediated through N-methyl-D-aspartate receptors. [7] A plasma level of 0.5–5 µg/mL is needed for clinical effects while a level of >5 µg/mL produces toxicity. Lignocaine infusion is associated with hemodynamic stability. It has a direct myocardial depressant effect, a peripheral vasodilating effect, and an effect on synaptic transmission and depth of anaesthesia thereby preventing swings in HR and blood pressure. [8]

Thus the aim of the study was to compare well-established paracetamol as an excellent peri-operative analgesic with lignocaine which is recently introduced into the armamentarium of present-day anaesthetists for the purpose.

Materials and Methods

This randomized single-blinded observational study was conducted in The Department of Anaesthesiology, critical care, and pain management at SRMS Institute of Medical Sciences, Bareilly, after obtaining prior approval from the ethical committee and after written,

informed consent was obtained from the patient. The study was conducted from 1st Feb 21 to 31st July 22. The sample size for this study was 72 patients i.e., 36 patients in each group.

Inclusion Criteria:

1. Patients in the age group of 18-50 years.
2. Patients belonging to ASA grades I and II.
3. Patients planned to be taken for elective exploratory laparotomy.

Exclusion Criteria:

1. Patients' refusal of written consent.
2. Patients with allergy/sensitivity to local anaesthetic agents.
3. Patients with bleeding disorders or on anticoagulants.
4. Patients who belong to ASA grades III and IV.
5. Pregnant patients.
6. Patients with cardiovascular, respiratory, or metabolic disorders with or without treatment.
7. Obese patients

A routine pre-anaesthetic visit was conducted for all patients, including taking the medical history of each patient and a thorough systemic examination. Routine and special investigations, as per the requirement was carried out accordingly. Before participation in the study, during the visit, all patients were explained the purpose of the study, the advantages and risks of the procedure to be performed, and possible side effects.

During the pre-operative assessment, patients were sufficiently educated about the 10 cm Visual Analogue Scale (VAS). All patients were instructed to remain nil per orally for at least 8 hours before surgery. All patients were randomly divided into two equal groups of participants each using a computer-based random number generator, i.e., Group I and Group II.

i.) GROUP I: Patients received Inj. 2% Lidocaine 1.5 mg /Kg IV bolus over 10 minutes before induction & intravenous infusion dose of Inj. 2% Lidocaine (1.5 mg/Kg/hr) was started before skin incision and continued for 1 hr.

ii.) GROUP II: Patients received Inj. Paracetamol 1 gm in 100 ml of 0.9% NS over 15 minutes injected 10 minutes after induction of anaesthesia.

Upon entering the O.T., intravenous access was secured and all standard monitors including NIBP, HR, RR, ECG, SPO2, and EtCO2 were attached. The monitor was set to measure BP at regular intervals of 5 minutes. The other parameters were under continuous monitoring and display. The patients were pre-medicated with Inj. Ondansetron 0.15mg/kg I.V, Inj. Glycopyrrolate 0.005 mg/kg I.V, Inj. Midazolam 0.05 mg/kg IV and Inj. Fentanyl 2 mcg/kg I.V and pre-oxygenated with 100% oxygen for 3-4 minutes and they were induced with Inj. Propofol 2mg/kg, and Inj. Succinylcholine 2mg/kg to facilitate endotracheal intubation. Maintenance of anaesthesia was achieved by giving O2 + N2O + Isoflurane and Inj. Vecuronium (0.12mg/kg bolus followed by 0.03 mg/kg intermittently).

After completion of the surgery, the patients were given Inj. Neostigmine and Inj. Glycopyrrolate. After a demonstration of recovery, from muscle relaxants, patients were extubated and shifted to Post-Anaesthesia Care Unit. After this procedure was completed, postoperatively, the patient was shifted to the post-operative recovery area and assessment of postoperative pain was done using VAS at 0-hour, 1 hour, 2 hours, 4 hours, 6 hours, 12 hours, 18 hours, and 24 hours. Sedation status was assessed using Ramsay's sedation scale.

Post-operative analgesic requirement and the time at which it is needed was noted in each group and compared. The first dose of postoperative pain was given based on

the VAS score and the demand of the patient. A rescue analgesic was given when the VAS score was 4 or higher. IV Tramadol 2mg/kg was the rescue analgesia of choice.

Incidence of Post-Operative Nausea and Vomiting was noted and recorded and the incidence of Group I and Group II were noted separately and compared. The same was also done to note and record other side effects like LA toxicity,

All data was observed, recorded, tabulated, and statistically evaluated by an observer (junior resident, anaesthesia) and an independent data analyst who was blinded to the study.

Statistical Analysis

Statistical testing was conducted with the statistical package for the social science system version SPSS 17.0. Continuous variables will be presented as mean±SD or median if the data was unevenly distributed. Categorical variables were expressed as frequencies and percentages. The comparison of normally distributed continuous variables between the groups was performed using Student's t-test. Nominal categorical data between the groups was compared using Chi-square test or Fisher's exact test as appropriate. Non-normal distribution continuous variables were compared using Mann Whitney U test. For all statistical tests, a p-value less than 0.05 were taken to indicate a significant difference.

Results

Table 1: Demographic details

Age (years)	**Group I (n=36)**	**Group II (n=36)**	**Total**	**P value**
18-20	2 (5.56%)	4 (11.11%)	6 (8.33%)	0.79*
21-30	8 (22.22%)	6 (16.67%)	14 (19.44%)	
31-40	6 (16.67%)	8 (22.22%)	14 (19.44%)	
41-50	20 (55.56%)	18 (50%)	38 (52.78%)	
Mean ± SD	38.42 ± 10.8	37.86 ± 10.62	38.14 ± 10.64	0.826‡
Range	18-50	18-50	18-50	
Gender				
Female	24 (66.67%)	20 (55.56%)	44 (61.11%)	0.334†
Male	12 (33.33%)	16 (44.44%)	28 (38.89%)	
Anthropometric parameters	Group I(n=36)	Group II(n=36)	Total	P value
Body mass index(kg/m²)				
18.5 to 24.99 kg/m² {Normal BMI}	24 (66.67%)	27 (75%)	51 (70.83%)	0.437†
25 to 29.99 kg/m² {Overweight}	12 (33.33%)	9 (25%)	21 (29.17%)	
Mean ± SD	23.78 ± 2.33	23.96 ± 2.09	23.87 ± 2.2	0.739‡
Weight(kg)				
Mean ± SD	61.06 ± 5.82	62.19 ± 6.82	61.62 ± 6.32	0.448‡
Height(cm)				
Mean ± SD	161.61 ±7.34	161.08 ± 6.66	161.35 ± 6.97	0.75‡

The distribution of age(years) was comparable between group I and group II. (18-20 years - 5.56% vs 11.11% respectively, 21-30 years - 22.22% vs 16.67% respectively, 31-40 years:- 16.67% vs 22.22% respectively, 41-50 years:- 55.56% vs 50% respectively) (p value=0.79). The mean ± SD of age(years) in group I was 38.42 ± 10.8 and in group, II was 37.86 ± 10.62 with no significant

difference between them. (p value=0.826). The distribution of gender was comparable between group I and group II. (Female:-66.67% vs 55.56% respectively, Male:-33.33% vs 44.44% respectively) (p value=0.334). No significant difference was seen in weight (kg) (p value=0.448), height(cm) (p value=0.75), and body mass index(kg/m²)(p value=0.739) between group I and group II. Mean ± SD of weight (kg), height (cm), body mass index (kg/m²) in group I was 61.06 ± 5.82, 161.61 ± 7.34, 23.78 ± 2.33 respectively and in group II was 62.19 ± 6.82, 161.08 ± 6.66, 23.96 ± 2.09 respectively with no significant difference between them.

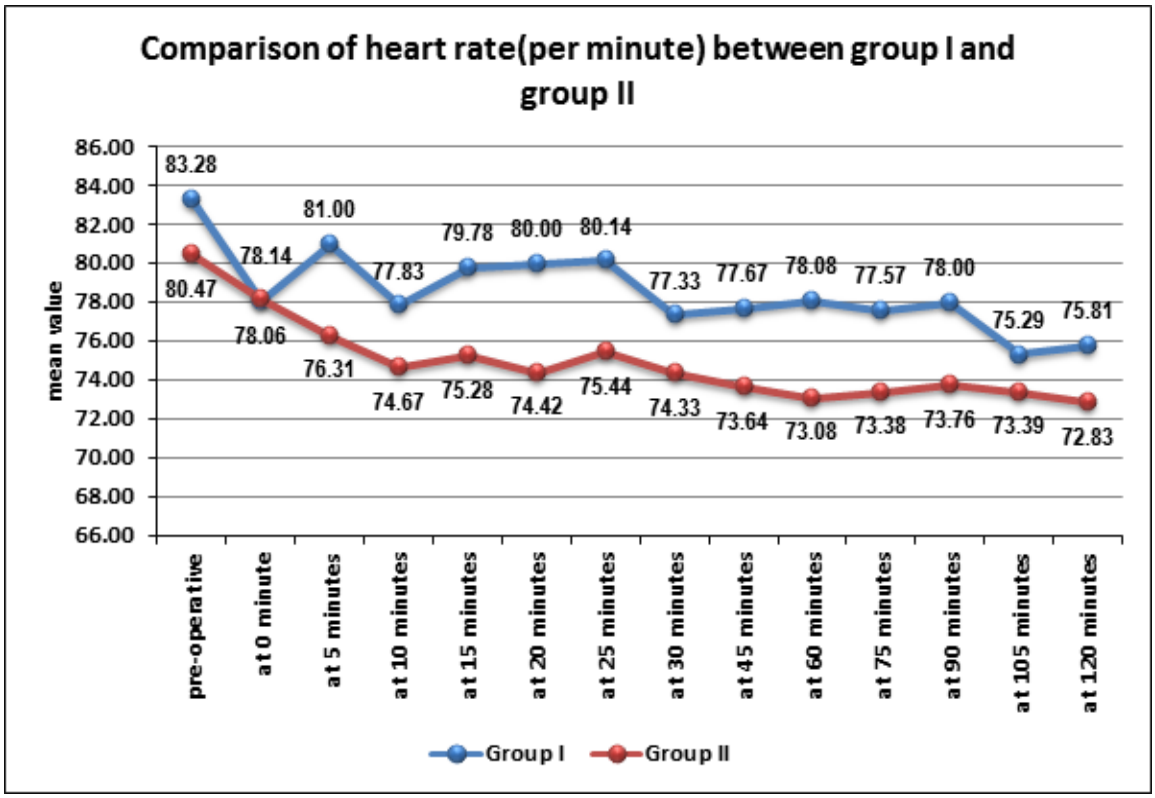

Figure 1: Comparison of heart rate (per minute) between group I and group II

No significant difference was seen in heart rate at pre-operative (p value=0.325), at 0 minute(p value=0.979), 5 minutes(p value=0.126), 10 minutes(p value=0.271), 15 minutes(p value=0.139), 20 minutes(p value=0.077), 25 minutes(p value=0.109), 30 minutes(p value=0.277), 45 minutes(p value=0.176), 60 minutes(p value=0.075), 75 minutes(p value=0.225), 90 minutes(p value=0.24), 105 minutes(p value=0.643),and at 120 minutes(p value=0.483) between group I & group II.

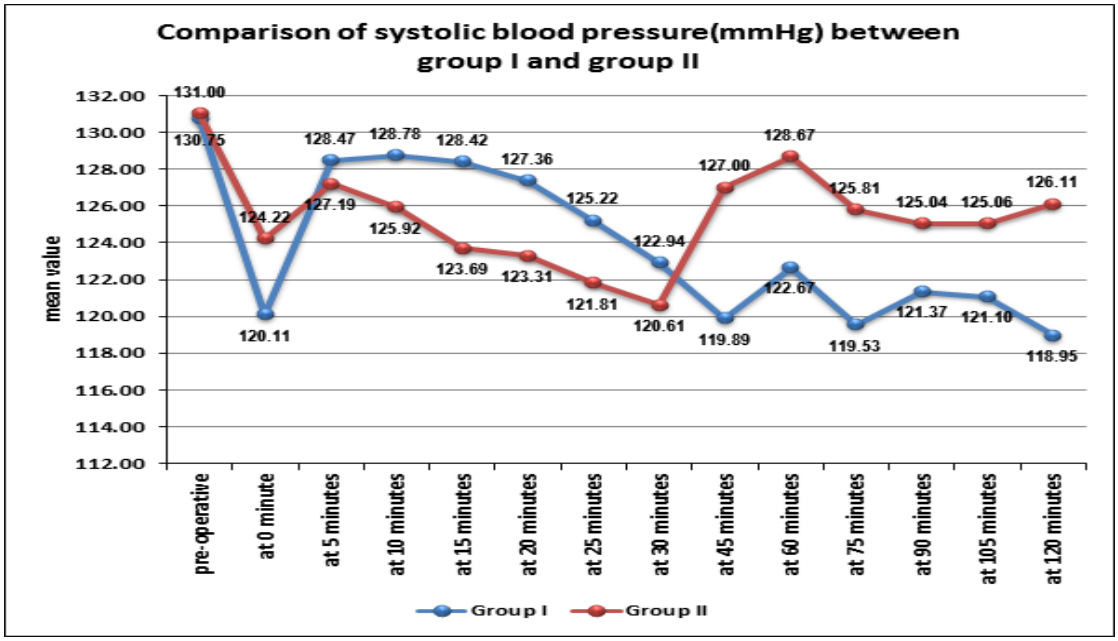

Figure 2: Comparison of systolic blood pressure (mmHg) between group I and group II

No significant difference was seen in systolic blood pressure(mmHg) at pre-operative (p value=0.94), 0 minute(p value=0.319), 5 minutes(p value=0.685), 10 minutes(p value=0.338), 15 minutes(p value=0.126), 20 minutes(p value=0.155), 25 minutes(p value=0.161), 30 minutes(p value=0.402), 75 minutes(p value=0.056), 90 minutes(p value=0.232), 105 minutes(p value=0.368), and at 120 minutes(p value=0.079) between group I and group II.

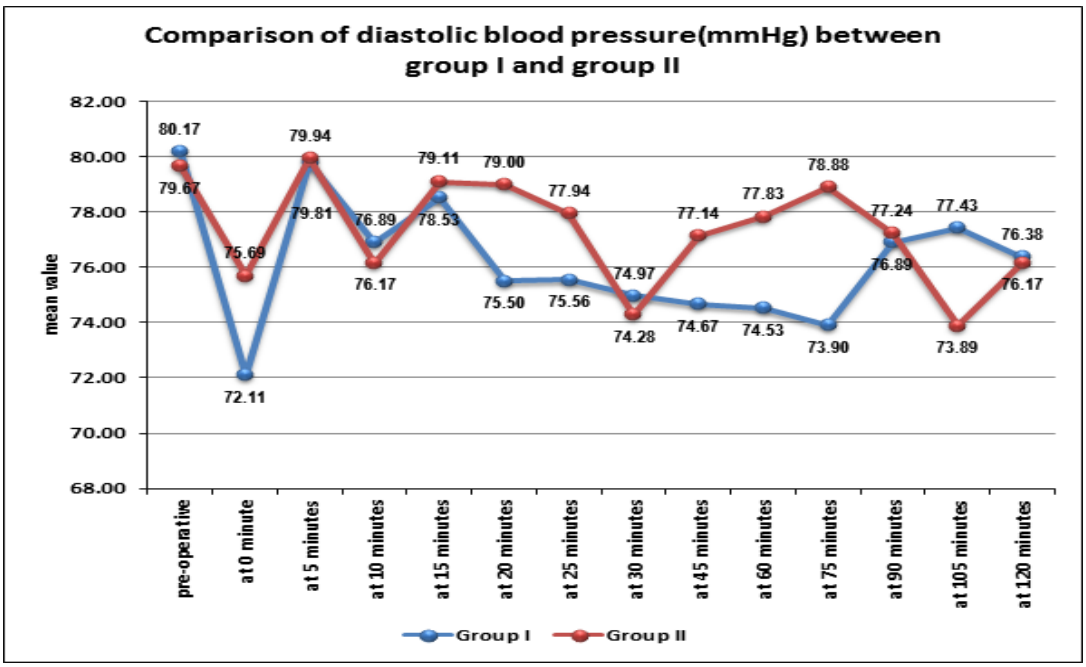

Figure 3: Comparison of diastolic blood pressure (mmHg) between group I and group II

No significant difference was seen in diastolic blood pressure(mmHg) at pre-operative (p value=0.785), at 0 minute(p value=0.116), at 5 minutes(p value=0.954), at 10 minutes(p value=0.76), at 15 minutes(p value=0.807), at 20 minutes(p value=0.139), at 25 minutes(p

value=0.276), at 30 minutes(p value=0.774), at 45 minutes(p value=0.257), at 60 minutes(p value=0.122), at 90 minutes(p value=0.886), at 105 minutes(p value=0.167), at 120 minutes(p value=0.934) between group I and group II.

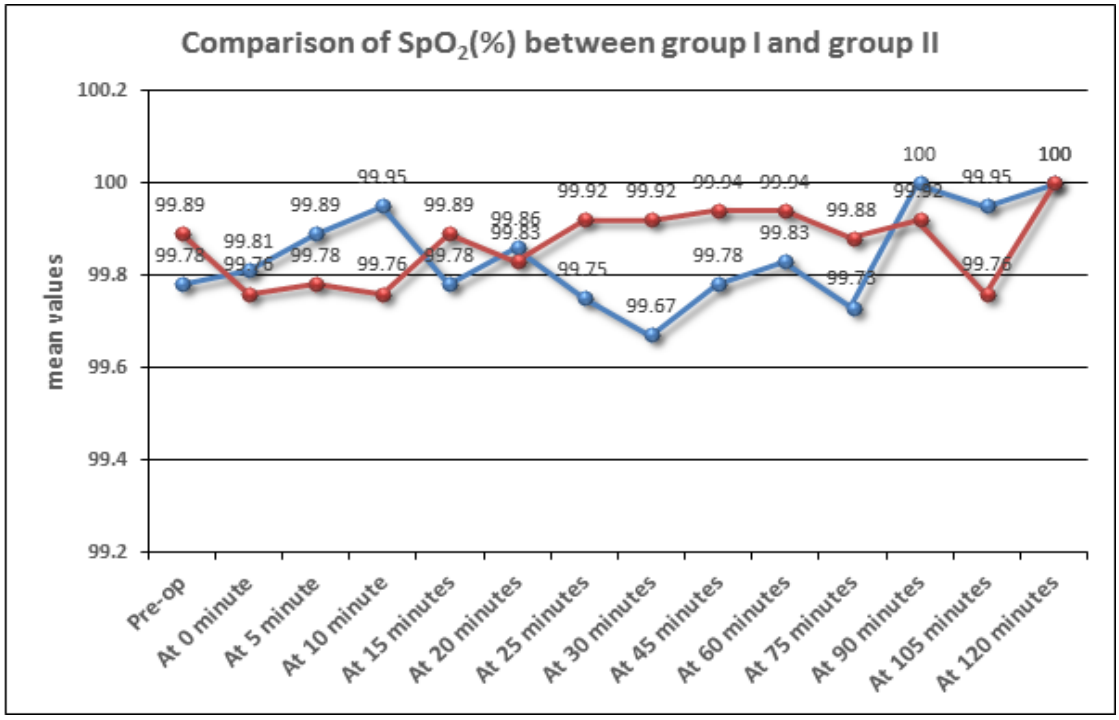

Figure 4: Comparison of SpO2 (%) between group I and group I

No significant difference was seen in SpO2(%) at 0 minutes(p value=0.354), 5 minutes (p value=0.378), at 15 minutes(p value=0.354), at 20 minutes(p value=0.813), at 25 minutes(p value=0.139), at 30 minutes(p value=0.058), at 45 minutes(p value=0.069), at 60 minutes(p value=0.276), at 75 minutes(p value=0.305), at 90 minutes(p value=0.162), at 105 minutes(p value=0.128), at 120 minutes(p value=1) between group I and group II.

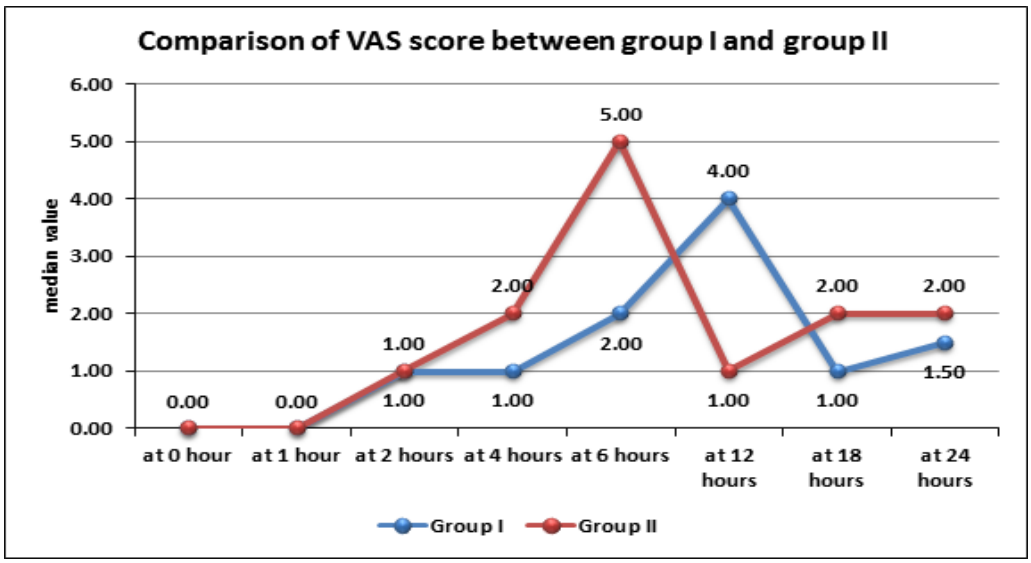

Figure 5: Comparison of VAS score between group I and group II

No significant difference was seen in VAS score at 0 hours (p value=0.852), at 1 hour(p value=0.405), at 2 hours(p value=0.755), at 24 hours(p value=0.107) between group I and group II. Median(25th-75th percentile) VAS score at 0 hours, at 1 hour, at 2 hours, and at 24 hours in group I was 0(0-1), 0(0-1), 1(0-1), 1.5(1-2.25) respectively and in group II was 0(0-1), 0(0-1), 1(0-1), 2(1-4) respectively with no significant difference between them.

Table 3: Comparison of total analgesic consumption (mg) between group I and group II

Total analgesic consumption(mg)	Group I(n=36)	Group II (n=36)	Total	P value
Mean ± SD	116.67 ± 37.8	161.11 ± 59.89	138.89 ± 54.53	0.0004‡
Median (25th-75th percentile)	100(100-100)	200(100-200)	100(100-200)	
Range	100-200	100-300	100-300	

The mean ± SD of total analgesic consumption(mg) in group II was 161.11 ± 59.89 which was significantly higher as compared to group I (116.67 ± 37.8).(p value=0.0004).

Discussion

The International Association for the Study of Pain defines [9] pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage". It is both a physiological sensation and an emotional response to a stimulus. Postoperative pain is a form of acute pain which is caused by surgical trauma associated with an inflammatory reaction and initiation of an afferent neuronal barrage and release of neuropathic mediators.

The result of this study demonstrated that there was no statistically significant difference in age, sex or anthropometric measurements of the patients, complications and duration of surgery. The intraoperative hemodynamics were assessed and no statistically significant difference was found in heart rate in the group of lignocaine and paracetamol. The systolic blood pressure at 45 minutes and 60 minutes was significantly higher in group I than in group II. The diastolic blood pressure at 75 minutes in group II was significantly higher than that of group I. The mean arterial pressure also showed a significant difference at 45 minutes, 60 minutes and 75 minutes (p-value <.05) between the lignocaine and paracetamol groups. Although there was better hemodynamic control in this study in the lignocaine group, it did not demonstrate any statistically significant difference in the groups. Previous study by BK Baral, BK Bhattarai, TR Rahman et al [10] have shown that intravenous lignocaine infusion attenuates the hemodynamic response associated with laryngoscopy and overall hemodynamic control.

Koshyari HS et al [11] showed that infusion of lignocaine leads to a decrease in blood pressure from baseline after induction of anaesthesia with a fixed dose of propofol. Lignocaine infusion is associated with hemodynamic stability. It has a direct myocardial depressant effect, a peripheral vasodilating effect, and an effect on synaptic transmission and depth of anaesthesia thereby preventing swings in HR and blood pressure. [12] Ali Q [13] in their study on the use of intravenous lignocaine in laparoscopic cholecystectomy found that MAP and HR were significantly lower in lignocaine group compared with placebo after intubation and pneumoperitoneum.

The pain score analysed in this study was measured using the visual analogue scale.

The study showed that VAS scores in the paracetamol group were significantly higher at 4 hours, 6 hours and 18 hours than in the lignocaine group. In the study by BK Baral, BK Bhattarai, TR Rahman et al10 overall mean VAS scores both at rest and on movement were less in the lidocaine group than in the normal saline group. The mean pain VAS scores in the lidocaine group remained significantly less than that in the normal saline group until 30 mins, but it was higher thereafter becoming significant at 60 minutes. Hika A et al [14] showed similar results to our study, in that the median pain score was lower in the immediate postoperative period and in 3rd postoperative hour with lignocaine. This similarity between the two studies is likely due to the infusion given starting with a loading dose of lidocaine 1.5mg/kg before induction of anaesthesia and continuing with an infusion of 1mg/kg immediately after induction of anaesthesia.

The time for 1st rescue analgesia was significantly higher in group I as compared to group II. Patients given lignocaine infusion had better and longer postoperative pain relief (5.22 ± 2.09 hours) than paracetamol infusion. These findings are comparable with Song X, Sun Y, Zhang X et al, which showed a longer time for 1st rescue analgesia requirement. It further indicated that intravenous lignocaine infusion attenuated the plasma level of proinflammatory cytokines (IL-6 and IL-8 respectively) following laparoscopic cholecystectomy. Mohammad Shimia et al. [15] conducted a study to assess postoperative pain relief by paracetamol and concluded that it relieved postoperative pain significantly but it did not represent the best regimen for reducing the need for rescue opioid analgesics after surgery. The study done by Hika et al14 showed similar results demonstrating a longer median time to first rescue analgesia in the lignocaine group (180 minutes) as compared to the non-exposed group (45 minutes).

This study also showed that analgesic consumption in group II was significantly higher as compared with group I. (p-value=0.0004) Lignocaine infusion has been known to decrease opioid requirement in the postoperative period. Koppert W, Weigand M, and Neumann F16 also demonstrated the preventive effects of perioperative intravenous lidocaine infusion on postoperative pain and reduced analgesic consumption after major abdominal surgery. But unlike in our study, they observed lower postoperative pain ratings in the lidocaine infusion group compared to control only during movement (such as deep inspiration and coughing) and not at rest. Studies like Mohammad Shimia et al [16] suggested that although paracetamol decreased postoperative pain significantly, it wasn't the best regimen to decrease the requirement of rescue opioid analgesics postoperatively. [17]

Conclusion

According to this research and a range of other studies it is appropriate and better to use lignocaine infusion in patients for postoperative pain control than paracetamol. Intra-operative hemodynamic control is comparable in the lignocaine and paracetamol group. Lignocaine demonstrated better postoperative analgesia and a lesser postoperative analgesic requirement in comparison to paracetamol. The time for first rescue postoperative analgesia is significantly higher in the lignocaine group as compared to the paracetamol group. The present study demonstrated lignocaine as a superior analgesic drug with context to paracetamol for postoperative pain relief in an exploratory laparotomy.

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