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Research Paper

A Comparison between the Efficacy of Paracetamol Plus Pethidine and Pethidine Alone for Postoperative Analgesia in Laparoscopic Cholecystectomy

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Abstract
Analgesics are the most important medication that should be provided to patients after having any surgical procedure. Analgesics differ in their type, potency, duration of action and side effects. Opioids are one of the most common analgesics used nowadays due to their good effects on reliving moderate to severe pain, but some of them have unpleasant side effects. However, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) or Paracetamol can be used to relieve mild to moderate pain and they have fewer side effects in comparison to Opioid. Thus, the investigators want to find out if using Paracetamol with Pethidine will give better analgesic effects and reduce the side effects.

Introduction

Pain is the most common complaint after laparoscopic cholecystectomy.[1.2] resulting in the use of opioid analgesics in up to 80% patients.[3] In addition, the pattern of pain after laparoscopic cholecystectomy is complex and unlikely to benefit always from identical analgesic treatment.[4]

Paracetamol (acetaminophen; *N*-acetyl-p-aminophenol) is an acetanilide derivative, safe, well-tolerated drug with proven efficacy as analgesic. Its clinical effects arise most likely from central action and intravenous administration provides rapid and predictable therapeutic plasma concentration. Paracetamol was introduced for intravenous administration in a unit-dose form, ready for infusion solution in 2002 (Perfalgan®; 1 g/100 mL).

The valuable analgesic properties of opioids such as Pethidine in the treatment of acute, intense post-operative pain are well recognized.[5]It has been found that routine treatment of opioids at the beginning of operation conferred significantly better pain control than opioids given at the end of surgery.[6] However, to reduce the opioid-related side effects and hasten recovery, drugs such as NSAIDs, paracetamol, COX-2 inhibitors, local anesthetics, steroids etc. are often used for their opioid-sparing action.[7.8]

Hypothesis and Objectives

Principal Research Hypothesis

Giving intravenous Paracetamol with intramuscular Pethidine will produce better postoperative pain relief instead of giving Intramuscular Pethidine alone for patients undergoing Laparoscopic cholecystectomy.

Principal Research Objective

The study wanted to show if there is usefulness of giving intravenous Paracetamol with intramuscular Pethidine in reliving the postoperative pain for the patients undergoing Laparoscopic Cholecystectomy.

Secondary Research Hypothesis

Giving intravenous Paracetamol with intramuscular Pethidine will decrease the incidence of Bradycardia, Hypotension, and Post-operative Nausea and Vomiting (PONV).

Secondary Research Objective

The study wanted to show if giving intravenous Paracetamol with intramuscular Pethidine can decrease the Pethidine related side effects (Bradycardia, Hypotension, and PONV)

Methodology

1- Sampling Method:

The samples were randomly divided into two groups. One group who had received intravenous Paracetamol and intramuscular Pethidine (Pp group), and the other who had received intramuscular Pethidine alone (P group) according to the following samples inclusion and exclusion criteria:

Inclusion Criteria

1. Female and Male patients within the group age of (15-75)
2. Patients' Physical Status (ASA) of I or II.

Exclusion Criteria

1. Patients who are allergic to NSAIDs or Paracetamol.
2. Patients who are on treatment by Opioids before the surgery.

2- Study Area

The study is applied in King Fahad Military Medical Complex and The Armed Forces Hospital in King Abdulaziz Airbase, Eastern province. Kingdom of Saudi Arabia.

3- Sample Size

28 patients randomly divided into two groups. "Pp" group contained 16 patients and "P" group contained 12 Patients.

4- Research Design

Experimental Study.

5-Methods of Data Collection

The Method was by checking and recording the Visual Analog Scale (VAS) for the samples in the following time intervals:

1 hour ,2 hours ,4 hours ,6 hours ,8 hours ,12 hours , and 24 hours postoperatively. The heart rate (by using Pulse Oximeter), non-invasive blood pressure (by using electronic sphygmomanometer), and the presence of PONV was recorded as (Yes-No question) at the same previous time intervals. Surgery duration was also recorded. The data was collected by the investigators and the nurses of the surgical ward who are not participating in the study.

6-Ethical consideration

The study was approved by the ethical committee of anesthesia department in PSMCHS, Airbase Hospital and KFMMC. All participants were assured that all personal information concerning their health status will be kept confidential. The participants were included in this study informed about the objectives and the need of this study, and they had the right to ask any questions or withdraw from the study. Written consent was obtained.

7- Statistical Methodology

The collected and presented data will be analyzed by using the following method:

The distribution of the all-qualitative variables (i.e., close ended) values of samples will be examined with frequency tables even for other demographic variables among samples. The comparison tables will also be calculated to find the association wherever necessary for comparing the qualitative variables by using chi square test. The quantitative variables will be analyzed by using Tow way classification of Repeated-Measures Analysis of Variance (ANOVA) to find the significant difference between the two treatment groups with repeated measures in different scheduled timings. A P value of ≤0.05 will be considered for statistical significance.

Results

Both groups* were similar in regard to age, weight, sex, ASA physical status and duration of surgery. **(See Figures 1, 2, 3, 4 and 5)**

*Paracetamol plus Pethidine = Pp Group Pethidine = P Group.

Figure 1: ASA Classification for both groups:

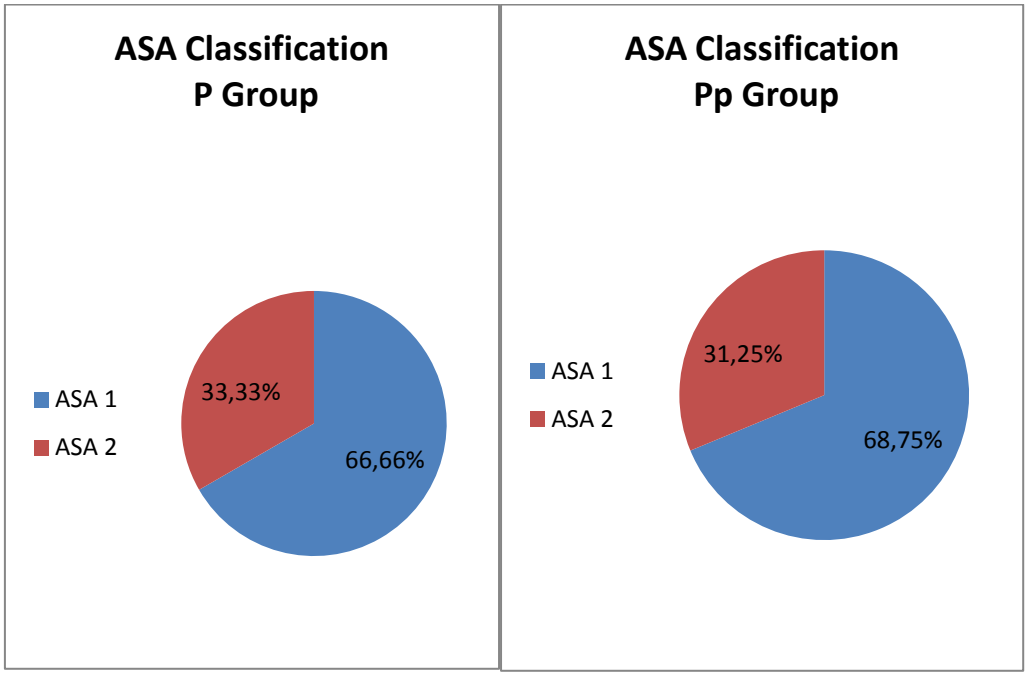


Figure 2: Age average for the both groups:

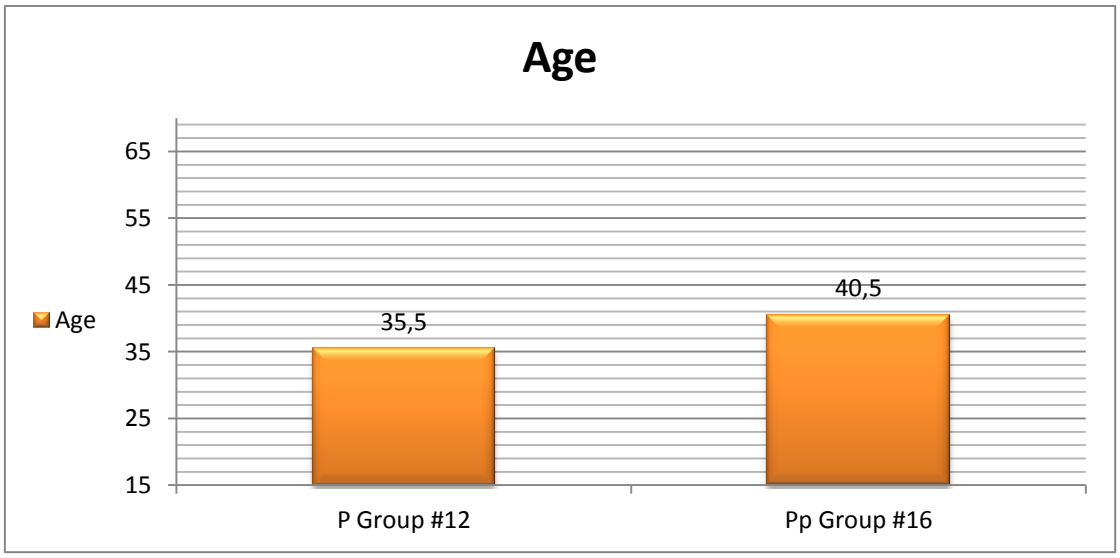


Figure 3: Weight average in both groups:

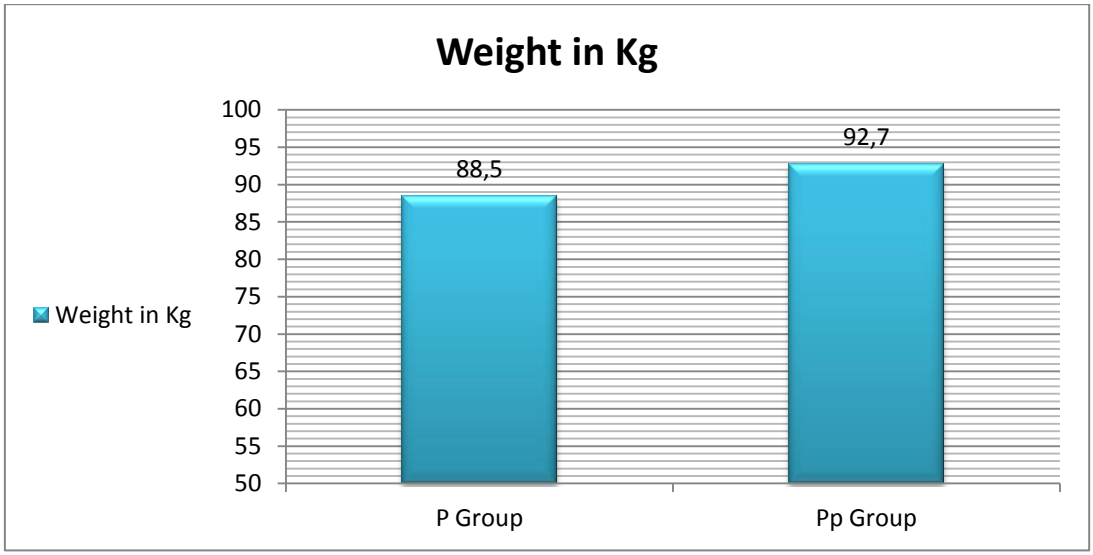


Figure4: The percentages of the female patients to male patients in both groups:

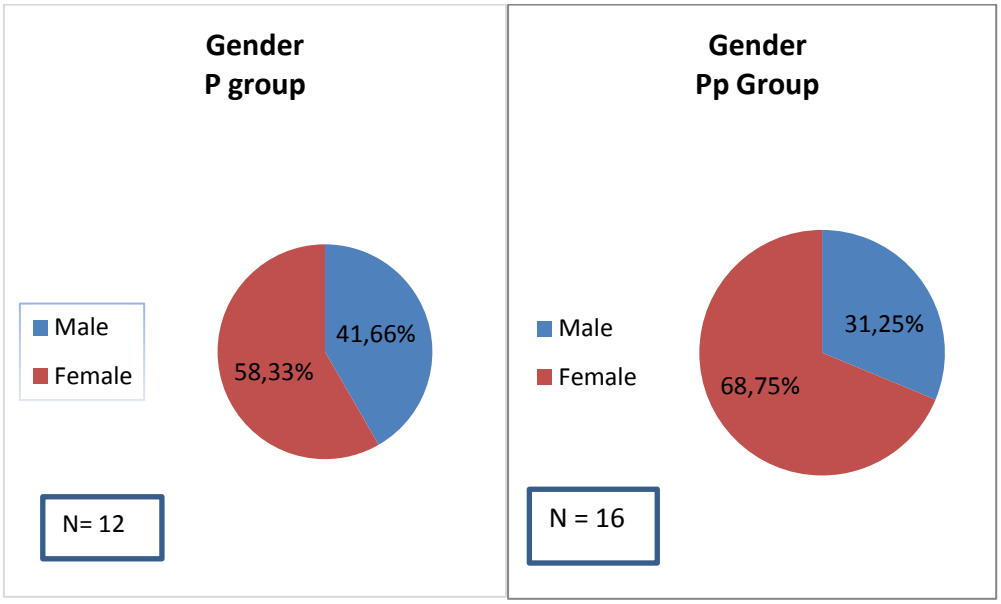
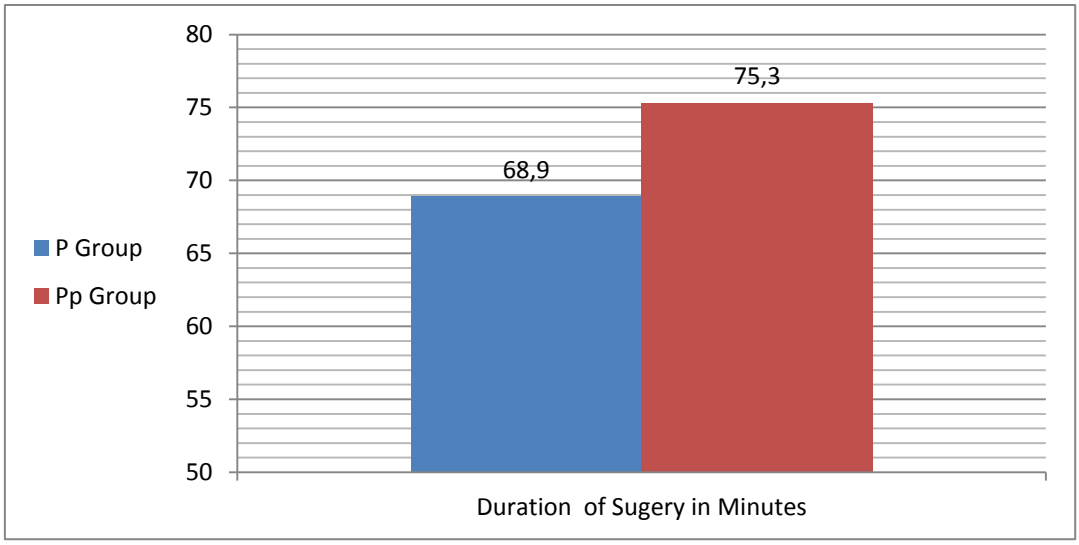


Figure 5: The average of the duration of surgery in both groups:

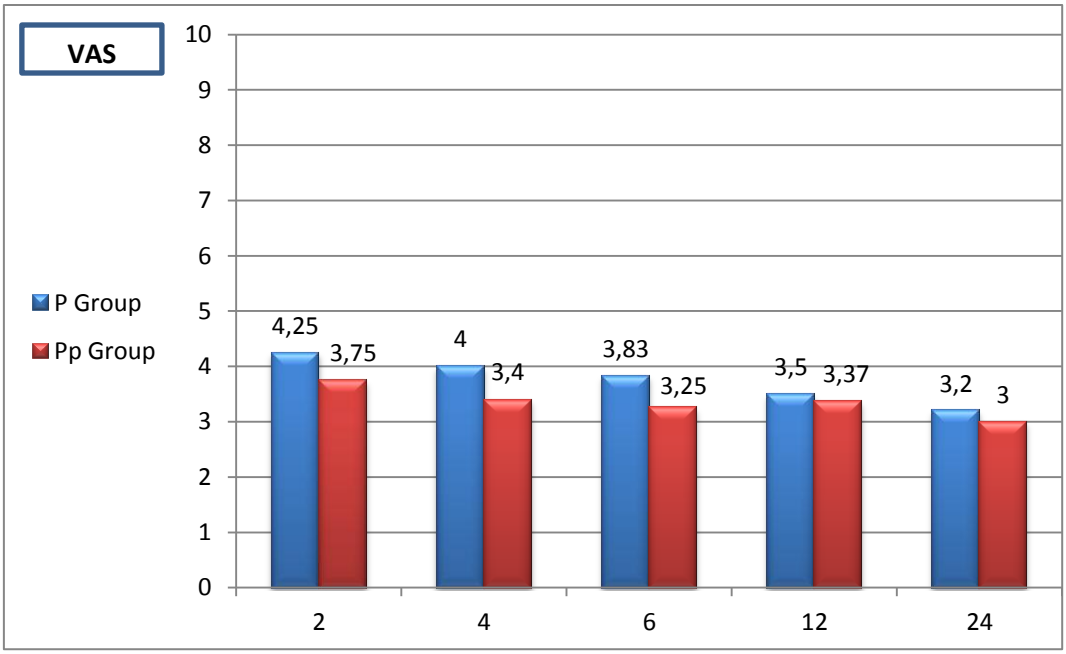


The mean VAS pain score over the 24-h period was similar in both groups**; (Table 1)**However, the mean VAS score at 2, 4 and 6 Hours after surgery was lower in the Pp Group. **(See Figure 6)**

Table 1: Mean VAS pain score in 24 Hours

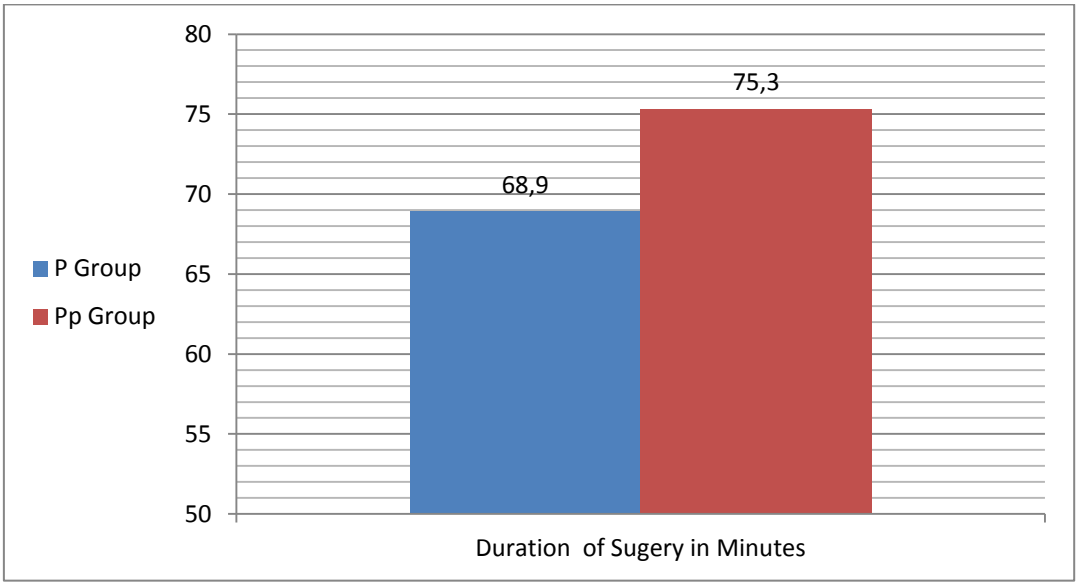
Group	Mean VAS (24 Hours)
P Group	**3.75**
Pp Group	**3.34**

Figure 6: The average of VAS pain score in different time intervals post-operatively in both groups.

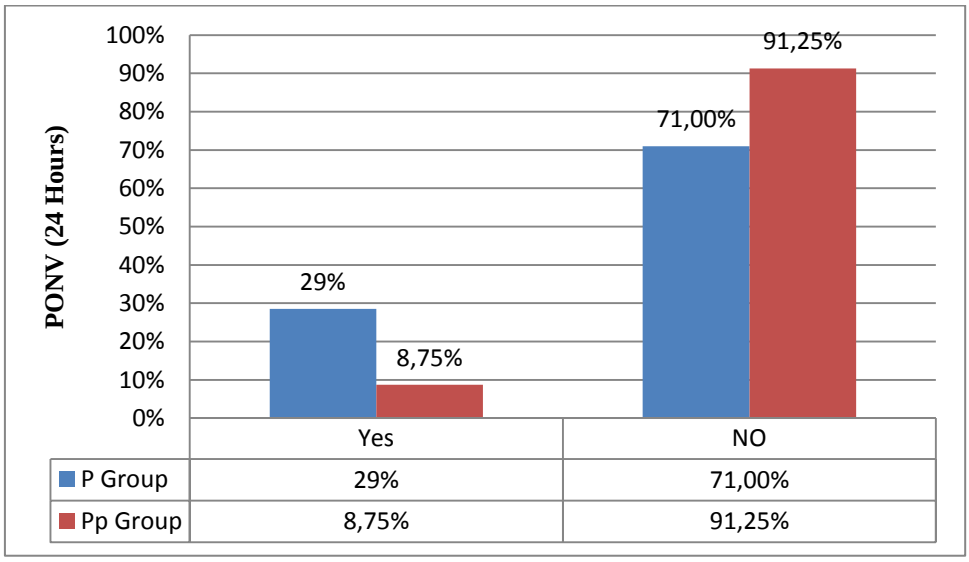


There was no significant difference in the duration of surgery in both groups.
(See figure 7)

Figure 7 Duration of Surgery in Both Groups:



The percentage of the patients who experienced PONV was less in Pp group. However, the patients in both groups had ONLY nausea without vomiting. (See Figure 8)



There were no significant differences in theheart rate and blood pressure values in both groups. However, heart rate and blood pressure were slightly less in P group.

(See Figure 9, Table 2)

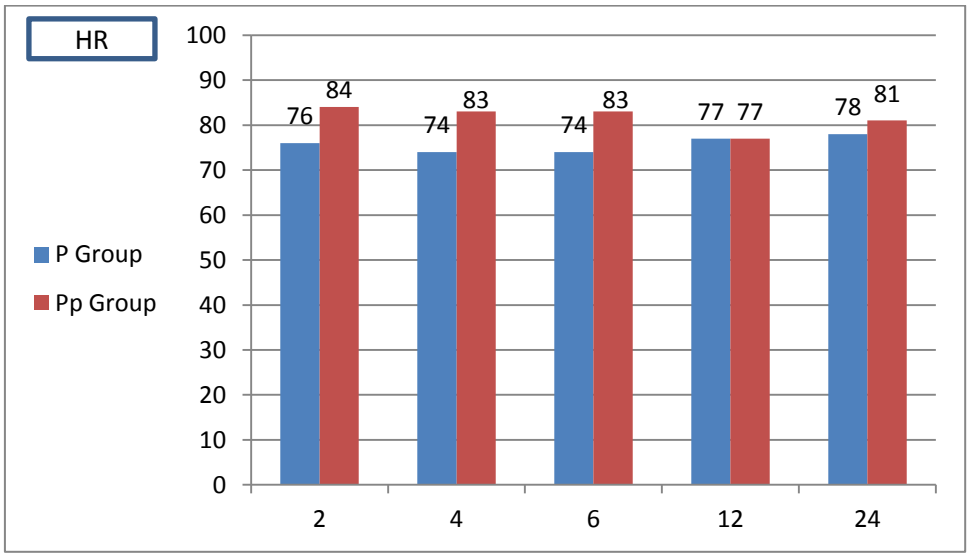


Table shows the average of the blood pressure for the both groups		
Hours:	**P Group**	**Pp Group**
2	112/66	124/74
4	115/69	123/72
6	112/68	120/72
12	115/69	119/70
24	117/70	120/69

Discussion

Poor pain control during the perioperative period leads to complications in both long- and short-term periods. Among these complications, pneumonia, deep vein thrombosis, pulmonary embolism, psychological trauma etc. can be severe. With a good analgesic treatment plan, the anxiety, morbidity, cost and length of hospital stay in the postoperative period are decreased. The complex nature of pain after laparoscopic cholecystectomy suggests that effective analgesic treatment should be multimodal.[9,10]

In a study conducted in 2010 by Memis and colleagues, they reviewed the effect of intravenous Paracetamol in reducing opioid consumption, time of extubation, and opioid side effects in intubated patients admitted to the ICU. Ultimately, they concluded that intravenous Paracetamol reduces opioid consumption, the extubation time, and opioid side effects, such as nausea, vomiting, and itching.[13]

In our study, we used intramuscular Pethidine 50-75 mg with/withoutintravenous paracetamol 1 gmin different groups as post-operative analgesic in laparoscopic cholecystectomy. We assessed the effects of adding paracetamol to pethidine on post-operative analgesia in comparison with pethidine alone regarding pain scores, heart rates, blood pressure and the incidents of PONV.

Our study showed that using intravenous paracetamol as post-op analgesic with the use of pethidine as a part of multimodal analgesic regime has good opioid sparing effect. This is consistent with the findings in various studies where opioid-sparing effects of NSAIDs, COX-2 inhibitors, and paracetamol have been found to be in the range of 20–30%.[11,12]

However, our study had a couple of limitations. First, there was time shortage which reduced the number of the sample size which was proposed. Second, we faced a lot of patients who refused to take a part in the study. Both of these could have improved the results of our study but owing to the short time we had and limited areas of study it was not possible.

Conclusion

Our study is the first such study conducted in Saudi Arabia population. It demonstrates the usefulness of intravenous paracetamol as an addition to Pethidine for the postoperative pain after laparoscopic cholecystectomy. Intravenous paracetamol use is associated with a satisfactory analgesia and smaller opioid consumption. This may be beneficial in the management of pain after laparoscopic cholecystectomy in patients prone to opioid-related complications.

Financial Disclosure

The authors declare they have no financial disclosure.

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