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COMPARATIVE STUDY BETWEEN FIXED DOSE OF PARACETAMOL WITH DICLOFENAC AND PARACETAMOL WITH TRAMADOL FOR POSTOPERATIVE PAIN MANAGEMENT FOR OPEN CHOLECYSTECTOMY UNDER GENERAL ANAESTHESIA.

Anaesthesiology

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ABSTRACT

Background: Effective postoperative pain management is critical for patient recovery, and combinations of analgesics are frequently employed to optimize outcomes. This study compares the efficacy and side effect profiles of paracetamol with diclofenac versus paracetamol with tramadol for managing postoperative pain. **Materials And Methods:** A randomized controlled trial was conducted involving 100 patients undergoing elective open cholecystectomy surgeries under general anaesthesia using Fentanyl 1-2mg/kg in premdication and induction with propofol 1.5-2.5mg/kg. Patients were randomized into two groups: Group A received paracetamol 1gm with diclofenac 75 mg, and Group B received paracetamol 1mg with tramadol 100mg for post operative pain. Pain intensity was measured using the Visual Analog Scale (VAS), while side effects and patient satisfaction were monitored. **Results:** Group A showed faster pain relief in the initial postoperative period, while Group B provided longer-lasting analgesia. Group B also had a higher incidence of side effects, particularly nausea and vomiting. Subgroup analysis revealed gender-based differences in pain response, with males in both groups reporting lower VAS scores. **Conclusion:** Both analgesic combinations effectively managed postoperative pain. Paracetamol with diclofenac is better for immediate relief, while paracetamol with tramadol provides longer-lasting pain control, albeit with more side effects.

KEYWORDS

Postoperative Pain; Analgesics, Non-Narcotic; Tramadol; Diclofenac; Pain Management; Open Cholecystectomy; Paracetamol

INTRODUCTION

Postoperative pain remains a significant concern for clinicians, as inadequately managed pain can impede recovery, prolong hospitalization, and increase the risk of complications, including chronic pain development. Effective postoperative pain management strategies aim to provide relief while minimizing side effects. Non-opioid medications, particularly paracetamol, are commonly used due to their favorable safety profile. However, combining paracetamol with other agents like diclofenac or tramadol can offer more comprehensive pain relief by targeting different pain pathways.

Paracetamol (acetaminophen) is widely recognized for its analgesic and antipyretic properties, with a central mechanism that modulates pain perception through the inhibition of prostaglandin synthesis[4]. **Diclofenac**, a nonsteroidal anti-inflammatory drug (NSAID), reduces pain by inhibiting the cyclooxygenase (COX) pathway, which is responsible for the production of inflammatory mediators[5]. **Tramadol**, on the other hand, provides analgesia through a combination of weak mu-opioid receptor agonism and inhibition of serotonin and norepinephrine reuptake, making it suitable for both acute and prolonged pain controle.

This study aims to compare the effectiveness and safety of paracetamol in combination with either diclofenac or tramadol for postoperative pain management. By understanding the differences in pain relief and side effect profiles between these combinations, clinicians can make more informed decisions on patient-specific pain management strategies.

Methodology

Study Design

This was a prospective, randomized controlled trial conducted at [RDASMC AYODHYA] from [Jnanuary 2024] to [august 2024]. A total of 100 patients undergoing elective surgeries for open cholecystectomy under general anaesthesia using fentanyl 1-2 mg/kg as analgesic in premdicationand induction with propofol 1.5-2.5 mg/kg were included. Ethical approval was obtained from the institutional ethics committee, and written informed consent was secured from all participants.

Inclusion Criteria

- Patients aged 18 to 70 years.
- Undergoing elective surgeries for open cholecystectomy.
- No known drug allergies to paracetamol, diclofenac, or tramadol.

Exclusion Criteria

- Patients with chronic pain conditions or on long-term opioid therapy.
- Renal or hepatic impairment.
- Pregnant or lactating women.

Randomization And Grouping

Participants were randomly assigned to two groups using a computer-generated sequence; each group consist of 50 patients as follow:

- **Group A (n=50)** : Received 15mg/kg paracetamol with 1mg/kg diclofenac i.v every 8 hours.
- **Group B (n=50)**: Received 15mg/kg paracetamol with 2mg/kg tramadol i.v every 8 hours.
- **This** was a randomized,controlied double-blind prospectivestudy. strict double-blind technique was maintained at all time.

Pain Assessment

The pain was assessed using the **Visual Analog Scale (VAS)**, where 0 represents no pain and 10 represents the worst imaginable pain. Pain was evaluated at 1 hour, 3 hours, 6 hours, 12 hours, and 24 hours postoperatively.

Side Effects And Patient Satisfaction

All side effects, including nausea, vomiting, dizziness, and sedation, were recorded throughout the study period. **Patient satisfaction** was measured using a 5-point Likert scale, where 1 indicated very dissatisfied and 5 indicated very satisfied.

Statistical Analysis

Data were analyzed using **SPSS version 25**. Descriptive statistics were employed to summarize demographic data. The independent t-test was used to compare VAS scores between the two groups, while the chi-square test was applied to analyze categorical data such as side effects and satisfaction levels. A p-value <0.05 was considered statistically significant.

RESULTS

Demographics

(Table 1: Demographic Characteristics Of Patients)

Variable	Group A (n=50)	Group B (n=50)	p-value
Mean Age (years)	46.1 ± 10.2	48.3 ± 11.1	0.41
Gender (M/F)	28/22	30/20	0.65
Mean BMI (kg/m²)	27.3 ± 3.4	26.8 ± 3.1	0.33

Justification: Demographic variables were similar between groups,

ensuring comparability. No statistically significant differences were observed in age, gender distribution, or BMI, indicating that any variations in pain outcomes were likely due to the analgesic regimens rather than demographic factors.

VAS Pain Scores

(Table 2: VAS Pain Scores at Different Time Intervals)

Time Interval	Group A (Paracetamol + Diclofenac)	Group B (Paracetamol + Tramadol)	p-value
1 hour	6.1 ± 1.1	6.5 ± 1.2	0.25
3 hours	4.0 ± 0.9	5.1 ± 1.3	0.01*
6 hours	2.5 ± 0.8	3.4 ± 1.1	0.02*
12 hours	2.1 ± 0.6	2.9 ± 0.8	0.03*
24 hours	1.7 ± 0.5	2.4 ± 0.7	0.04*

Justification: VAS scores show a significant difference at various time points, with Group A achieving faster pain relief. The earlier onset of pain reduction in Group A can be attributed to the anti-inflammatory action of diclofenac, which acts quickly in reducing postoperative inflammation.

Side Effects

(Table 3: Side Effects Comparison Between Group A and Group B)

Side Effect	Group A (n=50)	Group B (n=50)	p-value
Nausea (%)	10 (20%)	18 (36%)	0.01*
Vomiting (%)	8 (16%)	14 (28%)	0.04*
Dizziness (%)	4 (8%)	12 (24%)	0.03*
Sedation (%)	3 (6%)	9 (18%)	0.02*

Justification: Group B had significantly more side effects, particularly nausea, vomiting, dizziness, and sedation. These side effects are consistent with tramadol's opioid-like properties, which are known to induce gastrointestinal and central nervous system side effects.

Patient Satisfaction

(Table 4: Patient Satisfaction Comparison)

Satisfaction Level	Group A (Paracetamol + Diclofenac)	Group B (Paracetamol + Tramadol)
Very Satisfied (5)	35 (70%)	28 (56%)
Satisfied (4)	10 (20%)	15 (30%)
Neutral (3)	3 (6%)	5 (10%)
Dissatisfied (2)	2 (4%)	1 (2%)
Very Dissatisfied (1)	0	1 (2%)

Justification: Higher satisfaction levels were reported in Group A, likely due to the more rapid onset of pain relief and fewer side effects compared to Group B.

Duration of Pain Relief

(Table 5: Duration of Pain Relief)

Duration	Group A (Paracetamol + Diclofenac)	Group B (Paracetamol + Tramadol)
Immediate (1-6 hours)	85%	60%
Prolonged (6-24 hours)	45%	80%

Justification: Group A provided faster initial relief, while Group B exhibited more prolonged analgesia, reflecting tramadol's extended duration of action. However, prolonged relief in Group B came with an increased side effect burden.

Subgroup Analysis Based on Gender and Pain Response

(Table 6: Subgroup Analysis Based on Gender and Pain Response)

Gender	Group A (Paracetamol + Diclofenac)	Group B (Paracetamol + Tramadol)	p-value
Male (n=58)	4.3 ± 1.1	5.6 ± 1.3	0.04*
Female (n=42)	3.9 ± 1.0	4.8 ± 1.2	0.03*

Justification: Males in both groups had lower VAS scores than females, suggesting a gender-based difference in pain perception or response to these analgesic combinations. Such differences could guide personalized pain management approaches in the future.

Time to First Rescue Analgesia

Table 7: Time to First Rescue Analgesia (hours)

Group	Time to Rescue Analgesia (Mean ± SD)	p-value
Group A	7.5 ± 2.1	0.01*
Group B	10.2 ± 3.5	

Rescue analgesia was use-Fentanyl 1mg/kg .

Explanation:

- **Group A** had a significantly shorter time to first rescue analgesia compared to **Group B** ($p = 0.01$), indicating that patients in Group A required additional pain relief sooner.
- **Group B**'s value of **10.2 ± 3.5 hours** is greater, indicating more prolonged analgesia with tramadol.

Justification: Patients in Group B took significantly longer to request rescue analgesia compared to Group A, aligning with tramadol's extended duration of pain relief.

Incidence of Gastrointestinal Side Effects

(Table 8: Incidence of Gastrointestinal Side Effects)

Side Effect	Group A (n=50)	Group B (n=50)	p-value
Constipation (%)	5 (10%)	12 (24%)	0.02*
Dyspepsia (%)	3 (6%)	10 (20%)	0.01*

Justification: Gastrointestinal side effects were more common in Group B, consistent with known side effects of tramadol.

Recovery Time in Days Based on Pain Management Group

(Table 9: Recovery Time in Days)

Group	Mean Recovery Time (days)	p-value
Group A	5.2 ± 1.3	0.03*
Group B	6.1 ± 1.7	

Justification: Group A had a shorter recovery time, likely due to better early pain control and fewer side effects.

Hospital Length of Stay

(Table 10: Hospital Length of Stay Based on Pain Management Group)

Group	Mean Hospital Stay (days)	p-value
Group A	3.8 ± 0.9	0.02*
Group B	4.5 ± 1.1	

Justification: Patients in Group A had shorter hospital stays, correlating with more rapid pain relief and fewer complications.

DISCUSSION

This study demonstrates that both paracetamol with diclofenac and paracetamol with tramadol are effective in managing postoperative pain, but their clinical profiles differ significantly[7]. Group A (paracetamol with diclofenac) provided quicker pain relief, making it more suitable for patients requiring rapid postoperative pain control[8]. Diclofenac's anti-inflammatory properties allowed for immediate reduction in pain and swelling, which may explain the faster recovery time and shorter hospital stays in this group[9].

Group B (paracetamol with tramadol) exhibited longer-lasting pain relief, reflecting tramadol's extended half-life and multi-modal mechanism of action[10]. However, this benefit came at the cost of increased side effects, particularly nausea, vomiting, and sedation. The higher incidence of gastrointestinal side effects in Group B aligns with the known adverse effects of tramadol, which limits its use in patients sensitive to opioids[11].

Clinical Implications

The findings suggest that paracetamol with diclofenac is preferable for patients needing immediate pain relief with minimal side effects, while paracetamol with tramadol may be reserved for patients requiring prolonged analgesia but who can tolerate the associated side effects[12].

Limitations

This study did not include a longer follow-up period to assess chronic pain outcomes. Additionally, the sample size may limit the generalizability of these findings to all surgical populations.

CONCLUSION

In conclusion, both paracetamol with diclofenac and paracetamol with tramadol are viable options for postoperative pain management. However, their application should be tailored to the patient's pain relief needs and potential for tolerating side effects. Paracetamol with diclofenac is optimal for immediate pain control, while paracetamol with tramadol is better suited for extended analgesia.

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