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EVALUATING SAFETY AND PAIN CONTROL: INTRAVENOUS PARACETAMOL VS. PENTAZOCINE IN ABDOMINAL SURGICAL PROCEDURES

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Abstract

Background: Postoperative pain management is necessary for patient recovery after abdominal surgery. The study aimed to compare the efficacy and safety of intravenous paracetamol and pentazocine for postoperative pain control in adults undergoing abdominal surgery.

Methods: A total of 80 patients undergoing surgery at Department of Surgery, Varun Arjun Medical College & Rohilkhand Hospital were randomly allocated into two groups: Group A (n=40) received intravenous paracetamol, and Group B (n=40) received pentazocine. Visual Analog Scale (VAS) scores for pain, adverse events, and the need for rescue analgesia were evaluated.

Results: Group A reported significantly lower VAS scores at most time points except at 12 hours. Respiratory depression was significantly lower in Group A (p=0.045). The need for rescue analgesia was lower in Group A but was not statistically significant (p=0.059).

Conclusion: Intravenous paracetamol is more effective and safer than pentazocine for postoperative pain management in adult abdominal surgeries. Further studies are warranted to confirm these findings.

Keywords: Postoperative Pain Management, Abdominal Surgery, Visual Analog Scale, Adverse Events, Rescue Analgesia.

INTRODUCTION

Pain management following surgery is paramount in patient comfort and rapid recovery. Effective postoperative pain management is not only humane but also minimizes postoperative complications and shortens the duration of hospital stays. In abdominal surgery, adequate postoperative pain control is crucial, considering the possible pain intensity resulting from incisions, manipulation of intra-abdominal structures, and postoperative gastrointestinal functioning.²

Paracetamol (acetaminophen) is a commonly used analgesic and antipyretic agent. Its mechanism of action involves inhibiting prostaglandin synthesis in the brain.³ Administered intravenously, paracetamol provides rapid and consistent therapeutic levels in plasma, making it a valuable option for postoperative pain management.⁴ Studies have shown that intravenous paracetamol effectively reduces postoperative pain and opioid consumption in various surgical procedures.⁵

On the other hand, pentazocine, a synthetic opioid analgesic, acts as an agonist at kappa opioid receptors and a weak antagonist at mu opioid receptors.⁶ It is commonly employed in postoperative pain management and is known for its analgesic potency. Like other opioids, pentazocine offers powerful pain relief but is also associated with various side effects, such as respiratory depression, sedation, nausea, vomiting, and the potential for abuse or addiction.⁷

Although intravenous paracetamol and pentazocine have been individually assessed for their efficacy in postoperative pain management in various surgical contexts, direct comparisons between the two in adult abdominal surgery remain sparse. Understanding the relative efficacy, safety profiles, and patient satisfaction related to these agents in abdominal surgery can inform surgical practice and enhance patient care.

An appropriate analgesic for postoperative pain management hinges on balancing efficacy and side effect profile. While opioids like pentazocine have been a mainstay for moderate to severe pain control, concerns about side effects and the ongoing opioid crisis, have driven a search for alternative non-opioid analgesic agents.⁸ Intravenous paracetamol presents an attractive option because of its non-opioid nature and favourable side effect profile.

Moreover, the economic implications of postoperative pain management cannot be overlooked. Pain management costs include the direct costs of analgesics and the indirect costs related to extended hospital stays due to inadequate pain control, complications resulting from analgesics, and patient dissatisfaction. A comparative assessment of intravenous paracetamol and pentazocine regarding clinical outcomes and economic impact can significantly guide healthcare decisions and policy.⁹

This study, therefore, seeks to compare the efficacy and safety associated with intravenous paracetamol versus pentazocine for postoperative pain management in adult abdominal surgery. The findings aim to provide a comprehensive understanding of their roles, thereby assisting clinicians in making informed decisions about optimal pain management strategies for their patients.

MATERIALS AND METHODS

Study Design:

This prospective, randomized, open-label trial was conducted at the Department of Surgery, Varun Arjun Medical College & Rohilkhand Hospital, from January 2022 to December 2022. The institutional ethics committee approved the study. Informed written consent was obtained from all participants.

Participants:

80 adult patients aged 20-70 years undergoing elective abdominal surgery with an expected duration of more than one hour were enrolled in the study. Exclusion criteria were allergy to either

paracetamol or pentazocine, chronic opioid use, severe hepatic or renal dysfunction, and contraindications to any of the study medications.

Randomization:

Patients were randomized using computer-generated random numbers into two groups: intravenous paracetamol (Group A, n=40) and intravenous pentazocine (Group B, n=40). The randomization code was sealed in an opaque envelope and opened only after the statistical analysis. This openlabel design allowed for direct monitoring of drug effects and adverse events, although it may have introduced some bias. Nonetheless, the randomization process and strict eligibility criteria aimed to mitigate this bias.

Intervention:

Group A: Received intravenous paracetamol 1g diluted in 100 ml of normal saline, administered over 15 minutes, every 6 hours postoperatively.

Group B: Received intravenous pentazocine 30 mg diluted in 100 ml of normal saline, administered over 15 minutes, every 6 hours postoperatively.

Pain Assessment:

Pain intensity was measured using the Visual Analog Scale (VAS) during movement at 0, 1, 2, 4, 6, 12, and 24 hours postoperatively.

Safety Profile:

Adverse events, and the need for rescue analgesia were monitored and recorded.

Statistical Analysis:

Data were analyzed using SPSS version 25.0. Demographics were compared using the chi-square test for categorical variables and the Student's t-test for continuous variables. A p-value of less than 0.05 was considered statistically significant.

Sample Size:

The sample size was calculated by G*Power version 3.1.9.7 using a power of 0.8 and a significance level of 0.05, requiring 80 patients.

Data Collection:

Data were collected by trained nurses and entered into a pre-designed pro forma, which was subsequently entered into an electronic database.

Ethical Considerations:

Informed consent was obtained from all participants, and the study was conducted following the Declaration of Helsinki.

RESULTS

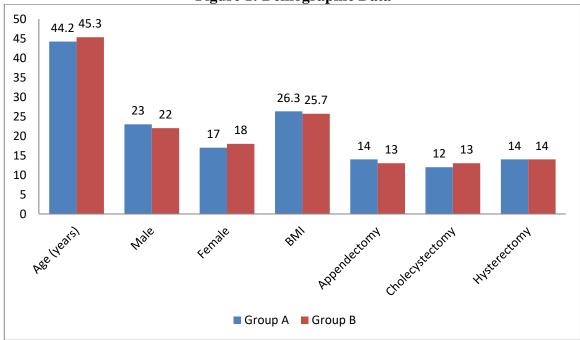
Demographic Data:

The two groups were comparable in age, sex, body mass index (BMI), and type of surgery (Table 1).

Table 1: Demographic Data

Variable		Group A (n=40)	Group B (n=40)	P-value
Age (years)		44.2±11.28	45.3±10.68	0.306
Sex (M/F)		23/17	22/18	0.821
BMI (kg/m ²)		26.3 ±3.4	25.7 ± 3.2	0.418
Type of Surgery	Appendectomy	14	13	
	Cholecystectomy	12	13	0.962
	Hysterectomy	14	14	



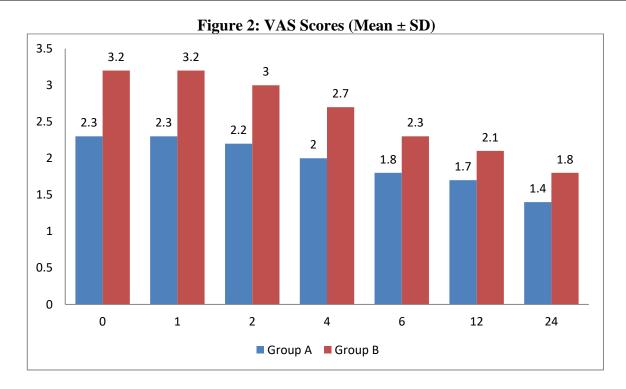


Pain Scores:

Table 2 shows Visual Analog Scale (VAS) scores for pain in Groups A and B at various time points. Group A consistently reported lower VAS scores at each time point than Group B, suggesting less pain. The p-values indicate that these differences are statistically significant at most time points (except at 12 hours, p=0.08), affirming the likelihood that these differences are not due to random chance.

Table 2: VAS Scores (Mean ± SD)

Time (hrs)	Group A	Group B	P-Value
0	2.3 ± 0.8	3.2 ± 0.9	0.00003
1	2.3 ± 0.9	3.2 ± 1.0	0.0002
2	2.2 ± 1.1	3.0 ± 1.2	0.0001
4	2.0 ± 0.8	2.7 ± 1.3	0.001
6	1.8 ± 0.6	2.3 ± 1.2	0.015
12	1.7 ± 0.5	2.1 ± 1.0	0.08
24	1.4 ± 0.3	1.8 ± 0.6	0.0004

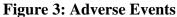


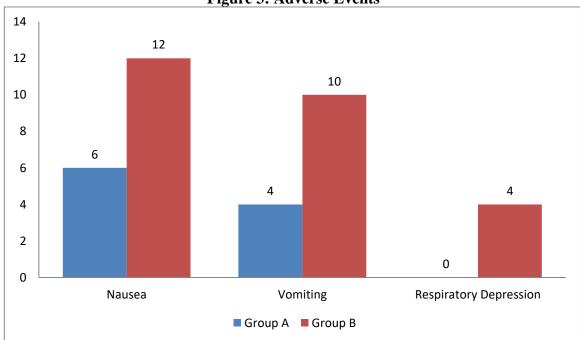
Adverse Events:

Respiratory depression (Table 3) was statistically significantly lower in Group A compared to Group B (p=0.045). However, the differences in rates of nausea and vomiting between the two groups were not statistically significant, with p-values of 0.157 and 0.108, respectively.

Table 3: Adverse Events

Adverse Events	Group A	Group B	P-value
Nausea	6	12	0.157
Vomiting	4	10	0.108
Respiratory Depression	0	4	0.045





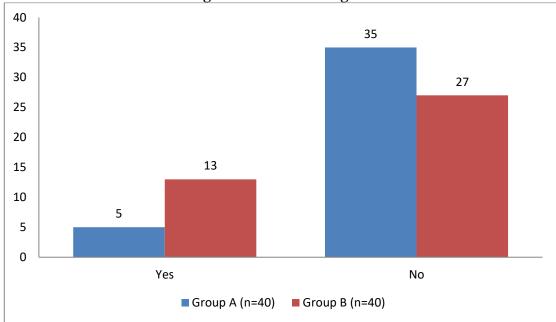
Rescue Analgesia:

The need for rescue analgesia was less frequent in Group A than in Group B, although the P-value of 0.059 suggests that this difference is not statistically significant at the 0.05 level. The P-value for patients not needing rescue analgesia (0.309) also indicates no significant difference between the two groups.

Table 4: Rescue Analgesia

Rescue Analgesia Needed	Group A (n=40)	Group B (n=40)	P-value
Yes	5	13	0.059
No	35	27	0.309





DISCUSSION

The primary objective of our study was to compare the efficacy and safety of intravenous paracetamol against pentazocine for postoperative pain management in adults undergoing abdominal surgery. Our findings reveal noteworthy differences in postoperative pain control, as evidenced by Visual Analog Scale (VAS) scores, between the two groups.

Efficacy in Pain Control:

Group A, receiving intravenous paracetamol, reported consistently lower VAS scores at multiple time intervals than Group B, which received pentazocine. The difference in VAS scores was statistically significant at almost all the time points except at 12 hours postoperatively. This result suggests that intravenous paracetamol may offer superior pain control to pentazocine in the immediate postoperative period. These findings align with previous studies indicating the efficacy of intravenous paracetamol in reducing postoperative pain. ^{10,11}

Adverse Events:

Respiratory depression was statistically significantly lower in Group A than in Group B, affirming the safety profile of intravenous paracetamol. However, the rate of nausea and vomiting between the two groups was not statistically significant. This could be attributed to both medications' relatively good safety profiles, albeit pentazocine has a more robust array of side effects like respiratory depression. 12,13

Rescue Analgesia:

Although the need for rescue analysis was lower in Group A, the difference was not statistically significant. This could be due to Group A's lower postoperative VAS scores, reducing the need for additional analysis. However, these findings should be interpreted cautiously due to the borderline P-value of 0.059.

Demographics and Surgical Types:

Our demographic data (Table 1) indicated that the two groups were well-matched in age, sex, BMI, and type of surgery, thus minimizing these factors as potential confounders.

Limitations:

Our study had limitations, including a small sample size and no long-term follow-up. Further research with larger sample sizes and different surgical types would enhance the robustness of these findings.

Conclusion

Our study suggests that intravenous paracetamol may offer advantages over pentazocine for postoperative pain management in adults undergoing abdominal surgery. Patients receiving intravenous paracetamol reported lower pain scores and experienced fewer adverse events, specifically respiratory depression. While the need for rescue analgesia was not statistically different between the two groups, the trends favour intravenous paracetamol. The groups were well-matched demographically, making these findings more robust. Despite certain limitations, such as the small sample size and the lack of long-term follow-up, these results warrant further research to validate the efficacy and safety of intravenous paracetamol as a better alternative to pentazocine for postoperative pain control in adult abdominal surgeries.

Abbreviations

- 1. VAS: Visual Analog Scale
- 2. SD: Standard Deviation
- 3. BMI: Body Mass Index
- 4. hrs: Hours
- 5. n: Number of Participants
- 6. kg/m²: Kilograms per Square Meter

Conflicts of Interest

The authors declare that they have no conflicts of interest regarding the publication of this paper.

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References

- 1. Kehlet H, Dahl JB. The value of "multimodal" or "balanced analgesia" in postoperative pain treatment. Anesth Analg. 1993;77(5):1048-56.
- 2. McGrath B, Elgendy H, Chung F, Kamming D, Curti B, King S. Thirty percent of patients have moderate to severe pain 24 hr after ambulatory surgery: a survey of 5,703 patients. Can J Anaesth. 2004;51(9):886-91.
- 3. Graham GG, Davies MJ, Day RO, Mohamudally A, Scott KF. The modern pharmacology of paracetamol: therapeutic actions, mechanism of action, metabolism, toxicity, and recent pharmacological findings. Inflammopharmacology. 2013;21(3):201-32.
- 4. Sinatra RS, Jahr JS, Reynolds LW, Viscusi ER, Groudine SB, Payen-Champenois C. Efficacy and safety of single and repeated administration of 1 gram intravenous acetaminophen injection

- (paracetamol) for pain management after major orthopedic surgery. Anesthesiology. 2005;102(4):822-31.
- 5. Moller PL, Sindet-Pedersen S, Petersen CT, Juhl GI, Dillenschneider A, Skoglund LA. Onset of acetaminophen analgesia: comparison of oral and intravenous routes after third molar surgery. Br J Anaesth. 2005;94(5):642-8.
- 6. Huang H, Bai X, Zhang K, Guo J, Wu S, Ouyang H. Antinociceptive effects and interaction mechanisms of intrathecal pentazocine and neostigmine in two different pain models in rats. Pain Res Manag. 2022;2022.
- 7. Viscusi ER. Patient-controlled drug delivery for acute postoperative pain management: a review of current and emerging technologies. Reg Anesth Pain Med. 2008;33(2):146-58.
- 8. Dowell D, Haegerich TM, Chou R. CDC Guideline for Prescribing Opioids for Chronic Pain—United States, 2016. JAMA. 2016;315(15):1624-45.
- 9. Jibril F, Sharaby S, Mohamed A, Wilby KJ. Intravenous versus Oral Acetaminophen for Pain: Systematic Review of Current Evidence to Support Clinical Decision-Making. Can J Hosp Pharm. 2015 May-Jun;68(3):238-47.
- 10. Macario A, Royal MA. A literature review of randomized clinical trials of intravenous acetaminophen (paracetamol) for acute postoperative pain. Pain Pract. 2011 Jun;11(3):290-6..
- 11. McNicol E, Tzortzopoulou A, Cepeda M, Francia M, Farhat T, Schumann R. Single-dose intravenous paracetamol or propacetamol for prevention or treatment of postoperative pain: a systematic review and meta-analysis. Br J Anaesth. 2011 May;106(6):764-75.
- 12. Fletcher D, Stamer U, Pogatzki-Zahn E, et al. Chronic postsurgical pain in Europe: An observational study. Eur J Anaesthesiol. 2015;32(10):725-34.
- 13. Remy C, Marret E, Bonnet F. Effects of acetaminophen on morphine side-effects and consumption after major surgery: meta-analysis of randomized controlled trials. Br J Anaesth. 2005 Apr;94(4):505-13.