Original Article

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Comparison of Various Intravenous Analgesics for Pain Management in Postoperative Total Abdominal Hysterectomy Patients: A Prospective Interventional Study

Obstetrics and Gynaecology Section

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ABSTRACT

Introduction: Total Abdominal Hysterectomy (TAH) often results in significant postoperative pain due to the invasive nature of the surgery and the involvement of abdominal or pelvic structures. Amongst the myriad pharmacological options available, intravenous IV diclofenac, tramadol, and paracetamol stand out for postoperative pain management due to their distinct mechanisms of action and efficacy profiles.

Aim: To compare the effectiveness of IV diclofenac, IV tramadol, and IV paracetamol in postoperative TAH patients.

Materials and Methods: This prospective interventional study was conducted in the Department of Obstetrics and Gynaecology at Jaipur National University Institute of Medical Sciences and Research Centre (JNUIMSRC), Jaipur, Rajasthan, India between September 2023 and November 2024. A total of 150 patients aged 35-55 years who were undergoing elective hysterectomy in the Inpatient Department (IPD) were recruited. Information was collected using a pretested, structured proforma for each patient. The patients were randomly assigned to three groups for postoperative pain management, with 50 patients in each group. Group A was administered IV diclofenac 75 mg eight hourly. Group B was administered IV paracetamol at 1 g 8-hourly. Group C was administered IV tramadol 50 mg in 100 mL NS 8-hourly. Visual Analogue Scale (VAS) was used to assess pain intensity at 6, 12, and 24 hours after surgery. Continuous variables were expressed as mean±standard deviation. Categorical data were expressed as percentages and proportions.

Results: The mean age of patients administered diclofenac was 43.60±4.73 years, with paracetamol was 44.10±4.33 years and with tramadol was 44.22±4.18 years, difference being statistically insignificant. The difference between the three groups was statistically significant (p-value=0.01), with the VAS score being lowest in the paracetamol group than in the other two groups postoperatively. The VAS scores in the IV paracetamol group were 6.26, 4.18, and 1.82 at 6, 12, and 24 hours postoperative, respectively. The VAS score in the IV diclofenac group was 7.14, 5.14, and 3.26 at 6, 12, and 24 hours postoperatively. Whereas the VAS scores in the IV tramadol group were 7.06, 4.22, and 2.14 at 6, 12, and 24 hours postoperatively. The most common side-effects observed were nausea, vomiting, and epigastric pain. Nine patients in the tramadol group had side-effects compared to seven patients in the diclofenac group and three patients in the paracetamol group. Additional medications were required for 10 patients in the diclofenac group, nine in the tramadol group, and six in the paracetamol group.

Conclusion: The findings of the study indicate that IV paracetamol provided superior pain relief compared with diclofenac and tramadol and was associated with fewer adverse effects.

Keywords: Diclofenac, Elective hysterectomy, Pain relief, Paracetamol, Tramadol

INTRODUCTION

Abdominal hysterectomy is one of the most commonly performed gynaecological surgeries for both benign and malignant conditions, including uterine leiomyoma, abnormal uterine bleeding, and pelvic organ prolapse. Hysterectomy may be performed through vaginal, laparoscopic, or abdominal approaches, with the choice depending on surgical indication, prior pelvic surgery, patient co-morbidities, body mass index, and surgeon expertise. Compared with minimally invasive techniques, open abdominal hysterectomy is associated with greater postoperative pain and longer recovery periods [1].

Among the myriad pharmacological options available, IV diclofenac, tramadol, and paracetamol stand out for postoperative pain management due to their distinct mechanisms of action and efficacy profiles. Diclofenac, paracetamol, and tramadol are three commonly used IV analgesics, each with distinct mechanisms of action and pharmacodynamic properties [1]. Diclofenac, a Non-Steroidal Anti-Inflammatory Drug (NSAID), works by inhibiting cyclooxygenase enzymes, reducing prostaglandin synthesis and thereby alleviating inflammation and pain [2]. Paracetamol, an analgesic and antipyretic agent, exerts its effects through central inhibition of prostaglandin synthesis and modulation of pain pathways [3]. Tramadol, an atypical opioid, provides analgesia through dual mechanisms: μ-opioid receptor agonism and inhibition of serotonin and norepinephrine reuptake [4]. While these medications are effective in controlling postoperative pain, their efficacy, side-effect profiles, and overall impact on patient recovery may vary significantly. The aim of the present study was to compare the effectiveness of IV diclofenac, IV tramadol, and IV paracetamol in postoperative TAH patients.

MATERIALS AND METHODS

A hospital-based prospective interventional study was carried out in the Department of Obstetrics and Gynaecology at JNUIMSRC, Jaipur, Rajasthan, India from September 2023 to November 2024. The study approval was obtained from the Institutional Ethics Committee, letter no. (IEC No.) JNU/Reg./2023/2386.

Inclusion criteria: Patients in the age group of 35-55 years, undergoing elective abdominal hysterectomy and gave written and informed consent were included in the study.

Exclusion criteria: Patients with history of cardiac disease, pulmonary disease, renal disease, systemic hypertension, hepatic disease, psychological disease, asthma, chronic pain syndromes and seizures, patients who had history of drug abuse or allergic to analgesic drugs and patients on antianxiety and antidepressant drugs were excluded from the study.

Study Procedure

A total of 150 patients undergoing elective hysterectomy were selected using convenience sampling. Patients were allocated into three groups according to the treating clinician's choice of analgesic. Therefore, each group comprised 50 patients.

The following drugs were administered based on the group allotted for postoperative pain:

- Group A- Administered IV Diclofenac 75 mg IV 8 hourly
- Group B- Administered IV Paracetamol 1 gram IV 8 hourly
- Group C- Administered IV Tramadol 50 mg in 100 mL NS IV 8 hourly

The Visual Analog Scale (VAS) is a widely used tool for assessing postoperative pain in patients undergoing TAH [5]. It allows patients to rate their pain on a scale from 0 (no pain) to 10 (worst pain), aiding in pain management decisions. VAS was used to assess pain intensity at 6, 12, and 24 hours after surgery. Groups were also compared with respect to side-effects and the need for additional medications for pain relief. Because rescue analgesia could influence subsequent pain scores, VAS assessments obtained after rescue medication administration were excluded from analysis. Therefore, crossover treatment did not contribute to the reported VAS comparisons.

STATISTICAL ANALYSIS

The data was entered using MS-Excel and analysed statistically using Statistical Package for the Social Sciences (SPSS) version 25.0. Continuous variables were expressed as mean value±standard deviation. Categorical data were expressed as percentages (%) and proportions. An appropriate statistical test (Chi-square test/ One-way ANOVA test) was used to infer the association between two variables and a p-value of <0.05 was considered statistically significant.

RESULTS

Among patients administered diclofenac, 30 were aged 35 to 45 years, and 20 were aged 46 to 55 years. The difference between groups based on age was not statistically significant (p-value=0.68) [Table/Fig-1].

Age groups	Diclofenac n (%)	Paracetamol n (%)	Tramadol n (%)	p-value*
35 to 45 years	30 (60)	33 (66)	34 (68)	0.68
46 to 55 years	20 (40)	17 (34)	16 (32)	
Total	50 (100)	50 (100)	50 (100)	
Mean±SD	43.60±4.73	44.10±4.33	44.22±4.18	0.76

[Table/Fig-1]: Distribution of subjects based on age group.
One-way ANOVA was used

All three groups were comparable in diagnosis, with no statistically significant difference (p-value=0.18). Seventeen patients had AUB-L in diclofenac group, 29 patients had AUB-L in paracetamol group [Table/Fig-2].

The difference between the three groups was statistically significant (p-value=0.01), with the VAS score being lowest in the paracetamol group compared with the other two groups at six hours postoperatively [Table/Fig-3].

The difference between the three groups was statistically significant (p-value=0.001), with the VAS score being lowest in the paracetamol group than the other two groups at 12 hours postoperatively [Table/Fig-4].

Diagnosis	Postoperative Medications			p-value*
	Diclofenac n (%)	Paracetamol n (%)	Tramadol n (%)	
AUB-L	17 (34)	29 (58)	22 (44)	0.18
AUB-A	09 (18)	13 (26)	17 (34)	
AUB-E	04 (08)	02 (04)	03 (06)	
AUB-M	02 (04)	01 (02)	02 (04)	
AUB-O	03 (06)	0	02 (04)	
AUB with PID	03 (06)	0	0	
AUB with chronic cervicitis	02 (04)	0	01 (02)	
AUB A/M with TO Mass	0	0	01 (02)	
Fibroid uterus	06 (12)	01 (02)	02 (04)	
Cervical fibroid	01 (02)	0	0	
Ovarian cyst	02 (04)	04 (02)	0	
Pyometra	01 (02)	0	0	
Total	50 (100)	50 (100)	50 (100)	

[Table/Fig-2]: Distribution of subjects based on diagnosis.
p-value <0.05 statistically significant; Chi square test applied; AUB: Abnormal uterine bleeding; L: Leiomyoma; A: Adenomyosis; E: Endometrial; M: Malignancy; O: Ovulatory dysfunction;PID:Pelvic inflammatory disease; TO Mass:Tubo-ovarian mass

Diagnosis	Postoperative Medications			p-value*
	Diclofenac	Paracetamol	Tramadol	
	Mean±SD	Mean±SD	Mean±SD	
VAS score at 6 hours	7.14±1.03	6.26±0.78	7.06±0.77	0.01

[Table/Fig-3]: Comparison of groups based on VAS score at 6 hours postoperatively.
p-value <0.05 statistically significant; One-way ANOVA test applied

Diagnosis	Postoperative Medications			p-value*
	Diclofenac	Paracetamol	Tramadol	
	Mean±SD	Mean±SD	Mean±SD	
VAS score at 12 hours	5.14±1.04	4.18±0.69	4.22±0.79	0.001

[Table/Fig-4]: Comparison of groups based on VAS score at 12 hours postoperatively.
p-value <0.05 statistically significant; One-way ANOVA test applied

The difference between the three groups was statistically significant (p-value=0.001), with the VAS score being lowest in the paracetamol group than the other two groups at 24 hours postoperatively [Table/Fig-5].

Diagnosis	Postoperative Medications			p-value*
	Diclofenac	Paracetamol	Tramadol	
	Mean±SD	Mean±SD	Mean±SD	
VAS score at 24 hours	3.26±0.98	1.82±0.59	2.14±0.53	0.001

[Table/Fig-5]: Comparison of groups based on VAS score at 24 hours postoperatively.
p-value <0.05 statistically significant; One-way ANOVA test applied

Nine patients in the tramadol group experienced side-effects, compared with seven in the diclofenac group and three in the paracetamol group. The common side-effects noted with the IV diclofenac group were GI irritation and nausea, IV tramadol was associated with nausea and vomiting, and IV paracetamol was associated with nausea. However, the difference between groups was not statistically significant (p-value=0.18) [Table/Fig-6]. Most of these side-effects were managed successfully with IV antiemetics (ondansetron, metoclopramide) and ensuring adequate hydration.

Ten patients in the diclofenac group, nine patients in the tramadol group, and six patients in the paracetamol group needed extra medications [Table/Fig-7]. However, the difference between the three groups was not statistically significant (p-value=0.54). The IV

diclofenac, IV paracetamol and IV tramadol were the only analgesics used in this study. Extra medications in the diclofenac group were paracetamol and tramadol in three and three patients, respectively; in the tramadol group, they were paracetamol and diclofenac in four and two patients, respectively; and in the paracetamol group, they were diclofenac and tramadol in two and two patients, respectively. Some patients requiring additional analgesia received both rescue drugs, not repeated doses of the same medication.

Side-effects	Postoperative Medications			p-value*
	Diclofenac n (%)	Paracetamol n (%)	Tramadol n (%)	
Yes	07 (14)	03 (06)	09 (18)	0.18
No	43 (86)	47 (94)	41 (92)	
Total	50 (100)	50 (100)	50 (100)	

[Table/Fig-6]: Comparison of groups based on side-effects.
p-value <0.05 statistically significant; Chi square test applied

Need for extra-medications	Postoperative Medications			p-value*
	Diclofenac n (%)	Paracetamol n (%)	Tramadol n (%)	
Yes	10 (20)	06 (12)	09 (18)	0.54
No	40 (80)	44 (88)	41 (92)	
Total	50 (100)	50 (100)	50 (100)	

[Table/Fig-7]: Comparison of groups based on need for extra medications.
p-value <0.05 statistically significant; Chi square test applied

DISCUSSION

Pain management is a critical component of postoperative care, particularly for patients undergoing major surgical procedures such as TAH. Despite advances in surgical techniques and anaesthetic practices, effective postoperative pain control remains a challenge due to the intensity and duration of pain associated with this procedure [1].

At 12 hours postoperatively, the difference between the three groups was statistically significant (p-value=0.001), with the VAS score lowest in the paracetamol group compared with the other two groups. In a study by Panda S et al., of 150 patients enrolled for hysterectomy, 50 were assigned to the abdominal, vaginal, and laparoscopic-assisted vaginal routes, respectively. 90% of patients required analgesia in the abdominal hysterectomy group, compared with 10.21% in the vaginal hysterectomy group and 19.57% in the LAVH group 24 hours postoperatively, a statistically significant difference [6].

In another study by Bisht P and Jain G, the postoperative mean VAS scores at different time points were lower in the paracetamol group than in the diclofenac group [7]. Nine (09) patients in the tramadol group had side-effects (nausea and vomiting) as compared to seven (07) patients in the diclofenac group (epigastric pain, nausea and vomiting) and three (03) patients in the paracetamol group (nausea). However, the difference between the three groups was not statistically significant (p-value=0.18). In the study by Agrawal A et al., the incidence of nausea and vomiting was lower with paracetamol than with tramadol, resulting in shorter hospitalisation and earlier discharge [8].

In another study by Bisht P and Jain G, the adverse effects like nausea, vomiting, and dizziness were seen more among the diclofenac group as compared to the paracetamol group, the difference was not statistically significant [7].

Ten patients in diclofenac, nine (09) patients in tramadol and six (06) patients in paracetamol group needed extra medications. In another study by Choudhary A and Swati PV they found that in the group diclofenac, nine women needed a rescue dose of tramadol, and 25 women did not require any rescue therapy, whereas in the group paracetamol, seven women required a rescue dose of tramadol, and 27 did not require it [9]. In another study by Bisht P and Jain G, rescue analgesia was required in 10% of patients in the paracetamol group, compared with 31.7% in the diclofenac group; this difference was statistically significant [7].

Limitation(s)

Limited participants may reduce the statistical power and generalisation of the findings. Findings from a single hospital or region may not be generalised to other healthcare settings. Limited monitoring time may overlook long-term efficacy and side-effects. Pain perception varies between patients and may lead to inconsistent data.

CONCLUSION(S)

The findings of the study indicate that IV paracetamol provided superior pain relief compared with diclofenac and tramadol and was associated with fewer adverse effects.

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