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STUDY ON SAFETY AND EFFICACY OF DIFFERENT MODALITIES IN THE POST-OPERATIVE PAIN MANAGEMENT IN A TERTIARY CARE TEACHING HOSPITAL

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ABSTRACT: Background: Postoperative pain control is an important part of effective postoperative care. However, 30 - 80% of postoperative patients complain about moderate to severe post-surgical pain as a result of the surgical procedure or a pre-existing disease. **Aim:** To assess the safety and efficacy of different modalities of postoperative pain management in post surgical wards of a tertiary care hospital. **Method:** It's a prospective study was conducted in 213 patients of either gender, aged between 18 - 65 years. Patients were followed up from surgery till discharge or till the 4th postoperative day, the drugs given for pain relief both as single drug and combination drugs and adverse effects were monitored. The severity of pain was assessed using a numeric pain rating scale after 1 h of surgery, then followed by 2 h, 4 h, 6 h, 12 h, 24 h, 48 h and 96 h. Patient satisfaction with the analgesic therapy given was recorded at the time of discharge or after 4th postoperative day using 5 point Likert's Scale. The data collected were tabulated and analyzed statistically using SPSS.16 software. **Results:** On comparing the various modalities of pain management, the combination therapy was found to be more effective than the single drug modality, as significant reduction in pain score was seen at 6th, 12th, 24th and 48th h with a p-value < 0.05. **Conclusion:** All the modalities used for postoperative pain management were safe and effective. The multimodal analgesic therapy for postoperative pain was more effective than the single modal analgesic therapy.

INTRODUCTION: Post-operative pain is often inadequately treated and optimal utilization of the available resources is essential for improving pain management. Good postoperative pain control is an imperative part of adequate postoperative care¹. It has been repeatedly confirmed by studies in the past 3 to 4 decades that 20 to 80% of patients undergoing surgery suffer from inadequately treated pain². The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience arising from actual or potential tissue damage or described in terms of such damage"³.

A common belief is that pain is a 'normal' consequence of surgery and injury, not being harmful to the patient and pain relief will obscure a surgical diagnosis or mask the signs of surgical complications⁴.

Many postoperative complications such as Sympathetic activation (*i.e.*, tachycardia, hypertension, increased myocardial work), adverse cardiac effects (*e.g.*, increased oxygen consumption, myocardial ischemia, heart failure), adverse respiratory effects (*i.e.*, reduced functional residual capacity, cough impairment, atelectasis, hypoventilation, hypoxemia), hypercoagulability and thrombosis, immunosuppression, physical deconditioning, mental and emotional changes, progression to central sensitization occur as a result of unrelieved postoperative pain⁵. A substantial reduction in postoperative morbidity and mortality can be achieved by a significant improvement in postoperative analgesia^{6,7}.

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Postoperative pain that remains unrelieved not only delays the discharge and recovery, but also results in poor patient outcomes by making them unable to participate in rehabilitation programs. Nevertheless, under treatment of pain continues, despite the availability of drugs and techniques for its effective management⁸. Pain perception differs remarkably among individuals as it is a subjective experience, hence patients' involvement and careful assessment of their pain is essential for successful pain relief, for which patients' self-reports and verbal pain-scoring methods are most reliable indicators⁹.

MATERIALS AND METHODS: A prospective study was conducted in the in the Post Anaesthesia Care Unit (PACU) and the post surgical wards of a tertiary care hospital in 213 patients of both genders, aged between 18 - 65 years. Patients who were not able to communicate and who were shifted to ICU after surgery were excluded from the study. All patients were followed up from the day of surgery till discharge or till 4th postoperative day, the drugs given for pain relief both as single drug and combination drugs were noted and adverse effects were monitored. REC-FOP/M/PHARM (PP)/12/10

Patient's demographical data, physical examination, past medical, surgical and medication history were recorded in the proforma. Type of surgery done, type of anaesthesia given were recorded. Vital signs such as heart rate, respiratory rate and blood pressure at the baseline, every 15 min for 1 h after surgery in the Post Anaesthesia Care Unit (PACU), at 2 h, 4 h, 6 h, 12 h and 24 h after surgery in the ward were recorded. The postoperative rescue analgesics used for the management of pain was recorded. The time to first dose of rescue analgesic was calculated. The length of stay of patients was recorded. All patients were followed up till discharge or till 4th postoperative day for pain relief and for adverse effects such as drowsiness, nausea, sleeplessness, vomiting, abdominal discomfort, constipation, itching, mood changes and difficult urination.

The severity of pain at rest was assessed using Numeric Pain Rating Scale¹⁰ at 1 h, 2 h, 4 h, 6 h, 12 h, 24 h, 48 h and 96 h after surgery. The Numeric Pain Rating Scale (NPRS) is a unidimensional measure of pain intensity in adults

including those with chronic pain. The scale consists of 11-points ranges from '0' representing one pain extreme (e.g. "no pain") to '10' representing the other pain extreme (e.g. "pain as bad as you can imagine" or "worst pain imaginable"). The NPRS can be administered verbally by asking the respondent to indicate the numeric value on the segmented scale that best describes their pain intensity. Scores range from 0 - 10 points, with higher scores indicating greater pain intensity.

Patient's satisfaction to the analgesic therapy given was recorded at the time of discharge or after 4th postoperative day using 5 point Likert's Scale. All the data collected were tabulated and analyzed statistically using SPSS.16 software. A p-value of <0.05 was considered as statistically significant.

RESULTS: Among in 213 patients, pre operatively, majority of the patients (48.35%) were given general anaesthesia, 30.04% of patients were given spinal anaesthesia and 21.12% of patients were given a combination of spinal and epidural anaesthesia **Table 1**.

TABLE 1: MODE OF ANAESTHESIA

S. no	Mode of anaesthesia	No. of patients (n=213)	Percentage (%)
1	General anaesthesia	103	48.35
2	Spinal anaesthesia	64	30.04
3	Combined spinal and epidural anaesthesia	45	21.12
4	Interscalene and cervical plexus block	1	0.46

Patients were grouped according to the mode of analgesia given after the surgery. Patients who received analgesics through only one route (either IM or IV) were grouped as Single modal group and the patients who received analgesics through more than one route were grouped as Multi modal group. Out of 213 patients 73 (34.27%) patients received single modal analgesia and 140 (65.72%) patients received multimodal analgesia. Out of 73 patients in the single modal group, 37 (50.6%) patients received only intramuscular (IM) analgesics and 36 (49.3%) patients received only intravenous (IV) analgesics. Out of 140 patients in the multi modal group, 60 (42.8%) patients received parenteral analgesics (both IM and IV), 14(10%) patients received parenteral and oral analgesics, 3 (2.1%) patients received parenteral and rectal analgesics, 52(37%) patients received parenteral and epidural

analgesics, 2(1.4%) patients received parenteral and regional blocks and 9 (6.4%) patients received combinations of different routes of analgesics (parenteral, oral, epidural, regional blocks, rectal and topical) **Table 2**.

TABLE 2: DIFFERENT MODALITIES OF POSTOPERATIVE PAIN MANAGEMENT

Modalities		No. of patients (n=213)	Percentage (%)
Single (n=73)	IM	37	17.37
	IV	36	16.9
Multi (n=140)	IM+IV	60	28.17
	Parentral + Oral	14	6.57
	Parentral + Rectal	3	1.41
	Parentral + epidural	52	24.4
	Parentral + blocks	2	0.94
Combinations		9	4.22

IM - Intramuscular, IV- Intravenous

There was no significant difference between the single modal and multimodal group with respect to age, height, weight, mean time to first analgesic dose (in min) post operatively and type of surgery (major vs minor) with a p-value of 0.579, 0.799, 0.298, 0.880 and 0.337 respectively using Mann-Whitney U test for significance **Tables 3 and 4**.

TABLE 3: DISTRIBUTION OF PATIENTS DEMOGRAPHIC DATA

S. no	Demographics	No of patients (mean)		p-Value
		Single modal (n=73)	Multi modal (n=140)	
1	Age (in years)	44.05	45.06	0.579
2	Height (in cm)	163.74	162.23	0.799
3	Weight (in kg)	69.24	67.70	0.298
4	Mean Time to first analgesic dose (in min)	111.61	116.30	0.880

p < 0.05 - statistically significant

TABLE 4: SEVERITY OF SURGERY

S. no	Type of surgery	Group		Total	p-value
		Single modal (n=73)	Multi modal (n=140)		
1	Minor	40	72	112	0.337
		(54.79%)	(51.53%)		
2	Major	33	68	101	
		(45.21%)	(48.57%)		

p < 0.05 - statistically significant

Out of 213 patients, 158 (74%) patients received tramadol, 86(40.4%) patients received diclofenac, 82(38.5%) patients received ketorolac, 63(29.5%) patients received paracetamol, 60(28.2%) patients received bupivacaine, 56(26.3%) patients received pentazocine and 6(2.8%) patients received piroxicam for postoperative pain treatment.

Of 213 patients, 152 patients experienced adverse effects which included nausea in 39 (25.6%) patients, difficulty in urination in 23 (15.1%), vomiting in 21 (13.8%), drowsiness in 20 (13.1%), constipation in 20(13.1%), Insomnia in 12 (7.8%), Itching in 10 (6.57%) and abdominal discomfort in 7 (4.6%) patients. The mean pain score of multimodal group was significantly lower than the single modal group at 2nd h, 4th h, 6th h, 12th h, 24th h, 48th h and 96th h after surgery with a p-value of 0.000, 0.000, 0.000, 0.000, 0.000, 0.003, 0.002 and 0.002 respectively. But no significant difference was found at 1st h with a p-value of 0.156 using Mann Whitney U test **Table 5**.

TABLE 5: COMPARISON OF SINGLE AND MULTI-MODAL EFFICACY IN POSTOPERATIVE PAIN MANAGEMENT

S. no	Time after surgery	Pain score (mean ± std. deviation)		p-Value
		Single modal	Multi modal	
1	1 st h	1.07 ± 1.305	1.36 ± 1.430	0.156
2	2 nd h	3.66 ± 1.204	2.71 ± 1.282	0.000*
3	6 th h	2.25 ± 0.572	1.62 ± 0.744	0.000*
4	12 th h	2.14 ± 0.694	0.99 ± 0.827	0.000*
5	24 th h	1.79 ± 0.865	1.13 ± 0.830	0.000*
6	48 th h	1.16 ± 0.800	0.81 ± 0.801	0.003*
7	72 th h	0.73 ± 0.786	0.80 ± 0.681	0.002*
8	96 th h	0.36 ± 0.586	0.51 ± 0.581	0.002*

p < 0.05 - statistically significant

On comparing IM and IV routes of single modal group using paired t test, the mean pain score was not significant at all timings except at 6th h and 12th h with the p-value of 0.015 and 0.044 respectively, where IV group had better analgesic effect than the IM group **Table 6**.

TABLE 6: COMPARISON OF EFFICACY OF DIFFERENT MODALITIES IN SINGLE MODAL GROUP

S. no	Time after surgery	Pain score (mean ± std. deviation)		p-Value
		IM(n=37)	IV(n=36)	
1	1 st h	1.14 ± 1.357	1.00 ± 1.265	0.661
2	2 nd h	3.68 ± 1.248	3.64 ± 1.175	0.897
3	4 th h	2.62 ± 0.924	2.36 ± 0.833	0.210
4	6 th h	2.41 ± 0.599	2.08 ± 0.500	0.015*
5	12 th h	2.30 ± 0.740	1.97 ± 0.609	0.044*
6	24 th h	1.86 ± 0.976	1.72 ± 0.741	0.485
7	48 th h	1.11 ± 0.906	1.22 ± 0.681	0.546
8	72 th h	0.84 ± 0.866	0.61 ± 0.688	0.220
9	96 th h	0.46 ± 0.650	0.25 ± 0.500	0.128

p < 0.05 - statistically significant; IM – Intramuscular; IV- Intravenous

On comparing the various pain treatment routes in multimodal group using Kruskal-Wallis test, the combination group was found to be more effective as significant reduction in pain score was seen at 6th, 12th, 24th and 48th h with a p-value of 0.000, 0.010, 0.000 and 0.002 respectively **Table 7**.

TABLE 7: COMPARISON OF EFFICACY OF DIFFERENT MODALITIES IN MULTI MODAL GROUP

Time after surgery	Pain score (mean \pm std. deviation)						p-value
	IM+IV (n=60)	PAR + Oral (n=14)	PAR+ Rectal (n=3)	PAR+ EPI (n=52)	PAR+ Blocks (n=2)	Combinations (n=9)	
1 st h	1.53 \pm 1.50	1.23 \pm 1.30	2.67 \pm 1.15	2.42 \pm 1.63	2.50 \pm 0.71	1.17 \pm 1.37	0.228
2 nd h	3.00 \pm 1.30	2.92 \pm 1.11	2.67 \pm 0.57	2.33 \pm 1.12	2.00 \pm 0.00	2.26 \pm 0.58	0.084
6 th h	1.92 \pm 0.69	1.85 \pm 0.68	1.00 \pm 0.00	1.40 \pm 0.53	1.50 \pm 1.00	1.33 \pm 0.69	0.000*
12 th h	1.68 \pm 0.74	1.38 \pm 0.76	1.67 \pm 0.57	1.06 \pm 0.68	1.50 \pm 0.71	0.89 \pm 1.85	0.010*
24 th h	1.52 \pm 1.00	0.92 \pm 0.49	1.67 \pm 0.57	1.02 \pm 0.74	1.00 \pm 0.00	0.67 \pm 0.87	0.000*
48 th h	1.12 \pm 0.84	0.62 \pm 1.04	0.67 \pm 0.57	0.58 \pm 0.67	0.50 \pm 0.71	0.82 \pm 0.74	0.002*
72 th h	0.88 \pm 0.71	0.92 \pm 0.72	1.00 \pm 0.00	0.93 \pm 0.80	1.00 \pm 0.00	1.00 \pm 0.73	0.124
96 th h	0.43 \pm 0.50	0.15 \pm 0.37	0.33 \pm 0.57	0.63 \pm 0.74	0.50 \pm 0.71	0.67 \pm 0.64	0.017*

p < 0.05 - statistically significant; PAR - Parenteral; IM - Intramuscular; IV - Intravenous

Patients' satisfaction on pain relief was assessed using a five point likert scale. Of 213 patients, 198 (92.96%) patients were satisfied with their postoperative pain treatment and there was no significant difference (p = 0.719) in patient's satisfaction between single modal and multimodal group using Chi- square test **Table 8**.

TABLE 8: PATIENT'S SATISFACTION ON PAIN RELIEF

Patient's satisfaction	Group		Significance p
	Single modal (n=73)	Multi modal (n=140)	
Very satisfied	15	30	0.719
Satisfied	53	100	
Neither satisfied nor dissatisfied	3	10	
Dissatisfied	2	5	
Very much dissatisfied	0	0	

DISCUSSION: Good postoperative pain management is necessary because inefficient treatment may result in obvious material and immaterial expenses and losses. Material expenses are the ones in the system of health care (prolonged hospitalization, the increased use of medications, medically related work absenteeism). Immaterial losses cause emotional anxiety and patient's dissatisfaction ¹¹.

Trudeau, *et al.*, stated that 70.1% of patients had pain score of zero and 83.3% of patients had pain score \leq 4 at the time of admission to Post Anaesthesia Care Unit (PACU) ¹². Similarly in our study we found that, 61.5% patients had zero pain score and 81.69% patients had pain score \leq 4 at the time of admission to PACU. Sommer *et al.*, showed 41% of patients experienced moderate to severe pain on the day of surgery and concluded that postoperative pain treatment was unsatisfactory after intermediate and major surgery ¹³. In contrast to that, in our study we found 38 % of patients

experienced moderate to severe postoperative pain on the day of surgery and had satisfactory postoperative pain treatment. Kehlet *et al.*, proposed that the combination of opioids and NSAIDs which has additive analgesic action reduces postoperative pain more effectively than the single drug therapy. Chen C *et al.*, found that the combination therapy with tramadol and diclofenac resulted in significant improvement in postoperative pain relief than monotherapy with tramadol and diclofenac ¹⁴.

In contrast, Moore RA *et al.*, found that there is a wealth of reliable evidence on the analgesic efficacy of single dose oral analgesics ¹⁵. In accordance with the former study, we found that the multidrug therapy was more effective than the single drug therapy in postoperative pain relief. Bonnal A *et al.*, compared multimodal analgesia and patient controlled oral analgesia in elective caesarean section and found that multimodal analgesia is advantageous than patient controlled analgesia in relieving pain but no differences were noted for other adverse events and maternal satisfaction ¹⁶. Roman Schumann *et al.*, in their study proposed that the multimodal therapy is more effective than the single modal therapy in postoperative pain management ¹⁷. Our study showed similar results on comparing multimodal with single modal therapy.

Wee MK *et al.*, compared the analgesic effects of two opioids through intramuscular route and observed a modest difference between the analgesia provided by diamorphine or pethidine for labour analgesia ¹⁸. Anders Peder *et al.*, proposed that the effectiveness of intramuscular injections is inferior to other routes of administration in postoperative pain management ¹⁹.

Similarly, in our study intramuscular route was less effective than other routes of administration. Tewodros Eyob Woldehaimanot *et al.*, found that the most common adverse effects in postoperative pain therapy were nausea, drowsiness and constipation². In our study the common adverse effects were nausea, difficult urination and vomiting. A study by Roman Schumann *et al.*, showed that adverse events were equivalent in both unimodal and multimodal therapy, as well as the length of stay (P- 0.529) and patient satisfaction (P- 0.790) were also found to be equivalent¹⁷.

Similarly, in our study adverse effects, length of stay and patient satisfaction were not significantly different in both the groups. Adriaan Albertus Murray *et al.*, examined the evidence from published data concerning the tolerability (indicated by the incidence of nausea, vomiting, sedation, pruritus, and urinary retention), of three analgesic techniques after major surgery; intramuscular analgesia (IMA), patient-controlled analgesia (PCA) and epidural analgesia and set standards of care after major surgery for nausea 25%, vomiting 20%, minor sedation 24%, excessive sedation 2.6%, pruritus 14.7%, and urinary retention requiring catheterization 23%⁸. In our study, the incidence was found to be nausea 18%, vomiting 11%, drowsiness 11%, pruritus 5.6% and urinary retention 9.4%. Hazem El Sayed Moawad *et al.*, found that adverse effects like analgesics, nausea, vomiting, pruritus were not significantly different in patients receiving epidural mode of analgesia and intravenous analgesia²⁰. The present study also observed that there was no significant difference in adverse effects in single and multimodal therapy.

Fizzah Farooq *et al.*, assessed the patient satisfaction with postoperative pain management and concluded that the majority of patients (89%) were satisfied with the therapy²¹. In a study conducted by Tewodros Eyob Woldehaimanot *et al.*, 90% of patients were satisfied with the analgesic therapy². In our study, 93% of patients were satisfied with the current analgesic therapy. The limitations of study was that adverse effects for specific drug could not be assessed as many patients received more than one drug for their pain as well for their disease conditions. As all the patients have to be followed frequently for the first

24 h, the more number of patients was not studied because of time limitations.

CONCLUSION: All the modalities used for postoperative pain management were safe and effective. The multimodal analgesic therapy for postoperative pain was more effective than the single modal analgesic therapy. The patient satisfaction was high with both the single modal and multimodal analgesic therapy.

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