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"Comparison Of Efficacy Of Intravenous Paracetamol And Intravenous Tramadol For Post Opertive Pain In Patients Undergoing Infraumbilical Surgeries" In Karpagavinayaga Institute Of Medical Sciences.

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Abstract
Aims: *To compare the efficacy of IV Paracetamol versus IV Tramadol for post-operative pain relief in cases undergoing infraumbilical surgeries.*
Method And Materials: *The study included 150 patients aged between 18-50 years of ASA I and ASA II physical status who underwent elective lower abdominal surgery. The patients were divided into two groups of 75 patients each. Group P received IV Paracetamol 15mg/kg and Group T received IV Tramadol 2mg/Kg. Parameters recorded in our study were pain score, sedation score, pulse rate, mean arterial pressure, SpO2 duration of analgesia, total number of rescue analgesics, and complications like Nausea and vomiting, hypotension, bradycardia and respiratory depression. The magnitude of change occurring in the different groups at each interval was also compared.*
Statistical Analysis Used: *Student T test, Mann whitney test, Chi square test, analysis of variance.*
Results: *The demographic profiles were comparable among the two groups. The mean duration of post-operative analgesia was 372.40 ±60.46 minutes in Group P and 369.86 ±64.39 minutes in Group T(P>0.05). The visual analogue scale (VAS) scores were comparable in both the groups. The number of doses of rescue analgesia required in postoperative period was similar. Sedation score was assessed in both group and it was found that tramadol group subjects were more sedated compared to the paracetamol group. Complications like nausea and vomiting were found more in tramadol group than paracetamol group.*
Conclusions: *Intravenous paracetamol is a safer and effective non-opioid analgesic for the treatment of postoperative pain in patient undergoing infra umbilical surgeries*
Keywords: *Paracetamol, Tramadol, Pain, Post-operative.*

I. Introduction

Pain is the most common symptom of any illness. The International Association for the Study of Pain (IASP) has defined pain as "An unpleasant sensory and emotional experience in association with either actual or potential tissue damage or described in terms of such damage".[1] Perioperative analgesia has traditionally been provided by opioid analgesia. However, extensive use of opioids is associated with a variety of perioperative side effects.[2] NSAIDs have been advocated to provide "multimodal" or "balanced" analgesia that decreases opioid dose requirements and may reduce associated adverse events while reducing postsurgical pain intensity.[3-7]Acetaminophen has a well-established safety and analgesic profile. The aim of this study was to evaluate the analgesic efficacy and safety of a single dose of 1g intravenous acetaminophen in comparison to intravenous tramadol for post-operative analgesia in patients undergoing infraumbilical surgeries.

II. Materials And Methods

After approval from the institutional ethical committee and after obtaining written informed consent from the patients, study was carried out in 150 patients undergoing infraumbilical surgeries. Inclusion criteria were ASA physical status I and II of either sex, age group 18-50 years and elective surgery. Patients having history of cardiac pulmonary, hepatic, renal or any metabolic disorders were excluded from the study. The patients were randomly allocated into two groups of 75 each. Group-P (Paracetamol) received i.v Paracetamol 15mg/kg and Group -T received i.v Tramadol 2mg/kg. The study drugs were given when they experienced moderate pain within 3 hours after regaining consciousness and following verbal command.

A study observer closely monitored and recorded the patient's pain intensity. The study drugs were infused on Patients reporting moderate pain intensity on a four point verbal pain intensity categorical scale(0 =

none, 1 = mild, 2 = moderate, 3 = severe)(Raymond S Sinatra et al).[8] A standard protocol for anaesthesia was followed for all the patients with preoperative instructions about visual analogue scores and premedication with standard dosages of inj. Pantoprazole 40mg, inj Ondansetron 4mg, inj. Midazolam 0.05mg/kg, inj. Glycopyrrolate 0.2mg and inj. Fentanyl 2microgram/kg 30 minutes prior to surgery. In the operating room all the standard monitors were attached. Anaesthesia was induced with propofol 2mg/kg and intubation was done with inj. succinylcholine 1.5mg/kg. Heart rate, Blood pressure and SpO2 were monitored and recorded. Anaesthesia was maintained with O2 + N2O +inj. Atracurium + inhalational agents. At the end of surgery residual neuromuscular blockade was reversed with inj. Neostigmine and inj. Glycopyrrolate. Pain was assessed by standard Visual analogue scale (VAS) at 0,1,3,6,9,12 and 24 hours postoperatively.

Here pain is described in terms of numbers. VAS is a visual scale that allows the patient in pain to visually select a point on a 10cm scale. The point selected would correspond to their personal experience of pain. This scale has two anchoring points in the 10cm scales: at the left side 0 represent "no pain" and at the right side 10 represent worst pain. Sedation was assessed at the same intervals postoperatively using a 4-point scale, where 0 = fully awake, 1 = awake but drowsy, 2 = sleeping but arousable by light touch or speech, and 3 = sleeping, not arousable(Hale Yarkan et al).[9]

Pain relief (Primary end point) was measured on a five point verbal scale(0=none to 4=complete) at the same interval upto 6 hours(Sinatra et al.)[8] VAS score of more than 3 was considered inadequate analgesia. Time to first dose of rescue analgesic was noted after the infusion of the study drug. The duration of analgesia was defined as the time between the onset of action and return of pain with VAS score more than 3. Incidence of nausea, vomiting and shivering was recorded in both groups during first 24 hours. All data were analysed by specific statistical methods applicable to the various sets of data. Tests employed were student T test, Mann whitney test, Chi square test and analysis of variance using the computer program Graph Pad Instat®. Microsoft® word and Excel have been used to generate graphs, table etc.

III. Results

Demographic data was comparable with respect to age, gender distribution and ASA physical status in both the groups (Table 1).

Demographic Profile	Group P Mean ± SD	Group T Mean ± SD	P value
Age(Years)	36.56 ± 8.51	38.08 ± 6.65	0.22
Weight(Kg)	50.52 ± 4.99	50.88 ± 4.70	0.65
ASA Physical(I/II)	66/9	68/7	0.79

Table 1. Demographic profile

There was no statistically significant difference noted in the Visual Analogue Scale in both the groups at various time interval in the first 24 hrs (P >0.05) (Table 2).

Time	Group P Mean ± SD	Group T Mean ± SD	p Value
0 Hrs Post Infusion	2.77 ± 0.73	2.70 ± 0.65	0.63
1 Hrs Post Infusion	1.78 ± 0.42	1.69 ± 0.34	0.13
3 Hrs Post Infusion	2.03 ± 0.41	2.16 ± 0.36	0.08
6 Hrs Post Infusion	2.46±0.69	2.62±0.55	0.33
9 Hrs Post Infusion	1.99 ±0.73	2.11± 0.60	0.17
12 Hrs Post Infusion	2.31± 0.56	2.53 ±0.74	0.10
24 Hrs Post Infusion	2.30 ±0.73	2.41±0.68	0.25

Table 2. Changes in VAS

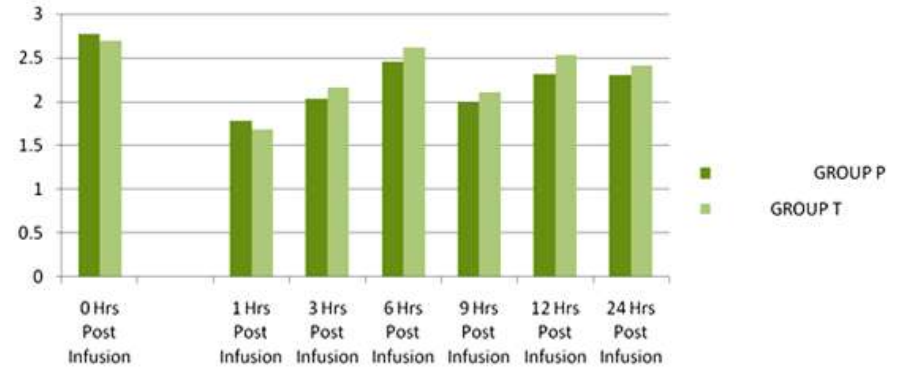

Figure 1. Visual analogue score comparison

The sedation score in the first few hours were more in the Tramadol group as compared to that of Paracetamol group. Toward the end of the 24th hour the sedation score were same.

There was no statistically significant difference noted in the requirement of total number of rescue analgesia in both the groups at various time interval in the first 24 hrs in both the groups($p > 0.05$).

Time	Group P Mean ± SD	Group T Mean ± SD	p Value
0 Hrs Post Infusion	0.62 ± 0.53	0.70 ± 0.59	0.38
1 Hrs Post Infusion	0.48 ± 0.60	2.14 ± 0.60	**<0.0001***
3 Hrs Post Infusion	0.17 ± 0.38	2.03 ± 0.60	**<0.0001***
6 Hrs Post Infusion	0.08 ± 0.27	1.08 ± 0.60	**<0.0001***
9 Hrs Post Infusion	0.21 ± 0.44	0.64 ± 0.50	**<0.0001 ***
12 Hrs Post Infusion	0.16 ± 0.36	0.37 ± 0.48	**0.002 ***
24 Hrs Post Infusion	0.05 ± 0.22	0.07 ± 0.21	0.56

Table 3. Sedation score comparison.

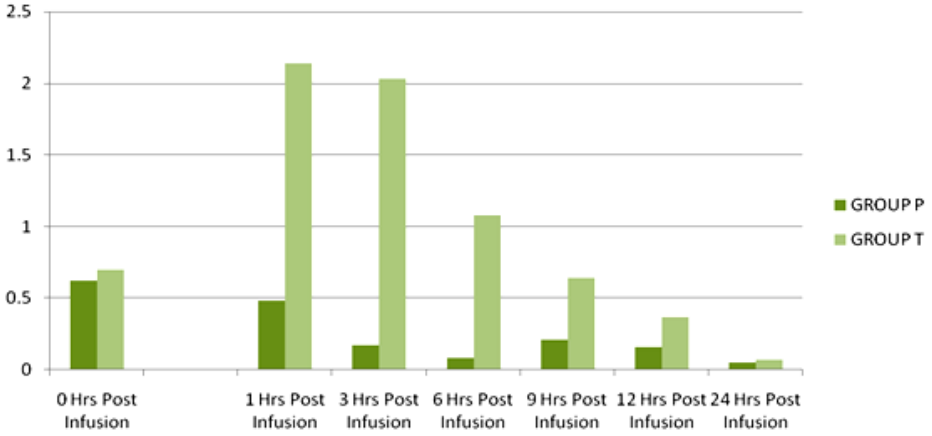

Figure 2. Sedation score

NO OF ANALGESIC DOSES	GROUP P		GROUP T	
	NO OF PATIENTS	PERCENTAGE	NO OF PATIENTS	PERCENTAGE
1	15	20%	10	13.33%
2	49	65.33%	50	66.67%
3	11	14.67%	15	20%
TOTAL NUMBER OF Pts	75		75	
Mean±SD	1.94±0.59		2.04±0.57	
P value= 0.34				

Table 4: Requirement of total doses of rescue analgesics in first 24 hours post-operatively

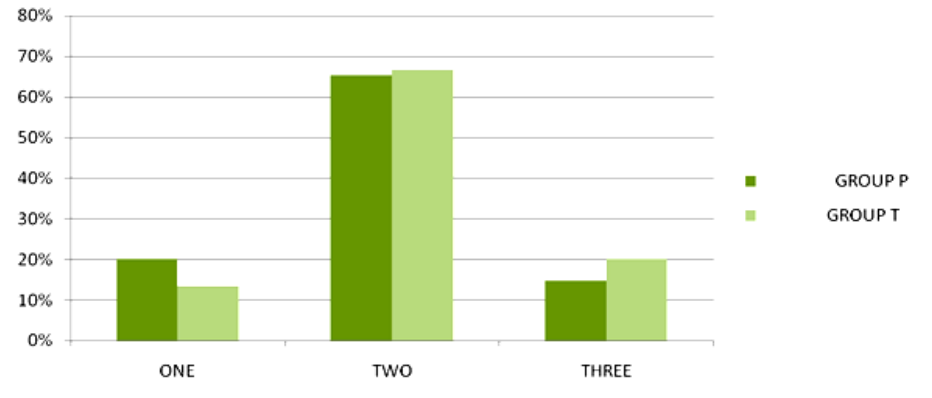

Figure 3: Total doses of rescue analgesia**.**

Complication	Group P Postoperative	Group T Postoperative	p value
Nausea and Vomiting	13	32	**0.001 ***
Hypotension	0	0	-
Bradycardia	0	0	-
Respiratory depression	0	0	-

Table 5. Complications.

There was no statistically significant difference noted in systolic, diastolic, mean blood pressure(Mm hg), pulse rate and SpO2 at various time interval in the first 24 hrs in both the groups(P >0.05).

IV. Discussion

Although pain is a predictable component of the postoperative experience, inadequate management of pain is very common. Inadequately treated post-operative pain may result in altered physiological and psychological changes that increase morbidity and mortality in patients. In our randomized study, we tried to demonstrate the comparative analgesic efficacy and safety profile of paracetamol vis-à-vis the commonly used drug tramadol, both administered intravenously.

Most of the opioid agonists are suitable to treat acute pain. However their use is not always without side effects commonly nausea, vomiting, pruritis, excessive sedation and respiratory depression that limit their generous use in treating patients with acute post-operative pain. Also, opioid agonists are limited by their availability in recent days.

Tramadol is a weak agonist at μ opioid receptor and is commonly used to treat post-operative pain in the dose of 1-2mg/kg. However, analgesic effect in patients of postsurgical period is not always proved to be adequate at its regular dosage.

Paracetamol has been widely used for over a century as an effective analgesic and as an antipyretic agent with an established efficacy and tolerability. Indeed, paracetamol is currently the most commonly prescribed drug for the treatment of postoperative pain as mono therapy or as multimodal therapy. Paracetamol has the advantage of being available in oral, rectal or intravenous formulations.

The intravenous route is especially advantageous in postsurgical situations when oral (e.g. infections with severe fever or vomiting or post-operative period where nil- per- oral is maintained) or rectal (e.g. high variability in uptake and bioavailability) routes are not suitable or effective.

has been found to be a useful antipyretic and moderately potent analgesic across various conditions, patient populations and circumstances. The remarkable tolerability and lack of serious side effects at clinical doses explain its popularity. However variable bioavailability of oral formulations and inability to use it in 'nil per oral' patients limited its use in perioperative conditions. With the introduction of a stable intravenous (IV) formulation of Paracetamol, it is now possible to use its analgesic effect in perioperative patients.

The study was designed to evaluate the analgesic effect of infusion Paracetamol for post-operative analgesia. It was compared with the commonly used drug IV Tramadol. We evaluated the effect of intravenous Paracetamol on post-operative pain. Sedation, nausea and vomiting which is common side effect of tramadol were also compared to iv paracetamol on patient who underwent lower abdominal surgery under general anaesthesia.

In our study, postoperative pain was assessed using a 10 cm Visual Analogue Scale (VAS) where '0' indicated 'No Pain' and '10' indicated 'worst imaginable pain'. The p value for VAS scores in Group P and Group T at 0,1,3,6,9,12 and 24 hrs were 0.66, 0.13, 0.08, 0.33, 0.17, 0.10and 0.25. All the p values were >0.05 so there was no significant difference in the VAS scores postoperatively between paracetamol and tramadol group.

The duration of analgesia or the characteristic of analgesia in both the groups were not statistically significant. The mean for Group P and Group T were 372.40±60.40 and 369±64.39 and the p value is 0.80 which is non-significant.

Rescue analgesic was provided when VAS score was >3. The number of doses of rescue analgesia required in postoperative period was similar.20% in Group P and 13.33% in Group T required 1 dose of rescue analgesia. 65.33% of patients in Group P required 2 doses of rescue analgesics while 66.67% of patients in Group T required 2 doses of rescue analgesics.14.67% in Group P and 20% in Group T required 3 doses of rescue analgesia.

The data from our study have highlighted the fact that both paracetamol and tramadol have good analgesic action. The mean score of VAS Scale in the two groups were similar and difference was not significant. The analgesic efficacy was evaluated and no statistical difference was found between the two groups regarding postoperative pain score, rescue analgesia consumption and the duration of analgesia.

Hale Yarkan. et al.,(2011).9 in their study evaluated the efficacy and quality of recovery with intravenous(iv) paracetamol versus tramadol for postoperative analgesia after adenotonsillectomy No

statistically significant difference was found in postoperative pain scores in either group which was similar to our study. Agitation scores, Aldrete scores, sedation scores, and number of patients who received rescue analgesia and time to administration of rescue analgesia were similar in both groups. The IV formulation of paracetamol was associated with similar analgesic properties and early recovery to that of IV tramadol after adenotonsillectomy in children.

Pendeville PE, et al.10 did study on tramadol vs. paracetamol in analgesia after day-case tonsillectomy in children. Postoperative pain score in recovery, numerical pain scale in the ward and at home, and rescue analgesic use were significantly lower in the tramadol group which however is not similar to our study. In their study however they administered high dose of tramadol (3mg/kg), this might be the reason that may have contributed to the pronounced low post-operative scores in their study.

Kilcaslan A et al.11 studied the effects of intravenous paracetamol on post-operative analgesia and tramadol consumption in caesarean operation. They concluded with the result that paracetamol is a safe and effective treatment option in post-operative pain for combination with tramadol, as it produces effective analgesia and reduces tramadol consumption.

Alhashemi (2006) et al.12 studied the analgesic effects of intravenous paracetamol vs. ibuprofen after caesarean section. In recovery room, morphine 0.05 mg · kg−1 IV was administered to all patients followed by patient-controlled analgesia (PCA) using morphine (2 mg dose, 10 min lockout, no infusion). No other analgesics or NSAIDs were allowed for 48 h Postoperatively, visual analogue scale(VAS) score was determined q1h for 4 h then q4h for 48 h. Data presented as mean ± SD.VAS scores over time were similar in both groups ($P = 0.155$). Patients in groups P and I received a total of 99.3 ± 37.7 and 93.3 ± 31.4 mg morphine, respectively ($P = 0.589$). They concluded that IV paracetamol is an effective alternative to oral ibuprofen for post-caesarean section analgesia.

J. A. Alhashemi and M. F. Daghistani (2006)13 studied the effects of intraoperative i.v. acetaminophen vs i.m. meperidine on post-tonsillectomy pain in children. They concluded that compared with i.m. meperidine, i.v. acetaminophen provided adequate analgesia, less sedation and earlier readiness for recovery room discharge among paediatric patients undergoing tonsillectomy.

Landwehr S, Kiencke P, Giesecke T, Eggert D, et al.14 assesed the clinical efficacy of IV paracetamol 1 g and IV metamizol 1 g on a 24-h dosing schedule in randomized, double-blinded, placebo-controlled study of 38 ASA physical status I-III patients undergoing retinal surgery. They concluded with the result that IV paracetamol 1g has a similar analgesic potency as IV metamizol 1g for postoperative analgesia after retinal surgery.

D. Hynes, M. McCarroll et al.,(2006).15 studied the analgesic efficacy of parenteral paracetamol (Propacetamol) and diclofenac in post-operative orthopaedic pain. They came with the conclusion that both active treatments were superior to placebo, and the overall efficacy of two intravenous infusions of propacetamol 2 g(equivalent to 1 g of paracetamol), 5 h apart, was not statistically different from that provided by a single intramuscular injection of diclofenac 75 mg over the first 5h post-dose and over the total 10-h study period. The safety was good.

In our study the p value for nausea and vomiting between the Group P and Group T is p-0.001(<0.05) which was significant. Increased incidence of nausea and vomiting was observed with tramadol group as compared to the paracetamol group which makes paracetamol infusion a better analgesia for cases which are associated with more incidence of nausea and vomiting such as gynecological operation.

Hale Yarkan et al.(2011)9 in their study found out that the frequency of nausea was not significantly different between the two group(22% in the paracetamol group and 38% in tramadol group)(P=0.171). Postoperative vomiting occurred in 19% of paracetamol group and 34% tramadol group which shows that paracetamol group has less post-operative nausea and vomiting which was similar to our study.

Dejonckheere M et al.,(2001)16 compared intravenous tramadol to propacetamol for postoperative analgesia following thyroidectomy. More patients complained of nausea and vomiting (p=0.01) during the first two hours following injection of tramadol which was a similar to our study.

Sedation was assessed using a 4-point scale, where 0 = fully awake, 1 = awake but drowsy, 2 = sleeping but arousable by light touch or speech, and 3 = sleeping, not arousable (Hale Yarkan Uysal et al).9 In our study the mean sedation score at 1 hour post infusion for paracetamol group was 0.48±0.60 and tramadol group was 2.14±0.60 (p<0.001). At the 3rd, 6th and 9th hour the p value were significant ie p<0.001 which shows that the tramadol group were more sedated but toward the end i.e, by 24th hour sedation scores for both the groups were similar.

J. A. Alhashemi and M. F. Daghistani12 found similar results as our study. Ramsay sedation scores were 3(SEM 0.2) and 4(SEM 0.3) for the acetaminophen and meperidine groups, respectively (P<0.05). Patients in the meperidine group continued to be more sedated 5 min after arrival in recovery (P<0.05). Acetaminophen group patients achieved an Aldrete score of 10 sooner than those in the meperidine group (P=0.005). They

concluded that compared with i.m. meperidine, i.v. acetaminophen provided adequate analgesia, less sedation and earlier readiness for recovery room discharge among paediatric patients undergoing tonsillectomy.
Hale Yarkan et al.,(2011)9 in their study found no significant difference in sedation score.(p=0.027). They used 1mg/kg tramadol whereas in our study 2mg/kg tramadol was used which may be the reason for the cause of more sedation in tramadol group.

V. Conclusion

From the present study it was observed that intravenous paracetamol infusion is a safer and effective non-opioid analgesic for the treatment of postoperative pain in patient undergoing infraumbilical surgeries. The analgesic efficacy was comparable to that of tramadol which is a standard analgesic used all over the world. Gynecological operation involving lower abdominal surgery is always associated with more incidence of nausea & vomiting and use of intravenous tramadol aggravates the incidence of post-operative nausea and vomiting (PONV). This study provides supportive evidence on the efficacy and tolerability of ready to use i.v. paracetamol 1 gram solution as mono-therapy or as an alternative to tramadol with fewer side effects.

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