

International Journal of Clinical Obstetrics and Gynaecology

ISSN (P): 2522-6614
ISSN (E): 2522-6622
© Gynaecology Journal
www.gynaecologyjournal.com
2019; 3(6): 103-109
Received: 21-09-2019
Accepted: 25-10-2019

Dr. S Mirunalini
Professor, Department of
Obstetrics and Gynaecology, Rajah
Muthiah Medical College and
Hospital, Annamalai University,
Chidambaram, Tamil Nadu, India

Dr. Subbulakshmi Sundaram
Associate Professor, Dept of
Anesthesiology, Rajah Muthiah
Medical College and Hospital,
Annamalai University,
Chidambaram, Tamil Nadu, India

Dr. C Jenitha
Post Graduate Student, Dept of
Obstetrics and Gynaecology, Rajah
Muthiah Medical College and
Hospital, Annamalai University,
Chidambaram, Tamil Nadu, India

Corresponding Author:
Dr. S Mirunalini
Professor, Department of
Obstetrics and Gynaecology, Rajah
Muthiah Medical College and
Hospital, Annamalai University,
Chidambaram, Tamil Nadu, India

Comparative study of analgesic effect of paracetamol infusion versus intramuscular tramadol injection after gynaecological surgeries: A prospective randomised clinical trial

Dr. S Mirunalini, Dr. Subbulakshmi Sundaram and Dr. C Jenitha

DOI: <https://doi.org/10.33545/gynae.2019.v3.i6b.400>

Abstract

Background: Postoperative pain inadequately treated result in suffering, as well as multiple physiological and psychological consequences which may adversely affect perioperative outcomes and contribute to increased length of stay. Paracetamol a NSAID is an Analgesic and Antipyretic agent. Tramadol an Opioid, has been shown to provide effective analgesia after both intramuscular and intravenous administration for the treatment of postoperative pain. This prospective study is to compare the Analgesic efficacy of intravenous paracetamol and intramuscular tramadol postoperatively.

Aims and Objectives: To compare the effect of Paracetamol infusion versus intramuscular Tramadol injection as post operative analgesia after gynaecological surgeries over 48 hours.

1. To compare patients' demand for analgesia and VAS score at different period of time over 48 hours.
2. To compare the number of doses given over 48 hours including the Rescue Analgesia given in less than 6 hours interval between doses
3. To compare the number of rescue analgesia needed in between the 6 hours interval between doses.

Methods: The study was conducted in the Department of Obstetrics and Gynaecology, Rajah Muthiah Medical College and Hospital, Annamalai University, Chidambaram from October 2018 – October 2019 in Gynaecological patients undergoing surgery selecting patients as per the Predetermined Inclusion and Exclusion criteria. and Postoperatively, the calculated doses of, in Group A (n=30) Paracetamol infusion and in Group B (n=30) Intramuscular Tramadol injection, given using Visual Analogue Scale (VAS) score for assessment of pain intensity

Results: Number of Patients Demand for Analgesia had a Significant (p-value=0.01) difference when VAS score ≥ 4 denoting less number of Demand in Group A. The total number of doses needed over 48 hours was less in Group A. The number of Rescue Analgesia needed in both groups had no Statistical difference. Also, the need for another drug was significantly less in Group A. Also, in all cases in Group B another drug was used as rescue analgesia but none in group a needed another drug as rescue analgesia. No PONV (Post operative nausea and vomiting) in Group A against 63.3% in Group B.

Conclusions: Paracetamol infusion is an effective and even superior post operative analgesic and safer alternative to intramuscular tramadol injection post operatively.

Keywords: Analgesia, paracetamol, tramadol, postoperative gynaecological cases, vas score

Introduction

Pain is a predictable component of any surgical procedure. IASP (International Association for the Study of Pain) defines Pain as "An Unpleasant Sensory and Emotional Experience in association with either actual or potential tissue damage or described in terms of such damage). Inadequately treated postoperative pain result in suffering, as well as multiple physiological and psychological consequences (e.g., impaired gastrointestinal motility, and impaired wound healing) which may adversely affect perioperative outcomes and contribute to increased length of stay^[13].

For decades Opioids and NSAIDs have been used in postoperative analgesia. They are not entirely devoid of undesirable effects like postoperative nausea and vomiting (PONV), respiratory depression, sedation, gastrointestinal bleeding and renal injury among others^[1]. Intravenous Paracetamol was approved and made available in United States in 2010. Inj. Paracetamol IV is an analgesic and antipyretic agent, interferes neither with platelet nor kidney functions nor does it present the unwanted side effects of NSAIDs^[14].

Tramadol has been shown to provide effective analgesia after both intramuscular and IV administration for the treatment of postoperative pain. The currently used postoperative analgesic in our hospital for all post operative patients is Intramuscular Inj. Tramadol. Therefore this prospective, randomized double-blinded experimental study was designed to compare IV Paracetamol and IM Tramadol for their Effectiveness as postoperative analgesia after Gynecological surgeries using VAS score [12].

Methods and Materials

This study included a total of 60 Gynaecology patients attending the Department of Obstetrics and Gynaecology & posted for gynaecological surgeries and planned for evaluation of analgesic effect of the drugs. The participants have been divided into two groups (SG and CG) of 30 each. SG was given Paracetamol infusion and CG was given intramuscular Tramadol to compare & analyze the level of satisfaction, the demand for analgesia (VAS score), and the number of doses and the rescue analgesia

requirement between the groups over 48 hours. BMI of the patient calculated. Liver function test and Renal function test noted. Dose of injection paracetamol calculated as 15 mg/kg/dose not exceeding 4g/day. Dose of injection tramadol calculated as 4 to 8mg/kg/day in divided doses not exceeding 400 mg/day After completion of the surgery over the study period of 48 hours, the patient visited at 0, 30 minutes, 1 hour. And then every hour till 12 hours from surgery. And then every four hours till next 12 hours. And every six hours till next 24 hours.

First dose of the drug given when VAS > 4. Maximum interval between two doses is equal to or > 6 hours. Minimum interval between two doses is 4 hours. Any dose given at or > 4 hours and less than 6 hours when VAS > 4 is Rescue Analgesia. Patient’s demand for Analgesia noted. Side effects noted. At 24 and 48 hours LFT and RFT repeated.

Results

Statistical evidence with P<0.05 considered significant

Table 1: Age distribution of the study population

	Minimum	Maximum	Mean	SD	Median	IQ Range
Group A (n=30)	17	65	45.9	9.5	46.0	41.5, 50.5
Group B (n=30)	28.0	70.0	46.2	10.4	45.5	39.75, 50.0

Independent t- test & Mann Whitney U test used; p = 0.91 p-value <0.05 is significant

The mean age of the participants in Group A was 45.9 ± 9.5 years and Group B was 46.2 ± 10.4 years. The statistical tests

that both the groups belonged to comparable age groups. (p>0.05). [Table 1]

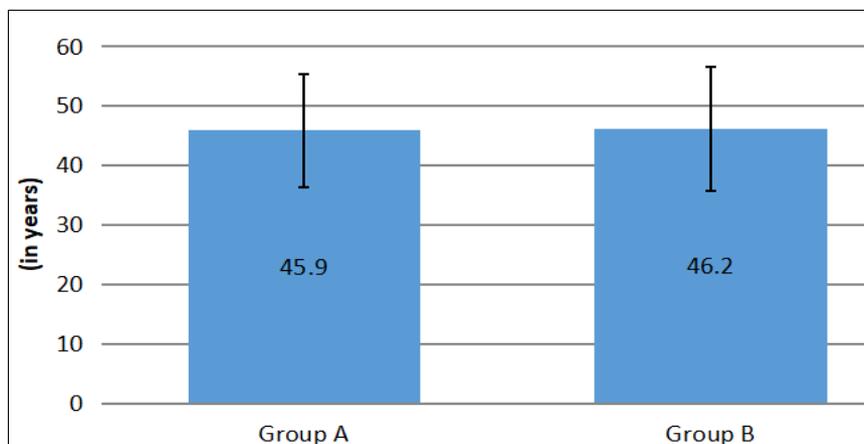


Fig 1: Age distribution

Table 2: Comparison of frequency of subjective need of analgesic when VAS score <4

	Minimum times	Maximum times	Mean	SD	Median	IQ Range
Group A (n=21)	0	3	0.17	0.6	0	0, 0
Group B (n=21)	0	3	0.20	0.7	0	0, 0

Independent t- test & Mann Whitney U test used; p=0.83 p-value <0.05 is significant;

Table 3: Comparison of frequency of subjective need of analgesic when VAS score ≥ 4

	Minimum times	Maximum times	Mean	SD	Median	IQ Range
Group A (n=21)	4	9	5.4	1.3	5	4.75, 6.0
Group B (n=21)	4	9	6.3	1.6	7	4.75, 7.0

Independent t- test & Mann Whitney U test used; p=0.01 p-value <0.05 is significant;

Moreover, when the subjective need for the analgesia was compared in VAS score <4 and VAS score ≥ 4 patients of both the intervention groups, (Table 2 and 3) significantly higher

need (7 times) was felt by the group B VAS score ≥ 4 patients than their counterpart (5 times), whereas VAS score < 4 group hardly felt the need of the same (Median = 0).

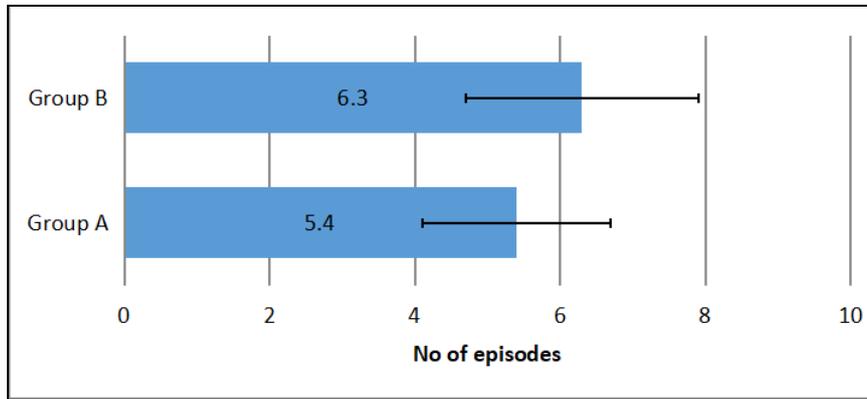


Fig 2: Subjective need of analgesia in VAS score ≥ 4

Table 4: Average No. of times VAS score <4

	Minimum times	Maximum times	Mean	SD	Median	IQ Range
Group A (n=21)	12	17	15.6	1.3	16	15, 16.25
Group B (n=21)	12	17	14.7	1.6	14	14, 16.25

Independent t- test & Mann Whitney U test used; p=0.01 p-value <0.05 is significant;

Table 5: Average No. of times VAS score ≥ 4

	Minimum times	Maximum times	Mean	SD	Median	IQ Range
Group A (n=21)	4	9	5.4	1.3	5	4.75, 6
Group B (n=21)	4	9	6.3	1.6	7	4.75, 7

Independent t- test & Mann Whitney U test used; p=0.01 p-value <0.05 is significant;

Visual Analog Scale rating was compared for the patient's satisfaction for the given analgesic and VAS score < 4 was considered satisfactory while VAS score ≥ 4 was considered continued pain perception and dissatisfaction among the groups. Table 4 & 5 show that out of 21 serial measurements, the median number of times the group A patients have had VAS

score <4 were significantly higher (16) than group B patients(14). Concordantly the median number of times the patients with VAS score ≥ 4 were significantly lower (5) in group A than group B (7). This gives us clue about the drug with better analgesic effect.

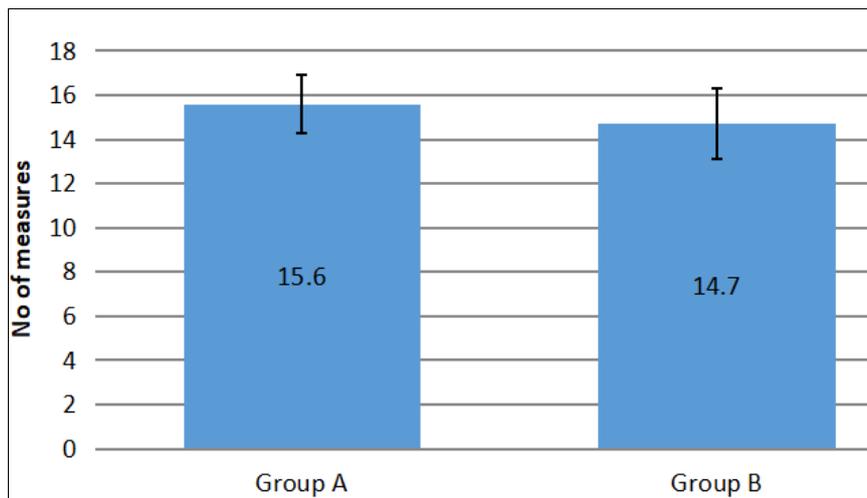


Fig 3: Average frequency of VAS score < 4

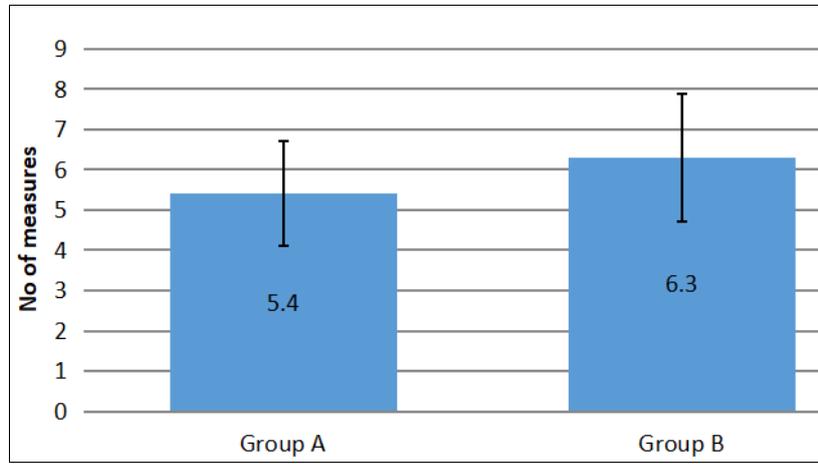


Fig 4: Average frequency of VAS score ≥ 4

Table 6: Number of add-ons of subsequent doses with start from initial dose

	Minimum times	Maximum times	Mean	SD	Median	IQ Range
Group A (n=21)	4	9	5.4	1.3	5	4.75, 6.0
Group B (n=21)	4	8	6.1	1.3	6.5	4.75, 7.0

Independent t- test, $p=0.05$ & Mann Whitney U test, $p=0.04$ p-value <0.05 is significant;

Table 6 shows the numerical comparison of subsequent dosing in both the groups. The tramadol group required significantly higher number of (median = 6.5) subsequent doses than the Paracetamol group (median= 5).

Table 7: Comparison of subsequent analgesia with start from initial dose

No of doses	Groups				χ^2	p-value
	Group A (n=30)		Group B (n=30)			
	No. Of patients	Percentage	No. Of patients	Percentage		
5 or less	18	60.0	9	30.0	5.5	.02
6 or more	12	40.0	21	70.0		

Pearsons Chi-square test used; p-value <0.05 is significant

When these numbers of subsequent doses (in table 6) were translated to subgroups of ≤ 5 and ≥ 6 (Table 7), there were significantly larger proportion of patients in the group B (70%) who receive 6 or more doses than those in group A (40%). This also highlights the effectiveness of the drug used in group A patients.

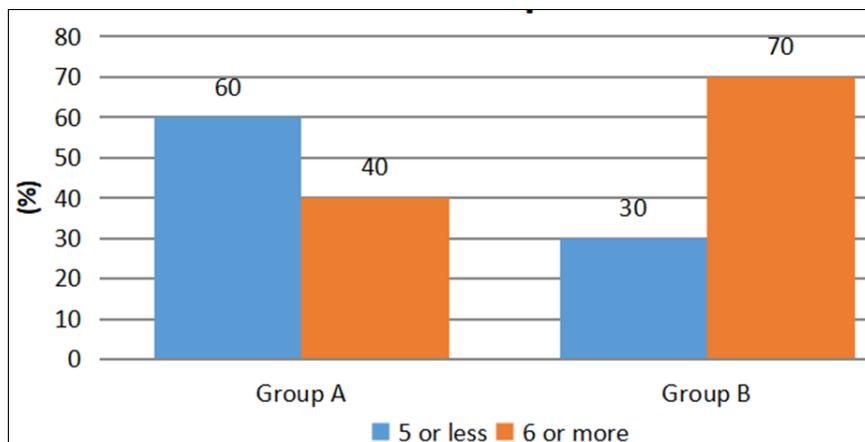


Fig 5: Need of subsequent doses

Table 8: Rescue analgesia comparison

No of doses of RA needed	Groups				χ^2	p-value
	Group A (n=30)		Group A (n=30)			
	No. of patients	Percentage	No. of patients	Percentage		
0	26	86.7	24	80.0	1.8	.73
1	4	13.3	5	16.7		
2	0	0.0	1	3.3		

Fishers exact test used; p-value <0.05 is significant

The requirement of rescue analgesia was lesser in both the groups in the first 48 hours. In group A, only four patients required RA that was given only once while the remaining 26 didn't receive any of it. Virtually in group B, 24 patients didn't

require RA while five required once and one person required twice during the first 48 hours. There was no statistical difference between the groups as the median requirement was found to be 0 in both the groups. [Table 8]

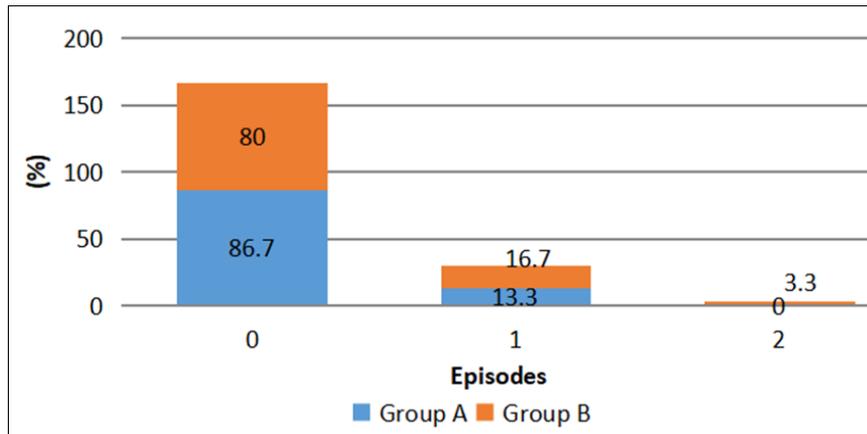


Fig 6: Need for rescue analgesia

Table 9: Requirement of another drug

Required	Groups				χ ²	p-value
	Group A (n=30)		Group B (n=30)			
	No. of patients	Percentage	No. of patients	Percentage		
Yes	2	6.7	8	26.7	4.3	.03
No	28	93.3	22	73.3		

Pearson's chi-square test used; p-value<0.05 is significant

The need for another drug was compared and described in table 9. More than quarter of the patients in group B (26.7%) required additional drug while only 6.7% of group A required additional

drug. This increased necessity found in group B patients than group A was statistically significant [Table 9].

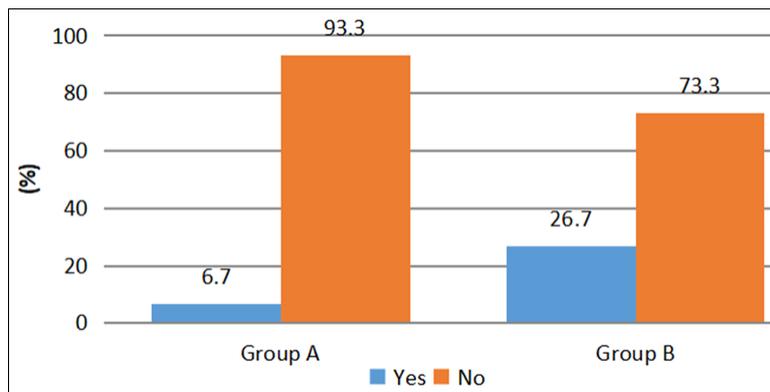


Fig 7: Need of another drug

Table 10: Comparison of side effects

Vomiting	Groups				χ ²	p-value
	Group A (n=30)		Group B (n=30)			
	No. Of patients	Percentage	No. Of patients	Percentage		
Present	0	0.0	11	63.3	13.5	<.001
Absent	30	100.0	19	36.7		

Pearson's chi-square test used; p-value<0.05 is significant

In addition to this none of the group A patients has had side effects while 63.3% of those in the other group have developed

side effects. This difference in occurrence was also found to be statistically significant. (Table 10)

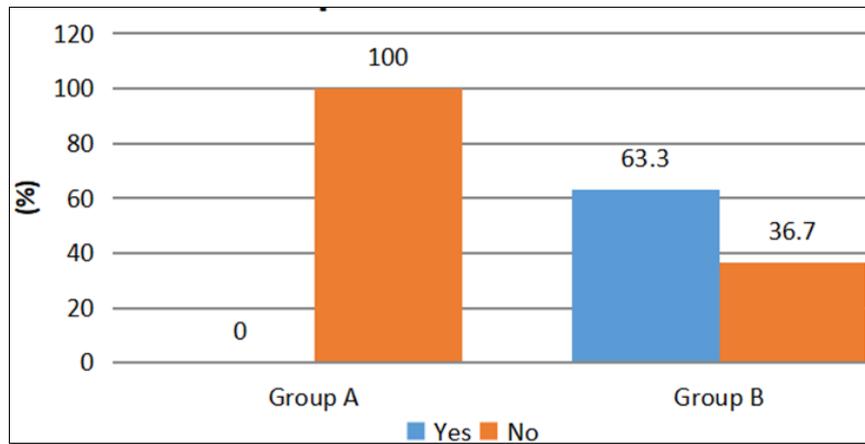


Fig 8: Comparison of side effects

Also No derangements in RFT and LFT postoperatively in both groups.

Discussion

Effective postoperative pain management improves clinical outcome. Opioids are widely used. However, their adverse effects such as PONV (Post operative nausea and vomiting), itching, and respiratory depression are of concern.

IV paracetamol being evaluated in hysterectomy, major surgeries, coronary by-pass, and orthopedic surgical procedures. Paracetamol, an active metabolite of phenacetin offers a crucial analgesia. Can be administered orally, rectally, intramuscularly and IV. Excretion takes place following conjugation in the liver. Peak action at 1 h and acts for 4–6 h. At excess dose Hepatic toxicity can occur^[1, 3].

Phenacetin metabolises to active Paracetamol which has Central Analgesic effect. Inhibits cyclooxygenases. Intravenous paracetamol enter BBB easily and its analgesic action starts within 15–20 min. Usual adverse effects seen with NSAIDs not found with Paracetamol.

Tramadol acts centrally. It is a synthetic opioid, an analgesic, Inhibits noradrenaline and serotonin reuptake. Thus transmission of pain impulses are modified giving analgesic effect. The lesser chance of respiratory depression, organ toxicities or abusiveness makes Tramadol a safer one. Tramadol is safe in those with cardiopulmonary instability, elders, obese, in patients with malfunctioning kidney and liver, and in NSAID contraindication.

Here in this study analgesic efficacy of intravenous Paracetamol as opposed to Intramuscular Tramadol injection studied in post surgical Gynaecological cases and Paracetamol infusion observed to be Statistically Efficient.

Nikoda *et al.*^[4] There are no studies comparing the efficacy of Paracetamol and Tramadol for postoperative analgesia for Laparotomies and so this study done by them. Studied the efficacy of IV paracetamol over IV tramadol in laparotomies. Showed IV paracetamol as a crucial nonopioid in multimodality therapy in immediate postsurgical pain, iv paracetamol is a safer alternative to tramadol, less PONV (Post operative nausea and vomiting) with paracetamol. Kela *et al.*^[2] Compared the efficacy of iv paracetamol vs iv tramadol in cardiothoracic surgery post surgically. Fall in VAS Score had no difference $p > 0.05$. Tramadol needed more Rescue Analgesia. No significant difference for PONV. Akcali *et al.*,^[10] in post extracorporeal shockwave lithotripsy procedure found comparable efficacy among iv paracetamol, tramadol and lornoxicam. Cattabriga *et al.*^[5] In postoperative median sternotomies paracetamol was

seen better when used along with tramadol. Uysal *et al.* In children after postadenotonsillectomy, IV paracetamol had early recovery, but comparable analgesic effect when compared with tramadol. Sinatra *et al.*^[6] after orthopedic surgical procedures IV paracetamol had speedy onset of analgesia against Tramadol. When Rescue analgesia needed Morphine used. Lee *et al.*,^[7] Post- Thyroidectomy study. Here paracetamol was seen to be an alternative to ketorolac for pain prevention and in both VAS score was similar. Pendeville *et al.*^[8] After day care tonsillectomies in children, postoperative analgesic scores (Children's hospital of eastern ontario pain scale) for recovery, in ward and at home, and rescue analgesic use were lower with the analgesic tramadol against paracetamol. Cakan *et al.*,^[9] After lumbar laminectomy and discectomy. repeated IV paracetamol against placebo Showed lower VAS scores, reduced PONV and more satisfaction in patients with iv paracetamol. Hiller *et al.*,^[11] After spine surgeries in children and adolescents IV paracetamol as adjuvant to oxycodone, improved analgesia, but did not reduce the use of oxycodone over 24 hours.

Conclusion

Injection Paracetamol infusion group had better patient satisfaction with decreased Demand for Analgesia, need for decreased number of doses of Analgesia, and lesser need for another drug and no side effects as compared to Intramuscular Tramadol injection group with no significant difference in need for Rescue analgesia.

Thus Paracetamol infusion is an effective and even superior post operative Analgesic and safer Alternative to intramuscular Tramadol injection post operatively.

Conflict of interest

There is no conflict of interest to be declared.

Authors contribution

All Authors contributed to this project and article equally. All Authors read and approved the final manuscript.

References

1. Mohammed Shahid BP, Manjula BV, Sunil I. Paracetamol vs Tramadol for postoperative analgesia. A comparative study of Intravenous Paracetamol and Intravenous Tramadol for postoperative analgesia in laparotomies. Mohammed.
2. Kela M, Umbarkar S, Sarkar M, Garasia M. Comparative study of efficacy of IV paracetamol vs IV tramadol for postoperative pain relief after cardiac surgery. Bombay Hosp J. 2011; 53:582-6.

3. Macario A, Royal MA. A literature review of randomized clinical trials of intravenous acetaminophen (paracetamol) for acute postoperative pain. *Pain Pract.* 2011; 11:290-6.
4. Nikoda VV, Makarova VV, Maiachkin RB, Bondarenko AV. Clinical aspects of analgesia with intravenous paracetamol in the early postoperative period. *Anesteziol Reanimatol.* 2006; (6):54-8.
5. Cattabriga I, Pacini D, Lamazza G, Talarico F, Di Bartolomeo R, Grillone G *et al.* Intravenous paracetamol as adjunctive treatment for postoperative pain after cardiac surgery: A double blind randomized controlled trial. *Eur J Cardiothorac Surg.* 2007; 32:527-31.
6. 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; 102:822-31.
7. Lee SY, Lee WH, Lee EH, Han KC, Ko YK. The effects of Paracetamol, ketorolac, and Paracetamol plus morphine on pain control after thyroidectomy. *Korean J Pain.* 2010; 23:124-30.
8. Pendeville PE, Von Montigny S, Dort JP, Veyckemans F. Double blind randomized study of tramadol vs. paracetamol in analgesia after day case tonsillectomy in children. *Eur J Anaesthesiol.* 2000; 17:576-82.
9. Cakan T, Inan N, Culhaoglu S, Bakkal K, Basar H. Intravenous paracetamol improves the quality of postoperative analgesia but does not decrease narcotic requirements. *J Neurosurg Anesthesiol.* 2008; 20:169-73.
10. Akcali GE, Iskender A, Demiraran Y, Kayikci A, Yalcin GS, Cam K *et al.* Randomized comparison of efficacy of paracetamol, lornoxicam, and tramadol representing three different groups of analgesics for pain control in extracorporeal shockwave lithotripsy. *J Endourol.* 2010; 24:615-20. [PubMed] [Google Scholar]
11. Hiller A, Helenius I, Nurmi E, Neuvonen PJ, Kaukonen M, Hartikainen T *et al.* Acetaminophen improves analgesia but does not reduce opioid requirement after major spine surgery in children and adolescents. *Spine (Phila Pa 1976).* 2012; 37:E1225-31.
12. Suhail Bandeym, Vivek Singh. Comparison between IV Paracetamol and Tramadol for Postoperative Analgesia in Patients Undergoing Laparoscopic Cholecystectomy. *J Clin Diagn Res.* 2016; 10(8):UC05-9. doi: 10.7860/JCDR/2016/21021.8274. Epub 2016 Aug 1.
13. Pesut B, Johnson J, Can J. *Nurs.* 1997; 10(4):86-107. Evaluation of an acute pain service.[PubMed] [Ref list]
14. Duggan ST1, Scott LJ. Wolters Kluwer Health, Adis, Auckland, New Zealand. demail@adis.co.nz. Intravenous paracetamol (acetaminophen) in surgery.