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Role of intravenous paracetamol for control of pain in post operative cases at tertiary care centre in Northern India

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Abstract

Introduction

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.[1] Accurate management of pain is one of the most important challenges of health care providers. One of the most important concerns of the patients in postoperative period is postoperative pain. Effective relief of postoperative pain is one of the primary targets as postoperative pain also affects the clinical outcomes of the surgeons.[4,5]

Materials and methods

The present study is based on 50 cases, who underwent open cholecystectomy through Kocher's subcoastal incision. 25 are study cases and 25 control cases admitted in the Surgery Department, Guru Nanak Dev Hospital, Amritsar. This study is conducted for the time period of one and half to two years. The study cases (group A) are given iv Paracetamol 1000 mg and inj Tramadol post operatively and control cases (group B) are given, only inj. Tramadol at 0 hour, 8 hour, 16 hour and 24 hours for post-operative pain management. This study deals with the role of iv paracetamol for control of pain in operated cases of open cholecystectomy. The effect of each dose in terms of pain, perception and any change in vitals are checked post operatively at 8 hour, 16 hour and 24 hours in both study cases and control cases.

Results

The result was based on age, sex, duration of symptoms, BMI, mean tramadol dose, BP, vitals, VAS score, length of hospital stay, side effects.

Conclusion

Data were collected related to amount of tramadol used, VAS score, length of hospital stay and side effects. The combination of intravenous paracetamol and tramadol is similar to intravenous tramadol alone in terms of pain control but is better than latter in terms of side effects like nausea, vomiting, dizziness and headache. So combination of intravenous paracetamol and tramadol could be preferred over intravenous tramadol alone during the post-operative period.

Keywords: Pain, postoperative pain, Paracetamol, tramadol, VAS score, length of hospital stay and side effects

Introduction

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage.[1]

Pain is a subjective feeling and cannot be defined satisfactorily. It varies from person to person. Acute pain is a very complex sensation which mainly extends beyond simple nociceptor input, the central processing of which is modulated strongly by emotive elements like fear, anxiety, depression and previous experience of pain. The word 'unpleasant' in the definition comprises the whole range of disagreeable feelings from being merely inconvenienced to misery, anguish, anxiety, depression and desperation, to the ultimate cure of suicide.[2]

Pain is not simply, a perception, it is a complex phenomenon or syndrome, only one component of which is the sensation actually reported as pain.

Tissue injury leads to nociception by direct mechanical and thermal damage to nerve endings, to inflammation by the release of chemicals and enzymes from nerves and damaged tissue and to hyperalgesia generated by algogenic substances & sprouting of damaged nerves to injured tissue.

Evidence has accumulated that bradykinins and the products of arachidonic acid metabolism promote the pain and hyperalgesia associated with inflammation. This may be the result of potentiation of bradykinin effect of prostaglandins and bradykinin itself may stimulate synthesis and release of prostaglandin by activation of phospholipase A. With exception of non-nucleated RBC, all cells of the body can synthesize prostaglandins, prostacyclin's and thromboxane which may be metabolized to prostaglandin endoperoxides by cyclooxygenase, or to hydroperoxyl derivatives by lipoxygenase pathways.[3]

Postoperatively, there is no clearly defined demarcation between acute and chronic pain. In general, acute pain is associated with distinct disease or injury and it is assumed that time course of the pain is limited to the period of repair of injury. However, some acute states may progress to become chronic.

Accurate management of pain is one of the most important challenges of health care providers. One of the most important concerns of the patients in postoperative period is postoperative pain. Effective relief of postoperative pain is one of the primary targets as postoperative pain also affects the clinical outcomes of the surgeons.[4,5]

Uncontrollable acute pain may result in prolonged hospital stay and unplanned hospital admissions and increased hospitalizations besides psychological and physiologic effects.[6] The accurate assessment of pain is challenging because pain perception is subjectively reported and may be influenced by the patient's attitude about health, disease, and personal expectations. These differences may be more than just idiosyncratic, for example, men and women not only experience pain differently, they may respond to analgesics differently. Central sensitization and hyperexitability developed after surgical incision results in amplification of postoperative pain. Some short-term reduction in postoperative pain and acceleration of recovery and long- term reduction in chronic pain development, benefits can be obtained in recovery

period by preventing central sensitization through analgesic treatment.[7,8] Pathophysiology of postoperative pain is multifactorial, and predominantly of inflammatory nature from skin incision and tissue damage. Inflammatory cytokines, interleukins and prostaglandins produced from the arachidonic acid pathway induce a neuro-inflammatory soup, which sensitizes peripheral Aδ and C fibers. Ischemia from retraction of tissue, as well as disrupted blood supplies, contributes to pain significantly, characterized by low tissue pH and high lactate levels at the site of incision.[9,10] Opioids are widely used to relieve postoperative pain due to their efficacy and effectiveness.[11] However, there are concerns about their adverse effects such as nausea, vomiting, respiratory depression and dependence. Nonsteroidal anti- inflammatory drugs (NSAIDs) have been widely applied for postoperative pain management after laparoscopic surgery.[12] Several trials showed that NSAIDs, either selective or non-selective, were not superior to placebo on shoulder pain control although they could reduce surgical pain or rescue narcotics requirement.[13]

Pharmacology

Paracetamol:

(N-Acetyl-para-aminophenol) also known as "APAP" or "paracetamol" is one of the most widely used medicines. It is a weak COX-1 and COX-2 inhibitor in peripheral tissues and possesses no significant anti-inflammatory effects. Recent evidence suggests that acetaminophen may inhibit a third enzyme, COX-3, in the central nervous system. COX-3 appears to be a splice variant product of the COX-1 gene. It does appear to selectively inhibit COX activities in the brain, which may contribute to its ability to treat fever and pain.[14] This activity does not appear to be direct inhibition by blocking an active site, but rather by reducing COX, which must be oxidized in order to function.[14]

It also appears that paracetamol might modulate the endogenous cannabinoid system in the brain through its metabolite, AM404. AM404 appears to inhibit the reuptake of the endogenous cannabinoid/vanilloid anandamide by neurons, making it more available to reduce pain. AM404 also appears to be able to directly activate the TRPV1 (older name: vanilloid receptor), which also inhibits pain signals in the brain.[14]

Tramadol:

It is synthetic analogue of codeine. Its analgesic effect is moderate. It is the only drug that acts upon two different mechanisms. One of its metabolites has a poor affinity to μ-opioid receptor without affecting delta and kappa receptors. The second mechanism is reuptake inhibition of neurotransmitters, norepinephrine and serotonin. Tramadol causes less side effects like respiratory depression and sedation encountered with other opioids in postoperative pain treatment.[15,16]

Aims and Objectives

- The aim of this research study was to examine the impact of intravenous paracetamol use in multimodal pain management on decreased opioid consumption.
- To decrease the average length of hospital, stay in the post-operative population.

Materials and Methods

The present study is based on 50 cases, who underwent open cholecystectomy through Kocher's subcoastal incision. 25 are study cases and 25 control cases admitted in the Surgery Department, Guru Nanak Dev Hospital, Amritsar. This study is conducted for the time period of one and half to two years. The study cases (group A) are given iv Paracetamol 1000 mg and inj Tramadol post operatively and control cases (group B) are given, only inj. Tramadol at 0 hour, 8 hour, 16 hour and 24 hours for post-operative pain management. Dosing interval was of 8 hours, first dose being 0 dose. This study dealt with the role of iv paracetamol for control of pain in operated cases of open cholecystectomy. The effect of each dose in terms of pain, perception and any change in vitals are checked post operatively at 8 hour, 16 hour and 24 hours in both study cases and control cases.

Observations

The present study was conducted on 50 patients who underwent open cholecystectomy with subcoastal Kocher's incision under general anesthesia, in the Department of Surgery at Government Medical College, Amritsar. In this study, patients were randomly divided into two groups of 25 each. Post operatively 25 patients (Group A) were given intravenous paracetamol and tramadol, whereas in other group (Group B) were given only intravenous tramadol. All the patients enrolled in the study, completed the study. All the observations and findings were recorded on proforma and following results were obtained.

Table-1 Mean tramadol dose (mg)

TIME (hrs)	Group A	Group B	p-value
0	70.00±28.86	76.00±38.51	0.536
8	54.00±13.84	56.00±21.98	0.702
16	37.00±12.75	50.00±12.50	0.001
24	19.00±10.89	27.00±6.92	0.003
Total	180.00±53.57	209.00±71.76	0.112

In Group A, 1 gm Of Paracetamol was given at 0, 8, 16 and 24 hours whereas in Group B No Paracetamol was given. In group A, the mean amount of Tramadol given at 0, 8, 16 and 24 hours were 70+28.28mg, 54.00+13.60mg, 37.00+12.5mg and 19.00+10.7 mg respectively. Similarly, in Group B, the mean amount of Tramadol given at 0, 8, 16 and 24 hours were 76.00+13.7mg, 56.00+21.5mg, 50.00+12.2 mg and 27.00 + 6.78mg respectively. The p value came out to be 0.112, which is non- significant.

Table-2

VAS SCORE 8 HRS	Group A		Group B		Total	
	No.	%	No.	%	No.	%
4.0	9	36.00	9	36.00	18	36.00
5.0	6	24.00	5	20.00	11	22.00
6.0	10	40.00	11	44.00	21	42.00

p value=0.933

In group A, at 8 hours post operatively, maximum patient 10 (40%) had VAS score of 6, followed by 9 (36%), who had VAS score 4 and rest 6 (24%) had a score of 5 with average vas score of 5.1±0.9. Similarly, in group B at 8 hours postoperatively, maximum patients 11 (44%) had vas score of 6, followed by 9 (36%), who had VAS score 4 and rest 5 (20%) had a score of 5 with average vas score of 5.0±0.9. p value of VAS when studied at 8 hours was 0.933, which is non significant.

Table-3

VAS SCORE 16 HRS	Group A		Group B		Total	
	No.	%	No.	%	No.	%
2.0	13	52.00	11	44.00	24	48.00
3.0	5	20.00	6	24.00	11	22.00
4.0	7	28.00	8	32.00	15	30.00

p value=0.850

In group A, at 16 hours post operatively, maximum patient 13 (52%) had VAS score of 2, followed by 7 (28%), who had VAS score 4 and rest 5 (20%) had a score of 3 with average VAS score of 2.8±0.8. Similarly, in group B at 16 hours postoperatively, maximum patients 11 (44%) had VAS score of 2, followed by 8 (32%), who had VAS score 4 and rest 6 (24%) had a score of 3 with average VAS score of 2.8±0.8. p value of VAS when studied at 16 hours was 0.850, which is non significant.

Table-4

VAS SCORE 24 HRS	Group A		Group B		Total	
	No.	%	No.	%	No.	%
.0	12	48.00	13	52.00	25	50.00
1.0	8	32.00	8	32.00	16	32.00
2.0	5	20.00	4	16.00	9	18.00

p value=0.927

In group A, at 24 hours post operatively, maximum patient 12 (48%) had VAS score of 0, followed by 8 (32%), who had VAS score 1 and rest 5 (20%) had a score of 2 with average VAS score of 0.7±0.8. Similarly, in group B at 24 hours postoperatively, maximum patients 13 (52%) had VAS score of 0, followed by 8 (32%), who had VAS score 1 and rest 4 (16%) had a score of 2 with average VAS score of 0.6±0.7. p value of VAS when studied at 24 hours was 0.927, which is non significant.

Table-5 Hospital stay

Hospital stay (Days)	Group A		Group B		Total	
	No.	%	No.	%	No.	%
1-2	1	4.00	0	0.00	1	2.00
3-4	19	76.00	17	68.00	36	72.00
5-6	4	16.00	7	28.00	11	22.00
>7	1	4.00	1	4.00	2	4.00
Mean stay	3.68±1.19		4.00±1.41		3.89+1.30	
p-value	0.587					

Most patients (72%) range between 3-4 days of hospital stay. Minimum hospital stay was of 2 days and maximum stay at hospital was of 8 days with mean stay of 3.89+1.30 and p-value = 0.587, which are non-significant.

Table-6

SIDE EFFECTS	Group A		Group B		p-value
	No.	%	No.	%	
Nausea	4	16 %	8	32 %	0.185
Vomiting	0	0 %	4	16 %	0.037
Dizziness	2	8 %	5	20 %	0.221
Heartburn	2	8 %	2	8 %	1.00
Headache	3	12 %	4	16 %	0.684
Dry Mouth	2	8 %	3	12 %	0.637
Rash	1	4 %	1	4 %	1.00

Group B patients had nausea (32%), vomiting (16%), dizziness (20%), headache (16%) and dry mouth (12%). Similarly, Group A patients had nausea (16%), dizziness (8%), headache (12%) and dry mouth (8%). However, no vomiting was experienced by group A patients.

Discussion

The present study included two groups (Group A and B). Group A included patients who received intravenous paracetamol and tramadol during the postoperative cases, whereas in group B included patients who received only intravenous tramadol. In this study we reviewed 50 patients. Each group consisted of 25 patients. The datas were collected related to amount of tramadol use, VAS score, duration of stay at hospital and side effects.

In the present study, group A, 1 gm of Paracetamol was given at 0, 8, 16 and 24 hours whereas in Group B no Paracetamol was given. In group A, the mean amount of Tramadol given at 0, 8, 16 and 24 hours were 70+28.28 mg, 54.00+13.60 mg, 37.00+12.5 mg and 19.00+10.7 mg respectively. Similarly, in Group B, the mean amount of Tramadol given at 0, 8, 16 and 24 hours were 76.00+13.7 mg, 56.00+21.5 mg, 50.00+12.2 mg and 27.00 + 6.78mg respectively. The p value came out to be 0.112, which is non-significant.

The study was conducted in 2014, to examine the impact of intravenous paracetamol use in multimodal pain management on decreased opioid consumption and decreased average length of hospital stay in the post colectomy population. In this study Group 1 included patients who had received IVAPAP during postoperative period, Group 2 included patients who had not received IVAPAP. There was difference between the groups on an average Morphine used as determined by Morphine equivalence, the IVAPAP group (Group 1) used less Morphine as compared to non IVAPAP group (Group 2) but the differences were not significant statistically (36 mg% V/s 38 mg%, p=0.0324). However, Group 2 non IVAPAP subjects. Over all received higher Morphine equivalence (1869 mg) of Opioids as compared to Group 1 (1625mg%) while it appeared that IVAPAP provided effective postoperative pain management, and the IVAPAP group tended to have lower opioid use. This study was not able to demonstrate significant difference on opioid use.17

In the present study in Group A, at 8 hours postoperatively, 10 (40%) patients had VAS Score of 6, followed by 9 (36%) patients who had VAS Score 4 and rest 6 (24%) patients had a VAS score of 5 with average VAS Score of 5.1+0.9.

Similarly, in Group B, at 8 hours postoperatively, 11 (44%) patients had VAS Score of 6, followed by 9 (36%) patients who had VAS Score 4 and rest 5 (20%) patients had a VAS score of 5 with average VAS Score of 5.0+0.9. p value was 0.933, which is non-significant.

In the present study in Group A, at 16 hours postoperatively, 13 (52%) patients had VAS Score of 2, followed by 7 (28%) patients who had VAS Score 4 and rest 5 (20%) patients had a VAS score of 3 with average VAS Score of 2.85+0.9.

Similarly, in Group B, at 16 hours postoperatively, 11 (44%) patients had VAS Score of 2, followed by 8 (32%) patients who had VAS Score 4 and rest 6 (24%) patients had a VAS score of 3 with average VAS Score of 2.80+0.8. p value was 0.850, which is non-significant.

In group A at 24 hours, postoperatively 12 (48%) had VAS Score of 0 followed by 8 (32%) had VAS Score of 1 and rest 5 (20%) patients a VAS score of 2 with average VAS Score' of 0.7+0.8.

In group B at 24 hours, postoperatively 13 (52%) had- VAS Score of 0 followed by 8 (32%) had VAS Score of 1 and rest 4 (16%)' patients a VAS score of 2 with average VAS Score of 0.6+0.7. p value was 0.927, which is non-significant.

The study was conducted in 2015, to compare the efficacy of intravenous paracetamol versus IV Tramadol for postoperative pain relief in cases undergoing lower abdominal surgery. 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 intravenous paracetamol 15mg/Kg and Group T received intravenous Tramadol 2mg/Kg. Parameters recorded in study were pain score, sedation score, pulse rate, mean arterial pressure, sp02 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. In this study, the formulation of intravenous paracetamol and IV Tramadol in lower abdominal surgery was associated with similar analgesic properties and early recovery. No significant differences were noted in postoperative pain scores in either group.18

In this study, most patients (72%) ranged between 3-4 days of hospital stay. Minimum hospital stay was of 2 days and maximum stay at hospital was of 8 days with mean stay of 3.89 +1.30 and p-value = 0.587.

Further analysis revealed that 76% of the Group A patients had a length of stay between 3-4 days whereas 68% patients of Group B had a length of stay between 3-4 days.

The study was conducted in 2014, to examine the impact of intravenous paracetamol use in multimodal pain management on decreased opioid consumption and decreased average length of hospital stay in the post colectomy population.The overall length of hospital stay was the same for each group, at four days. Further analysis revealed that approximately 50% (n=17) of the intravenous paracetamol group had a length of stay less than three days, whereas only 30% (n=11) of non-intravenous paracetamol subjects had a length of stay less than three days. Results demonstrated that there was no significant difference in length of stay between the two groups.17

In the present study Group B patients had more nausea (32%), vomiting (16%), dizziness (20%), headache (16%) and dry mouth (12%) as compared to Group A patients.

A single blind randomized controlled interventional study was conducted in 2016, in which 100 women undergoing caesarean section under spinal anesthesia were divided in two groups (50 in each group) using computer generated randomization. One group received intravenous paracetamol 1000 mg and another group intravenous Tramadol 50mg. The drugs were given 6 hourly for 24 hours. In this study 17 out of 50 patients (34%) in Tramadol group had various side effects like nausea, vomiting, dizziness, headache, dryness of mouth and breathing difficulty whereas four out of fifty patients (8%) in Paracetamol group (two patients had nausea, one had dizziness and one had vomiting) had side effects. This difference was statistically significant. There were no neonatal side effects in Tramadol group while one neonate in Paracetamol group had sleeplessness which was not statistically significant.19

Thus, results of our study are in accordance with the result obtained in the previous studies done on the same subject.

Summary and Conclusion

1. The study on role of intravenous paracetamol for control of pain in open post cholecystectomy cases, was done in Govt. Medical College, Amritsar. 50 cases were studied and the cases were divided in 2 groups, 25 each (Group A and Group B).
2. Post operatively 25 patients (Group A) were given intravenous paracetamol and tramadol, whereas in other group (Group B) were given only intravenous tramadol.

3. Data were collected related to age, gender, BMI, tramadol used post operatively and length of stay.

4. There was difference between the 2 group as the total mean tramadol used post operatively, the Group A (180.00+ 53.37 mg) used less tramadol as compared to Group B (209.00+71.76 mg) but the differences were not statistically significant (180.00+53.57 mg v/s 209.00+71.76 mg)

5. Group B patient's subjects received higher intravenous tramadol as compared to group A. this difference in intravenous tramadol dosing between 2 groups appeared to show effective post-operative pain management, and group A tended to have lower intravenous tramadol use, this study was not able to demonstrate a significant difference on intravenous tramadol use. It is likely that relatively small sample size lacked the power needed to demonstrate a significant difference.

6. Most patients (72%) ranged between 3-4 days of hospital stay. The mean stay of both the groups A and B were 3.68±1.19 v/s 4.00±1.41 respectively. It was also observed that 80% (n=20) of Group A had length of stay less than 4 days, whereas only 68% (n=17) of Group B had a length of stay less than 4 days.

7. To summarize, combination of intravenous paracetamol and tramadol is similar to intravenous tramadol alone in terms of pain control but is better than latter in terms of side effects like nausea, vomiting, dizziness and headache. So combination of intravenous paracetamol and tramadol could be preferred over intravenous tramadol alone during the post-operative period.

8. Further research is needed to determine if intravenous paracetamol is effective in reducing overall opioid consumption in a diverse sample of postoperative patients.

Conflicts of interest: None

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