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A Comparitive Study on Efficacy of Paracetamol Alone and Paracetamol with Diclofenac and Paracetamol with Ibuprofen in Post Tonsillectomy Pain Management in Children

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I. INTRODUCTION

Tonsillectomy is one of the commonest procedures performed by otorhinolaryngologists and is associated with severe pain post operatively . A variety of surgical techniques have been employed to reduce post tonsillectomy pain.Various opioid and non opioid analgesics have also been tried to minimize the post tonsillectomy pain . Analgesics in the post tonsillectomy period can be administered through various routes . Post tonsillectomy medication should provide an adequate reduction in morbidity with minimal or no side effects .

II. REVIEW OF LITERATURE

1 . Tawalbeh MI et al conducted a Comparative study of diclofenac sodium and paracetamol for treatment of pain after tonsillectomy in children which concluded saying Diclofenac sodium has a significant effect on decreasing the pain associated with swallowing postoperatively and on the general condition of the patient. Improved oral intake resulted in a lower incidence of nausea and vomiting and allowed safer and earlier hospital discharge.

2 . Hiller A et al conducted study on paracetamol and diclofenac alone and in combination for analgesia after elective tonsillectomy which showed Combined treatment with paracetamol and diclofenac with the dosages used provided clinically only a minor advantage over monotherapy with paraacetamol or diclofenac with respect to postoperative analgesia or the incidence of side-effects in adult tonsillectomy patients.

3 . A study was done by Tawalbech et al regarding the efficacy of diclofenac in reducing post tonsillectomy pain in children aged 3 – 14 years . Few children received diclofenac sodium (1-3 mg/kg) postoperatively and few received only paracetamol syrup (10-15mg/kg) in 4 divided doses . Children who received diclofenac sodium had significantly les pain , less elevation of temperature , more oral intake , and started drinking significantly sooner than the paracetamol group .

4 . A study was done by Parker DA et al on syrup formulations for post tonsillectomy analgesia comparing ibuprofen , aspirin and placebo . The results are reported and showed that ibuprofen have a greater therapeutic effect than aspirin and placebo .

5 . A study was conducted by Derry CJ et al on single dose oral ibuprofen plus paracetamol for acute post operative pain in children concluding that ibuprofen and paracetamol combinations provided better analgesia tham either drug alone in same dose.

III. AIMS AND OBJECTIVES

- To compare the efficacy of Paracetamol (PCM) alone, Paracetamol with Diclofenac (PCM- DICLO) and Paracetamol with Ibuprofen (PCM-IBU) in post tonsillectomy pain management in children.
- To study the onset of analgesic action of the drugs.
- To study the duration of analgesia of the drugs.
- To assess the time of first oral intake.

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- To assess the need for rescue analgesic.
- To know the incidence of side effects of the drugs administered.

IV. PATIENTS AND METHODS

INCLUSION CRITERIA:

1. Children in age group 6 – 18 years.
2. Patients undergoing tonsillectomy in MediCiti Institute of Medical Sciences from January 2020 to February 2021.

EXCLUSION CRITERIA:

1. Children with Diabetes, Hypertension and Seizure disorders.
2. Children with hepatic &renal dysfunctions and bleeding disorders.
3. Children allergic to paracetamol, diclofenac and ibuprofen.
4. Immunocompromised individuals.

TIME OF EVALUATION:

For children with administration of Paracetamol alone the 1st 2nd 3rd & 4th evaluations of PAIN SCALE will be during the first four consecutive intakes of syrup on post – op day zero and post-op day 1 every 8thhourly and the 5th evaluation will be on post op day 5.

For children with administration of paracetamol+diclofenac and paracetamol+ ibuprofen combinations the 1st 2nd &3rd evaluations of PAIN SCALE will be done during the first three consecutive intakes of syrup on post-op day zero and post-op day 1 every 12th hourly and 4th evaluation will be on post op day 5.

Baseline Visual Analogue Scale (VAS) scores will be noted and pain assessment will be done half an hour before giving syrup while in rest and swallowing.

The onset of analgesia, the duration of analgesia, the time of first oral feed and the side effect if presents will be noted.

Measures were taken to explain the need of the study to the parents of the participants and consent is obtained.

V. DATA ANALYSIS:

Mean and Standard deviation for all continuous variables will be calculated. Significant of difference in mean pain scores among the three different groups will be assessed by Analysis Of Variance. P value of < 0.05 will be considered si

VI. OBSERVATION AND RESULTS

The total numbers of participants involved in the study were 63.

TABLE 1: AGE DISTRIBUTION OF PATIENTS

AGE OF PARTICIPANTS	DRUG ADMINISTERED		
	PCM (n)	PCM-DICLO (n)	PCM-IBU (n)
6-10 years	7	7	7
11-15 years	7	7	7
16-20 years	7	7	7
TOTAL	21	21	21

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FIGURE 1: AGE DISTRIBUTION OF PATIENTS

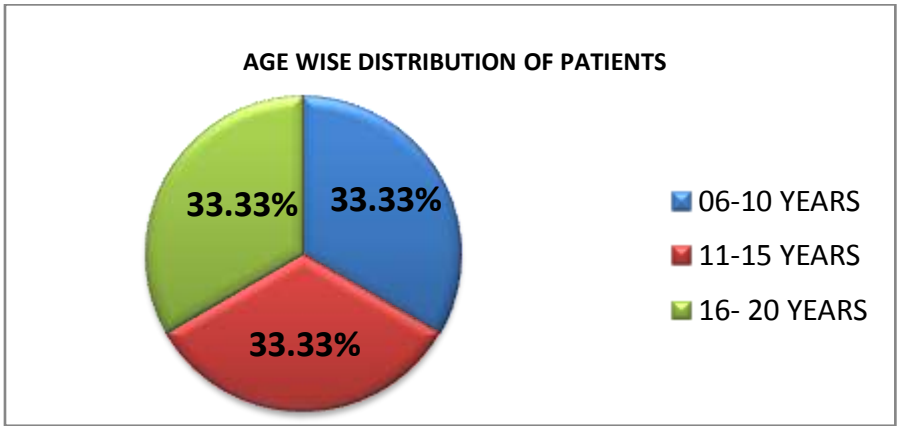

TABLE 2: SEX DISTRIBUTION OF CASES

DRUGS ADMINISTERD	SEX DISTRIBUTION OF CASES	
	MALE	FEMALE
PCM	7	14
PCM-DICLO	9	12
PCM-IBU	9	12
TOTAL (n)	25	48

FIGURE 2: SEX DISTRIBUTION OF CASES

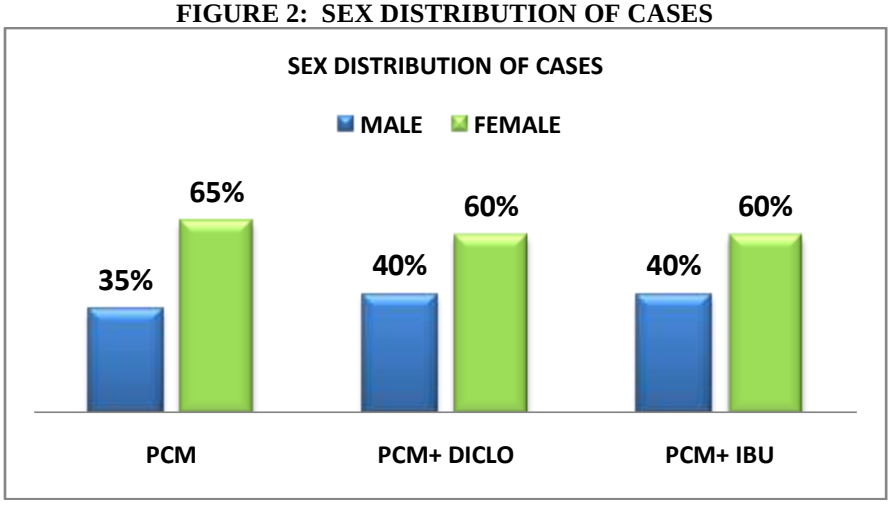

TABLE 3: VAS SCORES IN DIFFERENT AGE GROUPS

DRUG	AGE	VAS1		VAS 2		VAS 3		VAS 4		VAS 5	
		MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD	MEAN	SD

PCM	**06-10**	7.87	0.37	6.42	0.53	5.14	0.69	3.87	1.06	1.42	0.53
	11-15	7.85	0.37	6.28	0.48	4.57	0.53	3.14	0.69	1.71	0.48
	16-20	7.71	0.48	6.24	0.89	5.14	0.69	3,85	0.89	1.85	0.37
PCM-DICLO	**06-10**	7	0.81	5.57	0.97	4.42	0.97	1.57	0.53	NA	NA
	11-15	6.57	0.53	5.27	0.57	3.85	0.69	1.42	0.53	NA	NA
	16-20	7.42	0.53	6.14	0.89	5	0.81	1.28	0.48	NA	NA
PCM – IBU +	**06-10**	7	0.92	5.28	0.48	4.14	0.37	1.57	0.53	NA	NA
	11-15	7	0.57	5.57	0.78	4.29	0.95	1.57	0.53	NA	NA
	16-20	6.57	0.53	5.57	0.53	4.57	0.53	1.85	0.37	NA	NA

The overall mean VAS scores obtained for PCM was 4.89, while for PCM DICLO was 4.49 and 4.63 for PCM –IBU.

The results obtained further demonstrates that when paracetamol alone (PCM) was administered in children with the varying age groups, mean of 4.85 for 06-10 years, 4.88 for 11-15 years and 4.94 for 16-20 years, suggesting that VAS increased in par with age.

Likely, on administering paracetamol with diclofenac (PCM-DICLO) among those children with varying age groups, mean value of 4.64, 4.46 and 4.39 for the 06-10 years, 11-15 years and 16-20 years suggesting declination of VAS scores over the age. On further administration of drug paracetamol with ibuprofen (PCM-IBU), mean value of 4.54, 4.64 and 4.71 were noted for the age groups 06-10 years, 11-15 years and 16-20 years respectively. It is also observed that VAS scores increased in correspondence to the age groups. Thus the mean value of the results obtained for various age groups and the drugs administered were tabulated in Table 4 and Figure 3.

TABLE 4: AGE WISE DISTRIBUTION OF VAS SCORES

DRUG ADMINISTERED	**AGE WISE DISTRIBUTION OF VAS SCORE**		
	06-10 YEARS	**11-15 YEARS**	**16-20 YEARS**
PCM	**4.85**	**4.88**	**4.94**
PCM-D	**4.64**	**4.46**	**4.39**
PCM-I	**4.54**	**4.64**	**4.71**

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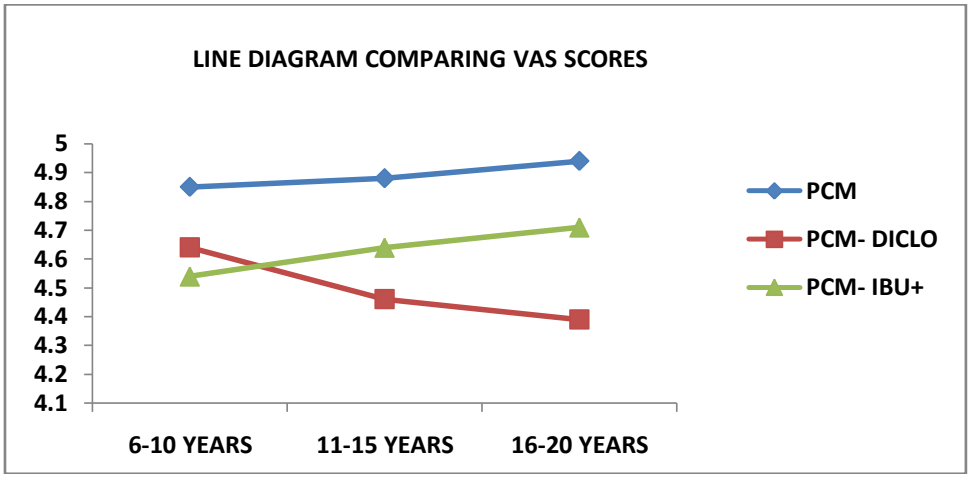
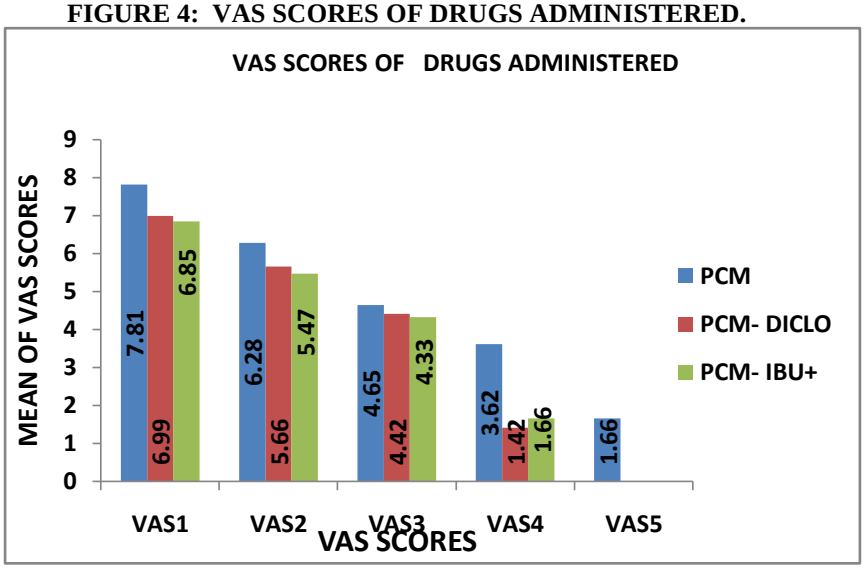
FIGURE 3: LINE DIAGRAM COMPARING VAS SCORES.



The mean value of VAS scores obtained (VAS 1,2,3,4 and 5) for PCM, mean VAS scores (VAS 1, 2, 3, and 4) for PCM-DICLO and PCM-IBU were represented in the Figure 4.

FIGURE 4: VAS SCORES OF DRUGS ADMINISTERED.

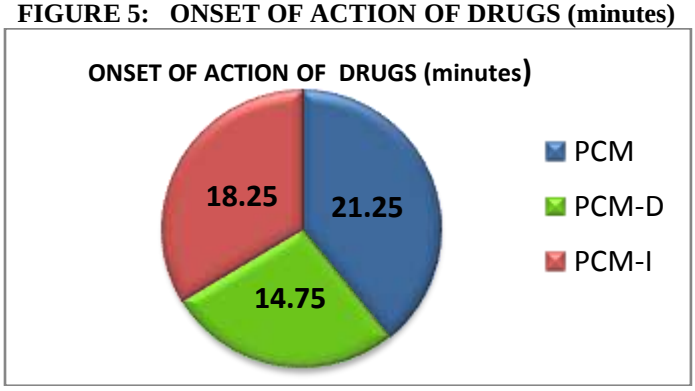


The study also aimed at identifying the onset of action of drugs PCM, PCM-DICLO and PCM-IBU. The values noted were 21.25 minutes for PCM, 14.75 minutes for PCM-DICLO and 18.25 minutes for PCM-IBU. The results are shown in Table 5 and in Figure 5.

TABLE 5: ONSET OF ACTION OF DRUGS

DRUGS ADMINISTERED	ONSET OF ACTION OF DRUGS (minutes)
PCM	21.25
PCM-DICLO	14.75
PCM-IBU	18.25

FIGURE 5: ONSET OF ACTION OF DRUGS (minutes)

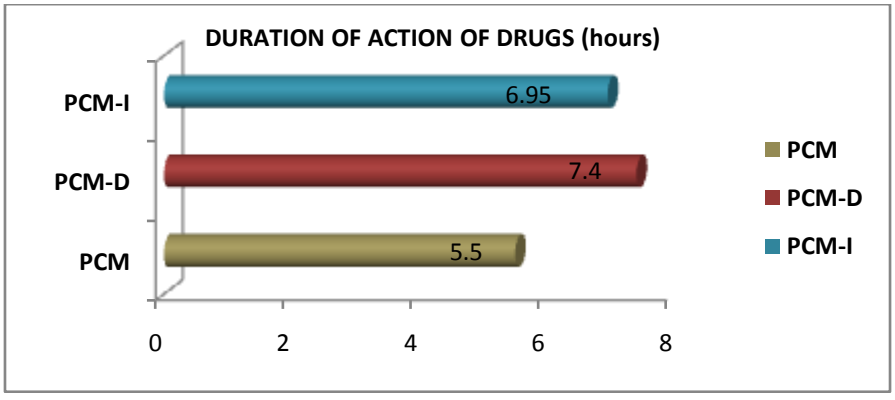


The study aimed at observing the duration of action of various drugs PCM, PCM-DICLO and PCM-IBU. The values noted were 5.5hours for PCM, 7.4 hours for PCM-DICLO and 6.95 hours for PCM-IBU. The results are shown in Table 6 and Figure 6.

TABLE 6: DURATION OF ACTION OF DRUGS

DRUGS ADMINISTERED	DURATION OF ACTION (hours)
PCM	5.5
PCM-DICLO	7.4
PCM-IBU	6.95

FIGURE 6: DURATION OF ACTION OF DRUGS



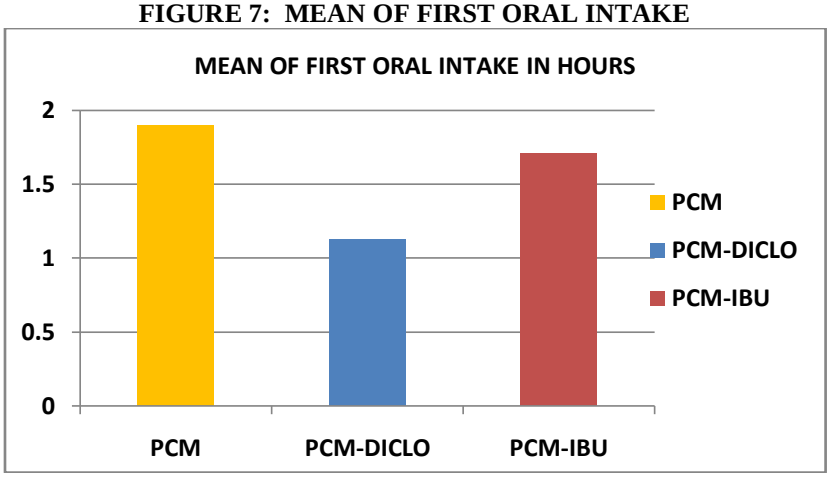
The values for the time of first oral feed for the drugs administered were noted. Mean of 1.90 hours for PCM, 1.13 hours for PCM-DICLO and 1.71hours for PCM-IBU were observed. The results of the same are represented in Table 7 and Figure 7.

TABLE 7: TIME OF FIRST ORAL INTAKE

DRUG ADMINISTERED	MEAN OF FIRST ORAL INTAKE (hours)
PCM	1.90

PCM-DICLO	1.13
PCM-IBU	1.71

FIGURE 7: MEAN OF FIRST ORAL INTAKE



On analyzing the side effects of the drugs administered over the study group, it was observed that none of the participants considered for the study in various age groups of PCM, PCM-DICLO and PCM – IBU had no significant complaints of side-effects (Table 8).

TABLE 8: SIDE-EFFECTS FOR THE VARIOUS DRUGS ADMINISTERED.

Drug administered	Side-effects
PCM	NIL
PCM-DICLO	NIL
PCM-IBU	NIL

Key to graphs and charts:
VAS - Visual Analogue Scale
VAS 1 - Visual Analogue Scale at first dose
VAS2 - Visual Analogue Scale at second dose
VAS3 - Visual Analogue Scale at third dose
VAS4 - Visual Analogue Scale at fourth dose
VAS5 -Visual Analogue Scale at fifth dose
BP - Blood Pressure
mm. Hg - Millimetres of mercury

VII. DISCUSSION

In current study the subjects were in the age group of 6-18 years. Females comprised roughly two-thirds of the study group

There are various studies demonstrating the efficacy of PCM, in post tonsillectomy pain relief and the efficacy of PCM-DICLO and PCM-IBU in various oral conditions. There are no studies comparing the efficacy and safety of PCM, PCM-DICLO and PCM-IBU in reducing post tonsillectomy pain. This is reported in correspondence to the statement observed in a study done by Abhishek Sahu et al, in 2013[4].

Abhishek Sahu et al (2015) studied the comparative efficacy Diclofenac Sodium versus combination of paracetamol and ibuprofen for acute postoperative tonsillectomy pain [4].

The participants of this study in common were subjected to dissection and snare method for surgical management of tonsillectomy and were further treated using oral Diclofenac or combination of paracetamol and ibuprofen. The

subjects were randomly divided into groups of two where group 1 received diclofenac sodium while the other were given combination of Paracetamol and Ibuprofen in tablet or syrup form after food from day 1 to day 5, and the pain was assessed clinically according to Visual Analog Scale. Mann-Whitney test was applied to compare outcome of pain, and no significant difference in pain score was observed on day 1. However, significant differences over pain score were noted on day 5. It was noted that combining paracetamol and NSAID confers additional analgesic effect over the usage of either drug. The author has also reported that pain reduction was significantly better when intervened with combined analgesic with Paracetamol and Ibuprofen than with Diclofenac sodium with no side effects.

COMPARISION OF ABHISHEK SAHU STUDY AND CURRENT STUDY

STUDIES COMPARED	TOTAL NO OF PATIENTS	DRUG ADMINISTERED	RESULTS
Abhishek Sahu	68	DICLO- 34; PCM +IBU – 34	PCM + IBU is effective than DICLO
Current Study	63	PCM – 21 PCM + DICLO - 21 PCM + IBU - 21	PCM+DICLO is effective than PCM+IBU and PCM

Further it was concluded that combination of analgesics (Paracetamol and Ibuprofen) for pain relief management in patients of post tonsillectomy appears to be most effective. In contrast, the current study results reveal that, PCM and PCM-IBU exhibited mean of 4.89 and 4.63 for the VAS scores, while 4.49 for PCM-DICLO. Therefore the result states that combination of PCM-DICLO was more effective compared to PCM – IBU.

The above mentioned statement was also noted in Tawalbech's study. Tawalbech MI, Nawasreh OO and Husban AM [1] conducted a comparative study of diclofenac sodium and Paracetamol for treatment of pain after adenotonsillectomy in children aged from 3-14 years.

COMPARISION OF TAWALBECH STUDY AND CURRENT STUDY

STUDIES COMPARED	TOTAL NO OF PATIENTS	DRUG ADMINISTERED	RESULTS
Tawalbech et al	80	DICLO- 40; PCM 40	DICLO is effective than PCM
Current Study	63	PCM – 21 PCM + DICLO - 21 PCM + IBU - 21	PCM+DICLO is effective than PCM+IBU and PCM

Romsing et al (2000) studied the effectiveness of Diclofenac or Acetaminophen for analgesia in pediatric tonsillectomy patients[19]. To establish effective drug regimen, authors compared the analgesic efficacy of oral diclofenac and high dose acetaminophen over post tonsillectomy pain. Subject ranging from the age groups 5-15 were randomly selected, and were subjected to administration of drugs such as diclofenac, acetaminophen for the first three days post surgery. The effect of post operative pain was noted at 7hours, 12hours, 18hours and 23hours. The results indicated that severe pain was observed in both groups. However, pain score in the group where diclofenac was administered were significantly lower at 12h compared to the group administered with acetaminophen.

COMPARISION OF ROMSING et al STUDY AND CURRENT STUDY

STUDIES COMPARED	TOTAL NO OF PATIENTS	DRUG ADMINISTERED	RESULTS
Romsing et al	48	DICLO- 24; ACETAMINOPHEN-24	DICLO is effective than ACETAMINOPHEN
Current Study	63	PCM – 21 PCM + DICLO - 21 PCM + IBU - 21	PCM+DICLO is effective than PCM+IBU and PCM

Hiller A, Silvanto M and Savolainen S conducted a comaparitive study on paracetamol and diclofenac alone and in combination for analgesia after elective tonsillectomy. The authors included 71 individuals post elective tonsillectomy in a randomized control method, followed by double blind study. Post anesthesia induction, participants received monotherapy with 2mg paracetamol (n=25) or 75mg diclofenac (n=25) or a combined treatment of both (2mg PCM+ 75mg DICLO) (n=21). To assess the post tonsillectomy pain a verbal rating scale and a Visual Analog Scale were employed.

COMPARISION OF HILLER et al STUDY AND CURRENT STUDY

STUDIES COMPARED	TOTAL NO OF PATIENTS	DRUG ADMINISTERED	RESULTS
Hiller et al	71	PROPACETAMOL-25 DICLO-25 PROPACETAMOL + DICLO - 21	PROPACETAMOL + DICLO is effective than DICLO and PROPACETAMOL
Current Study	63	PCM – 21 PCM + DICLO - 21 PCM + IBU - 21	PCM+DICLO is effective than PCM+IBU and PCM

The VAS scores were significantly lower in PCM- DICLO (4.49) group compared to PCM (4.89) and PCM-IB (4.63) group indicating that the patients in PCM-DICLO group had a better pain relief compared to the other test population. The results obtained from the current study falls the path of results that are observed in the study done by Abhishek et al (2013) [4].

The author had mentioned that VAS scores were noted to be significantly lower in those who were administered the combination of drugs (PCM-IB) than the monotherapy given (DICLO alone).

Huseyin Yaman Abdullah Belada Suleyman Yilmaz (2011) studied the effect of Ibuprofen on post operative hemorrhage following tonsillectomy in children.

COMPARISION OF HUSEYIN et al STUDY AND CURRENT STUDY

STUDIES COMPARED	TOTAL NO OF PATIENTS	DRUG ADMINISTERED	RESULTS

HUSEYIN ET AL	171	IBU - 62 PCM- 109	IBU is effective than PCM
CURRENT STUDY	63	PCM – 21 PCM + DICLO - 21 PCM + IBU - 21	PCM+DICLO is effective than PCM+IBU and PCM

Dr. Murali [5] in a study stated mean of PCM, DICLO and IBU when administered alone are noted as 30 minutes, 30-60 minutes and 10 minutes respectively. In the current study it was observed that mean of 21.2 minutes, 14.7 minutes and 18.25 minutes for PCM, PCM-DICLO, and PCM -IBU respectively. Therefore the results are comparable to those noted in the earlier study.

COMPARISION OF Dr. MURALI STUDY AND CURRENT STUDY

STUDY COMPARED	ONSET OF ACTION
Dr. R MURALI	PCM- 30 minutes DICLO – 30-60 minutes IBU – 10 minutes
CURRENT STUDY	PCM – 21.2 minutes PCM- DICLO – 14.7 minutes PCM – IBU 18.25

COMPARISION OF Dr. MURALI STUDY AND CURRENT STUDY

STUDY COMPARED	DURATION OF ACTION
Dr. R MURALI	PCM- 2-5 hours DICLO – 8 hours IBU – 6 – 8 hours
CURRENT STUDY	PCM – 5.5 hours PCM- DICLO – 7.4 hours PCM – IBU – 6.9 hours

The patients in the PCM-DICLO group had their first oral feed 1.13 hours (mean) after the first dose, PCM-IB group had after 1.71 hours (mean), and PCM group had after 1.9 hours (mean), and the difference between the three being significant. The time of first oral intake was earlier in PCM-DICLO group compared to PCM –IB and PCM group which was statistically significant (P value 0.001).

The results obtained from the current study are noted to be in par with those studied by Cliff et al (2010) where combination of PCM and NSAID remained to be more effective than PCM or NSAID alone. The time to the first oral intake, and duration of i.v. hydration, were significantly shorter and the quality of oral intake was significantly better in the PCM-IB group ($P < 0.05$).[2]

However, in the current study, there was no incidence of participants reporting to have experienced nausea and/or vomiting.

In the current study there was no need for rescue analgesia in either of the three groups.

Tawalbech et al and Romsing et al studied the adverse effects of drugs DICLO and PCM and concluded that there were low incidence of nausea and vomiting for DICLO [2].

There were no side effects of Diclofenac in this study, which is comparable to a study by Geeta Joshi, Pravesh Taneja, Bhavana C Patel, Bipin M Patel in which topical Ketamine, Lignocaine and Diclofenac (dispersible) were

compared for pain relief in patients with radiation-induced mucositis.

This study showed that topical PCM, PCM-DICLO and PCM-IB can be used in the management of post tonsillectomy pain, PCM-DICLO being comparatively better in reducing the pain, without any adverse effects.

It is also observed from the current study that, there were no significant cases reporting to have post operative bleeding causing the need for reoperation or readmission which could be due to the post operative medications that were provided to the participants. The results thus obtained are in correspondence to the study done by Riggin L et al in 2013.

Administration of PCM, PCM-DICLO and PCM-IB had no significant effects on pulse rate, blood pressure which is comparable to a study done by Erhan, Goksu, and Alpay in which 60 patients planned for adenotonsillectomy were included.

VIII. CONCLUSION AND SUMMARY

This study comparing the efficacy and safety of PCM, PCM-DICLO and PCM-IB in reducing the post tonsillectomy pain helped us to evaluate the effective analgesic for post-tonsillectomy treatment.

The parameters that were taken into consideration were the onset of analgesic action of the particular drug, duration of analgesic effect, time of first oral feed. Pain was assessed by VAS after each oral administration. The patients were also observed for the adverse effects of the study drugs. All the parameters were recorded and statistical analysis was done using mean and standard deviation and 't' test.

PCM given postoperatively among 6 to 10 years of age children showed least VAS score compared to VAS scores in the age group of 11 to 15 and 16 to 20 age groups .

PCM-DICLO given postoperatively showed VAS scores better in the age groups of 16 to 20 and 11 to 15 compared to age group of 6 to 10.

PCM-IBU given postoperatively showed better VAS scores in the age groups of 6 to 10 and 11 to 15 than compared to VAS score in 16-20 years.

The VAS scores were decreased in PCM and PCM-IB groups while the patients in PCM-DICLO group had significantly lower VAS scores indicating that PCM-DICLO provided better pain relief.

Oral PCM-DICLO, given in the immediate postoperative period following tonsillectomy, has a faster onset of action and longer duration of analgesic effect compared to PCM and PCM-IBU. Hence the time of first oral feed is earlier in PCM-DICLO group compared to PCM and PCM-IB group.

No significant side effects were observed in either group of PCM, PCM-DICLO and PCM-IBU groups.

This study comparing the efficacy and safety of PCM, PCM-DICLO and PCM-IB, in reducing the post tonsillectomy pain showed that although PCM, PCM-DICLO and PCM-IB can be used effectively in the immediate postoperative period following tonsillectomy under close monitoring, without any side effects. However, PCM-DICLO is a better option.

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