

## A Comparative Study of Intravenous Paracetamol Versus Intramuscular Diclofenac For postoperative Pain Relief in Tonsillectomy Patients

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### Abstract

**Introduction:** Post tonsillectomy pain relief is commonly inadequate as the pharynx is continuously active, swallowing saliva. I. m. Diclofenac provides good pain relief but pricks are usually unwelcome by children and it may cause dangerous side effects like inhibition of platelet aggregation (post op hemorrhage) and kidney problems. I.v Paracetamol is a good and safe alternative and the study was conducted to compare the 2 drugs.

**Aims:** To evaluate onset of analgesia, duration and efficacy of analgesia, and adverse effects if any between the 2 drugs.

**Settings and design:** 100 cases aged between 10 and 40 years posted selectively for tonsillectomy under general anaesthesia were randomly selected and divided into 2 groups. Groups P received Paracetamol 1g I.v for those more than 50 kg and 15 mg/kg for those between 30 and 50 kg over 10 min after delivery of second tonsil and this time was taken as time 0. Group D received inj. Diclofenac I.m 75 mg at the same time.

Subsequently data regarding pain relief at 30 min, 1h, 2h, 4h and 6h using Visual Analog Scale was collected. Duration of analgesia, number of patients asking for rescue analgesia were recorded.

**Statistical Analysis:** This was done using Student test and Chi square tests as and where needed.

**Results:** Comparison of pain scores 30 min and 1 h after drug administration showed superior pain relief with Paracetamol and at 4 and 6h better pain relief with Inj. Diclofenac. Duration of analgesia was significantly longer with inj Diclofenac.

**Conclusion:** We concluded that both I.v Paracetamol and I.m Diclofenac have equal efficacy. The onset was early in Inj. Paracetamol and longer with inj. Diclofenac.

**Keywords:** Inj. Paracetamol I V; Inj. diclofenac I.M; Tonsillectomy; Post operative analgesia.

### Introduction

*Pain-Historical review<sup>2</sup>:*

Man has been afflicted with this evil pain since beginning for as records of every race are examined one finds testimonials to the omnipresence of pain.

The International Association for Study of Pain

has defined pain as an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Despite advances in the knowledge and sophisticated technology relief of post tonsillectomy pain still remains a problem.

Paracetamol I V in comparison to oral route has

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superior pharmacokinetics and efficacy. Hyllested M et al<sup>6</sup> compared the analgesic and adverse effects of paracetamol with those of NSAIDs in post-operative pain and concluded that paracetamol is a viable alternative to NSAIDs in high-risk patients. Cakan T et al<sup>7</sup> studied analgesic efficacy, opioid sparing effect of paracetamol in combination with i.v. morphine after spine surgery and concluded that it did not have significant opioid sparing effect. Alhashemi JA et al<sup>8</sup> compared the effect of i.v. acetaminophen with i.m. meperidine in 80 children undergoing tonsillectomy and concluded that i.v. acetaminophen gave comparable effects. I.m diclofenac has well established its role as an effective post-operative analgesic but can cause unwanted platelet and kidney dysfunction. Platelet dysfunction can cause troublesome bleeding in ENT surgeries.

## Methods

Institutional ethical committee approval was taken and the study was conducted on 100 patients aged between 10 and 40 years belonging to ASA 1 and 2 categories who were selectively posted for tonsillectomy alone under general anesthesia.

Excluded were those who belonged to ASA g 3 and 4, those undergoing adenoids resection, those with history of drug allergy, bronchial asthma, gastrointestinal dysfunction, liver disease, renal disease and bleeding diathesis.

All patients were divided randomly into 2 groups, P and D. All patients received Inj Atropine is 0.01 mg/ kg. I.v and Inj. Fentanyl 2 microgram/ kg I.v as premeditation. After preoxygenation, anesthesia was induced with Inj. Thiopental sodium 5 mg/kg, intubated with Inj. Scoline. 2 mg/kg with appropriate sized cuffed endotracheal tube and maintained with halothane in 70% nitrous oxide and oxygen mixture. Intraoperative relaxation was provided with Inj. Vecuronium .05 mg/kg I.v. Residual neuromuscular blockage was reversed with Inj. Glyco. 01 mg/kg and Inj. Neostigmine .05 mg/kg I.v. ECG, Spo 2, EtCO<sub>2</sub>, NIBP and heart rate were monitored continuously.

After delivery of second tonsil, gp P patients received 1g I.v Inj Paracetamol for those weighing more than 50 kg and at a dose of 15mg/kg for those weighing between 30 and 50 kg infused over a period of 10 min. This time was taken as time 0. Gp D patients received Inj. Diclofenac 75mg I.m (2 mg/kg) at the same time.

Pain was assessed at 30 min, 1h, 2h, 4h and 6 h intervals using Visual Analog Scale as 0 – poor, 1- fair, 2 – good, 3- excellent. Duration of analgesia was taken from time 0 to resurfacing of pain. Need for rescue analgesic, Inj. Tramadol 2 mg/kg I.v was recorded. Hr and BP were also recorded.

## Statistical analysis

Quantitative data was analyzed by Student T test. Qualitative data was analyzed using Chi square/ Man Whitney U test. Statistical software namely SAS 9.2, SPSS 15.0, Stata 10.1, MedCalc 9.0.1, Systat 12.0 and R environment ver. 2.11.1 were used for the analysis and Microsoft Word and Excel were used to generate Graphs and Tables.

## Results

VAS scores were significantly lower for Inj. Paracetamol at 30 min and 1 h intervals. VAS Scores were significantly lower at 4h and 6h intervals for Inj. Diclofenac. Duration of analgesia was longer with the latter and onset was earlier with the former. There was no statistical difference between rescue analgesia requirements at 6 h in both groups. No significant side effects were seen in either group. The results are tabulated below.

**Table 1:** Comparison of age of participants.

Group	Mean(Sd)	P value
P	25.8	.550
D	26.8	

Statistically insignificant.

**Table 2:** Comparison of gender distribution.

Gender	Group P	Group D	P value
Male	28	27	.841
Female	22	23	
Total	50	50	

Statistically insignificant.

**Table 3:** Comparison of pulse rate between both groups at various intervals.

Time	P gp, Mean (sd)	D gp, Mean(sd)	P Value
Baseline	87.9 (9.07)	88.64(8.33)	.672
At 30 min	84.24 (7.57)	84.94(7.12)	.635
At 1 h	83.28 (7.13)	82.84(6.66)	.751
At 2 h	83.34 (7.03)	83.22(6.41)	.929
At 4 h	82.88 (6.65)	83.16(6.03)	.826
At 6 h	84.02 ()	84.16(6.36)	.915

**Table 4:** Comparison of systolic blood pressure between both groups at various intervals.

Time	P gp, Mean(sd)	D gp, Mean(sd)	P value
Baseline	121.76(3.32)	121.84(6.52)	.939
At 30 min	121.24(3.33)	120.24(5.06)	.246
At 1 h	121.16(3.88)	120.0(6.43)	.277
At 2 h	121.2(3.55)	120.52(4.93)	.430
At 4 h	120.96(3.36)	120.56(3.96)	.587
At 6 h	12.52(3.07)	121.4(4.3)	.873

Both tables 3 and 4 show statistically insignificant values.

**Table 5:** Comparison of diastolic blood pressure between both groups at various intervals.

Time	P gp, Mean (sd)	D gp, Mean (sd)	P value
Baseline	80.48(2.70)	77.88(4.523)	.001
At 30 mins	80.04(2.84)	77.76(4.62)	.004
At 1 h	80.08(2.59)	78.16(5.37)	.025
At 2 h	80.16(2.49)	78.76(4.12)	.042
At 4 h	80.44(2.07)	78.80(4.08)	.013
At 6 h	80.72(2.35)	79.48(3.07)	.026

Statistically insignificant.

**Table 6:** Comparison of onset of analgesia among both groups.

Group	Mean (sd)	p value
P	10.64(2.07)	<.001
D	38.40(4.10)	

Statistically significant.

**Table 7:** Comparison of initial pain scores immediately after extubation.

Group	Mean( IQR)	P value
P	6(6-7)	.295
D	6(6-7)	

Statistically insignificant

**Table 8:** Comparison of pain scores at 30 min.

Group	Mean( IQR)	P value
P	3(3-4)	<.001
D	5(5-6)	

Statistically significant

**Table 9:** Comparison of pain scores at 1h.

Group	Mean( IQR)	P value
P	2(2-3)	<.001
D	4(4-4)	

Statistically significant

**Table 10:** Comparison of pain scores at 2 h.

Group	Mean( IQR)	P value
P	2(1-3)	<.001
D	2(2-3)	

Statistically significant

**Table 11:** Comparison of pain scores at 4h.

Group	Mean( IQR)	P value
P	3(3-4)	<.001
D	1(1-2)	

Statistically significant

**Table 12:** Comparison of pain scores at 6h.

Group	Mean( IQR)	P value
P	4(4-4)	<.001
D	1(1-2)	

Statistically significant

**Table 13:** Comparison of total pain scores.

Group	D	P	t value	p value	Singnificance
Total pain relief score Mean +/- sd	2.82+/- .39	2.8+/- .40	.252	.801	NS

Statistically significant

**Table 14:** Comparison of duration of analgesia.

Group	Mean +/- sd	P value
P	5.87(.62)	<.001
D	7.71(.5)	

Statistically significant.

**Table 15:** Need for rescue analgesia.

Reascue analgesia	P	D	P value
Yes	6	9	
No	44	41	1.0
Total	50	50	

Statistically insignificant.

**Table 16:** Comparison of incidence of adverse effects between the two groups.

Complications	P	D	P value
Yes	4	9	.234
No	46	41	
Total	50	50	

Complications

P: headache:1, n/v: 1, pruritus: 2. D: n/v:3, epigastric discomfort: 6.

## Discussion

Pain is a sensory experience that is subjective and individualized. It frequently exceeds its protective nature and makes the post operative period a suffering. Despite the availability of a wide variety of agents, management of postoperative analgesia remains a challenge. In our study, the effects of I.v Paracetamol were compared with I.m Diclofenac as the latter is the most common standard analgesic used in our institution.

In the study, patients between ages 10 and 40

years (Table 1) were randomly selected with out any criteria for gender distribution (Table 2). All were healthy ASA 1 and 2 patients and underwent tonsillectomy under the same general anesthesia technique. They were divided randomly into groups P and D and received the study drugs in the above prescribed format.

In the study, average pulse rate (Table 3) and mean SBP (Table 4) and DBP (Table 5) in both groups at 30 min, 1 h, 2 h, 4 h, and 6 h did not vary significantly. Haynes D. et al<sup>5</sup> studied the efficacy of the same 2 drugs in post operative orthopedic pain and observed statistically insignificant changes in the vitals.

Onset of analgesia was 10.64+/-2.07 min with Inj Paracetamol and 38.4+/-4.10 with Inj Diclofenac (Table 6) which was statistically significant. Moller P L et al<sup>9</sup> in their study showed that onset for Paracetamol was 5 min and for Diclofenac was 26+/-8 min in Nuuttinen LS, et al<sup>10</sup> study.

There was no difference in the pain scores immediately after extubation (Table 7). Pain scores at intervals 30 min and 1 h after drug administration were significantly lower in the P group (Tables 8 and 9). Pain score at 2h were similar in both groups (Table 10). Pain scores at 4h and 6h intervals was lower in the D group which was statistically significant (Tables 11 and 12). In our study, total pain relief score in gp P was 2.8 +/- 0.4 and in gp D it was 2.82+/-0.39 (Table 13) which was not statistically significant which was similar to what was observed in Hynes D et al<sup>5</sup> study.

Duration of analgesia in gp P was 5.87+/-0.62 h and that in gp D was 7.71+/-0.5 h (Table 14). This showed that Diclofenac I.m had a longer period of analgesia which was similar to the Cengiz Kara et al<sup>3</sup> study that showed significantly increased pain scores in Paracetamol gp at 6 h interval. ADIS drug profile by Sean T Duggan and Lesley J Scott<sup>11</sup> has shown that the duration of action of paracetamol is between 4 to 6 hours which is comparable with our study.

Rescue analgesia was required in both groups in 6 patients each which was not statistically significant. (Table 15).

In our study, (Table 16) P gp showed headache and nausea in 1 patient and pruritus in 2 patients. In gp D there was observed epigastric pain in 6 patients, and 3 had nausea and vomiting.

None of the complaints were serious enough and were treated symptomatically. Similar side effects were seen in the Hiller A. et al<sup>4</sup> study, Hynes D et al<sup>5</sup> study and the Cengiz Kara et al<sup>3</sup> study.

## Conclusion

It was concluded that intravenous paracetamol produces rapid, excellent brief period of analgesia. Intramuscular Diclofenac provided equally efficient pain relief with an extended duration.

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