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Research Paper

COMPARATIVE EFFICACY OF DICLOFENAC SODIUM VERSUS COMBINATION OF PARACETAMOL AND IBUPROFEN FOR ACUTE POSTOPERATIVE TONSILLECTOMY PAIN: A RANDOMISED CONTROL STUDY

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Pain is a significant hindrance to the rehabilitation of a patient following tonsillectomy. This necessitates the need for adequate pain control to avoid poor oral intake, delayed recovery and prolonged hospitalization. The objective of the study is to compare the analgesic effect of Diclofenac sodium alone and combination of Paracetamol and Ibuprofen in controlling post tonsillectomy pain.The study also compares improvement in post tonsillectomy pain in patients above and below 15 years of age andto determine the duration of analgesic required. This is a Randomized Control study conducted in a tertiary care center. The study which spanned over a period of 6 months included 68 post tonsillectomy patientsin the age group of 5 to 30 years who were randomly allocated into two groups. One group was subjected to oral Diclofenac sodium while the other received a combination of Paracetamol and Ibuprofen. The study concluded that combining two analgesics for pain improvement in post tonsillectomy patients appears to be more effective, requires lesser dosage of individual drugs and causes lesser side effects than single drug therapy. With appropriate dosage of analgesics, post- tonsillectomy morbidity can be significantly reduced, reducing the duration of therapy in all age groups.

Keywords: Tonsillectomy, Diclofenac sodium, Paracetamol, Ibuprofen

INTRODUCTION

Tonsillectomy is one of the most frequently performed surgical procedures in children, with an estimated yearly rate in UK of 2.3/1000 for the population under the age of 12 years (Morton, 1999).However, in contrast to majority of the procedures, tonsillectomy produces a wound that heals by secondary intention, leading to the persistence of pain and secondary haemorrhage (Rakesh *et al*., 2012). It causes moderate to severe postoperative pain, and its treatment is still a topic of debate. The maximum intensity of

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pain which is seen immediately after operation and in the first three post-operative days may last upto 12 to 15 days (Marcelle Macnamara, 2008). Postoperative pain limits recovery from surgical procedure and can delay hospital discharge. However, postoperative pain following tonsillectomy has predictable characteristics which suggest that scheduled dosing regimens of safe and effective analgesic may be efficacious (Romsing *et al*., 1998 and Sutters *et al.,* 2004). Hence the development of effective analgesic protocols for the treatment of post tonsillectomy pain is a matter of utmost importance.

Various strategies for the management of post tonsillectomy pain have been proposed like infiltration of local anaesthetic agent, Non-Steroidal Anti-Inflammatory Drugs (NSAIDs), narcotics and oral analgesics (William S Mckerrow and Ray Clarke, 2008).

Different classes of analgesic drugs exert their effects through different mechanisms. Their side effects tend to be different and may be dose related. A combination of analgesics from different classes may provide additive analgesic effects with fewer side effects than when a single therapeutic drug is used. There has been a trend over recent years for combining NSAIDs with Paracetamol for the management of acute postoperative pain (Merry and Power, 1995 and Romsing *et al.*, 2002) but the therapeutic superiority of the combination over either drug alone remains controversial (Ong *et al.*, 2007).

OBJECTIVES

The aim of the study is:

1. To compare the analgesic effect of oral Diclofenac sodium and combination of Paracetamol and Ibuprofen in controlling post tonsillectomy pain.
2. To compare improvement in post tonsillectomy pain in patients above and below 15 years of age.
3. To determine the duration of analgesic required to control post tonsillectomy pain.

MATERIALS AND METHODS

Study design: A Randomized control study

Study period: Six months (June to November 2014)

Source of data: All patients admitted for undergoing tonsillectomy or adenotonsillectomy willing to participate in the study in KLE's Dr.Prabhakar Kore Hospital and MRC in Belagavi.

Sample size: 68 patients undergoing tonsillectomy with or without adenoidectomy in the age group of 5 to 30 years.

Inclusion criteria: Patients with chronic tonsillitis or adenotonsillitis.

Exclusion Criteria

- Children less than 5 years of age
- Patients with severe throat infection or upper respiratory tract infection
- Patients with allergy to aspirin and NSAIDs , asthma, bleeding disorders and peptic ulcer
- Patients in whome intraoperative cauterization done for bleeding
- Patients with untoward intraoperative injury or complications

METHODOLOGY

68 patients in the age group of 5 to 30 years who underwent tonsillectomy with or without adenoidectomy by dissection and snare method

were treated using oral Diclofenac sodium or combination of Paracetamol and Ibuprofen.

All patients underwent tonsillectomy or adenotonsillectomy under general anaesthesia following standard protocols of asepsis and haemostasis under the guidance of a senior ENT consultant. All patients received fentanyl (0.25 mcg/kg) intravenously, for pain during the immediate postoperative period. An antiemetic (Ondansetron) was administered as and when required in the immediate post-operative period which was otherwise uneventful in all the cases.

Ice pack was applied immediately after the surgery for a period of 15 to 30 min on both the sides. In the post-operative period, all the patients were given injection Diclofenac sodium 1.25 mg/kg body weight 4 h after surgery. Intravenous Ringer Lactate was given according to body weight in the post-operative period.

Oral feeds were commenced 6 h after surgery in the form of plain ice cream/cold milk. From the first post-operative day, patients were advised to start Hydrogen peroxide gargles and to consume adequate fluids and semi-solid foods while avoiding fruit juice as well as toast, cookies and other foods with “rough edges”. They were encouraged to resume their normal non-spicy diet at the earliest.

The study subjects were divided into two groups by allotting them with alternate numbers such that Group A consisted of 34 patients with odd numbers and Group B had 34 patients with even numbers.

Group A: Received Diclofenac sodium 1.5 mg/kg/day in two divided doses in either tablet or syrup form after food from day 1 to day 5.

Group B: Received combination of Paracetamol 8 mg/kg/dose and Ibuprofen 10 mg/kg/dose in two divided dosesin either tablet or syrup form after food from day 1 to day 5.

Post-operative pain was assessed clinically according to the Visual Analogue Scale (Figure 1) as well as motor activity both during rest and deglutition on day 1 and day 5. Visual analogue score was assessed on a 0-10 scale (0: no pain; 10: severe excruciating pain, Table 1). Intermediate or delayed complications were not reported in any case. All patients were discharged on day 1 after assessment and were told to follow up on day 5 for further assessment or if they developed bleeding, fever or increasing pain. They were discharged on a 5 day course of antibiotic (Amoxicillin 40 to 50 mg/kg/body weight in 3 divided doses) along with an analgesic, antacid and hydrogen peroxide gargles. Patient compliance was 100%.

Figure 1: Visual Analogue Scale

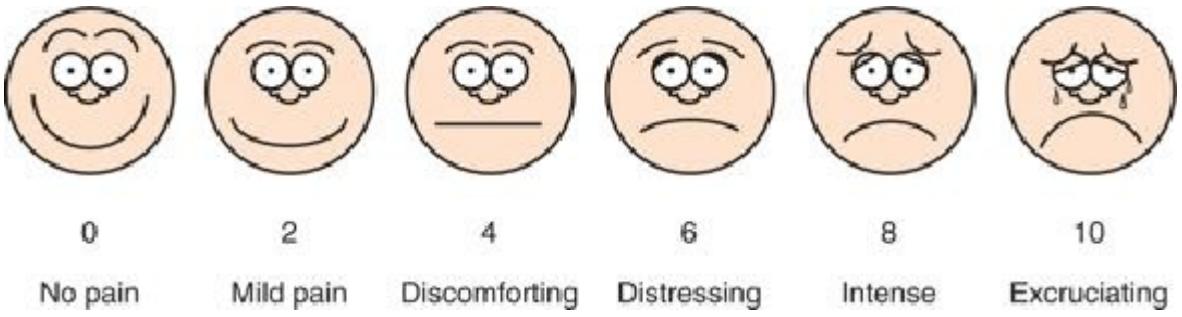

Table 1: Assessment of Pain Score

10	• Pain at rest/ disturbs sleep/ no relief with medications/ continues pain
8	• Not able to swallow/ pain on opening mouth/ speaking
6	• Pain during swallowing liquid
4	• Pain during swallowing solid
2	• Occasional pain
0	• No pain

Patients were assessed on day 5. The patients complaining of persisting pain were given additional course of the same analgesic for 5 more days and were asked to follow up after 2 weeks or in between if they had any complaints.

RESULTS AND ANALYSIS

A total of 68 patients were included in the study. There was a total drop out of 15 patients, of which 8 were in group A and 7 in group B, due to loss of follow-up on the fifth post-operative day. Thus, 26 patients were included in group A and 27 in group B (Table 2).

Table 2: Distribution of Sample

Total 68	Group A 34	Included 26
		Drop outs 8
	Group B 34	Included 27
		Drop outs 7

Of the total 53 patients, 24 were males and 29 were females.The study included 36 patients (68%) who were below the age of 15 years and 17 patients (32%) who were above the age of 15 years (Table 3).

Table 3: Age Distribution

Age distribution	Group A	Group B	Total
< 15 years	19	17	36
>15 years	7	10	17
Total	26	27	53

To compare the outcome of pain in each intervention group, Mann-Whitney test was applied. There was no statistically significant difference in pain score in the two groups on day 1 ($p = 0.191$) but significant difference was noticed in the pain score on day 5 ($p = 0.002$). Reduction in pain was statistically different in the two groups ($p<0.001$) (Table 4).

On assessing patients on the 5th post-operative day, 34 out of the total 53 patients (64%) did not complain of pain while 19 patients (36%) suffered from substantial pain. The study also shows that the reduction of pain was much better in patients below 15 years comprising of 83% (31 patients)when compared to more than 15 years of age comprising 14% (3 Patients) (Table 5).

DISCUSSION

On vast literature search, there is very less information available on post-tonsillectomy analgesia and there is no widely accepted standard protocol. Surgeons follow individualised regimens such as oral Paracetamol (20 mg/kg) and Diclofenac sodium (1 mg/kg) (Marcelle Macnamara, 2008).

Studies have suggested that combining Paracetamol and NSAID confers additional analgesic effect over the usage of either drug alone. The combination of Paracetamol and NSAID was found to be more effective than Paracetamol or NSAID alone in 85% and 64% of the studies, respectively (Seideman, 1993; Curatol and Sveticic, 2002; Mehlisch, 2002;

Table 4: Comparison of Pain Outcome

	Treatment	Pain day 1	Pain day 5	Pain reduction
Group A	Mean	9.0000	3.7692	5.2308
	N	26	26	26
	Std. Deviation	1.16619	2.06509	1.50486
	Median	10.0000	4.0000	6.0000
Group B	Mean	9.4074	2.2222	7.1852
	N	27	27	27
	Std. Deviation	.93064	1.39596	1.00142
	Median	10.0000	2.0000	8.0000
Total	Mean	9.2075	2.9811	6.2264
	N	53	53	53
	Std. Deviation	1.06263	1.90637	1.60098
	Median	10.0000	4.0000	6.0000

Table 5: Improvement as Per Age

	<15 years	>15 years
With pain at day 5	5	14
Without pain at day 5	31	3
Total	36	17

Lange *et al.*, 2007; Demeules *et al.*, 2003; Rafa, 2001 and World Health Organization, 1990).

Our study had a total sample size of 53 after 15 dropouts who were lost to follow up on 5th day. The male to female ratio was almost equal in the study. The study included 36 patients (68%) who were below the age of 15 years and 17 patients (32%) who were above the age of 15 years (Table 3).

Inadequate administration of the prescribed medication has been cited as a cause for poor post-operative pain control (Sutters and Miaskowski, 1997). In our study, compliance with drug therapy was 100%.

To compare the outcome of pain in each intervention group, Mann-Whitney test was applied. There was no statistically significant difference in pain score in the two groups on day 1 ($p=0.191$) but had statistically significant difference in the pain score on day 5 ($p=0.002$). Reduction in pain was statistically different in the two groups ($p<0.001$). Hence the pain reduction by Intervention 2 was significantly better than in Intervention 1, i.e., combined analgesic with Paracetamol and Ibuprofen was more effective in controlling pain than diclofenac sodium with no added side effects.

Pain scores have been found to be higher in the adult age group as compared to the paediatric age group(Sutters and Miaskowski, 1997). In our study, pain intensity on post-operative day 1 was almost equal in patients below and above 15 years of age. But only 14% of patientsbelow 15 years and 83% of patient's above 15 years of age complained of pain on the 5th post-operative day. A significant improvement of pain was noticed in 84% of patients below 15 years of age.

Studies have shown that the median time for cessation of pain post-tonsillectomy was 11 days with median duration of analgesia being 12 (5-25) days where pain on swallowing liquids lasted 7 days while the pain on eating lasted upto 11 days (Marcelle Macnamara, 2008). In our study, 64% of patients had no significant pain on the 5th day of follow up and did not require further analgesics. Hence with appropriate dosage of analgesics, there was a decrease in the long-term unwanted side effects of the drug as well as the cost of medication.

CONCLUSION

Combination of analgesics (Paracetamol and Ibuprofen) for pain improvement in patients of post tonsillectomy appears to be more effective, with less dosage of individual drugs and lesser side effects than single drug therapy. A significant improvement of pain was noticed in children below 15 years of age as compared to those above 15 years of age.With appropriate dosage of analgesics, post- tonsillectomy morbidity can be significantly reduced,reducing the duration of therapy in all age groups.

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