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COMPARATIVE EFFECT OF AN ANALGESIC AND A PLACEBO IN REDUCTION OF ORTHODONTIC PAIN IN PATIENTS UNDERGOING FIXED ORTHODONTIC THERAPY

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ABSTRACT

Objectives: To determine the amount of pain reduction using an analgesic-paracetamol and a placebo- xylitol chewing gum in patients undergoing fixed orthodontic therapy. **Methods:** Two groups were formed and each group was assigned 25 patients. After placing the first orthodontic arch wire patients were told to rate the pain before and after medication in a patient feedback form, **Results:** Chi-square test was used to find the significance of study parameters on categorical scale between two or more groups, Non parametric setting for qualitative data analysis was performed and pain reduction was seen in both the groups. **Interpretation and conclusion:** There was reduction of pain in both the groups- analgesic and placebo group indicating that the effects of placebo cannot be undermined. The pain reduction seen in the analgesic group as compared to placebo group was found statistically significant.

KEYWORDS: Analgesic-paracetmol, orthodontic therapy.

INTRODUCTION

The perception and response of pain differs in different persons of various genders and age. The International Association for the Study of Pain defines pain as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[1] There appears to be a variable response for pain among individuals undergoing orthodontic treatment, with some feeling high levels of pain and others just mild discomfort.[2-4]

Pain is the most common reason for physician consultation in most developed countries.[5,6] It is a major symptom in many medical conditions, and can interfere with a person's quality of life and general functioning.[7] Simple pain medications are useful in 20% to 70% of cases.[8] Most commonly used Over the counter medication for pain reduction in India include paracetamol, ibuprofen.

Pain in Orthodontics is usually felt after the initial archwire placement. Orthodontic forces applied to teeth cause compression of the periodontal ligament (PDL), leading to pressure, ischaemia, inflammation and oedema in the PDL space.[3] The various methods to relieve pain apart from medication, include electrical stimulation (TENS machines) (Roth & Thrash 1986; Weiss & Carver 1994), plastic chews (Hwang et al. 1994; Otasevic et al. 2006), tooth vibration (Marie et al. 2003), cognitive behavioural therapy (Wang et al. 2012) and text message follow up (Keith et al. 2013).

This perhaps emphasises the fact that the perception of pain is mediated by complex neural pathways, which are closely related to varying emotional states, including fear and more specifically, anxiety (Suzuki et al. 2004). Discomfort and pain after initial seperator or archwire placement are common experiences among orthodontic patients.[9]

Considering the vast literature on pain in patients undergoing orthodontic treatment, the main objectives of this study was to compare the pain reduction before and after using an analgesic and a placebo-xylitol chewing gum in patients with orthodontic fixed appliances.

MATERIALS AND METHODS

This randomised controlled clinical trial was performed across various clinics in Bangalore with the main aim to determine the use of analgesics (paracetamol) and placebo -xylitol (chewing gum) in reduction of pain in: first 24 hrs, three days and 1 week following fixed appliance placement during the placement of first archwire. At the same time patients were asked to record their levels of anxiety using a Likert scale (fig.1)

immediately following the fitting of the appliance and the placement of first arch wire.
A total sample size of 50 patients were taken irrespective of the sex and age group and were randomly allocated using lottery method to two groups:
Group 1-Analgesic group, having 25 subjects and
Group 2- Placebo group, having 25 subjects.

The Inclusion criteria included
1. Patients indicated for orthodontic treatment (both extraction and non extraction)
2. Educated patients, with a good mental ability & understanding
3. Good general and overall health
4. Patient's with Little's index 3-4mm.

The exclusion criteria included patients with a history of:
1. Hypersensitivity to paracetamol
2. Current or previous peptic ulceration, or bleeding of the stomach.
3. Mentally disabled patients.

All the patients were bonded with MBT 0.022 slot brackets and initial archwire of 0.014 NiTi was placed. The patients were explained about the pain which will be occurring after some hours after the procedure and were explained about the likert scale (1 to 10) and VAS scale where patient had to tick mark according to there perception of pain at 24hr, 3days and 1 week. Patients were instructed to return the feedback forms in the next visit. Group 1, Analgesic group was told to consume paracetamol for pain control and Group 2, Placebo group was told to chew xylitol chewing gum and record the reduction in pain on the feedback forms. The data was tabulated and statistical results were figure 1 obtained using various statistical methods.

Patient Feed back form

Name: **Age:** **Sex:**

1. Date of receiving the appliance?
2. How many hours after receiving the appliance did you have pain?
3. When did you have most serious pain?

	1	2	3	4	5	6	7
Day							

4. Mark with an tick on the scale corresponding to the pain you have experienced (from 1 to 10) during the next 7 days based on the visual analog pain scale (before taking medication).

	0	1	2	3	4	5	6	7	8	9	10
1st day											
2nd day											
3rd day											
4th day											
5th day											
6th day											
7th day											

5. When did your pain disappear after taking medication?

	0	1	2	3	4	5	6	7	8	9	10
1st day											
2nd day											
3rd day											
4th day											
5th day											
6th day											
7th day											

6. Visual analog pain scale.

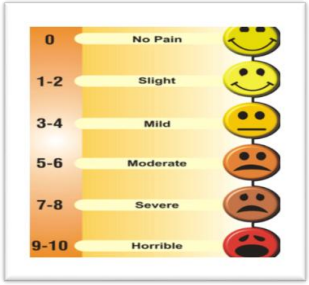


Figure 1: Patient consent form.

RESULTS

The questionnaires were returned by the patients and data was tabulated. Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean ± SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance is assessed at 5 % level of significance. Chi-square was used to find the significance of study parameters on categorical scale between two or more groups, Non-parametric setting for Qualitative data analysis was performed.

Table 1 and 2 depict the level of pain before and after medication. Graph 1,2 & 3.

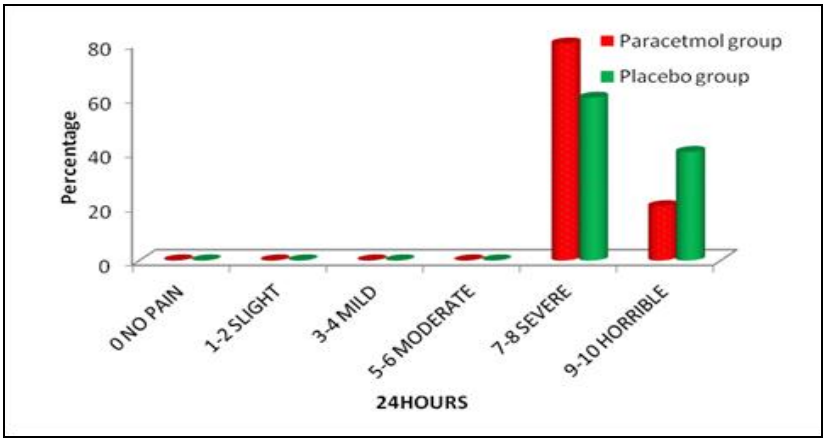
At 24hr interval: pain is experienced by patients of both groups in range of 7-10 on likert scale. After medication both the groups showed decrease in the pain but was more decreased in analgesic group.

At 2-6 day interval: Mild improvement in pain reduction is seen in both the groups,

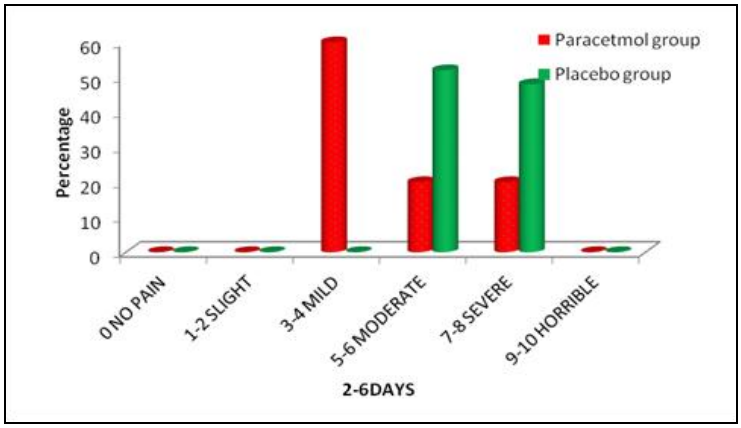
At 1 week in both groups interval: reduction in pain is seen in both the groups, with statistically significant results in analgesic group.

Table 1: Comparison of level of pain experienced before medication in two groups of patients studied.

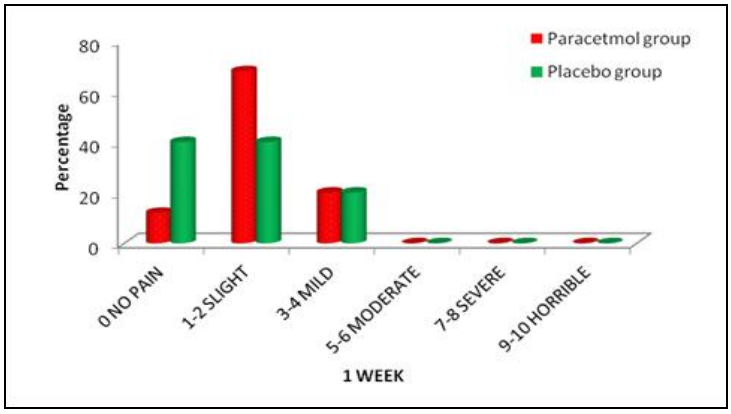
Level of pain experienced before medication	Paracetamol group		Placebo group		P value
	No.	%	No	%	
24 HOURS					
• 0 NO PAIN	0	0.0	0	0.0	0.217
• 1-2 SLIGHT	0	0.0	0	0.0	
• 3-4 MILD	0	0.0	0	0.0	
• 5-6 MODERATE	0	0.0	0	0.0	
• 7-8 SEVERE	20	80.0	15	60.0	
• 9-10 HORRIBLE	5	20.0	10	40.0	
• TOTAL	25	100.0	25	100.0	
2-6 DAYS					
• 0 NO PAIN	0	0.0	0	0.0	<0.001**
• 1-2 SLIGHT	0	0.0	0	0.0	
• 3-4 MILD	15	60.0	0	0.0	
• 5-6 MODERATE	5	20.0	13	52.0	
• 7-8 SEVERE	5	20.0	12	48.0	
• 9-10 HORRIBLE	0	0.0	0	0.0	
• TOTAL	25	100.0	25	100.0	
1 WEEK					
• 0 NO PAIN	3	12.0	10	40.0	0.059+
• 1-2 SLIGHT	17	68.0	10	40.0	
• 3-4 MILD	5	20.0	5	20.0	
• 5-6 MODERATE	0	0.0	0	0.0	
• 7-8 SEVERE	0	0.0	0	0.0	
• 9-10 HORRIBLE	0	0.0	0	0.0	
• TOTAL	25	100.0	25	100.0	



Graph 1: Reduction of pain with paracetamol and placebo during first 24 hrs.



Graph 2: Reduction of pain with paracetamol and placebo during first 2-6 days.



Graph 3: Reduction of pain with paracetamol and placebo after 1 week.

Table 2: Comparison of disappearance of pain after medication in two groups of patients studied.

Disappearance of pain after medication	Paracetamol group		Placebo group		P value
	No.	%	No	%	
24 HOURS					
• 0 NO PAIN	10	40.0	0	0.0	<0.001**
• 1-2 SLIGHT	10	40.0	0	0.0	
• 3-4 MILD	5	20.0	0	0.0	
• 5-6 MODERATE	0	0.0	5	20.0	
• 7-8 SEVERE	0	0.0	10	40.0	
• 9-10 HORRIBLE	0	0.0	10	40.0	
• TOTAL	25	100.0	25	100.0	
2-6 DAYS					
• 0 NO PAIN	12	48.0	0	0.0	<0.001**
• 1-2 SLIGHT	13	52.0	0	0.0	
• 3-4 MILD	0	0.0	0	0.0	
• 5-6 MODERATE	0	0.0	2	8.0	
• 7-8 SEVERE	0	0.0	13	52.0	
• 9-10 HORRIBLE	0	0.0	10	40.0	
• TOTAL	25	100.0	25	100.0	
1 WEEK					
• 0 NO PAIN	22	88.0	0	0.0	<0.001**
• 1-2 SLIGHT	3	12.0	0	0.0	
• 3-4 MILD	0	0.0	0	0.0	
• 5-6 MODERATE	0	0.0	15	60.0	
• 7-8 SEVERE	0	0.0	10	40.0	
• 9-10 HORRIBLE	0	0.0	0	0.0	
• TOTAL	25	100.0	25	100.0	

DISCUSSION

It is well known that anxiety and pain are very common experience among the patients undergoing orthodontic treatment especially after the placement of initial arch wire. Pre-procedural anxiety is related to increased levels of perceived pain for patients undergoing restorative dental treatment, such as periodontal treatment and implant placement as was seen by Klages et al and Fardal & McCulloch in their study.[10,11]

A lot of remedies and therapeutic agents have been used to decrease the amount of pain. The most common include the analgesic medication like paracetamol, ibuprofen. Clarity is needed whether anxious patients require more analgesia to manage their pain. Experimental work by Tang et al.[12] on pain perception in response to electrical stimulae in two groups of patients, namely low trait anxious (LTA) and high trait anxious (LTA), demonstrated that both groups had the same pain thresholds and yet the more anxious (HTA) patients perceived the electrical stimulus to be more painful.

The present study was done to determine the pain related perception of patients and to know the satisfaction levels and mindset of patients after taking analgesic and placebo. For that reason Xylitol chewing gum was given to one group of patients. Xylitol is a sugar free chewing gum and has antibacterial effect. Xylitol is non fermentable by cariogenic plaque bacteria and thus, does not lower the pH of plaque. As the plaque pH does not decrease, enamel demineralization is prevented, and plaque bacteria do not proliferate.

Paracetamol is the most common analgesic prescribed in orthodontics and patient is usually informed about the pain after the initial wire placement during the first 24 hrs. The probable mechanism for preoperative anti-inflammatory effect is the blockage of prostaglandin synthesis in peripheral tissue, inhibiting the cyclooxygenase pathway and therefore the production of PGE, side effects being, gastric ulceration, nausea, vomiting. Law et al[5] found that pre-emptive ibuprofen significantly decreased pain to chewing at two hours compared with postoperative ibuprofen or placebo. Similar to that, Bernhart et al[13] found decreased pain scores in patients taking pre- or postoperative ibuprofen compared with patients taking only postoperative ibuprofen.

This study observed that pain was reduced in both groups i.e analgesic-paracetamol group and placebo group-xylitol group. Mostly pain was reduced in the paracetamol group at 24 hrs,2-6 days and after 1 week interval. However, the effect of placebo group cannot be ignored as that group also showed some reduction in pain which can be due to the masticatory effect of chewing gum or mere satisfaction of patients psychology causing the placebo effect, which lead to decrease in pain, indicating placebo medication can be tried in patients as it has no side effects.

The drawback of this study was the less sample size and the strong point was that there was no patient attrition during the course of study. Gender distribution was not included in this study because of previous study results that had shown no correlation between pain and sex.[14-16]

CONCLUSION

1. Mostly the pain reduction was seen in the analgesic group as compared to placebo group which was statistically significant.
2. There was reduction of pain in both the groups analgesic and placebo group indicating that the effects of placebo cannot be undermined.

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