A Study of Promethazine Hydrochloride and Pentazocine Intramuscular Sedation Along with 2 % Lidocaine Hydrochloride and Adrenaline and Comparison to Placebo Along with 2 % Lidocaine Hydrochloride and Adrenaline for Surgical Extraction of Mandibular Third Molar

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Abstract

Background and Objectives The main objective is to study and compare the sedative and analgesic effects of intramuscular injection fortwin–phenegan along with local anesthetic and normal saline placebo along with local anesthetics in mandibular third molar surgery. We also assessed and compared the postoperative experience of the patient in relation to the pain intensity, time to first analgesic taken and total number of analgesics consumed over a period of 48 h in the two groups.

Materials and Methods Patients who came to the Department of Oral and Maxillofacial Surgery, The Regional Dental College; with complaints regarding mandibular third molar were chosen for the treatment. Patients were evaluated using Corah Dental Anxiety Scale (CDAS) and those patients having a score of CDAS 13 and above were selected. Sixty patients were selected out of which 30 patients formed group 1 and another 30 patients group 2. The patients were randomly divided with flip method into group 1 (study group) and or group 2 (controlled group).

Results Our study results showed that the operating conditions for both the groups at the end of surgery were similar without significant difference. Most of the surgical procedures were graded as excellent and good in both the

groups except that difficulty was encountered in two patients from group 1 and one from group 2.

Conclusion It could be concluded that particular drugs do not have much influence on the surgical procedure in our study, but it was found that patients from group 1 were more cooperative as compared to group 2 when difficulty was encountered during the surgical procedure.

Keywords Visual analogue scale (VAS) · Corah Dental Anxiety Scale (CDAS) · Ramsey sedation score (RSS)

Introduction

Dental anxiety has been shown to be one of the biggest obstacles for patients seeking needed care. Majority of individuals admit that they are fearful to some extent but many avoid dental care altogether [1]. An individual with a “specific phobia” is defined as having a fear and anxiety that is so great that it inhibits them from normal daily function [2]. These patients present the greatest challenge for the dentists. In this age of anxiety, pain control and sedation have become important aspects of dental care. It is now becoming more common for general practitioners to provide in-office sedation for routine dental procedures. A segment of the population that would otherwise not seek care because of fear or anxiety is now receiving treatment. The use of sedation for dental care has become a topic of intense interest [3]. When looking at fear and anxiety towards dentistry, majority of the general public have a low level of fear, but they are able to receive dental treatment through various coping mechanisms. A small, but significant portion of the public, have fears so great that it impedes their ability

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to properly maintain oral health care. These are the patients with a high level of fear who probably do not seek dental care on a regular basis. Between these two groups are those with moderate levels of fear and anxiety. This group may be able to tolerate minor dental treatment but have a higher level of anxiety for more involved treatment [4]. The aim of sedation is to induce a depressed level of consciousness that allows the patient to tolerate an unpleasant diagnostic or therapeutic procedure while maintaining airway control and cardio-respiratory function [5].

Promethazine (Phenergan) has been available since 1951 and although it has long been utilized as a sedative agent, it is a phenothiazine as well as an antihistamine. It has considerable anticholinergic, sedative, antiemetic, and some local anesthetic properties. Sedation and analgesia are distinct processes. Some patients require primarily sedation, some primarily analgesia provided by opioids or local anaesthetic agents, and some both sedation and analgesia. Painful procedures often require both sedation and analgesia because sedation alone in the presence of pain may cause confusion and restlessness. Non-painful procedures in uncooperative patients may require sedation only [6].

Pentazocine is a synthetically-prepared mixed agonist–antagonist narcotic (opioid analgesic) drug used to treat mild to moderately severe pain. The discovery of analgesic activity in this drug is important since it is a morphine antagonist and has not yet been found to produce or support tolerance or dependence [7].

Lidocaine possesses a significantly rapid onset of action, produces profound anesthesia, longer duration of action and greater potency. It represents the “gold standard” the drug to which all new local anesthetics are compared [8].

Placebo analgesia is more likely to work the more severe the pain [9]. It can be effective: one study found that for postoperative pain following extraction of the third molar, that a saline when injected while telling the patient it was a powerful painkiller was as potent as a 6–8 mg dose of morphine [10]. The placebo effect may be a component of pharmacological therapies: Pain killing and anxiety reducing drugs that are infused secretly without the patients’ knowledge are less effective than when the patients know that they are receiving them [11].

A study of intramuscular injection of promethazine (phenergan) and pentazocine (fortwin) sedation along with 2 % lidocaine with adrenaline has been undertaken in anxious patients to relieve anxiety and pain for surgical removal of mandibular third molar.

Materials and Methods

This clinical study has been carried out in the department of Oral and Maxillofacial Surgery, Regional Dental College

Guwahati, Assam. Patients were chosen randomly for the study who presented with complaints regarding mandibular third molars. Sixty patients were selected and were randomly divided by coin and flip method into:

Group 1 (study group): where fortwin–phenergan along with local anesthesia was administered.

Group 2 (controlled group): where placebo with local anesthesia was administered.

The selected patients were confined only to American Society of Anaesthesiologists’ (ASA) Physical status grade 1 of either sex within 18 was to 60 years. Patients excluded from the study were chronic alcoholics and or other drugs abusers, which may affect the action of the study drugs, pregnant patients, extremely obese patients and syndromic patients.

Patients were evaluated using Corah Dental Anxiety Scale (CDAS) and those patients having a score of 13 and above were selected [12, 13]. All the Patients were advised an intra oral peri apical (IOPA) X-ray of mandibular 3rd molar or orthopantomograph (OPG) and laboratory investigation if indicated [14]. Drugs which were used in this study are—Inj. Pentazocine (fortwin)—30 mg/ml in 1 ampule, Inj. Promethazine hydrochloride (phenergan)—25 mg/ml in 1 ampule, 2 % lignocaine hydrochloride with adrenaline (1:80,000), 2 ml normal saline—Placebo. Emergency drugs like naloxone, adrenaline, diazepam, Thiopental sodium etc. were kept ready. Written informed consent for conscious sedation and surgical procedure were taken, before surgery, from the patients and one responsible adult attendant [15, 16].

Procedure

Group 1 patients were positioned in a semi-supine position. The pulse oximeter was fitted and B.P. cuff placed. Baseline readings of pulse, SPO2 and blood pressure were recorded and 5 % DNS IV infusion line was established. Then, 1 ml of pentazocine (fortwin) and 1 ml of promethazine hydrochloride (phenergan) was drawn together in 2 ml syringe, which was injected deep intramuscularly. In another 2 ml syringe, 2 ml of 2 % lignocaine with adrenaline was drawn and injected in a manner for nerve block.

After waiting for 20 min to achieve the desired level of sedation [17], the mandibular 3rd molar was removed surgically. Pulse pressure, blood pressure and SPO2 were continuously monitored at every 15 min intervals in the pulse oximeter before, during and after surgical procedure [18]. A minimum of 4 h observation done in these patients. All the patients were discharged after ascertaining their response to verbal stimulation, absence of any signs or

symptoms of compromised respiration and a state of being fully awake without any adverse reactions. Postoperative instructions were given to the patients along with emergency phone numbers. Patients were also instructed to avoid alcohol, driving vehicle, machinery handling, document signing, etc. postoperatively.

Group 2 patients were prepared similar to group 1 except that the surgical removal of mandibular 3rd molar was done under normal saline (placebo) with local anesthetics. Normal saline (placebo) was injected deep intramuscularly and 2 % lignocaine with adrenaline was injected in a manner for nerve block.

All the patients in both groups were discharged with a 5 days course of antibiotics and analgesic tablets of 50 mg diclofenac. Patients were given next appointment after 7 days for suture removal. Patients were given an already prepared Visual Analog Scale (VAS) [19] form to score their pain experience every hour for 8 h.

Assessment

Preoperative, intraoperative and postoperative pulse rate, blood pressure and SPO2 were examined in semi-supine position in the dental chair and recorded in the proforma form till patient was discharged.

Anxiety level was recorded as per preoperative examination as mild, moderate, high and severe, also at 20 min post sedation and 240 min or at the time of discharge [12]. Similarly, sedation level was noted as per Ramsey sedation score (RSS) [20].

Operating conditions were assessed by the surgeons at the end of the procedure. These were designed as excellent, good, fair and poor depending on the degree of the patients co-operation, difficulty index for removal of mandibular 3rd molar.

After injecting fortwin–phenegan and placebo, the side-effects if present were recorded in the proforma. No patient was given any analgesic preoperatively. On discharge they were given a questionnaire which they were asked to complete at home for assessment of postoperative pain experience [21].

Parameters Recorded During the Study

1. Demographic and surgical data including age, gender, weight, height duration of surgery and amount of drugs used.
2. The patient's anxiety level and alertness before sedation and after 20 and 240 min post sedation.
3. Assessment of the operating conditions at the end of the surgery by the surgeon.
4. The side-effects of the sedation
5. Post-operative pain experienced after going home was assessed by questionnaires given to the patients as stated below:

- a. Pain intensity: patients were asked to record on a VAS every hour for 8 h after surgery.
- b. Time to first analgesic: patients were asked to record the time of first analgesic taken postoperatively.
- c. Total analgesics during the first 48 h: patients were instructed to record the total number of analgesics taken during the first 48 h post-operatively.
- d. Patients global assessment: patients were asked to provide an overall evaluation of their pain experience on a 4-point categorical scale and submit it on the 7th day when they came to remove the stitches. The categories of the scale were excellent, good, fair and poor (excellent—minimum pain versus poor—severe pain) [22].

Scoring System Used in the Study

Pain Score

Pain was assessed subjectively in this study by visual analogue scale scoring system ranging from 0 to 100. Patients were explained about the pain score prior to sedation in the following way

No pain	100 mm line marked	Worse possible pain
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Patient Global Assessment Score

1 = Excellent	2 = good	3 = fair	4 = poor
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The categories of the scale were 1 = excellent, 2 = good, 3 = fair and 4 = poor (excellent = minimum pain versus poor = severe pain).

Ramsey Sedation Score (RSS) [20]

Grade of sedation	Numerical
Patient anxious and agitated	1
Patient co-operative, oriented and calm	2
Patient drowsy but responds to commands	3
Patients asleep but responds to light glabellar tap or loud auditory stimulus	4
Patient asleep but with sluggish responds to glabellar tap or auditory stimulus	5
Patient asleep with no response at all	6

Results and Observations

The parameters recorded during the study included demographic and surgical data. The number of patients, age,

weight, sex distribution, duration of surgery and the sedative and anxiety level were recorded. VAS was employed to measure the pain intensity every 1 h for the first 8 h postoperatively. The time to first analgesic and the total number of analgesics consumed during the first 48 h was recorded postoperatively. The operating conditions at the end of surgery was assessed by the surgeon and side-effects noted if present. The overall satisfaction of the patient was evaluated at the end of the trial.

The sex distribution of male and female, age and weight distribution in the two groups does not show any difference (Tables 1, 2). Thirty patients from group 1 received 30 mg fortwin and 25 mg phenergan or 0.5 mg/kg body weight along with 2 ml local anesthetics while 30 patients from group 2 received 2 ml of normal saline as placebo along with 2 ml local anesthetics (Table 3). Mean score of patients in group 1 was 13.7 CDAS while score of group 2 patients was 13.1, which indicates that all are anxious patients (Tables 4, 8). Various grades of anxiety using CDAS in the two groups was analysed preoperatively and 20 min post sedation (Tables 5, 6).

It is been observed that, 20 min after injection of fortwin and phenergan to group 1 patients, all except one patient

showed no anxiety and the treatment was given done comfortably. Out of 30 patients in group 2, 24 were moderately and 4 were highly anxious. Only 2 patients showed no anxiety after placebo. Thus, group 1 patients were more sedated as compared to group 2 patients and it was statistically significant.

After 240 min or at time of discharge, 21 patients from group 1 showed mild anxiety, 8 patients moderate and 1 patient showed high anxiety level. Eight patients from group 2 showed mild anxiety, 18 moderate and 4 high anxiety levels. The result showed that, at the time of discharge, group 2 patients were more anxious as compared to group 1 patients and it was statistically significant (Tables 7, 8).

It is also observed that at 20 min post sedation, 20 patients from group 1 were at level/scale 3 of RSS while 10 patients were at level 4. On the other hand 9 patients in group 2 were at level 1, 19 at level 2 and only 2 patients were at level 3 of RSS. This showed that all the patients from group 1 were well sedated after 20 min but only 2 patients from group 2 were at an ideal sedation level (Table 9).

Table 1 Showing sex distribution and male–female number and percentage of the patients in the two groups

Sex	Group 1		Group 2		Total	
	No.	%	No.	%	No.	%
Male	18	60	17	56.7	35	58.2
Female	12	40	13	43.3	25	41.7
Total	30	100	30	100	60	100

Table 2 Demographic data of the patients showing age and weight distribution of the two groups

Particulars	Group 1	Group 2
Mean age in years	26.7	26.2
Mean weight in Kg	53.9	54.3

Table 4 Mean score of patient anxiety level using Corah Dental Anxiety Scale (CDAS) in the two groups

Particulars	Group 1	Group 2
Total number of patients	30	30
Mean score of anxiety level	13.7	13.1

Table 5 Various grades of anxiety using Corah Dental Anxiety Scale (CDAS) in the two groups pre-operatively

Scale of anxiety (CDAS preoperatively)	Group 1		Group 2	
	No of patients	Percentage	No of patients	Percentage
Mild	Nil	0	Nil	0
Moderate	Nil	0	Nil	0
High	27	90	28	93.3
Severe	3	10	2	6.7
Total	30	100	30	100

Table 3 Distributions of patients receiving different drugs, with doses, in the two groups

Group	No. of patients	Drugs used	Dose	Route
Group 1	30	Fortwin + phenergan	30 + 25 mg (1 + 1 i.e. 2 ml or 0.5 mg/kg body wt)	Deltoid muscles
		2 % lidocaine with adrenaline 1:80,000	2 ml	Nerve block and local infiltration
Group 2	30	Placebo (normal saline)	2 ml	Deltoid muscles
		2 % lidocaine with adrenaline 1:80,000	2 ml	Nerve block and local infiltration

Table 6 Various grades of anxiety 20 min post-sedation in group 1 and group 2 patients

Grades of anxiety 20 min post operatively	Group 1		Group 2	
	No. of patients	Percentage	No. of patients	Percentage
Mild	29	96.7	2	6.7
Moderate	1	3.3	24	80
High			4	13.3
Severe	–	–	–	–

Table 7 Various grades of anxiety 240 min/at time of discharge of the patients postoperatively in the two groups

Grades of anxiety 240 min/at time of discharge	Group 1		Group 2	
	No. of patients	Percentage	No. of patients	Percentage
Mild	21	70	8	26.7
Moderate	8	26.7	18	60
High	1	3.3	4	13.3
Severe	–	–	–	–

Table 8 Various scores of sedation using Ramsey Sedation Scale preoperatively in the two groups

Scores of Ramsey sedation scale preoperatively	Group 1		Group 2	
	No of patients	Percentage	No. of patients	Percentage
1. Patient anxious, agitated	30	100	30	100
2. Patient cooperative, oriented, calm	Nil	Nil	Nil	Nil
3. Patient responds to commands only	Nil	Nil	Nil	Nil
4. Patient exhibits brisk response to light glabellar tap or loud auditory stimulus	Nil	Nil	Nil	Nil
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus	Nil	Nil	Nil	Nil
6. Patient exhibits no response	Nil	Nil	Nil	Nil
Total	30	100	30	100

After 240 min post sedation or at the time of discharge, all the patients of both the groups regained their anxiety. Ten patients from group 1 were at RSS 1 and 20 patients were at RSS 2, while 18 patients from group 2 were at RSS 1 and 12 patients were at RSS 2. The patients from group 2

Table 9 Various scores of sedation using Ramsey Sedation Scale 20 min post-sedation in group 1 and 2

Scores of Ramsey sedation scale 20 min post-sedation	Group 1		Group 2	
	No. of patients	Percentage	No. of patients	Percentage
1. Patient anxious, agitated			9	30
2. Patient cooperative, oriented, calm			19	63.3
3. Patient responds to commands only	20	66.7	2	6.7
4. Patient exhibits brisk response to light glabellar tap or loud auditory stimulus	10	33.3		
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus				
6. Patient exhibits no response				
Total	30	100	30	100

Table 10 Various scores of sedation using Ramsey Sedation Scale 240 min/at the time of discharge post-sedation in the two groups

Scores of Ramsey sedation scale 240 min post-sedation	Group 1		Group 2	
	No. of patients	Percentage	No. of patients	Percentage
1. Patient anxious, agitated	10	33.3	18	60
2. Patient cooperative, oriented, calm.	20	66.7	12	40
3. Patient responds to commands only				
4. Patient exhibits brisk response to light glabellar tap or loud auditory stimulus				
5. Patient exhibits a sluggish response to light glabellar tap or loud auditory stimulus				
6. Patient exhibits no response				
Total	30	100	30	100

were more anxious as compared to group 1 at the time of discharge and it was statistically significant (Table 10).

One hour postoperatively, in group 1, pain score was mild in 28 patients, moderate in 1 patient and severe in 1 patient while in patients from group 2 it was mild in 8

patients, moderate in 8 patients and severe in 4 patients. Pain scores of group 2 patients were highly significant as compared to group 1 patients after 1 h postoperatively.

Pain scores at 4 h postoperatively in group 1 were none 1, mild 12, moderate 15 and severe 2 while patients from group 2 were mild 2, moderate 10, severe 13 and very severe 5. The result showed that after 4 h postoperatively, patients from group 2 experienced more pain as compared to group 1 patients. The overall pain experienced from 1 to 8 h postoperatively showed that group 2 patients experienced more pain as compared to group 1 patients (Tables 11, 12).

The mean time to take first analgesic tablets by the patients in group 1 was 247.9 min postoperatively while in group 2 patients it was 131.93 min. Thus it shows that the analgesic taken by group 1 are delayed by 115.97 min as

compared to group 2 patients which is highly significant and that the analgesic effects of fortwin–phenergan are more effective as compared to normal saline placebo (Table 13).

The mean number of analgesic tablets taken by group 1 patients was significantly less as compared to group 2 patients during the first 48 h post-operatively (Table 14).

Assessment of the surgical condition was done by the surgeon at the end of the operation. The results showed that the operating conditions for both the groups were not different (Table 15).

Patient's global assessment was done at the end of the study. The results showed no significant difference between the two groups (Table 16).

The most common side-effects were drowsiness and nausea in both the groups. Postoperative side-effects are

Table 11 Pain score after 1st, 4th, 8th h using Visual Analog Scale postoperatively, bar diagram and statistical analysis have been done in both groups

1 st hour		
Pain score with VAS	Group - 1	Group - 2
None	0	0
Mild	28	8
Moderate	1	8
Severe	1	4
Very severe	-	10
TOTAL	30	30

4 th hour		
Pain score with VAS	Group - 1	Group - 2
None	1	-
Mild	12	2
Moderate	15	10
Severe	2	13
Very severe	0	5
TOTAL	30	30

8 th hour		
Pain score with VAS	Group - 1	Group - 2
None	7	-
Mild	18	4
Moderate	1	14
Severe	3	9
Very severe	1	3
TOTAL	30	30

Table 12 Total pain experience during the first 8 h postoperatively using Visual Analog Scale (VAS) in the two groups

Pain score with VAS	Group 1	Group 2
None		
Mild	20	1
Moderate	10	9
Severe		18
Very severe		2
Total	30	30

Table 13 Time to take first analgesic (in minutes) post-operatively in the two groups

Particulars	Group 1	Group 2
Total number of patients	30	30
Mean time to take 1st analgesic post-operatively (min)	247.90	131.93

Table 14 Total number of analgesics taken in the first 48 h postoperatively in the two groups

Particulars	Group 1	Group 2
Total number of patients	30	30
Total no. of analgesic tablets taken in 48 h post-operatively (tablets)	3.17	5.53

more common in group 1 as compared to group 2 patients in that 14 patients from group 1 experienced drowsiness and 5 patients developed nausea while 5 patients from group 2 experienced drowsiness and 1 patient nausea. It can be concluded that even though the sedative and analgesic effects in group 1 were more effective and satisfactory but the side effects were more significant as compared to group 2 (Table 17).

Discussion

The control of pain and anxiety is an essential part of dental practice. Many strategies are used to achieve this goal, including psychological approaches, local anesthetics, and sedatives and general anesthetics, individually or in combination. The choice of the modality for a particular situation is based on the training, knowledge, and experience of the maxillofacial surgeon, the medical status of the patient, and the psychological and dental needs of the patient [23]. Therapeutic basis of alleviating anxiety is based on using pharmacological means.

Table 15 Assessment of the surgical condition by the surgeon at the end of the operation

Assessment of surgery by the surgeon	Group 1	Group 2
Excellent	13	15
Good	15	14
Fair	2	1
Poor	–	
Total	30	30

Table 16 Patient's global assessment at the end of the study

Patient assessment at the end of trial	Group 1	Group 2
Excellent	11	10
Good	17	15
Fair	2	4
Poor	0	0
Total	30	30

Table 17 Side effects of both groups

Side effects of the drug used	Group 1	Group 2
Drowsiness	14	5
Nausea	5	1
Total	19	6

In this age of anxiety, pain control and sedation have become important aspects of dental care. The use of sedation for dental care has become a topic of intense interest [3]. Anxiety and pain are intimately related. Anxiety can also lead to the exacerbation of pain [24]. Anxious patients were uncooperative during surgery and complicate the procedure [25].

Due to the compatibility of promethazine and pentazocine in the single syringe, similarity in the duration and onset of action, the safety of the drugs and cost effectiveness; the combination of promethazine and pentazocine as sedatives and pain control has been used widely in different surgical procedures along with local anesthetic [26, 27].

Despite the increased drowsiness with promethazine, there was no delay in discharge of the patients and sedation was higher in promethazine group when compared with placebo [28]. Our study showed that promethazine–pentazocine drug combination of group 1 is more advantageous significantly as compared to placebo of group 2, to achieve sedation and to relieve anxiety preoperatively.

Clinical effects of promethazine and pentazocine are generally apparent within 20 min of an intramuscular

injection. Duration of action is 4–6 h, although effects may persist up to 12 h. Patients allocated promethazine were tranquil or asleep by 20 min [17].

Even though the drug combinations of promethazine and pentazocine have been used extensively in different surgical procedures, a particular study has not been found especially in oral and maxillofacial surgery. In our study, we compared the sedative and analgesic effects of fortwin-phenergan to the effects of normal saline placebo for the surgical extraction of mandibular third molar in anxious patients. The aim of our study is an attempt to reduce the patient's anxiety and relieve pain.

It is well documented that placebo is associated with powerful non specific effects [29]. Some studies have shown that placebos have healing effects in conditions like angina pectoris [30], control of nausea and vomiting [28, 31, 32]. Chia in 2004 stated that there was no difference in the sedative effects between promethazine and placebo (normal saline) Parlow et al. [28] concluded that sedation was higher in promethazine group than placebo group. In our study, it was found that the sedative effect of promethazine was higher than placebo group which is highly significant (P value = 0.00).

The present clinical study was designated to evaluate the usefulness of intramuscular conscious sedation of promethazine hydrochloride and pentazocine along with 2 % lidocaine hydrochloride and adrenaline, and comparison to normal saline as placebo with lidocaine hydrochloride and adrenaline in anxious patients for the surgical removal of mandibular third molar.

Patients were selected randomly from the out patient Department of Oral And Maxillofacial Surgery, Regional Dental College Guwahati; Assam. The surgery was carried out under local anesthesia using 2 % lidocaine with 1:80,000 adrenalin [28, 32].

Sixty patients were selected using Corah Dental Anxiety Scale having a score of more than 13 which indicates anxious patients and were randomly divided into group 1 and group 2 with 30 patients in each group. Patients were randomly selected irrespective of caste, sex, race and religion and were between 18 and 60 years of age.

Our study included ASA physical status 1 only. Previous studies relating to conscious sedation conducted by Venchard et al. [33], Silegy and Jacks [15] and Krishnan and Jacks [19] have included both ASA physical status 1 and 2.

Corah [12] published CDAS, a questionnaire relating to dental history, giving anxiety rating as: below 9 is mild anxiety, 9–12 is moderate anxiety, 13–14 is high anxiety, and 15–20 is severe anxiety.

It was mentioned that the CDAS is the most widely used and validated test for dental anxiety. Facco et al. [13] stated that a CDAS higher than 12 indicated anxious patients. Also, studies by Thomson et al. [34], used CDAS to

measure the respondents' dental anxiety level and considered a score of 13 or higher as anxious.

The selection criteria in our study also used CDAS and those patients having CDAS score of 13 or higher were included. It was also found in our study that the CDAS was a useful method for obtaining the patient anxiety level.

Our study showed that by 20 min after intramuscular injection, all the patients from group 1 were well sedated except 1 patient, while 4 patients from group 2 were still in a state of high anxiety but all patients were manageable to perform surgery. This shows that, the anxiety levels of group 1 patients were reduced which is highly significant as compared to group 2 patients (P value = 0.00).

After 240 min or at the time of discharge, patients from both the groups regain their anxiety; 21 patients from group 1 showed mild anxiety, 8 patients moderate anxiety and 1 patient showed high anxiety while 8 patients from group 2 showed mild anxiety, 18 moderate and 4 high anxiety. This shows that group 2 patients regain their anxiety more significantly as compared to group 1 patients at the time of discharge (P value = 0.003).

Most sedation protocols strive for maintaining patients at a RSS [35]. In other studies, Sharma et al. [18] stated that patients were maintained in a state of conscious sedation (RSS) 2–3. Cruz [36] stated that patients were sedated at RSS of 3 and 4. Our study also aimed of sedating the patients at RSS 3 and 4.

In our study, after 20 min of giving the injection, it was found that all patients from group 1 were sedated to a desired level of RSS 3 and 4. In group 2, only 2 patients achieved RSS 3, 19 patients were RSS 2 and 9 patients were RSS 1. The desired level of sedation achieved was highly significant in group 1 as compared to group 2 patients (P value = 0.00).

It is interesting to note from our study that the drug combination of 25 mg phenergan with 30 mg fortwin intramuscular injection gave an ideal level of sedation.

Visual analogue scale is a measuring instrument that measures the amount of pain that a patient feels and is categorized as none, mild, moderate, severe and very severe pain [19]. The VAS is an accepted method of assessing pain in the post operative period [37, 38].

Pain was measured with a standard 0–100 mm VAS ranging from 0 for no pain, to 100 for worst possible pain [39]. Patients' pain intensity were recorded at 1, 4, 8, 12, 24 and 48 h post operatively [40].

In our study, the patients pain intensity was recorded every 1 h postoperatively up to 8 h to measure the post-operative pain experienced by the patients in both group 1 and group 2 and the resultant comparison between the two groups have been done in the 1st, 4th, and 8th h postoperatively. The mean pain intensity is calculated and compared between the two groups.

The pain scores in the 1st hour were none-0, mild-28, moderate-1 and severe-1 in group 1 patients while in group 2 patients, the pain scores were none-0, mild-8, moderate-8, severe-4 and very severe-10. Pain scores of group 2 patients were highly significant as compared to group 1 patients after 1 h post-operatively ($P = 0.00$). This shows that group 1 patients experience less pain as compared to group 2 patients 1 hour postoperatively.

In the 4th h, the pain scores were none-1, mild-12, moderate-15, severe-2 and very severe-0 in group 1 patients while in group 2 patients the scores were none-0, mild-2, moderate-10, severe-13 and very severe-5. Our study shows that at 4th h postoperatively, the pain intensity was markedly less in group 1 patients significantly as compared to group 2 patients ($P = 0.00$).

After 8th h, the pain score was none-7, mild-18, moderate-1, severe-3 and very severe-1 in group 1 patients while in group 2 patients, the scores were none-0, mild-4, moderate-14, severe-9 and very severe-3. Our study showed that group 1 patients experienced less pain as compared to group 2 after 8 h postoperatively (P value = 0.00).

The overall pain score of the patients from the first to 8 h postoperatively were mild-20, moderate-10 in group 1 patients and in group 2 patients were mild-1, moderate-9, severe-18 and very severe-2. Our study result showed that the intensity of pain was less in group 1 patients as compared to group 2 patients during the first to 8 h postoperatively ($P = 0.00$).

Clinical effects of promethazine and pentazocine are generally apparent within 20 min of an intramuscular injection. After 20 min, the anxiety and sedation level/score were recorded in all the patients.

In our study, 2 ml of 2 % lidocaine with adrenaline local anesthetics was given to the patients. Although an additional 2 ml of local anesthesia was given in 5 cases; 3 in group 2 and 2 in group 1; there was no failure to provide a satisfactory level of anesthesia.

The duration of surgery in both groups was almost similar with no significant difference. The mean duration of surgery was 38.4 and 40.3 min in group 1 and group 2 respectively. Assessment of the surgical condition by the surgeon at the end of the operation showed no significant difference between the two groups.

All the patients were kept for observation for their recovery from sedation and untoward effects. Almost all the group 1 patients were discharged after 240 min (4 h) from the time of intramuscular injection seeing that the patients recovered from the sedative effects. There were only two patients who were discharged after 5 h due to drowsiness in group 1 patients while all the patients from group 2 were discharged after 240 min after ascertaining their recovery from sedation. Assessments were made

using VAS, which is a simple and sensitive means of assessment, ideal for use in crossover studies [41].

On discharge of the patients, the VAS which has to be maintained every hour postoperatively was given to the patients and they were advised to maintain, continuously, the first 8 h pain intensity postoperatively. Also all the patients were instructed to note the first analgesics taken and the total amount of analgesics taken during the first 48 h. Patients were discharged with postoperative instructions along with 5 days antibiotics and pain killers and advised to come after 7 days for suture removal.

The mean postoperative pain score recorded in the VAS at 1st, 4th and 8th hours provided in the patient questionnaires were analysed in both the two groups.

In our study, the operating conditions were assessed by the surgeon at the end of the procedure. The assessment was designated as excellent, good, fair and poor depending on the duration of surgery & pain experienced by the patients during the surgical procedure, difficulty of the tooth removal and cooperation of the patients. Even though results showed no statistically significant difference between the two groups, patients from group 1 were more cooperative with better operating conditions possible due to more sedative effects as compared to group 2.

During the whole study period, no serious adverse effects were encountered regarding the drugs used, patients as well as the surgical procedure.

Patients Global Assessment

All the patients were asked to provide an overall evaluation of their pain experience on a 4-point categorical scale on the 7th day when they came to remove the stitch. The categories of the scale were excellent, good, fair and poor (excellent-minimum pain versus poor-severe pain) [22].

In our study, the scores in group 1 were excellent-11, good-17, fair-2 and poor-0, while the scores in group 2 patients were excellent-10, good-15, fair-4 and poor-0. The results showed that there was no significant difference between the two groups. It might be because cross-sectional studies have not been done in individual patients.

Pain is an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage [42]. Our study also showed that pain relieved by pentazocine was significantly higher than placebo group.

The pain intensity during the first 8 h are already mentioned earlier. The mean time to first analgesic which has been defined as the time from the end of surgery until intake of first analgesic were calculated in both the groups. In our study, the mean time of first analgesic taken was 247.90 min postoperatively in group 1 patients and 131.93 min in group 2 patients. The intake of first

analgesic by group 1 patients was delayed by 115.97 min as compared to group 2 patients which indicates that pain relieved by pentazocine was significantly longer as compared to placebo (P value = 0.00).

The mean total analgesic consumed during the first 48 h was analysed in both the groups. Patients from group 1 consumed 3.17 tablets while group 2 patients took 5.53 tablets. The result showed that the number of analgesic tablets taken by group 1 patients was less as compared to group 2 patients significantly during the first 48 h post-operatively (P value = 0.00). It shows that pain relief was longer in group 1 patients as compared to group 2 patients.

Side Effects and Complications

Severe complications were not encountered throughout the whole study period. The most common side effects were drowsiness and nausea in both the groups. Postoperative side effects are more common in group 1 as compared to group 2 patients in that 14 patients from group 1 experienced drowsiness and 5 patients developed nausea while 5 patients from group 2 experienced drowsiness and 1 patient nausea. It can be concluded that even though the sedative and analgesic effects in group 1 were more effective and satisfactory, the side effects were more in group 1 as compared to group 2.

Conclusion

Conscious sedation enables the surgeon to perform the necessary dental and maxillofacial surgery with minimal stress to the patient. On the basis of findings brought out in this study, the following conclusions were drawn:

1. Response in human to stress is considered to be a healthy response and necessary for life. Our study showed that, an optimum dose of promethazine and pentazocine drug combination achieved the desired level of sedation in anxious patients. It also improved the surgical conditions of the patients.
2. In our study, promethazine and pentazocine drug combination had significant advantage over placebo regarding the analgesic effect during surgery. It could be due to the analgesic properties of both the drugs.
3. Analysis of the time to first analgesic postoperatively was markedly delayed in promethazine and pentazocine group as compared to placebo group significantly. So, our study showed that patients experienced less pain postoperatively in group 1 as compared to group 2 patients.
4. It was also found in our study that more the difficulty and trauma encountered during the surgical procedure,

the more was the benefit. It was also expected from our study that more traumatic and painful surgical procedures other than impacted mandibular third molar surgery could be performed using a combination of promethazine and pentazocine for intramuscular sedation.

5. Eventhough titration of the drug used is not possible in intramuscular sedation, it was found in our study that a combination of promethazine and pentazocine with a proper dosage produced an ideal level of sedation without an adverse effect.
6. It has also been found that though the drug combination of promethazine and pentazocine has the property of producing localized tissue irritation and pain, frequently, at the injection site, none of the patients complained of this possible adverse effect. It can be considered as a safe drug, in this regard, when used properly.
7. Our study showed that the major disadvantage of sedation produced by promethazine and pentazocine combination was the longer duration of action which lasts at least 4 h.

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References

1. Dionne RA, Gordon SM, McCullagh LM, Phero JC (1998) Assessing the need for anesthesia and sedation in the general population. *J Am Dent Assoc* 129(2):167–173
2. Task Force on DSM–IV APA 2000 Diagnostic and statistical manual of mental disorders: DSM-IV-TR, 4th edn. American Psychiatric Association, Washington, DC
3. Goodchild JH, Freck AS, Silverman MD (2003) Anxiolysis in dental practice. ADA guidelines for the use of conscious sedation, deep sedation, and general anesthesia for dentists. Available at: www.ada.org/prof/ed/guidelines/cs-guide.html. Accessed on: Nov. 1, 2002
4. Chanpong B, Haas DA, Locker D (2005) Need and demand for sedation or general anesthesia in dentistry: a national survey of the Canadian population. *Anesth Prog* Spring 52(1):3–11
5. Markic J (2010) 18th expert committee on the selection and use of essential medicines
6. Hung CT, Chow YF, Fung CF, Koo CH, Lui KC, Lam A (2002) Safety and comfort during sedation for diagnostic or therapeutic procedures. *Hong Kong Med J* 8(2):114–122
7. Cass LJ, Frederik WS, Teodoro JV (1964) Pentazocine as an analgesic clinical evaluation. *JAMA* 188(2):112–115
8. Malamed SF (2004) Handbook of local anesthesia, 5th edn. Mosby, St. Louis
9. Levine JD, Gordon NC, Bornstein JC, Fields HL (1979) Role of pain in placebo analgesia. *Proc Natl Acad Sci USA* 76(7):3528–3531

10. Levine JD, Gordon NC, Smith R, Fields HL (1981) Analgesic responses to morphine and placebo in individuals with postoperative pain. *Pain* 10(3):379–389
11. Colloca L, Lopiano L, Lanotte M, Benedetti F (2004) Overt versus covert treatment for pain, anxiety, and Parkinson's disease. *Lancet Neurol* 3(11):679–684
12. Corah NL (1969) Development of a dental anxiety scale. *J Dent Res* 48:596
13. Facco E, Zanette G, Manani G (2008) Talian version of Corah's dental anxiety scale: normative data in patients undergoing oral surgery and relationship with the ASA physical status classification. *Anesth Prog* 55(4):109–115. doi:[10.2344/0003-3006-55.4.109](https://doi.org/10.2344/0003-3006-55.4.109)
14. Fattahi T (2006) Perioperative laboratory and diagnostic testing—what is needed and when? *Oral Maxillofac Surg Clin N Am* 18(1):1–6
15. Silegy T, Jacks ST (2003) Pediatric oral conscious sedation. *J Calif Dent Assoc* 31(5):413–418
16. Donaldson M, Gizzarelli G, Chanpong B (2007) Oral sedation: a primer. *Anesth Prog* 54:118–129
17. Huf G, Coutinho ES, Adams CE, TREC Collaborative Group (2007) Rapid tranquillisation in psychiatric emergency settings in Brazil: pragmatic randomised controlled trial of intramuscular haloperidol versus intramuscular haloperidol plus promethazine. *BMJ* 335(7625):869
18. Sharma P, Julka A, Gadia R, Chhabra A, Dehnan M (2009) Evaluation of single-stage adjustable strabismus surgery under conscious sedation. *Indian J Ophthalmol* 57:121–125
19. Krishnan R, Shivananda S, Raman U (2008) Pre-emptive analgesia for elective maxillofacial surgery using 0.25 % bupivacaine. *Indian J Anaesth* 52(5):556–561
20. Ramsay MAE, Savege TM, Simpson BRJ, Goodwin R (1974) Controlled sedation with alprazolone–alpradolone. *Br Med J* 2:656–659
21. Gould D et al (2001) Examining the validity of pressure ulcer risk assessment scales: developing and using illustrated patient simulations to collect the data. *J Clin Nurs* 10:697–706
22. Kranke P, Morin AM, Roewer N, Eberhart LH (2004) Patients' global evaluation of analgesia and safety of injected parecoxib for postoperative pain: a quantitative systematic review. *Anesth Analg* 99(3):797–806. doi:[10.1213/01.ANE.0000133139.68208.92](https://doi.org/10.1213/01.ANE.0000133139.68208.92)
23. Dionne RA, Gift HC (1988) Drugs used for parenteral sedation in dental practice. *Anesth Prog* 35:199–205
24. Weisenberg M, Avirim O, Wolf V, Raphaeli N (1984) Relevant and irrelevant anxiety in the reaction to pain. *Pain* 20:371–383
25. Smyth JS (1993) Some problems of dental treatment. Part 1. Patient anxiety: some correlates and sex differences. *Aust Dent J* 38:354–359
26. Iyer NS (2004) Caesarean section under local anesthesia. FOGSI national initiative on relevance, techniques and advocacy. An analysis of practices, and recommendations. The proceedings of national consensus meet, Thiruvananthapuram, Kerala, 3 July 2004
27. Chitra KLS, Nirmala AP, Gayetri R, Jayanthi NV, Shanthi JS (2004) Misgav Ladach cesarean section versus Pfannenstiel cesarean section. *Obstet Gynecol Ind* 54(5):473–477
28. Parlow J, Meikle A, van Vlymen J, Avery N (1999) Post discharge nausea and vomiting after ambulatory laparoscopy is not reduced by promethazine prophylaxis. *Can J Anaesth* 46(8):719–724
29. Brown WA (1998) Harnessing the placebo effect. *Hosp Pract* 33:107–116
30. Benson H, McCallie DP (1979) Angina pectoris and the placebo effect. *New Engl J Med* 300(25):1424–1429. doi:[10.1056/NEJM197906213002508](https://doi.org/10.1056/NEJM197906213002508)
31. Sandhya, Yaddanapudi L (1994) Evaluation of two antiemetic agents during outpatient gynaecological surgery. *Singapore Med J* 35(3):271–273
32. Cheung CW et al. (2005) A comparison of dexmedetomidine and midazolam for sedation during wisdom teeth extraction
33. Venchard GR (2006) Improved sedation for oral surgery by combining nitrous oxide and intravenous Midazolam: a randomized, controlled trial. *Int J Oral Maxillofac Surg* 35(6):522–527
34. Thomson WM et al (1996) Dental anxiety among Australians. *Int Dent J* 46(4):320–324
35. Ebert TJ (2001) Special Report: Current strategies in ICU sedation. Abbott Laboratories
36. Cruz JR (2009) Clonidine as pre-anesthetic medication in cataract extraction: comparison between 100 microg and 200 microg. *Rev Bras Anesthesiol* 59(6):694–703
37. Myles PS (1999) The pain visual analog scale. *Anesth Analg* 89:1517–1521
38. Rainville P (2000) Measurement of pain in Bell's orofacial pain Okeson JP, 4th edn. pp 10–45
39. Tade AO, Salami BA, Ayoade AB (2009) Pentazocine pain relief in adult patients with acute abdominal pain: a prospective randomized clinical trial. *East Central Afr J Surg* 14(2):44–49
40. Ghafari MH, Akrami M, Nouralishahi B, Sadegh A (2009) Pre-operative gabapentin or clonidine decreases postoperative pain and morphine consumption after abdominal hysterectomy. *Res J Biol Sci* 4(4):458–463. doi:[10.3923/rjbsci.2009.458.463](https://doi.org/10.3923/rjbsci.2009.458.463)
41. Jensen MP, Karoly P, Braver S (1986) The measurement of clinical pain intensity; a comparison of six methods. *Pain* 27:117–126
42. Bonica JJ (1979) The need of a taxonomy. *Pain* 6(3):247–252. doi:[10.1016/0304-3959\(79\)90046-0](https://doi.org/10.1016/0304-3959(79)90046-0). ISSN 0304-3959