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The Use of an Anxiolytic Medication (Placida Tablet) as an Outpatient Oral Premedication to Supplement Anxiety Relief in an Anxious Patient before Orthodontic Treatment - A Primer on Anxiolysis for Orthodontic Patients

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Abstract: ***To compare the effects of a single session of acute administration of placida (an anxiolytic containing flupenthixol and melitracen) 300 orthodontic treatment phobic patients were allocated by simple random sampling from the opd at smile and shine orthodontic care, Pune. the drug was administered to them with an informed consent as an anxiety precaution tablet before the commencement of orthodontic treatment on the 1st appointment date. after completion of the procedure , patients were given an anxiety analogue scale questionnaire and the study was analysed based on the questionnaire as follows: 70% patients experienced no anxiety, fear or apprehension throughout the procedure and the placeda tablet successfully promoted anxiolysis. 20% patients experienced anxiety relief , but were still a little apprehensive and anxious during the treatment. placeda promoted only partly relief. 10% patients participants felt as anxious, nervous and apprehensive as they were before taking the placeda tablet.***

1. Introduction

The use of sedatives and anxiolytics has established efficacy and safety for managing anxiety regarding dental treatment. This article will provide essential information regarding the pharmacology and therapeutic principles that govern the appropriate use of orally administered Placida tablet to provide mild sedation and anxiolysis. Dosages and protocols are intended for the purpose of mild anxiety relief purely and not for providing moderate or deeper sedation levels. Majority of the patients admit that they are fearful to some extent about orthodontic treatment but many avoid care altogether. An individual with a "specific phobia" present the greatest challenge to the orthodontist. Small but significant portions of public have fears so great that it impeded their ability to properly maintain oral health care and seek orthodontic treatment. To overcome this drawback, a newly introduced drug called placeda was administered to 300 orthodontic treatment phobic patients and the results of anxiolysis was analysed based on a questionnaire given to the patients at the end of the 1st appointment.

About Placida
Placida 0.5mg/10mg tablet falls under a category of drugs known as thioxanthenes and is an antianxiety drug

- Manufacturer:- Mankind
- Composition:- Flupenthixol 0.5mg+Melitracen 10mg tablet

Aims
To relieve the anxiety caused in orthodontic patients by advocating a drug named placeda

Objectives
1) To assess whether if the given drug actually promoted anxiety relief in the patient.
2) If no, did it at least reduce the fear and apprehension levels in the patient that he/she used to witness during his prior treatments.
3) To calculate the percentage of participants with and without anxiety relief.

Inclusion Criteria
1) Orthodontic phobic patients
2) Female patients
3) Age group:- 15-40 years
4) Treatment not started
5) Patients requiring orthodontic treatment only

Exclusion Criteria
1) Older age patients
2) Young males
3) Allergic patients
4) Non apprehensive patients
5) Pregnant females
6) Patients already on anxiolytics
7) Medically compromised patients

2. Materials and Methods

To analyse the positive effects of placeda, a sample size of 300 patients were collected from the opd of smile and shine orthodontic care, Pune. The sample was collected by simple random sampling method by taking into consideration the inclusion and exclusion criteria enlisted above.

The study included only all the new patients who haven't undergone any orthodontic treatment appointments before. The patients were given a consent form which was to be signed before the commencement of the interventional study.

The purpose of giving the placida tablet was also explained to them verbally and only after the patients consent, the tablet was administered and treatment started.

The same protocol was employed on all patients and 300 patients were gathered over a period of 6 months and the patient was evaluated based on the questionnaire he/ she filled after the completion of orthodontic procedure

Protocol employed was as follows:

1) Patient was made to sit in a relaxed room for 10 minutes after he/ she walked into smile and shine dental clinic, Pune.
2) Patient was then asked to fill the consent form for agreeing to be a part of the interventional study.
3) After proper consent with the patients signature, Placida tablet administered to the patient and ask the patients to relax for another 10 mins
4) Orthodontic Treatment started
5) During the treatment the patient was evaluated by the orthodontist for signs of apprehension, fear or anxiety.
6) After completion of the treatment patient was given the questionnaire format for taking his inputs about his experience

Sample Participant Consent Form:
Consent to Participate in a Research Study
Smile and Shine Orthodontic Care, Pune
Title of Study:"The Use Of An Anxiolytic Medication (Placida Tablet) As An Outpatient Oral Premedication To Supplement Anxiety Relief In An Anxious Patient Before Orthodontic Treatment"- A Primer On Anxiolysis For Orthodontic Patients

vestigators:

1st :-	**Dr. Bhushan Jawale**		**Phone:**	9850299277
2nd:-	**Dr. Lishoy Rodrigues**		**Phone:**	9975444631

Introduction

- You are being asked to be in a research study of a drug named Placeda which is studied for its effectiveness in anxiety relief.
- You were selected as a possible participant because of your fear].
- We ask that you read this form and ask any questions that you may have before agreeing to be in the study.

Purpose of Study

- The purpose of the study is to relieve the anxiety caused in an orthodontic patient by advocating a drug named Placida
- Ultimately, this research may be published as a part of a journal or presented as a paper.

Description of the Study Procedures

If you agree to be in this study, you will be asked to do the following things:

1) Take a tablet named Placida half an hour before the commencement of the orthodontic treatment procedure.
2) Fill a questionnaire form after completion of the treatment appointment.

Risks/Discomforts of Being in this Study

- There are no reasonable foreseeable (or expected) risks as the dose of Placida given in this study is intended for the purpose of anxiety relief only and not for providing moderate or deeper sedation
- There may be unknown risks.

Benefits of Being in the Study

- The benefits of participation are that if Placida has a true anxiolytic effect on the participant, it can be used as a precautionary medication before every orthodontic treatment.

Confidentiality

- This study is anonymous. We will not be collecting or retaining any information about your identity.
- Your identity will not be disclosed in the material that is published. However, you will be given the opportunity to review and approve any material that is published

Right to Refuse or Withdraw

- The decision to participate in this study is entirely up to you. You may refuse to take part in the study at any time without affecting your relationship with the investigators of this study. Your decision will not result in any loss or benefits to which you are otherwise entitled. You have the right not to answer any single question, as well as to withdraw completely from the interview at any point during the process; additionally, you have the right to request that the interviewer not use any of your interview material.

Right to Ask Questions and Report Concerns

- You have the right to ask questions about this research study and to have those questions answered by me before, during or after the research .If you like, a summary of the results of the study will be sent to you.

Consent

- Your signature below indicates that you have decided to volunteer as a research participant for this study, and that you have read and understood the information provided above. You will be given a signed and dated copy of this form to keep, along with any other printed materials deemed necessary by the study investigators.

Subject's Name (print): _____
Subject's Signature: _____ **Date:** _____
Investigator's Signature: _____ **Date:** _____

The protocol of the study was to administer placeda to the participant just 10 minutes before the commencement of the 1st appointment. Patients were made to sit in a calm room after administration of the tablet for 10 minutes and then the treatment was started by asking the patient to directly come In the operating room from the calm room after 10 minutes. After the treatment was completed, the participants were given a questionnaire to fill.

Questionnaire Format

1) Did you experience any discomfort during the entire treatment procedure?
   a) YES (0)
   b) NO(1)
2) Were you nervous or anxious during the duration of the treatment procedure?
   a) YES(0)
   b) NO(1)
3) Your fear and apprehensiveness about the procedure:-
   a) Was more before taking placeda(1)
   b) Was more after taking placeda(0)
4) Did taking placeda tablet benefit you and promote anxiety relief?
   a) YES(1)
   b) NO(0)
5) Was your experience on the dental chair this time better than all your previous experiences?
   a) YES(1)
   b) NO(0)

After studying 300 participants, the data was summarized and analysed based on the questionnaire, considering the patient views and experiences throughout the entire treatment procedure of the 1st appointment and each form was scored from 0-5 depending on the positive or negative feedback of each question of the 5 questions given in the questionnaire. After a comparative evaluation of 300 patients depending on the questionnaire and its score from 0-5, the study was completed and the results were assessed.

3. Results

1) Out of 300 participants, approximately 212 participants experienced complete anxiety relief and were not at all apprehensive or fearful during the entire treatment span. They stated that placeda benefitted them by reducing the anxiety completely and also their experience on the dental chair was better than all the previous experiences in which they faced anxiety, fear and apprehension. These 212 patients had a questionnaire score of 5.
2) 63 participants had a questionnaire score of 3. They experienced mild anxiety relief, that is, they did not experience high levels of anxiety. They were partly anxious during the procedure, but not as anxious as they were before taking placeda. Overall to summarize, placeda did have a positive effect on their apprehension, fear and anxiety, but did not completely eliminate it. These 63 participants did partly experience the benefits of placeda.
3) -25 out of the 300 patients, produced a questionnaire score of 1, i.e., they did not experience any discomfort or pain during the orthodontic treatment, but their anxiety levels did not reduce after taking placeda. In short, neither placeda, nor the calm room could passivate their anxiety, fear and apprehension levels.

4. Conflicts of Interest

Although it may seem that a normal patient is being exposed to the wrath of an anxiolytic medication, the dosages of the drug given in this study is intended for the purpose of anxiety relief only and not for providing moderate or deeper sedation.

5. Conclusion

The use of the anxiolytic drug placeda, may not have been beneficial in 100% of the patients studied, but majority of the participants of this study witnessed relief of anxiety, apprehension, fretfulness, nervousness and agitation by taking the tablet before the start of the orthodontic treatment.

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