

Patients with Special Needs (PSNs) and Slow Paced Breathing

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Abstract

Background: A great need for further scientific assessment of non-pharmacological anxiety management practices and for a quantification of the extent of any benefit provided by it has been proclaimed.

Methods: We have analysed the effectiveness of device-guided breathing by using the Taxxos-Atemtakter™ to reduce the patient's levels of anxiety. 56 anxious patients were randomly assigned to a control group (C) or a guided breathing group (GB) before undergoing treatment. Anxiety levels were assessed by using validated questionnaires (Hierarchical Anxiety Questionnaire; State-Trait Anxiety Inventory) before and after seeing the dentist.

Results: Both groups showed a significant reduction of anxiety levels. However, patients in the GB-group experienced a significantly higher anxiety drop, compared to the C group ($p=0.02$). Patients in the GB-group revealed higher pre-post differences regarding state anxiety than in the C group. This reduction was statistically significant ($p=0.04$) in the group of moderately anxious patients.

Conclusions: Device-guided breathing is an effective technique to lower dental anxiety during treatment particularly for moderately anxious patients. Its practice is safe, easy and economically reasonable.

Practical implications: Taxxos-Atemtakter™ can be integrated easily and time saving in the treatment process. It can be recommended for the daily use with anxious patients in dental practices.

Keywords: Device-guided breathing; Taxxos-Atemtakter; Dental anxiety; State anxiety; Trait anxiety

Introduction

The dental treatment of patients with special needs (PSNs)

The term "patients with special needs" (PSNs) indicates a group of people with one or several chronic or acute health conditions, requiring specialized as well as individualized clinical management. Because of anxiety, these patients often do not cooperate. In many cases, they are incapable to generate emotional control. This represents one of the great challenges for adequate outpatient care [1,2].

In contrary to fear, which has an important function in evolutionary history, anxiety is of pathogen nature. Fear is an essential mechanism of protection against danger by serving as a relevant warning signal [3]. It provides the body with necessary resources to avert or escape threats via activating the sympathetic nervous system, the so-called fight or flight-response as already described in 1915 by Walter Bradford Cannon (1871-1945) [4]. However in patients with anxiety-related mental-health problems the evolutionary reasonable character of fear has got lost by misalignment to non-life-threatening objects or proceedings.

Dental phobic patients for example experience state anxiety during dental treatment [5]. Whereas the dentist's routine arms her/him to perform most of the everyday dental interventions with rare complications and without additional efforts, the treatment of anxious patients is a complex challenge. In addition to the treatment of children, multi-morbid and disabled patients, the dental therapy of anxious patients in particular is perceived as stressful and uneconomical; the treated person him or herself experiences the situation as a serious burden [6]. According to a statement of the German Society of Oral and Maxillofacial Medicine, 60-80 percent of all people feel anxiety when seeing the dentist [7]. One in five patients is considered highly anxious, whereas five percent of all individuals try to avoid dental treatment completely and undergo therapy only if it is inevitable. These

patients suffer from dental phobia which can lead to panic reactions in a triggering situation for example while sitting on the dentist's chair and having the task of opening the mouth [8].

In the psychiatrist's workaday life it is not unusual, that patients ask in the run-up to the dental intervention for an attestation to get a general anaesthesia paid by the health insurance. In effect, from the medical as well as the economic point of view a general anaesthesia during the extraction of third molars for example may only doubtfully be justifiable in most cases. But nevertheless this becomes more and more common [9]. For their freedom of anxiety dental phobic patients are even willing to pay privately for procedural sedation or general anaesthesia. The advertising pleading for general anaesthesia in dental phobic individuals partially seems to be a sort of commercial exploitation, like exemplified by the worldwide-web-slogan "only one general anaesthesia and you'll have your wished denture" [10]. Due to financial restrictions these cost-intensive therapeutic approaches often are not performable for people with a low socio-economic status, who primarily still have a higher prevalence of caries and thus an extensive need for treatment [11]. Apart from that it remains questionable to expose the even highly dental phobic patients to the complications of general anaesthesia and to the loss of consciousness, of collaboration and of protective reflexes during narcosis.

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To calm and relax the moderately anxious patient it is common to perform sedation orally or parenterally with benzodiazepines, like Midazolam (Dormicum) or inhaled with nitrous oxide. In doing so, anterograde amnesia is effected by different methods in whom nitrous oxide (conscious sedation) is preferable. This practice is said to be widely used and well defined in specific protocols. In contrary to general anaesthesia, the method of conscious sedation has the advantage of being safe and usable in an ambulatory environment. But some precautions are required: Recovery time and postoperative medical surveillance in the dental office of at least 1 hour must be guaranteed. The immediate access to a specific benzodiazepine antagonist (flumazenil) in the dental office has to be ensured for emergency management of overdose. The patient must be educated not to drive or take on responsibilities for the next 12-24 hours [12-14]. Because of these disadvantages non-pharmacological techniques are recommendable in appropriate cases.

Psychotherapeutic measures and hypnosis [15] have success rates of up to 70 percent in the medium term [7]. The aim of treatment is the reduction of individual avoidance behavior in order to enable the beginning of a long-term dental care. After therapy, regular visits to the dentist hence are necessary to further reduce anxiety [16]. Anxious patients should find the dental treatment as pleasant as possible. Biofeedback, brief relaxation and music distraction can contribute to this [17,18]. A positive influence of deep controlled diaphragmal breathing has already been proven with regard to a general reduction in anxiety and stress [19,20] because fear can be reduced by decreasing the breathing rate [21,22]. Exhalation decreases the heart rate, inhalation speeds it up. The reason for this is the respiratory sinus arrhythmia (RSA), which is by no means pathological but the sign of a functioning nervous system [23]. In contrast to the heart rate, breathing can be controlled arbitrarily [24]. It is thus the basic principle of many relaxation techniques such as yoga, autogenous training or hypnosis [25]. RESPeRATE™, a guided-breathing device using biofeedback via chest belt/sensor and earphones has already been proven to be effective in reducing dental anxiety related to injections [17].

Armfield and Heaton in 2013 have proclaimed a great need for the evaluation of the concrete benefit provided by non-pharmacological techniques of anxiety management in dental clinics [26]. Thus, this study focuses on the issue in which extent slow, guided abdominal breathing without direct technical feedback will lead to anxiety relief during dental treatment.

Materials and Methods

Sample and study procedure

During this study, in a dental practice in Leipzig/Germany, we treated and interviewed 56 patients who considered themselves anxious or who were noticed for their anxious behavior. Criteria of inclusion and exclusion were defined by taking into account indications and contraindications of the Taxxos-Atemtakter™ (Figure 1). Inclusion criteria were dental diagnosis of caries, which could be treated with a filling in one visit, age ≥ 18 years and signing informed consent. Exclusion criteria were age < 18 years, old age (> 70 ys), presence of a more serious dental diagnosis than caries, severe mental disorders (such as schizophrenia), physical disorders/disabilities (such as dyskinesia, paraplegia), presence of cardiovascular symptoms, severe somatic diseases and furthermore abuse of alcohol, of medication or of drugs. At the first appointment patient education and information on data protection has been provided. In case of the patient's participation, an informed consent (patient information, data protection information) was handed over. At the second appointment, written informed consent

was obtained and subjects were randomly assigned to either the guided-breathing group (GB) or the control group (C) in a 1: 1 ratio. Since both dentist and patient were informed about the assignment to GB or C, blinding was not possible.



Figure 1: Taxxos-Atemtakter™. Personal Photography by Lukas Frank 2017.

Before treatment, patients received the following questionnaires: Hierarchical Anxiety Questionnaire (HAQ) to assess dental anxiety [6], State-Trait Anxiety Inventory [27] to assess state anxiety (STAI-S) and trait anxiety (STAI-T). All obtained data was checked for completeness by the dentist (L.F). Sufficient time was provided for answering all questions in the waiting area. Instructions regarding the Taxxos-Atemtakter™ were given to the subjects of GB in the surgery. The use of the device was explained and the appropriate breathing rhythm was determined, so that diaphragmal breathing could be performed easily and without effort. Afterwards, caries was removed and the cavity was filled. Subjects of the control group underwent the same procedure but without using the Taxxos-Atemtakter™. All patients were treated under similar conditions, i.e. no differences in dentist, staff, room, background noise, odors, and lighting. As a matter of principle, local pain elimination was carried out, if requested. After the end of therapy, participants returned to the waiting area to complete the second STAI-S questionnaire. If favoured by the patient, there was a final talk about the individual experience with the dental treatment. All GB-subjects were asked to describe their impressions concerning the device and to give a positive, neutral or negative feedback.

Questionnaires

Hierarchical Anxiety Questionnaire (HAQ)

As the questionnaire provides information about dental anxiety as a consistent trait, it was administered before treatment [6]. The questionnaire exists in a German version as the Hierarchischer Angstfragebogen (HAF). The HAF is a validated instrument with proven reliability and a high correlation to the internationally used Corah's Dental Anxiety Scale (coefficient of 0.88) [6,28-33]. Before completing the questionnaire, the patient is instructed: "Please imagine the situations listed below. Then tick the appropriate box". A total of 11 questions had to be answered, all of which relate to specific anxiety-inducing situations before or during dental treatment, e.g. "Imagine hearing the typical sound of the drill. How do you feel?" Possible answers are "relaxed", "restless", "stressed", "anxious" and "sick with fear". Answers are scored from 1 ("relaxed") to 5 ("sick with fear"). Accordingly, between 11 and 55 points can be achieved and subjects are categorized into "low anxious" (11-30 points), "moderately anxious" (31-38 points) and "highly anxious" (39-55 points).

State-Trait Anxiety Inventory (STAI)

The State-Trait Anxiety Inventory, established by Spielberger et al. [34] exists in a German version, translated by Laux et al. [35]. The STAI questionnaire is widely used in diagnosing anxiety. It has also been proven in clinical use for determining anxiety related to dental treatment. Its validity and reliability have been verified [36,37]. The questionnaire consists of 2 lists, the STAI-S (state anxiety) and the STAI-T (trait anxiety). Each list contains 20 statements about the temporary emotional state (STAI-S) and the general emotional state, which is constant in time (STAI-T). Questions are formulated in the context of anxiety (e.g. "I feel like crying.") and in the context of anxietylessness (e.g. "I feel happy."). Scores range from 20 to 80, showing lower or higher anxiety levels. As we intended to analyse the gradual change of state anxiety, the STAI-S questionnaire was completed twice, before and after treatment [27].

Device

The Taxxos-Atemtakter™ is about the size of a matchbox and generates approximately 6 vibrations per minute. It has a smooth, robust plastic housing and provides the appropriate breathing rhythm (vibration=exhalation, vibration free=inhalation).

If the device is used incorrectly, i.e., if inhalation and exhalation times are confused, hyperventilation symptoms such as dizziness may occur. It is therefore important to ensure that the air is exhaled during vibration time and not inhaled. On the top side there is a button, which can be used to control the Taxxos-Atemtakter™. It is activated by pressing it for three seconds. If necessary, breathing intervals can be shortened or extended by pushing the button (Table 1). Intervals should be chosen by the patient so that breathing runs easily and effortlessly.

Pushing the button	Breathing interval	Inspiration (in sec.)	Expiration (in sec.)	Breathing rate per minute
2 x	very short	2,1	3,1	11,5
3 x	Short	3,1	4,7	7,7
4 x	normal/ long	4,1	6,2	5,8
5 x	very long	5,1	7,7	4,7

Table 1: Breathing intervals.

The device is CE certified and rated as non-critical in accordance with the German hygiene requirements in the dental practice [38].

Ethics

This study was planned and conducted in accordance with good clinical practice (GCP) recommendations [39]. It has been approved by the Ethics Committee of the University Hospital of Regensburg, Germany.

Statistical Analysis

Collected data were evaluated using statistical software SPSS, version 23.0. Resulting outputs were plotted using MS-Excel 2016. The standard error of the mean was used as the scattering measure. Statistics for nominal data (gender) were computed using Chi-square test and correlations were determined using Pearson's R. Comparisons of means were conducted using t-test for independent and dependent measures or non-parametric alternatives (Mann-Whitney U test or Wilcoxon test) where applicable.

Results

A total of 57 subjects participated in the study. One questionnaire was filled out incorrectly and had to be rejected, resulting in a sample

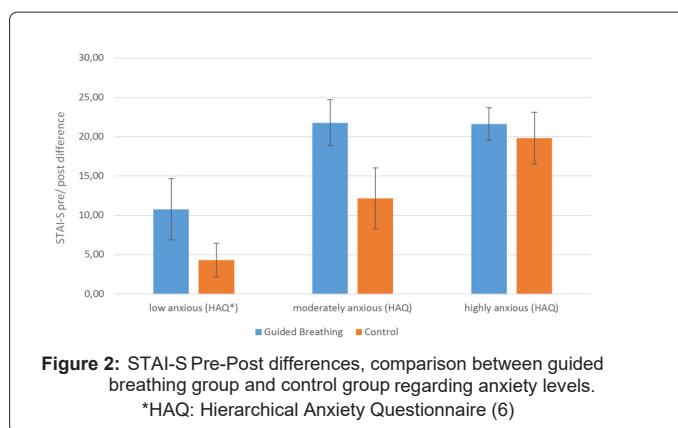
size of 56. All patients were randomly assigned to either guided-breathing group (GB, n=28) or control group (C, n=28). The ratio of women was 57% in the study group and 60% in the control group. The age of the participants ranged from 19 to 68 years. Male subjects were on average 31, female subjects 39.7 years old. All participants were matched for age (p=1) and gender (p=0.79). STAI-S pre scores as a measure of anxiety levels before treatment were similar in both groups (GB: mean 53.5, SE 2.4 and C: mean 47.8, SE 2.1). According to the HAQ analysis, 21 subjects were low anxious (GB-group: n=9; C-group: n=12), 15 moderately anxious (GB-group: n=9; C-group: n=6) and 20 highly anxious (GB-group: n=10; C-group: n=10).

Regarding the total sample, in both the GB and the C group, STAI-S pre values (before treatment) were significantly higher than STAI-S post values (after treatment) (p<0.001). In the GB group STAI-S pre-post differences were significantly higher (p=0.02) than in the C group (Table 2). In all investigated HAQ groups ("low anxious", "moderately anxious", "highly anxious") the STAI-S pre-post differences were higher in the GB group than in the C group. Statistically significant (p=0.04) was the group of moderately anxious patients (Figure 2).

Group	Mean STAI-S* pre Score (SE)**	Mean STAI-S post Score (SE)	Mean difference STAI-S pre and STAI-S post scores (SE)	P- Value, difference between STAI-S pre and post scores (GB-group vs. C-group)
Guided Breathing (n=28)	53,5 (2.5)	35,1 (1.2)	18,2 (1.9)	0.02
Control (n=28)	47,7 (2.2)	36,2 (1.5)	11,5 (2.1)	

*STAI-S: State-Trait Anxiety Inventory, State Anxiety (27)
**SE: Standard Error

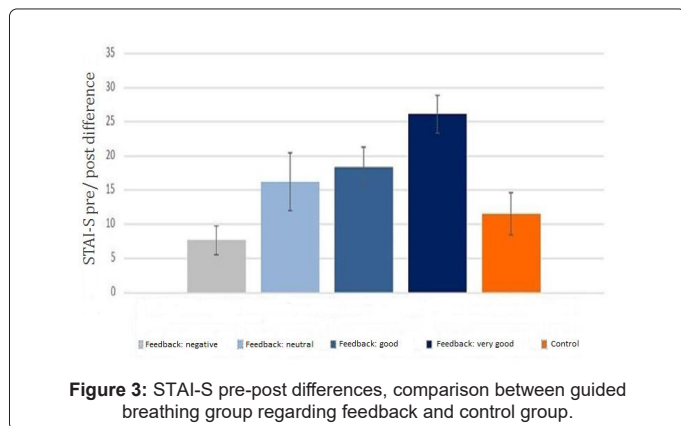
Table 2: State-anxiety at initial and final evaluation, overall sample.



Out of 28 subjects in the GB group, 11% (n=3) gave a negative, 46% (n=13) a neutral, 18% (n=5) a good and 25% (n=7) a very good feedback. Patients with negative feedback had significantly lower pre-post STAI-S differences than patients with very good feedback. Subjects of the control group had significantly lower pre-post STAI-S differences than patients who had given a very good feedback (Figure 3). A very good feedback was reported by 3 out of 10 highly anxious patients (30%), by 3 out of 9 moderately anxious patients (33%) and by 1 out of 9 low anxious patients (11%).

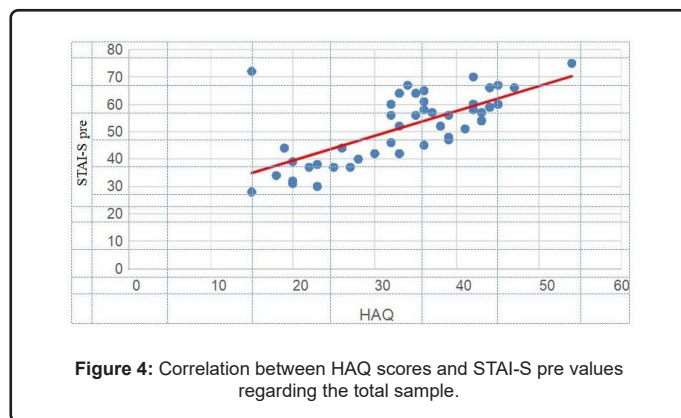
- Feedback negative: No positive interaction with the Taxxos-Atemtakter®, no benefit.

- Feedback neutral: Neither positive nor negative interaction, no benefit.



- Feedback good: Positive interaction, limited benefit.
- Feedback very good: Positive interaction, high benefit, further treatment with Taxxos-Atemtakter® requested.

There was a significant, positive linear correlation between HAQ scores and STAI-S pre-values in the overall sample (Pearson R=0.75, N=56, p<0.001). The higher the HAQ score, the higher the STAI-S pre value (Figure 4). Statistical analysis also showed a significant, positive linear correlation between STAI-T and STAI-S pre values in the overall sample (Pearson R=0.37, N=56, p=0.005).



Discussion

The study has proven that slow guided diaphragmal breathing leads to a significant reduction in anxiety during dental treatment. The Taxxos-Atemtakter™ was used to provide an appropriate, subjectively pleasant breathing rhythm to patients.

Although it was difficult to find highly anxious participants a total of 20 subjects (36%) was acquired. Patients were fairly evenly distributed over the three groups: low (n=21), moderately (n=15) and highly (20) anxious. There were no significant differences between the GB and C groups in gender ratio, average age and STAI-S pre scores.

The STAI-S pre-post differences, as a measure of anxiety relief over time were significant in both groups. An obvious explanation for that may be that the dental treatment triggering anxiety ex ante by now has been well survived by all the patients. Besides, the team`s empathic

communication towards the patient as a basic strategy to reduce anxiety was the same in the GB-group as well as in the C-group. But these arguments do not disprove the effectiveness of Taxxos-Atemtakter®: the STAI-S pre-post differences were significantly higher in the GB-group than in the C-group. Moderately anxious subjects showed the highest statistically significant STAI-S pre/ post differences compared to the C-group. This could be caused by the fact that the moderately anxious subjects precisely have an enough strong psychological strain to engage in the handling of the device without being paralysed by high grade anxiety.

Individual verbal feedback analysis after treatment revealed very positive interactions between patients and the Taxxos-Atemtakter™ among the highly anxious (30%) and moderately anxious (33%) subjects. Overall 25% of all subjects gave a very good feedback, i.e., every 4th patient who was treated with the device could clearly benefit from its use and requested follow-up treatment with this breathing method. Nevertheless, 30% of highly anxious and 89% of low anxious patients showed no benefit.

Subjects with negative or neutral feedback in particular criticized the disturbant mix of the Taxxos-Atemtakter`s™-vibration and the "vibration of the drill", which made it difficult to adjust one`s breathing to the corresponding rhythm. Alternative approaches like optical or acoustic signals provided by headphones or screens would be necessary to stimulate breathing rhythm and intervals. Using the Taxxos-Atemtakter™ is easy to learn for both dentist and patient. Previous experience with guided deep breathing is beneficial but not necessary. Slow paced breathing shortens the therapy by inducing patient`s relaxation.

In addition to other non-pharmacological methods to reduce anxiety during dental treatment such as biofeedback, brief relaxation or music distraction the diaphragmal breathing guided by the Taxxos-Atemtakter™ is an effective approach. Positive effects of these methods should be compared in future studies. Follow up studies are necessary to evaluate the long term effect of the device, for example by detecting the STAI-S not only before and after the dental treatment, but also before the following dental intervention. Furthermore, larger sample sizes as well as potentially more painful dental procedures such as surgery or root canal treatments are needed to evaluate our results.

Limitations

Only one dentist performed all treatments. The extent of communication between patient and dentist/staff was not assessed. Furthermore, pain levels during treatment should have been evaluated and correlated with the reduction of state anxiety. Patients should have been questioned whether they took benzodiazepines before consulting the dentist. As this was an initial study with a limited number of participants, the results are preliminary.

Conclusions

In the field of device-guided breathing, a new method has been found to reduce anxiety during dental treatment. Particularly moderately anxious patients can benefit from using the Taxxos-Atemtakter™ and its correlating breathing pattern. The device can be integrated easily and time saving in the treatment process. It can be recommended for the daily use with anxious patients in dental surgery and is an alternative to biofeedback, music distraction or brief relaxation. Further research is required to verify the results of this preliminary study.

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