Auricular Acupuncture for Dental Anxiety: A Randomized Controlled Trial

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Auricular acupuncture can be an effective treatment for acute anxiety, but there is a lack of direct comparisons of acupuncture to proven standard drug treatments. In this study we compared the efficacy of auricular acupuncture with intranasal midazolam, placebo acupuncture, and no treatment for reducing dental anxiety. Patients having dental extractions ($n = 67$) were randomized to (i) auricular acupuncture, (ii) placebo acupuncture, and (iii) intranasal midazolam and compared with a no treatment group. Anxiety was assessed before the interventions, at 30 min, and after the dental extraction. Physiological variables were assessed continuously. With the no treatment group as control, the auricular acupuncture group, and the midazolam group were significantly less anxious at 30 min as compared with patients in the placebo acupuncture group (Spielberger Stait-Trait Anxiety Inventory X1, $P = 0.012$ and <0.001, respectively). In addition, patient compliance assessed by the dentist was significantly improved if auricular acupuncture or application of intranasal midazolam had been performed ($P = 0.032$ and 0.049, respectively). In conclusion, both, auricular acupuncture and intranasal midazolam were similarly effective for the treatment of dental anxiety.
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Patient anxiety before dental treatment is common. It was estimated that 31% of adults are fearful of dental treatment (1). Moreover, many studies worldwide report that about 10% of people have a dental phobia (2). Patients who are highly anxious about receiving dental treatment may delay or cancel appointments, often at short notice. The avoiding behavior as well as the anxiety previous to dental treatment have a negative impact on dental treatment and dental health and may result in referrals to hospital sedation units for routine dental care. Therefore, dental anxiety seems to be a good model for studying a potentially anxiety-reducing procedure such as auricular acupuncture.

Traditionally, dental anxiety has been managed using pharmacological techniques. Benzodiazepines are the most frequently used drugs in clinical situations associated with anxiety and panic disorders (3). Midazolam seems to be superior to other benzodiazepines because of its short duration of action (20–40 min) and short elimination half-life (1 h 30 min to 3 h). The intranasal route offers a significant advantage over orally or rectally administered midazolam because it bypasses the portal system and does not underlie the high hepatic first-pass elimination. Given as an intranasal spray instead of drops, the absorption of midazolam via nasal mucosa has been reported to be virtually complete (83%) because little of the substance is swallowed (4). However, the use of benzodiazepines or other sedative medication may be associated with adverse events, such as respiratory depression or prolonged sedation.

Biofeedback techniques and hypnotherapy may be valuable adjuncts for the treatment of anxious and apprehensive patients. Time constraints, and reluctance of the practitioner to delve into behavioral therapy, limit the use of the nonintrusive therapies.

Alternative inexpensive interventions such as acupuncture are therefore worth considering as treatment for dental anxiety that is not associated with the risk of prolonged sedation or respiratory depression. Previous reports have suggested that (auricular) acupuncture can be used for the treatment of chronic anxiety as well as acute situational anxiety (5–7), but its efficacy has not been studied in a direct head-to-head comparison with a standard drug treatment.

Therefore, we designed a study to determine whether auricular acupuncture can decrease acute dental anxiety and compared it with the standard pharmacological sedative medication midazolam, noninvasive placebo auricular acupuncture, and no treatment.

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METHODS

Patients

The study was approved by the Hannover Medical School Human Investigation Ethics Committee. Depending on the limited availability of the main investigators (B.F. and A.H.) patients were recruited and treated between August and October 2003, between March and April 2004, and between November and December 2004. Eighty-one consecutive patients from the outpatient clinic of the Department of Oral and Maxillofacial Surgery of the Hannover Medical School, who were scheduled for dental extraction, were screened for the study, and 67 eligible patients were recruited. Nine patients rejected participation in the study and five were excluded because they did not meet the inclusion criteria or showed one or more of the exclusion criteria. Inclusion criteria were dental extraction, age of 18–65 yr, German speaking, and informed consent. Exclusion criteria were allergy to benzodiazepines, addiction to any drugs or alcohol or the use of such substances preoperatively, any major psychiatric, neurologic, or cardiopulmonary disorder, previous acupuncture treatment, anticoagulation, and pregnancy or lactating. The risks and possible discomforts, as well as the benefits of the procedures, were explained to the patients and their written informed consent to participate in the study was obtained, as required by the local ethics committee. Before enrollment, patients were told that they would be randomly assigned to no treatment, intranasal midazolam, or to one of two different forms of acupuncture treatments and that it was not known which of the two forms was more effective. In addition, patients in the placebo auricular acupuncture group were told that the needles would only be inserted gently and superficially and that an elastic cube would, therefore, be necessary to support the needle (see later). The names of the recruited patients were transmitted to the Department of Biometrics, Hannover Medical School. A list with random numbers was prepared by one of its members (L.H.).

Interventions

According to the prepared list, the 67 patients were randomly assigned to one of the three treatment groups ($n = 19$ in each group) and to a no treatment control group ($n = 10$). The three treatment groups consisted of:

1. Auricular acupuncture group: Subjects in this group received ear acupuncture by using the relaxation, tranquilizer, and master cerebral points in the external ear on the nondominant side. These points are documented to produce preoperative anxiety reduction (7). Seirin B-type needles no. 3 (0.2 × 0.15 mm) were used.
2. Placebo auricular acupuncture group: This group received placebo ear acupuncture by using the finger and liver points, which do not have any documented effects on anxiety reduction. A placebo needle system was used, in which the tip of the needle is blunt so as to cause a pricking sensation mimicking real acupuncture without actually puncturing the skin. To support the needle, an elastic foam was used which was fixed upon the area of the acupoint (8,9). In contrast to superficial sham acupuncture, this form of control may be associated with less unspecific physiological effects.
3. Midazolam group: The drug was administered as a standard injectable solution ([midazolam] Dormicum 5 mg/mL, Hoffmann-La Roche, Grenzach-Wyhlen, Germany) with a spray bottle, with three successive puffs into each nostril. The spray bottle delivered a fine aerosol and the mean midazolam dose per activation was 0.675 mg (range, 0.582–0.745 mg). Thus, each patient received an average dose of 4 mg (range 3.5–4.5 mg) midazolam (10).

Spielberger State-Trait Anxiety Inventory

The German version of the Spielberger State-Trait Anxiety Inventory form X1 (STAI X1) was used to measure state anxiety (how one feels at a particular moment), and form X2 (STAI X2) was used to assess trait anxiety (how one usually feels). The state anxiety score is based on 20 items for which a person rates anxiety on a scale from 1 (almost never) to 4 (very much so). The trait anxiety score is composed in a similar fashion with 20 questions designed to measure anxiety. The STAI has been validated for various situations and populations in several studies (11,12). Each questionnaire required 3–5 min for completion.

Visual Analog Scale of Anxiety

The visual analog scale (VAS) comprised an undivided 10-cm line, with 0 meaning "I am not anxious at all," and 10 meaning "I am extremely anxious." Patients were instructed to mark one point on the line that corresponded to the intensity of their anxiety at that moment. Such scales have been widely used in psychiatry and anesthesia to assess pain and other sensations and emotions (13).

Sedation Score

Patient sedation was evaluated by one of the authors (A.H.) using a five-point sedation scale (1 = agitated; 2 = alert, restless; 3 = calm, eyes spontaneously open; 4 = drowsy, responds to minor stimulation; 5 = asleep, rousable but does not respond to minor stimulation). The scale was devised by Wilton et al. (14) to evaluate the level of sedation of preschool children who had received intranasal midazolam drops for sedation before anesthesia for surgery.

Quality of Dental Treatment Condition

At the end of the dental treatment the quality of the treatment condition was evaluated by the dentist

using a five-point scale (1 = very poor; 2 = poor; 3 = satisfactory; 4 = good; 5 = excellent).

Physiologic Status

Heart rate (HR) and oxygen saturation (OS) were continuously monitored during the study period.

Procedure

Forty minutes before the dental treatment, a session began with the patients completing form X1 of the STAI. Thereafter, patients rated their anxiety using the VAS. HR and OS measurements were started. Thirty five minutes before the dental treatment, according to the randomization list, one of the three interventions was started. HR and OS were recorded at 5, 10, 15, 20, 25, and 30 min (follow-up 1) and after dental treatment (follow-up 2). Needles were left in place for 25 min after insertion. The STAI X1 and X2, VAS, and sedation scale were completed at 30 min and after dental treatment. After dental treatment the quality of the treatment condition was assessed by the dentist. Dental extraction was performed under local anesthesia with articaine hydrochloride. Both the investigators performing follow-up examinations (A.H.) and statistical procedures (L.H.), and the dentist were blind to treatment condition, blinding the acupuncture practitioner (B.F.) was impossible because of methodological reasons. The interventions were performed in such a way that the patients in the different intervention groups had no contact with each other. Patients were blind regarding both acupuncture procedures. Blinding was not achieved from the patients' perspective in the intranasal midazolam, auricular acupuncture, or no treatment groups. However, in normal dental practice, neither intranasal midazolam nor auricular acupuncture is part of routine care for reducing anxiety. Before the study no patient had experienced any of these techniques for reducing dental anxiety. Therefore, there was no specific patient expectation regarding any of the interventions. Additionally, both interventions were associated with about the same amount of contact time between the therapist and the patients and produced a similar degree of local sensation.

Statistical Analysis

Original sample-size calculations were based on one-way analysis of variance (one-way ANOVA). Under this premise, the study was planned to have a power of 85% to detect a group difference of 7 and 25 on the STAI scale, respectively, with an assumed common standard deviation of 23 points, and assuming a 5% dropout rate. However, the Hollenhorst et al. study (10) showed similar group differences on the STAI but a common standard deviation of just 12, which would have led to a group size of $n = 6$. Therefore, and due to ethical reasons, we decided to allocate 2:1 between each intervention group and the no treatment group.

Baseline characteristics were analyzed using one-way ANOVA. To analyze the changes in behavioral (STAI X1, VAS, and sedation score) and physiological (HR, OS) anxiety levels along the various time points, repeated measurements in the general linear model were used. To localize the difference among the intervention groups, we calculated the mean differences between the follow-up and the baseline values and used one-way ANOVA. Using ANOVA, normal distribution of the anxiety variables has been assumed because of the type of these variables which are the result of a superposition of small stochastic influences. By means of the central limit theorem of probability theory, normality of those variables can be assumed. To compare each group against the no treatment group, two-sided *post hoc* Dunnett's *t*-tests were used, with the no treatment group as control. Differences were regarded as significant with $P < 0.05$. Results are reported as mean ± SD. Data were analyzed with the use of SPSS version 12.01 (SPSS, Chicago, IL).

RESULTS

Before the interventions, groups did not differ significantly in terms of STAI X1 and X2, VAS, sedation score, and physiologic variables as the observed differences regarding mean age and gender distribution were not statistically significant (Tables 1 and 2).

In repeated measurement analyses, the following parameters displayed significant time by group interaction, largely due to differences between the no treatment group and intervention groups: STAI X1 (Wilks'-Lambda, 0.666; $P < 0.001$), VAS (Wilks'-Lambda, 0.772; $P = 0.012$), and sedation score (Wilks'-Lambda, 0.542; $P < 0.001$) (Table 2). HR (Wilks'-Lambda, 0.631; $P = 0.414$) showed no significant time by group interactions.

The mean differences of the anxiety levels between baseline and follow-up 1 (at 30 min) were significantly different among groups (one-way ANOVA, STAI X1, $P < 0.001$; 95% CI −9.30 to −4.07; VAS, $P = 0.040$; 95% CI −1.71 to −0.75). *Post hoc* testing revealed that STAI X1 differed mainly between auricular acupuncture versus no treatment ($P = 0.012$; 95% CI −18.93 to −1.97) and midazolam versus no treatment ($P < 0.001$; 95% CI −26.35 to −9.39), respectively (Fig. 1). Concerning VAS, only the difference between midazolam versus no treatment ($P = 0.011$; 95% CI −3.91 to −0.43) was significant (Table 2). The mean difference between anxiety levels at baseline and follow-up 2 (after dental treatment) showed no significant intergroup differences.

Significant intergroup differences were also found for the mean differences of the sedation score (follow-up 1, $P < 0.001$, 95% CI −0.42 to 0.82; follow-up 2, $P = 0.013$, 95% CI −0.05 to 0.29). For follow-up 1, *post hoc* tests showed that all intervention groups contributed equally to this result. In contrast, the significant intergroup difference at follow-up 2 was produced solely by the difference between midazolam versus no treatment ($P = 0.015$; 95% CI 0.12–1.31) (Table 2).

Table 1. Sample Characteristics, Trait Anxiety (STAI X2), and Physiological Variables at Baseline[a]

	Auricular acupuncture	Placebo auricular acupuncture	Intranasal midazolam	No treatment
N	19	19	19	10
Age (yr)	40.21 ± 12.07	41.53 ± 13.12	32.26 ± 12.13	41.30 ± 16.96
Gender (F/M)	10/9	8/11	6/13	6/4
STAI X2	43.90 ± 14.31	39.95 ± 10.58	47.00 ± 8.96	41.90 ± 8.23
HR (bpm)	83.95 ± 16.89	87.74 ± 8.89	80.26 ± 12.27	76.00 ± 8.08
OS (%)	97.12 ± 1.41	96.42 ± 2.32	97.00 ± 1.56	98.10 ± 1.10

HR = heart rate (bpm); OS = oxygen saturation (%); STAI = Spielberger Stait-Trait Anxiety Inventory (range 20–80), X2 form for trait anxiety.

[a] Values are expressed as mean ± SD.

Table 2. Behavioral Variables at Baseline, Follow-Up 1 (at 30 min), and at Follow-Up 2 (After Dental Treatment)[a]

	Baseline	Follow-up 1	Follow-up 2
STAI X1 (20–80)			
Auricular AP (*N* = 19)	50.47 ± 8.83	43.53 ± 9.99*	41.84 ± 12.72
Placebo AP (*N* = 19)	49.32 ± 13.49	45.21 ± 10.82	39.16 ± 9.87
Midazolam (*N* = 19)	56.53 ± 9.61	42.16 ± 9.12*	38.68 ± 9.19
No treatment (*N* = 10)	53.00 ± 9.61	56.50 ± 9.10	47.20 ± 12.78
VAS (0–10)			
Auricular AP (*N* = 19)	4.25 ± 3.02	3.03 ± 2.16	1.73 ± 1.71
Placebo AP (*N* = 19)	4.36 ± 3.00	3.21 ± 2.74	1.20 ± 1.65
Midazolam (*N* = 19)	5.35 ± 2.41	3.32 ± 2.41*	1.72 ± 1.68
No treatment (*N* = 10)	5.57 ± 2.53	5.71 ± 2.83	1.61 ± 1.56
Sedation score (1–5)			
Auricular AP (*N* = 19)	2.69 ± 0.55	3.30 ± 0.64*	2.58 ± 0.75
Placebo AP (*N* = 19)	2.53 ± 0.61	3.37 ± 0.68*	2.79 ± 0.54
Midazolam (*N* = 19)	2.42 ± 0.84	3.47 ± 1.02*	2.84 ± 0.83*
No treatment (*N* = 10)	2.80 ± 0.42	2.20 ± 0.42	2.50 ± 0.53
Dental Treatment condition (1–5)			
Auricular AP (*N* = 19)			4.68 ± 0.75†
Placebo AP (*N* = 19)			4.26 ± 0.87
Midazolam (*N* = 19)	n.p.	n.p.	4.63 ± 0.68†
No treatment (*N* = 10)			3.90 ± 0.88

STAI = Spielberger Stait-Trait Anxiety Inventory (range 20–80) X1 form for stait anxiety; VAS = visual analog scale for anxiety (0 = not at all to 10 = extremely intense); n.p. = not possible.

[a] Values are expressed as mean ± SD.

* Difference from baseline significant ($P < 0.02$) versus difference from baseline in the no treatment group, two-sided *post hoc* Dunnett's *t*-test.

† Difference from baseline significant ($P < 0.05$) versus difference from baseline in the no treatment group, two-sided *post hoc* Dunnett's *t*-test.

In agreement with the anxiety measures, the assessment of patient compliance by the dentist showed a significant difference between auricular acupuncture versus no treatment ($P = 0.032$; 95% CI 0.06–1.51) and midazolam versus no treatment ($P = 0.049$; 95% CI 0.00–1.46) (Table 2).

The HR values decreased over time in all treatment groups, whereas the no treatment group showed an increase. However, differences were significant only for random time points (data not shown). There were no appreciable group differences in OS at any time; the values remained above 95% during the whole observation period for all patients.

Some patients ($n = 7$, 36.8%) complained of nasal burning for a few minutes after intranasal midazolam administration. No adverse effects were reported in the other groups.

Post hoc power analysis using the STAI values showed an increase of the power to 90% (calculated with nQuery Advisor: significance level, $\alpha = 0.05$; number of groups, $G = 4$; variance of means, $V = 22.693$; common standard deviation, $\sigma = 10.00$; effect size, $V/\sigma^2 = 0.2269$; N as multiple of n_1, $\Sigma r_i = \Sigma n_i/n_1 = 3.526$; total sample size, $n = 67$).

DISCUSSION

To our knowledge, this is the first study comparing auricular acupuncture to intranasal midazolam for reducing dental anxiety. We demonstrated that, in the treatment of dental anxiety, no difference between auricular acupuncture and intranasal midazolam could be detected, but that the active interventions were superior to no treatment. Furthermore, the anxiety-reducing effect started as early as 30 min after insertion of the needles or application of midazolam, respectively. The duration of sedation was less prolonged in the auricular acupuncture group than in the midazolam group. The significantly better treatment conditions in the active intervention groups suggest clinical significance. Auricular acupuncture provided the same improved patient compliance during the dental procedure without prolonged sedation. Some

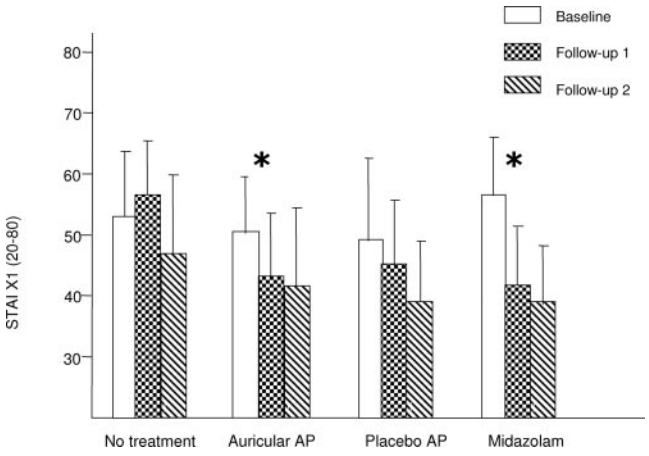

Figure 1. Changes in STAI X1 (Spielberger Stait-Trait Anxiety Inventory, X1 form for stait anxiety, range 20–80) are displayed (means and SD). A significant intergroup difference (follow-up 1 (at 30 min)—baseline) was found ($P < 0.001$, analysis of variance test). Using the two-sided *post hoc* Dunnett's *t*-test mainly the difference (follow-up 1—baseline) between auricular acupuncture (AP) versus no treatment ($P = 0.012$) and the difference (follow-up 1—baseline) between midazolam versus no treatment ($P < 0.001$) contributed to this significance (asterisk). AP = acupuncture.

patients reported a burning sensation when they received intranasal midazolam. No adverse events from auricular acupuncture were observed in any patient.

However, placebo auricular acupuncture also decreased anxiety somewhat; these effects may have been caused by a placebo system that was not totally inert (15) or by psychological effects, such as patients' expectations and beliefs which, in acupuncture trials especially, can not only modulate treatment effects and neuronal substrates (16,17), but also baseline values. Additionally, as shown for chronic pain patients, physicians or investigators may somehow subtly communicate their expectations to patients during the procedure (18). However, we tried to reduce such effects to a minimum by having a dental student (B.F.) do the interventions. He was carefully trained for each procedure, but was not instructed on the theoretical background of acupuncture or the pharmacologic therapy of anxiety. Furthermore, communication between investigator and patients was restricted to a minimum. In addition, baseline assessment and all follow-up assessments were done by an independent investigator (A.H.) who was unaware of the treatment.

Although patients were blind regarding both acupuncture procedures, blinding was not achieved from the patients' perspective whether intranasal midazolam, auricular acupuncture, or no treatment were given. This may have been a source of significant bias. On the other hand, placebo or sham acupuncture may exert potential physiologic effects, which make it difficult to use such procedures for a double-dummy technique. Furthermore, it is not uncommon for acupuncture trials to compare against standard care (19), that is, no specific treatment for dental anxiety.

Another potential limitation is that patients were included consecutively, regardless of heterogenous groups regarding general dental anxiety. However, the STAI baseline scores indicate that tooth extraction creates a specific anxiety, the awareness of which may be used to explore the consequences of dental anxiety in general. Additionally, the STAI baseline scores are about the same as those in the Hollenhorst et al.'s study (10) which investigated intranasal midazolam to prevent claustrophobia induced by magnetic resonance imaging.

Further potential limitations of our study are the relatively small population size, the small no treatment control group, and the lack of assessing pain that might be a potential source of bias in the settings of this study, although dental extraction was performed under local anesthesia.

Several reviews have investigated the role of acupuncture in dentistry and concluded that acupuncture could supplement conventional treatment modalities for the treatment of dental pain, facial pain, gagging reflex, and temporomandibular dysfunction (20–23). Our study is the first controlled investigation comparing auricular acupuncture directly to benzodiazepine, placebo-acupuncture, and no treatment. The findings suggest auricular acupuncture as a suitable and easy method to reduce dental anxiety. In contrast to midazolam, auricular acupuncture was not associated with prolonged sedation and the risk of respiratory depression. Avoiding these side effects may result in earlier discharge from the dental office and decreased costs. With the results of this study the anxiety-reducing effect of auricular acupuncture has been confirmed and is similar to that found for preoperative anxiety and anxiety in prehospital transport settings (7,24,25).

Overall, there is a substantial body of data showing that auricular acupuncture is worthwhile and should be considered as a sedative and tranquilizing treatment. However, there are no data available regarding the exact mechanism of ear acupuncture, but somatotopic orientation of the ear points suggests regionally specific effects on relevant structures of the human brain. In the context of body acupuncture, this suggestion is supported by functional magnetic resonance imaging findings in humans and immunohistochemistry findings in animal experiments (26,27).

Further research in this field with a larger study population is warranted, but dentists should be encouraged to use auricular acupuncture as an adjunct to other nonpharmacologic and pharmacologic strategies.

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