

The Use of Tenoten and Tenoten (Pediatric Formulation) as a Drug for Premedication in Adults and Children during Outpatients Dentist Visit

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Translated from *Byulleten' Eksperimental'noi Biologii i Meditsiny*, Vol. 148, Suppl. 1, pp. 88-90, August, 2009
Original article submitted August 1, 2008

The use of tenoten and tenoten (pediatric formulation) for premedication in adults and children before dental treatment reduces patient anxiety; the effect is comparable with that of classical anxiolytics and is not accompanied by side effects. These preparations can be recommended for wide use in dentistry.

Key Words: *tenoten; tenoten (pediatric formulation); phenazepam; dentistry*

Emotional stress before dental procedures is a common cause of treatment refusal, it provokes various general somatic complications and therefore, surmounting of these negative states is a very important problem [2]

The leading role in psychological protection of the patient is played by benzodiazepine anxiolytics. However, the use of classical tranquilizers in outpatient settings is limited due to their side effects. In light of this, the search for new approaches to premedication before dental treatment in patients with emotional and autonomic disturbances is in progress. Anxiolytic preparations tenoten and tenoten (pediatric formulation) containing antibodies to S-100 protein in ultralow doses are widely used in clinical practice.

MATERIALS AND METHODS

Clinical study was performed on adults (21-65 years) and children (2-6 years) waiting for dental care manipulations.

In adult patients, psychic and functional state is evaluated using Corah's Dental Anxiety Scale. We selected 165 patients (70 men and 95 women) with signs of emotional stress: nervousness, tension, anxiety, and

fear. Patients with concomitant diseases and patients without anxiety were not included in the study.

Adult patients were divided into 5 groups and received either placebo (calcium gluconate, $n=30$), or tenoten 2 sublingual tablets with 5-min interval, ($n=35$), or tenoten 2×2 sublingual tablets with 5-min interval ($n=50$), or diazepam (seduxen, 5 mg, $n=25$), or phenazepam (1 mg, $n=25$). All preparations were given 30 min before dental treatment.

Patient's well-being, activity, and mood were evaluated using WAM questionnaire (card test), situational anxiety and patient's state were evaluated using Spielberger—Khanin scale. Quantitative evaluation of the efficiency of the test preparation was performed by the method of sensometry using a Sensotest device (Geosoft): tactile sensitivity threshold (TST), pain sensitivity threshold (PST), and pain tolerance threshold (PTT) were measured. Patient's emotional state was assessed using a scale proposed by V. A. Gologorskii with recording of patient's general state, blood pressure, and heart rate [1]. All parameters were assessed before premedication and 30 and 60 min after drug administration. Against the background of premedication, caries treatment and tooth preparation for fixed denture were performed.

Were also examined 65 children (39 girls and 26 boys) with signs of emotional stress: nervousness, fear,

motor and verbal agitation. No general pathology was observed in children during the period of the study.

The children were divided into 3 groups. They received either placebo (calcium gluconate, 1 tablet, $n=15$), or tenoten (pediatric formulation, TP, 1 sublingual tablet, $n=30$), or diazepam (seduxen, $\frac{1}{2}$ tablet, 2.5 mg, $n=20$). The drugs were given 30 min before treatment. Functional and psychic state of the children was evaluated from clinical observation and using MCDAS scale. Children behavior was evaluated by the rate of approaching and position in dentist chair, face, verbal activity, and motor reactions. Against the background of premedication, treatment for moderate caries was performed. Application anesthesia was applied, when needed.

RESULTS

In adult patients, tenoten, phenazepam, and diazepam produced a considerable and moderate effect on anxiety evaluated by Spielberger—Khanin and Gologorskii scales and WAM test. This effect developed as soon as 20-30 min after intake and increased after 60 min. The level of situational anxiety under the effect of tenoten returned to normal in 85-95% patients. Mean values of anxiety elimination according to Spielberger—Khanin scale were: 26% in the tenoten group, 21% in the diazepam group, and 28% in the phenazepam group.

All studied preparations reduced anxiety in patients with low, medium, and high levels of situational anxiety, but maximum effect of tenoten was attained in patients with high anxiety (Fig. 1). In patients of tenoten, diazepam, and phenazepam groups with high level of anxiety, this parameter decreased by 31, 25, and 24%, respectively.

Evaluation of patient's state by WAM scale showed that the mean values of well-being improvement were 58% in the tenoten group, 55% in the diazepam group, and 46% in the phenazepam group, while the mean values of mood improvement were 58% in the tenoten group, 37% in the diazepam group, and 54% in the phenazepam group. The values of well-being and mood improvement in patients with high level of anxiety according to WAM test were 26% and 58% in the tenoten group, 40% and 32% in the diazepam group, and 26% and 31% in the phenazepam group, respectively. Thus, evaluation of the effects with WAM scale showed that tenoten was not inferior to diazepam and phenazepam by the capacity to improve patient's well-being and mood.

Evaluation of the efficiency of tenoten premedication by Gologorskii scale showed that fear, anxiety, tension, and nervousness were eliminated 20 min after drug intake, psychogenic dyspnea and tachycardia also decreased. The integral efficiency of preparations used

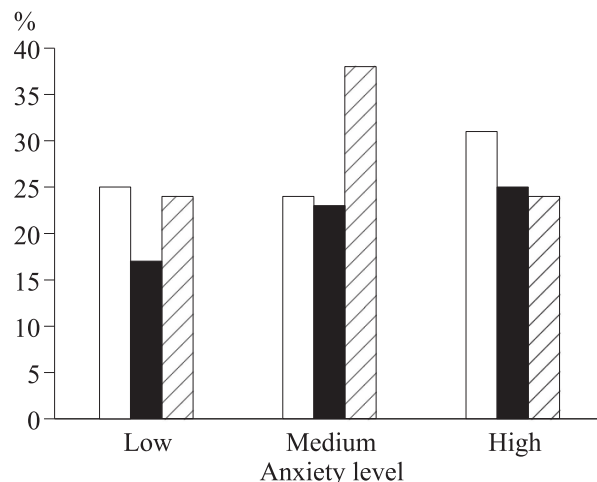


Fig. 1. Effect of tenoten (4 tablets) on emotional state of patients with different levels of situational anxiety waiting for dental procedures (Spielberger-Khanin scale). Open bars: tenoten; dark bars: diazepam; hatched bars: phenazepam.

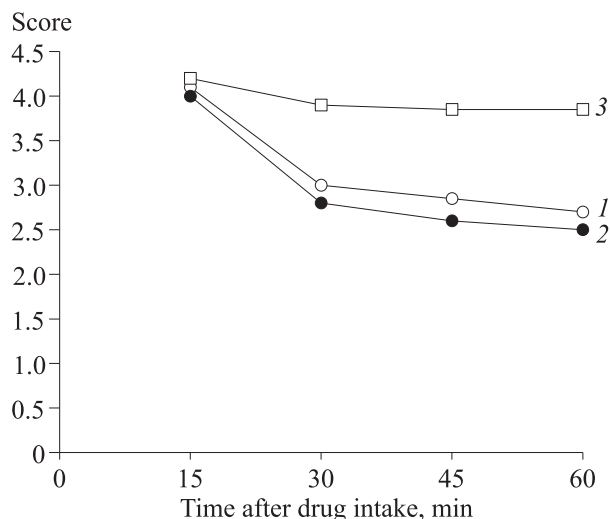


Fig. 2. Effect of premedication with TP (1), diazepam (2), and placebo (3) before dental treatment on anxiety level (MCDAS scale) in children with negative behavior.

for premedication was 1.57 for tenoten (2 tablets), 2.14 for tenoten (4 tablets), 2.42 for diazepam, and 2.57 for phenazepam. This suggests that the efficiency of tenoten increases with increasing its dose and that the preparation is only slightly inferior to diazepam and phenazepam by its anxiolytic effect.

Tenoten did not affect systolic blood pressure and reduced diastolic pressure, while diazepam and phenazepam reduced systolic blood pressure and had no effect on diastolic pressure. Tenoten reduced HR, while diazepam and phenazepam increased this parameter.

Premedication with diazepam and phenazepam was accompanied by side effects (muscular relaxation, sleepiness, and delayed reflex response) in 47-58%

patients. These side effects were not observed against the background of tenoten treatment.

The efficiency of tenoten was also confirmed by sensometry. It was found that tenoten, diazepam, and phenazepam exhibited equally pronounced anxiolytic effects. Tenoten insignificantly increased TST and PST (by 5 and 11%, respectively) and significantly increased PTT (by 68 and 93% after premedication with 2 and 4 tablets, respectively). Diazepam and phenazepam also little affected TST and PST, but significantly increased PTT (by 80 and 70%, respectively).

In children, TP and diazepam also produced considerable and equally potent effects on anxiety level evaluated by MCDAS scale. The effects of the preparations were observed as soon as 15-30 min after treatment. The drugs produced an anxiolytic effect in children with low, medium, and high level of anxiety. The maximum effect was observed in children with high anxiety level: the decrease in anxiety level 30 min after treatment with TP, diazepam, and placebo was 46, 50, and 14%, respectively.

In children with emotional stress, the mean score before premedication varied from 4.0 to 4.2. After premedication, the mean scores were 3.0, 2.8, and 3.9 in the TP, diazepam, and placebo groups, respectively. Behavioral reaction in children of the TP, diazepam, and placebo groups improved by 1.1 (26.83%), 1.2 (30%), and 0.3 (7.1%), respectively (Fig. 2).

TP produced a pronounced effect in children with low anxiety level, whereas diazepam was less effective in these patients.

The effect of placebo developed more rapidly and was more transient than the effect of drugs (in case when they were administered by the same specialist).

TP reduced HR in children by 20-30 bpm. Side effects (muscular relaxation, sleepiness, and delayed reflex response) were observed in 38% children receiving diazepam. These side effects were not observed after TP administration.

Our findings suggest that tenoten and TP exhibit pronounced anxiolytic effects comparable with the effects of diazepam and phenazepam. Being administered to patients waiting dental treatment, tenoten (in adults) and TP (in children) eliminate anxiety and improve well-being and mood in patients with low, medium, and, especially, with high levels of anxiety. Tenoten increased the threshold of pain tolerance. Tenoten induced no appreciable changes in blood pressure. Tenoten and TP reduce stress-elevated HR and have no side sedative and myorelaxant effects, which is very important in outpatient settings.

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