

# The Use of Tenoten (Pediatric Formulation) in the Therapy of Chronic Tension-Type Headaches in Children

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Tension-type headaches are the most common type of headaches in children. No effective treatment for this disease is developed yet. After treatment with tenoten, the number of days with headache in 9-17-years-old children decreased by 40.9%, the mean headache intensity score decreased to 1.

**Key Words:** *chronic tension-type headache; therapy; tenoten (pediatric formulation)*

Chronic tension-type headaches (CTTH) in children constitute about 50-60% in the structure of headaches and are referred to primary headaches [2,5]. In CTTH, aponeurosis and pericranial muscles are involved in the process, which leads to compression of nociceptive receptors on surface vessels of the head. The pain is caused by long-term stress influence. CTTH are characterized by regular frequency (not less than 15 episodes per month), have typical clinical picture (diffuse constricting hoop-like pain), and do not significantly impair working capacity [3,5] (Table 1). Additional methods of examination reveal no organic pathology of the brain [1].

CTTH poorly respond to treatment. Standard methods of drug correction: antidepressants (amitryptiline, prozac, coaxil), anticonvulsants (topamax, gabapentin), myorelaxants (sirdalud, midocalm), non-steroidal anti-inflammatory drugs (nurofen, aspirin) [6], and preparations of other groups apart from their doubtful efficiency produce numerous side effects, which is of crucial importance in pediatric practice. Some preparations are contraindicated for the use in children neurology and psychiatry. On the other hand, inadequate therapy of CTTH is fraught with high risk of disease prolongation in adult age and a decrease in patient's quality of life.

Non-drug methods of therapy are widely used for the treatment of CTTH. Biological feed-back methods aimed at the development of an unconditioned reflex restricting painful stimulation, massage of the collar area, acupuncture, and methods of psychological correction gained general acceptance are effective, but not always available (due to lack of equipment and specialists or in cases when patients live far from medical institutions) and their application is limited.

Here we studied the efficiency of tenoten (pediatric formulation, TP) in CTTH.

## MATERIALS AND METHODS

We examined 15 children (11 girls and 4 boys) aging 9-17 years (mean age  $14 \pm 2$  years) with CTTH diagnosed according to criteria of International Headache Classification, 2nd Edition.

Apart from history taking and clinical examination, we used the data of the visual analog scale (VAS) of pain intensity and McGill Pain Questionnaire (MPQ).

VAS in a straight line with graduations from 0 to 10, where 0 corresponds to "no pain" and 10 corresponds to "intolerable excruciating pain". The examinees evaluated headache intensity by themselves. The mean VAS score was  $3 \pm 1$ .

**TABLE 1.** Modern Classification and Diagnostic Criteria for CTTH

ICD-10 code	Type of pain	Diagnostic criteria
G44.2	CTTH	A. Headache occurring not less than 15 days per months for more than 3 months (not less than 180 days per year)
G44.22	CTTH accompanied by pericranial muscle tension	B. Headache persisting for few hours or sustained headache
G44.23	CTTH not accompanied by pericranial muscle tension	C. Headache has at least two of the following characteristics: 1) bilateral localization; 2) constricting/squeezing pattern; 3) pain intensity from mild to moderate; 4) headache does not increase during physical exercise D. Has two symptoms 1) only one of three symptoms: photophobia or phonophobia or mild nausea; 2) headache is not accompanied by nausea and vomiting E. Is not related to other causes

McGill Pain Questionnaire (MPQ) contains 20 characteristics of headache allowing evaluation of its sensory, emotional, and quantitative components. According MPQ analysis, the rank index of the pain was  $2 \pm 1$ .

The mean duration of headache in children was  $5 \pm 2$  h per day, the mean duration of episode corresponded to diagnostic criteria of CTTH.

Additional methods of diagnostics (electroencephalography, computed tomography and/or magnetic resonance imaging, duplex scanning of head and neck vessels) and examination by specialists revealed no pathological changes than can cause headache. The diagnosis CTTH was confirmed in all patients.

All children received monotherapy with TP, a preparation containing ultralow doses of antibodies to brain-specific S100 protein, in a dose of 1 sublingual tablet 25-30 min before meal 3 times a day for 8 weeks. This preparation was chosen because it is

characterized by pathogenetic mechanism of action and the absence of side effects.

S-100 protein is involved into pathogenesis of anxious disorders, an important cause of CTTH. No serious and documented side effects during TP treatment were reported.

## RESULTS

After the course of treatment, improvement was achieved in all cases. The children noted an improvement in subjective well-being, mood, and exercise tolerance. Three kids refused day sleep because they felt well. Parents of the examined children reported better school results; the kids also spent less time and less frequently sought help when preparing homework than before the therapy.

Repeated testing showed positive dynamics: VAS score for headache intensity decreased to 1 ( $p < 0.05$ ),

**TABLE 2.** Clinical Characteristics of Examined Children

Parameter	Before treatment	After treatment
VAS score	$3 \pm 1$	$1 \pm 1^*$
MPQ rank index of pain (mean index)	$2 \pm 1$	$1 \pm 1$
Number of adjectives characterizing pain (according to MPQ)	$12 \pm 2$	$7 \pm 3^{**}$
Number of episodes per month	$22 \pm 3$	$9 \pm 2^{**}$
Pain duration, hours	$5 \pm 2$	$4 \pm 2$

**Note.**  $^*p < 0.05$ ,  $^{**}p < 0.01$  compared to values before therapy.

the number of episodes per month decreased by 40.9% with an insignificant decrease in pain duration during daytime (Table 2).

Repeated MPQ testing showed a decrease in pain index and the number of adjectives used in the test to 50% (Table 2).

In one child, symptoms of dyspepsia developed on day 3 of treatment, but thorough analysis and examination by gastroenterologist showed that these symptoms were a result of eating inappropriate food and disappeared after relevant treatment. The child successfully completed the course of TP treatment. Thus, no undesirable effects of TP therapy were recorded over the entire period of dynamic observation.

We conclude that TP can be recommended as a safe and effective preparation for the treatment of CTTH in children. TP has a pathogenetically substantiated mechanism of action; it affects an important

element in the development of anxious disorders and, ultimately, CTTH. Our study showed well tolerability of TP in children and the absence of side effects.

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