The Use of Tenoten Preparation in Complex Therapy of Hypomotoric Biliary Dyskinesia

V. I. Simanenkov, E. G. Poroshina, and S. V. Tikhonov

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A positive effect of tenoten on the course of biliary dyskinesia in patients with anxiety and depressive disorders was demonstrated. Tenoten can be recommended for the treatment of functional cholangio-pancreatoduodenal motility disturbances.

Key Words: *biliary dyskinesia; tenoten; asthenia; state anxiety; trait anxiety*

Urgency of functional disorders of the biliary zone is mentioned in Rome Consensus (1999), where the term "dysfunctional disorders of the biliary tract" was approved. Two types of disorders are distinguished irrespective of their etiology: gallbladder dysfunction and Oddi's sphincter dysfunction [4]. The character of functional disturbances and variety of clinical symptoms are related to complexity of the anatomical structure of this portion of the gastrointestinal tract and to peculiarities of humoral regulation [3].

The prevalence of dysfunctions of the biliary tract is little studied [2], no epidemiological data are available. According to reports of Rome Study Group for Etiology and Prevention of Cholelithiasis, among individuals with ultrasonography-excluded cholelithiasis, the incidence of biliary colic was 7.6% in men and 20.7% in women [5].

Standard therapy for these states apart from spasmolytics, choleretics, and cholekinetics includes psychotropic drugs [1]. Anxiolytics and antidepressants are prescribed depending on the severity of psychotropic symptoms.

For our study we chose tenoten, a preparation created in Russia. This drug exhibits anxiolytic, antidepressant, and antiasthenia activities, and therefore is classified as day-time anxiolytic. The effect of tenoten is determined by modulation of biological activity of brain-specific S-100 protein. The involvement of this protein into the formation of emotional disturbances was proven. Tenoten is a safe preparation; it has no contraindications and side effects.

Here we evaluated the effect of tenoten on reduction of anxious and somatic symptoms (pain, burning, belching, bitterness) in patients with biliary dyskinesia (BD) and on biliary tract motility.

MATERIALS AND METHODS

The study included 31 patients. The main group comprised 21 patients (18 women and 3 men) with verified BD. The mean age of patients was 41 years (23-63 years). History of BD was 13 years on average. The patients kept a diet and received tenoten over one month according to the following scheme: 2 tablets 3 times a day for 2 weeks and then 1 tablet 3 times a day for subsequent two weeks.

The control group consisted of 10 patients (8 women and 2 men), mean age 35 years (20-64 years), and history of BD 15 years on average.

The patients of both groups received artichoke extract in a dose of 200 mg 3 times a day for 4 weeks. Abdominal pains were controlled with drotaverin.

Before the start of the study, the patients of the main and control group complained of fatty food intolerance, spasmodic pain in right hypochondrium, often related with meal, nausea, burning, unstable stool. All patients also had personality disorders (reduced emotional background, increased anxiety, and fatigability).

Department of Therapy and Clinical Pharmacology, St. Petersburg State Medical Academy of Postgraduate Education

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The inclusion criteria were patient's age 18-65 years, verified BD and anxiety-phobic disorders (generalized anxiety disorder, mixed anxiety and depressive disorder, neurasthenia). Exclusion criteria were: diffuse pathologies of the liver, acute pancreatitis, exacerbation of ulcer disease, alcoholism, cholelithiasis, psychoses, severe heart failure NYHA class III-IV, acute myocardial infarction and stroke, decompensated renal diseases.

The drug efficiency was evaluated by changes in clinical status and parameters of ultrasonic examination of the biliary tract with load testing (only in the main group); mental status was studied by Spielberger—Khanin self-evaluation test, Hamilton rating scale for anxiety, and asthenia questionnaire before the study and after 1-month tenoten treatment. After completion of the study, the patients were asked to evaluate the treatment results by a 10-point visual analog scale, where 0 corresponded to "very bad" and 10 corresponded to "very good" result. Abdominal pain, burning, and meteorism were also evaluated by a 10-point scale. Stool was evaluated by Bristol stool form scale.

The data were processed using Mann—Whitney *U*, Kolmogorov—Smirnov, and Wilcoxon tests.

RESULTS

One female patient of the main group refused tenoten because of loose stool and forgetfulness, which existed before the start of the study. She was excluded from the study. Tenoten treatment compliance in the main group after 1 month was 78%.

The level of depression (evaluated by Hamilton scale) in the main group significantly decreased after therapy, in contrast to the control group. Trait and state anxiety evaluated by Spielberger—Khanin test also significantly decreased in this group.

Asthenic syndrome decreased in both groups (in the main group this decrease was more pronounced). Apart from psychopathological symptoms, some clinical symptoms (epigastric pain, belching, burning, meteorism) also decreased in the main group. In the control group, no appreciable changes in the severity of pain syndrome were noted after 1-month therapy. Moreover, the intensity and frequency of burning increased.

Changes in the Bristol stool form scale score were insignificant.

Ultrasonic examination after tenoten treatment revealed a significant increase in gallbladder contraction in response to load test (39.35 *vs.* 28%, $p<0.05$).

The patients rated the efficiency of treatment as 7 (by 10-point visual analog scale), clinical evaluation of treatment results by the physician was 8 (Fig. 1, 2). In the control group, patient rated the treatment results as 5 and clinical rating also was 5.

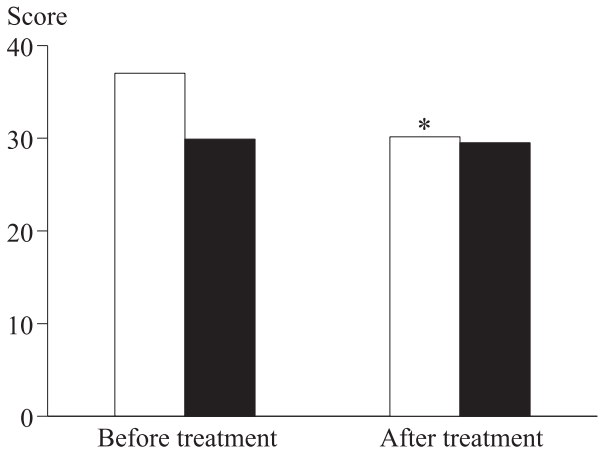

Fig. 1. Dynamics of state anxiety according to Spielberger-Khanin test. Here and on Fig. 2: open bars: main group; dark bars: control group. *$p<0.001$ compared to the corresponding values before treatment.

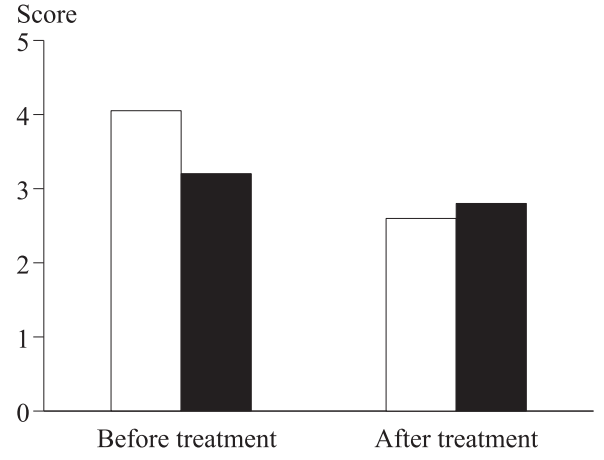

Fig. 2. Pain syndrome before and after treatment.

Thus, course therapy with tenoten significantly improved mental status of patients, decreased the signs of social and psychic dysadaptation and the severity of asthenic disorders. Tenoten normalized motility of the biliary tract and upper portion of the gastrointestinal tract, which manifested in reduction of pain syndrome, burning, and belching.

REFERENCES

1. A. A. Il'chenko, *Klin.Perspekt. Gastroenterol. Gepatol.,* No. 5, 25-29 (2002).
2. A. V. Kalinin, *Ibid*., No. 3, 25-34 (2003).
3. A. V. Kalinin and L. I. Butorova, *Ibid*., No. 4, 25-34 (2001).
4. D. A. Drossman, Z. Li, E. Andruzzi, *et al., Dig. Dis. Sci.*, **38**, No. 9, 1569-1580 (1993).