The clinical of DETA-AP and DETA-RITM devices of gastric ulcer and duodenal ulcer (during partial remission).

Approved by
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(Seal: State Educational Institution of Higher Professional Education
Bashkir State Medicine University of the Federal Agency for Health Care and Social Development)

Minutes
of Clinical Tests to Study
the Efficiency of Treatment Applying DETA-AP-13 device
2009

Research basis:

Test aim: To assess the opportunities to apply DETA-AP-13 device manufactured by OOO ELIS Research and Development Enterprise in medical practice on the territory of the Russian Federation in case of gastric ulcer and duodenal ulcer (during partial remission).

Type of testing: open, non-random, comparative.

Test task:

1. to determine the clinical efficiency of DETA-AP-13 in case of gastric ulcer and duodenal ulcer as the sole therapy.
2. to study the clinical efficiency of DETA-AP-13 application in case of gastric ulcer and duodenal ulcer.
3. to assess the safety of DETA-AP-13 application in case of gastric ulcer and duodenal ulcer (during partial remission) as the sole therapy.

Plan of testing: clinical testing is conducted with 22 patients. Patient were selected in accordance with the specified inclusion criteria.

Inclusion criteria: Twenty two persons with laboratory serological tests through immune and enzyme analysis of titre of specific antibodies to antigens of Helicobacter pylori participated in the testing. Tests and treatment were carried out on the basis of informed voluntary consent of the patient according to the Order No. 163 (Industry-specific Standard (OST) 91500.14.0001-2002) of the Ministry of Health of the Russian Federation.

Time and place of the tests: in a clinic, at home.

Represented for the tests:
1. DETA-AP-13 device manufactured by OOO ELIS Research and Development Enterprise (Moscow), 1 item; software of the device provides antiparasitic therapy.
2. DETA-AP-13 device is authorized for application in medical practice (Registration certificate of the Federal Service on Surveillance in Healthcare and
Test results:
The research of clinical efficiency of different ways to treat gastric ulcer and duodenal ulcer (during partial remission) was carried out among 22 patients (2 men, 16 women being from 20 to 60 years old and 4 children from 12 to 15 years old). Gastric ulcer and duodenal ulcer were diagnosed clinically and evidenced by the data of immunological studies and functional diagnosis of gastrointestinal tract organs applying electroacupuncture.

The control group (drug therapy only) consisted of 12 persons (5 men and 5 women being from 25 to 55 years old and 2 children being from 10 to 12 years old). The study groups were of similar sex, age, nosological entities, severity of the underlying disease and intensity of clinical implications of gastric ulcer and duodenal ulcer (during partial remission). Only patients having gastric ulcer and duodenal ulcer during partial remission participated in the testing.

Treatment method. DETA-AP-13 device was prepared to the treatment in accordance with the DETA-AP-13 Device Manual. The device was switched on and off in accordance with the instructions of the Manual. During the session the device was located within a radius of 20-30 cm from epigastric area. The session duration is 2640 seconds, one session a day, the course takes from 5 to 6 days.

The efficiency of different treatment methods for gastric ulcer and duodenal ulcer is assessed through daily clinical examinations, including assessment of the general state of health, condition of skin, functions of the gastrointestinal tract (appetite, dyspepsia, abdominal pains, belching). Concerning laboratory examinations specific antibodies to antigens of Helicobacter pylori were determined through immune and enzyme analysis. Concerning examinations methods applying medical equipment electric potential of points SPED 3-dex, IG -4 dex и sin, TR-5-dex, IG -4 -dex, IG -4 –sin was measured.

Clinical monitoring of patients treated by the device as the sole therapy of gastric ulcer and duodenal ulcer and combined treatment, including prebiotics, natural enterosorbent and antibiotics revealed a more pronounced positive effect comparing to the control group expressed as reduction of gastrointestinal dyspepsia, increased functional activity of gastrointestinal tract organs, determined by electroacupuncture diagnosis method, and reduction of titre of specific antibodies applying immune and enzyme analysis.
Table 1.
Dynamics of the major clinical symptoms, immunological parameters and indicators of gastrointestinal tract activity, determined by electroacupuncture diagnosis method among the patients having gastric ulcer and duodenal ulcer (during partial remission).

<table>
<thead>
<tr>
<th>Symptoms</th>
<th>The 1st group DETA-AP-13 device N=11</th>
<th>The 2nd group DETA-AP-13 device + drug complex N=11</th>
<th>The 3rd group drug complex N=10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Paleness of skin</td>
<td>Before—treatment</td>
<td>After—treatment</td>
<td>After—treatment</td>
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<tr>
<td></td>
<td>Before</td>
<td>After</td>
<td>Before</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>2</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>82%</td>
<td>27%</td>
<td>18%</td>
</tr>
<tr>
<td>Asthenic syndrome</td>
<td>Before—treatment</td>
<td>After—treatment</td>
<td>After—treatment</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>3</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>73%</td>
<td>27%</td>
<td>9%</td>
</tr>
<tr>
<td>Abdominal pains</td>
<td>Before—treatment</td>
<td>After—treatment</td>
<td>After—treatment</td>
</tr>
<tr>
<td></td>
<td>10</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>91%</td>
<td>18%</td>
<td>7%</td>
</tr>
<tr>
<td>EIA high tite of specific antibodies according to IgG</td>
<td>Before—treatment</td>
<td>After—treatment</td>
<td>After—treatment</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>75%</td>
<td>18%</td>
<td>9%</td>
</tr>
<tr>
<td>Electroacupuncture diagnosis (average indices)</td>
<td>Before—treatment</td>
<td>After—treatment</td>
<td>After—treatment</td>
</tr>
<tr>
<td>TR-5-dex</td>
<td>25-30</td>
<td>25-35</td>
<td>25-35</td>
</tr>
<tr>
<td></td>
<td>35-45</td>
<td>35-50</td>
<td>25-40</td>
</tr>
<tr>
<td>SPED 3-dex</td>
<td>10-25</td>
<td>13-27</td>
<td>13-28</td>
</tr>
<tr>
<td></td>
<td>30-40</td>
<td>35-50</td>
<td>35-40</td>
</tr>
<tr>
<td>IG -4-dex</td>
<td>7-15</td>
<td>8-17</td>
<td>10-25</td>
</tr>
</tbody>
</table>
Tolerance. It should be noted that DETA-AP-13 is well-tolerated, there is no general and local adverse reactions. The therapy did not have negative impact on the concomitant pathology of patients.

Conclusion.

1. DETA-AP-13 device regarding its functional and application features fully complied with the requirements of medical practice in treating gastric ulcer and duodenal ulcer.
2. Pronounced clinical efficiency of DETA-AP-13 device is detected as the sole therapy and in combination with drug therapy comparing to traditional treatment methods.
3. There is no contraindication to the use of DETA-AP-13 device among the patients having lambliosis of intestinal tract.
4. DETA-AP-13 device may be used during the hospital and out-patient treatment and at home.

Recommendations.

On the basis of the above stated facts, on the clinical tests, we propose to add the device to the regional standard equipment for outpatient institutions and clinics, as well as hospitals (minimum requirements therefore are determined by Order of the Ministry of Health Care and Social Development of the Russian Federation No. 753 dated December 01, 2005) for the following specialists:
1) General Practitioner.
2) Gastroenterologist.
3) Pediatrician.

In this case DETA-AP-13 devices may be purchased on budgetary funds, or at the expense of patients for personal use.

The said recommendation will be legitimate according to an order of an authority regulating health care in the region and will have positive impact on the improvement of medical services for people.

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