effects of domperidone combined with doxepin hydrochloride in treatment of functional dyspepsia.

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abstract

objective: this study was aimed to explore effects of domperidone combined with doxepin hydrochloride in treatment of functional dyspepsia.

methods: from aug 2015 to feb 2017, 100 patients with functional dyspepsia were selected from yuyao people’s hospital as the study subjects and were randomly divided into control group (n=50) and experimental group (n=50) in which patients in the control group were treated with conventional drugs treatment of domperidone while patients in the experimental group received domperidone treatment combined with doxepin hydrochloride. clinical effects in two groups were observed.

results: treatment efficiency of the experimental group was significantly higher than that of the control group (p<0.05), the degree of anxiety and depression of the experimental group is lower than that of the control group after treatment (p<0.05) with no significant difference (p>0.05). the scores in such clinical symptoms as stomach pain, bloating, stomach burning and belching, the incidence of adverse effect and recurrence rate of the experimental group were significantly lower than that of the control group (p<0.05).

conclusion: domperidone combined with doxepin hydrochloride has notable effects in treatment of functional dyspepsia and possesses application value due to its function of improving clinical symptoms, effectively reducing the incidence of adverse effect and recurrence rate and enhancing activity daily living of the patients.

keywords: domperidone, doxepin hydrochloride, functional dyspepsia, effect.

introduction

recent years, the development of the people’s life changes our diet habits, which induces more digestive system disease, especially functional dyspepsia, the most common and prevailing gastrointestinal disease among the majority [1].

functional dyspepsia mainly refers to pathological change of the gastric mucosa specificity caused by a variety of reasons, with the symptoms including abdominal pain, nausea, vomiting, stomach burning, belching, abdominal distension and poor appetite, seriously affects patient’s daily life and work [2].

in the current clinical treatment of the disease, western medicines are often applied to relieve symptoms and improve the unhealthy emotion of patients.

in this study, 100 patients from our hospital were selected as the study subject to explore clinical effects of domperidone combined with doxepin hydrochloride in treatment of functional dyspepsia and provide reference for clinical therapy.

material and methods

general data

from aug 2015 to feb 2017, 100 patients with functional dyspepsia were selected from our hospital as the study subjects and were randomly divided into control group (n=50) and experimental group (n=50) in which there were 28 males and 22 females in the experimental group at the age of 22 to 62 with the average of (42.3 ± 8.4) and a disease course of (3.1 ± 1.2) months on average, while among the control group there were 26 males and 24 females at the age of 24 to 63 with the average of (42.5 ± 7.6) and a disease course of (3.8 ± 1.5) months on average.

the comparison of general data in two groups is of statistical significance by way of independent sample test, p>0.05.

inclusion and exclusion standards

inclusion standard: patients with the results of various inspections including blood biochemical test, b ultrasound, blood and urine routine examination in conformity with the functional dyspepsia indicators [3]; patients with symptoms
like persistent stomach pain, abdominal distension, nausea, vomiting, anti-acid and belching without any drug treatment [4]; Patients voluntary to participate gave their consent and approved by the hospital medical committee.

**Treatment methods**

All patients were given basic drugs treatment and healthy diet guidance, on this basis patients of the control group were treated with domperidone (manufacturer: Xian-Janssen Pharmaceutical Ltd. approved by H10910003, specifications: 10 mg/tablet), 10 mg for oral administration, 30 min before meals, 3 times/d [5].

Patients in the experimental group were additionally treated with domperidone followed by the treatment of the control group (manufacturer: Shanghai Sympharma Co., Ltd. approved by H31021425), with the initial dose of 25 mg/time, 3 times/d and then with the maintenance of 50 mg to 100 mg, 2 times/d.

**Observation index**

Clinical effects in two groups; Scores in such clinical symptoms as stomach pain, bloating, stomach burning and belching, the incidence of adverse effect and recurrence rate and the degree of anxiety depression (by way of SAS, SDS scores).

**Evaluation criterion**

Efficacy evaluation criteria: Healed: clinical symptoms like stomach pain completely disappeared; Improved: clinical symptoms like stomach pain disappeared basically with the alleviation of pain; Effective: clinical symptoms like stomach pain were improved with pain relief; Invalid: clinical symptoms like stomach pain remained unchanged or even went worse. Total effective rate:=healed rate+improved rate+effective rate.

Score criteria of various symptoms (stomach pain, bloating and stomach burning and belching): “0” shows no symptoms; “1” means symptoms occasionally appear; “2”: symptoms appear but not frequently; “3”: symptoms occur frequently with obvious discomfort; “4” shows symptoms become severe and the patients required to be treated with drug control [6-8].

**Statistical analysis**

Normal distribution measurement data were described as Mean ± SD. T-test and χ^2 test were applied with statistical significance of P<0.05.

**Table 3. Score of anxiety depression degree before and after treatment.**

<table>
<thead>
<tr>
<th>Group</th>
<th>SAS score</th>
<th>SDS core</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Before treatment</td>
<td>After treatment</td>
</tr>
<tr>
<td>Control</td>
<td>62.14 ± 5.26</td>
<td>57.45 ± 4.14</td>
</tr>
<tr>
<td>Experiment</td>
<td>62.34 ± 4.57</td>
<td>42.36 ± 4.23</td>
</tr>
</tbody>
</table>

Results

**Treatment effects analysis**

Total effective rate of the experimental group is higher than that of the control group (P<0.05) shown in Table 1.

<table>
<thead>
<tr>
<th>Group</th>
<th>Significant effect</th>
<th>Effective</th>
<th>Invalid</th>
<th>Total rate effective</th>
</tr>
</thead>
<tbody>
<tr>
<td>Experiment</td>
<td>25 (50.00)</td>
<td>23 (46.00)</td>
<td>2 (4.00)</td>
<td>48 (96.00)</td>
</tr>
<tr>
<td>Control</td>
<td>19 (38.00)</td>
<td>18 (36.00)</td>
<td>12 (24.00)</td>
<td>38 (76.00)</td>
</tr>
<tr>
<td>x^2</td>
<td></td>
<td></td>
<td></td>
<td>8.305</td>
</tr>
<tr>
<td>P</td>
<td></td>
<td></td>
<td></td>
<td>0.003</td>
</tr>
</tbody>
</table>

**Scores of various symptoms**

The scores in such clinical symptoms as stomach pain, bloating, stomach burning and belching of the experimental group were significantly lower than that of the control group (P<0.05) shown in Table 2.

<table>
<thead>
<tr>
<th>Group</th>
<th>Stomach pain</th>
<th>Bloating</th>
<th>Stomach burning</th>
<th>Belching</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>1.64 ± 0.38</td>
<td>1.57 ± 0.21</td>
<td>0.89 ± 0.25</td>
<td>1.15 ± 0.14</td>
</tr>
<tr>
<td>Experiment</td>
<td>0.56 ± 0.35</td>
<td>0.68 ± 0.24</td>
<td>0.36 ± 0.12</td>
<td>0.72 ± 0.12</td>
</tr>
<tr>
<td>t</td>
<td>14.782</td>
<td>19.733</td>
<td>13.769</td>
<td>16.489</td>
</tr>
<tr>
<td>P</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
<td>&lt;0.05</td>
</tr>
</tbody>
</table>

**The degree of anxiety depression**

There was no significant difference in SAS, SDS scores between two groups before treatment while the SAS, SDS scores of the experimental group was lower than that of the control group after treatment (P<0.05) shown in Table 3.

<table>
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**The incidence of adverse effect and recurrence rate**

Recurrence rate of the experimental is 2%, significantly lower than that of the control group 16%. Data comparison result between two groups shows x^2=5.982, P=0.014.
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Table:

<table>
<thead>
<tr>
<th></th>
<th>t</th>
<th>0.202</th>
<th>18.027</th>
<th>0.174</th>
<th>10.271</th>
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</thead>
<tbody>
<tr>
<td>P</td>
<td>&gt;0.05</td>
<td>&lt;0.05</td>
<td>&gt;0.05</td>
<td>&lt;0.05</td>
<td></td>
</tr>
</tbody>
</table>

Conclusion

Domperidone combined with doxepin hydrochloride has notable effects in treatment of functional dyspepsia and possesses application value due to its function of improving clinical symptoms, effectively reducing the incidence of adverse effect and recurrence rate and enhancing activity daily living of the patients.

Discussion

Nowadays, people’s diet habits have changed a lot with the improving of life and lead to moderately more digestive diseases [9]. Functional dyspepsia turns out to be the most common and widespread digestive diseases in the clinic study, mainly likely to closely related to the factors such as gastrointestinal motility disorder, gastric electric rhythm disorders and gastric paraesthesia [10,11]. The disease may occur at any age with its main clinical symptoms like abdominal pain, abdominal distension, stomach discomfort, nausea and vomiting, poor appetite and belching [12]. According to relevant research, some scholars believe that the occurrence of the disease is not only related to the gastrointestinal disorders, but also to the clinical nerve irritability state [13]. Treatment of functional dyspepsia is time-consuming with poor effects, which may increase worries of the patients and bring them such bad feelings as anxiety and depression. Also, under the regulation of the central nervous system, it inhibits gastrointestinal peristalsis, reduces secretion and eventually leads to gastrointestinal dysfunction with a series of dyspepsia symptoms [14,15]. In the clinical treatment, this disease is more often treated with medicine to control symptoms and meanwhile, the patients should pay attention to making timely prevention, developing good eating habits and regularizing time and quantities of the meals, eating less spicy and greasy food and avoiding overeating [16].

Patients with this disease are mainly treated with drugs of gastrointestinal motility resistance and antidepressant drugs. Attention should be paid to relieve the patient’s emotional stress while improving their clinical symptoms and eventually to speed up the recovery [17]. In this study, domperidone was mainly applied to take a symptomatic treatment of gastrointestinal motility and it is one of peripheral dopamine receptor antagonists, more commonly seen in clinical trial. Domperidone has a certain affinity with dopamine receptors in the gastrointestinal tract, enables to selectively block the function of dopamine receptor and has certain effects on gastrointestinal motility and gastric emptying. What’s more, it also increases muscle tension, and promotes the gastrointestinal tract and esophageal peristalsis, reduces abdominal pain, inhibits gastric acid secretion so as to better regulate the coordination of stomach and duodenum [18,19]. The drug is the first choice for clinically symptomatic treatment of gastric bowel peristalsis and widely used in clinical practices. But the disease is prone to relapse after the drug treatment, thus increasing the patient’s distress and hindering their recovery. Doxepin hydrochloride, a kind of new tricyclic drugs, is currently the most common type of anti-anxiety drugs in clinical research. It has such functions as sedation, hypnosis and anti-anxiety and helps to reduce secretion of gastric acid and inhibit generation of pepsin [20]. Most of the patients with functional dyspepsia are associated with stress responses like anxiety, worry, depression and sleep disturbance, so in the clinical treatment, the patients should also be collaboratively treated with anti-anxiety drugs followed by the symptomatic treatment of alleviating gastrointestinal peristalsis [21]. In this study, domperidone (drug of gastrointestinal motility resistant) treatment combined with doxepin hydrochloride (anti-anxiety drug) in the experimental group had striking better effects compared with the control group merely with symptomatic treatment, and the scores of anxiety and depression as well as recurrence rate were lower by contrast (P<0.05).

To sum up, domperidone combined with doxepin hydrochloride has notable effects in treatment of functional dyspepsia and possesses application value due to its function of improving clinical symptoms, effectively reducing the incidence of adverse effect and recurrence rate and enhancing activity daily living of the patients.

References


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