Clinical study on the efficacy of iodine–131 in combined with Fufangjiakang tablets in the treatment of Graves’ disease

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ABSTRACT

Objective: To observe the clinical efficacy of iodine-131 (131I) in combined with Fufangjiakang tablets in the treatment of Graves’ disease. Methods: A total of 60 patients with Graves’ disease who were admitted in our hospital from January, 2013 to January, 2015 were included in the study and randomized into the treatment group and the control group with 30 cases in each group. The patients in the treatment group were given 131I in combined with Fufangjiakang tablets, while the patients in the control group were only given 131I treatment. A follow-up visit was paid 2, 4, and 12 months after treatment, respectively. The levels of serum FT3, FT4, sTSH, TRAb, and TNF-α before and after treatment in the two groups were detected. The adverse reactions occurred during the treatment period in the two groups were compared. Results: The comparison of serum FT3, FT4, sTSH, TRAb, and TNF-α levels before treatment between the two groups was not statistically significant. With the extending of treatment time, the levels of FT3, FT4, TRAb, and TNF-α were significantly reduced when compared with before treatment, while sTSH level was significantly increased when compared with before treatment. After treatment, the levels of FT3, FT4, TRAb, and TNF-α at each timing point in the treatment group were significantly higher than those in the control group, while sTSH level was significantly lower than that in the control group. The comparison of the occurrence rate of adverse reactions occurred during the treatment period between the two groups was not statistically significant. Conclusions: 131I in combined with Fufangjiakang tablets in the treatment of Graves’ disease can effectively reduce the serum FT3, and FT4 levels, and strengthen the body immune function with a significant efficacy.

1. Introduction

The toxic diffuse goiter is also called Graves’ disease, belonging to the autoimmune disease, and is a kind of multi-system syndrome[1-3]. Beside the thyroid gland, the diffuse goiter, the high metabolism syndrome, the skin lesion, the thyroid acropachy, and eye syndrome are also involved in the Graves’ disease[4]. Some researches demonstrate that[5] Graves’ disease is closely associated with the genes, and is of genetic tendency, with more females involved than that in the males. 131I is an effective drug to treat Graves’ disease with a significant long-term effect, but due to a certain limitation of the biological effect, the clinical symptoms in partial patients in the early treatment stage can be aggravated, which can affect the patients’ treatment confidence[6]. The study is aimed to explore the clinical efficacy of 131I in combined with Fufangjiakang tablets in the treatment of Graves’ disease.

2. Materials and methods

2.1. Clinical materials

A total of 60 patients with Graves’ disease who were admitted in our hospital from January, 2013 to January, 2015 were included in
the study, among which 12 were male, and 48 were female; aged from 16 to 62 years old, with an average age of (25.8±6.4) years old; course from 1 to 6 years, with an average course of (3.2±1.2) years. All the patients were in accordance with the diagnostic criteria of Graves’ disease formulated by the Endocrinology Branch of Chinese Medical Association, with the thyroid gland diffusely enlarged in a I-IV degree, and significant hyperthyroidism signs (insomnia, palpitation, hyperorexia, fatigue, dysphoria, bulimia, hydrosis, afraid heat, emaciation, hand tremor, increased defeacation times, and exophthalmos, possessing more than 5 items of the above symptoms). Those who had infection, gestation, diabetes, primary diseases of vital organs, and other autoimmune diseases were excluded from the study.

2.2. Methods

The patients were divided into the treatment group and the control group with 30 cases in each group according to different treatment protocols. The comparison of age distribution, gender, and course between the two groups was comparable (P>0.05). The patients in the treatment group were given ¹³¹I in combined with Fufangjiakang tablets. ¹³¹I sodium oral liquid was purchased from Beijing Atom High-Technology Application Company Limited with the approval number of H10960248. Before treatment, the thyroid function scanning in combined with palpation were used to evaluate the thyroid weight. According to the data of thyroid weight, the dosage of ¹³¹I was adjusted. The standard was each gram of thyroid gland/2.22-3.7 MBq ¹³¹I. The dosage was appropriately increased or reduced when taking the age, course, and condition into considerations. The Fufangjiakang tablets were purchased from Hunan Fuxing Feige Pharmaceutical Company Limited with an approval number of Z20023070, PO, 6-7 tablets each time, 3 times a day. The patients in the control group were only given ¹³¹I treatment. Food rich in iodine was forbidden 1 week before treatment. The anti-thyroid drugs were ceased. The patients were informed to pay attention to rest, to avoid mental stimulation, and to prevent infection. A radiological protection was performed for the patients’ relatives.

2.3. Observation indicators

A follow-up visit was paid 2, 4, and 12 months after treatment, respectively. The clinical efficacy after treatment in the two groups was compared. The levels of serum FT₃, FT₄, sTSH, TRAb, and TNF-α before and after treatment in the two groups were detected. The adverse reactions occurred during the treatment period in the two groups were recorded.

2.4. Statistical analysis

SPSS 12.0 software was used for the statistical analysis. Data were expressed as mean ± SD. T test was used for the comparison of the measurement data, and Chi-square test was used for the comparison of the enumeration data. P<0.05 was regarded as statistically significant.

3. Results

3.1. Comparison of the levels of FT₃, FT₄, sTSH, TRAb, and TNF-α before and after treatment between the two groups

The comparison of serum FT₃, FT₄, sTSH, TRAb, and TNF-α levels before treatment between the two groups was not statistically significant (P>0.05). With the extending of treatment time, the levels of FT₃, FT₄, TRAb, and TNF-α were significantly reduced when compared with before treatment (P<0.05), while sTSH level was significantly increased when compared with before treatment (P<0.05). After treatment, the levels of FT₃, FT₄, TRAb, and TNF-α at each timing point in the treatment group were significantly higher than those in the control group (P<0.05), while sTSH level was significantly lower than that in the control group (P<0.05) (Table 1).

3.2. Adverse reactions

In the observation group, during the treatment period, 5 (16.7%) had rash, 3 (10.0%) had gastrointestinal reaction, 7 (23.3%) had granulocytopenia, and 1 (3.3%) had agranulocytosis, while in the control group, 6 (20.0%) had rash, 2 (6.7%) had gastrointestinal reaction, 7 (23.3%) had granulocytopenia, and no patients had agranulocytosis. The comparison of the occurrence rate of rash, gastrointestinal reaction, granulocytopenia, and agranulocytosis during the treatment period between the two groups was not statistically significant (P>0.05).

4. Discussion

Table 1

<table>
<thead>
<tr>
<th>Groups</th>
<th>n</th>
<th>Before treatment</th>
<th>2 months after treatment</th>
<th>4 months after treatment</th>
<th>12 months after treatment</th>
<th>Before treatment</th>
<th>2 months after treatment</th>
<th>4 months after treatment</th>
<th>12 months after treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>30</td>
<td>29.21±2.27</td>
<td>18.72±1.31*#</td>
<td>12.25±3.24*#</td>
<td>4.50±0.98*#</td>
<td>29.34±2.33</td>
<td>20.12±2.31*</td>
<td>18.72±1.31*</td>
<td>4.50±0.98*#</td>
</tr>
<tr>
<td>Control</td>
<td>30</td>
<td>55.12±17.72</td>
<td>38.06±9.99*#</td>
<td>24.52±3.78*#</td>
<td>15.60±5.33*#</td>
<td>56.0±16.12</td>
<td>42.16±10.09*</td>
<td>24.52±3.78*</td>
<td>15.60±5.33*#</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0.31±0.06</td>
<td>0.83±0.09*#</td>
<td>1.80±3.16*#</td>
<td>2.88±0.63*#</td>
<td>0.32±0.05</td>
<td>0.60±0.10*</td>
<td>0.83±0.09*#</td>
<td>2.88±0.63*#</td>
</tr>
<tr>
<td></td>
<td></td>
<td>47.40±5.93</td>
<td>37.76±4.97*#</td>
<td>28.67±0.93*#</td>
<td>18.16±1.64*#</td>
<td>48.11±4.23</td>
<td>39.94±5.62*</td>
<td>28.67±0.93*</td>
<td>18.16±1.64*#</td>
</tr>
<tr>
<td></td>
<td></td>
<td>5.63±1.23</td>
<td>4.78±1.14*#</td>
<td>3.60±1.34*#</td>
<td>2.01±1.33*#</td>
<td>5.82±1.01</td>
<td>5.01±1.33*</td>
<td>3.60±1.34*</td>
<td>2.01±1.33*#</td>
</tr>
</tbody>
</table>

*P<0.05, when compared with before treatment; #P<0.05, when compared with the control group.
Graves’ disease belongs to the specific autoimmune disease, common in the clinic, with complicated pathogenesis, and is associated with various factors, whose clinical symptoms are not only limited to the thyroid, but is a multi-system syndrome. Due to the high metabolism syndrome and thyroid enlargement existing in the majority of the patients, it is called Graves’ disease[7-10]. Currently, the anti-thyroid drugs, the radionuclide iodine, surgery, and interventional embolization are mainly involved in the treatment of Graves’ disease, among which the anti-thyroid drugs are the mostly widely applied, the iodine preparation is mainly applied in the crisis and preoperative operation, and can also be lonely adopted[11].

Some researches demonstrate[12] the autoimmune dysfunction plays an important role in the pathogenesis of Graves’ disease, the pathological injury is the inflammation reaction, and the cytokines released by Th1/Th2 are directly involved in the genesis and development of Graves’ disease. TNF-α is an in vivo immune effector molecule, and is mainly produced by T lymphocytes and macrophages, with an extensive biological effect[13]. Some researches demonstrate that[14] the serum TNF-α level in patients with Graves’ disease is significantly higher than that in the healthy individuals, verifying that TNF-α is involved in the immune inflammation reaction and the pathogenesis of Graves’ disease. TRAb is mainly produced by the thyroid lymphocytes. It is generally recognized that its abnormal elevation is the main factor for developing Graves’ disease[15]. In the study, the serum TRAb level in the two groups was higher than that in the healthy individuals, also proving that the abnormal TRAb level plays a certain role in the pathogenesis of Graves’ disease. The half-life of 131I in the thyroid is about 3.5-4.5 d. The thyroid in uptaking 131I is of high-selectivity, and the efficacy of 131I in the treatment of Graves’ disease has already been verified[16]. Fufangjiakang tablets are mainly composed of prunella vulgaris, roast turtle shell, raw oyster shell, scrophularia nipoensis, and radix pseudostellariae, and can reduce the energy metabolism and TT3 concentration in hyperthyroidism patients, with a significant efficacy[17]. The results in the study showed that the levels of FT3, FT4, TRAb, and TNF-α at each timing point in the treatment group were significantly higher than those in the control group (P<0.05), while sTSH level was significantly lower than that in the control group (P<0.05), showing that the efficacy of 131I in combined with Fufangjiakang tablets in the treatment of Graves’ disease is superior to that by the pure 131I treatment. Moreover, the comparison of the occurrence rate of rash, gastrointestinal reaction, granulocytopenia, and agranulocytopenia during the treatment period between the two groups was not statistically significant (P>0.05), suggesting that 131I in combined with Fufangjiakang tablets in the treatment of Graves’ disease will not enhance the occurrence rate of complications during the treatment period, with an accurate efficacy.

In conclusion, 131I in combined with Fufangjiakang tablets in the treatment of Graves’ disease can effectively reduce the serum FT3, and FT4 levels, and strengthen the body immune function with a significant efficacy.

References