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INTRODUCTION

Objective: The purpose of this study was to determine the regeneration-facilitating effects of novel facial nerve treatment using basic fibroblast growth factor (bFGF) promoting the regeneration of denervated nerves in patients with severe Ramsay Hunt Syndrome.

Study Design: Prospective clinical study.

Methods: Ten patients with Ramsay Hunt Syndrome after more than 2 weeks following the onset of severe or complete paralysis corresponding to degree of denervation exceeding 90% by electroneuronography (ENoG) were treated with the new procedure. The facial nerve between tympanic and mastoid segments was exposed via mastoidectomy. A bFGF-impregnated biodegradable gelatin hydrogel was placed around the exposed nerve. Regeneration of the facial nerve was evaluated by using the House-Brackmann (H-B) grading system. The outcomes were compared with the authors’ previous study, which reported outcomes of the patients who underwent conservative treatment (n = 37) or conventional decompression surgery (n = 20).

Results: The goode recovery (H-B grade 1 or 2) rate of the novel treatment (100.0%) was significantly better than the rate of conservative treatment (67.6%) and conventional surgery (65.0%). Every patient in the novel treatment group improved to H-B grade 2 or better even when undergone between 24 and 104 days after onset.

Conclusion: Advantages of this novel treatment are efficacy in the cases of severe Ramsay Hunt Syndrome and long effective period after onset of the paralysis. To the authors' knowledge, this is the first clinical report of the efficacy of bFGF using a new drug delivery system in patients with severe Ramsay Hunt Syndrome.

METHODS AND MATERIALS

Patients and Protocol

Patients with RHS were recruited from Ehime University Hospital between October 2006 and April 2012. This study included 10 patients who opted to have the novel treatment and met the following criteria: (1) older than 16 years; (2) severe or complete facial paralysis corresponding to House-Brackmann (H-B) grade 5 or 6; (3) degree of denervation exceeding 90%, determined using electroneuronography (ENoG); (4) clinical follow-ups available for more than 12 months; (5) no accompanying systemic disease such as severe diabetes mellitus or neoplasms; and (6) informed consent obtained. The outcomes were compared with the patients, who underwent conservative treatment (n = 37) or conventional decompression surgery (n = 20) at Ehime University Hospital. We used the same criteria in conservative treatment group and conventional decompression surgery group. The statistical analyses were performed using χ² test.

Novel Treatment Procedure

The facial nerve was decompressed from the tympanic segment to the stylomastoid foramen via the transmastoid approach to prescribe the bFGF. To prevent postoperative conductive hearing loss, all ossicles were left intact. Half of the bony facial canal was uncapped. The nerve sheath was not incised to avoid possible damage to the facial nerve. A bFGF-impregnated biodegradable gelatin hydrogel sheet was divided into 10 pieces, which were then placed around the exposed facial nerve (Fig. 1).

RESULTS

The novel treatment group consisted of 5 men and 5 women with a mean age of 40 years. The mean period from the onset of paralysis to treatment was 46.3 days in the novel treatment group (Table 1). The longest period between the onset and the novel treatment was 104 days (Fig. 3).

Table 1. Characteristics of the patients in each group.

<table>
<thead>
<tr>
<th></th>
<th>Novel Surgery</th>
<th>Conventional surgery</th>
<th>Non surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of patients</td>
<td>10</td>
<td>20</td>
<td>37</td>
</tr>
<tr>
<td>Mean age</td>
<td>40</td>
<td>44</td>
<td>51</td>
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<tr>
<td>Sex, %male</td>
<td>50</td>
<td>45.5</td>
<td>43.2</td>
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<tr>
<td>Mean period between onset and surgery</td>
<td>46.3 (24-104)</td>
<td>35.9 (15-71)</td>
<td>N/A</td>
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</table>

The range of period between onset and surgery is in parenthesis below mean period.

DISCUSSION

It may be possible that the novel treatment is effective in facilitating recovery of RHS after more than 2 weeks following the onset of severe paralysis.

The mechanism of the facilitating recovery using bFGF-impregnated gelatin hydrogel is probably that bFGF acts on the regenerating facial nerve in the labyrinth segment.

As the next step, the multicenter randomized trial of the novel treatment for RHS is conducted to fully evaluate the usefulness of this treatment.

REFERENCES