CLINICAL STUDY

EFFICACY OF INTRATYMpanic STEROID INJECTION IN BELL'S PALSY

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SUMMARY
Aim: The aim of this study was to evaluate the therapeutic effect of intratympanic steroid injection combined with systemic steroid treatment in Bell's palsy.

Methods: The patients treated for Bell's palsy between December 2016 and January 2019 were divided into two groups including those treated with systemic steroid (Group S) and those treated with intratympanic steroid in addition to systemic steroid (Group S+IT). Functional evaluation of the facial nerve was performed with House-Brackmann (H-B) grading system before and at the 6th month after the treatment.

Results: There were 21 patients in Group S and 16 patients in Group S+IT. Application H-B grades were 3.7±0.8 (3-5) in Group S and 3.8±0.7 (3-5) in Group S+IT, and there was no significant difference between them (p:0.391). Post-treatment 6th month H-B grades were 1.3±0.7 (1-4) in Group S and 1.2±0.5 (1-3) in Group S+IT, and there was no significant difference between them (p:0.726). When the groups were evaluated within themselves, significant improvement was observed between pre-treatment and post-treatment 6th month H-B grades (p<0.001).

Conclusion: Adjuvant intratympanic steroid injection had no therapeutic effect in Bell's palsy according to functional evaluations at the end of the 6th month.

Keywords: Bell's palsy, intratympanic steroid, systemic steroid, idiopathic facial nerve paralysis

BELL'S PARALİZİSİNDE İNTRATIMPANİK STEROİD ENJEKSIYONUNUN ETİNLİĞİ

ÖZET
Amaç: Bu çalışmamın amacı, Bell's palsy tedavisinde systemik steroid ve intratimpanik steroid kombinasyonu kullanarak etkili olup olmadığını değerlendirmektedir.


Bulgular: Grup S'de 21 ve Grup S+IT'de 16 hasta vardı. Bu Grupların H-B evreleri Grup S'de 3.7±0.8 (3-5) ve Grup S+IT'de 3.8±0.7 (3-5) idi ve aralarında anlamlı farklılık yoktu (p:0.391). 6. ay H-B evreleri Grup S'de 1.3±0.7 (1-4) ve Grup S+IT'de 1.2±0.5 (1-3) idi ve aralarında anlamlı farklılık yoktu (p:0.726). Gruplar kendi içerisinde değerlendirildiğinde ise, tedavi öncesi ve tedavi sonrası 6. ay H-B evreleri arasında belirgin anlamlı iyileşme görülmüştür (p<0.001).

Sonuç: Intratimpanik steroid enjeksiyonunun Bell's palsy tedavisinde edebildiği belirlenemememiştir.

Anahtar Sözcükler: Bell’s paralizi, intratimpanik steroid, sistemik steroid, idiopatik fasiyal paralizi
such as hyperbaric oxygen therapy and acupuncture have been tried, but there is still a lack of evidence of their effectiveness. An alternative and adjuvant treatment option is intratympanic steroid injection. There are a limited number of studies evaluating the effects of intratympanic steroid injection in Bell's palsy\textsuperscript{3,4}. We aimed to evaluate how intratympanic steroid injection affects healing outcome when used as an adjuvant to systemic steroids in Bell's palsy.

**MATERIAL and METHODS**

The study was conducted in accordance with the ethical standards stated in the "Declaration of Helsinki". The study was approved by the local ethics committee (protocol number: 2019/42).

**Patients**

Patients treated for Bell's palsy in our clinic between December 2016 and January 2019 were evaluated retrospectively. The patients who met the inclusion criteria including 1) 18-65 years of age, 2) first experience of facial paralysis, 3) with unilateral facial paralysis for 14 days or less and developed within 72 hours, 4) with House-Brackmann (HB) grade III and above, 5) with normal otologic examination, 6) no history of previous otologic surgery, 7) with no skin lesions, and 8) no history of head and neck chemo-radiotherapy were included in our study. The patients with the exclusion criteria including 1) in whom high dose steroid treatment was contraindicated, 2) with any pathology detected on temporal bone-neck magnetic resonance imaging, 3) who did not come to follow-up or did not have sufficient follow-up period for the study were excluded from the study.

All patients were followed up in hospital for an average of 7 days and received systemic steroid treatment with or without intratympanic steroid injection. As a systemic steroid treatment, all patients received high-dose steroid treatment and the dose was gradually reduced (250, 200, 150, 100, 80, 50, 40mg). Facial function assessment was performed blindly by an otolaryngologist at the 6th month after discharge.

**Intratympanic injection procedure**

Informed consent was obtained from the patients and the application was implemented after explaining intratympanic steroid treatment method and possible complications. The patients who accepted the application were treated with systemic steroid therapy and 5 doses of intratympanic steroid treatment every other day. With the aid of a microscope, 10% lidocaine (Jetosel©, Osel, Turkey) was applied with cotton sponge soaked for 10 minutes, and then steroid injection was applied to anterior-inferior quadrant of the tympanic membrane with a 27-gauge dental injection syringe to form an air-fluid level in the middle ear (1 ml, dexamethasone 5 mg/ml- Decort©, Deva, Turkey). After the injection, patients were asked to avoid moving their heads, talking, and swallowing for 30 minutes.

**Facial paralysis grading**

The facial paralysis grades obtained during the hospitalization (before treatment) and at the 6th month examination after the treatment were recorded. In our clinic, H-B grading system is used for grading facial paralysis. Grade I was accepted as normal facial function and complete recovery criteria. Grade II was accepted as normal forehead symmetry and ability of eye closure with minimal effort, Grade III as no forehead movement and the ability of eye closure with maximum effort, Grade IV as insufficiency of eye closure with forced exertion, Grade V as resting asymmetry with barely perceptible motion, and Grade VI as muscle tone loss. According to this system, patients with Grade I, which are completely recovered, are considered "healing"\textsuperscript{5}.

**Groups and statistical analysis**

The patients included in our study were divided into two groups as high-dose systemic steroid treatment group (Group S) and high-dose steroid treatment in addition to intratympanic steroid injection group (Group S+IT). Statistical analysis was performed using Statistical Package for Social Sciences (SPSS) version 20.0 (SPSS Inc.; Chicago, IL, USA). The pre-treatment and post-treatment 6\textsuperscript{th} month H-B grades within each group and the pre-treatment and 6th month H-B grades of both groups were analyzed using t-test.
RESULTS

Thirty-seven patients were included in the study. There were 21 patients in Group S and 16 patients in Group S+IT. Demographic data, facial paralysis sides, and pre-treatment and post-treatment 6th month H-B grades are presented in detail in Table 1.

Significant improvement was observed between the pre-treatment and 6th month H-B grades within each group (p<0.001). There were 17 (80.9%) patients with complete recovery in Group S and 13 (82.25%) patients in Group S+IT (Figure 1). However, when the groups were compared with each other, there was no significant difference between the pre-treatment and post-treatment 6th month H-B grades (Table 1).

No adverse effects of systemic steroids were observed in both groups. No complications such as tympanic membrane perforation, hearing loss or infection were observed due to intratympanic application.

Table 1: Demographic and clinic data of the patients (H-B: House-Brackmann)

<table>
<thead>
<tr>
<th></th>
<th>Group S</th>
<th>Group S+IT</th>
<th>p values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>42.1±15.5</td>
<td>42.7±21.4</td>
<td>-</td>
</tr>
<tr>
<td>Gender (female/male)</td>
<td>10/11</td>
<td>9/7</td>
<td>-</td>
</tr>
<tr>
<td>Side (right/left)</td>
<td>12/9</td>
<td>7/9</td>
<td>-</td>
</tr>
<tr>
<td>Pre-treatment H-B grade</td>
<td>3.7±0.8 (3-5)</td>
<td>3.8±0.7 (3-5)</td>
<td>0.391</td>
</tr>
<tr>
<td>6th month H-B grade</td>
<td>1.3±0.7 (1-4)</td>
<td>1.2±0.5 (1-3)</td>
<td>0.726</td>
</tr>
</tbody>
</table>

DISCUSSION

The aim of this study was to evaluate the effect of intratympanic steroid injection on healing when used in combination with systemic steroid treatment in the treatment of Bell’s palsy. Our results indicate that intratympanic steroid injection in addition to classical treatment has no effect on the complete recovery rates at the end of the post-treatment 6th month.

The pathophysiological mechanisms causing Bell’s palsy have not been clearly elucidated. However, functional deficits that
occur after the healing process cause serious morbidities, including especially psychological trauma due to facial asymmetry. Therefore, antiviral agents, especially steroids and medical agents such as pentoxifylline and alternative methods such as acupuncture have been used to prevent sequelae. Systemic steroids are widely accepted to be used as the first choice in treatment. The systemic steroid was first used by Rothendler in 1953 for the treatment of Bell's palsy. Subsequently, it has become the main treatment option supported by large controlled studies. The steroid facilitates the recovery of facial functions by reducing the edema of the nerve and suppressing the inflammatory process. In addition, it reduces sequelae rates after Bell's palsy.

Intratympanic steroid injection was first used in the treatment of inner ear diseases such as Meniere's disease, tinnitus and sudden sensorineural hearing loss. In recent years, it is thought that topical steroid administration might be effective in facial paralysis by utilizing the dehiscence of the facial nerve in the middle ear. The incidence of facial canal dehiscence was reported to be 55-74% in temporal bone examinations. Baxter reported a 57% incidence of dehiscence and reported that the most common site was near the oval window niche. Therefore, steroid treatment in the middle ear cavity might be a potential transfer route to the facial nerve. In the literature, there are limited studies on this subject. Bryant reported the first in 1973 that intratympanic steroid therapy might have therapeutic effects for Bell's palsy. After a long break, Chung et al. reported that intratympanic steroid treatment had no significant effects on healing in Bell's palsy but accelerated the healing time. Similarly, in our study, we observed that intratympanic steroid injection in Bell's palsy did not affect the full recovery rate after 6 months of follow-up. However, we could not assess the effect on recovery rate since we did not evaluate the recent period after Bell's palsy.

Complete recovery rates after 6 months in patients receiving systemic steroids as a routine treatment modality in Bell's Palsy are between 85% and 90%. In addition, the recovery rates of patients who receive steroid treatment alone and steroid treatment combined with mannitol and pentoxifylline were similar. Moreover, there was no change in the recovery rates when the antiviral agent was administered together with systemic steroids in patients admitted in the first 72 hours. We applied intratympanic steroid treatment in combination with systemic steroid treatment and did not observe any change in recovery rates.

We conclude that the level of efficacy of intratympanic steroid injection might change in patients with dehiscence after evaluating the facial dehiscence of temporal bone computed tomography (TBCT) before the application. However, TBCT has no place unless there is a history of trauma or disease such as chronic otitis media in the routine evaluation of facial paralysis. Routine TBCT might cause ethical problems due to the radiation to be given and might increase the cost considerably. In case of failure of response after the completion of systemic treatment in a facial paralysis in which resistance to treatment will develop over time, it might be considered as rescue therapy and applied to patients with dehiscence by TBCT screening. However, data is not yet sufficient for this. Additionally, for patients with systemic steroid therapy contraindicated, intratympanic injection can also be performed independently after TBCT screening if there is dehiscence of the facial nerve. However, clinical evidence of applying intratympanic steroid injection only in Bell's palsy remains insufficient.

The main limitation of our study might be not being able to evaluate the effect of intratympanic steroid injection on recovery rate since we did not do early evaluation. Moreover, our study has a relatively small sample size and there is no comparison group using other adjuvant therapies such as pentoxifylline and hyperbaric oxygen therapy. Further studies with larger patient series and more than one adjuvant therapy might provide different data.

**CONCLUSION**

In conclusion, the use of intratympanic steroid injection in Bell's palsy in combination with systemic steroid treatment does not affect recovery rates. However, large-scale studies involving more patients are needed to assess the
efficacy of combined or stand-alone treatment of intratympanic steroid injection.

**Conflict of Interests:** None (All authors confirm that)

**Financial support:** None

**REFERENCES**


