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Original Article

Intratympanic Steroid Treatment of Bell's Palsy in Patients with Comorbid Disease: A Preliminary Report

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OBJECTIVES: This study evaluated the efficacy of intratympanic steroid injection (ITSI)as initial treatment and therecovery speed for Bell's palsy (BP)inpatients with diabetes mellitus (DM)and/or hypertension (HT).

MATERIALS AND METHODS: In total,90 patients with comorbid diseases diagnosed with BP received either ITSI (study group, n=61) or systemic steroid treatment (SST) (control group, n=29).The facial nerve function was assessed using the House–Brackmann (HB) grading system for up to 6 months or until complete recovery from BP. To investigate a relationship with the complete recovery time from BP, hematologic and baseline characteristic parameters were analyzed.

RESULTS: The complete recovery rate of the ITSI and SST groups was 47.5% and 44.8% at the 1st month, 70.5% and 89.7% at the 3rd month, and 96.7% and 100% at the 6th month of the study, respectively. Lymphocyte and neutrophil values were significantly associated with the complete recovery time from BP. No major adverse events from ITSI itself were noticed during the procedure and during the follow-up of the treatment.

CONCLUSION: Both treatment types have no superiorities over each other in initial treatment for BP in patients with comorbid diseases. ITSI is effective and safe and may avoid the unwanted side effects associated with systemic steroids inthese patients.

KEYWORDS: Bell's palsy, steroid, intratympanic injection, diabetes mellitus, hypertension

INTRODUCTION

Bell's palsy (BP), also called idiopathic facial paralysis, is defined as acute-onset, lower motor neuron paralysis of the facial nerve and is considered as the most common cause of facial paralysis with an annual incidence of approximately 30 per 100,000 population [1]. Its pathophysiology remains poorly understood; however, various causes have been proposed, such as viral infection, vascular ischemia, autoimmune inflammation, and hereditary factors. Moreover, based on magnetic resonance imaging findings, an inflammatory process causing nerve swelling has been suggested as a major cause of BP [2, 3].

The natural course of BP is favorable and approximately 70% of patients with BP recover completely within 6 months without treatment; however, the remaining 30% will suffer varying degrees of sequelae with functional, psychosocial, and esthetic disturbances [4]. BP treatment is aimed at preventing sequelae and is based on the presumed pathophysiological process of inflammation of the facial nerve. Therefore, steroids arethe most widely accepted therapy [5, 6].Although systemic steroid treatment (SST) is the gold standard treatment, there can be contraindications for treatment of chronic diseases such as diabetes mellitus (DM), hypertension (HT), peptic ulcer disease, tuberculosis, psychosis, and renal and hepatic dysfunction. In these pathologies, intratympanic steroid injection (ITSI) might be a better choice. This treatment method offers clinicians direct access to the most likely site of the disease through natural dehiscence of the facial canal and the canaliculus of the chorda tympany without the unwanted side effects of SST [7, 8]. The hypothesis was based on the histological studies where in the prevalence of facial canal dehiscence was reported to be 56%-74% [9-11].

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To the best our knowledge, an analysis of the efficacy of ITSI as an initial treatment for BP in patients with DM and/or HT has not been reported in the English literature. Thus, we investigated the effect of ITSI versus SST on the complete recovery rate of BP in patients with DM or/and HT.

MATERIALS AND METHODS

Patients and Settings

In total, 90 consecutive patients were retrospectively enrolled in this observational clinical study between February 2015 and December 2018. This study was approved by the Sakarya University local ethical committee. Patients with DM and/or HT were enrolled if they were diagnosed with BP with no other facial palsy causes identified. Patients who received antidiabetic and antihypertension treatment were considered as being diabetic and hypertensive, respectively. The patients were treated with ITSI plus antiviral agent (study group) or oral steroid plus antiviral agent (control group); the therapeutic outcomes of the two treatment regimens were compared. Clinical data including age, sex, time from first onsetof palsy to treatment initiation, the presence of comorbid diseases, baseline and regular examination of facial palsy, and complete blood count (CBC) were obtained by reviewing the medical records of patients. The facial nerve function was assessed using the House-Brackmann (HB) grading system [12] weekly during the first month, followed by monthly follow-up up to 6 months or until complete recovery. All patients were examined and graded by the same investigator. Patients with mild to severe of BP (worse than HB grade 2) were considered for inclusion. Complete recovery was defined as an improvement of the HB score to grade 1 without sequelae. CBC including neutrophil, lymphocyte, and platelet counts; mean platelet volume; and red blood cell distribution width was performed using Abbott Cell-Dyn 3700 Hematology Analyzer (GMI, Minnesota, USA). These parameters were used to determine the platelet–lymphocyte ratio and neutrophil–lymphocyte ratio. The exclusion criteria were allergy to antiviral treatment, previous facial palsy, or inadequate data of treatment and follow-up. All enrolled patients were administered valacyclovir 500 mg tablets thrice daily for 7 days. In the study group, dexamethasone (4 mg/mL) was injected into the middle ear every 3 days for 2 weeks. The patients in the control group received oral prednisolone 1 mg/kg up to 60 mg once daily for 5 days,followed by tapered doses for a week.

Table 1. Baseline characteristics and measured laboratory parameters of the patients with Bell's palsy

		Total (n=90)	Systemic steroid treatment (control group) (n=29)	Intratympanic treatment (study group) (n=61)	p
Age		50.78±11.34	55.55±11.21	48.51±10.76	0.005
Gender	Female	49 (54.4)	15 (51.7)	34 (55.7)	0.896
	Male	41 (45.6)	14 (48.3)	27 (44.3)	
DM	No	36 (40.4)	5 (17.2)	31 (51.7)	0.004
	Yes	54 (59.6)	24 (82.8)	30 (48.3)	
HT	No	17 (19.1)	2 (6.9)	15 (25)	0.080
	Yes	73 (80.9)	27 (93.1)	46 (75)	
Initial HB grade		3 [3-4]	3 [3-4]	3 [3-4]	0.564
Initial HB grade	2	14 (15.6)	6 (20.7)	8 (13.1)	0.904
	3	34 (37.8)	10 (34.5)	24 (39.3)	
	4	31 (34.4)	10 (34.5)	21 (34.4)	
	5	8 (8.9)	2 (6.9)	6 (9.8)	
	6	3 (3.3)	1 (3.4)	2 (3.3)	
Time†		1 [0-1]	1 [0-1]	0 [0–1]	0.199
Neutrophil (10^3/u)		4.65 [3.41-6.07]	3.99 [3.38-5.55]	4.94 [3.69-6.1]	0.092
Lymphocyte (10^3/u)		2.29 [1.64-2.96]	2.45 [1.96-2.86]	2.26 [1.62-2.99]	0.562
Platelet (10^3/u)		241 [205-272]	223.5 [193-259]	244 [207-276]	0.122
PLR		110.89 [80.56-136.3]	99.49 [80.5-121.55]	113.5 [84.28-141.79]	0.097
NLR		2.01 [1.35-3.09]	1.73 [1.35-2.12]	2.12 [1.39-3.31]	0.121
MPV (fl)		7.87 [7.23-8.71]	8.02 [7.43-8.89]	7.83 [7.16-8.71]	0.358
MPV/ Platelet		0.03 [0.03-0.04]	0.03 [0.03-0.04]	0.03 [0.03-0.04]	0.319
RDW (%)		15.5 [14.8-16.2]	15.7 [14.6-16.2]	15.45 [14.8-16.15]	0.936
Recovery time (week)		8 [4-12]	8 [3-12]	8 [4-16]	0.536

Data are shown as count (%). mean±standard deviation or median [IQR]; †between palsy onset and treatment start; HB: House-Brackman; DM: diabetes mellitus; HT: hypertension; PLR: platelet-lymphocyte ratio; NLR: neutrophil-lymphocyte ratio; MPV: mean platelet volume; RDW: red blood cell distribution width.

Injection Technique

ITSI was performed on an out patient basis. After clearing any wax and confirming an intact tympanic membrane under microscopic examination, local anesthesia was administered using a 10% lidocaine pump spray (Xylocaine, 10 mg/dose; Astra Zeneca Korea, Seoul, South Korea). Using a 25-gauge spinal needle, ITSI was performed in the posterior–inferior tympanic membrane. Following the injection, the patients remained recumbent with the chin elevated sharply for at least 15 min; the patients were asked to avoid head movements or to speak or swallow.

Statistical Analysis

Descriptive analyses were performed to provide information on the general characteristics of the study population. Kolmogorov–Smirnov test was used to evaluate whether the distribution of variables was normal. Accordingly, all variables were not normally distributed. Therefore, Kruskal–Wallis test was used to compare the hematologic characteristics and HB grades among the study and control groups. For post-hoc comparisons between the pairs of groups, Bonferroni adjusted Mann–Whitney U test was used. Kaplan–Meier and log-rank test were used to examine whether there was a significant difference between groups in terms of recovery time. Cox regression was used to evaluate factors affecting the duration of recovery at 3 months. Continuous and discrete data are presented as median and interquartile range. Categorical variables were compared using chi-square testand are presented as count and percentage. $p<0.05$ was considered significant. Analyses were performed using Statistical Packages for the Social Sciences (SPSS) statistical software version 23.0. (IBM Corp.; Armonk, NY, USA).

RESULTS

Of the 90 patients, there were 41 (45.6%) males and 49 (54.4%) females. The median age of the patients was 50.78±11.34 years. From the 90 patients, 61 were treated with ITSI, whereas 29 were treated with SST. The demographics and clinical data of the patients are shown in Table 1. There were no statistical differences between the two groups with regard to the initial HB grades andthe interval from BP onset to initial treatment ($p>0.05$). Table 2 shows the HB grades of facial function in the groups initially and at follow-up after treatment. The complete recovery rate of the ITSI and SST groupswas 47.5% and 44.8% at the 1st month, 70.5% and 89.7% at the 3rd month, and 96.7% and 100% at the 6th month of the study, respectively (Table 2, Figure 1).

No major complications to the medications administered or to the ITSI procedure itself were noticed during the treatment and follow- up. However, mild otalgia and slight vertigo were documented during ITSI, and insomnia and hyperglycemia were observed in two patients treated with SST.

Independent variables affecting recovery time were assessed in patients at 3 months of treatment (Table 3). We found that the lymphocyte and neutrophil counts were significantly associated with the recovery time from BP. However, the recovery time was not affected

Table 2. Distribution of HB grades of facial function in the patientsinitially and at follow-up after treatment

After treatment of follow-up	HB grades	The complete recovery	II	III	IV	V	VI
Systemic steroid treatment (control group)	Initial		6 (20.7)	10 (34.5)	10 (34.5)	2 (6.9)	1 (3.4)
	1st week		9 (31)	11 (37.9)	7 (24.1)	2 (6.9)	
	2nd week	4 (13.8)	10 (34.5)	13 (44.8)	1 (3.4)	1 (3.4)	
	3rd week	8 (27.6)	15 (51.7)	4 (13.8)	2 (6.9)		
	1st month	13 (44.8)	13 (44.8)	1 (3.4)	2 (6.9)		
	2nd month	18 (62.1)	9 (31)	1 (3.4)	1 (3.4)		
	3rd month	26 (89.7)	1 (3.4)	2 (6.9)			
	4th month	27 (93.1)	1 (3.4)	1 (3.4)			
	5th month	27 (93.1)	2 (6.9)				
	6th month	29 (100)					
Intratympanic treatment (study group)	Initial		8 (13.1)	24 (39.3)	21 (34.4)	6 (9.8)	2 (3.3)
	1st week		20 (32.8)	22 (36.1)	16 (26.2)	3 (4.9)	
	2nd week		35 (57.4)	16 (26.2)	10 (16.4)		
	3rd week	12 (19.7)	32 (52.5)	13 (21.3)	4 (6.6)		
	1st month	29 (47.5)	21 (34.4)	10 (16.4)	1 (1.6)		
	2nd month	41 (67.2)	17 (27.9)	3 (4.9)			
	3rd month	43 (70.5)	17 (27.9)	1 (1.6)			
	4th month	49 (80.3)	11 (18)	1 (1.6)			
	5th month	59 (96.7)	2 (3.3)				
	6th month	59 (96.7)	2 (3.3)				

HB: House-Brackman

Table 3. Cox regression model in which factors affecting recovery time were assessed in the patients at 3 months of treatment

Variables	β	SE of β	p	OR	95.0% CI for OR
Treatment Type	-0.216	0.288	0.454	0.806	0.458-1.418
Time†	-0.305	0.171	0.074	0.737	0.528-1.03
Initial HB Grade	-0.26	0.138	0.059	0.771	0.588-1.01
Neutrophil (10^3/u)	0.537	0.166	0.001	1.711	1.237-2.367
Lymphocyte (10^3/u)	-0.842	0.323	0.009	0.431	0.229-0.811
Platelet (10^3/u)	-0.005	0.003	0.071	0.995	0.989-1

HB: House-Brackman;† Between palsy onset and treatment start

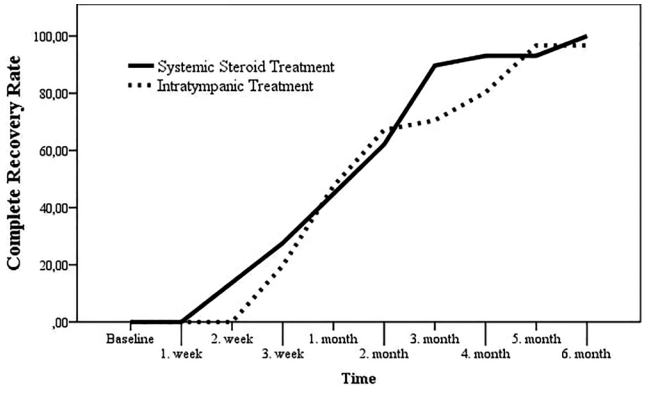

Figure 1. Course of the recovery rate of the two groups.

in terms of the treatment type (p=0.454). Moreover, there was no statistically significant difference between the two groups in terms of the cumulative recovery rate (p=0.287) (Figure 2).

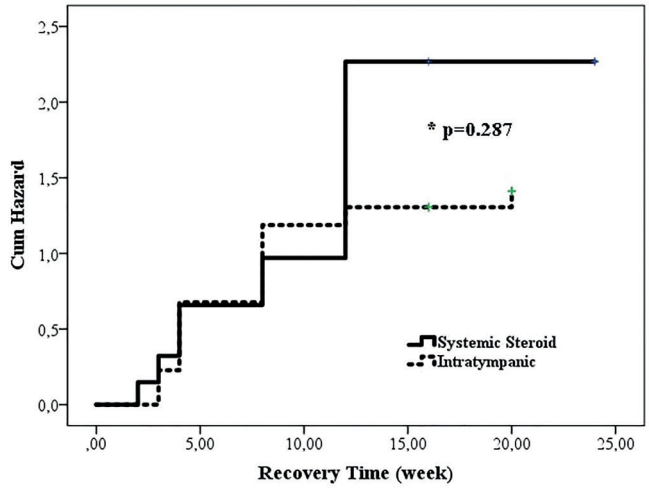

Figure 2. Cumulative recovery rate of Bell's palsy in the two groups (*Kaplan–Meier analysis, long-rank test).

DISCUSSION

Although the exact pathophysiological mechanisms causing the onset of BP are still unclear, the systemic use of steroidsis common as initial treatment in patients with BP. In the English literature, the available moderate- to-high-quality evidence from randomized controlled studies reveals a significant benefit from treating BP with steroids [6]. Steroids are used to avoid an inflammatory processsince inflammation and edema causecompression of the facial nerve. Thereby, they can facilitate the repair of facial nerve function.

There are two methods that can be used to increase the concentration of steroids in the facial canal. One is a systemic method such as oral or intravenous administration, and the other might bea topical method via natural dehiscence of the facial canal and the canaliculus of the chorda tympani by intratympanic injection [7, 8]. The systemic method has been used commonly as thefirst treatment for BP, but a high systemic steroid concentration may carrythe risk of unwanted sideeffects [13], particularly in elderly patients and those with DM and HT. However, only a few studies have focused on patients with DM or HT since the presence of such comorbid diseases has been accepted as exclusion criteria in many studies related to BP. Therefore, in the English literature, we have little knowledge about the side effects of SST in patients with BP and DM/HT. In our study, we observed no permanent damage of the tympanic membrane or serious complications associated with ITSI. In the SST group, only two patients showed mild adverse effects such as insomnia and hyperglycemia.

In this study, the preliminary results support the proposal that ITSI as initial treatment is effective for BP in patients with DM and/or HT. The complete recovery ratein our study was 47.5% at the 1st month, 70.5% at the 3rd month, and 96.7% at the 6th month for ITSI. There was no statistical difference in the recovery rate during the 6 months of follow-up between two groups after treatment. According to Saito et al. [14], high-dose steroid treatment could be safely used for BP in patients with DM with subcutaneous injection of insulin. Of 58 patients with DM, the complete recovery rate was 97.4% for a treatment protocol including systemic steroid, pentoxifylline, 20% mannitol, and hydroxy-ethyl starch. In another study, the complete recovery rate was 89.1% in patients with HT, 85.2% in patients with DM, and 87% in patients with DM and HT, using a combination of systemic steroid and antiviral treatment [15]. This study also revealed that therapeutic responses to steroid alone and combination treatment were similar in all three groups. In our study, we offered antiviral therapy in addition to both ITSI and SSTto all patients because their symptoms were onset within 72 hours. According to meta-analyses and reviews, the combined antiviral and corticosteroid treatment leads to higher recovery ratesthan SST alone. However, this effect does not quitereach statistical significance, and the quality of the evidence is low [16, 17].

In 1991, Itoh first reported on the use of ITSI in the treatment of Meniere's disease, followed by Silverstein in 1996 who reported on ITSI for tinnitus and sudden sensorineural hearing loss [18, 19]. According to a systematic review, ITSI alone for sudden sensorineural hearing

loss appears equivalent to treatment with systemic steroid [20]. However, there have been a few literature reviews on ITSI for avoiding the complication of systemic steroids in patients with comorbid diseases. Han et al. [21] consider ITSI as an initial treatment for sudden sensorineural hearing loss to prevent hyperglycemia in patients with DM. Moreover, the other related study suggested that ITSI offers a valid and safe administration compared with systemic steroid for patients with uremia and sudden sensorineural hearing loss [22].

Except for steroid and antiviral treatment, physical therapies including tailored facial exercises, acupuncture, thermotherapy, and electrical stimulation have been used in thetreatment of BP. However, there is no high-quality evidence to support any significant benefit from such therapies [23]. Surgical decompression might be considered in the early management of BP. Moreover, Liu and He [24] lately recommended stellate ganglion block for recovery of BP in patients with DM [24]. In the study comparing the stellate ganglion block to SST, the recovery rate was 83% at the 1st month and 94.4% at the 3rd month for this treatment.

Intratympanic steroid treatment for BP was first reported by Bryant in 1973, followed by Chung who used it in combination with systemic steroid about 40 years later [7, 8]. In the light of anatomic and surgical observations, ITSI might beprovided to result in a high steroid concentration in the facial canal through facial canal dehiscence and the canaliculus of the chorda tympany. The prevalence of facial canal dehiscence reported in histologic studies of temporal bone ranges from 56% to 74% [9-11]. The data showed that the oval window area is the primary site for the dehiscence. Due to both these routes usually being on the posterior superior area of the middle ear cavity, if the patient's head is tilted backward in the supine position during the ITSI procedure, direct steroid transmission to the facial nerve might be quite helpful. However, future animal studies are needed to investigate whether the steroid solution can reach the facial nerve, particularly the labyrinthine segment through the facial canal dehiscence.

In addition, we considered to evaluate independent variables such as hematologic parameters to see whether they could affect the recovery time of BP in patients. We found that the lymphocyte and neutrophil count were significantly associated with the complete recovery time. As neutrophil values increased, the complete recovery time also increased, but as the lymphocyte count increased, the recovery time decreased. Recently, studies have proposed that hematologic values could be useful inflammatory markers in clinical practice and in predicting BP prognosis [25-27].

The limitations of this study are relatively small number of patients with severe BP and the difference of age between the two groups. However, many previous reports revealed no correlation between age, sex, and nonrecovery in patients with BP [28, 29].

CONCLUSION

To our knowledge, this is the first study to investigate the efficacy of ITSI as an initial treatment for BP in patients with DM and/or HT. Our study showed that ITSI might be a good choice to prevent the unexpected complications of systemic steroids in such patients. However, prospective controlled studies are needed to research the treatment efficacy of ITSI in more patients.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Sakarya University School of Medicine.

Informed Consent: Informed consent is not necessary due to the retrospective nature of this study.

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