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Methylprednisolone sodium succinate retroauricular injection combined with acupuncture in the treatment of Bell's Palsy

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ABSTRACT

Background: Retroauricular injection is a local steroid hormone administration method commonly used to treat deafness or tinnitus. The acute stage of Bell's Palsy is an acute disease that requires steroid therapy. Retroauricular injection may replace oral administration of steroid hormones in the treatment of this disease as well as reduce the occurrence of adverse reactions.
Methods: This study included patients with Bell's Palsy within seven days of onset. A total of 120 patients were enrolled as the study subjects and randomly divided into two groups: the experimental group and the control group. Both groups received routine acupuncture treatment and took a traditional Chinese medicine decoction corresponding with the syndrome type. Methylprednisolone sodium succinate was injected into the bone surface of retroauricula in the experimental group, and prednisone acetate was orally administered in the control group. The main outcome indicators were the House–Brackmann (HB) grade, the facial disability index (FDI), and time of postauricular pain after one month of treatment.
Results: There were no significant differences in the HB grade (2.00 ± 1.06 vs. 1.88 ± 1.06, P=), FDIP (97.25 ± 6.00 vs. 97.17 ± 7.39, P=), and FDIS (0.60 ± 3.02 vs. 1.33 ± 4.27, P=) at 30 days after treatment between the two groups ($P > 0.05$). Postauricular pain disappeared earlier in the experimental group (3.66 ± 1.67 days) than in the control group (6.31 ± 2.34); the difference was statistically significant ($P \leq 0.001$). The adverse reaction rate was lower in the experimental group (15.00%) than in the control group (21.66%).
Interpretation: Although the dose of steroid hormone injected into the bone surface of retroauricula in the treatment of Bell's Palsy is lower than the administered dose of oral hormones, it has the same curative effect; however, it has a better effect regarding to the duration of postauricular pain and adverse reactions.

1. Introduction

Steroid hormone therapy is recognized as an effective clinical treatment method for hearing impairment diseases, such as Meniere's

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disease and sudden deafness [1,2]. Although the systemic use of steroids is presently the preferred treatment [3], it has evident side effects, and its application is not suitable for some patients with underlying diseases. Compared with oral administration and intravenous infusion of hormones, local injection can more effectively reduce the incidence of systemic adverse reactions [4]. Injection into the bone surface of retroauricula is a commonly used local hormone administration method for the treatment of ear diseases, and it has been listed as a local hormone administration method. According to the 2015 version of Chinese Guidelines for Sudden Deafness, steroid hormone therapy is first recommended for systemic administration, while local administration can be used as remedial treatment, including intratympanic injection and retroauricular injection [5]. Tympanic injection, which also belongs among local administration methods, is an invasive operation that may cause serious adverse reactions [1]. This may be due to the fact thar the drug gets lost from the eustachian tube; hence, the drug concentration in the focus area cannot be ensured [6]. In 2007, Xiaoqi Yang et al. first employed the method of retroauricular injection to treat sudden deafness, with good results. Subsequently, retroauricular injection was gradually applied to patients with sudden refractory deafness and patients with underlying diseases who could not be treated with steroid hormones. With the deepening of related research, the pathogenesis of sudden deafness is presently found to be closely related to viral infection, inner ear ischemia, oval membrane rupture, and other factors.

Steroid hormones are often used in clinical treatment of this disease; they have anti-inflammatory and detumescence effects on inflammation and microvascular edema of the inner ear cochlea, can promote blood flow, and improve the symptoms of hypoxia in the inner ear [7]. Treatment via local application can lower the increase rate of neutrophils and immunosuppression caused by steroid hormones [8,9].

The evidence-based guidelines for the treatment of Bell's Palsy published by the American Academy of Neurology in 2012 suggest that steroid hormones should be used for treatment within 72 h of the disease onset [10]. Steroid hormones also play a role in relieving neuroedema in the treatment of Bell's Palsy. A study [11] revealed that injecting steroid hormones into the stylomastoid foramen could promote facial nerve recovery.

It has been proven that the treatment method of local injection can make steroids infiltrate the facial nerve canal [12] (stylomastoid foramen), which travels in the mastoid process behind the ear. By retroauricular injection, the steroid hormones are absorbed through the postauricular vein. It penetrates more quickly and effectively through the tiny blood vessels to the inner ear, relieving the inflammatory response of the inner ear. Compared with oral steroid hormones, retroauricular injection administration has the advantages of high local blood concentration, long peak time, and reduced side effects of systemic hormone use. The efficacy and safety of retroauricular injections have been widely recognized in treating sudden deafness. In this study, we hope to use topical steroids as an alternative to oral or intravenous steroids. In the present study, Bell's Palsy was treated by (1) injecting steroid hormones into the bone surface of retroauricula in combination with conventional acupuncture and oral symptomatic traditional Chinese medicine (TCM) and (2) orally administrating hormones in combination with conventional acupuncture and oral symptomatic TCM. We aimed to provide a route of administration of topically applied steroid hormones for the treatment of Bell's Palsy.

2. Clinical data

2.1. Subjects

The present study was carried out in the Acupuncture Rehabilitation Center of Yinchuan Traditional Chinese Medicine Hospital. The subjects were patients with Bell's Palsy hospitalized at the institution between July 2020 and February 2022. As the treatment involves the use of hormones, the patients were randomly assigned to two groups using the random number table method: group A (n = 60; treated with postauricular injection of methylprednisolone sodium succinate + routine acupuncture + TCM herbal drugs) and group B (n = 60; treated with oral prednisolone acetate tablets + routine acupuncture + TCM herbal drugs). Patients were accepted according to the inclusion and exclusion criteria. All included patients signed informed consent and hormone use consent forms.

2.2. Inclusion and exclusion criteria

2.2.1. Diagnostic criteria

Diagnostic criteria of "idiopathic facial paralysis" with reference to textbook Neurology [13]: (1) Acute onset, the disease peaks 2–3 days after onset; (2) unilateral facial paralysis, disappearance of frontal lines, abnormal facial expressions and movements (or their absence), inability to close the facial fissure completely or at all, drooping of mouth corners, and tilting to the healthy side; and (3) the possibility of facial paralysis caused by cerebral hemorrhage, cerebral infarction, tumor, and other diseases is ruled out by the imaging examination.

2.2.2. Inclusion criteria

(1) Patients who met the diagnostic criteria; (2) patients with an interval of <7 days between the onset of the disease and admission to the hospital; (3) patients aged 18–75 years; and (4) patients who gave their informed consent and participated voluntarily.

2.2.3. Exclusion criteria

(1) Patients diagnosed with central facial paralysis and other diseases; (2) patients who had not received other treatments before participating in the trial; (3) patients with recurrent facial paralysis; (4) patients with facial paralysis caused by the herpes simplex virus; (5) patients with serious hypertension, diabetes, liver and kidney dysfunction, and serious systemic diseases; and (6) women in pregnancy.

2.3. Criteria for elimination and withdrawal

(1) Patients with serious adverse reactions; (2) patients who voluntarily withdrew during the trial; (3) patients who received other drugs and therapies during the trial; and (4) patients who terminated the treatment during the trial when the symptoms did not reach the recovery level or the House–Brackmann (HB) grade did not reach grade I.

2.4. Blinding method

The present study was a clinical observation of the method's curative effect. While the evaluator could not be completely blinded to the treatment method, he/she was blinded during the evaluation of the curative effect. When the patient was admitted to the hospital, the physician in charge determined whether he/she could be included in the study. At the time of inclusion, the physician in charge grouped the patients using the random number table method and recorded the hormone administration method used by the doctors in charge. During the evaluation process, the evaluator recorded the patient data, such as the medical record number and patient name. During the process, the evaluator and acupuncturist did not know the grouping. The blindness was uncovered after 30 days of treatment, and the subjects were counted in their respective groups.

3. Methods of intervention

3.1. Control group

The acupuncturists who performed the treatment were all doctors above the attending physician with 10 years of clinical experience. To ensure the consistency of the treatment effect, the acupuncturists were also uniformly trained in the retroauricular injection technique. The clinical treatment mainly comprised electroacupuncture and steroid hormone therapy. The treatment plan was created based on "Evidence-Based Acupuncture Clinical Practice Guide Bell's Palsy (Revised Version)" [14] and the Clinical Diagnosis and Treatment Guide of Traditional Chinese Medicine Internal Medicine Facial Paralysis Disease [15]. The 16 acupuncture points chosen for stimulation were: the yangbai point, taiyang point, jingming point, tongzimiu point, sizhukong point, sibai point, dicang point, xiaguan point, quanliao point, yingxiang point, bilateral quchi point, bilateral hegu point, and bilateral yifeng point. The 40 × 0.30 mm disposable sterile acupuncture needle was used for the procedure, and the electroacupuncture parameter was adjusted to a continuous wave of 2–5 Hz. The treatment took 30 min every day and lasted for either 30 days or until the HB grade I was reached. Oral TCM herbs were selected according to syndrome differentiation and treatment; these were taken continuously for 10 days. Patients with other diseases were treated according to the corresponding disease treatment plan.

Patients in the control group were treated with routine acupuncture combined with corresponding TCM herbs and oral prednisone acetate. A hormone dose of 1 mg*kg/d was continuously used for the first 5 days, and the steady reduction method was adopted from the sixth day to the tenth day. Hormone use was stopped on the eleventh day.

3.2. Experimental group

Acupuncture and TCM administration in the experimental group were the same as in the control group. The hormone was administered by injecting methylprednisolone sodium succinate into the bone surface of retroauricula; the injection was started on the first day of admission and was applied every other day a total of 5 times. Operation: The mixture of 0.5 mg/kg of methylprednisolone sodium succinate for injection (Pfizer Manufacturing Belgium NV) and 0.9 ml of sterile water for injection + 0.1 ml of 2% lidocaine

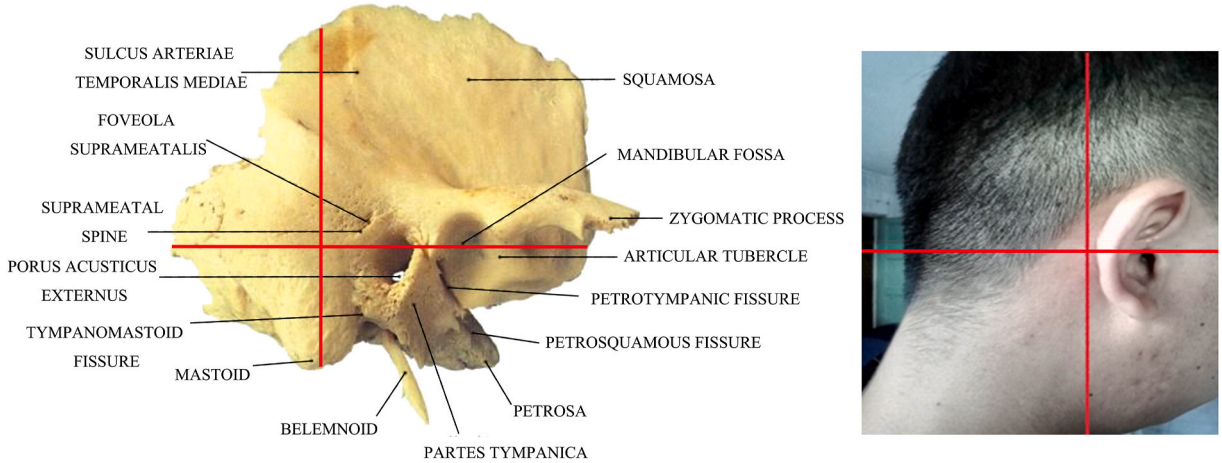

Fig. 1. Drug injection site.

hydrochloride injection (Suicheng Pharmaceutical Co., Ltd., China) was drawn in the syringe. The postauricular injection site was located in a shallow depression between the superior mastoid crest, the posterior extension of the external auditory meatus, and the superior spine of the external auditory canal. The injection site could be determined by using the method of horizontal extension of the root of the ear 0.5 cm behind the upper edge of the external auditory canal (Fig. 1). The nurse held a 1-ml syringe in the right hand (with the liquid inside); the syringe was stabbed into the body at approximately 120° to the sagittal plane of the human body and at approximately 45° to the coronal plane of the human body. The depth of the needle insertion was approximately 0.5 cm, with the needle tip touching the periosteum. When blood was not observed during the withdrawal of the needle, the drug solution was injected slowly, with a duration of approximately 1 min. The needle was pushed forward at a constant speed while the assistant used a sterile cotton swab to gently wipe the pinhole, thus preventing drug exudation. Squeezing and kneading the pinhole with force was not allowed.

Both groups of patients were treated for 30 days. If the patient's symptoms reached the recovery level or H–B grade reached grade I, the treatment was stopped. The first 15 days of treatment were in the inpatient department, and the last 15 days were in the acupuncture clinic. The cumulative dosage of steroid hormones in the two groups is presented in Table 1.

4. Outcome indicators

The main indexes for the evaluation of facial nerve function were the HB grade and the facial disability index (FDI). The treatment items in HB rating were evaluated separately. After a joint evaluation conducted by two evaluators, the results were filled into the case collection form. An evaluation was performed on the day of admission and on day 5, 10, 15, 20, 25 and 30. For the safety indexes, an electrocardiogram (ECG), a routine blood test, and liver and renal function examinations were performed at the time of admission and after the hormone application to evaluate whether the hormone application affected the physiological function of the subjects.

5. Statistical analysis

Two-tailed tests were used for all statistical analyses. The two independent samples *t*-test was used when the data conformed to a normal distribution, and the variances were not statistically different. When the data did not conform to a normal distribution, a nonparametric rank sum test was used. A P value of <0.05 was considered statistically significant. Quantitative data were expressed as mean $\pm$ standard deviation.

6. Results

6.1. General data

A total of 183 patients met the diagnostic criteria during the study period; 12 of them were above the upper age limit, and 28 of them refused to participate in the study. Hence, a total of 143 patients were included in the present study and divided into two groups: the observation group and the control group ($n = 60$ each). A total of 13 patients were excluded from the observation group: 2 with Hunter's facial paralysis, 7 with an incomplete treatment, and 4 with disease recurrence; and 10 patients were excluded from the control group: 1 with Hunter's facial paralysis, 7 with an incomplete treatment, and 2 with disease recurrence (Fig. 2). There were no significant difference in indicators, such as age, disease course, admission time after onset, HB grade, and FDI scale, between the observation group and the control group (Table 2).

6.2. Efficacy indicators

6.2.1. HB grade

There was no statistically significant difference in HB grade between the two groups on the day of admission and at day 5, 10, 15, 20, and 30 of admission ($P > 0.05$); there were significant differences in the HB grades between every two time points and among the four time points during the first 15 days ($P \leq 0.05$) and no statistical difference between every two time points from the fifteenth day to the twentieth day ($P > 0.05$, Table 3, Fig. 3).

6.2.2. HB grade sub-items

After splitting each evaluation criterion of the HB grade, the researchers scored each evaluation item separately and conducted a correlation analysis with the HB grade: the recovery of facial and frontal symptoms, ocular symptoms, and oral symptoms were significantly correlated with the HB grade; meanwhile, synkinesis and spasticity from the tenth and twentieth day, respectively, were not significantly correlated with the HB grade. In addition, there was a negative correlation between the synkinesis from the twentieth

Table 1
Total equivalent consumption of methylprednisolone sodium succinate used by a 60-kg patient (mg).

Group	First 5 days	Last 5 days	Whole course
Control group	240	120	360
Experimental group	75	75	150

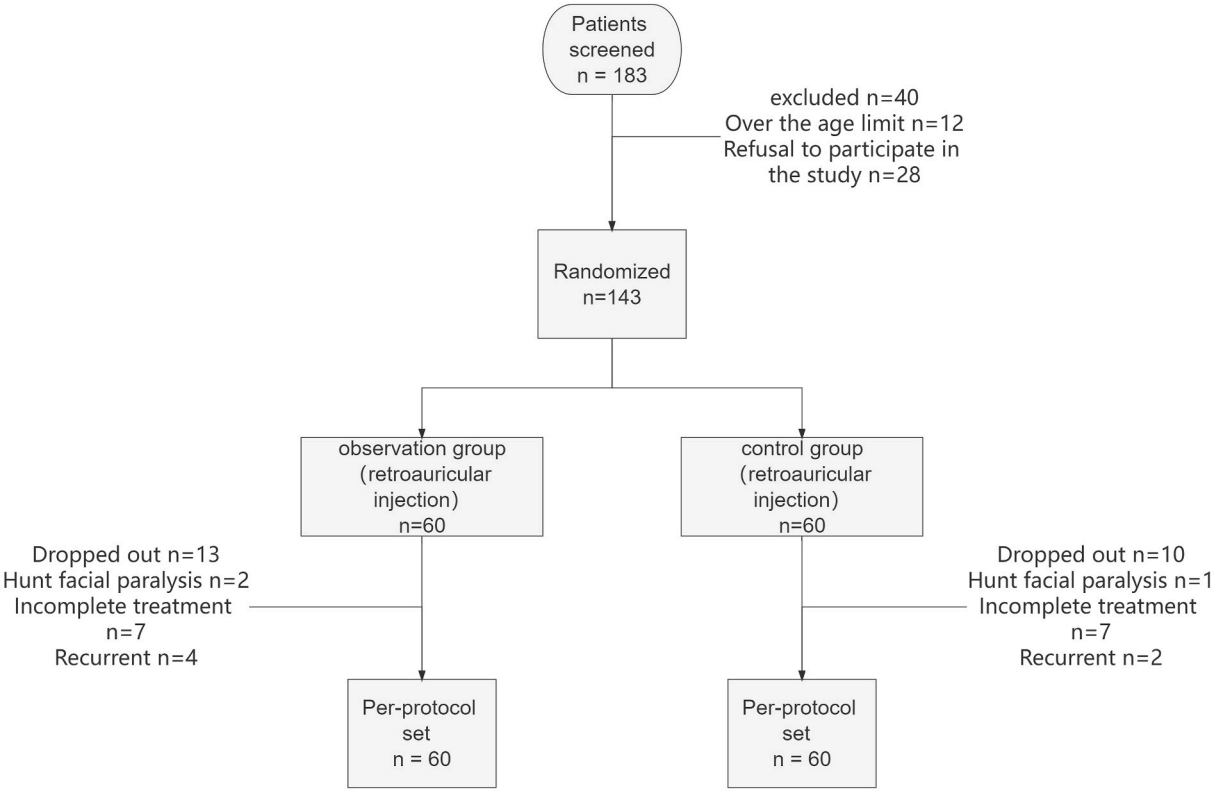

Fig. 2. Patient included.

Table 2
Baseline characteristics of the included patients.

	No. (%) of patients	
	Observation group	Control group
Characteristic	n = 60	n = 60
Women	25 (41.67)	30 (50)
Men	35 (58.33)	30 (50)
Age,yr,mean ± SD	51.78 ± 15.40	48.87 ± 16.50
Interval between onset of palsy and start of treatment		
≤72 h	37 (61.67)	31 (51.67)
>72 h to ≤168 h	23 (38.33)	29 (48.33)
House–Brackmann score		
2	6 (10.00)	3 (5.00)
3	11 (18.33)	8 (13.33)
4	26 (43.33)	31 (51.67)
5	15 (25.00)	14 (23.33)
6	2 (3.33)	4 (6.67)
Facial Disability Index score, mean ± SD		
Physical function subscale	57.33 ± 14.57	54.25 ± 16.92
Social/well-being subscale	14.86 ± 13.76	20.73 ± 16.23

Table 3
H–B grade change.

Group	Case number	The day of admission	Day 5	Day 10	Day 15	Day 20	Day 30
Control group	60	4.13 ± 0.91	3.47 ± 1.00	2.77 ± 1.03	2.15 ± 1.04	2.00 ± 1.12	1.88 ± 1.06
P value among different stages			0.000	0.000	0.001	0.449	0.548
Experimental group	60	3.93 ± 0.99	3.48 ± 1.12	2.75 ± 1.10	2.18 ± 1.08	2.02 ± 1.14	2.00 ± 1.06
P value among different stages			0.021	0.000	0.005	0.432	0.921
P value between groups		0.252	0.931	0.932	0.864	0.936	0.547

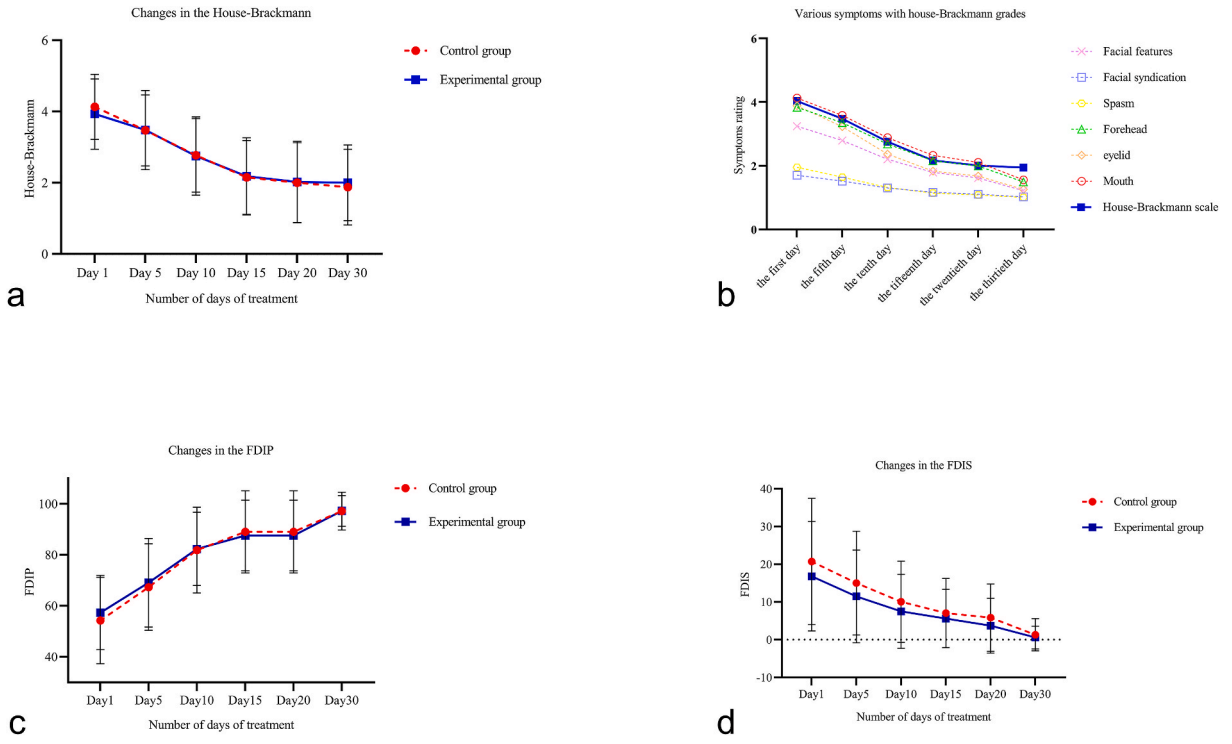

Fig. 3. Facial paralysis related scale. a: House-Brackmann grade change; b: Correlation analysis between the score of each single evaluation indicator and House-Brackmann grade; c: FDIP scores of two groups of patients during treatment; d: FDIS scores of two groups of patients during treatment.

day and the HB grade (Table 4, Fig. 3).

6.2.3. *Total FDI score*

There were no significant differences in the total scores of physical function and the total scores of social function during treatment between the two groups (all $P > 0.05$). The total scores of physical function of the two patient groups were significantly higher during the process than before treatment, and the total score of social function was significantly lower than before treatment (all $P < 0.05$, Table 5, Fig. 3).

6.2.4. *Postauricular pains*

Most patients with Bell's Palsy experience postauricular pains. In this study, a total of 95 patients had symptoms of postauricular pains; however, there were no significant differences in the time of pain onset and the time of admission after the illness onset between the two groups ($P > 0.05$), and the postauricular pains disappeared faster in the experimental group than in the control group; the difference was extreme and statistically significant ($P \leq 0.001$, Table 6, Fig. 4).

6.2.5. *Adverse reactions*

In the control group, there were 13 cases of adverse reactions, with a total of 17 person-times and an adverse reaction rate of 21.66%: a total of 10 patients had an increased blood glucose level, 4 had insomnia, and 3 had increased blood pressure. In the

Table 4
Correlation analysis between the score of each single evaluation indicator and H–B grade.

	R value	Face	Synkinesis	Spasm	Forehead	Eye area	Mouth area
H–B grade	The day of admission	.727**	.324**	.242**	.729**	.690**	.763**
	Day 5	.761**	.309**	.292**	.775**	.721**	.787**
	Day 10	.788**	0.145	.283**	.782**	.767**	.759**
	Day 15	.770**	0.030	.195*	.806**	.791**	.819**
	Day 20	.689**	−0.040	0.119	.750**	.719**	.793**
	Day 30	.588**	−0.092	0.092	.765**	.667**	.758**

**: At the 0.01 level (two-tailed), the correlation is significant.
*: At the 0.05 level (two-tailed), the correlation is significant.
a: Cannot calculate because at least one variable is constant.

Table 5
FDI scores of two groups of patients during treatment.

Group	Control group	P value among different stages	Experimental group	P value among different stages	P value between groups
FDIP					
Case number	60		60		
The day of admission	54.25 ± 16.92		57.33 ± 14.57		0.287
Day 5	67.33 ± 16.96	0	69.08 ± 17.35	0	0.478
Day 10	81.83 ± 16.82	0	82.33 ± 14.39	0	0.861
Day 15	89.00 ± 16.07	0.019	87.58 ± 13.89	0.044	0.606
Day 20	93.14 ± 9.21	0.086	92.83 ± 8.49	0.014	0.848
Day 30	97.17 ± 7.39	0.009	97.25 ± 6.00	0.001	0.946
FDIS					
Case number	60		60		
The day of admission	20.73 ± 16.23		16.83 ± 14.48		0.175
Day 5	15.00 ± 13.73	0.039	11.47 ± 12.29	0.031	0.14
Day 10	10.07 ± 10.76	0.031	7.53 ± 9.80	0.055	0.18
Day 15	7.07 ± 9.18	0.103	5.60 ± 7.77	0.234	0.347
Day 20	5.87 ± 8.91	0.469	3.73 ± 7.25	0.175	0.153
Day 30	1.33 ± 4.27	0.001	0.60 ± 3.02	0.003	0.28

experimental group, there were 9 cases of adverse reactions, with a total of 11 person-times and an adverse reaction rate of 15.00%: a total of 9 patients had increased blood glucose, 2 had insomnia, and 2 had local congestion at the injection site (Table 7, Fig. 5).

6.2.6. Security indicators

During the research process, the authors of the present study tested safety indicators with routine blood tests, liver function tests, renal function tests, and ECGs. The tests were performed before the start of the study and after the end of hormone administration. There were no differences in the main indexes of the routine blood tests and the renal function test between the two groups ($P > 0.05$); in terms of liver function, there were significant differences in alanine aminotransferase levels before and after treatment between the two groups ($P \leq 0.05$, Table 8).

There were no significant changes in ECG between admission and discharge in the two groups.

7. Analysis

Bell's Palsy was named after Sir Charles Bell, who first discovered it in 1830 [16]. It is an idiopathic unilateral facial nerve paralysis resulting in complete or incomplete paralysis of the innervated area of the facial nerve on the affected side. Bell's Palsy is the most common facial nerve paralysis. Its incidence in China varies from region to region at 6.3–31.1/0.1 million [17–19]. It has a rapid onset, is accompanied by weakened facial nerve function, and progressively exacerbates within 1–3 days. An external auditory canal or postauricular pain occurs in 60% of patients. The cause of Bell's Palsy is presently unclear; theories suggest that the cause is viral infection, neurological ischemia, and/or immunodeficiency [20]. Viral infection and nerve ischemia cause inflammation and edema of the facial nerve as well as functional injury of the area innervated by the facial nerve [21,22]. A comprehensive program can be adopted for treatment of the disease; the methods of improving blood circulation, reducing facial nerve edema and ischemia, relieving nerve compression, and improving facial nerve function are mostly adopted. Steroid hormones have good anti-inflammatory and anti-edematous effects, and can effectively relieve facial paralysis caused by facial nerve edema; they are currently the first choice in clinical treatment [23]. In many studies, local injection of steroid hormones has been employed to treat sudden deafness. This method can help avoid drug dispersion in the systemic circulation, increase target organ drug concentrations, and reduce systemic steroid hormone concentration. The peak intravascular concentration in local veins was 3.03 times higher than that of intramuscular

Table 6
Postauricular pains.

Group	Number of cases with pain	First appearance time	Which day after onset of facial paralysis was the patient admitted to hospital	Which day after admission did the pain disappear
Control group	48	1.35 ± 0.73	3.18 ± 1.33	6.31 ± 2.34
Experimental group	47	1.21 ± 0.54	3.40 ± 1.81	3.66 ± 1.67
P		0.288	0.456	0.000

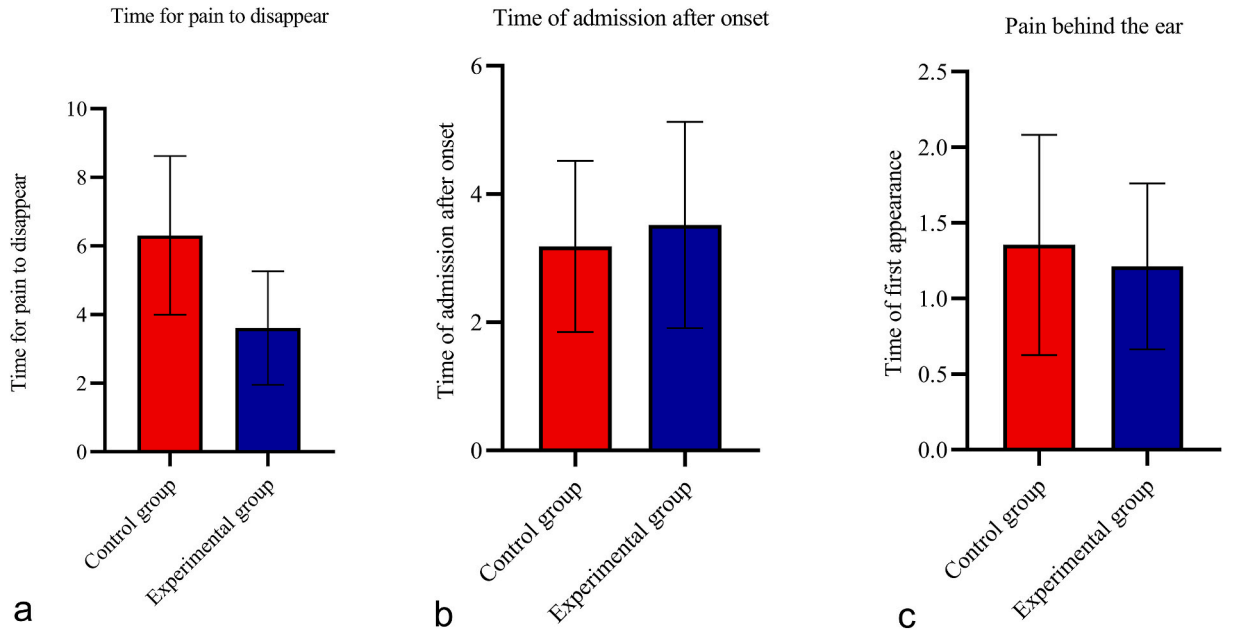

Fig. 4. Postauricular pain situations. a: First appearance time; b: Which day after onset of facial paralysis was the patient admitted to hospital; c: Which day after admission did the pain disappear.

Table 7
Adverse reactions.

Group	Adverse reactions	Elevated blood glucose	Insomnia	Elevated blood pressure	Postauricular congestion
Control group	13	10	4	3	0
Experimental group	9	7	2	0	2

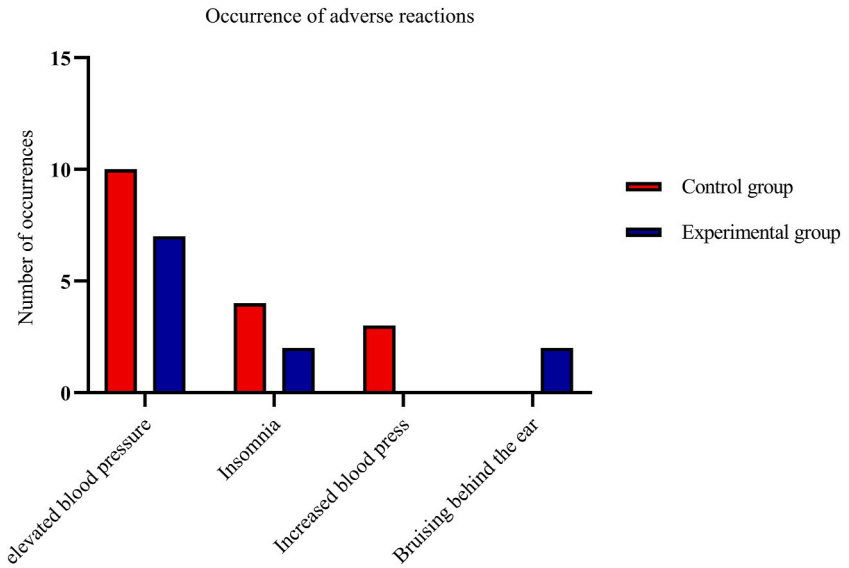

Fig. 5. Adverse reactions.

injections, and the concentration of circulating drugs was 0.13 times higher than that of intramuscular injection [24]. It can avoid adverse reactions caused by systemic steroid hormones, thus allowing normal steroid treatment for patients who are not suitable for acute treatment with steroids due to underlying diseases. Tympanic injection, the local hormone administration method firstly used in

Table 8
Safety indexes.

		Group	Before treatment	After treatment	P value
Routine blood tests	Leukocyte count	Control group	7.69 ± 2.57	8.03 ± 2.72	0.487
		Experimental group	8.37 ± 2.57	7.94 ± 2.43	0.349
		P value	0.148	0.86	
	Red blood cell count	Control group	4.76 ± 0.52	4.75 ± 0.48	0.893
		Experimental group	4.80 ± 0.59	4.79 ± 0.53	0.951
		P value	0.704	0.632	
	Platelet count	Control group	234.79 ± 58.24	239.15 ± 50.45	0.662
		Experimental group	227.43 ± 56.93	228.27 ± 55.03	0.935
		P value	0.486	0.261	
Liver function	ALT	Control group	22.77 ± 14.36	31.75 ± 22.48	0.01
		Experimental group	25.22 ± 14.90	36.63 ± 31.61	0.013
		P value	0.361	0.332	
	AST	Control group	19.25 ± 5.94	20.08 ± 6.93	0.481
		Experimental group	19.05 ± 6.07	21.28 ± 11.13	0.175
		P value	0.856	0.48	
	Blood glucose	Control group	5.59 ± 1.54	5.31 ± 1.42	0.318
		Experimental group	6.46 ± 2.62	5.85 ± 2.33	0.179
		P value	0.028	0.132	
Kidney function	Urea	Control group	5.42 ± 1.71	5.09 ± 1.27	0.231
		Experimental group	5.80 ± 1.46	5.44 ± 1.42	0.173
		P value	0.193	0.155	
	Creatinine	Control group	61.59 ± 14.92	60.80 ± 13.25	0.761
		Experimental group	61.65 ± 15.23	61.15 ± 13.59	0.85
		P value	0.982	0.887	

Meniere's disease and sudden deafness, has also been used in the treatment of Bell's Palsy, and can effectively relieve the symptoms of facial nerve edema [25]. Meanwhile, retroauricular injection is a local steroid hormone administration method that was first used to treat sudden deafness; its clinical efficacy has been confirmed in many studies [26,27].

Although the mechanism of action remains unclear, the current theory is that it can be absorbed into the sigmoid sinus by osmosis or absorbed through the postauricular vein and then enter the inner ear through tiny blood vessels to improve cochlear or auditory nerve edema. Compared with tympanic injection, retroauricular injection has a better curative effect in the treatment of sudden deafness, Meniere's disease, and other diseases. It also has fewer adverse reactions and is easier to conduct, patients in the oral steroid hormone group had a higher post-treatment heart rate than the post-auricular steroid hormone injection group during administration, and a higher percentage of patients on oral steroids had sleep disturbances than those on post-auricular steroid hormone injections [28]. It is a new treatment method aiming to replace the tympanic injection.

The treatment of Bell's Palsy is similar to the treatment of sudden deafness and Meniere's disease. Another available treatment method is the use of steroid hormones. Retroauricular injection is a local steroid hormone application method that can effectively deliver the drug around the facial nerve through local microcirculation and infiltration, thus improving facial nerve edema and relieving facial nerve compression. Compared with systemic administration, this method reduces the blood drug concentration to the greatest extent, improves the drug concentration near the local lesion, has a high safety rate, and results in a better recovery in the later period of the disease.

In the present study, retroauricular injection of methylprednisolone sodium succinate was adopted for the treatment of Bell's Palsy. In terms of the total use of steroid hormones, the equivalent dose of the retroauricular injection in the methylprednisolone sodium succinate group was less than half of the oral prednisone group dose. The dose in the first 5 days was only 1/4 of the oral prednisone group dose, and the relative dose of steroid hormones was lower; this method was able to effectively reduce the concentration of steroid hormones in the systemic blood circulation, reduce the adverse reactions caused by the application of steroid hormones, and reduce the impact on blood glucose and blood pressure. In addition, the local drug concentration of the lesion was increased, the retention time of the drug in the local area of the lesion was increased, and the drug itself was more effective.

During the study, there were no statistical differences in the HB grade and FDI score before and after the treatment between the control group and the experimental group. Retroauricular injection of steroid hormones helps relieve facial nerve edema, and it could effectively replace oral hormone administration.

There was no statistically significant difference in the HB grades at all time points between the two groups; there was no difference in efficacy between the experimental group and the control group; there was a statistical difference in HB grade between every two time points from day 1–15 of admission ($P \leq 0.05$); and there was no statistical difference between every two time points from the fifteenth day to the twentieth day ($P > 0.05$). The HB score recovery of most of the patients occurred within the first 15 days. Although the acute stage of Bell's Palsy occurs in the first 7 days after the onset, it takes a certain period of time to recover after the facial nerve is damaged, and the most obvious recovery period lasts 15 days. From the fifteenth day to the twentieth day, the recovery begins to slow down, and the patients should enter the treatment sequelae stage.

After the score was split, it was found that the early recovery period of synkinesis was highly correlated with the HB grade; however, from the tenth day, the correlation was not significant. The reason for this is probably that when the HB grade starts from grade III, the evaluation of synkinesis is carried out using the description of "obvious but not serious synkinesis".

Similarly, the correlation of spasms with the HB grade from the twentieth day was also not significant. Spasm recovery did not change with the HB score, the evaluations of synkinesis and spasm were not easily distinguishable from grade III, and the scores of the two were infinitely close to 1 around the fifteenth day. As grade I in the HB grade is a complete cure level, a synkinesis and spasm score of 1 in the categorical score meant that there was no difference in terms of symptoms and recovery.

Synkinesis is a symptom occurring after facial nerve edema; the nerve conduction here is abnormal due to the damage of the facial nerve, and the corners of the mouth follow the "twitching" when the eyes are closed. Upon repairing the facial nerve, its abnormal connection disappears, and synkinesis and spasm recover faster than other symptoms, such as incomplete eyelid closure and disappearance of the nasolabial groove caused by facial muscle paralysis. Facial muscle paralysis is relieved to a certain extent as the facial nerve recovers; however, there are still some symptoms that require exercise to gradually improve after the recovery of the facial nerve. Therefore, the recovery rate of symptoms caused by facial muscle paralysis is slower than in synkinesis and spasm.

All symptom and HB grade changes were examined, and it was found that there was no significant change in the HB score between the thirtieth and twentieth day. This could be due to the fact that the HB grade of some patients with a severe level of illness was still at grade III. In some patients, most symptoms had improved, but there was still one symptom that had not returned to normal. A grade I rating meant that the patient's symptoms had completely recovered and the treatment was terminated. Hence, the presence of one symptom after treatment was rated as grade II. Most of the symptoms were trending towards a score of 1 on the thirtieth day.

There were no statistical differences in the FDIP and FDIS scale scores between the control group and the experimental group. In the experimental group, there were statistical differences between the FDIP scores at every two time points ($P \leq 0.05$). In the control group, there were statistical differences between every two remaining time points ($P \leq 0.05$), with the exception of the difference between the fifteenth and twentieth day ($P > 0.05$). Because of the 10-day interval between days 20 and 30, a significant change in score should have occurred in the first 15 days. As can be seen in the figure, naked eye observation showed that the average score had exceeded 80 points and approached the full score since the tenth day. Some symptoms recovered slowly, but most patients experienced a significant change.

Since the fifteenth day, the space for score growth was limited due to the few remaining symptoms. Patients with lower scores also had more residual sequelae that were more difficult to treat; hence, the rate of change in scores gradually slowed down. The initial value of the FDIS score of the two patient groups was low, with an average score of approximately 20 points; there was no statistically significant change between most pairs of time points, and there was a statistically significant difference (1) between the day of admission and the fifth day and (2) between the twentieth and the thirtieth day ($P \leq 0.05$).

The score changes in the early stage should indicate that the patients had a basic understanding of Bell's Palsy after admission education as well as a basic expectation for the prognosis of the disease; furthermore, they were not worried that the disease was uncurable, and the nervousness experienced at the beginning of the illness had been relieved. The continuous change happening from the fifth day to the tenth day was likely caused by the fact that after the improvement of a certain proportion of the disease, the patient's confidence in the recovery of the disease was deepened. The final decrease in the scores from the twentieth day to the thirtieth day was likely due to the trend of most patients recovering at this stage.

Further investigation revealed that the onset time of postauricular pain was within one day before and after the onset of facial paralysis symptoms; the difference between the experimental group and the control group was not statistically significant ($P > 0.05$). Furthermore, there was no statistically significant difference in the hospitalization stay between the two groups ($P > 0.05$). After treatment, the symptom of postauricular pain was relieved faster in the experimental group than in the control group; there was a very significant difference in the time of pain disappearance ($P \leq 0.001$).

Bell's Palsy, the branches of the facial nerve canal develop edema. Due to the lack of compensatory space in the facial canal, edema of the nerves in the facial canal may lead to ischemia, which in turn further aggravates the occurrence of edema; this forms a vicious circle leading to local pain. The administration of steroid hormones by retroauricular injection can effectively increase the local drug concentration and prolong the time of action. The symptom of postauricular pain caused by facial nerve edema was relieved faster in the experimental group than in the control group. This may be due to the fact that local injection of steroid hormones can (1) make the treatment more effective in the local infiltration of the lesions and (2) exert the steroids' effects. In the present study, local administration effectively shortened the time of postauricular pain; however, it had no significant effect on the recovery of facial paralysis symptoms. The occurrence of adverse reactions was generally lower in the experimental group than in the control group; however, there was no significant difference in adverse reactions among various steroids, and the adverse reaction of local postauricular congestion occurred in patients who received various steroids. Other studies reported that retroauricular injection definitely lowered the adverse reaction incidence of steroids but did not completely remove it.

In terms of safety indicators, most of the inspection indicators were normal; however, there was a statistical difference in alanine aminotransferase levels before and after the treatment in both patient groups. However, it did not exceed 60 U/L, and the average value was low, which caused a certain burden on the liver. No serious liver damage occurred.

8. Limitations

The present study had several limitations. Although the grouping based on the treatment method was not exposed, there were obvious differences in the treatment plan between the experimental group and the control group: the experimental group was treated via local hormone injection, while the control group was treated via oral hormones. Thus, complete blinding could not be achieved at the patient level.

The healer and bed management clinician was responsible for the operation of the retroauricular injection and oral drug administration; in this regard, blindness could also not be achieved, as the differences between the two operations were too noticeable.

The subjects themselves were not informed of the grouping results. Furthermore, no high evaluation was given to the retroauricular injection method during the treatment process; the patients were only informed that it was one of the treatment methods that would be performed.

In the ward, retroauricular injection was not only adopted for Bell's Palsy, but patients with sudden deafness or Meniere's disease were also treated with this method in large numbers.

However, subjects could observe the differences in treatment for the same disease and perceive the groupings. In addition, due to the lack of doctors and medicines in the last century, steroid hormones have been abused in the treatment of respiratory diseases and febrile diseases at this stage. For this reason, Chinese patients generally have a certain dislike towards steroid hormone treatment, making it necessary for medical workers to popularize the science of steroid hormones during the treatment process in order to relieve patients' nervousness about the application.

In the FDIS scale evaluation, the emotional symptoms described by patients were milder when the evaluator conducted the evaluation alone. After the completion of the current evaluation, patients will be informed that the disease progress seems to be going very well. However, in the process of this study, the clinical operators informed the study administrators that some patients were irritable during treatment, and there was a certain difference in the FDIS score when compared with the current score. The reason for this may be that the time chosen by the evaluators was mostly dinner time (after the treatment for the day had been completed). The evaluators also encouraged the patients and helped them understand their condition throughout the research process.

9. Conclusion

The efficacy of retroauricular injection of methylprednisolone sodium succinate combined with conventional acupuncture treatment in patients with Bell's Palsy was comparable to that of oral prednisone acetate tablets; it also had a better effect on postauricular pain relief. The dose of methylprednisolone retroauricular injection was lower than the equivalent hormone dose of oral prednisone acetate tablets, and there were fewer systemic side effects. In clinical practice, if some patients are obviously not suitable for receiving oral or intravenous steroids, the retroauricular injection of steroids can be used instead. Retroauricular injection of steroid hormones can relieve the symptom of postauricular pain more quickly than oral administration. Although there is no significant difference in overall efficacy, it has advantages in relieving local symptoms.

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki (as was revised in 2013). The study was approved by Ethics Committee of the Yinchuan Traditional Chinese Medicine Hospital (HY-202191235). Written informed consent was obtained from all participants.

Author contribution statement

Ling Chen: Conceived and designed the experiments; Analyzed and interpreted the data; Contributed reagents, materials, analysis tools or data.

Guo-Hui Li: Conceived and designed the experiments; Performed the experiments; Contributed reagents, materials, analysis tools or data; Wrote the paper.

Teng-Yu Chen: Performed the experiments; Analyzed and interpreted the data; Wrote the paper.

Yun-Xue Zheng: Performed the experiments; Wrote the paper.

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Availability of data and material

All data generated or analyzed during this study are included in this article. Further enquiries can be directed to the corresponding author.

Data availability statement

Data will be made available on request.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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