

A Primary Observation of Botulinum Toxin A Injection as a Preventive Treatment of Migraine without Aura

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Abstract

Objective: To observe the efficacy and safety of botulinum toxin type A (LANTOX) injection in the prevention of migraine without aura (3-5 attacks monthly) were treated by using multi-point injection of LANTOX in pericranial muscles. During one-month baseline period before injection and three month follow-up period after injection, patients were asked to make “headache daily”, showing headache frequency. The number of days using acute migraine medication and the occurrence of migraine associated symptoms.

Result: The migraine frequency, the number of days using acute migraine medication and occurrence of migraine associated symptoms in 17 patients after treatment were significantly reduced compared with those in baseline period and LANTOX injection were well tolerated with only a few local side effects by these patients.

Conclusion: Accordingly to this primary clinical observation, headache frequency, pain-killer usage, and migraine accompanying symptoms can be reduced by perocranial injection of LANTOX in patients with migraine without aura.

Further randomized placebo – controlled studies are needed to draw the conclusion that pericranial injection of LANTOX be widely used as a preventive treatment for migraine without aura.

Migraine is a common disease with risk about 690/100,000 with 37/100,000 morbidity in China. There are two main types: with or without aura. Tension and anxiety are the most common factors. The idea of complete treatment on migraine included the control of onset of symptoms and prevention treatment. Until now, beta-blocker and methysergide are two of the FDA approved medical treatment for the prevention of migraine. However, limitation of these treatments and obvious side effects limited its usage. Since there is no long term therapeutic effect, the preventive effects of these medicines are not ideal.

Information and Method

1. Information

Since January 2003 to May 2004, there are 17 patients with migraine without aura. It coincided with IHS clinical standard in 1988, that is, onset of symptom with

minimum 5 times and coincided with the following characteristics: (1) onset of symptom 4-72 hours; (2) unilateral; (3) throbbing pain ; (4) moderate to severe headache; (5) over- workload; (6) nausea, vomiting, afraid of noise and light, cold of limbs. There are 5 males and 12 females patients with age 19~25 (average 34.0 ± 7.19), pathogenesis for 3-11 years (average 7.0 ± 2.21 years). Ergot and non-hormonal anti-inflammatory drugs treatments were used during the acute onset period. There are 6 cases of using propranolol and sibelium as intermit preventive treatment.

The patients excluded the following criteria were observed: (1) comparative persistence headache with neurological disorder, (2) nerves and muscle junction disease, (3) pregnant and lactation period, (4) highly sensitive to drug.

2. Method

1. After one month basic observation period, LANTOX injection treatment was done. After that, there is a three-month observation consequently, which without any restriction of previous analgesic treatment. Results were obtained as “headache daily” during the observation period before and after treatment include the following parameters: (1) onset frequency of headache; (2) days of taking analgesic tablets during onset of symptoms; (3) symptoms other than headache.

2. Dosage and Method of Injection of LANTOX: (1) LANTOX was obtained from Lanzhou Institute Biological Products, dilute with saline to obtained 5u/ml concentration before injection. (2) Dosage and Injection Site: 4 points at frontal muscle and 2 points at temporal muscle of each side, 4 points at muscles between eye brow and, 4 points at musculus occipitalis. The dosage for each injection points are 0.1ml, totally 25u. (3) Observation after Treatment: The average value of onset frequency, days of taking analgesic tablets during onset of symptoms and symptoms other than headache with 17 patients at basic period and after treatment for 3 consequent months were compared.

Results

There are 17 patients with migraine without aura. The onset frequency, days of taking analgesic tablets during onset of symptoms and symptoms other than headache at basic period and after treatment for 3 consequent months after statistical analysis were showed in Table 1.

Table 1

Time	Frequency of Headache (Frequency/Month)	No. of Days of using Analgesic Treatment (Day/Month)	No. of symptoms other than headache
Basic period	4.53±1.01	5.71±1.21	3.00±0.71
After treatment (months)			
1	1.82±0.64	2.74±0.90	1.35±0.94
2	2.00±1.79	3.24±0.66	1.24±0.44
3	2.53±0.51	3.24±1.09	1.76±0.44
P value	<0.01	<0.01	<0.01

Side effects: In general, there is no adverse side effect. There are 6 patients had no effort in corrugator muscle, 5 cases of weakness when opening eyes and partial swelling of eyes. All cases recovered within 1 to 3 weeks.

Discussion

Base on the observation on limited cases, there is an obvious decrease in onset frequency, days of taking analgesic tablets during onset of symptoms and symptoms other than headache after LANTOX multi-injection on cranial muscle. These represented that LANTOX have preventive effect as well as treatment effect on migraine. Moreover, no toxic adverse side effects were observed and the patients showed good tolerance.

Migraine is one of the common onset mechanisms of headache. Mental factors such as tension and anxiety are some of the factors of cranial muscles spasticity. LANTOX could inhibit the chemical release of acetylcholine from neuromuscular junction to nerves, which leading to local muscle paralysis. Thus relief or blocked the nervous transmission could triggered the preventive process of migraine.

However, the use of LANTOX injection to cranial muscles for treating migraine need to be confirmed by more randomized case studies and control experiments.

References

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