

Clinical Report 1 (Japan)

Development of Acupuncture Therapy for Aspiration Pneumonia and Traditional Medicine Outpatient Clinic of Tohoku University Hospital

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The Super-aging Society Japan and Aspiration Pneumonitis

Based on an announcement made by the cabinet the ratio of elderly in Japan (the portion of the population older than 65 years) has increased steadily every year since investigations have been started (in 1968) and in 2007 the ratio exceeded 21%, resulting in a super-aging society, and by October 2008 this ratio has reached 22.1%. By the year 2055 the ratio will reach 40.5%, so that is has been estimated, that one in every 2.5 people will be an elderly. (2008, Current situation of the elderly population and the state of implementation of countermeasures for the aging society.)

Pneumonitis is the fourth frequent cause of death in Japan. More than 90% of the deceased are elderly over the age of 65. A characteristic form of pneumonitis in elderly people is aspiration pneumonitis. The deglutition and cough reflex are defense mechanisms protecting the lungs from aspiration. A major cause of pneumonitis in the elderly are diminished deglutition and cough reflexes due to cerebrovascular disorders of the cerebral basal ganglia (Nakagawa T, et al. Arch Intern Med 1997; 157:321-324). Vascular disorders in the basal ganglia lower the amount of dopamine produced in the nigrostriatal body. In this way the amount of substance P (SP) released from the sensory branch of the vagal nerve to the pharyngeal and tracheal mucosa decreases. Since the SP represents an important trigger stimulus for the deglutition or cough reflex, a reduction in the amount of SP also decreases those reflexes (Yamaya M, et al. JAGS. 2001; 49:85-90). In cases with a diminished deglutition reflex the aspiration may not

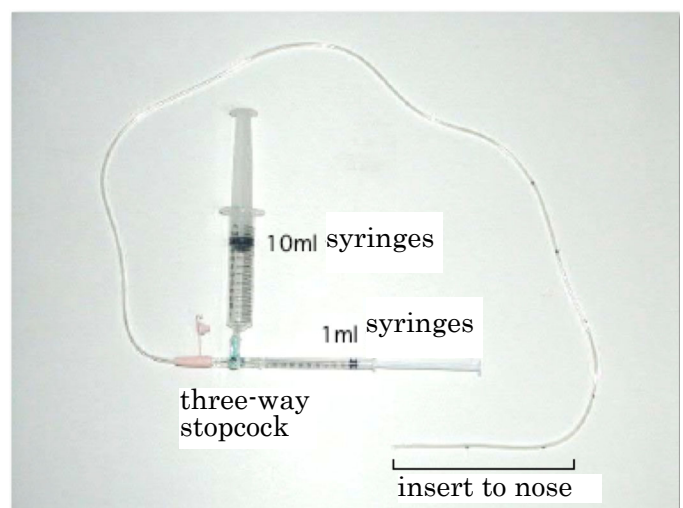
be noticed (inapparent aspiration), allowing saliva or intraoral bacteria to enter the lungs.

Evaluation of the deglutitional function: measurement of the deglutition reflex latency

For the assessment of the deglutitional function videofluorographic studies are employed, but their performance is restricted to facilities capable of performing them and definitely are not easy. For this study we used the latency time of the swallowing reflex: LTSR developed at the Department of Geriatrics of the Tohoku University as a measuring method for the deglutitional function and as an assessment technique. This method has the advantage that it allows measurement everywhere and available evidence suggests a correlation with aspiration pneumonitis.

Multipurpose 8F tubes and syringes (1 ml, 10 ml) are attached to a three-way stopcock, the tip of the tube inserted to a depth of about 12 cm and left dwelling the pharynx of the examinee, then 1 ml of distilled water is injected (Figure 1) and the LTSR defined as the period from the begin of the injection of the distilled water to the begin of the pharyngeal elevation. It is common knowledge that there is a risk of aspiration, when this LTSR exceeds 5 seconds.

Figure 1: Kit for the measurement of the deglutition reflex latency



Necessity of acupuncture treatment

During the treatment of patients with dysphagia oral application of the required drugs may not possible precisely because there are difficulties in swallowing. For this reason new treatment forms are required that improve the deglutition reflex without relying on oral drug application.

Development of an acupuncture treatment for improving the deglutition reflex

Aspiration is considered to be due to a lack of proper control of deglutition and inhalation and in traditional Chinese medicine one of the causes is attributed, based on the visceral manifestation theory, to the weakened functions "harmonizing array" of the stomach and "qi absorption" of the kidneys.

Further, since patients with cerebrovascular disorders may not be able to use their extremities at will, an approach using acupuncture therapy can easily be conceived. Moreover, as a treatment form using stimulation of safe sites it is effective in the clinical setting. Under these circumstances we chose to use the sea point of the brighter yang stomach meridian and the source point of the lesser yin kidney meridian as stimulation sites.

Below the results of two trials are described.

Research 1:

Deglutition reflex and acupuncture treatment for patients with cerebrovascular disorders

Seki T, Kurusu M, Tanji H, Arai H, Sasaki H, Acupuncture and swallowing reflex in poststroke patients. *J Am Geriatr Soc.* 51(5) 726-727, 2003.

Background and purpose

Therapies requiring the oral application of drugs are limited in patients who have problems eating. Thus, nonpharmacologic methods promoting recovery of the swallowing function have to be developed. In this study we examined the effects of needle stimulation at Ashi Sanri (ST36) and Taikei (KI3) on decreased swallowing reflexes.

Materials and methods

The study included 41 patients with sequelae of cerebrovascular disorders (average age $\pm$ standard deviation 76 ± 2 years), all of whom presented with a history of deglutition disorders. The primary lesion of the cerebrovascular disorder was located in most patients in the basal ganglia and the adjoining deep white matter. Patients with infarct sites in the brain stem were excluded.

The LTSR was defined as the time from the begin of injecting 1 ml of distilled water through a transnasal catheter into the pharynx until the begin of the swallowing movement. The measurement was performed 5 times and the measurement value defined as the mean value excluding maximal and minimal values.

The Ashi Sanri and Taikei were needled. Seirin disposable stainless steel needles (diameter, 0.16 mm; length 40 mm) were inserted at the acupoints on the left and right to a depth of 1 cm. The needles were neither manipulated manually nor used for electrical stimulation. After retaining the needles for 15 minutes the needles were removed. Breathing based tonification or sedation was not used either.

The LTSR was performed immediately before the needling and 30 minutes after removing the needles.

Saliva and blood samples were also obtained immediately before the needling and 30 minutes after removing the needles. The sampled saliva and blood was stored as -80°C and subsequently their substance P content measured. For this purpose we used a radioimmune assay and followed the instructions of the manufacturer for quantitative measurements. The amount of substance P immediately before the needling and after the needle stimulation were compared.

In seven of the examinees the LTSR was measured daily from the day after the needle stimulation for one week.

Results

Figure 2 shows that the LTSR significantly improved after a single needle stimulation (average value before needle stimulation: 10.2 ± 1.4 seconds, average value after needle stimulation: 4.5 ± 0.6 seconds). After adjusting for age, sex and activities of daily living and primary disease (cerebral infarct, cerebral hemorrhage) a logistic regression analysis was performed and showed that the longer the LTSR was before the needle stimulation, the better were the therapeutic effects ($P=.002$).

Moreover, the effects of needle stimulation on the LTSR continued for 7 days. The average LTSR before and after needling as well as 1, 2, 3, 4 and 7 days later were 12.8 ± 4.5 , 3.2 ± 0.7 , 6.2 ± 2.5 , 6.7 ± 2.8 , 5.6 ± 2.1 , 3.6 ± 1.4 and 2.2 ± 0.2 seconds respectively.

The concentration of substance P in plasma (average of 25.9 ± 3.0 vs 26.6 ± 3.0 pg/mL) and saliva (average of 15.2 ± 2.9 vs 17.7 ± 3.4 pg/mL) showed no significant variation before and after the needle stimulation.

Health disturbances like local infections etc. were not observed.

Figure 2 (below)

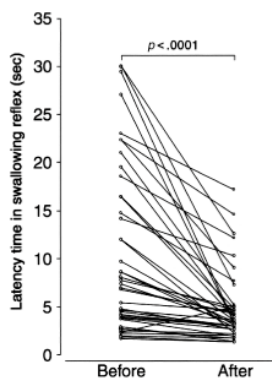


Figure 2. Latency time in swallowing reflex in poststroke patients at baseline and 30 minutes after acupuncture.

Discussion

A network of cholinergic, histaminergic and dopaminergic nerves is involved in the control of the swallowing reflex (Jia YX, et al. *Geriatr Gerontol Int* 2001). The activities of several sites in the brain

are related to spontaneous swallowing (Zald DH, et al. *Ann Neurol* 1999) and since acupuncture is known to regulate the subcortical grey matter, it may be inferred that acupuncture treatment causes local activation of the brain.

Research 2:

Deglutition reflex and acupuncture treatment for patients with cerebrovascular disorders: videofluorographic studies

Seki T, Iwasaki K, Arai H, Sasaki H, Hayashi H, Yamada S, Toba K.

Acupuncture for Dysphagia in poststroke patients: a videofluoroscopic study. *J Am Geriatr Soc.* 53(6):1083-4. 2005.

Background and purpose

We reported that needle stimulation of Ashi Sanri and Taikei improved the swallowing reflex. Here we used videofluorography to investigate whether needle stimulation improved swallowing disorders or the swallowing in patients with cerebrovascular disorders.

Materials and methods

The study included 32 patients living a health care center for the elderly in Sendai city (average age $\pm$ standard deviation; 84 ± 4 years; 20 women, 12 men) in whom cerebrovascular disorders had been diagnosed using MRI. A written informed consent was obtained from these patients. The examinees were randomly divided into two groups. The patients in the needle stimulation group (average age $\pm$ standard deviation; 77 ± 9 years; 10 women, 8 men) received acupuncture treatments 3 times a week over a period of 4 weeks. The needle stimulation was the same as the one used in research 1. The control group included 14 persons (average age $\pm$ standard deviation; 79 ± 5 years; 10 women, 4 men) and received only the ordinary care without needle stimulation.

The videofluorography was performed in the needle stimulation group before and after the first needle stimulation and in the fourth week before and after the last treatment. In the control group it

was performed before observation begin and following completion of the observation after four weeks. For a single videofluorographic examination the patients were asked to swallow 5 ml of water over a period of 5 minutes, 5 ml of liquid diet and solid food (cookies corresponding to 5 ml) in arbitrary order. The water and food was mixed with barium (Enemastar Enema Powder, FUSHIMI Pharmaceutical, Marugame, Japan). For the imaging during the videofluorography the patients were asked to assume either a sitting position or lie on their side. For the imaging a DVD/HDD recorder (RD-XS30, Toshiba, Tokyo, Japan) was used, connecting it to an imaging device (Prestige, GE Medical Systems, Tokyo, Japan). Thirty frames per second were taken and the measurements performed using an image processing software (Premier 6.0, Adobe Systems, Tokyo, Japan) by a radiological technician, who was not informed about the group to which the examinee belonged. If after swallowing water or food boli were still observed in the epiglottal groove or the piriform recess, this was defined as pharyngeal retention. If water or food boli reached the trachea below the height of the vocal cord folds, this was defined as aspiration. The patients were observed from the moment the swallowing instruction was issued to the examinees until the water and food boli had reached the esophagus.

Body temperature of the examinees was measured daily at 2 o'clock in the afternoon. The number of days when the body temperature exceeded 37.8°C during the 4-week period were recorded.

Results

In the needle stimulation group the time required the swallowing before test begin until the swallowed material reaches the esophagus was for water on the average ($\pm$ SD) 1.7 ± 1.0 , for liquid diet 8.7 ± 13.2 and for solid food 10.4 ± 7.0 seconds. In the control group the respective times were for water 1.9 ± 0.6 , liquid diet 4.5 ± 3.7 and for solid food 9.7 ± 7.6 seconds.

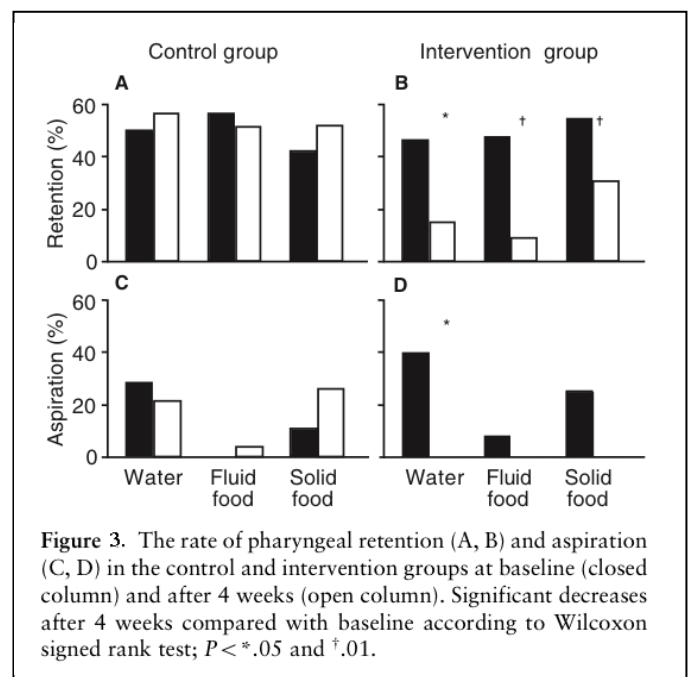
Four weeks later these values were in the needle

stimulation group 1.1 ± 0.3 sec ($p < .05$), liquid diet 5.0 ± 4.8 sec ($p < .05$) and for solid food 11.8 ± 9.3 seconds. In the control group the times were for water 2.1 ± 0.9 , liquid diet 5.4 ± 5.4 and for solid food 10.1 ± 6.9 seconds. In the needle stimulation group the swallowing time for water and liquid diet was compared to the pretest value after four weeks significantly shortened.

Figure 3 shows the percentage of pharyngeal retention and aspiration in the two groups of examinees. The degree of pharyngeal retention had significantly decreased in the needle stimulation group, but in the control group no significant change was observed. Aspiration before test begin was in the needle stimulation group 40% for water, 8% for liquid diet and 25% for solid food, but after four weeks aspiration was no longer observed for any of the food forms.

In the control group no significant change in the ratio of aspiration was observed between the pretest condition and the condition after 4 weeks. The number of days body temperature exceeded 37.8°C was in the needle stimulation group 4 out of 356 days, whereas it was in the control group 28 out of 394, showing that it was significantly higher in the control group than in the needle stimulation group ($P < .01$).

Figure 3 (below)



Discussion

Needle stimulation of Ashi Sanri and Taikei improves the incidence of pharyngeal retention and aspiration in patients with cerebrovascular disorders repeatedly suffering from aspiration.

Conclusions

These results indicated the possibility that needle stimulation of Ashi Sanri and Taikei can improve the swallowing reflex, reduces the amount of pharyngeal retention and aspiration and thus may prevent aspiration pneumonitis.

These studies are characterized by

- 1) the needle stimulation consisted only of direct insertion, retention for 15 minutes and removal of the needles, not using any manual manipulation or electrical stimulation of the inserted needles at all;
- 2) this can conceivably be designated a clinical trial of acupuncture therapy of the examinees not based on pattern identification, but from the perspective of the western medical diagnosis; here (1) indicates, that even acupuncture therapy using only simple retention of the needles alone can have marked clinical effects, while (2) indicates that clinical trials including examinees selected based on western medical diagnosis may show the effectiveness of the acupuncture therapy.

This study showed great potential for acupuncture treatment, but the medical education in Japan almost does not include teaching about acupuncture at all, so that even simple acupuncture treatments present for the physicians in the clinical setting a great hurdle and obstruct the spread of this treatment modality. For this reason we performed trials using stimulation with low frequency currents with surface electrodes attached to Ashi Sanri and Taikei after completion of the above described two trials. The results showed, that a similar degree of improvement of the LTSR was observed. This indicates that both needle insertion and low frequency currents induce identical changes in the human body. If improvements of the swallowing function can be obtained without inserting needles, this treatment modality is considered to become popular in the clinical setting. On the other hand, comparing the degree of improvement of the swallowing reflex between the studies 1 and 2 and this latter study showed that the insertion of filiform needles produces a greater degree of improvement as compared to low frequency currents. The results of these studies are scheduled to be published in the Journal of The American Geriatrics Society. (Akamatsu C, Seki T. et al. Improvement of swallowing reflex after electrical stimulation to lower leg acupoints in patients after stroke. JAGS. in press.)

Department of Kampo Medicine of Tohoku University

The Department of Kampo Medicine of Tohoku University does not use only Kampo medicine, but embraces an integrated approach to traditional medicine originating from China also using acupuncture treatment, Suina and traditional dietary guidance. In the past the departments of geriatrics and respiratory diseases used Kampo medicine and acupuncture in their outpatient service, but in 2003 the Tohoku University established a lecture for advanced Kampo medical practice within its faculty of medicine and also a department of Kampo (internal) medicine within its university hospital. Here a department using mainly Kampo preparations in its Kampo outpatient service and an acupuncture and Kampo outpatient section using a combination of Kampo preparations and acupuncture treatment were established. Since April 2008 a Kampo outpatient section was also set up within the obstetrics and gynecologic department.

Demand for Kampo outpatient services and outpatient background

The number of patients is steadily growing. The broad age range of the patients ranges from 0 to 90 years. The acupuncture and Kampo outpatient service is booked for one year ahead and cares mainly for patients with intractable diseases. For this reason the most frequent target illnesses are myasthenia gravis, Parkinsonism, ALS and similar neuromuscular diseases, glaucoma, cancer, GVHD etc.

Research into Kampo medicine and acupuncture treatment

This department has published about the effects of Yokkansan for the treatment of mental disorders associated with dementia, acupuncture treatment (needling of Taikei and Ashi Sanri) for cerebral stroke associated with dysphagia, the effects of acupuncture treatment on lowering ocular tension

in patients with glaucoma and similar results.

In the acupuncture and Kampo outpatient service the therapeutic effects are evaluated before and after each acupuncture treatment session, using the results as therapy feedback, whereby a system that might be called 'Evidence Based Clinical Acupuncture' is being built. Building a system that will allow to put acupuncture treatment and Kampo medicine to use in clinic represents one of our goals.

Medical education

The education is not directed only towards physicians, but also acupuncturists and medical students and thus the department represents one of the few medical faculties that performs clinical practice in acupuncture and has therefore earned a very high reputation among the students. Fifth year students of the medical faculty are divided into small groups of 5-6 students and are taught once every two weeks, including instructions in practical examination, brewing Kampo medical decoctions and practicing insertion of acupuncture needles. From among the sixth grades 6-7 applicants can partake in practical training courses of 1-2 months. Here they will receive lectures about the theoretical foundations, participate in outpatient practice and participate in practical training in the pharmacy or pharmaceutical botany.

Using the advantages of a general hospital, a system of cooperative care and research with each department is being established.