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# Effect of Press Needles on Swallowing Reflex in Older Adults with Cerebrovascular Disease: A Randomized...

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and risk of lobar hemorrhage to be identified but is an indication of an association between occurrence of SCLH and different apoA-1 plasma levels. Data regarding apoA-1 as a risk factor for SCLH could be more adequately acquired using a prospective study design. Second, statistical power was poor because of the small sample size.

If these findings are confirmed in further studies with larger samples and different designs, apoA-1 plasma level could become a promising diagnostic and predictive marker of CAA, as well as a potential target for prevention strategies in CAA-related hemorrhage.

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Conflict of Interest: The editor in chief has reviewed the conflict of interest checklist provided by the authors and has determined that the authors have no financial or any other kind of personal conflicts with this paper.

Author Contributions: Massimiliano Godani: study concept and design, wrote the manuscript. Roberta Baldi: analysis and interpretation of data, wrote the manuscript.

Elisa Raggio: analysis and interpretation of data. Elisabetta Traverso: acquisition of data.

Elisa Giorli: acquisition of data. Massimo Del Sette: supervised the manuscript.

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# EFFECT OF PRESS NEEDLES ON SWALLOWING REFLEX IN OLDER ADULTS WITH CEREBROVASCULAR DISEASE: A RANDOMIZED DOUBLE-BLIND CONTROLLED TRIAL

To the Editor: The global population is aging. Pneumonia is a leading cause of death in elderly adults, especially those with dysphasia and microaspiration. Because aspiration pneumonia is related to impairment of the swallowing and cough reflex, the development of preventive strategies is needed to improve such protective reflexes to reduce the incidence of pneumonia in older people. In Japan, pneumonia is the third leading cause of death. It was previously reported that acupuzncture at two points on the legs (ST36 and KI3) improved the swallowing reflex after stroke and reduced pharyngeal retention and aspiration.

To investigate the effectiveness of acupuncture with press needles in improving the swallowing reflex in elderly adults with cerebrovascular disease, a three-arm randomized double-blind controlled multicenter trial was conducted by incorporating sham patches and sham points. Individuals aged 65 and older who had had a stroke and had dysphasia were recruited consecutively from two hospitals and two nursing homes in Sendai, Japan. The purpose and design of the study were explained to each individual, and informed consent was obtained. The Tohoku University ethics committee approved the study protocol.

Twenty-nine individuals (10 men, 19 women; mean age  $\pm$  SD 82.2  $\pm$  7.1) were recruited and assigned randomly to three groups: group 1, press needles (Pyonex; Seirin Corporation, Shizuoka, Japan) on the ST36 and KI3; group 2, sham patches on the acupuncture points; and group 3, press needles on sham points. The needles were 0.2 mm in diameter and 0.6 mm long. The design of the sham patch was identical to that of the press needle except most of the needle had been cut off, so that only the head of the needle remained in the resin. Patches were applied and changed every day for 4 weeks. Latent time of swallowing reflex (LTSR), plasma substance P (SP), Barthel Index, Mini-Mental State Examination, and days of fever were measured at baseline and 4 weeks later.

Table 1 shows the outcomes of this study. The primary outcome was change in LTSR. A statistically significant shortening of LTSR was evident in Group 1  $(6.9 \pm 2.3 \text{ vs } 2.5 \pm 0.3 \text{ seconds}, P = .005)$ , whereas no statistically significant difference was observed in the other two groups. There was a significant difference between the three groups in change in LTSR (P = .009). Change in LTSR in Group 1 was significantly different from that in Group 2 (P = .008) but not Group 3 (P > .99). There was a significant difference in LTSR at day 28 between Groups 1 and 2 (P = .001), but no significant difference between Groups 1 and 3 (P = .51). Plasma SP did not change significantly during the study in any group, and no differences in secondary outcomes were observed in any group

Table 1. Primary and Secondary Outcomes

Outcome	Group 1, n = 10	Group 2, n = 10	Group 3, n = 9	Group 1 vs Group 2	Group 1 vs Group 3
				<i>P</i> -Value <sup>a</sup>	
Primary					
LTSR, seconds	s, mean (SE)				
Baseline	6.9 (2.3)	4.0 (1.1)	14.9 (6.2)		
Day 28	2.5 (0.3)	8.5 (2.8)	8.4 (3.4)	.008 <sup>b</sup>	>.99 <sup>b</sup>
<i>P</i> -value	.005°	.20 <sup>c</sup>	.26 <sup>c</sup>		
Plasma substa	ince P, pg/mL, mean (SE)	)			
Baseline	709.4 (297.9)	809.5 (117.7)	483.4 (129.1)		
Day 28	643.0 (245.2)	801.6 (104.2)	550.4 (121.2)		
<i>P</i> -value	.37 <sup>c</sup>	.91 <sup>d</sup>	.77 <sup>d</sup>		
Secondary outco	mes				
Barthel Index,	mean (SE)				
Baseline	15.5 (10.2)	17.5 (7.6)	8.3 (7.1)		
Day 28	15.0 (10.4)	18.0 (7.7)	8.9 (7.7)		
<i>P</i> -value	.66 <sup>c</sup>	.32 <sup>c</sup>	.32 <sup>c</sup>		
Mini-Mental St	tate Examination Score, n	nean (SE)			
Baseline	8.2 (2.8)	5.9 (2.7)	3.7 (2.2)		
Day 28	8.3 (2.9)	6.1 (2.9)	3.7 (2.3)		
<i>P</i> -value	.86 <sup>d</sup>	.41 <sup>c</sup>	>.99 <sup>c</sup>		
Days of fever,	mean (SE)				
Baseline	5.0 (3.1)	3.7 (1.5)	1.6 (0.7)		
Day 28	7.0 (3.0)	5.6 (2.4)	1.2 (0.7)		
<i>P</i> -value	.29 <sup>c</sup>	.06 <sup>c</sup>	.26°		
Body mass inc	dex, kg/m $^2$ mean $\pm$ SD				
Baseline	19.2 ± 1.4	$15.8 \pm 3.3$	$20.2\pm1.3$		
Day 28	$16.6 \pm 2.6$	$18.1 \pm 3.1$	$20.3\pm1.3$		
<i>P</i> -value	.17 <sup>d</sup>	.10 <sup>d</sup>	.67 <sup>c</sup>		

SE = standard error.

between baseline and Day 28. Peripheral blood tests were performed to assess inflammatory and nutritional status. No statistically significant differences were observed in white blood cell count, C-reactive protein, total protein, albumin, or total cholesterol between baseline and Day 28. There were no significant differences in any parameters. Neither press needle nor sham needle treatment caused any side effects.

Attachment of press needles at the two leg acupuncture points improved the swallowing reflex of elderly adults with cerebrovascular disease. Lack of a significant difference between acupuncture points and sham points indicates that the attachment of the fine needle itself has some effect on the swallowing reflex. Even if the press needles are placed at positions that deviate from the acupoints (e.g., sham points in this study), LTSR may improve, which is clinically convenient. This type of acupuncture may become a new adjuvant method for the prevention and treatment of pneumonia in elderly adults.

The limitations of the present study were the small sample size and short follow-up time. In addition, only Group 3 included participants with extremely poor LTSR at baseline, which could have been why there was no difference between Groups 1 and 3 in LTSR at Day 28. Further studies are required to investigate the effect of the press needle on swallowing function.

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<sup>&</sup>lt;sup>a</sup>Intergroup comparisons of change in latent time of swallowing reflex (LTSR).

bKruskal-Wallis test.

<sup>&</sup>lt;sup>c</sup>Wilcoxon signed rank test.

<sup>&</sup>lt;sup>d</sup>Paired-*t* test.

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# AGING AND WITHIN- AND BETWEEN-DAY VARIABILITY ASSESSED USING 7-DAY/24-HOUR AMBULATORY BLOOD PRESSURE MONITORING

To the Editor: Blood pressure (BP) being highly variable, ambulatory BP monitoring (ABPM) more thoroughly depicts underlying BP fluctuations and predicts cardiovascular risk better than conventional measurements. ABPM also assesses the extent of BP decrease (dip) during sleep. "Nondipping" (ND), defined as a day:night ratio (DNR) of less than 10%, is reportedly associated with target organ damage and cardiovascular events, independently of overall mean BP. 1,2 Day-to-day variability in circadian BP characteristics is often observed in 7-day ABPM records. Changes with age in the extent of day-to-day variability in 24-hour SBP mean and DNR were examined.

A greater morning BP surge on Mondays was found in Uraus, a rural northern Japanese town,<sup>5</sup> but not in Tosa, a southern Japanese city. Geographic differences in changes with age in circadian features of BP were explored between these two cities and Tokyo.

A total of 644 community-dwelling subjects living in Tokyo, Uraus (Hokkaido), or Tosa (Kochi Prefecture) were

initially recruited. Of the 644, 609 (368 women, 241 men, aged 23–79) who provided ABPM records spanning at least 6 days were included in this study. As reported earlier, <sup>5–8</sup> BP was measured oscillometrically at 30-minute (7:00 a.m. to 10:00 p.m.) or 60-minute (10:00 p.m. to 7:00 a.m.) intervals, using monitors (TM-2431, A&D Co., Tokyo, Japan) validated for accuracy. Paily (24-hour) averages and DNR values were computed.

Hypertension (HT) was defined as a 24-hour mean BP greater than 130/80 mmHg. ND was defined as a DNR of systolic BP (SBP) of less than 10%. Mean 24-hour BP and DNR were used to subdivide the 609 subjects into four groups (Classification 1: Group 1 = consistent normotension (NT), Group 2 = NT on day 1 but HT on  $\geq$ 1 of the following 6 days (masked HT), Group 3 = HT on day 1 but NT on  $\geq$ 1 of the following 6 days (masked NT), Group 4 = consistent HT; Classification 2: Group 1 = consistent dipping (DP), Group 2 = DP on Day 1 but ND on  $\geq$ 1 of the following 6 days (masked ND), Group 3 = ND on day 1 but DP on  $\geq$ 1 of the following 6 days (masked DP), Group 4 = consistent ND).

The incidence of consistent and inconsistent classification was compared using the Kruskal-Wallis test (significance at the .05 probability level) for subjects in three age groups (23–49, n = 113; 50–64, n = 257; 65–79, n = 239), for all subjects, for men and womem separately, and for subjects in each of the three cities (Table 1).

Inconsistent classifications from day to day increased with age (P < .001), masked NT being more frequent than masked HT (Table 1, left). Results were significant for women (P < .001) but not for men (P = .22) and for citizens of Uraus (P < .001) and Tosa (P = .005) but not Tokyo (P = .72). Inconsistent DNR classifications also increased with age, overall and for men and women separately (all P < .001), being significant in Uraus (P = .01) but not in Tosa (P = .09) or Tokyo (P = .54) (Table 1, right).

Depressive mood affects BP and BP variability,<sup>7,8</sup> with individuals with depression having a more-prominent circaseptan component in SBP, associated with subjective sleep disturbances. Aging was found to affect the extent of day-to-day BP variability, more so in women than in men, perhaps because day-to-day variability is already high in younger men. An age effect was not found in Tokyo, where the incidence of consistent HT was already high in the younger age group.

An age effect in DNR classification was significant for men and women but only in Uraus (Hokkaido prefecture) in northern Japan, where winters are cold. Results in Tosa are similar but not significant, perhaps because the clement weather of southern Japan favors a higher incidence of consistent dippers in all age groups. A busy and noisy lifestyle in Tokyo may account for the largest percentage of inconsistent day-to-day classification (80.2%).

DNR classification is almost invariably more inconsistent than BP-mean classification. Habituation to the monitor may account for the numerically higher incidence of masked normotension than masked HT, observed primarily in elderly adults (P = .02).

In conclusion, aging affects day-to-day BP variability in 24-hour BP mean and in DNR. Several consensus