

Blinding indices and blinding scenarios of practitioners and patients with acupuncture needles for double blinding

In acupuncture studies, it is necessary to expose blinded patients to control devices such as placebo/sham needles with a blunt tip, which allows the skin to be touched but not penetrated. Several recent systematic reviews have investigated the success of patient blinding with Streitberger, Park and Takakura placebo/sham needles in a series of validation and clinical trials using Bang's blinding index (BI),^{1,2} which indicates the degree of potential unblinding beyond balance for each arm of real and placebo treatment.² In a review papers, it was pointed out that the BIs for Takakura needles for double blinding were unavailable.¹ Further, for study Ib (see table 1),³ Moroz *et al* reported the BIs of patients calculated from the number of subjects who did,

or did not, experience the sensation of skin penetration,² which differed from the BIs calculated from the number of correct and incorrect guesses, even though we reported that "none of the subjects commented in the questionnaire that they had received a non-penetrating needle".³ The patient BIs for study Ib³ reported by Moroz *et al* were not appropriate. Therefore, we report practitioner-sourced BIs, which have not been presented before, along with patient BIs from five validation studies³⁻⁷ (table 1).

The BI (ranging from -1 to 1) is a statistical tool that can be used to objectively assess the effectiveness of blinding and has been recently introduced into acupuncture studies.^{1,2} The BI is calculated based upon the number of correct guesses, incorrect guesses and don't knows regarding treatment allocation.^{1,2} According to proposed criteria, a BI ≥ 0.2 indicates that the treatments have been correctly guessed (unblinded); a BI ranging from -0.2 to 0.2 indicates the treatments have been

randomly guessed (random guess); and a BI ≤ -0.2 indicates the treatments have been incorrectly guessed (opposite guess).² In total, nine blinding scenarios are possible when we consider all pairs created by 'random guess', 'opposite guess' and 'unblinded' options in real and sham/placebo arms.²

Table 1 shows the BIs derived from our studies³⁻⁷ employing pairs of penetrating real and skin-touch placebo needles^{3,4,6,7} or penetrating real needles only.⁵ The overall practitioner BIs for both penetrating real and skin-touch placebo needles indicate 'random guesses', which means that the effectiveness of practitioner blinding seems promising. The practitioner BI in study V,⁷ in which acupuncturists adopted the Chinese style of needle administration, indicates 'unblinding' for both real and placebo needles. On the other hand, acupuncturists adopted the Japanese style of needle administration in other studies. To pursue successful practitioner blinding, we suggest that only acupuncturists who have learnt the Japanese style

Table 1 Practitioner and patient blinding indices (BIs) and blinding scenarios for the use of Takakura needles in double blinding

Study			Study I ³		Study II ⁴	Study III ⁵	Study IV ⁶	Study V ⁷	Total
			Takakura <i>et al</i> 2007		Takakura <i>et al</i> 2008a	Takakura <i>et al</i> 2008b	Takakura <i>et al</i> 2013	Vase <i>et al</i> 2015	
			Ia	Ib					
Number of participants			10 practitioners, 1 subject	1 practitioner, 60 subjects	1 practitioner, 114 subjects	1 practitioner, 30 subjects	1 practitioner, 109 subjects	6 practitioners, 67 patients	
Practitioner blinding	Penetrating real needles	Number	170 needles	60 needles	114 needles	60 needles	109 needles	32 treatments	
		BI	-0.05	0.17	-0.22	-0.47	0.06	0.56	-0.05
		95% CI	-0.19 to 0.08	-0.08 to 0.42	-0.40 to -0.04	-0.69 to -0.24	-0.12 to 0.25	0.28 to 0.85	-0.13 to 0.03
	Skin-touch placebo needles	Number	230 needles	60 needles	114 needles	-	109 needles	35 treatments	
		BI	0.06	0.00	0.00	-	-0.12	0.71	0.05
		95% CI	-0.06 to 0.18	-0.25 to 0.25	-0.18 to 0.18	-	-0.31 to 0.07	0.48 to 0.95	-0.04 to 0.13
Blinding scenario			Random/random	Random/random	Opposite/random	Opposite/-	Random/random	Unblinded/unblinded	Random/random
Patient blinding	Penetrating real needles	Number	-	-	114 needles	60 needles	109 needles	32 treatments	
		BI	-	-	0.37	0.33	0.56	0.38	0.43
		95% CI	-	-	0.20 to 0.54	0.09 to 0.57	0.40 to 0.72	0.05 to 0.70	0.33 to 0.53
	Skin-touch placebo needles	Number	-	-	114 needles	-	109 needles	35 treatments	
		BI	-	-	-0.12	-	0.19	0.20	0.05
		95% CI	-	-	-0.30 to 0.06	-	0.01 to 0.38	-0.12 to 0.52	-0.07 to 0.18
Blinding scenario			-	-	Unblinded/random	Unblinded/-	Unblinded/random	Unblinded/unblinded	Unblinded/random

of acupuncture should be employed when Takakura needles are used for double blinding in clinical trials.

For patient blinding scenarios in table 1, the ‘random guess’ for the skin-touch placebo arm appears promising because the patient BI of skin-touch placebo needles was 0.2 in study V,⁷ in which patients guessed the nature of the treatment with five needles, whilst ‘random guess’ was indicated by the BIs in study II⁴ and study IV.⁶ By contrast, the ‘random guess’ status for the penetrating real arm appears to be extremely difficult since the statuses in all studies were ‘unblinded’, as reported by a previous review.^{1,2} In addition to the ‘random guess’ status for both real and placebo arms, ‘unblinded’ in the real arm and ‘opposite guess’ in the placebo arm are also considered to reflect successful patient blinding as a ‘wishful thinking’ scenario, in which patients in both the real and placebo arms tend to believe that they received real treatment.² If the latter scenario is acceptable, patient blinding appears to be more easily achievable than in the former scenario.

It is difficult to blind participants successfully in an acupuncture trial and this needs to be taken into consideration when assessing the efficacy of blinding in acupuncture research. In particular, it is difficult to blind studies when the number of needles per treatment, the number of treatments and the depth of needle insertion are increased. Needless to say, imperfect or partial blinding can be better than no blinding at all; therefore we would recommend that placebo/sham needles are used in clinical trials and that the level of blinding success is carefully evaluated.²

**Nobuari Takakura,^{1,2} Miho Takayama,^{1,2}
Masako Nishiwaki,¹ Hiroyoshi Yajima^{1,2}**

¹Department of Acupuncture and Moxibustion, Tokyo Ariake University of Medical and Health Sciences, Tokyo, Japan

²Department of Physiology, Showa University School of Medicine, Tokyo, Japan

Correspondence to Dr Nobuari Takakura, Department of Acupuncture and Moxibustion, Faculty of Health Sciences, Tokyo Ariake University of Medical and Health Sciences, 2-9-1 Ariake, Koto-ku, Tokyo 135-0063, Japan; takakura@tau.ac.jp

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Competing interests NT and the educational foundation of Hanada Gakuen possess a U.S. patent 6575992B1, a Canadian patent CA 2339223, a Korean patent 0478177, a Taiwan patent 150135, a Chinese patent ZL00800894.9 (Title: Safe needle, placebo needle, and needle set for double blind) and two Japanese patents 4061397 (Title: Placebo needle, and needle set for double blinding) and 4315353 (Title: Safe needle) on the needles described in this manuscript. NT is a salaried employee of the educational foundation of Hanada Gakuen.

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