

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 of acupuncture should be employed

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

			Study I ³		Study II ⁴	Study III ⁵	Study IV ⁶	Study V ⁷		
			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	Total	
Study			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		

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

Nobuaki 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 Nobuaki 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

Acknowledgements This work was supported by funding from the Japan Society for the Promotion of Science (JSPS) KAKENHI Grant numbers JP15K08938 and JP16K09266 (Japan).

Contributors NT, MT, MN and HY drafted the manuscript.

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.

Provenance and peer review Not commissioned; internally peer reviewed.

© Article author(s) (or their employer(s) unless otherwise stated in the text of the article) 2017. All rights reserved. No commercial use is permitted unless otherwise expressly granted.



To cite Takakura N, Takayama M, Nishiwaki M, *et al.* *Acupunct Med* Published Online First: [please include Day Month Year]. doi:10.1136/acupmed-2017-011430

Accepted 7 August 2017

Acupunct Med 2017;**0**:1–2.
doi:10.1136/acupmed-2017-011430

REFERENCES

- Zhang CS, Tan HY, Zhang GS, *et al.* Placebo devices as effective control methods in acupuncture clinical trials: a systematic review. *PLoS One* 2015;10:e0140825.
- Moroz A, Freed B, Tiedemann L, *et al.* Blinding measured: a systematic review of randomized controlled trials of acupuncture. *Evid Based Complement Alternat Med* 2013;2013:1–12.
- Takakura N, Yajima H. A double-blind placebo needle for acupuncture research. *BMC Complement Altern Med* 2007;7:31.
- Takakura N, Yajima H. A placebo acupuncture needle with potential for double blinding - a validation study. *Acupunct Med* 2008;26:224–30.
- Takakura N, Takayama M, Kawase A, *et al.* Double-blind acupuncture needling: does patient reaction reveal needle authenticity? *Med Acupunct* 2008;20:169–74.
- Takakura N, Takayama M, Kawase A, *et al.* Double-blind acupuncture needle: a potential tool to investigate the nature of pain and pleasure. *ISRN Pain* 2013;2013:1–4.
- Vase L, Baram S, Takakura N, *et al.* Can acupuncture treatment be double-blinded? An evaluation of double-blind acupuncture treatment of postoperative pain. *PLoS One* 2015;10:e0119612.



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

Nobuari Takakura, Miho Takayama, Masako Nishiwaki and Hiroyoshi Yajima

Acupunct Med published online August 23, 2017

Updated information and services can be found at:

<http://aim.bmj.com/content/early/2017/08/23/acupmed-2017-011430>

These include:

References

This article cites 6 articles, 1 of which you can access for free at:

<http://aim.bmj.com/content/early/2017/08/23/acupmed-2017-011430#ref-list-1>

Email alerting service

Receive free email alerts when new articles cite this article. Sign up in the box at the top right corner of the online article.

Notes

To request permissions go to:

<http://www.bmj.com/company/products-services/rights-and-licensing/>

To order reprints go to:

<http://journals.bmj.com/content/subscribers>

To subscribe to BMJ go to:

<http://group.bmj.com/subscribe/>