

# Minimal Clinically Important Difference in Patients with Acute Neck Pain Undergoing Conservative Treatment with Korean Medicine

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**Purpose:** To determine the minimal clinically important difference (MCID) and substantial clinical benefit (SCB) for patients with acute neck pain undergoing conservative treatment.

**Patients and Methods:** This secondary data analysis of a randomized controlled trial investigated 128 individuals with acute neck pain receiving conservative treatment. The MCID and SCB of pain, functional disability, and quality of life were assessed using anchor-based methods. Patients' global impression of changes at week 9 was used as the anchor. A receiver operating characteristic curve was constructed, and the Youden index was employed to determine the optimal cut-off point. Area under the curve (AUC) values were calculated to assess accuracy. Minimal detectable changes (MDCs) were estimated using a distribution-based approach.

**Results:** The study cohort comprised 60.2% female patients with an average age of  $40.7 \pm 12.7$  years. The visual analog scale (VAS) score for pain during movement at baseline was  $64.5 \pm 10.6$ . The outcome measures' estimated MCID values (AUC) were as follows: VAS for pain during movement,  $-19.9$  (0.89) and at rest,  $-17.5$  (0.83); Northwick Park Neck Pain Questionnaire score,  $-14.7$  (0.78); neck disability index,  $-10.6$  (0.77); and physical component summary (PCS),  $2.0$  (0.83). The SCB estimates indicated thresholds of outcome improvement to be 1.5–3-fold higher. The MDC for PCS (9.49) exceeded its MCID and SCB.

**Conclusion:** This study provides estimates for multidimensional MCID and SCB in acute neck pain treated conservatively. These values may assist clinicians in interpreting outcomes and setting meaningful treatment goals in clinical practice.

**Keywords:** acute neck pain, minimal clinically important difference, conservative treatment, disability, quality of life

## Introduction

Neck pain is a common condition and one of the leading contributors to disability worldwide.<sup>1,2</sup> The point prevalence of neck pain per 100,000 population is estimated to be 3551.1. In terms of age and sex patterns, the point prevalence of neck pain is higher in females and increases with age.<sup>2</sup> The highest prevalence is observed in individuals aged 45–54 years.<sup>3</sup> Risk factors for neck pain include psychopathology, lifestyle, and medical history.<sup>4,5</sup> Neck pain can be categorized as acute, sub-acute, or chronic based on the duration of pain. Nearly half of affected individuals develop persistent pain.<sup>4,6</sup> Approaches for treating and managing neck pain include conservative treatment, injections, and surgery.<sup>7</sup> Conservative treatments for neck pain include therapeutic exercise, electrotherapy, medications such as non-steroidal anti-inflammatory drugs (NSAIDs), and acupuncture.<sup>8</sup> In East Asia, particularly in Korea, traditional Korean medicine—including acupuncture, Chuna manual therapy, and pharmacopuncture—is widely used as a conservative treatment for neck pain.<sup>9–11</sup>

Minimal clinically important difference (MCID) and substantial clinical benefit (SCB) have been developed and utilized for evaluating meaningful changes for patients, and there has been growing interest in patient-reported outcome measures in recent years. MCID is defined as the minimal improvement perceived as beneficial by patients, with no side effects and within a cost-effective range,<sup>12</sup> while SCB is defined as a substantial improvement experienced and reported by patients.<sup>13</sup> Anchor-based methods, which use an external reference as an independent measure, are commonly used for calculating MCID and SCB.<sup>14</sup>

Estimating thresholds of improvement perceived and reported by patients based on these approaches can be useful in designing clinical trials, determining sample sizes, interpreting clinical outcomes, and making clinical decisions.

MCID values for conservative treatment for neck pain have mainly been determined based on the numeric rating scale (NRS) for pain and the Neck Disability Index (NDI). MCID estimates were represented in terms of changes in NRS scores (range: 0–10) by 1.5–2.5 points,<sup>15,16</sup> and changes in NDI scores (range: 0–50) by 3.5–7.5 points.<sup>16,17</sup> However, these estimates were obtained from patient populations with chronic neck pain or mixed durations of pain and are not applicable to patients with acute neck pain. There have been only a limited number of studies on the calculation of MCID for patients with acute neck pain.<sup>18</sup> One study conducted in Spain (2008) reported an MCID estimate in terms of changes in NRS score by 0.5 points using an anchor-based method,<sup>15</sup> while another study in the Netherlands (2006) reported an MCID estimate in terms of changes in NDI score by 1.66 points.<sup>19</sup> In the present study, we aim to update findings from previous studies by estimating the MCID and SCB for patients with acute neck pain using an anchor-based method. In addition to outcome measures for pain and functional disability, EuroQol 5-Dimension 5-Level (EQ-5D-5L) and the 12-Item Short-Form Health Survey (SF-12), which are instruments for quality-of-life (QoL) assessment, were used to provide a comprehensive and multidimensional perspective on acute neck pain. We also investigated the responsiveness of measures by assessing the standard error of measurement (SEM) and minimal detectable change (MDC) using a distribution-based approach.

## Methods

### Patient Sample

This study employed secondary analysis of data from a multicenter randomized controlled trial (RCT)<sup>20</sup> to explore the effectiveness of motion-style acupuncture (MSAT) for non-specific acute neck pain. MSAT is an acupuncture method involving active or passive movement stimulation after needle insertion, and its effectiveness has been evaluated in a published RCT for acute low back pain.<sup>21,22</sup>

In the original RCT,<sup>20</sup> A total of 128 patients with acute neck pain were recruited from four hospitals in Korea. The inclusion criteria were individuals experiencing neck pain onset or worsening within the past month, with a Visual Analog Scale (VAS) rating of 5 or higher for neck pain at rest or during movement (flexion, extension, rotation, left and right lateral flexion). Exclusion criteria included neck pain due to specific causes such as trauma, tumors, infections, or inflammatory diseases, as detailed in the original study protocol. Patients were randomized to either MSAT, which involves neck rotations performed with acupuncture needles in place, or standard acupuncture. In both groups, needles were inserted at common points (TE15, SI15, LI16) with manual stimulation to elicit the deqi sensation. The standard acupuncture group additionally received needling at points such as GB20, BL10, and SI14 based on clinical judgement. Each 15 min session was conducted two to three times per week over a two-week period (total of 4–6 sessions), with the frequency adjusted based on pain severity and clinical judgement by the treating physician. All patients signed an informed consent form, and detailed information about the clinical study can be found in the published study protocol.<sup>20</sup> Both intervention arms from the original RCT were included in this secondary analysis. The primary results of the study will be published in a separate paper. The study protocol was approved by the Institutional Review Board of Jaseng Hospital of Korean Medicine (JASENG 2020–07-014, JASENG 2020–07-015, JASENG 2020–07-016, JASENG 2020–07-017). As this analysis used only de-identified data and aligned with the original objectives of the clinical trials, additional institutional review board approval was not required. All investigators were trained to follow the Declaration of Helsinki, the Korean Good Clinical Practice Guidelines, study protocol, and standard operating procedure.

### Measurement

In this study, MCID estimates for outcomes of pain, functional disability, and QoL were measured for patients with acute neck pain. All outcomes were measured as per patient-reported outcomes. These were measured by trained and blinded investigators through interviews with patients. Pain was measured using the VAS.<sup>23</sup> During the pain assessment with VAS, patients were instructed to indicate the level of neck pain on movement and at rest along a continuous line of 100 mm in length, with one end indicating no pain and the other indicating the worst pain imaginable; larger scores on the scale represent greater pain intensity.

Functional disability caused by neck pain was assessed using the Northwick Park Neck Pain Questionnaire (NPQ)<sup>24</sup> and NDI.<sup>25</sup> NPQ is a self-reported questionnaire on the subjective feeling of pain intensity experienced by a patient for neck pain during activities of daily living and the consequent disability. It consists of nine questions in total. Each question is rated on a 5-point scale from 0 to 4, where 4 points indicate the worst pain and disability. The NDI is the most commonly used instrument for assessing disability due to neck pain, and it measures the extent of disability affecting a patient's daily life. It consists of 10 questions in total, and each item of the question is rated on a 6-point scale from 0 to 5, where 5 points indicate the most severe level of disability. NDI and NPQ scores were converted into percentage values with 100 points as the full score. Both instruments have demonstrated adequate reliability and validity in Korean populations.<sup>26,27</sup>

Patient QoL was assessed using the EQ-5D-5L<sup>28</sup> and SF-12 version 2.<sup>29</sup> EQ-5D-5L is used for the assessment of five dimensions—mobility, self-care, usual activities, pain, and anxiety/depression—into five levels. In the present study, the estimates of Korean preference weights for EQ-5D-5L reported in a previous study were applied.<sup>30</sup> SF-12 is a self-reported measure consisting of 12 questions on physical and mental health. In SF-12, weights are applied for conversion into physical component summary (PCS) and mental component summary (MCS) scores. PCS and MCS scores range from 0 to 100, with higher scores indicating higher QoL. The PCS and MCS scores were calculated using PROCORE version 2.1 (©QualityMetric, Inc.) with reference to the US population norms (2009). The Korean validated version of the SF-12 was used in this study.<sup>31</sup>

The Patient Global Impression of Change (PGIC) was used as an anchor for the calculation of MCID and SCB estimates.<sup>32</sup> This instrument measures changes in the overall clinical status perceived by patients as they undergo treatment, and the patients rate their change based on a 7-point single-item scale ranging from “very much worse” to “very much improved”. The response scale used is as follows: 1, very much improved; 2, much improved; 3, minimally improved; 4, no change; 5, minimally worse; 6, much worse; or 7, very much worse. MCID was defined as a threshold value that differentiates between PGIC scores 1–3 (responders) and PGIC scores 4–7 (non-responders). SCB was defined as a threshold value that differentiates PGIC scores 1–2 (responders) from PGIC scores 3–7 (non-responders).

## Statistical Analysis

We used measures at the baseline and 9th week in the analysis. The pain, functional, and QoL outcomes were translated into changes from baseline to the 9th week. The change from baseline in terms of PGIC was also presented.

Missing data at the end of treatment were handled using the method of multiple imputation. Woaye-Hune<sup>33</sup> underlined the necessity for appropriate management of missing data in studies on the estimation of MCID, and the multiple imputation method was used for this purpose. Multiple imputation is a representative method of handling missing data in clinical trials.<sup>34</sup> Procedures of multiple imputation under the missing at random (MAR) assumption enable unbiased imputation for missing values. The procedures of multiple imputation introduced by Van Buuren et al<sup>35</sup> were used to build an imputation model considering missing data patterns, their values, and distribution, and the Markov chain Monte Carlo algorithm was applied to perform multiple imputation. Twenty imputation sets were generated, and estimates were pooled based on Rubin's rule.

The estimates of MCID and SCB were calculated using anchor-based methods. The receiver operating characteristic (ROC) curve was used to estimate the optimal cut-off point to differentiate responses. The ROC curve was constructed based on sensitivity and specificity. The Youden index was used to determine the optimal cut-off point on the ROC curve. The Youden index identifies the threshold that maximizes the sum of sensitivity and specificity, which is the farthest from the diagonal line of the ROC curve. The estimated cut-off point was validated based on the area under the ROC curve (AUC).<sup>36</sup> The confidence interval (CI) of the AUC was estimated with 2000 bootstraps. We determined the estimated threshold to be reliable when the AUC was  $\geq 0.7$  and the lower interval of the CI was  $\geq 0.5$ . MCID and SCB were also estimated according to sex.

A distribution-based approach was applied to estimate the SEM and MDC. SEM was calculated using the formula,  $SD \times \sqrt{(1-r)}$ , where SD denotes the standard deviation of the baseline outcome, and r indicates the test-retest reliability. For the value of r, the intraclass correlation coefficient reported in a previous study was used: VAS: 0.97,<sup>37</sup> NPQ: 0.83,<sup>26</sup> NDI: 0.93,<sup>27</sup> EQ-5D-5L: 0.75,<sup>38</sup> PCS: 0.73; MCS: 0.64.<sup>39</sup> MDC values were calculated as  $1.96 \times \sqrt{2} \times SEM$ .<sup>40</sup> R version 4.1.1 (©The R Foundation for Statistical Computing) was used for our analysis.

## Results

In the present study, data from all 128 enrolled participants were analyzed. **Table 1** presents the baseline characteristics of the participants. Seventy-seven of the participants (60.2%) were female. The mean age of the study population was  $40.7 \pm 12.7$  years, and the BMI was  $23.9 \pm 4.2$ . Radiographic findings showed forward head posture in 105 patients (82.0%), narrowing in 27 patients (21.1%), and degeneration in 8 patients (6.2%). Both groups received nearly the same number of treatments (MSAT group:  $5.5 \pm 0.8$ ; Control group:  $5.5 \pm 1.0$ ). The values of outcome measures at week 9 and representation in terms of change from baseline are presented in [Supplementary Table 1](#).

**Table 2** presents the 9-week changes in outcomes for categories of PGIC. The VAS score for pain during movement decreased by  $30.9 \pm 17.9$  in the minimally improved group of PGIC (48 patients, 37.5%) and by  $12.2 \pm 14.6$  in the no-change group of PGIC (16 patients, 12.5%). The NPQ score decreased by  $12.7 \pm 10.8$  and  $8.3 \pm 9.5$  in each of these groups, respectively, and the NDI score decreased by  $10.1 \pm 9.5$  and  $6.4 \pm 8.4$ , respectively. The EQ-5D value increased by  $0.05 \pm 0.10$  and  $0.03 \pm 0.08$  in each group, respectively; the PCS score increased by  $3.1 \pm 5.1$  and decreased by  $2.1 \pm 5.2$ , respectively. Outcome improvement was consistently greater for patients who reported being “much improved” (37 patients, 28.9%) or “very much improved” (27 patients, 21.1%) compared with those who reported being “minimally improved”.

**Table 3** presents the estimation results of MCID and SCB for each outcome measure: The MCID values of the outcome measures were as follows: the VAS score for pain during movement,  $-19.9$  (AUC: 0.89 [95% CI: 0.81–0.96]); the VAS score of pain at rest,  $-17.5$  (AUC: 0.83 [95% CI: 0.72–0.93]); the NPQ score,  $-14.7$  (AUC: 0.78 [95% CI: 0.66–0.88]); the NDI score,  $-10.6$  (AUC: 0.77 [95% CI: 0.65–0.87]); and the PCS score,  $2.0$  (AUC: 0.83 [95% CI: 0.71–0.92]). The instruments for these outcome measurements showed 1.5- to 3-fold higher thresholds in the estimation of SCB. The reliability in the estimation of SCB for each outcome was similar to that of MCID. Additionally, the reliability in the estimation of SCB increased for EQ-5D-5L (threshold: 0.02; AUC: 0.71 [95% CI: 0.61–0.79]).

In addition to the above analyses, we performed subgroup analyses according to sex (female and male) and age group ( $\geq 40$  and  $< 40$  years). For the VAS score, thresholds with high reliability were obtained for all subgroups. Apart from the PCS, the estimated thresholds were generally higher in female patients than in male patients (female threshold: 0.9, male threshold: 2.1) and in the  $\geq 40$  years age group than in the  $< 40$  years age group (age  $\geq 40$  years threshold: 1.1, age  $< 40$

**Table 1** Baseline Characteristics of Participants

		Total (N = 128)
Sex	Female	77 (60.2)
	Male	51 (39.8)
Age (Years)		$40.7 \pm 12.7$
BMI (kg/m <sup>2</sup> )		$23.9 \pm 4.2$
Time from onset (Days)		$16.5 \pm 7.6$
Straight neck*		105 (82.0)
Narrowing*		27 (21.1)
Degeneration*		8 (6.2)
VAS for pain in movement		$64.5 \pm 10.6$
VAS for pain in rest		$52.3 \pm 16.7$
NPQ		$40.2 \pm 10.5$
NDI		$32.3 \pm 10.7$
EQ-5D-5L		$0.76 \pm 0.10$
PCS		$44.6 \pm 6.6$
MCS		$46.5 \pm 10.3$

**Notes:** Baseline characteristics are presented with mean  $\pm$  SD and number (percentage). \*Radiographic findings were determined by X-ray.

**Abbreviations:** VAS, Visual Analogue Scale; NPQ, Northwick Park Neck Pain Questionnaire; NDI, Neck Disability Index; EQ-5D-5L, EuroQoL 5-Dimension 5-Level; PCS, Physical Component Summary; MCS, Mental Component Summary.

**Table 2** Mean Changes in Outcomes by Response to PGIC

	N	VAS for Pain at Movement	VAS for Pain at Rest	NPQ	NDI	EQ-5D-5L	PCS	MCS
Very much improved	27	-54.1 ± 15.8	-41.5 ± 20.3	-31.7 ± 9.6	-26.4 ± 10.9	0.13 ± 0.10	9.8 ± 7.9	7.8 ± 11.5
Much improved	37	-48.1 ± 15.5	-43.0 ± 20.1	-25.8 ± 13.4	-21.2 ± 12.5	0.10 ± 0.11	6.1 ± 6.8	5.7 ± 9.1
Minimally improved	48	-30.9 ± 17.9	-25.0 ± 18.2	-12.7 ± 10.8	-10.1 ± 9.5	0.05 ± 0.10	3.1 ± 5.1	2.8 ± 8.8
No change	16	-12.2 ± 14.6	-10.2 ± 17.1	-8.3 ± 9.5	-6.4 ± 8.4	0.03 ± 0.08	-2.1 ± 5.2	2.6 ± 6.5

**Notes:** Changes from baseline in outcomes were presented by PGIC. A negative value represents a decrease in pain and disability, whereas a positive represents an improvement in quality of life. The changes from baseline were presented as mean ± standard deviation.

**Abbreviations:** PGIC, Patient Global Impression of Change; VAS, Visual Analogue Scale; NPQ, Northwick Park Neck Pain Questionnaire; NDI, Neck Disability Index; EQ-5D-5L, EuroQoL 5-Dimension 5-Level; PCS, Physical Component Summary; MCS, Mental Component Summary.

**Table 3** Estimated MCID and SCB

	Threshold	Specificity	Sensitivity	AUC
<b>MCID</b>				
VAS for pain at movement	-19.9	0.87	0.85	0.89 (0.81–0.96)*
VAS for pain at rest	-17.5	0.78	0.84	0.83 (0.72–0.93)*
NPQ	-14.7	0.69	0.87	0.78 (0.66–0.88)*
NDI	-10.6	0.70	0.77	0.77 (0.65–0.87)*
EQ-5D-5L	0.06	0.48	0.86	0.66 (0.46–0.80)
PCS	2.0	0.70	0.91	0.83 (0.71–0.92)*
MCS	3.3	0.55	0.73	0.57 (0.47–0.70)
<b>SCB</b>				
VAS for pain at movement	-33.2	0.84	0.67	0.83 (0.76–0.90)*
VAS for pain at rest	-34.0	0.71	0.76	0.79 (0.71–0.87)*
NPQ	-19.4	0.83	0.80	0.84 (0.77–0.91)*
NDI	-14.3	0.82	0.73	0.83 (0.75–0.90)*
EQ-5D-5L	0.02	0.81	0.54	0.71 (0.61–0.79)*
PCS	6.4	0.59	0.85	0.73 (0.64–0.82)*
MCS	4.5	0.55	0.66	0.61 (0.51–0.71)

**Notes:** The threshold for MCID and SCB was estimated with receiver operating characteristic (ROC) curve. A negative value represents a decrease in pain and disability, whereas a positive represents an improvement in quality of life. AUC was presented with 95% confidence interval. \* AUC's point estimate > 0.7 or higher, and confidence interval's lower bound > 0.5 or higher.

**Abbreviations:** MCID, Minimal Clinically Important Difference; SCB, Substantial Clinical Benefit; AUC, Area Under the Curve; VAS, Visual Analogue Scale; NPQ, Northwick Park Neck Pain Questionnaire; NDI, Neck Disability Index; EQ-5D-5L, EuroQoL 5-Dimension 5-Level; PCS, Physical Component Summary; MCS, Mental Component Summary.

years threshold: 2.5) ([Supplementary Tables 2–1](#) and [Supplementary Table 2–2](#)). The calculated SEM and MDC values are presented in [Supplementary Table 3](#). The absolute value of MDC was smaller than MCID and SCB of VAS, NPQ, and NDI, except for EQ-5D-5L, PCS, and MCS.

## Discussion

In this study, MCID and SCB estimates for pain, functional disability, and QoL were calculated and analyzed for 128 patients with acute neck pain. The estimated MCID for the VAS score for neck pain was -19.9 during movement and -17.5 at rest. For functional outcomes, the MCID was -14.7 for the NPQ score and -10.6 for NDI. Regarding QoL, the estimated MCID for the PCS of SF-12 was 2.0. SCB estimates for the respective outcome measures were also obtained, with a high reliability.

Most existing research on MCID values of conservative treatment in patients with neck pain has been conducted on patient populations with chronic pain or mixed populations regarding pain duration. Only two studies have been conducted on patients with acute or subacute pain. Vos et al<sup>19</sup> obtained a threshold estimate for the NDI score (range: 0–50) to be 1.66 for 79 Dutch

patients with acute neck pain. However, the estimated threshold in their study is a minimal detectable change calculated using a distribution-based method. Clinically important differences should primarily be based on thresholds estimated by anchor-based methods, with distribution-based methods used as secondary means to support anchor-based methods.<sup>41</sup> In this study, MCID estimates were calculated using anchor-based methods for a larger number of samples compared to those in the previous study, making the results more relevant for clinical decision-making.

The estimated MCID for the NRS score for pain (scale: 0–10) for 290 Spanish patients reported by Kovacs et al<sup>15</sup> was 0.5. When the estimates were compared on the same scale, their result was approximately four times smaller than the estimate in this study. It is challenging to pinpoint the exact cause of this difference. The patient population in their study included a higher percentage of women (Kovacs et al:<sup>15</sup> 77.5%; our study: 60.2%) and older patients (Kovacs et al:<sup>15</sup> 54.1%; our study: 40.7%) and reported more severe pain intensity (NRS [0 to 10] in Kovacs et al:<sup>15</sup> 7.2; VAS for pain during movement [0 to 100] in our study: 64.5). However, there is no evidence that this level of difference in age and pain intensity could have led to such a remarkable difference in MCID estimation. Alternatively, the difference may be attributable to ethnicity. Pain sensitivity varies depending on the ethnicity of the patient population,<sup>42–44</sup> and several previous studies have reported high pain sensitivity and low pain threshold among Asians.<sup>43,45,46</sup> In such cases, more substantial clinical improvement may be needed to reduce the pain perceived by the patient below the threshold level. However, there has been a paucity of studies on pain sensitivity conducted for the Asian population,<sup>43</sup> making it difficult to come to a definitive conclusion on this issue.

Furthermore, in the present study, we investigated MCID for QoL using PCS scores. To the best of our knowledge, this is the first MCID research on the QoL of patients with acute neck pain who received conservative treatment. Neck pain is one of the leading causes of disability and compromised QoL.<sup>47–49</sup> The perceived improvement in neck pain by the patients signifies not only an improvement in terms of pain but also in biomechanical performance, activities of daily living, and self-efficacy.<sup>50</sup> In other words, clinical improvement perceived by patients signifies an improvement in QoL, including physical capacity and role participation.<sup>51</sup> Therefore, the findings of this study provide a multidimensional approach to clinical decisions regarding the treatment of neck pain.

This study has some limitations. First, although we validated MCID and SCB based on AUC, MCID and SCB of EQ-5D, MCS and PCS were smaller than MDC. In this case, although patients achieved MCID in QoL, we could not ignore that those achievements were within the measurement errors or chance. Clinicians should fully consider the pain and disability of patients. Second, the sample size in some PGIC categories might be insufficient. In particular, the number of patients reporting no change in the PGIC score outcome was small (12.5%). Previous studies also observed this trend; for example, in the study by Kovacs et al,<sup>15</sup> only 8% of the patients reported no change. Third, patients in the present study were followed up for only 9 weeks. To establish a long-term management plan for neck pain, further studies with long-term follow-up are required. Fourth, in this study, acupuncture and motion-style acupuncture were both administered as conservative treatments. If types of treatment interact with the relationship between clinical outcomes and patient satisfaction, this may influence the generalized interpretation of findings in this study. Finally, pain was considered the primary outcome of the RCT study; therefore, the question in the PGIC specified pain as an example. Thus, patients might respond to the PGIC only based on their pain, not on their overall symptoms.

In conclusion, through measurements and analyses in this study, estimates for multidimensional MCID for conservative treatment in patients with acute neck pain were derived. These findings are expected to serve as useful information in the design of clinical trials and clinical decision-making for pain, disability, and QoL in patients with acute neck pain. To enhance the applicability of these thresholds in clinical settings, future studies should explore their integration with other treatment modalities and consider factors such as patient satisfaction, pain sensitivity, and ethnicity. Furthermore, identifying potential barriers to implementation in real-world practice may enhance their clinical utility. Studies with larger and more diverse populations and longer follow-up periods are warranted to assess long-term effects and generalizability.

## Data Sharing Statement

The datasets generated and/or analyzed during the current study are not publicly available due to the potential identification of individuals, but they can be obtained from the corresponding author upon reasonable request.

## Ethical Considerations

The study protocol was approved by the Institutional Review Board of Jaseng Hospital of Korean Medicine (JASENG 2020-07-014, JASENG 2020-07-015, JASENG 2020-07-016, JASENG 2020-07-017). All investigators were trained to follow the Declaration of Helsinki, the Korean Good Clinical Practice Guidelines, study protocol, and standard operating procedure.

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## Disclosure

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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