Quality assessment of Japanese clinical practice guidelines including recommendations for acupuncture

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ABSTRACT

Background: The quality of clinical practice guidelines (CPGs) should be extensively evaluated. This study aimed to evaluate Japanese CPGs that include recommendations for acupuncture.

Methods: In a literature search, CPGs including recommendations for acupuncture published in Japan until October 2021 were sought. We assessed (1) whether the CPGs were developed in accordance with the Grading Recommendations Assessment, Development and Evaluation (GRADE) system, (2) the quality of the CPGs using the Appraisal of Guidelines for Research and Evaluation (AGREE) II, and (3) whether the strength of the recommendations for acupuncture was consistent with each CPG’s predefined procedure.

Results: Seventeen CPGs including 23 recommendations in total were identified and assessed. (1) Three CPGs were in accordance with the GRADE system. (2) The mean score of overall assessment using AGREE II was 4.5 on a 7-point Likert scale. The mean domain scores were 77% for domain 1 (scope and purpose), 54% for domain 2 (stakeholder involvement), 48% for domain 3 (rigor of development), 78% for domain 4 (clarity of presentation), 20% for domain 5 (applicability), and 51% for domain 6 (editorial independence). (3) The strength of the recommendations for acupuncture in two CPGs was judged to be underestimated. Some of the CPGs contained elementary problems that were not considered in AGREE II.

Conclusion: The methodological quality of Japanese CPGs including recommendations for acupuncture was not necessarily high. Since technical issues exist in each field of therapy, the respective experts should be involved in developing and reviewing CPGs to disseminate accurate health information.

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1. Introduction

Clinical practice guidelines (CPGs) are defined as “statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options.” At present, CPGs are widely used in the field of healthcare as a tool for applying evidence to clinical practice. As of August 2021, the new International Guideline Library of Guideline International Network (GIN) contained around 3000 guidelines that have mostly been developed or endorsed by organizational members of GIN, and a PubMed search also yielded more than 3000 articles including the word “guideline” (filter applied: practice guideline).

The use of trustworthy CPGs can help reduce preventable harm, suboptimal outcomes, and unnecessary costs and may improve the process and structure of care. However, the relationship between adherence to CPGs and improved patient outcomes is debatable. One of the reasons for this discrepancy may be the differences in the quality of CPGs applied in each case and condition. In fact, published CPGs have been systematically evaluated in some countries, and the results of these assessments suggest that there is room for improvement in some aspects, such as relevance for patients, rigor of development, and editorial independence. Therefore, the quality of CPGs should be extensively evaluated by external reviewers.

In Japan, the Ministry of Health and Welfare (present: Ministry of Health, Labour and Welfare) encouraged the development of CPGs in the late 1990s. Seto et al. evaluated CPGs pub-
lished between 2000 and 2014 in Japan, which were developed in accordance with the concept of evidence-based medicine (EBM). They found that CPGs in Japan had been improving generally. However, the quality of those that included recommendations for acupuncture has not been reviewed and evaluated in Japan. From a global perspective, 1311 CPGs or treatment guidelines that recommended using acupuncture for 96 medical conditions were published worldwide between 1991 and 2017. Additionally, in Korea and China, the quality of CPGs that include recommendations for acupuncture has been assessed; however, they are exclusively on Korean Medicine and Traditional Chinese Medicine.6,16

Accordingly, we evaluated the quality of Japanese CPGs regarding modern Western medicine that include recommendations for acupuncture. We also assessed the appropriateness of each recommendation in terms of consistency with a predefined procedure. We believe that this study will verify whether evidence of acupuncture is conveyed correctly to healthcare professionals and medical consumers in Japan through CPGs.

2. Methods

2.1. Sources of CPGs

Japanese CPGs that included recommendations for acupuncture were searched for a presentation at the 9th Japan-Korea Workshop on Acupuncture and EBM in 2018 by Fukazawa et al. They used the Toho University/Ichushi (Japana Centra Revu Medicina) Clinical Practice Guideline Information Database (https://guide.line.jamas.or.jp/), the collection of CPGs in Toho University Medical Media Center, and the Medical Information Network Distribution Service ( Minds) Guideline Library (https://minds.jcqhc.or.jp/) in 2015 and 2018. All CPGs listed in the above sources were checked, and those that included recommendations for acupuncture were selected.

Additionally, we performed this process again in January 2019 and December 2021 to update the list. In the fourth search in December 2021, we also used Amazon.com and related academic societies’ websites because Japanese databases of CPGs might not have been exhaustive enough, and we could not use the Toho University Medical Media Center due to the COVID-19 pandemic. Thus, we collected all CPGs that included recommendations for acupuncture and were published until October 2021 in Japan.

2.2. Inclusion criteria

1. CPGs including recommendations for acupuncture for any disease or condition if available.
2. Japanese-written CPGs that were edited and published in Japan.
3. CPGs of standard therapy in modern Western medicine.
4. Current versions of CPGs if they were revised.

2.3. Exclusion criteria

1. CPGs that did not include the strength of recommendation even if they listed the word “acupuncture.”
2. CPGs limited to traditional, complementary, or alternative therapies.
3. CPGs compiled for patients and not for medical professionals.

2.4. Assessment procedures

2.4.1. Accordance with the GRADE system

The Grading Recommendations Assessment, Development and Evaluation (GRADE) system was developed by the GRADE Working Group to reduce unnecessary confusion arising from multiple systems for grading evidence and recommendations.15 We checked whether the collected CPGs stated that they were developed in accordance with the GRADE system. If the CPGs followed the GRADE System, we evaluated them based on the “Criteria for applying or using GRADE.”20

2.4.2. Assessment using AGREE II

We evaluated the quality of each CPG using the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument.21 AGREE II is a quantitative evaluation tool that assesses the methodological rigor and transparency in guideline development. It comprises 23 items organized within six domains, followed by two global rating items (overall assessment). The six domains are scope and purpose (items 1–3), stakeholder involvement (items 4–6), rigor of development (items 7–14), clarity of presentation (items 15–18), applicability (items 19–21), and editorial independence (items 22–23). All 23 items are rated on a 7-point Likert scale, where 1 indicates “strongly disagree” (no information or very poor reporting) and 7 indicates “strongly agree” (exceptional quality of reporting). In the overall assessment, evaluators rated the overall quality using a 7-point Likert scale and decided whether to recommend use of the guideline.22

In the present study, before starting the evaluation, the evaluators (YO, SM, and HY) met face-to-face and carefully evaluated the quality of one CPG that was not the subject of this project. They subsequently discussed the process of evaluation and reached an agreement on the kind of points to be checked and taken into account. Finally, they evaluated the included CPGs independently and calculated domain scores according to the AGREE II method; domain scores were calculated by summing up all the scores of the individual items in each domain and by scaling the total as a percentage of the maximum possible score for that domain. The scaled domain score (%) was calculated as (obtained score - minimum possible score)/(maximum possible score - minimum possible score) × 100.22

2.4.3. Appropriateness of the strength of recommendations

The three evaluators (YO, SM, HY) independently assessed the following aspects:

1. Whether or not the strength of recommendation for acupuncture was decided in consistency with each CPGs’ predefined procedure
2. Whether or not important evidence, such as published systematic reviews and meta-analyses, had been collected and considered in deciding the strength of recommendation
3. The correctness of the summary and/or texts explaining the recommendation and the relevant evidence

Using an assessment sheet, the evaluators chose an answer of “yes” or “no” for each point of assessment above, and “no” responses were supplemented with specific comments. Disagreements were resolved by consensus through discussions among the three evaluators.

3. Results

We found a total of 17 CPGs including 23 recommendations for acupuncture (Fig. 1). They were published by academic societies of modern Western medicine and healthcare (Table 1).23-39 The definition of evidence level and strength of recommendation varied depending on each CPG included.

3.1. GRADE system

Three CPGs explicitly stated that the guidelines were developed in accordance with the GRADE system, although they actually satisfied at most four of the six items of the “criteria for
stating that the GRADE system was used” suggested by the GRADE Working Group. In contrast, the Clinical Practice Guidelines for Cancer Rehabilitation 2nd Edition did not state the use of the GRADE system, but actually satisfied all six items. Thirteen CPGs were developed in accordance with the domestic Minds Manual for Guideline Development 2007, 2014, 2016, and 2017. The 2014, 2016, and 2017 editions are partially based on the GRADE system. The other three CPGs did not provide information on the type of manuals they were based on (Table 1).

3.2. AGREE II

The mean score was 77% for domain 1 (scope and purpose), 54% for domain 2 (stakeholder involvement), 48% for domain 3 (rigor of development), 78% for domain 4 (clarity of presentation), 20% for domain 5 (applicability), and 51% for domain 6 (editorial independence). The mean score of the overall assessment was 4.5 out of 7. In eight (47%) of the 17 CPGs, the overall assessment score was 4 or less.

Regarding our recommendations for using the guidelines, all CPGs except two (facial palsy and low back pain) were judged as “Yes” or “Yes, with modifications” by two or more evaluators. However, none of the CPGs were judged as “Yes” by all three evaluators (Table 2).

3.3. Recommendations for acupuncture

Table 3 shows the strength of the recommendation for acupuncture in each CPG. We judged two recommendations of two CPGs as underestimated: “Clinical Guidance for Facial Palsy - Bell’s Palsy and Hunt Syndrome,” and “Japanese Orthopaedic Association (JOA) Clinical Practice Guidelines on the Management of Low Back Pain, 2nd Edition.”

The CPGs for facial palsy rated acupuncture as “C2” (“Do not recommend because there is no evidence”) but cited literature showed only limited evidence of efficacy of this treatment. However, based on the predefined criteria of this guideline, we judged that “C1” (“Can be considered to use, but there is not enough evidence”) would have been more appropriate because some positive clinical trials have been published although the quality was not sufficient.

The CPGs for low back pain included a lot of serious misinformation on acupuncture due to errors in literature selection, data extraction, and data input. In brief, wrong numbers were mistakenly inserted into the meta-analysis software (e.g., plus instead of minus); only one randomized controlled trial (RCT) out of the five selected for meta-analysis was on needle-inserting acupuncture (two were on auricular point acupressure, one was on laser acupuncture, and one was on acupressure backrest), etc. These serious errors led to the opposite and incorrect conclusion that acupuncture is not superior to the control groups. Therefore, we judged the CPG as inappropriate and untrustworthy.

Incidentally, the following two CPGs were considered to be underestimating acupuncture in the previous version, but we judged that they were properly corrected in the latest version. The CPGs for chronic headache published in 2013 rated acupuncture for tension-type headache as “Grade C” (“No clear evidence to recommend”). However, the cited literature including a Cochrane systematic review, showed rather clear evidence and supported the use of acupuncture for this condition: for example, “acupuncture could be a valuable non-pharmacological tool in patients with frequent episodic or chronic tension-type headaches.” In the latest version published in 2021, this underestimation for tension-type

![Flow diagram showing the literature search and screening process. CPGs, clinical practice guidelines; Minds, Medical Information Network Distribution Service.](image-url)
headache has been revised to a “Weak recommendation (suggest to use)”. The CPGs for IBS published in 2014 \(^{25}\) rated acupuncture as “Strongly recommend against.” In the latest version, acupuncture is “suggested to be used when a patient does not respond to standard therapies or antidepressant” based on several RCTs and two meta-analyses.\(^{35}\)

4. Discussion

In the present study, we found that the quality of Japanese CPGs including recommendations for acupuncture varies from 2 to 6 in the overall assessment with AGREE II, and only three of the 17 CPGs followed the GRADE system, albeit insufficiently in two. Although 13 of the 17 CPGs stated that they were developed in accordance with the domestic “Minds Manual,” of which the 2014, 2016, and 2017 versions were partially based on the GRADE system (Table 1), it is unclear to what extent the GRADE system is directly reflected in each CPG.

4.1. AGREE II

As for the assessment of each domain of AGREE II, scores regarding Domain 1 (scope and purpose) and Domain 4 (clarity of presentation) were relatively high, while Domain 5 (applicability) score was low. This trend seems common in all CPGs, regardless of whether they pertained to modern Western medicine or complementary medicine.\(^{14,16,17,53}\) (Fig. 2). It should be noted that the assessment using AGREE II is an overall assessment of each CPG and is not necessarily consistent with the validity of the acupuncture section. Moreover, as we have discussed later, both the AGREE and AGREE II instruments focus on the methodological issues relevant to guideline development and reporting, but do not evaluate the clinical appropriateness or validity of the recommendations themselves.\(^{21}\) Therefore, we directly assessed the validity of the recommendations for acupuncture in terms of consistency with each CPG’s predefined procedure and evidence to date.

4.2. Recommendations for acupuncture

The results of this assessment showed an underestimation of the strength of recommendations for acupuncture in two CPGs. Even if they considered safety, costs, availability, and patient preference together, as well as evidence of effectiveness, we believe that at least the recommendation for acupuncture for low back pain is still underestimated, considering Cochrane reviews\(^ {54}\) and CPGs\(^ {55}\) published outside Japan.

From a global viewpoint, recommendations for acupuncture in CPGs are inconsistent, even for the same clinical condition.\(^ {56,57}\) The National Institute for Health and Care Excellence (NICE) in the UK published guidelines (2016) for low back pain and sciatica.\(^ {58}\) It recommended not offering acupuncture in managing these conditions, while the previous (2009) version recommended this therapy for the same condition.\(^ {59}\) One of the reasons for this inconsistency would be a different interpretation of the specific effect of sham needling as a control in RCTs.\(^ {60-64}\) but this issue is not discussed in detail here. We have instead focused on how CPG development groups sometimes exclude acupuncture or evaluate

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### Table 1

Japanese CPGs including recommendations for acupuncture.

| No. | Title of CPG | Year of publication | Organization that developed/published the CPG | System or manual on which the CPG was based\(^ {1}\) |
|-----|--------------|---------------------|-----------------------------------------------|-----------------------------------------------|
| 1   | Clinical Guidance for Facial Palsy -Bell’s Palsy and Hunt Syndrome\(^ {1,23}\) | 2011 | Japan Society of Facial Nerve Research | Unknown |
| 2   | Practical Guideline for Amyotrophic Lateral Sclerosis (ALS) 2013\(^ {14}\) | 2013 | Japanese Society of Neurology | Minds 2007 |
| 3   | Clinical Guidelines for Overactive Bladder Syndrome, 2nd Edition\(^ {15}\) | 2015 | The Japanese Continence Society | Minds 2007, 2014 |
| 4   | Clinical Practice Guidelines for Alopecia Areata\(^ {26}\) | 2017 | Japanese Dermatological Association | Unknown |
| 5   | Clinical Practice Guidelines for Fibromyalgia 2017\(^ {27}\) | 2017 | Japan College of Fibromyalgia Investigation | GRADE, Minds 2014 |
| 6   | Japanese Orthopaedic Association (JOA) Clinical Practice Guidelines on the Management of Low Back Pain, 2nd Edition\(^ {18}\) | 2019 | The Japanese Orthopaedic Association | Minds 2014 |
| 7   | Clinical Practice Guidelines for Non-Odontogenic Toothache Revised edition\(^ {19}\) | 2019 | Japanese Society of Orofacial Pain | Minds 2017 |
| 8   | Japanese Orthopaedic Association (JOA) Clinical Practice Guidelines on the Management of Lateral Epicondylitis, 2nd Edition\(^ {10}\) | 2019 | The Japanese Orthopaedic Association | Minds 2014 |
| 9   | Clinical Guideline for Interstitial Cystitis/Bladder Pain Syndrome\(^ {20}\) | 2019 | The Society of Interstitial Cystitis of Japan | Minds 2007 |
| 10  | Clinical Guidelines for Female Lower Urinary Tract Symptoms 2nd Edition\(^ {22}\) | 2019 | The Japanese Continence Society | Minds 2007, 2014 |
| 11  | Clinical Practice Guidelines for Cancer Rehabilitation 2nd Edition\(^ {13}\) | 2019 | The Japanese Association of Rehabilitation Medicine | Minds 2017 |
| 12  | Clinical Practice Guidelines for the Diagnosis and Management of Tinnitus 2019\(^ {14}\) | 2019 | Japan Audiological Society | Minds 2016 |
| 13  | Evidence-based Clinical Practice Guidelines for Irritable Bowel Syndrome 2020 (2nd Edition)\(^ {23}\) | 2020 | The Japanese Society of Gastroenterology | GRADE |
| 14  | 2020 Evidence-Based Guidelines for Midwifery Care\(^ {26}\) | 2020 | Japan Academy of Midwifery | Unknown |
| 15  | Clinical Practice Guidelines for the Management of Chronic Pain\(^ {17}\) | 2021 | The Committee for Clinical Practice Guideline for the Management of Chronic Pain | Minds 2017 |
| 16  | Japanese Guidelines for the Management of Stroke 2021\(^ {18}\) | 2021 | The Japan Stroke Society | Minds 2017 |
| 17  | Clinical Practice Guidelines for Headache 2021\(^ {19}\) | 2021 | Japanese Society of Neurology | GRADE, Minds 2014 |

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\(^{1}\) Because there was no official English translation, the authors translated the titles into English.

\(^{2}\) GRADE, Grading Recommendations Assessment, Development and Evaluation; Minds, Medical Information Network Distribution Service Manual for Guideline Development 2007,\(^ {40}\) 2014,\(^ {41}\) 2016,\(^ {42}\) or 2017;\(^ {43}\); CPGs, clinical practice guidelines.
Table 2

Scaled domain scores and overall assessments using AGREE II.

| CPGs (Head number corresponds to Table 1) | Scaled domain score | Overall assessments 1 (lowest) – 7 (highest) | Median of three evaluators | Three evaluators' answer to a question "I would recommend this guideline for use" |
|-------------------------------------------|---------------------|-----------------------------------------------|----------------------------|--------------------------------------------------------------------------|
|                                           | Domain 1 (Scope and purpose)  | Domain 2 (Stakeholder involvement)  | Domain 3 (Rigor of development)  | Domain 4 (Clarity of presentation)  | Domain 5 (Applicability)  | Domain 6 (Editorial independence)  |                                           |                                                                 |                                                                 |
|                                           | %                   | %                             | %                             | %                             | %                             | %                             |                                           |                                                                 |                                                                 |
| 1. Facial palsy23                          | 67%                | 43%                           | 11%                           | 69%                           | 1%                            | 0%                            | 2                                           | Yes, with modifications: 1 No: 2                       | Yes: 1                                                                 |
| 2. ALS54                                   | 52%                | 41%                           | 19%                           | 69%                           | 11%                           | 22%                           | 3                                           | Yes, with modifications: 2 Yes, with modifications: 3 |                                                                 |
| 3. Overactive Bladder Syndrome25           | 98%                | 56%                           | 51%                           | 93%                           | 25%                           | 67%                           | 5                                           | Yes, with modifications: 2 Yes, with modifications: 3 |                                                                 |
| 4. Alopecia Areata26                       | 56%                | 37%                           | 49%                           | 87%                           | 14%                           | 75%                           | 6                                           | Yes, with modifications: 2 Yes, with modifications: 3 |                                                                 |
| 5. Fibromyalgia27                          | 94%                | 83%                           | 67%                           | 93%                           | 19%                           | 64%                           | 5                                           | Yes, with modifications: 2 Yes, with modifications: 1 No: 2 |                                                                 |
| 6. Low Back Pain16                         | 74%                | 44%                           | 62%                           | 80%                           | 36%                           | 56%                           | 2                                           | Yes, with modifications: 1 Yes: 2                    |                                                                 |
| 7. Non-Odontogenic Toothache16             | 87%                | 57%                           | 47%                           | 76%                           | 31%                           | 89%                           | 6                                           | Yes, with modifications: 1 Yes, with modifications: 3 |                                                                 |
| 8. Lateral Epicondylitis10                 | 72%                | 30%                           | 50%                           | 72%                           | 19%                           | 61%                           | 4                                           | Yes, with modifications: 1 Yes: 1                    |                                                                 |
| 9. Interstitial Cystitis/Bladder Pain Syndrome11 | 67%                | 56%                           | 36%                           | 72%                           | 18%                           | 33%                           | 4                                           | Yes, with modifications: 2 Yes: 1                    |                                                                 |
| 10. Female Lower Urinary Tract Symptoms15  | 83%                | 61%                           | 30%                           | 76%                           | 19%                           | 36%                           | 4                                           | Yes, with modifications: 2 Yes: 2                    |                                                                 |
| 11. Cancer Rehabilitation13               | 80%                | 70%                           | 76%                           | 83%                           | 31%                           | 44%                           | 6                                           | Yes, with modifications: 2 Yes, with modifications: 1 No: 1 |                                                                 |
| 12. Tinnitus14                            | 89%                | 65%                           | 47%                           | 80%                           | 17%                           | 78%                           | 5                                           | Yes, with modifications: 1 Yes: 2                    |                                                                 |
| 13. IBS15                                  | 76%                | 57%                           | 63%                           | 80%                           | 28%                           | 69%                           | 5                                           | Yes, with modifications: 1 Yes: 2                    |                                                                 |
| 14. Midwifery Care16                       | 91%                | 44%                           | 28%                           | 63%                           | 13%                           | 28%                           | 4                                           | Yes, with modifications: 2 Yes: 1                    |                                                                 |
| 15. Chronic Pain17                         | 72%                | 67%                           | 72%                           | 78%                           | 17%                           | 50%                           | 6                                           | Yes, with modifications: 1 Yes: 1                    |                                                                 |
| 16. Stroke18                               | 81%                | 59%                           | 49%                           | 76%                           | 13%                           | 36%                           | 4                                           | Yes, with modifications: 1 Yes: 2                    |                                                                 |
| 17. Headache19                             | 74%                | 56%                           | 56%                           | 76%                           | 24%                           | 64%                           | 6                                           | Yes, with modifications: 1 Yes: 2                    |                                                                 |
| **Mean (95% CI)**                          | **77%**            | **54%**                        | **48%**                        | **78%**                        | **20%**                        | **51%**                        | **4.5 (3.8–5.2)**                               |                                                                 |                                                                 |

AGREE II, Appraisal of Guidelines for Research and Evaluation II; CPGs, clinical practice guidelines; ALS, amyotrophic lateral sclerosis; IBS, irritable bowel syndrome; CI, confidence interval.

Fig. 2. Comparison of each Appraisal of Guidelines for Research and Evaluation (AGREE) II or I domain score among the four studies. * The study by Seto et al.18 used AGREE I, not II.
Table 3
Strength of recommendations for acupuncture in the Japanese CPGs.

| Guidelines (Head number corresponds to Table 1) | Strength of recommendation on acupuncture | Appropriateness of recommendation based on independent evaluators’ consensus |
|-----------------------------------------------|------------------------------------------|--------------------------------------------------------------------------------|
| 1. Facial palsy| Grade C2 (out of A to D): do not recommend because there is no evidence | Underestimated |
| 2. ALS | Grade C1 (out of A to D): no firm evidence, but recommend to use for pain | Fair |
| 3. Overactive Bladder Syndrome | Grade C1(out of A to D and I): no firm evidence, but recommend | Fair |
| 4. Alopecia Areata | Grade C2 (out of A to D): recommend not to do | Fair, but should have been classified in "I" (inconclusive) if this category existed |
| 5. Fibromyalgia | “Propose to do” (less than “strongly recommend”) | Fair |
| 6. Low Back Pain | No recommendation because of no evidence | Underestimated (for the details, see text) |
| 7. Non-Odontogenic Toothache | No recommendation because of no evidence | Fair |
| 8. Lower Epicondylitis | Inconclusive because of no evidence | Fair |
| 9. Interstitial Cystitis/Bladder Pain Syndrome | Grade C1 (out of A to D and I): no firm evidence, but recommend | Fair |
| 10. Female Lower Urinary Tract Symptoms | Grade C1 (out of A to D and I): no firm evidence, but recommend | Fair |
| 11. Cancer Rehabilitation | Grade B2: weak recommendation (to use) | Fair |
| 12. Tinnitus | Grade D2: weak recommendation (NOT to use) | Fair |
| 13. IBS | Weak recommendation (to use) | Fair |
| 14. Midwifery Care | Inform that acupuncture can be an option of relieving pains of the delivery | Fair |
| 15. Chronic Pain | Inform that acupuncture can be an option of accelerating labor. | Fair |
| 16. Stroke | Recommend not to perform for induction of labor | Fair |
| 17. Headache | Recommended for complex regional pain syndromes, in conjunction with training | Fair |

CPGs, clinical practice guidelines; ALS, amyotrophic lateral sclerosis; IBS, irritable bowel syndrome.

acupuncture in inappropriate ways with possible biases. As Birch et al. suggested, when developing CPGs that review the evidence for acupuncture, an expert in acupuncture should be involved. To our knowledge, experts of acupuncture were included as members of the development groups in only two published CPGs in Japan: the Clinical Practice Guidelines for Fibromyalgia 2017, in which acupuncture use was proposed, and the Clinical Practice Guidelines for the Management of Chronic Pain. 47

4.3. Issues to be solved in some CPGs

In the present study, some of the CPGs published in Japan had elementary problems, such as failure to comply with predefined procedures/classification, inadequate literature search and selection for clinical evidence, and erroneous data extraction/analysis. Such errors are not taken into account in AGREE II, which we used to evaluate CPGs. In fact, the CPGs for low back pain obtained relatively high scores (i.e., higher than the mean score in four out of six domains; see Table 2) despite the many errors described above. AGREE instruments are commonly used in the assessment of methodological quality of CPGs, and do not evaluate the clinical appropriateness or validity of the recommendations themselves. Therefore, to assess the trustworthiness of CPGs, it is necessary to use several different tools, in addition to AGREE II, to evaluate from multifaceted perspectives.

One of the most serious problems was that only four (for fibromyalgia, cancer rehabilitation, chronic pain, and headache) of the 17 CPGs had an independent systematic review team, and only six (for alopecia areata, fibromyalgia, non-odontogenic toothache, interstitial cystitis/bladder pain syndrome, female lower urinary tract symptoms, and headache) clearly stated that they set up an independent external review committee, which are considered essential. Such circumstances might contribute to serious errors, which can destroy the overall credibility of CPGs published in Japan. Therefore, this problem needs to be solved as soon as possible. Periodical and continuous external review is necessary after publication.

4.4. Limitations

The present study had some limitations. First, we attempted to identify all Japanese CPGs including recommendations for acupuncture, but there may have been some CPGs whose information had not been included in the Toho University/Ichushi Clinical Practice Guideline Information Database, Minds Guideline Library, or on Amazon.com. We should make an effort to collect such missing CPGs by means of hand search in the future. Second, although we believe that the three evaluators reached a certain degree of uniformity in the evaluation using AGREE II through prior simulation, it is not clear whether there is external validity. However, because we used AGREE II mainly for assessing the relative comparison among the six domains, this issue would not affect the interpretation of the present results.

4.5. Conclusion

In conclusion, the overall methodological quality of Japanese CPGs including recommendations for acupuncture was not necessarily high. Some CPGs have incorrect or inappropriate recommendations due to underestimation in light of the available evidence, noncompliance with predefined procedures/classification, inadequate literature search and selection for clinical evidence, and/or erroneous data extraction/analysis. The absence of acupuncture experts, independent systematic review teams, and independent external review committees seem to be the main background of these problems, which should be addressed in the future.
Although we focused on acupuncture in the present study, there may be the similar problems in recommendations for other therapies that are not well recognized by the majority of healthcare professionals. Apart from the elementary problems discussed above, unique technical issues that only experts recognize and understand in each field of therapy might exist, like controversy over the unique needle sensation called “Deqi”6,7 and the specific effect of sham needling in acupuncture RCTs.60–64 Experts in the respective fields of therapies should be aware of this possibility and continuously review the relevant published CPGs for the dissemination of accurate health information.

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CRediT authorship contribution statement

Yuse Okawa: Investigation, Conceptualization, Formal analysis. Data curation, Writing original draft, Writing review & editing. Hitoshi Yamashita: Investigation, Conceptualization, Formal analysis, Data curation, Writing original draft, Writing review & editing. Shoko Masuyama: Conceptualization, Writing review & editing. Yohji Fukazawa: Investigation, Writing review & editing. Ikuro Wakayama: Investigation, Writing review & editing.

Conflict of interest

Hitoshi Yamashita is an editorial board member of this journal, but the editorial board member status has no bearing on editorial consideration. The authors have no other conflict of interest to declare.

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Ethical statement

No ethical approval was required as this study did not involve human participants or laboratory animals.

Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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