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Systematic Review

Trends in the design quality of randomized clinical trials on acupotomy over the past 21 years and influencing factors: a CONSORT-based systematic review from 2003 to 2024

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ABSTRACT

Introduction Acupotomy is an innovative combination of acupuncture with surgical treatment that is widely used for pain-related conditions. There has been an increasing number of randomized controlled trials (RCTs) in acupotomy, their design and reporting quality remain inconsistent. Additionally, these RCTs have not been systematically evaluated in accordance with the Consolidated Standards for Reporting of Trials (CONSORT) framework. **Methods** A systematic search was performed in China National Knowledge Infrastructure (CNKI) and PubMed until January 2024 to identify eligible acupotomy RCTs using keywords related to "Acupotomy" and "RCT." Each study was assessed based on the 2010 CONSORT guidelines. Descriptive statistics, nonparametric tests, and regression analyses were conducted to compare the quality scores and examine potential influencing factors. **Results** We included 141 studies; among them, 93 and 48 RCTs were from the CNKI and PubMed, respectively. The mean quality scores of CNKI- and PubMed-indexed RCTs were 42.5 (median, 42; range, 24–74) and 53.4 (median, 49; range, 33–82). Further, the mean scores of each item and proportion of studies with excellent scores were higher in PubMed-indexed studies than in CNKI-indexed studies (2.1, 41.1% *vs.* 1.7, 32.3%). Among the 25 items, PubMed-indexed RCTs had higher scores in 23 (92%) items, with 13 items showing significant differences. Regarding the impacting factors, the number of authors, sample size, and funding were correlated with nine, four, and nine items, respectively. There were no significant differences among hospitals at different levels. The municipal gross domestic product per capita positively affected the total score. **Conclusions** The quality of RCTs on acupotomy has improved over two decades. Domestic articles covered a broader regional scope, while international trials demonstrated better adherence to the CONSORT guidelines. These findings highlight the need to improve awareness regarding trial design, ensure adherence to reporting standards, and support research teams through training and funding.

KEYWORDS

acupotomy, randomized controlled trial, quality evaluation of design, CONSORT, traditional Chinese medicine

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1. Introduction

Acupotomy is an innovative needling technique rooted in traditional Chinese medicine (TCM) that integrates acupuncture with microinvasive surgical principles.[1] It involves the use of a blade needle combined with a flat surgical scalpel at the needle tip.[2,3] By stripping adhesions and releasing deep soft tissue contractures through a flat knife tip,[4] acupotomy is widely used to treat musculoskeletal pain, soft tissue injuries, and bone hyperplasia such as knee osteoarthritis.[4-6]

Acupotomy is gaining increasing attention as a modern extension of acupuncture, which is a widely recognized complementary and alternative medicine (CAM) therapy.[7] Acupotomy has demonstrated effectiveness in improving pressure-pain thresholds and reducing inflammatory factors.[8,9] Acupotomy was initially derived from nine needles recorded in the *Spiritual Pivot* (*Ling Shu*),[10] with subsequent refinement by Prof. Han-zhang Zhu in 1976.[11,12] Its alternative names include acupotomology, acupotome, needle knife, needle scalpel, miniscalpel, stiletto needle, sword-like needle, mini needle knife, and xiaozhendao.[13] Despite its promise as a novel alternative to nonpharmacologic interventions[14], its clinical effectiveness and safety remain unclear, which impedes its continued development.[15,16]

Randomized controlled trials (RCTs) are the gold standard for evaluating and efficiently translating research data into clinical practice.[17] Given the requirement of extensive patient data to identify modest between-treatment differences, a well-designed and rigorously conducted RCT may yield the most valid and precise scientific evidence.[18] Therefore, RCTs can adequately assess the efficacy of an intervention.[19] There have been recent RCTs on the efficacy of acupotomy against specific pain types or diseases, including lumbar spinal stenosis and cervical spondylosis.[20,21]

However, methodological rigor and reporting quality are critical determinants of the quality of RCTs.[22] To this point, some RCTs had low quality and insufficient reporting of adverse events,[23] which poses risks to evidence-based practice.

To increase trial utility, replicability, and transparency,[24] the Consolidated Standards for Reporting of Trials (CONSORT) statement was developed,[17] which has been endorsed academically,[25,26] and is widely recognized internationally.[27,28] The CONSORT statement stipulates the standards for trial design, data analysis, and result interpretation.[29] It is a 25-item checklist for guiding the design and reporting of RCTs.[30] However, the adoption of the CONSORT statement was relatively late in China,[31,32] with only a few Chinese medical journals recommending its use.[33] Accordingly, this topic has been increasing attention.[34-36]

Most clinical studies on acupotomy have focused on systematic reviews and meta-analyses of RCTs, with only few assessing CONSORT compliance.[37] Therefore, we aimed to assess the design quality of RCTs on acupotomy based on the CONSORT 2010 statement, observe developmental trends, and

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identify major influencing factors.

2. Methods

This systematic review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement. The study protocol was prospectively registered at the Centre for Open Science's Open Science Framework Registry (doi.org/10.17605/-OSF.IO/N85VX).

2.1. Eligibility criteria

We only included RCTs involving human participants, with no language restrictions. Acupotomy can be performed alone or in combination with drugs or other therapeutic agents. There were no restrictions on the acupotomy technique or type (traditional, point, and other new types).

We excluded studies involving needle-knife fistulotomy (NK-F), as well as draft study protocols, case-control studies, follow-up studies of previously published trials, systematic reviews, meta-analyses, and non-completed studies. Additionally, we excluded several clinical trials from the China National Knowledge Infrastructure (CNKI) that did not meet the blinding, control, or randomization requirements.

2.2. Search strategy

We included all RCTs regarding the efficacy of acupotomy in the PubMed and CNKI databases that were published until January 2024. We applied all keywords regarding "Acupotomy" and "RCT", including acupotomology, needle knife, and the transliterated term "xiaozhendao." Appendix 1 shows the search strategy.

2.3. Selection process

Study eligibility was determined using a multistep screening process. Initially, the article titles were reviewed, followed by the abstracts and, ultimately, the full texts. Three researchers (JJL, YTZ, and XZL) conducted independent searches using specific terms and cross-verified the results to ensure consistency. The final list of included articles was determined through consensus in group meetings.

2.4. Data collection

Included articles were evaluated using the revised CONSORT 2010 checklist, CONSORT interpretation guidance document, and cited examples. Appendix 2 presents the CONSORT 2010 checklist and its details. Initially, we attempted to apply the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA), which is a specialized guideline for acupuncture trials.[38,39] However, its focus is limited to details regarding the intervention measures, including needle specifications, treatment sites (point selection or depth), treatment dosage (stimulation intensity and retention time), practitioner qualifications, and control measures. Accordingly, we opted to use the CONSORT statement since interventions are considered within the CONSORT items.

2.5. Synthesis methods

Since the 25 CONSORT items are not assigned weights.[40,41] we assigned each item with four points (total: 100 points) based on the relevant research literature. Among the 25 items, 12 are divided into two sub-items. The remaining 13 items were assigned four points for adequate reporting, two points for inadequate reporting or only mentioning, and zero points for missing items. The 12 items with sub-items were assigned two points for each sub-item, one point for inadequate reporting or mentioning only, and 0 points for missing items. The sum of the two sub-items was determined to be the score for the parent item.[42]

An item was considered adequately reported if it was explicitly detailed and included in the required structural subdivisions. If the content was sufficient but appeared in a non-standard structure, the report was considered insufficient or only mentioned. Additionally, the setting location for data collection in item 4b was only considered adequate if the content was included but was not limited to the hospital, department, time of collection, or time of treatment. Item 15 required a table of baseline data for participants in the results section; however, if this table was only included in the methods section, the reporting was considered inadequate.

Three researchers independently evaluated 141 studies. They were professionals from the University of Macau with backgrounds in medical administration and training in RCT assessment using the CONSORT checklist. The definition of each checklist item was discussed and agreed upon before data extraction. The full text of each RCT was independently assessed by an evaluator. In case of low inter-assessor concordance, a fourth professional assessor was introduced to further assess the full text, with the score being determined through consultation among all four reviewers (YB).

2.6. Data items

In addition, we extracted the following data: year of publication, sample size, number of authors, hospital level, number of established beds, foundation support for the study, and regional municipal gross domestic product (GDP) per capita value (Chinese Yuan, CNY) for the publication year (the publication region was determined based on the address of the first author's institution). We systematically investigated the influence of these factors on RCT quality across the three levels. At the micro level, the publication year may reflect the evolution of academic standards, while sample size is linked to statistical power and indicates the scale of the study and medical resource investment. At the meso level, the hospital grade and number of established beds serve as tangible indicators of the institutional scale, which reflect the hospital's research capacity and resources. At the macro-level, funding support typically involves rigorous peer review, which often mandates a more stringent research design. Finally, the regional GDP per capita captures a broader economic context, with influencing factors including research investment, talent attraction, academic exchange, and healthcare resource availability.

2.7. Statistical analysis

All data were collected using an extraction form. Descriptive statistics were performed using Microsoft Excel 2007 (Microsoft Corporation, Redmond, WA) and SPSS 29 (International Business Machines Corporation, Armonk, NY). Statistical significance was set at $P < 0.05$.

Cohen's kappa was used to assess the inter-assessor agreement for each CONSORT item. Kappa values of 0.6–0.8 and >0.8 were considered to indicate substantial and almost perfect agreement, respectively.

For the linear regression analysis, the date of study publication and the GDP per capita (CNY) of the hospital's city were used as independent variables, while the total score was used as the dependent variable. Additionally, we assessed the correlation of the reporting quality with the number of beds, number of authors, and sample size. A nonparametric test was used to explore the impact of other factors on each item and total score.

3. Results

An initial literature search identified 1483 studies published between October 1994 and January 2024. After screening the titles and abstracts, we excluded 32 and 6 studies from PubMed and CNKI, respectively, that were irrelevant (involved cutting techniques such as NK-F) or duplicate articles.

After full-text screening the remaining 1445 articles, we excluded 1291 articles from CNKI that did not meet the conditions of randomization, control, or blinding. Additionally, six articles from PubMed were excluded based on their failure to meet the inclusion criteria. Accordingly, we included 93 RCTs from CNKI.[21,43-132] and 48 RCTs from PubMed.[3,47,48,51,52,70,76,123,127,133-159] published between September 2003 and January 2024. Details regarding the excluded articles are presented in the PRISMA flow diagram,[160] which is shown in Figure 1.

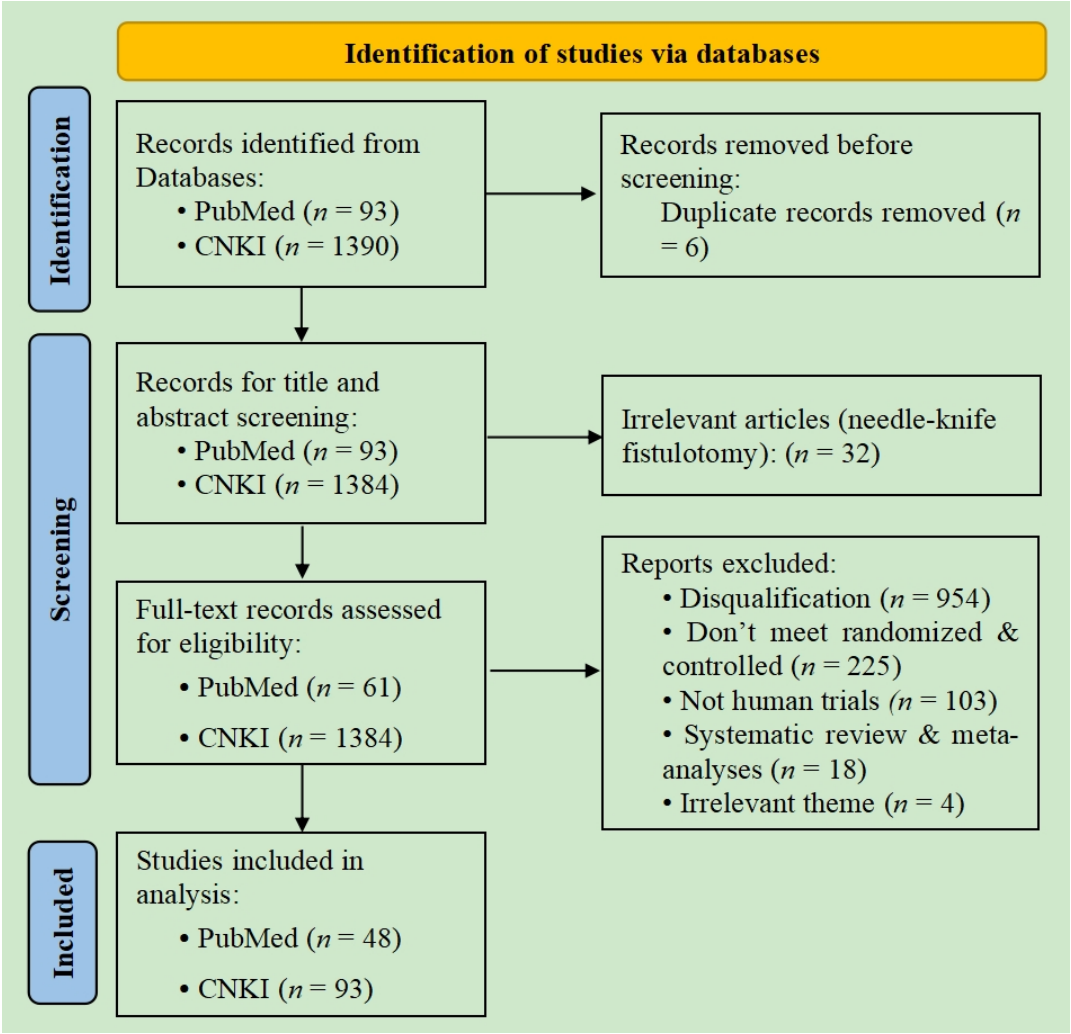

Figure 1 PRISMA flow diagram

Notes: CNKI: China National Knowledge Infrastructure; PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses.

The included RCTs focused on musculoskeletal and connective tissue disorders, which are among the primary application areas for acupotomy. Specifically, there were studies on arthritis (25 articles), cervical spondylosis (23 articles), lumbar disc herniation (17 articles), and lumbar transverse process syndrome (10 articles). Furthermore, numerous studies addressed regional pain and functional impairments, including pain (8 articles), shoulder periarthritis (including frozen shoulder, 6 articles), carpal tunnel syndrome (3 articles), and plantar fasciitis (2 articles). Other studies involved neurological conditions such as cervicogenic vertigo (12 articles), cervicogenic headache (2 articles), neurological dysfunction (4 articles), trigger finger (2 articles), and spasms (1 article). Finally, some studies explored systemic conditions, including hypertension (2 articles), diabetes mellitus (1 article), and obesity (1 article), as well as other localized disorders, such as thyroiditis (1 article), anal fissure (1 article), and dry eye syndrome (2 articles).

3.1. Overall results according to publication year from CNKI and PubMed

As shown in Figure 2, we included 141 studies; among them, 93 and 48 RCTs were from the CNKI and PubMed, respectively. The mean reporting quality scores of RCTs from the CNKI and PubMed were 42.5 (median, 42; range, 24–74) and 53.4 (median, 49; range, 33–82).

Among the 93 CNKI-indexed studies, 6 (6.5%) each had scores >60 and <30. Among the 48 PubMed-indexed studies, 14 (29%) and 0 (0%) studies had scores >60 and <30, respectively.

The quality of reporting improved over time. Specifically, there were correlations between the year of publication and the total reporting score for both CNKI ($t = 4.59$, $P < 0.01$) and PubMed ($t = 6.307$, $P < 0.001$) studies.

3.2. Overall results in different regions from CNKI and PubMed

Table 1 shows the distribution of articles according to reporting quality (scores: 0–30, 30–60, and >60).

Regarding the region of publication, the CNKI articles were sourced from 21 provinces/municipalities/ autonomous regions. Among PubMed-indexed studies, 14 articles (29.2%) from 9 provinces/municipalities/ autonomous regions (47.4%) had scores >60. Furthermore, there were three articles from the South Korea, which all had scores >60. For both databases, most studies were conducted in Beijing and Guangdong. Regarding the article number, CNKI had a wider range of publishing countries. Contrastingly, regarding the article quality, PubMed had a greater proportion of excellent articles.

3.3. Item scores for included CNKI and PubMed-indexed studies

Figure 3 shows the mean scores for each item in either database. Across all 25 items, all included studies showed relatively high scores for items 16 (numbers analyzed), 21 (generalizability), and 5 (interventions), as well as rel-

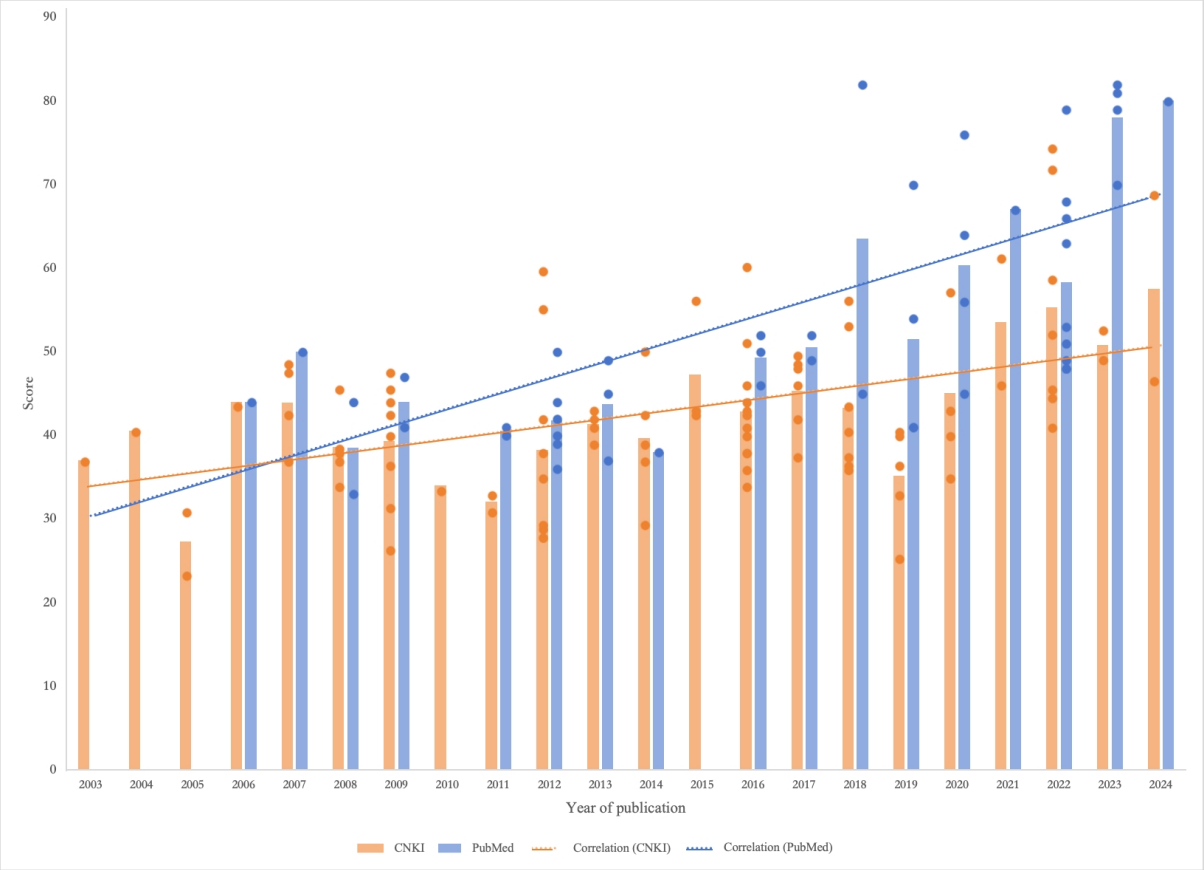

Figure 2 Bar chart with scatter plots of publication year versus reporting quality scores

Notes: CNKI: China National Knowledge Infrastructure.

Table 1 The article numbers and quality between CNKI and PubMed

Database	Provinces/municipalities/ autonomous regions	Amount	Amount proportion	Percentage of score >60
CNKI	Anhui	3	3.2%	100.0%
	Beijing	20	21.5%	95.0%
	Fujian	4	4.3%	100.0%
	Guangdong	12	12.9%	91.7%
	Guangxi	2	2.2%	100.0%
	Guizhou	1	1.1%	100.0%
	Henan	4	4.3%	100.0%
	Hubei	3	3.2%	100.0%
	Hunan	1	1.1%	100.0%
	Jiangsu	6	6.5%	100.0%
	Jiangxi	5	5.4%	100.0%
	Jilin	2	2.2%	0.0%
	Liaoning	3	3.2%	100.0%
	Shandong	1	1.1%	100.0%
	Shanghai	7	7.5%	85.7%
	Shanxi	1	1.1%	100.0%
	Sichuan	8	8.6%	87.5%
	Tianjin	2	2.2%	100.0%
	Xinjiang	2	2.2%	100.0%
	Yunnan	1	1.1%	100.0%
	Zhejiang	5	5.4%	100.0%

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Database	Provinces/municipalities/ autonomous regions	Amount	Amount proportion	Percentage of score >60
PubMed*	Anhui	4	8.3%	100.0%
	Beijing	9	18.8%	100.0%
	Fujian	2	4.2%	100.0%
	Gansu	3	6.3%	100.0%
	Guangdong	5	10.4%	100.0%
	Guangxi	1	2.1%	100.0%
	Hebei	1	2.1%	100.0%
	Henan	1	2.1%	100.0%
	Hubei	1	2.1%	100.0%
	Hunan	2	4.2%	100.0%
	Jiangsu	4	8.3%	100.0%
	Inner Mongolia	1	2.1%	100.0%
	Shandong	3	6.3%	100.0%
	Shanghai	1	2.1%	100.0%
	Sichuan	1	2.1%	100.0%
	Tianjin	1	2.1%	100.0%
	Zhejiang	4	8.3%	100.0%
	Chongqing	1	2.1%	100.0%

Notes: CNKI: China National Knowledge Infrastructure. *In PubMed, the South Korea contributed three articles (6.3%), all of which demonstrated good reporting quality (score >60).

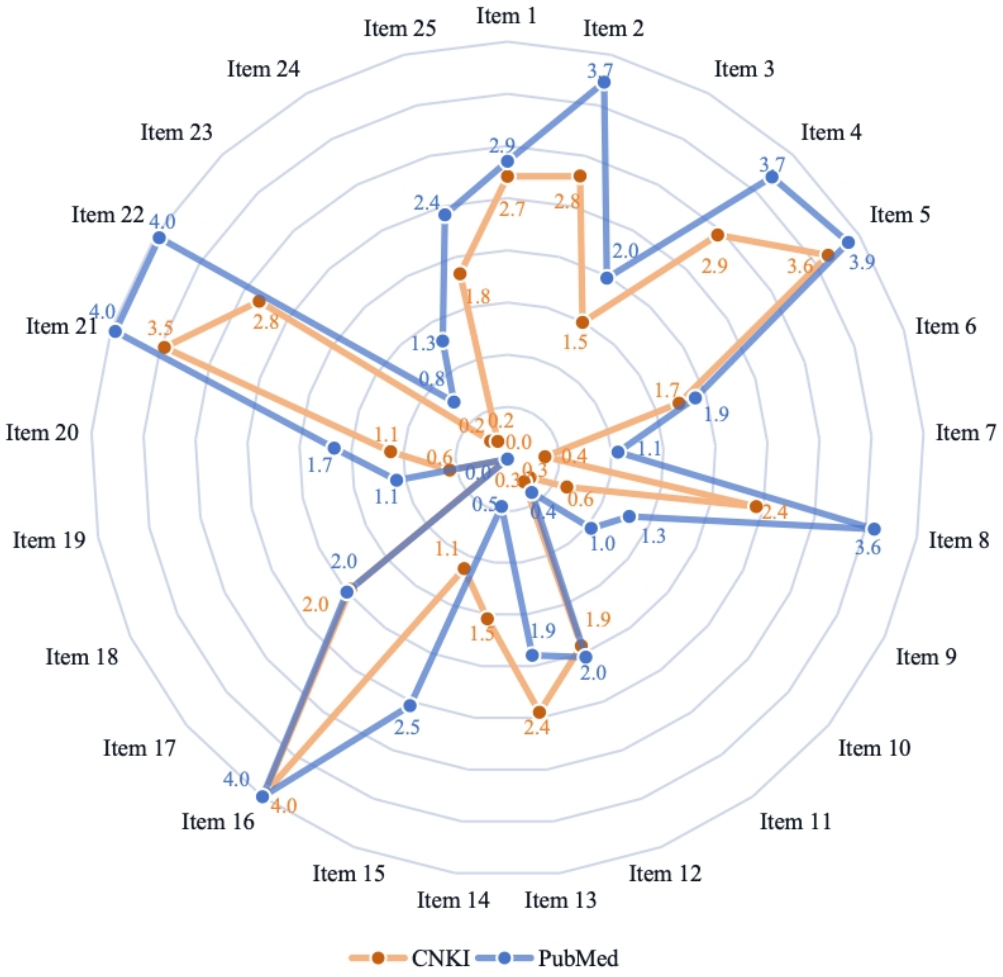

Figure 3 The average scores of the 25 items in the CNKI and PubMed-indexed studies

Notes: CNKI: China National Knowledge Infrastructure.

atively low scores for items 11 (blinding), 18 (ancillary analyses), and 23 (registration). Compared with CNKI-indexed studies, PubMed-indexed studies scored better for 23/25 (92%) items, with the largest between-database differences being observed for items 15 (baseline data) and 22 (interpretation).

As shown in Table 2, 13 items showed significant differences in the non-parametric test. Compared with CNKI-indexed studies, PubMed-indexed studies showed higher scores for items 2 (background and objectives), 3 (trial design), 4 (participants), 7 (sample size), 8 (sequence generation), 10 (implementation), 15 (baseline data), 21 (generalizability), 22 (interpretation), and 24 (protocol), as well as the total score. Contrastingly, CNKI-indexed studies showed higher scores for items 13 (participant flow) and 14 (recruitment) than PubMed-indexed studies.

In addition, we collected the frequencies of excellent (score: 3–4), acceptable (score: 1–2), and failed (score: 0) responses (Table 3).

Table 2 The median and total scores for the 25 items in the CNKI and PubMed-indexed studies

Items	Quality score		Mann-Whitney z	P
	CNKI (n = 93)	PubMed (n = 48)		
Item 1	2.0 (2.0, 4.0)	2.0 (2.0, 4.0)	−0.704	0.481
Item 2	3.0 (2.0, 4.0)	4.0 (3.0, 4.0)	−4.510	<0.001**
Item 3	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−2.483	0.013*
Item 4	3.0 (3.0, 4.0)	4.0 (3.3, 4.0)	−4.490	<0.001**
Item 5	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−1.521	0.128
Item 6	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.707	0.479
Item 7	0.0 (0.0, 1.0)	0.0 (0.0, 2.0)	−3.038	0.002**
Item 8	3.0 (2.0, 3.0)	4.0 (4.0, 4.0)	−5.921	<0.001**
Item 9	0.0 (0.0, 1.0)	0.0 (0.0, 4.0)	−1.746	0.081
Item 10	0.0 (0.0, 0.0)	0.0 (0.0, 2.0)	−2.983	0.003**
Item 11	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−0.315	0.753
Item 12	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−1.770	0.077
Item 13	2.0 (2.0, 3.0)	2.0 (0.0, 4.0)	−2.222	0.026*
Item 14	2.0 (1.0,2.0)	0.0 (0.0, 0.0)	−7.165	<0.001**
Item 15	1.0 (0.0, 2.0)	2.0 (2.0,4.0)	−4.908	<0.001**
Item 16	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−1.020	0.308
Item 17	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−1.195	0.232
Item 18	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−0.718	0.472
Item 19	0.0 (0.0, 1.0)	0.0 (0.0, 2.0)	−1.056	0.291
Item 20	0.0 (0.0, 2.5)	0.0 (0.0, 4.0)	−0.977	0.329
Item 21	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−3.001	0.003**
Item 22	3.0 (3.0, 4.0)	4.0 (4.0, 4.0)	−6.998	<0.001**
Item 23	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.791	0.073
Item 24	0.0 (0.0, 0.0)	0.0 (0.0, 4.0)	−4.122	<0.001**
Item 25	3.0 (0.0, 4.0)	4.0 (0.0, 4.0)	−1.331	0.183
Total score	42.0 (37.0, 47.5)	49.0 (42.5, 65.5)	−4.574	<0.001**

Notes: CNKI: China National Knowledge Infrastructure. Data are expressed as median (interquartile range). Significant differences between CNKI and PubMed for each item and total score are indicated as *P < 0.05 and **P < 0.01.

Table 3 The frequency of items with excellent and acceptable scores in each database

Items	CNKI (n = 93)		PubMed (n = 48)	
	Excellent, n (%)	Acceptable, n (%)	Excellent, n (%)	Acceptable, n (%)
1	36 (38.71%)	56 (60.22%)	21 (43.75%)	27 (56.25%)
2	68 (73.12%)	21 (22.58%)	48 (100.00%)	0 (0.00%)
3	0 (0.00%)	93 (100.00%)	0 (0.00%)	48 (100.00%)
4	84 (90.32%)	8 (8.60%)	46 (95.83%)	2 (4.17%)
5	90 (96.77%)	3 (3.23%)	45 (93.75%)	3 (6.25%)
6	3 (3.23%)	89 (95.70%)	1 (2.08%)	47 (97.92%)
7	2 (2.15%)	22 (23.66%)	5 (10.42%)	17 (35.42%)
8	54 (58.06%)	38 (40.86%)	42 (87.50%)	3 (6.25%)
9	10 (10.75%)	16 (17.20%)	13 (27.08%)	5 (10.42%)
10	3 (3.23%)	15 (16.13%)	7 (14.58%)	12 (25.00%)

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Items	CNKI (n = 93)		PubMed (n = 48)	
	Excellent, n (%)	Acceptable, n (%)	Excellent, n (%)	Acceptable, n (%)
11	0 (0.00%)	21 (22.58%)	0 (0.00%)	11 (22.92%)
12	0 (0.00%)	93 (100.00%)	1 (2.08%)	47 (97.92%)
13	35 (37.63%)	58 (62.37%)	17 (35.42%)	13 (27.08%)
14	9 (9.68%)	77 (82.80%)	3 (6.25%)	8 (16.67%)
15	13 (13.98%)	46 (49.46%)	21 (43.75%)	19 (39.58%)
16	92 (98.92%)	1 (1.08%)	48 (100.00%)	0 (0.00%)
17	1 (1.08%)	92 (98.92%)	0 (0.00%)	48 (100.00%)
18	0 (0.00%)	1 (1.08%)	0 (0.00%)	0 (0.00%)
19	11 (11.83%)	17 (18.28%)	10 (20.83%)	6 (12.50%)
20	23 (24.73%)	19 (20.43%)	20 (41.67%)	0 (0.00%)
21	88 (94.62%)	5 (5.38%)	47 (97.92%)	1 (2.08%)
22	72 (77.42%)	20 (21.51%)	47 (97.92%)	1 (2.08%)
23	6 (6.45%)	3 (3.23%)	9 (18.75%)	0 (0.00%)
24	3 (3.23%)	7 (7.53%)	13 (27.08%)	5 (10.42%)
25	47 (50.54%)	5 (5.38%)	29 (60.42%)	0 (0.00%)
Average	NA (32.26%)	NA (35.53%)	NA (41.08%)	NA (26.92%)

Notes: CNKI: China National Knowledge Infrastructure; NA: not applicable. Data are expressed as frequency (n) and percentage (%).

The mean scores of the 25 items and average proportion of studies with excellent scores were higher in PubMed-indexed studies than in CNKI-indexed studies (2.1, 41.1% *vs.* 1.7, 32.3%). Taken together, PubMed-indexed studies showed the best results with respect to the sum of proportions of acceptable and excellent reporting of items.

Combining the findings shown in Table 3 with Figure 3, all included studies showed relatively low scores for items 3 (trial design), 11 (blinding), 18 (ancillary analyses), and 23 (registration). Additionally, CNKI-indexed studies showed significantly lower scores for items 15 (baseline data), 8 (sequence generation), 2 (background and objectives), 24 (protocol), and 22 (interpretation) than PubMed studies.

3.4. Impact of hospital sizes, numbers of authors, and sample sizes on reporting quality

Figure 4 shows the correlations of the 25 items and total scores with the number of beds, annual outpatient visits, number of authors, and sample size.

In both databases, the number of authors was significantly correlated with 9 items, including items 25 (funding) and 10 (implementation) as well as the total scores. The sample size was significantly correlated with items 9 (allocation concealment mechanism) and 13 (participant flow) for CNKI-indexed studies, as well as items 6 (outcomes) and 19 (harms) for PubMed-indexed studies. Among CNKI-indexed studies, the item scores were not correlated with the number of beds, annual outpatient visits, or items. However, for PubMed-indexed studies, the number of beds established in affiliated hospitals was negatively correlated with item 5 (interventions) and positively correlated with item 10 (implementation); further, the annual outpatient visits were negatively correlated with item 4 (participants).

3.5. Impact of different grades of hospitals

Among the 93 CNKI-indexed studies, 73 and 20 were from grade A and non-grade A tertiary hospitals, respectively. Among the 48 PubMed-indexed studies, 39 and 9 were from grade A and non-grade A tertiary hospitals, respectively. The mean scores for each item was used to assess the effect of each hospital type.

The nonparametric test revealed no significant between-grade differences in terms of the 25 items. However, in both databases, the mean total scores were higher in grade A tertiary hospitals (42.5, 53.9) than in non-grade A tertiary hospitals (42.0, 51.7) (Table 4). For CNKI-indexed studies, the mean total scores were higher in grade A tertiary hospitals (53.9) than in non-grade A tertiary hospitals (51.7); further, grade A tertiary hospitals showed better scores in items 5 (interventions), 9 (allocation concealment mechanism), and 15 (baseline data). For PubMed-indexed studies, the mean total score was similar between grade A and non-grade A tertiary hospitals (both 1.7). Further, none of the studies reported item 18 (ancillary analyses).

3.6. Impact of funding on quality

Table 5 shows the relationship between the presence of funding and the 25-item scores. In both databases, the means total scores were higher in studies with funding than in those without. Further, the scores for nine (36%) items differed according to the presence of funding independently in PubMed and CNKI. Specifically, studies with funding showed higher scores for items 9 (allocation concealment mechanism), 10 (implementation), 11 (blinding), and 25 (funding) than studies without funding.

3.7. The effect of economic level in different regions on the quality of reports

All 93 CNKI articles were from China. Contrastingly, among the 48 PubMed articles, 45 were from China and 3 were from the South Korea. For both databases, most articles were from East China, with their quality scores widely ranging from good to bad (Figure 5). All three reports from the South Korea showed excellent quality scores.

For the CNKI-indexed studies, articles from the Eastern and Northeastern regions showed the highest and lowest scores, respectively. For the PubMed-indexed studies, articles from the South Korea and the Eastern Region showed the highest scores, whereas those from the Central Region showed the lowest scores.

Further regression analysis revealed that the municipal GDP per capita in the year of publication had a significant positive correlation with the total score (Figure 6; $P < 0.01$).

3.8. The effect of analysis of factors affecting the design quality of acupotomy RCTs

To identify the affecting factors, we analyzed the Spearman's rank correlation coefficients for the year of publication, hospital level and size, sample

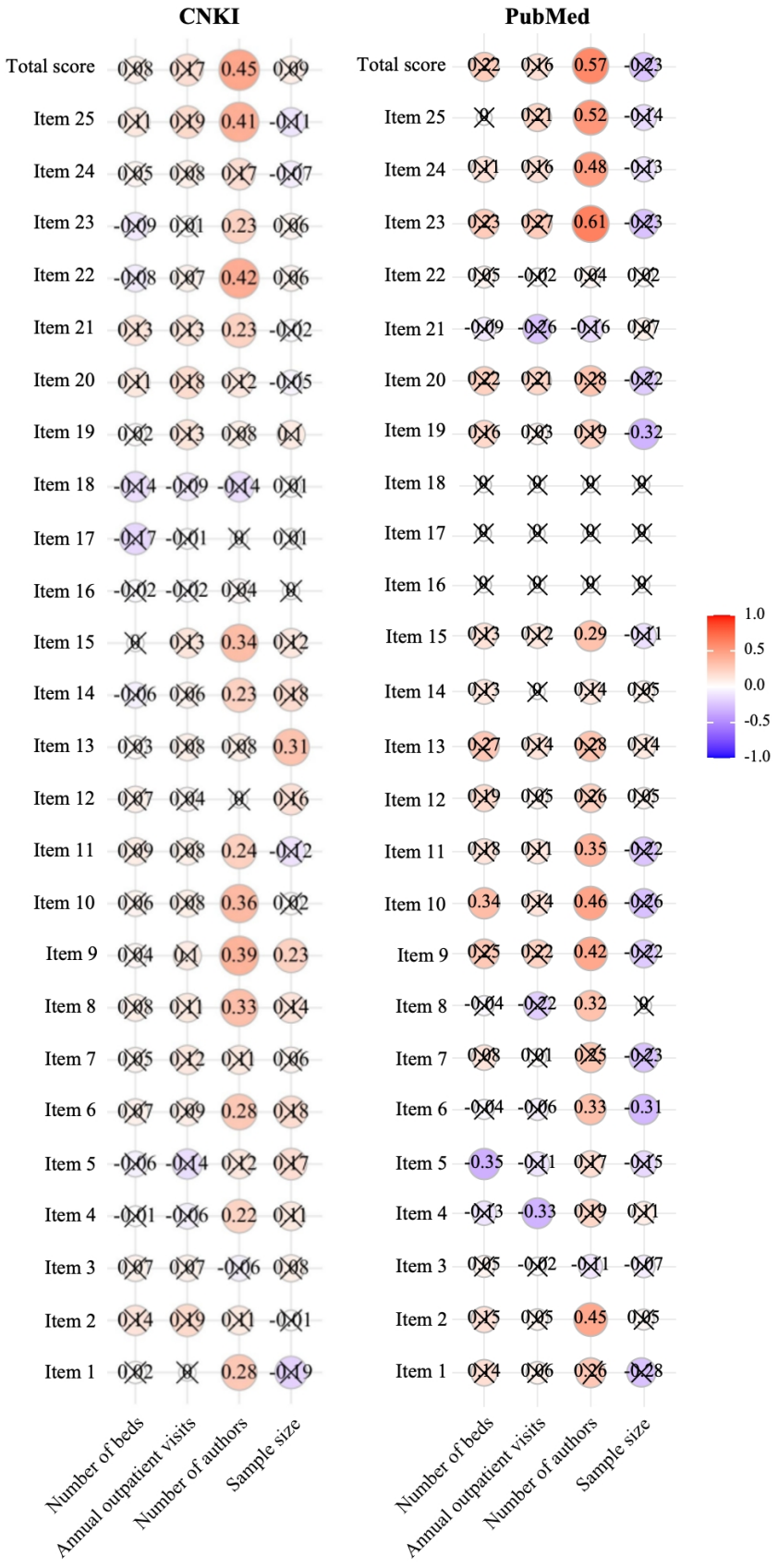

Figure 4 Correlations of the total scores with the number of beds, annual outpatient visits, number of authors, and sample size

Notes: CNKI: China National Knowledge Infrastructure.

Table 4 The nonparametric test of different grades of hospitals and total scores

	CNKI		*Z*	*P*	PubMed		*Z*	*P*
	Grade A tertiary (n = 73)	Non-grade A tertiary (n = 20)			Grade A tertiary (n = 39)	Non-grade A Tertiary (n = 9)		
Item 1	2.0 (2.0, 4.0)	2.0 (2.0, 4.0)	−0.708	0.479	2.0 (2.0, 4.0)	2.0 (2.0, 4.0)	−0.641	0.522
Item 2	3.0 (3.0, 4.0)	3.0 (2.0, 3.8)	−1.926	0.054	4.0 (3.0, 4.0)	4.0 (3.0, 4.0)	−0.463	0.643
Item 3	2.0 (2.0, 2.0)	2.0 (1.0, 2.0)	−1.893	0.058	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.480	0.631
Item 4	3.0 (3.0, 4.0)	3.0 (3.0, 3.0)	−1.845	0.065	4.0 (3.0, 4.0)	4.0 (3.5, 4.0)	−0.280	0.779
Item 5	4.0 (4.0, 4.0)	4.0 (3.0, 4.0)	−2.635	0.008**	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.661	0.508
Item 6	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−1.755	0.079	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.143	0.886
Item 7	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	−1.574	0.115	0.0 (0.0, 2.0)	0.0 (0.0, 2.0)	−0.453	0.650
Item 8	3.0 (2.0, 3.0)	2.0 (2.0, 3.0)	−1.904	0.057	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−1.356	0.175
Item 9	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	−1.961	0.050	0.0 (0.0, 4.0)	0.0 (0.0, 2.0)	−0.863	0.388
Item 10	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.215	0.224	0.0 (0.0, 2.0)	0.0 (0.0, 1.0)	−1.025	0.305
Item 11	0.0 (0.0, 0.0)	0.0 (0.0, 0.8)	−0.064	0.949	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	−0.054	0.957
Item 12	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.917	0.359	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.480	0.631
Item 13	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	−0.076	0.940	2.0 (0.0, 4.0)	1.0 (0.0, 3.5)	−0.654	0.513
Item 14	2.0 (1.0, 2.0)	1.5 (1.0, 2.0)	−1.404	0.160	0.0 (0.0, 0.0)	0.0 (0.0, 1.0)	−0.629	0.530
Item 15	1.0 (0.0, 2.0)	0.0 (0.0, 1.0)	−2.407	0.016*	2.0 (2.0, 4.0)	2.0 (1.0, 4.0)	−0.731	0.465
Item 16	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.968	0.333	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	NA	2.000
Item 17	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−1.845	0.065	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	NA	2.000
Item 18	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.910	0.056	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	NA	2.000
Item 19	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	−0.375	0.708	0.0 (0.0, 2.0)	0.0 (0.0, 1.0)	−0.825	0.409
Item 20	0.0 (0.0, 2.0)	1.0 (0.0, 3.0)	−0.883	0.377	0.0 (0.0, 4.0)	0.0 (0.0, 4.0)	−0.557	0.578
Item 21	4.0 (4.0, 4.0)	4.0 (3.0, 4.0)	−1.692	0.091	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.480	0.631
Item 22	3.0 (3.0, 4.0)	3.0 (2.0, 3.8)	−1.019	0.308	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.480	0.631
Item 23	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−0.775	0.438	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−0.645	0.519
Item 24	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.740	0.082	0.0 (0.0, 4.0)	0.0 (0.0, 4.0)	−0.046	0.963
Item 25	3.0 (0.0, 4.0)	0.0 (0.0, 3.8)	−1.807	0.071	4.0 (0.0, 4.0)	4.0 (2.0, 4.0)	−1.169	0.242
Average	43.0 (37.0, 49.0)	40.0 (31.8, 43.0)	NA	NA	50.0 (41.0, 67.0)	48.0 (43.0, 57.5)	NA	NA
Total score	2.0 (2.0, 4.0)	2.0 (2.0, 4.0)	−1.957	0.050	2.0 (2.0, 4.0)	2.0 (2.0, 4.0)	−0.449	0.653

Notes: CNKI: China National Knowledge Infrastructure; NA: not applicable. Data are expressed as median (interquartile range). Significant differences between grade A tertiary and non-grade A tertiary in CNKI and PubMed are indicated as $^{*}P < 0.05$ and $^{**}P < 0.01$.

size, number of authors, funding, municipal GDP per capita, and total score (Tables 6 and 7). Here, we found that the year of publication, number of authors, funding, and municipal GDP per capita were significant affecting factors in both databases.

4. Discussion

To our knowledge, this is the first study to evaluate the design quality of acupotomy RCTs according to the 2010 CONSORT statement. Previous studies on acupotomy have been mainly systematic reviews and meta-analyses, which rely on risk of bias as the primary quality metric.[161-165] Contrastingly, few studies have applied the CONSORT checklist for design evaluation. Further, these few studies only assessed a subset of items.[166-168] Contrastingly, we applied all 25 items with equal weighting to emphasize structural completeness and reporting standardization. By adopting the internationally recognized CONSORT guidelines,[169,170] this study provided a more comprehensive quality appraisal of acupotomy RCTs.

4.1. Improvements for the overall quality

Our findings indicated a need to improve the overall quality of acupotomy RCTs. Across the 141 included studies, both the mean and median CONSORT scores were ≈42, which indicated moderate adherence to reporting standards. Further, <10% and <30% of CNKI and PubMed-indexed studies, respectively, achieved scores >60. This highlights a widespread issue with methodological and reporting rigor. Additionally, CNKI-indexed studies generally had lower quality than PubMed-indexed studies. Similar concerns have been raised in prior studies indicating a currently low quality of acupotomy therapy.[171]

Despite the publication of the updated CONSORT statement in 2010, the overall reporting quality of RCTs remains unsatisfactory across various fields, including dentistry, psychiatry, psychology, and cardiothoracic surgery.[172-176] Qi et al. similarly showed that the quality of current RCTs was not as high as expected,[177] with the publication of the CONSORT guidelines not having a significant effect on the quality of RCTs. However, the authors' awareness of the CONSORT items was relevant to the improvement in RCT quality.[172,178,179]

This broad pattern in RCTs has also been observed in acupotomy research. Although we observed a slight improvement in the design quality of RCTs over time, the overall quality remained low, especially among domestically published domestic articles. This can be attributed to the relatively late introduction and limited dissemination of CONSORT standards in China.[31,32] Moreover, RCT reporting quality is closely associated with the training background of researchers, the original trial design, and journal requirements. Therefore, improving the quality of acupotomy RCTs requires systematic efforts to strengthen methodological training as well as promote rigorous adherence to the CONSORT checklist.[177,180]

Table 5 The nonparametric test of funding and total score

Items	CNKI		*Z*	*P*	PubMed		*Z*	*P*
	Funded (n = 51)	Non-funded (n = 42)			Funded (n = 28)	Non-funded (n = 20)		
Item 1	2.0 (2.0, 4.0)	2.0 (2.0, 4.0)	−1.637	0.102	4.0 (2.0, 4.0)	2.0 (2.0, 3.5)	−2.113	0.035*
Item 2	3.0 (2.0, 4.0)	3.0 (2.0, 4.0)	−0.744	0.457	4.0 (4.0, 4.0)	3.5 (3.0, 4.0)	−2.988	0.003**
Item 3	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.127	0.899	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.845	0.398
Item 4	3.0 (3.0, 4.0)	3.0 (3.0, 3.0)	−3.397	0.001**	4.0 (4.0, 4.0)	4.0 (3.0, 4.0)	−0.665	0.506
Item 5	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.725	0.468	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−2.094	0.036*
Item 6	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−2.212	0.027*	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−1.099	0.272
Item 7	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	−1.159	0.247	0.5 (0.0, 2.0)	0.0 (0.0, 2.0)	−1.228	0.220
Item 8	3.0 (2.0, 4.0)	2.0 (2.0, 3.0)	−3.119	0.002**	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.971	0.331
Item 9	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	−2.401	0.016*	1.0 (0.0, 4.0)	0.0 (0.0, 0.0)	−2.244	0.025*
Item 10	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	−2.617	0.009**	1.0 (0.0, 2.0)	0.0 (0.0, 0.8)	−2.053	0.040*
Item 11	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	−2.281	0.023*	0.0 (0.0, 1.8)	0.0 (0.0, 0.0)	−2.411	0.016*
Item 12	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.416	0.677	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.845	0.398
Item 13	2.0 (2.0, 3.0)	2.0 (2.0, 3.0)	−0.188	0.851	2.0 (0.0, 4.0)	2.0 (0.0, 3.5)	−0.815	0.415
Item 14	2.0 (1.0, 2.0)	2.0 (1.0, 2.0)	−2.266	0.023*	0.0 (0.0, 1.0)	0.0 (0.0, 0.0)	−1.223	0.221
Item 15	1.0 (0.0, 2.0)	1.0 (0.0, 1.0)	−1.741	0.082	4.0 (2.0, 4.0)	2.0 (0.5, 4.0)	−1.758	0.079
Item 16	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.123	0.902	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	NA	2.000
Item 17	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	−0.181	0.856	2.0 (2.0, 2.0)	2.0 (2.0, 2.0)	NA	2.000
Item 18	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.102	0.270	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	NA	2.000
Item 19	0.0 (0.0, 1.0)	0.0 (0.0, 1.0)	−0.238	0.812	0.0 (0.0, 3.5)	0.0 (0.0, 1.5)	−1.030	0.303
Item 20	0.0 (0.0, 3.0)	0.0 (0.0, 2.0)	−0.674	0.500	0.0 (0.0, 4.0)	0.0 (0.0, 4.0)	−0.784	0.433
Item 21	4.0 (4.0, 4.0)	4.0 (3.8, 4.0)	−0.653	0.514	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.845	0.398
Item 22	3.0 (3.0, 4.0)	3.0 (2.0, 3.0)	−2.790	0.005**	4.0 (4.0, 4.0)	4.0 (4.0, 4.0)	−0.845	0.398
Item 23	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.536	0.125	0.0 (0.0, 4.0)	0.0 (0.0, 0.0)	−2.783	0.005**
Item 24	0.0 (0.0, 0.0)	0.0 (0.0, 0.0)	−1.020	0.308	1.0 (0.0, 4.0)	0.0 (0.0, 0.0)	−2.244	0.025*
Item 25	4.0 (4.0, 4.0)	0.0 (0.0, 0.0)	−8.786	<0.001**	4.0 (4.0, 4.0)	0.0 (0.0, 0.0)	−6.566	<0.001**
Total score	44.0 (41.0, 52.0)	37.5 (31.8, 41.5)	−4.707	<0.001**	52.0 (46.5, 74.5)	41.0 (39.3, 50.0)	−3.600	<0.001**

Notes: CNKI: China National Knowledge Infrastructure; NA: not applicable. Data are expressed as median (interquartile range). Significant differences between funded and non-funded are indicated as *P < 0.05 and **P < 0.01.

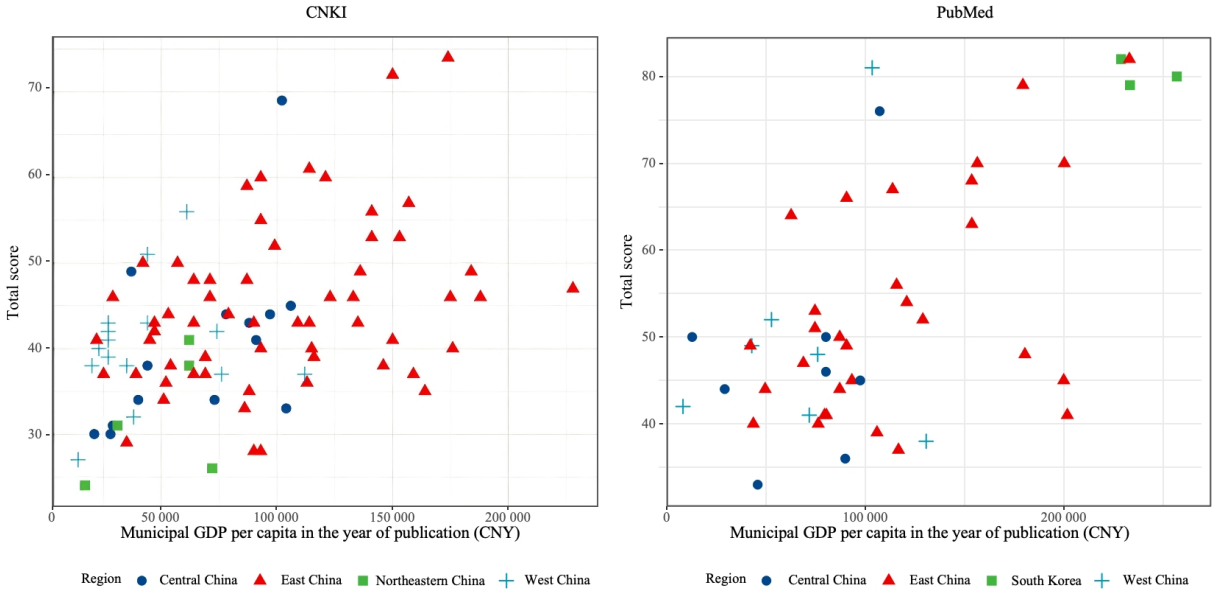

Figure 5 Scatterplot of regional GDP per capita in the year of publication and the quality scores

Notes: CNKI: China National Knowledge Infrastructure; CNY: Chinese Yuan; GDP: gross domestic product.

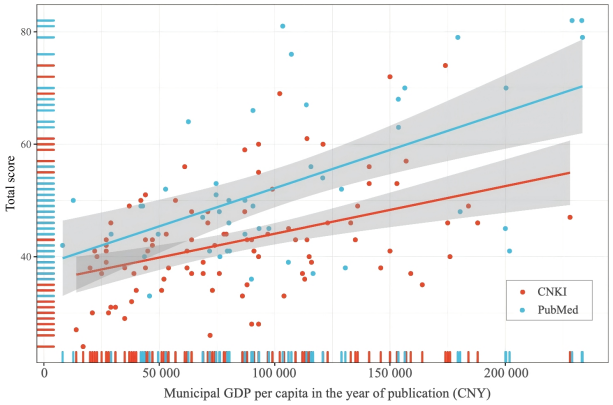

Figure 6 Scatterplot of GDP per capita in the year of publication and scores of report quality

Notes: CNKI: China National Knowledge Infrastructure; CNY: Chinese Yuan; GDP: gross domestic product.

4.2. Quality disparities across CONSORT items

Although PubMed articles showed higher scores on more items than CNKI articles, there were large differences in scores among the 25 items, with some items being irregularly reported. PubMed-indexed studies showed higher scores in 23/25 (92%) items than in CNKI-indexed studies. However, all studies showed relatively scores for ancillary analyses, blinding, recruitment, and registration, which can be attributed to the lack of rigor in the blinding methods, poor recruitment methods, and omission of key information.[181,182]

There were consistently low scores for items 7, 9, 10, 11, 14, 18, 19, 23, and 24, which primarily involved sample size justification, bias control, blinding, and reporting transparency.

The low scores for item 7 (sample size) largely stemmed from lack of a priori sample size estimation in earlier studies. This reflects a historical underappreciation of the statistical power in TCM RCTs. Further, the scores for items 9 (allocation concealment mechanism) and 10 (implementation) collectively indicated a simplified understanding of the randomization process. Specifically, many studies treated "randomization" merely as an allocation principle and did not demonstrate a complete workflow encompassing sequence generation, allocation concealment, and implementation in order to avoid selection bias. Item 11 (blinding) was frequently compromised due to insufficient reporting of the blinding of participants, outcome assessors, and data analysts. The low scores for item 14 (recruitment) could be attributed to historical page limits in journals and a misplaced emphasis on excessive conciseness in the methods sections, which leads to the omission of crucial details. Item 19 (Harms), which mandates the reporting of all adverse events, was rarely fulfilled. This can be attributed to a tendency to underreport negative events in order to avoid casting therapies or studies in an unfavorable light. Items 23 (registration) and 24 (protocol) were insufficiently reported, especially CNKI-indexed studies published during the earlier period when trial registration was not mandatory or widespread. The observed improvement in recent publications is a direct result of mandates from policies, funding, and academic journals, which have resulted in a positive shift towards standardized reporting norms.

None of the studies reported ancillary analyses (item 18), which may have affected the trial results or led to study duplication. Reporting ancillary analyses is essential for improving research transparency and efficiency.[183] Additionally, there have been few reports regarding the methodological quality in the areas of randomization methods, allocation concealment, and blinding

Table 6 Spearman's rank correlation coefficient among affecting factors and the total score in CNKI

	Year of publication	Grade A tertiary hospital	Number of beds	Annual outpatient visits	Sample size	Number of authors	Funded	Municipal GDP per capita	Total score
Year of publication	1								
Grade A tertiary hospital	0.021	1							
Number of beds	−0.017	0.498**	1						
Annual outpatient visits	0.112	0.447**	0.723**	1					
Sample size	0.124	0.047	0.093	0.198	1				
Number of authors	0.1	0.232*	0.152	0.191	0.243*	1			
Funded	0.340**	0.156	0.108	0.196	−0.053	0.414**	1		
Municipal GDP per capita	0.712**	0.155	−0.133	0.209*	0.114	0.204	0.373**	1	
Total score	0.384**	0.204	0.078	0.189	0.147	0.455**	0.491**	0.413**	1

Notes: CNKI: China National Knowledge Infrastructure; GDP: gross domestic product. Significant differences are indicated as $^{*}P < 0.05$ and $^{**}P < 0.01$.

Table 7 Spearman's rank correlation coefficient among affecting factors and total score in PubMed

	Year of publication	Grade A tertiary hospital	Number of beds	Annual outpatient visits	Sample size	Number of authors	Funded	Municipal GDP per capita	Total score
Year of publication	1								
Grade A tertiary hospital	−0.025	1							
Number of beds	−0.076	0.409**	1						
Annual outpatient visits	−0.022	0.148	0.628**	1					
Sample size	−0.28	−0.188	−0.088	0.033	1				
Number of authors	0.407**	0.018	0.182	0.09	0.016	1			
Funded	0.463**	−0.081	0.026	0.195	−0.198	0.551**	1		
Municipal GDP per capita	0.625**	0.126	0.044	0.152	−0.267	0.383**	0.354*	1	
Total score	0.681**	0.062	0.257	0.162	−0.254	0.598**	0.488**	0.606**	1

Notes: GDP: gross domestic product. Significant differences are indicated as $^{*}P < 0.05$ and $^{**}P < 0.01$.

details,[184,187] which can be attributed to the fact that methodological content was previously analyzed separately from other CONSORT projects.[188,189]

In RCTs, a lack of blinding may lead to a risk of bias in treatment effects.[190] Although the blinding methods have been debated,[191] the integrity of blinding must be maintained by assigning sufficient resources, consideration, and programming.[192] Another major challenge in clinical trials is the recruitment of physicians and patients.[193] Most trials did not complete the recruitment on time, which led to longer recruitment times, less reliable results, and additional costs.[194] Improved recruitment methods, as well as monitoring and management of poor recruitment, are necessary to improve the success and timeliness of recruitment.[195] Furthermore, as emphasized at the International Conference on the Harmonization of Technical Requirements for Pharmaceuticals for Human Use, study registration is an essential indicator of research transparency.[196] Taken together, based on the updated CONSORT guidelines, researchers should focus on the overall structural integrity of RCT designs.

4.3. Greater potential for the use of CONSORT in grade A tertiary hospitals

Across both databases, most acupotomy RCTs were conducted in grade A tertiary hospitals, which suggests that higher-level institutions are relatively more engaged in RCTs. Additionally, RCTs from these hospitals tended to have high overall CONSORT scores. Notably, among PubMed-indexed studies, the average scores was higher in studies from grade A tertiary hospitals than in those from lower-level institutions; however, this difference was no observed among CNKI-indexed studies.

In China, grade A tertiary hospitals are the highest-ranking hospitals.[197-201] These hospitals have more stringent requirements for RCT protocols, which may be attributed having relatively more advanced equipment. In turn, the improved environment for RCTs allows provision of more accurate data sources and results.[202] Multicenter RCTs may allow meeting of the required timelines and increased cost-effectiveness by initiating, recruiting, and collecting data and samples in different areas.[203] Taken together, high-quality multicenter RCTs could strengthen the external validity of the findings in practice.[204]

However, we observed poor reporting of sample size (Item 7), allocation concealment mechanism (Item 9), implementation (Item 10), blinding (Item 11), recruitment (Item 14), ancillary analysis (Item 18), and harm (Item 19), indicating the need for hospitals to highlight these details. Additionally, relevant authorities should introduce policies to encourage cooperation and exchange between hospitals of different grades, clarify the roles and priorities of their respective clinical fields, and realize the rational allocation of high-quality medical resources. This will allow maximization of each hospital's strengths, promotion of the conduct of high-quality RCTs, and strengthening of the scientific research capacity of hospitals.[205,206]

4.4. Increasing scores over time

There were correlations between the year of publication and the total scores across both databases. Since the first CNKI- and PubMed-indexed RCTs published in 2003[132] and 2006,[207] respectively, there has been gradual improvement in the quality of articles. Notably, 14/48 (29%) PubMed-indexed studies with scores >60 points were published after 2018, which suggests that more recent trials are better aligned with the reporting standards.

This is consistent with previous reports that the reporting quality of medical literature significantly improved with the adoption of the CONSORT guidelines.[208-210] Although the CONSORT statement was first published in 1996[211] and officially translated and endorsed by the CONSORT panel in 2007, early adoption in China was limited. Nonetheless, the overall quality of RCTs published in Chinese journals was reported to improve from 2005 to 2015.[33,180,212]

This can be attributed to the development of science and technology, improvement in medical equipment and technology for clinical experiments, and a favorable medical experimental environment. Additionally, progressive refinement of preliminary experiments has provided abundant theoretical and practical experience for subsequent experiments, which has led to improved quality of experimental reports.

The observed increase in CONSORT scores reflects the growing familiarity of researchers with the CONSORT guidelines, which in turn improves their research reporting skills.[213] Further, frequent revisions to the CONSORT checklist have improved its clarity and accuracy, which in turn improves the reporting quality.[9,214]

4.5. Factors affecting the design quality of RCTs

Although CNKI-indexed studies demonstrated broader geographic coverage, PubMed-indexed studies exhibited a higher overall design quality. All three RCTs from the South Korean were rated as high quality. In China, Eastern China was most likely to have high quality RCTs, which can be attributed to relatively high economic levels; contrastingly, Western and Central regions had low-quality RCTS, which reflects the low GDP. These findings are consistent with the subsequent analysis of regional economic levels, which revealed that the municipal GDP per capita in the year of publication had a significant positive correlation with the total score.

Regarding other impact factors, the indicators of hospital size, including the number of authors, had a relatively strong impact. The 9 items such as item 25 (funding), and item 10 (implementation) and total score, were significantly correlated with across both databases. The sample size was positively and negatively correlated with two items in CNKI- and PubMed-indexed studies, respectively. The number of beds and annual outpatient visits showed no relationship with the items in CNKI-indexed studies. Moreover, the number of beds established in affiliated hospitals was negatively correlated with item 5 (interventions) and positively correlated with item 10 (implementation). Contrastingly, annual outpatient visits were negatively correlated with only item 4 (participants) in PubMed-indexed studies.

Furthermore, funding was correlated with the total score and some items, with the average total scores being higher in studies with funding than in those without. Similarly, Balasubramanian et al. reported that a large number of authors, multicenter studies, and statements of funding sources were significantly associated with better quality reporting among RCTs on general surgery.[215-217] However, simply increasing the sample size and hospital size does not completely address the issue of reporting quality.[218] Furthermore, some studies conducted in large hospitals or more economically developed regions may have low quality reporting. This is consistent with a previous reported that although the number of authors had a meaningful impact on the study quality, the sample size and commercial funding reports had a relatively less impact.[219] Parish et al. concluded that scientific collaboration (number of authors) is associated with a greater citation impact.[220] Although the primary responsibility for improvement in reporting quality rests with the investigators,[221] reviewers and editors of surgical journals could promote this process by endorsing the CONSORT guidelines.[222,223] Specifically, they may require authors to follow the guidelines as a condition for publication and assess the reliability of RCTs to be published.[224]

Taken together, it is important to advocate for more efficient cooperation and resource sharing, including cross-regional, cross-hospital, and multi-team cooperation in order to improve the feasibility and efficiency of trials, which will establish a more regularized standard of research based on consensus.[225,226]

4.6. Different design qualities between CNKI- and PubMed-indexed studies

PubMed-indexed studies outperformed CNKI-indexed studies in most CONSORT items, with significant differences being observed in 13 items. Specifically, PubMed articles demonstrated notable strengths in areas including items 2 (background and objectives), 3 (trial design), 4 (participants), 7 (sample size), 8 (sequence generation), 10 (implementation), 15 (baseline data), 21 (generalizability), 22 (interpretation), 24 (protocol), and total score. Conversely, the CNKI-indexed studies performed better on items 13 (participant flow) and 14 (recruitment). These shortcomings centered on the rigor of the study design, methodological standardization, reporting details, and

transparency.

These differences can be attributed to resource and capacity constraints, an inadequate knowledge of international standards, and cultural and linguistic differences. Specifically, domestic researchers may have limited exposure to internationally standardized frameworks such as the CONSORT statement, which results in lower-quality reporting of items such as background and objectives, trial design, participant characteristics, and sample size calculations. Moreover, owing to word limits, domestic journals may place less emphasis on the study design and methodology section of an article, placing more emphasis on results and discussion. This further decreases the incentive to follow international standards. The weak performance of domestic studies on items such as registration (Item 23) and protocol (Item 24) reflected insufficient attention to study transparency and standardization, as well as a potential lack of understanding and use of clinical trial registration platforms. Regarding cultural differences, language and scientific communication barriers may further affect the clarity and completeness of reporting, especially when adapted to the structural and rhetorical conventions of international journals. To bridge these disparities, domestic researchers should further learn and apply international research norms, improve the rigor of study designs and methodologies, and increase support for complex study designs. Additionally, the incentive mechanism should be optimized to encourage a focus on research quality and standardization.

For items 13 (participant flow) and 14 (recruitment), domestic studies may have been better designed with detailed descriptions of participant flow to ensure the reproducibility of the acupotomy operation. Additionally, domestic researchers may be better at reporting these items in the Chinese context, which may be relatively unclear when reported in English.

4.7. Future directions

In future studies, it is important to improve the number of included articles, weight allocation of CONSORT items, and analysis of CONSORT compliance. Given the lack of unified international terminology for acupotomy, we restricted our search to CNKI and PubMed. CNKI and Wanfang had a high degree of overlap, with approximately 90% of studies in Wanfang being indexed in CNKI. For biomedical research, 97.2% of the articles indexed in the Web of Science are also indexed in PubMed. Compared to PubMed, Scopus primarily provides broader coverage of conference proceedings; however, our study intentionally focused on published journal articles. Future systematic reviews should expand the search strategy to incorporate additional specialized databases, including the Cochrane Central Register of Controlled Trials and Embase, in order to maximize search comprehensiveness. In addition, there were publication gaps in some years, which may have influenced the trend analysis.

Second, this study performed weight allocation of the 25 CONSORT items. However, there were sub-items for different items, with differences in content, length, and significance. Accordingly, this resulted in differences in the quality evaluation of different design aspects. Initially, we attempted to design an expert consultation survey to assign differential weights; however, this was impeded by time constraints and a low response rate. Therefore, for simplicity and comparability, we assigned equal weights of four points to each item, which is consistent with several prior studies.

Finally, the CONSORT guidelines should be refined. Currently, they comprise short statements that can be interpreted differently according to research background and experience. Future revisions should include examples or detailed instructions.[227] Furthermore, the limited sample size impeded statistical analyses. Accordingly, inclusion of more relevant literature and standardized evaluations may allow more in-depth analysis of the influencing factors.

Given the observed spectrum of diseases covered by the included RCTs, future acupotomy RCTs should strengthen the evidence base to address the existing gaps. For established indications such as arthritis and spinal disorders, large-scale, multicenter superiority or non-inferiority trials should be conducted using standard therapies as comparators, with incorporation of long-term follow-up and patient-centered outcome measures. For neurogenic syndromes such as cervicogenic vertigo, the mechanisms underlying treatment should be elucidated using imaging and neurophysiological techniques. In addition, high-quality RCTs are warranted for common yet understudied conditions such as frozen shoulder and plantar fasciitis. Advancing acupotomy research beyond mere efficacy validation towards in-depth exploration of its mechanisms of action and clinical applications will facilitate its integration within the modern medical system.

5. Conclusion

In conclusion, there has been gradual improvement in the design quality of RCTs over the past two decades. Domestic articles covered a broader regional scope, while international trials demonstrated better adherence to the CONSORT guidelines. These findings highlight the need to improve awareness regarding trial design, ensure adherence to reporting standards, and support research teams through training and funding. To our knowledge, this is the first study to systematically evaluate the design quality of acupotomy RCTs using the CONSORT 2010 checklist. Therefore, our findings provide a foundation for improving future research designs and reporting. Promoting greater familiarity with CONSORT, encouraging multicenter collaboration, and supporting methodological training are critical steps towards enhancing the quality and credibility of acupotomy evidence.

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Author Contribution Statement

Jun-jie Li: Conceptualization, methodology, data curation, investigation, formal analysis, writing – original draft, and writing – review and editing. **Dong-mei Xue:** Writing – review and editing. **Yan-tong Zhou:** Investigation, formal analysis, and validation. **Xin-zhu Lu:** Investigation, formal analysis, and validation. **Ying Bian:** Conceptualization, methodology, supervision, funding acquisition, and writing – review and editing.

Declaration of Competing Interest

The authors have no competing interests to declare that are relevant to the content of this article.

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