



Quality Assessment of Traditional Persian Medicine Observational Studies

Mojtaba Norouzi¹, *Ali Akbar Haghdoost², Mohammad Setayesh³

1. Department of Biostatistics and Epidemiology, Faculty of Public Health, Kerman University of Medical Science, Kerman, Iran
2. HIV/STI Surveillance Research Center, and WHO Collaborating Center for HIV Surveillance, Institute for Futures Studies in Health, Kerman University of Medical Sciences, Kerman, Iran
3. Department of Persian Medicine, Faculty of Traditional Medicine, Kerman University of Medical Sciences, Kerman, Iran

*Corresponding Author: Email: ahaghdoost@gmail.com

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Abstract

Background: Although observational studies are valuable sources of scientific evidence, they are prone to bias and confounding. This study aimed to assess the quality of observational studies in Traditional Persian medicine (TPM).

Methods: A systematic search was conducted in national and international databases up to the end of 2022 to identify observational studies on TPM. The quality of articles was evaluated using the STROBE checklist and CARE guidelines.

Results: Out of the 192 articles identified, 109 met the eligible criteria for quality assessment. Cross-sectional and case-control studies had a mean STROBE score of 1.2 ± 0.51 out of 2, with the introduction section scoring highest and the results and methods sections scoring lowest. The worst reported items in the method section involved sensitivity analyses, bias control, and management of missing data. Case reports and case series had a mean score of 1.4 ± 0.55 out of 2, with the section on therapeutic interventions scoring the highest. Other sections like keywords, follow-up and outcomes, diagnostic assessment, patient perspective, and informed consent scored below one.

Conclusion: Many reviewed articles did not adhere to the recommended formatting in the evaluation tools, making it challenging to assess their quality. Having said that, the quality of observational studies in the field of TPM is a point of concern.

Keywords: Quality assessment; Observational study; Medicine, Persian; CARE guidelines

Introduction

Traditional, complementary, and alternative medicine, including Traditional Persian Medicine (TPM), has a long-standing presence in the global healthcare system (1). Throughout history, individuals have utilized these approaches to address

their fundamental healthcare needs (2), and even today; these practices are utilized worldwide for disease prevention, control, and management (3). Over half of the member countries of WHO have now established a national policy regarding



the utilization of traditional, complementary, and alternative medicine (4). TPM has garnered attention from researchers across various disciplines in recent years, leading to an increase in the number of published articles in this area (5).

However, in addition to the increase in the number of Traditional Persian Medicine (TPM) studies, it is crucial to focus on their quality, especially in observational studies. Observational studies are essential in medical research methodology and serve as a dependable source of information (6). For instance, the cohort study design is widely utilized in research and its results rank second to randomized controlled trials (7). While case reports and case series are positioned at the base of the Level of Evidence pyramid (8), they are valuable for identifying and describing new diseases (9). These types of studies have been utilized in the diagnosis and management of conditions like COVID-19 (10). Although observational studies are more prone to bias and confounding compared to interventional studies (11), they do not face certain constraints present in interventional research, such as ethical considerations, costs, and limitations on follow-up duration and sample size (12,13). The reporting of observational studies is often criticized for lacking clarity and precision (14). Consequently, numerous guidelines have been developed in recent years to enhance the reporting quality of various study types (15).

Clear and comprehensive reporting in research is essential for readers to grasp the study's planning, execution, findings, and conclusions. Moreover, the credibility of research hinges on the critical evaluation of study design, implementation, and analysis by external parties. Transparent reporting is also vital for assessing the incorporation of results in systematic reviews (16). Guidelines and recommendations exist to aid in the thorough reporting of observational studies, such as the "Strengthening the Reporting of Observational Studies in Epidemiology" (STROBE) and "CAse REport" (CARE) guidelines (17,18). The STROBE Statement offers a checklist for reporting analytical epidemiology studies, encompassing cohort, case-control, and cross-sectional studies

(16). The CARE guidelines were developed to facilitate the publication of precise, comprehensive, and transparent case reports, as inconsistent and incomplete reporting can diminish the value of such reports (19). Some peer-reviewed journals have adopted these guidelines as a submission framework to enhance the quality and transparency of health research (20,21).

To the best of our knowledge, no research has been conducted to assess the quality of TPM observational studies. Identifying deficiencies in these studies can help drive efforts toward standardized reporting. Therefore, we assessed the adherence of TPM observational studies to the STROBE declaration and CARE guidelines. The findings of this study will be useful to researchers and stakeholders aiming to enhance the quality and transparency of TPM observational studies.

Methods

We defined six steps in our systematic review: 1) search strategy; 2) searches in the databases; 3) evaluation of inclusion and exclusion criteria; 4) evaluation of reporting quality; 5) data collection; and 6) statistical analysis.

Search strategy

To search databases, we combined two sets of keywords. The first set defined different types of observational studies, and the second set defined TPM as follows: (case report OR case series OR cross-sectional studies OR case-control studies OR cohort studies OR longitudinal studies OR prospective OR retrospective OR observational studies OR epidemiologic studies) AND (Iranian traditional medicine OR traditional Iranian medicine OR Persian medicine OR Persian traditional medicine). On Jan 29, 2023, we searched the main International and Persian databases such as PubMed, ISI Web of Science, Scopus, Google Scholar, the Science Information Database SID (WWW.SID.ir), and MagIran (WWW.Magiran.com). Persian and English articles published up to the end of Dec 31, 2022, were extracted. Two independent reviewers cate-

gorized the articles based on their study design and type of document. Any discrepancies in the results were resolved through discussion with a third expert to achieve a consensus.

Inclusion and Exclusion Criteria

The criteria for inclusion encompassed observational studies that explicitly stated the investigation of certain aspects of TPM in their texts. Randomized trial designs, systematic reviews and meta-analyses, guidelines, letters to the editor, conference abstracts or papers, and animal experiments were all excluded.

Risk of bias assessment

To evaluate the risk of bias in the included studies, the STROBE checklist was employed for cohort, case-control, and cross-sectional studies, while the CARE guidelines were utilized for case reports and case series studies. Each study was assigned a mean score ranging from 0 to 2. A mean score below .67 indicated a high risk of bias, a mean score between .67 and 1.34 signified a moderate risk of bias, and a mean score of 1.35 or higher indicated a low risk of bias.

Assessment of the quality of reporting

The quality assessment of articles was done using the STROBE checklist and CARE guidelines (17,18). The STROBE Statement consists of a checklist comprising 22 essential items for the proper reporting of observational studies. These items cover various sections of the article, including the title and abstract, introduction, methods, results, discussion, and additional information such as funding. While 18 items are common across all three-study designs, four items are design-specific, with different versions. Some items require separate information for cases and controls in case-control studies or exposed and unexposed groups in cohort and cross-sectional studies. Although presented as a unified checklist, separate checklists tailored to each of the three study designs are available. The CARE guidelines

include a checklist of 13 crucial items aimed at ensuring completeness and transparency in published case reports and case series studies. These items address different parts of the article, such as the title, keywords, abstract, introduction, patient information, clinical findings, timeline, diagnostic assessment, therapeutic intervention, follow-up and outcomes, discussion, patient perspective, and informed consent. The tools and numbers calculated for measuring the quality of the articles had a ratio scale. Each item was scored on a scale of 0 to 2: 0 for no description, 1 for inadequate description, and 2 for adequate description (22). All items were weighted equally, and any items that did not apply to a specific study were labeled as inapplicable.

Data collection

The following variables were recorded in this study: the number of authors, the year of publication, the language of articles, the field of studies, affiliation to a traditional medicine center, the type of study, and the latest impact factor of journals.

Statistical Analysis

For each item, the frequency and the relative frequency, as well as the mean and standard deviation (SD) of the scores, were calculated. In the statistical analysis, we employed the Mann-Whitney and Spearman's correlation coefficients. Statistical significance was defined as a *P*-value less than 0.05. Stata 14.2 (Stata Corp, College Station, TX, USA) was used for all analyses.

Results

Overall, 1251 articles were identified. After removing duplicates and screening based on title and abstract, 127 articles were left for full-text evaluation. Finally, 109 articles were selected as being eligible (Fig. 1).

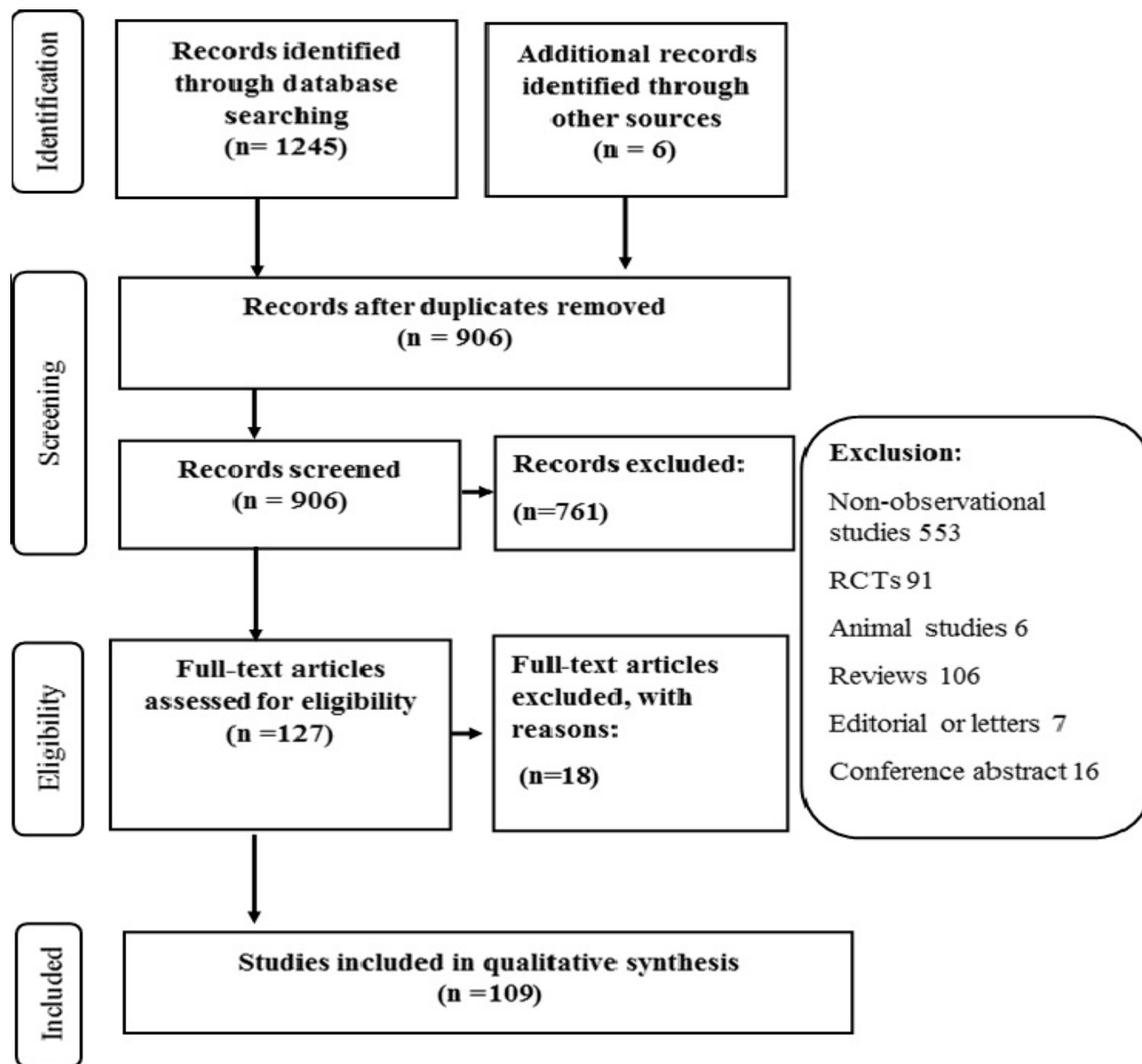


Fig. 1: PRISMA flow diagram to assess the reporting quality of Traditional Persian Medicine observational studies

A descriptive analysis of the articles was done. In terms of study type, cross-sectional studies had the most instances (67 cases), and case-control and case series studies had the fewest (4 cases). Furthermore, temperamentology was the most studied field (Fig. 2). Furthermore, the evalua-

tion of bias risk revealed that 17.4% of the studies were deemed to have a low risk of bias. Moreover, 66% and 16.6% of the studies were categorized as having moderate and high risk of bias, respectively (Fig. 3).

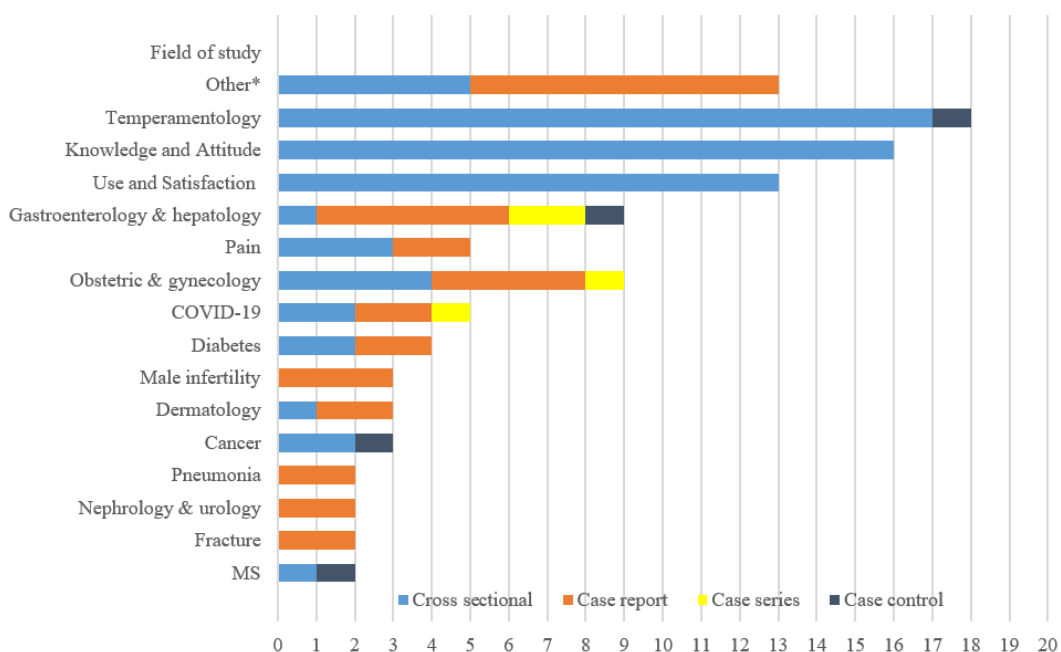


Fig. 2: The distribution of the study field in observational studies of Traditional Persian Medicine until the conclusion of 2022

* Burns, Dyslipidemia, Neonatal, Questionnaire, Hypertensive (cross-sectional studies). Thrombosis, hypothyroidism, Pica, Hypercholesterolemia, restless legs syndrome, Systemic lupus erythematosus, Refractory Autoimmune Hemolytic Anemia, Relapsing Sudden Hearing Loss (case report).

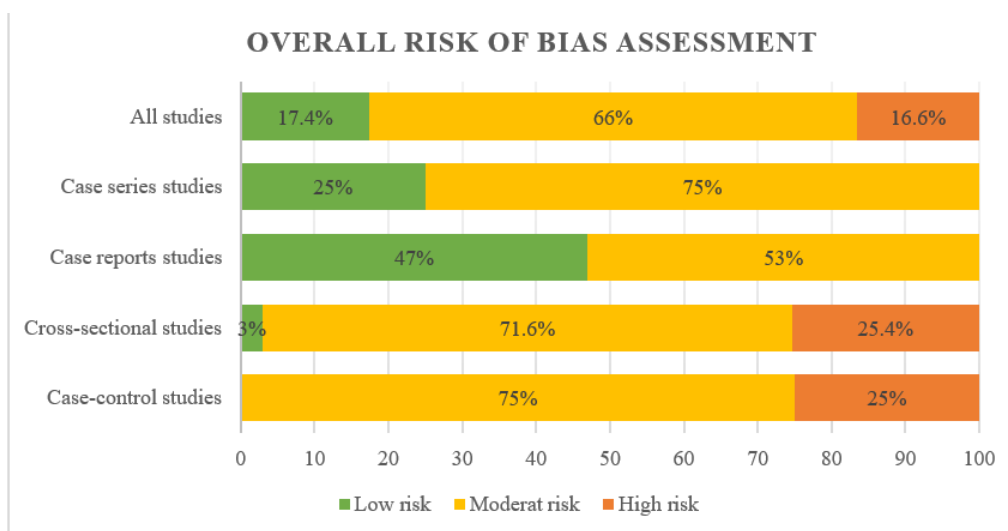


Fig. 3: Overall risk of bias assessment of Traditional Persian Medicine observational studies up to the end of 2022

The articles were qualitatively evaluated using the STROBE checklist. The average score for all articles was 1.2 ± 0.51 out of two. While most studies provided adequate information in the title, summary, and introduction sections, there was

insufficient reporting for item 1a. The introduction section had the highest mean STROBE score, while the results and methods sections had the lowest. The worst cases reported in the methods section were related to sensitivity anal-

yses, bias, and missing data items. The study design item received the highest mean score in this section. The flow diagram and limitations items had the lowest scores in the results and discus-

sion sections, respectively. Over 43% of studies provided sufficient information for the Funding item. (Table 1).

Table 1: Frequency and mean score of Traditional Persian Medicine observational studies up to the end of 2022 based on the STROBE checklist

Number	Item*	Number of articles Applicable for item	Not reported item Frequency (%)	Inadequately reported item Frequency (%)	Adequately reported item Frequency (%)	Average ± SD
Title and abstract (mean = 1.40 ± 0.61)						
1a	Indicate the study's design	71	40(56.34)	1(1.41)	30(42.25)	0.86 ± 0.99
1b	what was done and what was found	71	0(0.00)	4(5.63)	67(94.37)	1.94 ± 0.23
Introduction (mean = 1.93 ± 0.24)						
2	Background/rationale	71	0(0.00)	1(1.41)	70(98.59)	1.99 ± 0.12
3	Objectives	71	0(0.00)	10(14.08)	61(85.92)	1.86 ± 0.35
Method (mean = 0.75 ± 0.57)						
4	Study design	71	8(11.27)	2(2.82)	61(85.92)	1.75 ± 0.65
5	Setting	71	4(5.63)	44(61.97)	23(32.39)	1.27 ± 0.56
6a	Participants: Give the eligibility criteria	71	22(30.99)	17(23.94)	32(45.07)	1.14 ± 0.87
6b	Participants: matched studies	4	2(50.00)	2(50.00)	0(0.00)	0.50 ± 0.58
7	Variables	71	8(11.27)	54(76.06)	9(12.68)	1.01 ± 0.49
8	Data sources/ measurement	71	20 (28.17)	43(60.56)	8(11.27)	0.83 ± 0.61
9	Bias	71	58(81.69)	11(15.49)	2(2.82)	0.21 ± 0.46
10	Study size	71	29(40.85)	16(22.54)	26(36.62)	0.96 ± 0.89
11	Quantitative variables	71	33(46.48)	24(33.80)	14(19.72)	0.73 ± 0.77
12a	control of confounding	71	8(11.27)	59(83.10)	4(5.63)	0.94 ± 0.41
12b	subgroups and interactions	71	40(56.34)	31(43.66)	0(0.00)	0.44 ± 0.50
12c	missing data	71	69(97.18)	2(2.82)	0(0.00)	0.03 ± 0.17
12d	matching of cases and controls/ analytical methods	71	42(59.15)	22(30.99)	7(9.86)	0.51 ± 0.67
12e	sensitivity analyses	56	50(89.29)	6(10.71)	0(0.00)	0.11 ± 0.31
Result (mean = 0.69 ± 0.52)						
13a	numbers of individuals	71	12(16.90)	55(77.46)	4(5.63)	0.89 ± 0.46
13b	reasons for non-participation	71	51(71.83)	19(26.76)	1 (1.41)	0.30 ± 0.49
13c	flow diagram	71	70(98.59)	0(0.00)	1 (1.41)	0.04 ± 0.26
14a	characteristics of study participants	71	23(32.39)	10(14.08)	38(53.52)	1.21 ± 0.91
14b	number of participants with missing	71	45(63.38)	23(32.39)	3(4.23)	0.41 ± 0.56
15	Outcome data	71	0(0.00)	39(54.93)	32(45.07)	1.45 ± 0.50
16a	Give unadjusted estimates	71	2(2.82)	60(84.51)	9(12.68)	1.10 ± 0.38
16b	Report category boundaries	26	11(42.31)	14(53.85)	1(3.85)	0.62 ± 0.57
16c	relative risk into absolute risk	22	8(36.36)	13(59.09)	1(4.55)	0.68 ± 0.57
17	Other analyses	71	56(78.87)	13(18.31)	2(2.82)	0.24 ± 0.49
Discussion (mean = 1.40 ± 0.64)						
18	Key results	71	1(1.41)	15(21.13)	55(77.46)	1.76 ± 0.46
19	Limitations	71	36(50.70)	4(5.63)	31(43.66)	0.93 ± 0.98
20	Interpretation	71	1(1.41)	38(53.52)	32(45.07)	1.44 ± 0.53
21	Generalizability	71	2(2.82)	32(46.48)	36(50.70)	1.48 ± 0.56
Other information						
22	Funding	71	40(56.34)	0(0.00)	31(43.66)	0.87 ± 0.99

* Item 14c (Summarize follow-up time) was not applicable for any of the studies.

The articles were assessed for quality based on the CARE guidelines. The average score for all articles was 1.4 ± 0.55 out of two scores. Sections such as the title, introduction, clinical findings, and timeline achieved a mean score of 1.63 or higher. The highest mean score in the CARE guidelines was observed in the therapeutic interventions section, while the lowest scores were in

the keywords, follow-up and outcomes, and diagnostic assessment sections. Items 8b and 8d from the diagnostic assessment section, items 10c and 10d from the follow-up and outcomes section, and items 11a, 12, and 13 from the discussion section had an average score of less than one (Table 2).

Table 2: Frequency and mean score of Traditional Persian Medicine observational studies up to the end of 2022 based on CARE guidelines

Item no.	Topic / Item description*	Number of articles Applicable for item	Not reported item Frequency (%)	Inadequately reported item Frequency (%)	Adequately reported item Frequency (%)	Average \pm SD
1	Title	38	7(18.42)	0(0.00)	31(81.58)	1.63 \pm 0.76
2	Key Words	38	28(73.68)	1(2.63)	9(23.68)	0.50 \pm 0.86
Abstract (mean = 1.62 \pm 0.57)						
3a	Introduction	38	2(5.26)	25(65.79)	11(28.95)	1.34 \pm 0.54
3b	Main symptoms	38	4(10.53)	6(15.79)	28(73.68)	1.63 \pm 0.67
3c	main diagnoses	38	2(5.26)	8(21.05)	28(73.68)	1.68 \pm 0.57
3d	Conclusion	38	2(5.26)	3(7.89)	33(86.84)	1.82 \pm 0.51
4	Introduction	38	0(0.00)	5(13.16)	33(86.84)	1.67 \pm 0.34
Patient Information (mean = 1.65 \pm 0.51)						
5a	De-identified patient	38	2(5.26)	4(10.53)	32(84.21)	1.79 \pm 0.53
5b	Primary concerns	38	0(0.00)	5(13.16)	33(86.84)	1.87 \pm 0.34
5c	history	38	2(5.26)	22(57.89)	14(36.84)	1.32 \pm 0.57
5d	Relevant past interventions	38	2(5.26)	10(26.32)	26(68.42)	1.63 \pm 0.59
6	Clinical Findings	38	0(0.00)	8(21.05)	30(78.95)	1.79 \pm 0.41
7	Timeline	38	2 (5.26)	10(26.32)	26(68.42)	1.63 \pm 0.59
Diagnostic Assessment (mean = 1.00 \pm 0.52)						
8a	Diagnostic testing	38	1(2.63)	8(21.05)	29(76.32)	1.74 \pm 0.50
8b	Diagnostic challenges	38	28(73.68)	8(21.05)	2(5.26)	0.32 \pm 0.57
8c	Diagnosis	38	1(2.63)	34(89.47)	3(7.89)	1.10 \pm 0.32
8d	Prognosis	29	8(27.59)	16(55.17)	5 (17.24)	0.90 \pm 0.67
Therapeutic Interventions (mean = 1.87 \pm 0.42)						
9a	Types of intervention	38	1(2.63)	2(5.26)	35(92.11)	1.89 \pm 0.39
9b	Administration of intervention	38	1(2.63)	4(10.53)	33(86.84)	1.84 \pm 0.44
Follow-up and outcomes (mean = 0.97 \pm 0.50)						
10a	Assessed outcomes	38	0(0.00)	8(21.05)	30(80.56)	1.79 \pm 0.41
10b	Important follow-up diagnostic	38	1 (2.63)	10(26.32)	27(71.05)	1.68 \pm 0.53
10c	Intervention adherence and tolerability	38	33(86.84)	4(10.53)	1(2.63)	0.16 \pm 0.44
10d	Adverse and unanticipated events	38	31(81.58)	4(10.53)	3(7.89)	0.26 \pm 0.60
Discussion (mean = 1.13 \pm 0.51)						
11a	Strengths and limitations	38	23(60.53)	12(31.58)	3(7.89)	0.47 \pm 0.65
11b	Relevant medical literature	38	2 (5.26)	0(0.00)	36(94.74)	1.89 \pm 0.45
11c	Rationale for conclusions	38	0(0.00))	8(21.05)	30(78.95)	1.79 \pm 0.41
11d	primary "take-away" lessons	38	2(5.26)	4(10.53)	32(84.21)	1.78 \pm 0.53
12	Patient perspective	38	38(100.00)	0(0.00)	0(0.00)	0.00 \pm 0.00
13	Informed consent	38	22(57.89)	0(0.00)	16(42.11)	0.84 \pm 1.00

* Item 9c (Changes in intervention) was not applicable for any of the studies

The quality of the reports varies based on the study type. Overall, case report articles received the highest average score and report quality,

while cross-sectional articles had the lowest score and report quality (Fig. 4).

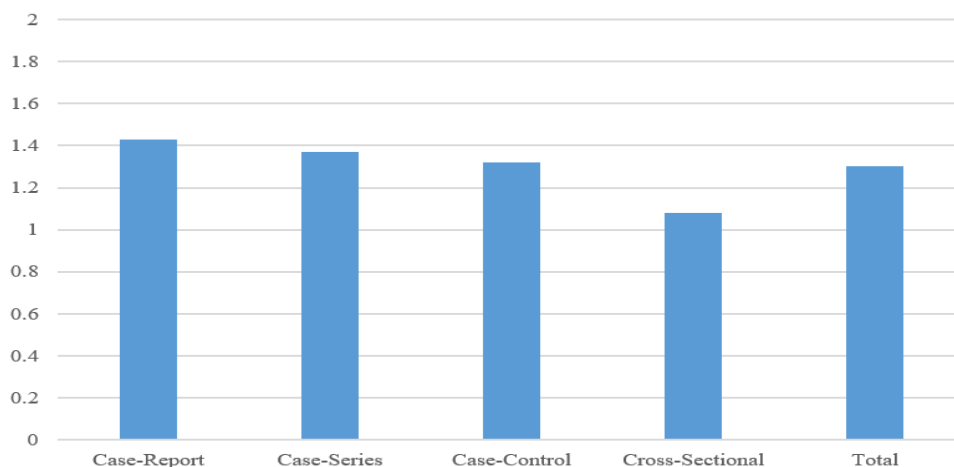


Fig. 4: Reporting quality of Traditional Persian Medicine observational studies according to the type of study up to the end of 2022

The Mann-Whitney method analysis revealed significant associations between some variables and improved quality of reports. Although this association was not significant for the number of authors, it was significant for the article's language and affiliation to a TPM research center or school. A subgroup analysis was performed for affiliation to a TPM research center or school. This variable was shown to have a significant as-

sociation with better quality reports only for Persian articles ($P < 0.001$), not for English articles ($P = 0.84$). A positive and significant linear association was also found between the journal's latest impact factor ($r = 0.21$), the years of study ($r = 0.95$), and the quality of reports (Table 3). Over the years of investigation, both the publishing trend and the quality of TPM observational studies have improved (Fig. 5).

Table 3: The association between independent variables and quality of Traditional Persian Medicine observational studies up to the end of 2022

Independent variables		Frequency (%)	Mean scores \pm SD	Mann-Whitney P-value	Spearman's correlation coefficients
Language of articles	Persian	48(44)	0.82 \pm 0.28	<0.001	
	English	61(56)	1.23 \pm 0.23		
Number of Authors	≤ 5	82(23.74)	1.10 \pm 0.35	0.14	
	>5	27(76.26)	1.13 \pm 0.27		
	Affiliation to a Traditional Persian Medicine research center/school				
	Yes	66 (60.55)	1.20 \pm 0.27	< 0.001	
	No	43(39.45)	0.83 \pm 0.29		
Subgroup Analysis	Persian articles	15(22.7)	1.04 \pm 0.33	< 0.001	
	English articles	51(77.3)	1.22 \pm 0.23		
Years of study		-	1.30 \pm 0.27	< 0.001	(0.95)
Journal Metrics					
Last Impact Factor		-	0.39 \pm 1.20	0.02	(0.21)

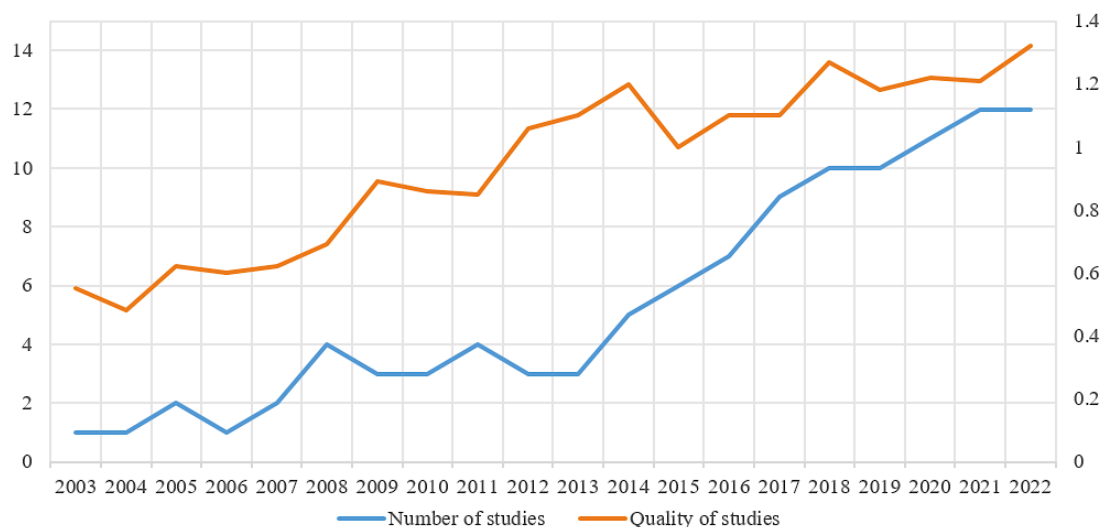


Fig. 5: Distribution of the number of Traditional Persian Medicine observational studies together with their qualities up to the end of 2022

Discussion

As per the STROBE evaluation, the quality of the report concerning the result and method sections scored below one. Following the CARE guidelines, the sections with the lowest average score were keywords, follow-up and outcomes, and diagnostic assessment. Overall, there was a higher prevalence of cross-sectional studies compared to other types of studies, but they exhibited lower quality. Additionally, no cohort studies were conducted during the specified time frame. The study identified a significant correlation between the article's language, affiliation with a TPM research center or school, and the journal's latest impact factor with improved report quality. To enhance the reliability and comprehensibility of reports, it is essential to provide detailed information on the study design, implementation, and results in the method and results sections (16). However, our findings, consistent with other studies (23,24), highlight concerns regarding the quality of reporting in these sections. Key elements such as bias, missing data, sensitivity analyses, study size, and flow diagram received the lowest scores in these sections. Biases can impact the evidence derived from observational

studies (11). As a result, considering potential sources of bias is vital. However, potential sources of bias were inadequately described in this study, like another research (25,26). While missing data can influence study generalizability and bias, its reporting was infrequent in this study, mirroring findings from other investigations (27,28). In observational studies, sensitivity analyses are commonly utilized as a means to assess the study's resilience against unmeasured confounding (29). However, similar to findings in other studies (27,30), the frequency of reporting sensitivity analyses in this study was notably low. Calculation of sample size is essential for effective participant recruitment and the identification of significant differences (31). Nevertheless, in our investigation, as observed in prior studies (32,33), the reported sample size was insufficient. The level of reporting in flow diagrams was also notably low, aligning with findings from earlier research (25,33,34). Researchers can enhance the interpretability of their studies by providing comprehensive and detailed reports of their methods and results.

Case reports serve as a valuable source of innovative medical ideas and knowledge (9). The increasing number of case reports in the presence

of clinical trials and systematic reviews under-scores their significance (35). According to CARE guidelines, items such as diagnostic challenges, prognosis, intervention adherence and tolerability, adverse and unanticipated events, strengths and limitations, patient perspective, and informed consent received a low mean score. Additionally, a majority of articles lacked sufficient reporting of keywords. These findings align with previous research (22,36), except for the item of keyword reporting being adequate in prior studies. Well-written and well-presented case reports have the potential to detect early warning signs of prospective benefits and drawbacks. Therefore, authors must adhere to reporting guidelines to enhance the quality of case reports (19).

Similar to the findings (37), the prevalence of cross-sectional articles was higher compared to other types of studies. However, the reporting quality of cross-sectional articles in this study was lower than that observed in another study (33). Due to the limited number of case-control and case series studies, as well as the predominance of Persian-language cross-sectional articles, the reliability of the results may be compromised, and the study quality could be influenced by the language used in the articles. In contrast to the increasing number of cohort studies in traditional Chinese medicine (38), no cohort studies were conducted in Traditional Persian Medicine during the period under examination. Given that cohort studies are commonly employed in research and their outcomes are considered next in line to randomized controlled trials (7), traditional medicine experts must pay more attention to cohort studies in their research aims.

Similar to previous research, the recent impact factor of the journal (39,40) and the language of the article (41) were found to be significantly correlated with the quality of the reports. These findings may be attributed to variations in journal acceptance policies. Consistent with the findings of Habibi et al. (40), a notable link was identified between affiliation with a Traditional Persian Medicine research center or school and improved report quality. However, subgroup analysis re-

vealed that this association was not statistically significant for English publications. Therefore, the observed correlation may be influenced by the language of the article or random chance.

Limitations

This study had several limitations. Initially, articles from the Embase database were not included due to the unavailability of access. However, given the database overlaps, this limitation is unlikely to affect significantly the accuracy of the results. Additionally, the assessment of article quality solely relied on the authors' reports without additional information requested. Finally, due to insufficient evidence, all checklist items were weighted equally.

Conclusion

The quality of TPM observational studies is a point of concern. The adherence of case-control and cross-sectional studies to STROBE guidelines specifically in the Results and Methods sections raised concerns. The recommendation for TPM experts is to emphasize adherence to the relevant checklist in future studies, particularly in the methodological section, to enhance the reliability of findings.

From study design to publication, both researchers and journals should comply with the STROBE checklist and CARE guidelines. Since TPM and modern medicine have differing philosophical and theoretical foundations, it is advisable to create a localized STROBE checklist while enhancing research methodologies for TPM studies. Furthermore, because cohort studies are so important in creating scientific data, traditional medicine experts should pay more attention to them.

Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission,

redundancy, etc.) have been completely observed by the authors.

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Data availability

Data related to this article can be obtained from the corresponding author on request.

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Conflict of interest

There is no conflict of interest between the authors.

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