



ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ
ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ



ΠΡΟΓΡΑΜΜΑ ΜΕΤΑΠΤΥΧΙΑΚΩΝ ΣΠΟΥΔΩΝ

**«Μεθοδολογία Βιοϊατρικής Έρευνας, Βιοστατιστική
και Κλινική Βιοπληροφορική»**

Τίτλος

Assess the reporting quality of Meta-analysis of RCTs in Heart failure with preserved ejection fraction (HFpEF) published from 2000 to 2019 using the PRISMA statement.

Αξιολόγηση της ποιότητας αναφοράς μετα-αναλύσεων τυχαιοποιημένων κλινικών μελετών στην καρδιακή ανεπάρκεια με διατηρημένο κλάσμα εξώθησης, οι οποίες δημοσιεύθηκαν από το 2000 έως το 2019, με τη χρήση του εργαλείου PRISMA.

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A. Abstract

Background The lack of established benefit of examined interventions in RCTs conducted in HFpEF population has led to the conduction of several meta-analyses (MAs), in an effort to better summarize the available evidence. MAs are at the top of in the hierarchy of evidence, providing that their quality is high.

Purpose The aim of this study was to evaluate the reporting quality of meta-analyses of RCTs in HFpEF according to PRISMA statement.

Methods PubMed and Web of science databases were systematically searched for English language meta-analyses of RCTs involving patients with HFpEF published from 1st January 2000 through 17th of July 2019. Quality of reporting was performed using PRISMA statement and ranking of journals. Association of number of authors, number of included RCTs and mention of adherence to PRISMA, with PRISMA compliance, was also investigated.

Results The search yielded 34 eligible meta-analyses. Four items were reported in all the studies. At least 90% and 70% of the included studies complied with 15 and 18 items of PRISMA statement, respectively. Protocol and registration, search strategy and funding were reported in less than 50% of the studied meta-analyses. No differences were observed in reporting of each PRISMA statement item between reports published in journals with high and lower impact factor. Better compliance was associated to the number of included studies.

Conclusions Quality of reporting in meta-analyses of RCTs in HFpEF is satisfactory irrespectively of journals' impact factor. However, there is room for further improvement in reporting of specific items of PRIMSA checklist.

Keywords

HFpEF, PRISMA, meta-analysis

Abbreviations

HFpEF, heart failure preserved ejection fraction

HFnEF, heart failure normal ejection fraction

IF, impact factor

MA, meta-analysis

RCT, randomized controlled trial

PRISMA, Preferred Reporting Items of Systematic reviews and Meta-Analyses

A. Περίληψη

Εισαγωγή Η απουσία τεκμηριωμένου οφέλους των μελετώμενων παρεμβάσεων από τυχαιοποιημένες κλινικές μελέτες στην καρδιακή ανεπάρκεια με διατηρημένο κλάσμα εξώθησης (ΚΑΔΚΕ), οδήγησε στη διενέργεια μετα-αναλύσεων, με σκοπό την καλύτερη αξιολόγηση των διαθέσιμων δεδομένων.

Σκοπός Σκοπός της παρούσας μελέτης, είναι η ποιοτική αξιολόγηση των μετα-αναλύσεων των τυχαιοποιημένων κλινικών μελετών στη ΚΑΔΚΕ, σύμφωνα με το εργαλείο PRISMA.

Μέθοδοι Πραγματοποιήθηκε αναζήτηση των ηλεκτρονικών βάσεων PubMed και Web of science για μετα-αναλύσεις τυχαιοποιημένων κλινικών μελετών σε ασθενείς με ΚΑΔΚΕ, οι οποίες δημοσιεύθηκαν στην αγγλική γλώσσα, από τη 1^η Ιανουαρίου του 2000 έως και τη 17^η Ιουλίου του 2019. Η ποιοτική αξιολόγηση έγινε βάσει του εργαλείου PRISMA και του συντελεστή απήχησης των περιοδικών. Λήφθηκαν υπόψιν ο αριθμός των συγγραφέων και των μελετών της κάθε μετα-ανάλυσης καθώς και η σαφής αναφορά στη συμμόρφωση με τις οδηγίες του εργαλείου PRISMA.

Αποτελέσματα Προέκυψαν 34 αποτελέσματα από την αναζήτηση. Τέσσερα σημεία του PRISMA αναφέρονται σε όλες τις μελέτες. Τουλάχιστον 90% και 70% των συμπεριλαμβανόμενων μελετών συμμορφώνονται με 15 και 18 σημεία του PRISMA αντίστοιχα. Δεν παρατηρήθηκαν στατιστικά σημαντικές διαφορές στην ποιότητα των μελετών οι οποίες δημοσιεύθηκαν σε περιοδικά με υψηλό και με χαμηλότερο συντελεστή απήχησης. Η καλύτερη συμμόρφωση στο εργαλείο PRISMA σχετίστηκε με τον αριθμό των συμπεριλαμβανόμενων μελετών σε κάθε μετα-ανάλυση.

Συμπεράσματα Η ποιότητα των μετα-αναλύσεων των τυχαιοποιημένων κλινικών μελετών, όπως αξιολογήθηκε με το PRISMA, ήταν ικανοποιητική, αν και υπάρχει περιθώριο βελτίωσης.

Λέξεις κλειδιά

Καρδιακή ανεπάρκεια με διατηρημένο κλάσμα εξώθησης, μετα-ανάλυση

B. Introduction

Heart failure is a clinical syndrome that has been characterized a global pandemic, affecting over 26 million people worldwide(1). Approximately half of the patients with signs and symptoms of heart failure have a preserved ejection fraction(2). While clinical trials in heart failure with reduced ejection fraction (HFrEF) have yielded several drugs and devices that substantially improve outcomes, in HFpEF, trials have failed to demonstrate the efficacy of any tested treatments in improving morbidity and mortality. However, several concerns, regarding study design of the aforementioned trials, have been raised(3). The failure of large trials to reach a positive endpoint has been attributed to numerous factors. HFpEF is a quite heterogenous syndrome in terms of patient phenotypes, underlying etiologies, pathophysiological pathways and comorbidities(4,5). Meta-analysis is a statistical procedure that systematically assesses previous research studies and integrates their results to extract conclusions. One of the main benefits of meta-analyses is that they provide a quantitative review of large and sometimes inconsistent evidence. Along with systematic reviews, they are on the top in the hierarchy of evidence (6,7). Several meta-analyses in HFpEF population have been conducted to test the hypothesis that combining RCTs with neutral conclusions might bring a positive result for interventions not only on mortality and heart failure hospitalizations but also on softer endpoints such as quality of life, exercise tolerance and diastolic function. Sufficient reporting of methodological approaches, results and risk of bias is of incremental value when assessing the strengths and limitations of the derived evidence. Evaluation of quality reporting allows for better interpretation of current evidence and implementation of their results for developing clinical practice guidelines. To address the need for optimizing the quality of reporting in systematic reviews and meta-analyses, Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA) statement has been developed in 2009, which focused on the reporting of systematic reviews and meta-analyses of RCTs (8). PRISMA urges integrity and transparency of reporting and should be used both as a guide for reporting and as a quality rating tool. So far, no thorough evaluation of reporting of meta-analyses of RCTs in HFpEF, based on PRISMA statement, has been conducted. The aim of the present study was to evaluate the quality of reporting of meta-analyses of RCTs in HFpEF in adherence to the PRISMA statement. The impact of the journal ranking in the reporting quality was also investigated.

C. Materials and Methods

Data sources and search strategies

PubMed and Web of Science databases were searched for all meta-analyses of randomized controlled trials (RCTs) involving patients with heart failure and preserved ejection fraction from 1st January 2000 to 17th July 2019. The search terms included: “HFpEF” OR “HFnEF” OR “heart failure and preserved ejection fraction” OR “heart failure and normal ejection fraction” OR “diastolic heart failure”. Results were filtered for meta-analyses, English language and studies on human subjects, using predesigned and validated filters. A manual search of reference lists of all identified studies was also performed for additional studies.

Study selection - Eligibility of studies

Records retrieved from database search were screened by title and abstract after deduplication. Selected records, that were considered as potentially relevant, were further screened for eligibility in full text. Retrieved articles were considered eligible if they were (i) meta-analyses of RCTs, (ii) investigated patients with heart failure and preserved ejection fraction and (iii) had been published in English language, as full papers in peer reviewed journals indexed in PubMed or Web of science. Meta analyses of observational studies and nonsystematic, narrative reviews were excluded.

Data extraction and reporting assessment tool

For all included meta-analyses the following data were collected: year of publication, journal, impact factor, number of authors, number of included articles in the meta-analysis and mention of adherence to Preferred Reporting Items of Systematic reviews and Meta-Analyses (PRISMA).

PRISMA statement, which is a 27-item checklist that consists of seven sections (title, abstract, introduction, methods, results, discussion and funding) was used as assessment tool for the reporting quality of meta-analyses of RCTs. As PRISMA was developed in 2009 and all the included meta-analyses were published after 2010, dividing the studies into subcategories according to publication date (pre-PRISMA, post-PRISMA period) was deemed of no substantial benefit. An extraction form consisting of 33 items was developed and was initially piloted on three manuscripts, as proposed by the literature(9).

Methodological evaluation

The meta-analyses of randomized controlled trials were evaluated based on the PRISMA statement overall and according to the ranking of journals. All items were investigated in terms of whether they were reported and not whether they were actually performed during the study. Items were scored as a positive response (“yes”) if they were reported adequately to allow the reader decide that the definition had been met. Supplementary data were searched after the evaluation of the articles and considered in cases of explicit reference to them. If reporting of one of the items was sufficiently done in an appendix or a protocol to which was correctly referred, the item was assessed as a positive response. Items that were not reported or were partially reported were coded as negative responses (“no”). When an item was reported in a different section of the trial it was considered as a negative response.

The greater than 75% compliance with PRISMA statement items, i.e. the percentage of meta-analyses that addressed at least 75% of the 27-item checklist, was calculated. Compliance greater than 75% was considered as adequate. The included records were also classified in accordance with each Journal’s Impact Factor for 2018. Journal metrics were obtained from Institute for Scientific Information (ISI) impact factor (IF) 2018. Assessment of quality in high ranked journals versus lower ranked journals was performed. As a cut-off, IF=4.96 was selected since it represents the 75th upper quartile of the impact factors of all the included journals. The included records were divided into subgroups based on their compliance to PRISMA and comparisons between subgroups were performed, using Fischer’s exact test. The mean PRISMA compliance of the records published in journals with current impact factor greater than 4.96 and lower than 4.96 was calculated and an independent samples t-test was performed to compare the two groups. Pearson’s correlation was used to assess the correlation between PRISMA score and prespecified variables (journal impact factor, number of authors, number of included studies in the meta-analysis). Statistical analysis was carried out using Microsoft excel 2019 and IBM SPSS Statistics version 23.

D. Results

Study search results

Our initial search yielded 145 potentially relevant studies for review from the following literature sources (Pubmed n=69, Web of science n=76). After deduplication, 95 records were

screened by title and abstract. Via eligibility screening, 36 records were excluded and 59 records were screened by full text. The reference lists of included studies were also searched for additional meta-analyses, identifying two other studies. Consequently, a total of 34 studies were included for analysis (Figure 1).

Main results

The mean PRISMA compliance was $80.6 \pm 12.2\%$. Four items were reported in all the studies (100%) and 15 items were reported by at least 90% of the included meta-analyses. Additionally, 18 items were reported by 70% of the studies (Table 1 and Figure 2). On the contrary, nine PRISMA items were reported in less than 75% of the included studies and three of them (protocol and registration, search and funding) were reported in less than 50% of the reports (Table 2).

The 34 articles were published in 24 different journals. Out of the total of 34 studies, 26 were published in lower impact factor journals and 8 in journals with an impact factor greater than 4.96, which were considered as high-ranked journals. No statistically significant differences were observed in reporting of each PRISMA statement item between reports published in journals with high and lower impact factor. There was no significant association of the IF with the different levels of compliance ($p=0.922$). Both in high ranked journals and in lower ranked ones, almost two thirds of the reports complied with more than 80% of the PRISMA items (Table 3).

The mean compliance of the articles published in low ($IF < 4.96$) and high-ranked journals ($IF \geq 4.96$) were 79.91 and 82.87 respectively. The difference between the two was not found statistically significant (Independent samples t-test, p -value=0.56). Mention of adherence to PRISMA was not associated with greater than 75% PRISMA compliance (p -value=0.092).

Correlation with other variables

PRISMA score was not correlated with number of authors ($r=0.174$, p -value=0.325) but was found to be moderately correlated to the number of included articles in each meta-analysis ($r=0.429$, p -value **0.011**) (Figure 3).

Table 1. Assessment of reporting of PRISMA items in the total reports of systematic reviews of RCTs in HFpEF and according to the impact factor of journals

PRISMA items	N (%) reporting item		
	Total reports (N=34)	Lower IF reports (IF<4.96) (N=26)	High IF reports (IF≥ 4.96) (N=8)
1. Title	33 (97.1)	26 (100)	7 (87.5)
2. Structured summary	22 (64.7)	16 (61.5)	6 (75)
3. Rationale	34 (100)	26 (100)	8 (100)
4. Objectives	32 (91.2)	23 (88.5)	8 (100)
5. Protocol and registration	6 (17.6)	3 (11.5)	3 (37.5)
6. Eligibility criteria	30 (88.2)	23 (88.5)	7 (87.5)
7. Information sources	33 (97.1)	25 (96.2)	8 (100)
8. Search	8 (23.5)	6 (23.1)	2 (25)
9. Study selection	33 (97.1)	25 (96.2)	8 (100)
10. Data collection process	29 (85.3)	21 (80.8)	8 (100)
11. Data items	31 (91.2)	24 (92.3)	7 (87.5)
12. Risk of bias in individual studies	25 (73.5)	19 (73.1)	6 (75)
13. Summary measures	34 (100)	26 (100)	8 (100)
14. Synthesis of results	32 (94.1)	24 (92.3)	8 (100)
15. Risk of bias across studies	26 (76.5)	18 (69.2)	8 (100)
16. Additional analyses	23 (67.6)	17 (65.4)	6 (75)
17. Study selection	33 (97.1)	25 (96.2)	8 (100)
18. Study characteristics	32 (94.1)	25 (96.2)	7 (87.5)
19. Risk of bias within studies	19 (55.9)	16 (61.5)	3 (37.5)
20. Results of individual studies	33 (97.1)	25 (96.2)	8 (100)
21. Synthesis of results	33 (97.1)	25 (96.2)	8 (100)
22. Risk of bias across studies	22 (64.7)	17 (65.4)	5 (62.5)
23. Additional analysis	24 (70.6)	19 (73.1)	5 (62.5)
24. Summary of evidence	34 (100)	26 (100)	8 (100)
25. Limitations	33 (97.1)	26 (100)	7 (87.5)
26. Conclusions	34 (100)	26 (100)	8 (100)
27. Funding	16 (47.1)	12 (46.2)	4 (50)

Table 2. Lowest ($\leq 75\%$) reported PRISMA items in the total reports of meta analyses of RCTs in HFpEF and according to the IF

PRISMA items	N (%) reporting item		
	Total reports (N=34)	Lower IF reports (IF<4.96) (N=26)	High IF reports (IF \geq 4.96) (N=8)
2.Structured summary	22 (64.7)	16 (61.5)	6 (75)
5.Protocol and registration	6 (17.6)	3 (11.5)	3 (37.5)
8.Search	8 (23.5)	6 (23.1)	2 (25)
12.Risk of bias in individual studies	25 (73.5)	19 (73.1)	6 (75)
16.Additional analyses	23 (67.6)	17 (65.4)	6 (75)
19. Risk of bias within studies	19 (55.9)	16 (61.5)	3 (37.5)
22. Risk of bias across studies	22 (64.7)	17 (65.4)	5 (62.5)
23. Additional analysis	24 (70.6)	19 (73.1)	5 (62.5)
27. Funding	16 (47.1)	12 (46.2)	4 (50)

Table 3. Reporting quality of meta-analyses of RCTs based on the different levels of compliance with PRISMA items according to journals' impact factor

Impact factor	<50%	[50-65%)	[65-80%)	$\geq 80\%$	Total
IF<4.96	1 (3.8%)	2 (7.7%)	6 (23.1%)	17 (65.4%)	26
IF \geq 4.96	0	1 (12.5)	2 (25%)	5 (62.5%)	8
Total	1 (2.9%)	3 (8.8%)	8 (23.5%)	22 (64.7%)	34

Compliance is defined as the reporting frequency (%) of the PRISMA items for each article

Brackets indicate the proportion (%) of articles published in high or low ranked journals according to their level of compliance with the PRISMA statement

Figure 1. The flow diagram depicts the flow of information through the different phases of literature search. It maps out the number of records identified, included and excluded, and the reasons for exclusions.

Figure adapted from(8)



Figure 2. Percentage of studies adequately reporting each PRISMA checklist item.

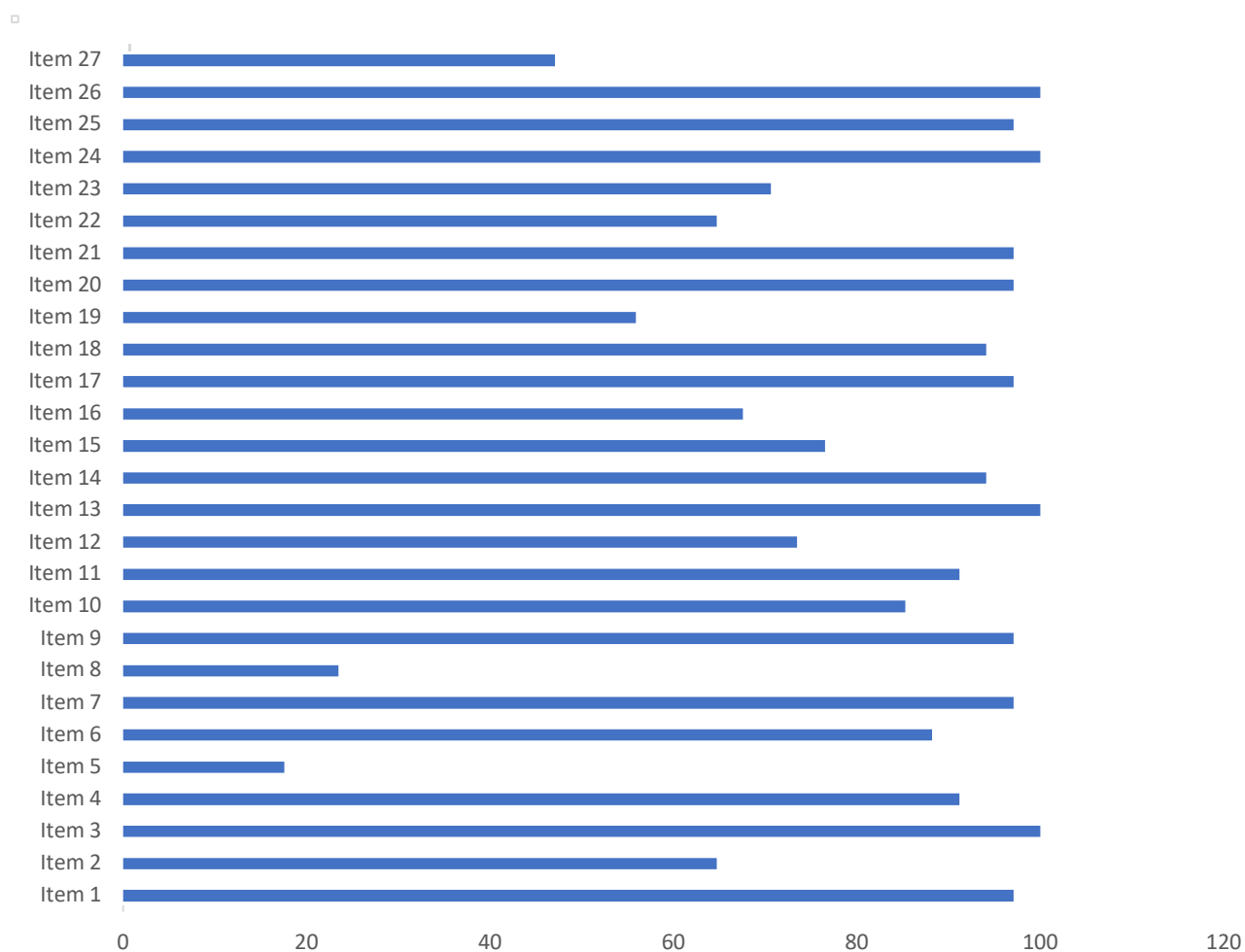
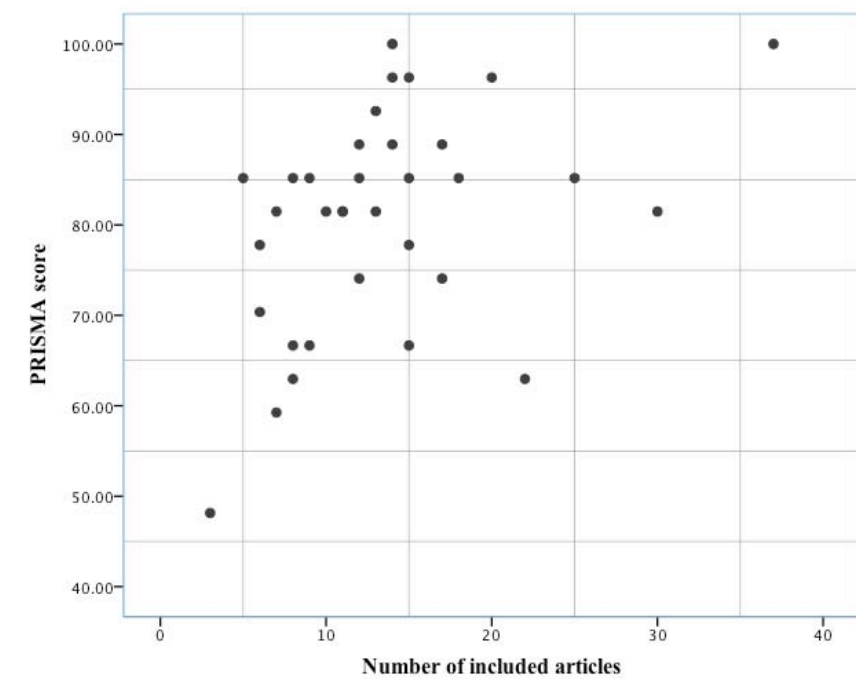


Figure 3.



E. Discussion

To our knowledge, the present study is the first to systematically identify all meta-analyses of RCTs in HFpEF and assess the quality of reporting in accordance with the PRISMA statement. The reporting of each item of the 27-item checklist was assessed and the effect of each journal's ranking was taken into consideration. Overall, the reporting quality was relatively high with a mean compliance score of 80.6%. However, some essential aspects of PRISMA checklist were generally underreported. In most of the included studies there was absence of indication of a review protocol and registration information including registration number. Review protocols are essential for minimizing duplication of research and enhancing transparency and integrity (10,11). The reporting quality of full search strategy was found to be poor, rendering assessment of validity of meta-analyses of RCTs challenging. While assessment of sources of potential bias of the included RCTs in each meta-analysis is of high importance in the selection progress, reporting of risk of bias of each individual study was unsatisfactory. The same applies for reporting of sources of funding, which was only present in less than half of the included meta-analyses. Level of financial support and role of funders may influence interpretation of the results and thus, should not be omitted(12). Similar findings regarding quality of reporting have been identified by previous studies in several medical fields(13–18). We found no impact of journals' ranking in reporting of each PRISMA item. The overall reporting quality of meta-

analyses was also not found to be associated with the ranking of journals. Furthermore, mention of adherence to PRISMA statement did not seem to affect the overall compliance. A positive correlation between the PRISMA score and the number of included articles in each meta-analysis was identified.

In the field of heart failure with preserved ejection fraction, assessment of RCTs investigating pharmacological therapies, has been performed using the Consolidated Standards of Reporting Trials (CONSORT) statement. Zheng et al found inadequate reporting standards of HFpEF RCTs (19) and highlighted that reporting of high quality is imperative for further meta-analyzing the results of RCTs and interpretation of their results.

As mentioned above, the reporting quality of meta analyses of RCTs using the PRISMA statement has been evaluated in other medical fields. Nawijn et al evaluated quality of reporting of systematic reviews and meta-analyses in emergency medicine and found that reviews published in journals requiring PRISMA adherence had better reporting quality compared to the ones that were published in journals with no such instructions(15). Keith Tan et al assessed the reporting quality of meta-analyses published in the top five general surgery and top five vascular surgery journals in the pre and post-PRISMA era and found a small improvement in reporting quality after the publication of PRISMA statement(20). Panic et al investigated the impact of PRISMA endorsement on reporting quality of journals in gastroenterology and hepatology and came to the conclusion that implementation of PRISMA resulted in higher methodological and reporting quality(21). Underreporting of several items of PRISMA was documented by Peters et al who aimed to assess reporting quality of systematic reviews and meta-analyses of otorhinolaryngologic articles(16).

Study limitations

Our study has certain limitations. To begin with, literature search was limited to PubMed and Web of Science. Thus, we may have missed articles through the initial search. Results were restricted to English language which may introduce bias in our study. Furthermore, the selected scoring system for PRISMA adequacy was binary. It may well be argued that a scaled scoring system could have been used instead. Finally, the keywords used in the search strategy might have led to omission of suitable records.

Conclusions

To conclude, our attempt to evaluate the reporting quality of meta-analyses of RCTs on heart failure with preserved ejection fraction indicated a relatively acceptable compliance with

PRISMA checklist. However, there is still room for improvement in a few fields. No significant difference between articles published in higher ranked journals and lower ranked journals was noted. Furthermore, explicit mention of adherence to PRISMA did not prove to be associated with better PRISMA compliance. Endorsement of PRISMA checklist by journals and authors will potentially further enhance the reporting quality of meta-analyses, assist interpretation of treatment effects and facilitate health care providers with implementing evidence-based results in their daily clinical practice.

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