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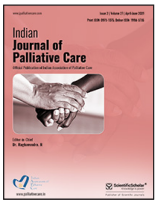

Review Article

Quality of Palliative Care Guidelines in Patients with Heart Failure: A Systematic Review of Quality Appraisal using AGREE II Instrument

Imane Bagheri[1], Hojatollah Yousefi[2], Masoud Bahrami[2], Davood Shafie[3]

[1]Department of Adult Health Nursing, College of Nursing and Midwifery, [2]Department of Adult Health Nursing, Nursing and Midwifery Care Research Center, [3]Department of Cardiology, Heart Failure Research Center, Cardiovascular Research Institute, Isfahan University of Medical Sciences, Isfahan, Iran.

ABSTRACT

Objectives: While the principles for developing clinical practice guidelines (CPGs) are well established, the quality of published guidelines is very diverse. The present study was conducted to evaluate the quality of existing CPGs in palliative care for heart failure patients.

Material and Methods: The study was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-analyses. A systematic search was conducted in the Excerpta Medica Database, MEDLINE/PubMed, CINAHL databases and Guideline internet sites: National Institute for Clinical Excellence, National Guideline Clearinghouse, Scottish Intercollegiate Guidelines Network, Guidelines International Network and National Health and Medical Research Council for CPGs published through April 2021. Criteria for including CPGs were: Containing palliative measures for patients with heart failure over 18 years old and preferably interprofessional guidelines that focus on only one dimension of palliative care or focus on diagnosis, definition and treatment were excluded from the study. After initial screening, five appraisers rated the quality of the final selection of CPGs using the Appraisal of Guidelines for Research and Evaluation, 2nd edition (AGREE II).

Results: From 1501 records, seven guidelines were selected for analysis. The 'scope and purpose' and 'clarity of presentation' domains obtained the highest mean and 'rigor of development' and 'applicability' domains obtained the lowest mean scores. Three categories of recommendations were: (1) Strongly recommended (guidelines 1, 3, 6 and 7); (2) recommended with modifications (guideline 2) and (3) not recommended (guidelines 4 and 5).

Conclusion: Clinical guidelines for palliative care in patients with heart failure were of moderate-to-high quality, with the main deficiencies occurring in the rigor of development and applicability domains. The results inform clinicians and guideline developers of the strengths and weaknesses of each CPG. To improve the quality of palliative care CPGs in the future, it is recommended that developers pay detailed attention to all domains of the AGREE II criteria. Funding agent: Isfahan University of Medical Sciences. (IR.MUI.NUREMA.REC.1400.123)

Keywords: Heart failure, Palliative care, Guideline, AGREE II instrument

INTRODUCTION

Heart failure is a chronic, progressive and fatal disease.[1] It is now a worldwide epidemic;[2-5] approximately 37.7 million people worldwide suffer from heart failure.[6] According to American Heart Association (AHA) statistics, in 2018, nearly 5.7 million people in the United States had heart failure with estimates expected to reach more than 8 million people over the age of 18 by 2030.[1,7,8] In Iran, the prevalence of heart failure of more than 8% is high compared to other countries in the region.[9] Despite the increasing use of medical treatment and advances in technology, these patients have progressive symptoms and problems until the last days of life, including shortness of breath, pain, anxiety, depression, sleep disturbance and fatigue.[10,11] Consequently, they suffer from physical and emotional distress,[12,13] the proper management of which requires the use of a comprehensive and interprofessional care program.[14,15]

Palliative care is a comprehensive and supportive care program for patients nearing end-of-life that uses an interprofessional approach. It is recommended by the guidelines of important cardiovascular associations, including the American College of Cardiology, AHA, The International Society for Heart and Lung Transplantation and

***Corresponding author:** Hojatollah Yousefi, Department of Adult Health Nursing, School of Nursing and Midwifery, Nursing and Midwifery Care Research Center, Isfahan University of Medical Sciences, Isfahan, Iran. yousefi@nm.mui.ac.ir

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the Heart Failure Society of America. Palliative care focuses on quality of life and the ability to improve the patient's symptoms and function[16-19] by addressing physical, mental and psychological concerns as well as providing support for grief for patients and their families.[20] The World Health Organisation defines palliative care as: 'An approach that improves the quality of life of patients and their families living with a life-threatening condition, through the prevention and alleviation of suffering, through early identification and careful assessment and treatment of pain and other problems of a physical, psychosocial and spiritual nature.'[21]

The emphasis on maintaining the quality of life of patients, improving treatment measures and decisions and improving the quality of care has led to the development of interdisciplinary guidelines by many professional organisations over the past decade.[22] Clinical practice guidelines (CPGs) summarise the best available evidence and provide guidance for healthcare providers during their daily practice. CPGs can support the knowledge-to-action cycle effectively if they were developed using a systematic and rigorous methodology.[23] While the principles for developing CPGs are well established, their proliferation has raised concerns about quality. Published reports of CPG appraisals indicate that the quality is generally poor, though it appears to have recently improved and that their applicability is generally low.[24] Appraisals of CPGs for palliative care for heart failure patients do not take into account the most recently published guidelines.

Many sets of standards or criteria for appraisal of CPGs have been published, including the Guidelines International Networks,[25] the GIN-McMaster Checklist[26] and the AGREE II Reporting Checklist.[27] Studies have shown that AGREE II, which has been widely adopted, is the only tool that has a validated scoring system.[28,29] There is a paucity of palliative research in such areas as cardiovascular.[30] Therefore, it is necessary to adapt and develop guidelines to appraise existing CPGs, The purpose of the present study is to evaluate the quality of existing guidelines on palliative care for heart failure patients using the Appraisal of Guidelines for Research and Evaluation, 2nd edition (AGREE II) criteria and to identify the strengths and weaknesses of each guideline.

MATERIAL AND METHODS

Study design

The present study is part of a larger study conducted to implement palliative care CPGs using the ADAPTE approach; The ADAPTE approach provides a systematic approach to adapting guidelines produced in one setting for use in a different cultural and organisational context.[31] The study was conducted according to the Preferred Reporting Items for Systematic reviews and Meta-analyses. To assess CPG quality, we initiated a comprehensive guideline review using AGREE II.

Inclusion and exclusion criteria

Criteria for including CPGs were: (1) Clear introduction as a clinical guide, (2) containing palliative measures for patients with heart failure, (3) the target population is adults over 18 years old, (4) preferably interprofessional, focusing on care rather than treatment and (5) approval by a national or international professional organisation. Primary studies, systematic reviews, pathways, textbooks, publications, short summaries, conference abstracts, letters, duplicate guidelines, guidelines that focus on only one dimension of palliative care or focus on diagnosis, definition and treatment were excluded from the study.

Literature search

The searches were conducted in April 2021 using the following databases: Excerpta Medica Database, MEDLINE/PubMed, CINAHL and Guideline internet sites that were searched, including National Institute for Clinical Excellence, National Guideline Clearinghouse, Scottish Intercollegiate Guidelines Network, Guidelines International Network, Canadian Cardiovascular Society, American College of Cardiology and National Health and Medical Research Council.

Search strategy

Terms searched included (Guideline OR Recommendation OR Protocol OR Pathway) AND ('Palliative care' OR 'Terminal Care' OR 'Hospice Care' OR 'End of life care') AND ('Heart failure' OR 'Cardiac Failure' OR 'Heart Decompensation' OR 'Myocardial Failure') and no year limit. Language restrictions were not applied. In addition, references to each guideline and grey literature were reviewed for other relevant guidelines.

Data extraction/synthesis of results

Search results were uploaded to Endnote software and duplicates were removed. Two researchers (IB and HY) independently screened the titles and abstracts according to the eligibility criteria. Full texts were retrieved when abstracts gave insufficient information ([Figure 1] shows the study selection process). IB extracted the following information 19 CPGs: Purpose, guidelines titles, authors, publication year, country, the organisation that produced the guideline and main key recommendations. The full text of the 19 CPGs was evaluated by the research team (IB, HY, MB and DSH) during a face-to-face meeting. Disagreements between evaluators were resolved through discussion and seven CPGs were finally selected for quality evaluation [Figure 1].

Data quality

To assess CPG quality, we used the Appraisal of Guidelines for Research and Evaluation (AGREE II) instrument. The AGREE II instrument consists of 23 items organised into six domains: (1) Scope and purpose (items 1–3); (2) stakeholder involvement (items 4–6), (3) rigor of

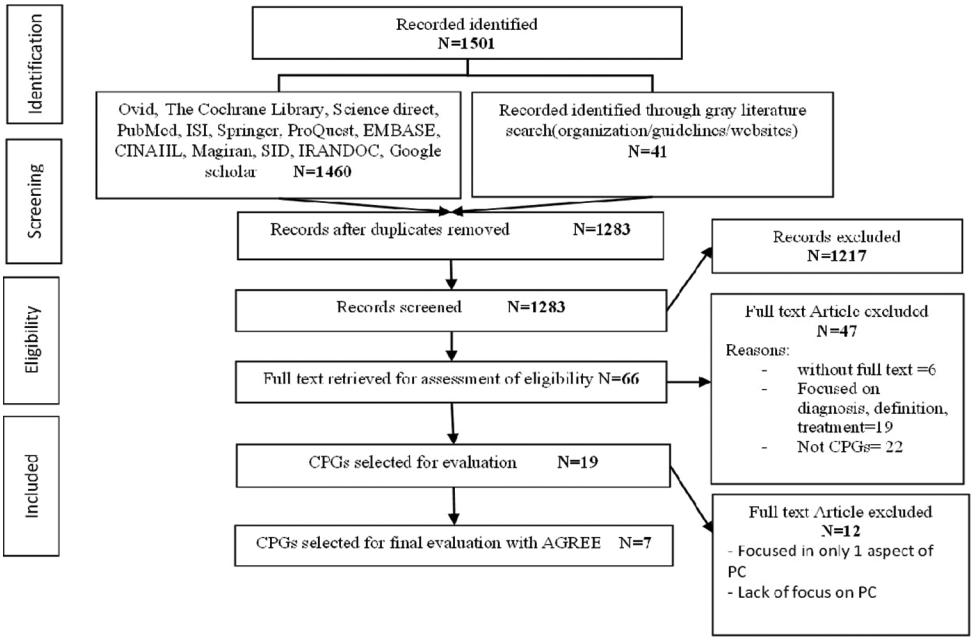

Figure 1: Flow chart of CPGs search and selection.

development (items 7–14); (4) clarity of presentation (items 15–17); (5) applicability (items 18–21) and (6) editorial independence (items 22–23).[32] Reviewers assessed each item and assigned a score from 1 (strongly disagree) to 7 (strongly agree).[33] The overall quality of the guideline (1–7) and the recommendation was also assessed. A standardised score (0–100%) was calculated by summing up item scores within each domain for each reviewer, then standardising it as a percentage of the maximum possible score.[34]

Five appraisers independently scored the guidelines using the AGREE II system. Four appraisers had a doctorate in nursing and one appraiser was a heart failure specialist physician. Before the evaluation, two training sessions were held (MB, one of the team members who specialised in using the AGREE II instrument, trained the others) to acquaint appraisers with how to use the AGREE II instrument. The instrument usage guide was provided to the appraisers in a printed file and the contact number of the principal investigator was provided for appraisers to ask any questions. To interpret the scores based on similar studies using AGREE II instrument, the CPGs fall into three categories: (1) Strongly recommended (guidelines that scored 50% or higher in all domains), (2) 'Recommended with modifications' (guidelines that scored 50% or more in the overall assessment) and (3) 'not recommended' (guidelines that do not score of 50% or more in all the domains or in the overall assessment).[35]

RESULTS

Description of studies

We identified 1501 records from databases, guideline websites and manual searches. After excluding duplicate and irrelevant records, 66 records were considered to be potentially relevant; after selection, a total of seven CPGs satisfied the inclusion criteria [Figure 1]. [Table 1] summarised the features of each of the selected CPGs: Developing organisation, country, compilation method, year of publication, audience and target patient population.

AGREE II appraisal

[Table 2] contains scores in each domain based on the AGREE II appraisal. The quality of the CPG was relatively moderate-to-high overall. We did strongly recommend four of the seven CPGs, as they received a standardised score of 50% or greater on all domains (Guideline numbers 1, 3, 6 and 7). We recommended one guideline with modifications, as it received an overall assessment of 50% or greater (Guideline number 2). We did not recommend two guidelines, as they neither received a standardised score of 50% or greater on all domains nor an overall assessment of 50% or greater (Guideline numbers 4 and 5) [Table 2 and Figure 2].

Domain 1. Scope and purpose are concerned with the overall aim of the guideline, the specific health questions and the target population.[32] The mean score of all CPGs was 88.07% (SD = 13.34) and the scores of all CPGs were higher than 50%. The 'Palliative care in heart failure New York Heart Association (NYHA) Classes III and IV' and 'CPGs for Quality Palliative Care' guidelines achieved the highest score (100%) in this domain. The objective(s) of the guideline and the population (patients, public, etc.) to whom the guideline is meant to apply are specifically described in all guidelines, but in the three guidelines (2, 4 and 5), the clinical questions addressed by the guideline are not explicitly mentioned.

Table 1: Characteristic of seven heart failure clinical practice guidelines.

Title	Developing organisation	Country	Compilation method	Publication year	Audience	Target patient population
Number of 1: Palliative care in heart failure NYHA Class III and IV	Integral Cancer Centre Netherlands	Netherlands	GRADE/ Evidence-based consensus	2018	Healthcare professional	Patients with NYHA Class III and IV
Number of 2: Living and dying with advanced heart failure A palliative care approach	The Scottish Government Better Health, Better Care: Action Plan	UK	Evidence-based consensus	2008	Heart failure specialist nurse or other suitably trained health professional	People with end-stage heart failure
Number of 3: Clinical Practice Guidelines for Quality Palliative Care	National Coalition for Hospice and Palliative Care	America	Evidence-based consensus	2017	Health care organisations and clinicians	Patients with serious illness
Number of 4: Consensus document and recommendations on palliative care in heart failure of the Heart Failure and Geriatric Cardiology Working Groups of the Spanish Society of Cardiology	HF and Geriatric Cardiology Working Groups of the Spanish Society of Cardiology	Spain	---	2019	----	Patients with heart failure
Number of 5: The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: Focus on Sleep Apnoea, Renal Dysfunction, Mechanical Circulatory Support and Palliative Care	Canadian Cardiovascular Society	Canada	GRADE	2011	Physicians and other health team members	Patients with advanced heart failure
Number of 6: Care of dying adults in the past days of life	NICE	England	Evidence-based consensus	2015	• Health and social care professionals who care for people who are dying • Commissioners and providers of care for people in the past days of life	Adults (18 years and over) who are dying during the past 2–3 days of life
Number of 7: End of life care for adults: service delivery	NICE	England	Evidence-based consensus	2019	• Commissioners, planners and coordinators of health and social services • Providers of health and social care • Health and social care practitioners • Adults approaching the end of their life, their careers and families	Patients in the past weeks and months of life

NYHA: New York Heart Association, NICE: The National Institute for Health and Care Excellence

Table 2: Clinical practice guideline domain scores using the AGREE-II instrument.

Guideline number	Clinical Practice Guideline title	Scope and Purpose	Stakeholder Involvement	Rigor of Development	Clarity of Presentation	Applicability	Editorial Independence	Overall assessment	Classification level
1	Palliative care in heart failure NYHA class III and IV	100	100	52.9	92.2	76.6	100	93.3	Highly recommended
2	Living and dying with advanced heart failure: a palliative care approach	64.4	63.3	8.7	82.2	40	6.6	60	Recommended with modifications
3	Clinical Practice Guidelines for Quality Palliative Care	100	65.5	57.5	88.8	83.3	50	76.6	Highly recommended
4	Consensus document and recommendations on palliative care in heart failure of the Heart Failure and Geriatric Cardiology Working Groups of the Spanish Society of Cardiology	80	41.1	14.5	48.8	26.6	50	33.3	Not recommended
5	The 2011 Canadian Cardiovascular Society Heart Failure Management Guidelines Update: Focus on Sleep Apnoea, Renal Dysfunction, Mechanical Circulatory Support and Palliative Care	81.1	42.2	20	60	21.6	46.6	30	Not recommended
6	Care of dying adults in the past days of life	95.5	92.2	93.7	93.3	73.3	73.3	93.3	Highly recommended
7	End of life care for adults: service delivery	95.5	92.2	93.7	93.3	73.3	73.3	80	Highly recommended

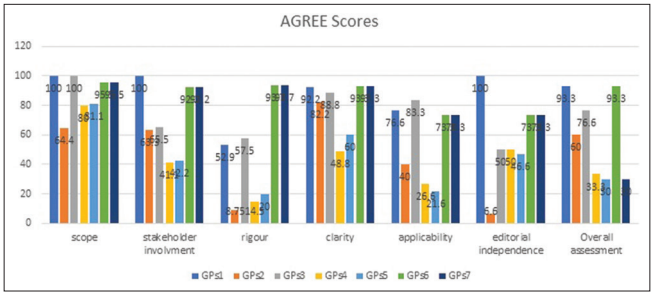

Figure 2: Comparison of the quality of the clinical practice guidelines studied in this report.

Domain 2. Stakeholder involvement focuses on the extent to which the CPG was developed by the appropriate stakeholders and represents the views of its intended users.[32] The mean score of the CPGs was 70.9 % (SD = 24.3) and the scores of five CPGs were higher than 50% and two CPGs lower than 50%. The 'Palliative care in heart failure NYHA Classes III and IV' guideline achieved the highest score (100%) in this domain and 'Consensus document and recommendations on palliative care in heart failure of the Heart Failure and Geriatric Cardiology Working Groups of the Spanish Society of Cardiology' guideline achieved the lowest score (41.1%). The guideline developers include individuals from all relevant professional groups in all guidelines except number 5. The views and preferences of the target population (patients, public, etc.) have been sought for three guidelines (1, 6 and 7). The target users of the guideline are clearly defined in all CPGs except guideline 4.

Domain 3. The rigor of development relates to the process used to gather and synthesise the evidence and the methods to formulate and update the recommendations.[32] The mean score of the CPGs was 48.71 (SD = 35.9). The scores of four guidelines were higher than 50%, but the scores of three CPGs were lower than 50%. The 'Care of dying adults in the past days of life' and 'End of life care for adults: service delivery' guidelines achieved the highest score (93.3%) in this domain. For only three of the seven guidelines (3, 6 and 7), systematic methods were used to search for evidence, the criteria for selecting the evidence and the strengths and limitations of the body of evidence are clearly described. In three guidelines (1, 6 and 7), the methods for formulating the recommendations are clearly described. In four guidelines (1, 3, 6 and 7), the health benefits, side effects and risks have been considered in formulating the recommendations in the guideline and there is an explicit link between the recommendations and the supporting evidence. Only two guidelines (6 and 7) were externally reviewed by experts before their publication. A procedure for updating the guideline is provided in only three guidelines (1, 6 and 7 only).

Domain 4. Clarity of presentation deals with the language, structure and format of the guideline.[32] The mean score of the CPGs was 79.80% (SD=18.06). Scores of all guidelines were higher than 50% except for the 'Consensus document and recommendations on palliative care in heart failure of the Heart Failure and Geriatric Cardiology Working Groups of the Spanish Society of Cardiology' guideline, with a score of 48.8%. In all CPGs except guidelines 4 and 5, the recommendations are specific and unambiguous, the different options for management of the condition or health issue are presented and key recommendations are easily identifiable.

Domain 5. Applicability pertains to the likely barriers and facilitators to implementation, strategies to improve uptake and resource implications of applying the guideline.[32] The mean score of the CPGs was 56.38% (SD = 26.04); the scores of four guidelines were higher than 50%, but the scores of three guidelines were lower than 50%. The 'CPGs for Quality Palliative Care' guideline, with a score of 83.3%, had the highest applicability score. Facilitators and barriers to guideline application are neglected in three of the seven guidelines (2, 4 and 5). Only guidelines 2, 3, 6 and 7 provide advice and/or tools on how the recommendations can be put into practice. The potential resource implications of applying the recommendations have been considered in all guidelines except guidelines 4 and 5. All guidelines, except guideline 2, present monitoring and/or auditing criteria.

Domain 6. Editorial independence is concerned with the formulation of recommendations not being unduly biased by competing interests.[32] The mean score of the CPGs was 57.11% (SD = 29.23). The scores for five guidelines were higher than 50% and lower than 50% for two guidelines. The 'Living and dying with advanced heart failure: A palliative care approach' guideline with a score of 6.6% had the lowest score in editorial independence. Four guidelines (2, 3, 4 and 5) do not mention that the views of the funding body did not influence the content of the guideline. Except for guideline 2, all guidelines documented and expressed the potential conflict of interest of the members of the development team.

Overall assessment includes the rating of the overall quality of the guideline and whether the guideline would be recommended for use in practice.[32] The mean score of the overall quality of the CPGs was 66.6% (SD = 26.44). Five of seven CPGs (1, 2, 3, 6 and 7) scored higher than 50% in the overall evaluation.[36-40] In the classification of the quality of the guidelines according to the AGREE II score, the use of four CPGs was strongly recommended.[36-39] The use of one CPG was recommended with modifications[40] and the use of two CPGs was not recommended.[41,42]

DISCUSSION

This study is the first to evaluate the quality of palliative care guidelines for patients with heart failure using AGREE II.

The quality of the CPG was relatively moderate-to-high overall. We did strongly recommend four of the seven CPGs, as they received a standardised score of 50% or greater on all domains. The 'scope and purpose' and 'clarity of presentation' domains obtained the highest mean and 'rigor of development' and 'applicability' domains obtained the lowest mean scores.

The domains of 'scope and purpose' and 'clarity of presentation' obtained the highest mean scores. The objective(s) of the CPG and the patients to whom the CPG is meant to apply are consistently present in the guidelines but the clinical question(s) are often absent or incomplete, greater attention is needed in this area by guideline editors. In the 'clarity of presentation' domain, the recommendations are specific and unambiguous, the different options for the management of the condition or health issue are clearly presented and key recommendations are easily identifiable.

'Rigor of development' and 'applicability' are the most poorly described domains, yet 'rigor of development' is considered the strongest indicator of quality among all the domains and has a major role in personal decision-making about using the content of a CPG to guide patient care.[43] Within this domain, several CPGs did not describe Systematic methods to search for evidence, criteria for selecting evidence, strengths and limitations of the evidence, methods of making recommendations, an explicit relationship between recommendations and supporting evidence, external review by experts before the publication of the CPG or a procedure for updating the guideline. Further attention to this domain is, therefore, necessary when developing or updating a CPG. The reason for the low score of the 'Applicability' domain is the lack of discussion about facilitators, barriers, potential sources of recommendations and monitoring and/or audit criteria. Due to the newness of palliative science, there is limited information and details on how to use and operate palliative care CPGs, especially for patients with heart failure.[42,44,45] Among the six domains, the 'Applicability' domain plays a crucial role.[33] Given the high costs of developing CPGs, their use in practice should be facilitated and reported, with updating and clarification based on both research and implementation evaluation.

Few CPGs clearly stated stakeholder involvement, especially the views and preferences of the target patients. To improve the quality of guidelines, more attention should be paid to including the views and preferences of the target population in compiling CPGs as well as describing the views and influence on the content of the professional organisations that provide funding for CPG development.

Limitations

Some of the appraisers had no previous experience with the AGREE II instrument. In our methodology, there was no blinding to either authors or organisations that developed these CPGs, which may be a potential source of bias. However, the research team members were already familiar with most of the identified CPGs, thus true blinding was not possible. Another limitation was the reliance on computerised searches to identify CPGs and references. Although a robust set of search criteria was formulated and tested before guideline identification, there is a possibility that some CPGs were missed. However, a paper search may have resulted in more human error.

Finally, it should be mentioned that quality scores reflect the appraiser's assessment of the quality of each CPG. We are aware that the robustness of CPGs is more than just the AGREE II score. It has been a common pitfall to put undue emphasis on any aggregate 'overall score.' Moreover, it should be emphasised that no guideline is perfect. Therefore, we decided not to report this aggregate overall score and instead present all results in detail in [Table 2], to show separate results for each of AGREE II questions for every identified guideline.

What this study adds

According to the AGREE II evaluation, the quality of CPGs for palliative care of heart failure is moderate-to-high. We found methodological and applicability limitations affecting CPG quality. The future CPG developers should improve adherence to the AGREE II guidelines.

CONCLUSION

Our findings indicate that the quality of CPGs for palliative care of heart failure is moderate-to-high according to the AGREE II evaluation. We found methodological and applicability limitations affecting CPG quality. The future CPG developers should improve adherence to the AGREE II guidelines. The present study acquaints clinicians and researchers with the principles of guideline assessment. By providing the strengths and weaknesses of palliative care guidelines in the field of heart failure, the study findings can serve as a resource for clinicians as they evaluate their choice of CPG for clinical application. For researchers, the findings point to the need for more rigorous research on the impact of the quality of clinical guidelines on clinician adherence and patient outcomes.

Author contributions

IB and HY conceived the presented idea. They also planned and conducted the literature search and the data collection. IB and MB contributed to the design and the analytical methods. MB and BI contributed to data interpretation. DSH collaborated in writing and editing the article. HY is responsible for the overall content of the article.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent.

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Conflicts of interest

There are no conflicts of interest.

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