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Study Protocol: Systematic Review and Meta-Analysis on the Effectiveness of Pharmacist Intervention on Health-Related Quality of Life and Clinical Outcomes among Patients with Heart Failure

Mulubirhan Tirfe Tesfay[1]*, Alemseged Beyene Berha[2], Haileselassie Berhane Alema[3], Ephrem Engidawork[2], Tewolde Teklu Gebreselassie[1]

[1]Department of Pharmacy, Aksum University, Axum, Ethiopia
[2]Department of Pharmacology and Clinical Pharmacy, Addis Ababa University, Addis Ababa, Ethiopia
[3]Department of Public Health, Aksum University, Axum, Ethiopia

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***For Correspondence:**
Mulubirhan Tirfe Tesfay, Department of Pharmacy, Aksum University, Axum, Ethiopia
E-mail: mulubirhantirfe@gmail.com
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ABSTRACT

Background: Heart Failure (HF) is associated with severe complications, hospitalization, and poor quality of life. Patients with Heart Failure had poor physical and emotional symptoms, poor functional status and worse health outcomes.

Objective: The aim of this systematic review and meta-analysis will be to investigate whether pharmacist intervention is effective in improving Health-Related Quality of Life (HRQoL) and clinical outcomes among patients with Heart Failure.

Method: Systematic review and meta-analysis will be conducted. Published journals in English and indexed in Medline (PubMed), Embase, Cochrane library Scopus, and Google scholar will be searched from 1990 to present. Data will be extracted by one author and will be approved by other two authors independently. Data will be analyzed in accordance with the Cochrane handbook. Standardized mean differences will be used as an estimate of the effect size. Quality of included studies will be assessed using the modified Downs and Black checklist. Analysis for the dichotomous outcome studies will be converted into standardized mean difference and present with 95% confidence intervals. The review is approved in the International Prospective

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Register of Systematic Reviews (PROSPERO) with registration ID CRD42020158236.

Discussion: Currently there are important gaps on the effectiveness of pharmacist intervention in improving Health-Related Quality of Life and clinical outcomes. We believe this review will provide comprehensive evidence on the effectiveness of pharmacist intervention among patients with HF.

Keywords: Heart Failure; Pharmacist intervention; Quality of life; Meta-analysis

INTRODUCTION

Heart Failure (HF) is a cardiac structural and/or functional abnormality leading to failure of the heart to deliver oxygen at a rate commensurate with the requirements of the metabolizing tissues [1]. Diagnosis of HF is confirmed based on clinical history, physical examination (Framingham criteria), chest X-ray and echocardiography findings and laboratory exams specifically plasma B-type Natriuretic Peptide and N-terminal B-type Natriuretic Peptide measurement [2,3]. Clinical outcomes among patients with HF were mortality (all-cause and HF specific death), hospitalization, readmission and morbidity endpoints used in different trials and taken as definition by the European Society of Cardiology HF association consensus document [4].

Globally, about 26 million people were living with HF with poor patient outlook and worse survival [5]. HF put significant stress on patients, caregivers and the health care system. There was higher five year mortality rate among HF patients due to sudden death from ventricular arrhythmia [6].

Multidisciplinary health professionals including nurses, pharmacists and dietitian's intervention on patient education, medication teaching and nutrition guidance, respectively, proved to have positive outcomes and lowered mortality [7]. Lower educational status was associated with an increased hospitalization of HF patients [8]. Low health literacy, which can be defined as Brief Health Literacy Screen ≤ 9, was associated with higher risk of mortality and increased risk of hospital readmission [9]. Heart Failure patients who have higher literacy have better understanding of their disease state, self-efficacy and self-care, thus patients with low literacy level were associated with worse HF related Quality of Life (QoL) [10].

Comparison of QoL among the healthy old age group versus ill old age HF patients showed a lesser QoL in the later ones. Using physical symptom as strongest measure, older adults with HF had poorer physical and emotional symptoms, poorer functional status and more worse health perception [11]. Using the German version generic QoL measure (SF-36) containing eight dimensions, scores of five of the eight QoL domains were reduced to around one-third in NYHA class III patients [12]. In the study conducted in Serbia, the poor QoL were due to lower income, longer history of chronic HF, longer hospital stay, multiple medications, higher NYHA class, depression and cognitive impairment [13].

Communicating hospitalized HF patients effectively at the time of discharge regarding their future clinical status improved QoL of patients [14]. In this case, the involvement of pharmacists demonstrated better medication adherence compared to other health professionals and had greater impact on the ability to inform, solve problem and support patients directly [15].

The pooled data of the systematic review and meta-analysis study on the pharmacist-led medication reconciliation programs, showed a significant reduction in adverse drug event-related hospital and emergency department visits, reduction in hospital readmissions and improved medication adherence [16,17]. Overall, pharmacists significantly improved Health-Related Quality of Life (HRQoL) through pharmaceutical care interventions in terms of general health, social and physical functioning [18] .

Pharmacists can review medication charts and make interventions such as medication reconciliation for discharged patients and correct medication discrepancies, dealing with barriers to medication documentation and interdisciplinary communication [19]. Pharmacist-led medication review and reconciliation were effective in improving medication adherence and patient outcomes, as well as in reducing hospitalization improving post-hospital medication safety and health care utilization [16,17]. Pharmacists play significant roles in handling HF patients by minimizing disease symptoms, improving medication compliance and enhancing chronic disease management [20].

Clinical pharmacists can identify and resolve pharmaceutical care issues and provide optimal care when working in collaboration with other health care professionals [21]. Clinical pharmacist lower prescription errors and medication discrepancies through the discharge service to HF patients. The clinical pharmacist's activities includes: Review of medications, communication with cardiologists, general practitioners and community pharmacists, providing patient information and preparing written overview of discharge medication [22].

Pharmacists decreased readmission of HF patients and improved care through continuum of care such as discharge counselling services and resolving medication reconciliation discrepancies. Patients discharged with the diagnosis of HF who received continuum of care had lower 30-day all-cause readmission rate [23].

Providing pharmaceutical care service to patients with HF had significant clinical and humanistic benefits. Pharmacist-led pharmaceutical care programs were shown to improve exercise tolerance (2-min walk test), forced vital capacity, medication adherence and HRQoL measured by the Minnesota living with Heart Failure questionnaire [24].

The systematic review and meta-analysis study demonstrated multidisciplinary interventions for HF reduced both hospital admission and all-cause mortality [25]. Pharmaceutical care interventions significantly improved HRQoL measures. However, the pooled data on HF- specific measures indicated no significant impact of pharmaceutical care utilization [18]. Therefore, the aim of this systematic review and meta-analysis is to investigate whether pharmacist intervention is effective on Quality of Life and clinical outcomes among patients with HF.

MATERIALS AND METHODS

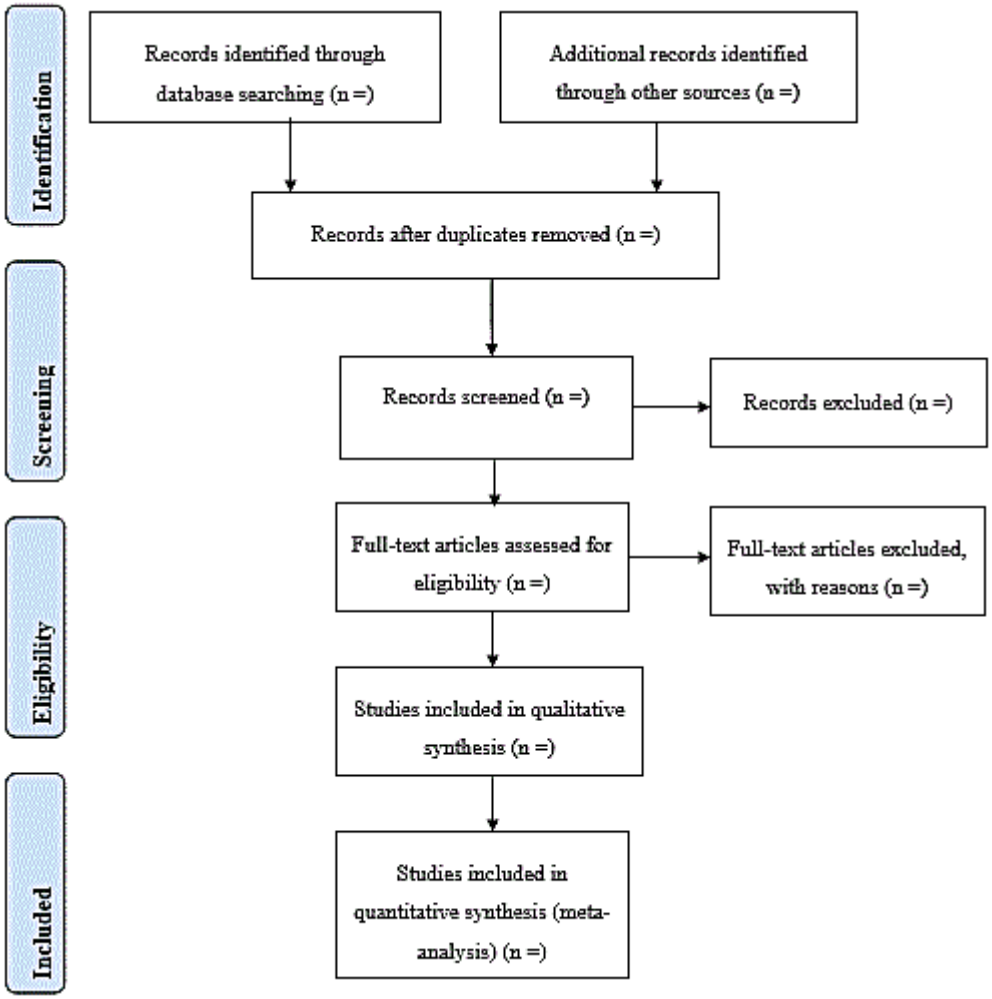
The aim of this study protocol is to provide a clear way to review systematically from various indexing databases and synthesize the data that whether pharmacist intervention is effective on HRQoL and clinical outcomes compared to usual/standard care. This review will address systematic literature search strategy, describe data sources identified in the review, set inclusion and exclusion criteria for the study, describe data extraction process, assess quality measures for the systematic review, and describe statistical procedures for the quantitative analysis. We aim to address our key research question that whether pharmacist intervention is effective on improving HRQoL and clinical outcomes (in terms of reduced hospitalization and mortality) among patients with HF compared to usual/standard care.

Study registration

The review is approved in the International Prospective Register of Systematic Reviews (PROSPERO) with registration number CRD42020158236 after confirming that there was no other similar study under review process.

In order to include all relevant information the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) checklist will be employed as a tool (Additional file 1) [26]. The PRISMA flow diagram will be used for identification, screening, eligibility and inclusion of studies at different stages of the review process (Figure 1).

Figure 1. PRISMA flow diagram of the study.



Review question and eligibility criteria

We believe the following questions are highly relevant to policy makers and service providers. Our review will focus on the journals that are randomized controlled trial only.

- Is pharmacist intervention effective on Health-Related Quality of Life among patients with HF compared to usual/standard care?

- Does pharmacist intervention improve clinical outcomes (reduces patient hospitalization and mortality) among patients with HF compared to usual/standard care?

Eligibility criteria: Studies that reported pharmacist intervention and provided data on Health-Related Quality of Life (or Quality of Life) and clinical outcomes (mortality, hospitalization) will be included in this review. Additionally, studies that reported pharmacist-led multidisciplinary team interventions will be included. The following studies will be excluded: Case reports and case series, case-controls, cohorts, observational and non-research articles and commentaries. Abstracts from conference and journals whose full-text cannot be retrieved will be excluded. In addition, studies that will not report primarily pharmacist intervention such as nurse-led multi-disciplinary team interventions, interventions requiring telephone monitoring, telemedicine, and web-based interventions will be excluded. Therefore, original peer-reviewed articles of randomized controlled trial that report pharmacist intervention and consider HRQoL and clinical outcomes among patients with HF will be eligible for inclusion.

Search strategy and data source

Databases indexed in Medline (PubMed), Cochrane library, Scopus and Google scholar will be conducted to retrieve journals. Original peer reviewed articles published in English language from 1990 to present will be identified using the terms Heart Failure, pharmacist intervention, Health-Related Quality of Life and clinical outcomes. In our search medical subject heading (MeSH) and Boolean operators will be employed to search journals using 'heart failure' (MeSH) or 'cardiac failure' (MeSH) and 'pharmacist intervention' or 'clinical pharmacist intervention' or 'pharmaceutical care' and 'Health Related Quality of Life' or 'Quality of Life' and 'clinical outcome' or 'health outcome' or 'patient outcome'. We limited the studies to randomized controlled trials using the term 'randomized controlled trial'. Titles of all retrieved studies will be screened and abstracts of the selected articles will be further evaluated. Article screening and the selection process will be carried out by the primary author and then independently reviewed by two other authors.

Data extraction

Data will be extracted by one author and will be approved by other two authors independently. Any discrepancy will be resolved by agreement. The following information will be extracted from included studies: name of first author, year of publication, study setting/country, study design, number of participants, follow-up/duration, type of intervention and main outcomes of the study. For data management, we will use the ENDNOTE reference software version 7 (Thomson Reuters, Stamford, CT, USA) in title review, abstract screening, and removal of duplicates.

Quality assessment

Studies will be reviewed independently to assess the quality of included studies to minimize the risk of bias using the modified Downs and Black checklist designed to evaluate both randomized controlled trials and nonrandomized studies. The check list contains 27 items covering quality of reporting, confounding, bias, and representativeness of sample size [27].

Data synthesis and analysis

We will analyse data in accordance with the Cochrane handbook [28]. We will pool data from studies which are sufficiently similar. Meta-analysis will be performed when we find at least two studies that report the same HRQoL and clinical outcome

measures to see the pooled effect of pharmacist intervention. When this is not possible due to insufficient number of studies, we will conduct narrations of the study results. Heterogeneity of included studies will be assessed using the standard Cochrane Q statistics and the I2 (Kendall's tau) statistics. Publication bias will be assessed using funnel plots, and forest plot will be constructed using a random effect model. Because of variability in reporting among studies, standardized mean differences will be used as an estimate of the effect size. Analysis for the dichotomous outcome studies will be converted into standardized mean difference and will be presented with 95% confidence intervals. The analyses will be conducted using the Cochrane Review Manager (RevMan) V.5.3 software (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration, 2014). The study will be reported utilizing Preferred Reporting Items for Systematic Reviews and Meta-Analyses Protocols (PRISMA-P) 2015 statement [26]. For dichotomous outcome data, we will calculate effect size as odds ratio with 95% Confidence Interval (CI). For continuous outcome data, we will convert into Standardized Mean Difference (SMD) and present with 95% Confidence Interval (CI).

RESULTS AND DISCUSSION

Heart Failure is a syndrome associated with higher rates of hospitalization, morbidity, mortality and poor quality of life. Pharmacist interventions have improved Quality of Life on specific diseases; however, the systematic review and meta-analysis study of pharmaceutical care intervention on HRQoL proved no statistically significant impact of pharmaceutical care intervention on HF [18]. Currently, there are important gaps on the effectiveness of pharmacist intervention. We believe this review will provide comprehensive evidence on the effectiveness of pharmacist intervention among patients with HF. Currently we have screened more than 1820 abstracts and identified more than 145 potential studies which we will intend to retrieve their full text review.

We are updating the review process and the PRISMA file is under development. Our search yielded more than 660 articles of these 306 were excluded based on titles and abstracts. Currently we identified more than 30 potential journals to be included for analysis.

CONCLUSION

Heart Failure is a syndrome with adverse outcomes on patient's quality of life. Pharmacist-led intervention have improved Quality of Life in Heart Failure through medication adherence, reducing hospitalization and overall disease management. Pharmacists are better positioned to counsel patients and address problems among patients with Heart Failure.

The summative finding of this systematic review and meta-analysis will provide clear evidence that whether or not the delivery of pharmacist intervention to patients with Heart Failure can lead to significant Health-Related Quality of Life and clinical outcomes.

DECLARATIONS

Acknowledgement

We would like acknowledge to Aksum University.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Availability of data and material

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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None.

Authors' contributions

MTT and ABB designed the study, led the search strategy for abstraction, plans for data extraction, and drafted the first version of the manuscripts with significant inputs from EE, HBA and TTG. All authors have given final approval of the version to be published.

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