Diabetic dyslipidaemia and its determinants among people with diabetes in South Africa: a systematic review and me-ta-analysis protocol

Mashudu Nemukula, Fentahun Adane, Arun Kumar Malaisamy, Neel Sarovar Bhavesh, Harold Majane, Sechene Stanley Gololo

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Abstract

Diabetic dyslipidaemia (DD), characterized by a classical triad of abnormal lipid profiles among the diabetes population, presents a major public health concern in South Africa, particularly among Black South Africans. The increasing prevalence of DD significantly contributes to the development of atherosclerotic cardiovascular disease (ACVD). With the incidence of diabetes rising from 4.5% in 2010 to 12.7% by 2021, urgent preventive measures and effective treatments are crucial to tackle the risk of premature mortality. This systematic review and meta-analysis protocol seeks to examine the existing literature on DD to provide an understanding of its prevalence and associated predictors among the diabetic population in South Africa, with the intention of informing more effective clinical and public health interventions. The available literature on DD will be systematically searched in the common scholarly database and reviewed accordingly. All published and un-published studies conducted in South Africa before the year 2024, written in English will be in-cluded. The results of the analysis will aid in crafting the design of targeted interventions and pol-icies to advance the management of DD and, subsequently, to reduce the increased risk of ACVD among the diabetic population. This protocol has been registered in the PROSPERO database (ID: CRD42024614221).

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Study Protocol

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Abstract: Diabetic dyslipidaemia (DD), characterized by a classical triad of abnormal lipid profiles among the diabetes population, presents a major public health concern in South

Africa, particularly among Black South Africans. The increasing prevalence of DD significantly contributes to the development of atherosclerotic cardiovascular disease (ACVD). With the incidence of diabetes rising from 4.5% in 2010 to 12.7% by 2021, urgent preventive measures and effective treatments are crucial to tackle the risk of premature mortality. This systematic review and meta-analysis protocol seeks to examine the existing literature on DD to provide an understanding of its prevalence and associated predictors among the diabetic population in South Africa, with the intention of informing more effective clinical and public health interventions. The available literature on DD will be systematically searched in the common scholarly database and reviewed accordingly. All published and unpublished studies conducted in South Africa before the year 2024, written in English will be included. The results of the analysis will aid in crafting the design of targeted interventions and policies to advance the management of DD and, subsequently, to reduce the increased risk of ACVD among the diabetic population. This protocol has been registered in the PROSPERO database (ID: CRD42024614221)

Keywords: South Africa; diabetic dyslipidaemia; systematic review; meta-analysis

1. Introduction

Diabetic dyslipidaemia (DD) is one of the major public health concerns, particularly in patients with diabetes. It is an established determinant for the development of atherosclerotic cardiovascular disease (ACVD) and contributes to increased rates of morbidity and mortality. Despite the international efforts to improve management of diabetes, DD remains a significant contributor to the burden of cardiovascular morbidity, especially in developing countries [1, 2]

The prevalence of DD is significantly high in developing countries, where the burden of diabetes is on the rise [3]. In South Africa, DD is a growing concern, with several studies indicating that a significant proportion of individuals with diabetes have lipid abnormalities, namely hypertriglyceridemia, decreased levels of high-density lipoprotein cholesterol (HDL-C) and elevated levels of low-density lipoprotein cholesterol (LDL-C). This lipid profile aggravates the risk of developing ACVD, which is emerging as the leading cause of preventable mortality in the country [4–6].

In South Africa, diabetes and its associated metabolic disorders, including lipid abnormalities, are increasingly prevalent among certain ethnic groups, with a notably higher prevalence seen among Black South Africans [7, 8]. According to the International Diabetes Federation, the prevalence of diabetes in South Africa has notably increased from 4.5% in 2010 to 12.7%, with an estimated 4.58 million people aged 20-70 years affected, of whom 52.4% were undiagnosed [9, 10]. Moreover, South Africa has the second highest number of people living with type 2 diabetes mellitus in sub-Saharan Africa [11]. These metabolic disorders are significant determinants of the national burden of ACVD and premature mortality, with diabetes-related cardiovascular death predicted to increase significantly in the coming years if preventive measures and effective treatment strategies are not implemented [12–14]

Despite the ongoing public health initiatives and policies aimed at addressing diabetes and the determinants of cardiovascular disease, the prevalence of DD continues to rise, particularly among young individuals and those with poor glycemic control [15, 16]. Existing studies have shown that DD is prevalent among diabetic patients who have suboptimal glycemic control and engage in unhealthy lifestyle choices such as poor dietary habits and sedentary lifestyles [17, 18]. Therefore, there is a need for updated studies to

better understand the epidemiology of DD, especially in the context of South Africa, to inform targeted intervention strategies and improve patient outcomes.

Predictors of DD include socio-demographic factors such as age, gender, ethnicity, education level, and household income, including the presence of other comorbid conditions such as hypertension, obesity and chronic kidney disease [19, 20]. Moreover, psychological factors, such as stress as well as sedentary lifestyle factors, contribute to the development and progression of DD among diabetes mellitus individuals [21]. Understanding these predictors is important for developing more effective interventions to manage lipid abnormalities in diabetes mellitus.

The aim of this systematic review and meta-analysis review is to estimate the pooled prevalence of DD among the diabetic population of South Africa and to assess the association between DD and its predictors. The review intends to provide an understanding of how certain predictors influence lipid profiles in diabetes mellitus. In addition, the review also seeks to inform targeted interventions aimed at reducing the incidence of DD and its associated cardiovascular risks in South Africa.

2. Method and Material

2.1 Overall approach

The systematic review will be conducted following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines [22] on studies reporting on DD among people with diabetes in South Africa. Following this approach will ensure a transparent and systematic process for identifying, selecting and including relevant studies (figure 1). The protocol is registered with the international database for systematic reviews PROSPERO (registration number CRD42024614221).

Figure 1. PRISMA flowchart illustrating the systematic search process

2.2 Population of interest

The population of interest will include South Africans diagnosed with diabetes mellitus, including both type 1 and type 2 diabetes. The emphasis is on the diabetic population presenting with DD, characterised by lipid abnormalities such as hypertriglyceridemia, reduced HDL-C and elevated LDL-C. Non-diabetic individuals will not be considered part of the review.

2.3 Eligibility criteria

Studies reporting data on DD (hypertriglyceridemia, low HDL-C and elevated LDL-C) among South Africans with diabetes mellitus will be considered. Observational studies such as cross-sectional, cohort and case-control will be included. Studies reporting data on prevalence or predictors of diabetic dyslipidaemia will be included. Studies that were not conducted among South Africans, including those involving non-diabetic populations, will be excluded. Reviews, case reports, editorials, and conference abstracts reporting on diabetic dyslipidaemia will be disregarded. Studies without relevant lipid profile data will also be excluded.

2.4 Search strategy

Studies for this systematic review and meta-analysis will be accessed through electronic and other relevant sources. We intend to use common database searches like

PubMed/MEDLINE, Embase, Scopus, Web of Science, ScienceDirect, African Index Medicus, Google Scholar and local databases such as African Journals Online, and SABINET, we will also use other relevant data sources such as email and institutional repositories from university community. Our search will include all published and unpublished studies conducted in South Africa before December 2024, that will be written in English language. The searches will be conducted using MeSH terms, combined key terms, text word and search strings taken from the review questions. To access the records, the following combination key terms will be used: ("Diabetic dyslipidaemia" AND "lipid profile" OR "HDL-C" OR "LDL-C" OR "Triglycerides") AND ("Diabetes mellitus" OR “T1DM’ "T2DM") AND ("predictors" OR "risk factors" OR “determinants” OR “contributing factors”) AND ("South Africa"). After identifying the key relevant studies, their references will be also locked into ancestor search strategy. Similarly, other studies which cited them will be locked online using the descendant search strategy.

2.5 Articles Screening and Data Extraction

Two members of the review team will independently screen the titles and abstracts of all studies identified through the database search. Prior to screening, all duplicate records will be removed. A full text review will be conducted for studies that appear to meet the inclusion criteria based on their title and abstract. Full text articles will then be evaluated to meet the predefined inclusion and exclusion criteria. Articles reporting on South African population with diabetes mellitus and DD markers and outcomes will be included. Studies not involving South African populations, including non-diabetic populations or gestational diabetes or prediabetes will be excluded. Non-original research and studies that lack adequate data on lipid profiles or cardiovascular disease outcome will be excluded. All essential data will be extracted and recorded in Microsoft Excel TM using a checklist data

extraction format made by the review team. Two members of the review team will independently extract the data. Study characteristics, population characteristics, exposure and intervention, outcomes, effect estimates data will be collected and recorded. Any discrepancies will be reviewed and discussed. All data will be securely stored, with regular backups in place to safeguard against any potential loss. In the case of missing critical data, the corresponding authors of the studies will be contacted for clarification or more information. If the missing data cannot be retrieved, the impact of these gaps in the review will be discussed, and sensitivity analyses will be performed to check how vigorous our review findings are.

2.6 Risk of Bias Assessment

The review will incorporate a rigorous risk of bias assessment to evaluate the quality of the selected studies, using tailored tools depending on the study design. For observational studies such as case-control, cross-sectional and cohort studies, Newcastle Ottawa Scale will be used to evaluate bias in terms of selection methods, comparability and outcomes [23]. Studies will be classified as high, moderate, or low quality. In the case of randomized controlled trials, the Cochrane Risk of Bias Tool will access the bias rating them as low, high, or unclear risk. In addition, an adapted Joanna Briggs Institute checklist will assess cross-sectional studies, focusing on inclusion criteria, exposure and outcome measurement reliability, and statistical appropriateness [24]. Two independent reviewers will evaluate each study to determine and resolve any discrepancies, with a pilot assessment ensuring consistency. High-risk studies will be disqualified from quantitative data synthesis and form part of qualitative data synthesis or included in the sensitivity analysis. The overall risk of bias results will be summarized in a table format, and the findings will be interpreted considering the quality of the study and the level of bias.

2.7 Data Synthesis and Statistical Analysis

The review will integrate both quantitative and qualitative data synthesis, depending on the availability of data and consistency across studies. For qualitative data synthesis, descriptive synthesis method will used to provide a detailed overview of the included studies, highlighting key aspects such as study design, population demographics, sample sizes, and regional distribution across South Africa. A table will be developed noting author, year, study location, type of diabetes mellitus, prevalence rates of DD and reported predictors. Trends and patterns, including regional prevalences, will also be documented. For quantitative data synthesis, a meta-analysis will be conducted to estimate the overall prevalence of DD and assess the strength of relationships of DD and predictors among South Africans with diabetes mellitus. A random effect model will be used due to the expected heterogeneity in characteristics of the population including the definition of dyslipidaemia across studies. The pooled prevalence will be calculated, and a logistic regression meta-analysis will assess predictors. Heterogeneity will be examined using the Cochran's Q test and I^2 statistics, with subgroups and sensitivity analyses to identify potential causes of variance. For articles that cannot be meta-analyzed, qualitative data synthesis will be used to highlight trends and variances across populations and outcomes. Publication bias will be assessed using funnel plots (with at least ten papers included) and Egger's or Begg's tests. The analysis will be conducted using the R (version 4.3.0 or higher) package for flexibility in effect size handling, heterogeneity analysis, and visualization. Stata (version 18) will also be used for meta-regression. Power analysis will also be conducted to ensure sufficient sample size for statistically significant effects. ROC curve analysis will be conducted to evaluate the diagnostic accuracy of specific predictors and predictive models [25, 26]. Results from both qualitative and quantitative data synthesis will be presented

through forest plots, subgroup forest plots, and summary tables, presenting findings on pooled prevalence, odds ratios for predictors, heterogeneity statistics, and sensitivity analyses [27–30].

2.8 Subgroup and Sensitivity Analysis

To minimize random discrepancies, a pilot data extraction will be conducted on subgroups and subsets of studies to ensure consistency and accuracy in the data extraction process. This will be done based on the areas in which the studies were conducted. In addition, all the extracted data will be safely deposited, and all files will be backed up to prevent any data loss

2.9 Ethical Considerations and Dissemination

The study is a systematic review that does not involve direct interaction with human participants or the use of identifiable personal data, ethical approval will not be required. The review findings will be submitted for publication in a peer-reviewed scientific journal specializing in diabetes, cardiovascular health, or public health. The communication plan details involve preparing a manuscript for submission to a reputable journal, conference presentations of the review findings, and institutional and community engagement.

3. Discussion

The systematic review and meta-analysis will be conducted to determine the pooled prevalence of DD among South Africans with diabetes mellitus. The review will also evaluate the relationship between DD and its determinants. The review will provide an

overview of how certain socio-demographic and clinical factors influence the lipid profile in the diabetic population. The findings will be compared with existing data from other African countries and global trends. Notwithstanding the public health burden of DD, there is a lack of systematic reviews reporting on the prevalence of DD in South Africa. This review will reveal significant insight into the public health challenges associated with DD, including its cardiovascular complications. It will assess the various determinants of DD, including socio-demographic factors and health disparities. Providing a comprehensive understanding of these factors will subsequently inform the development of targeted interventions and strategies for effective management and prevention of DD among the diabetic population, which will eventually enhance the health outcomes.

This meta-analysis will yield significant findings that will be used in crafting better tailored inventions for managing DD in South Africa. Given the country's diverse socio-economic and cultural landscape, the findings will have the potential to apprise the global strategies for tackling DD. While efforts by the South African healthcare system to manage complications related to diabetes, have shown some advancements, the findings of this review will place interest on a more multi-faceted approach. This approach will not only put emphasizes on clinical management and treatment guidelines but also public health education, patient support and community-based programs. In addition, the findings obtained can contribute to the development of future policies, which will offer a beneficial framework for other countries facing similar challenges in mitigating the health burden of DD and its complications.

The implementation of effective policies to manage DD and associated determinants among South Africans with diabetes is significant to the country's public health strategy. Such strategies could incorporate enhancing screening programs for lipid abnormalities,

encouraging adherence to lipid-lowering therapies, incorporating nutritional counselling, and addressing socio-economic barriers to effective management of DD. The findings of this systematic review and meta-analysis can influence the development of future policies, subsequently aiding them to be more effective. These can lead to a significant reduction in the prevalence and associated complications of DD, decrease in health disparities among diabetic populations, and subsequently improving the overall public health outcomes in South Africa. Moreover, the findings may have broader implications for global health strategies, as these successful interventions across different populations.

Strengths and Limitations of This Study

This review offers significant strengths, including a comprehensive analysis of existing data collected from multiple studies to provide a more detailed understanding of the prevalence and predictors of DD in South Africa. It addresses a critical gap in the body of knowledge by focusing on an under-explored area of focus, as there is lack of systematic review or meta-analysis reporting on DD in South Africans for the past five years. The review will adhere to PRISMA guidelines to ensure the consistency of the methodology and transparency, while the identification of specific predictors may go beyond the prevalence data to inform targeted interventions. Subgroup and sensitivity analyses will help strengthen the findings of the review and provide a clearer interpretation by examining differences across socio-demographic and clinical factors.

There are several limitations that may arise and should be taken into consideration. Firstly, the proposed review may include potential heterogeneity occurring from variations in study designs, populations, and methods for evaluating lipid profiles, which may hypothetically hinder data synthesis. Secondly, publication bias may present a risk, as studies with significant findings are more likely to be published and skewing the results. Thirdly, the

findings cannot be generalized beyond South Africa owing to regional differences in population, healthcare systems, and lifestyle factors. Restricting the search to non-English electronic databases or studies may cause language bias excluding relevant published studies in other languages.

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Conflicts of Interest: The review will be carried out without any financial gain or commercial ties that might be viewed as a possible conflict of interest, according to the authors.

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Supplementary Files