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Health-Related Quality of Life Among Diabetic Patients' Post-Surgical Amputation: A Systematic Review

M. Albarqi Ahmad Abdullah*
Lincoln University College, Petaling Jaya, Selangor, Malaysia

***Abstract*: Background: Diabetic foot ulcers could lead to amputations, significantly impacting the lives of individuals with diabetes. Methodology: The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram was used. Critical appraisal tools such as the AXIS tool for cross-sectional studies, the CONSORT checklist for randomized controlled trials, and the STROBE checklist for observational studies were used to make sense of evidences. Results: Of the 303 studies found on databases, only 8 was used. The systematic review demonstrated that diabetic patients who undergo surgical amputation experience significant challenges across 8 domains of the HRQOL. Conclusion: In order to enhance health-related quality of life for diabetic patients' post-surgical amputation, the domains of Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health must collectively enable physical task performance, manage activities of daily living limitations, relieve pain, ensure positive health prognosis, provide energy, foster social interactions, address emotional challenges, and maintain psychological well-being.**

***Keywords*: HRQOL, DFU, type 2 diabetes, HRQOL among DFU.**

1. Introduction

Diabetic foot ulcers (DFUs) can lead to amputations, significantly impacting the lives of individuals with diabetes (Bandarian et al. 2022). In type 2 diabetes, there are primarily two problems (Ojo 2019): 1) the pancreas does not produce enough insulin, a hormone that regulates the movement of sugar into the cells, and 2) cells respond poorly to insulin and take in less sugar. These issues not only exacerbate the risk of complications like DFUs but also have profound effects on overall health and quality of life (Uivaraseanu et al. 2020). That is why this systematic review synthesized findings from several studies, each focusing on different domains of health-related quality of life (HRQoL).

The aim of this systematic review was to determine the HRQoL among diabetic patients' post-surgical amputation. By examining various studies, the review provided a comprehensive understanding of how amputations due to DFU complications affect the patients' lives HRQoL. This holistic view was essential for developing effective health promotion strategies and interventions that could improve the quality of life for these patients.

2. Methodology

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram in figure 1 detailed the process of identifying, screening, and including studies for this systematic review (Page et al. 2021). The process began with the identification stage, where a total of 303 records were found through Google Scholar as database searches. There were no additional records identified from other sources.

In the screening stage, the first step was to remove duplicate records, which amounted to 153 duplicates. This left 150 articles to be screened based on their titles and abstracts. During this screening process, 84 articles were excluded. The reasons for exclusion were varied: 72 articles were from unrelated sites or topics, 8 were review articles or meta-analyses, and 4 were in languages other than English.

The remaining 66 records were then assessed for eligibility. At this stage, more articles were excluded for specific reasons: 8 articles were found to lack sufficient data, and 50 articles were identified as retrospective or not research-based.

Ultimately, this rigorous process of identification, screening, and eligibility assessment led to the inclusion of 8 studies in the quantitative synthesis, which was the systematic review. These final 8 studies represented a small fraction of the initial 303 records, highlighted the stringent criteria and thorough evaluation involved in conducting a systematic review following the PRISMA guidelines.

Critical appraisal tools were essential for assessing the validity, reliability, and applicability of research studies (Patel et al. 2022). Different study designs required different appraisal tools to ensure a comprehensive evaluation. Each of the 8 studies utilized an appropriate critical appraisal tool based on its design, with the AXIS tool for cross-sectional studies (Downes et al. 2016; Vu et al. 2024), the CONSORT checklist for randomized controlled trials (Cuschieri 2019a), and the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist for observational studies (Cuschieri 2019b). The appraisals highlighted strengths such as

*Corresponding author: albarqi007@hotmail.com

clear objectives, robust methodologies, and comprehensive reporting, while also identified limitations related to bias, generalizability, and causality. These critical evaluations underscored the importance of rigorous study design and transparent reporting in advancing the understanding of HRQOL in patients with DFUs.

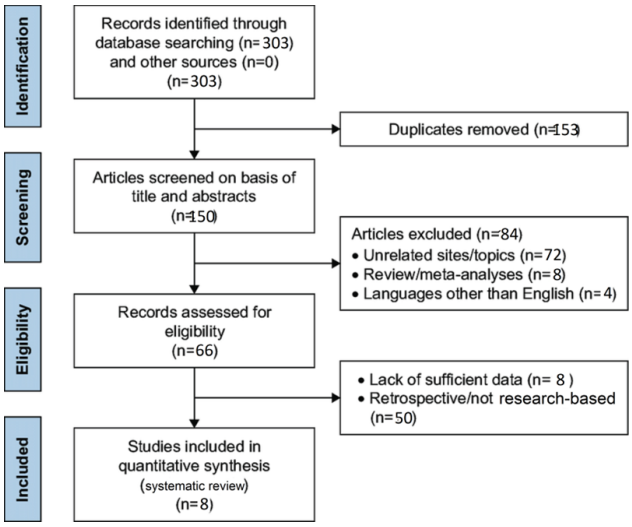

Fig. 1. PRISMA guideline

3. Results

Of the 303 studies found on databases, only 8 was used in this review.

Álvaro-Afonso et al. (2023): This study utilized a cross-sectional design to assess health-related quality of life among Spanish patients with diabetic foot ulcers using the Diabetic Foot Ulcer Scale – Short Form. Álvaro-Afonso et al. (2023) examined physical functioning among patients with diabetic foot ulcers, highlighting those limitations in physical activities are predominantly due to health problems. The study underscored the significant impact of these limitations on patients' daily lives, reducing their ability to engage in regular physical activities.

The study of Álvaro-Afonso et al. (2023) was appraised using the AXIS tool assesses several domains, including the clarity of study objectives, appropriateness of study design, sample size justification, measures used, and statistical analysis. The study by Álvaro-Afonso et al. (2023) scored well on clarity and design appropriateness, clearly defining their objectives and using the DFU Scale – Short Form effectively. However, some limitations were noted in the sample size justification and potential biases related to the cross-sectional nature of the study, which may affect the generalizability of the results.

Byrnes et al. (2024): This study employed a cross-sectional design to investigate health-related quality of life in people with different diabetes-related foot ulcer health states, including healed, non-infected, infected, hospitalized, and amputated ulcer states. Byrnes et al. (2024) focused on the role-physical domain, which referred to the impact of physical health on usual role activities, including work and other daily tasks. Their study found that physical health problems severely limit patients' ability to fulfil these roles, which could lead to decreased overall life satisfaction and productivity.

The study of Byrnes et al. (2024) was also appraised using the AXIS tool for its strengths in its comprehensive assessment of multiple health states and its robust data collection methods. The clear delineation of different ulcer states (healed, non-infected, infected, hospitalized, and amputated) added depth to the analysis. However, similar to other cross-sectional studies, the inability to establish causality was a noted limitation. Additionally, there was a potential risk of selection bias, as participants might differ in significant ways from the general population of diabetic foot ulcer patients.

Colas-Ribas et al. (2022): This study was an unblinded, randomized, controlled, cross-over study to evaluate the effects of a microprocessor-controlled ankle-foot unit on energy expenditure, quality of life, and postural stability in persons with transtibial amputation. In the domain of bodily pain, Colas-Ribas et al. (2022) investigated the experiences of amputees, noting that many patients perceive bodily pain as similar to phantom limb sensations. This phenomenon could be distressing and challenging to manage, further complicating the recovery and adaptation process post-amputation.

The study of Colas-Ribas et al. (2022) was appraised using the CONSORT checklist tool to evaluate elements such as randomization, blinding, participant flow, and outcomes reporting. Colas-Ribas et al.'s (2022) study scored high on randomization and reporting participant flow, clearly detailing their randomization process and crossover design. The lack of blinding, while typical in crossover studies involving physical devices, was acknowledged as a potential source of performance and detection bias. The study's thorough reporting on energy expenditure, quality of life, and postural stability outcomes provided valuable insights despite these limitations.

Dehghan Nayeri et al. (2020): This research was a randomized clinical trial that examined the effect of nurse-led care on the quality of care and levels of HbA1C in patients with diabetic foot ulcers. General health perceptions, as studied by Dehghan Nayeri et al. (2020), were found to be significantly disturbed among patients with diabetic foot ulcers. The study highlighted that these patients often have a more negative view of their overall health, which could affect their mental well-being and willingness to participate in health-promoting activities.

Dehghan Nayeri et al. (2020) also used the CONSORT checklist tool for its appraisal. The study examined the effect of nurse-led care on the quality of care and levels of HbA1C in patients with diabetic foot ulcers. This study excelled in its randomization and blinding procedures, ensuring that bias was minimized. The detailed reporting on the intervention and control conditions allowed for a clear understanding of the nurse-led care model's impact. However, the study faced challenges with participant adherence and retention, which were addressed in the discussion as limitations affecting the overall validity and reliability of the findings.

Gennai et al. (2021): The study was a randomized controlled trial conducted at a single center to determine health-related quality of life outcomes and hospitalization length of stay after

micro-fragmented autologous adipose tissue injection in minor amputations for diabetic foot ulceration (MiFrAADiF Trial). Gennai et al. (2021) explored the vitality domain, focusing on patients' energy levels and fatigue. Their findings indicated that vitality was considerably compromised in this population, with many patients experiencing chronic fatigue that hampers their ability to maintain an active lifestyle.

Gennai et al. (2021) also use the CONSORT checklist tool for its appraisal. The study focused on HRQOL outcomes and hospitalization length of stay following micro-fragmented autologous adipose tissue injection in minor amputations for diabetic foot ulceration. This trial was well-reported, with strengths in randomization and detailed intervention descriptions. The single-center nature of the study, however, raised questions about the generalizability of the findings. Additionally, the study faced potential biases related to the single-blind design, which influenced both patient and assessor perceptions of outcomes.

Iversen et al. (2020): This was a cluster randomized controlled trial (DiaFOTo) that explored the effect of a telemedicine intervention for diabetes-related foot ulcers on health, well-being, and quality of life. Social functioning, as reported by Iversen et al. (2020), was another critical domain affected by diabetes-related amputations. The study revealed that both physical and emotional problems limit patients' social activities, leading to social isolation and reduced quality of life. This isolation could further exacerbate feelings of depression and anxiety, compounding the overall negative impact on mental health.

Iversen et al. (2020) was also critically appraised using the CONSORT extension for cluster trials. This study explored the effect of a telemedicine intervention for diabetes-related foot ulcers on health, well-being, and quality of life. The study's strengths included a clear rationale for using a cluster design, appropriate statistical methods for handling clustering, and comprehensive outcome reporting. Challenges included potential variations in implementation fidelity across clusters and the inherent difficulties in blinding participants and personnel in telemedicine interventions. These factors were thoroughly discussed, highlighting areas for caution in interpreting the results.

Mairghani et al. (2023): The study employed a cross-sectional design to examine health-related quality of life in patients with diabetic foot ulcers in the Kingdom of Bahrain. Mairghani et al. (2023) discussed the role-emotional domain, noting that emotional problems significantly hinder patients' ability to perform usual role activities. Emotional distress could stem from various sources, including the physical limitations imposed by the amputation, the pain experienced, and the psychological impact of the condition.

Mairghani et al. (2023) used the AXIS tool for appraisal. The study was strong in defining its objectives and employing validated measures for assessing quality of life. However, like other cross-sectional studies, it faced limitations in establishing causality and potential biases related to participant self-selection and response rates. The study's regional focus also raised questions about the broader applicability of the findings to other populations with diabetic foot ulcers.

Siracuse et al. (2023): The study used a clinical trial, utilizing an observational study design to investigate the relationship between WIfI (Wound, Ischemia, and foot Infection) stage and quality of life at revascularization. Siracuse et al. (2023) addressed the domain of mental health, highlighting that general mental health, including psychological distress and well-being, is profoundly affected in patients' post-amputation. This distress often correlated with the severity of the physical condition, indicated a need for comprehensive mental health support as part of the treatment and rehabilitation process.

Siracuse et al. (2023) used the STROBE checklist is suitable for appraising observational studies. The study investigated the relationship between WIfI stage and quality of life at revascularization. It excelled in its detailed reporting of participant characteristics, interventions, and outcomes. The observational design allowed for real-world insights but also introduced potential confounding factors and biases that were acknowledged in the study's limitations. The use of a large, well-characterized cohort from the clinical trial enhanced the study's validity, but the authors noted the need for further research to establish causality and explore long-term outcomes.

Overall, the systematic review determined that diabetic patients who undergo surgical amputation experience significant challenges across multiple domains of HRQOL. These challenges underscore the importance of a holistic approach to patient care, addressing not only the physical aspects of the condition but also the emotional and social implications to improve overall outcomes.

4. Discussion

Health promotion emerges as the result of the synthesis of new knowledge from the eight domains of the HRQOL determined in this systematic review. Each domain — Physical Functioning, Role-Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role-Emotional, and Mental Health — provides critical insights into the multifaceted impact of DFU complications, particularly post-surgical amputations, on patients' lives (Armstrong et al. 2023). Understanding the intricacies of these HRQOL domains allows for a

Table 2

Domains	Studies	Findings
Physical Functioning	(Álvaro-Afonso et al. 2023)	Limitations in physical activities because of health problems
Role-Physical	(Byrnes et al. 2024)	Limitations in usual role activities because of physical health problems
Bodily Pain	(Colas-Ribas et al. 2022)	Bodily pain is felt as a phantom limb
General Health	(Dehghan Nayeri et al. 2020)	General health perceptions are disturbed
Vitality	(Gennai et al. 2021)	Vitality (energy and fatigue)
Social Functioning	(Iversen et al. 2020)	Limitations in social activities because of physical or emotional problems
Role-Emotional	(Mairghani et al. 2023)	Limitations in usual role activities because of emotional problems
Mental Health	(Siracuse et al. 2023)	General mental health (psychological distress and well-being)

comprehensive approach to health promotion that addresses the unique needs of DFU patients' post-surgical amputations.

Physical Functioning is crucial as it ensures patients can perform essential daily tasks and maintain their independence (Hao et al. 2021). Enhancing this domain involves developing interventions that improve mobility and physical capability, thereby directly influencing patients' ability to lead active and fulfilling lives.

Role-Physical impacts the capacity to perform activities of daily living (ADL), highlighting the importance of managing physical limitations (Brousseau-Foley et al. 2022). Effective health promotion must focus on rehabilitation and support systems that mitigate these limitations, enabling patients to regain and sustain their daily routines.

Bodily Pain management is essential for overall comfort and quality of life (Dubský et al. 2022). By synthesizing knowledge from this domain, health promotion strategies can prioritize pain relief measures, which significantly reduce suffering and enhance daily functioning.

General Health encompasses the overall health prognosis, providing patients with a sense of well-being and optimism (Parrettini, Caroli, and Torlone 2020). Health promotion efforts must ensure comprehensive care that fosters positive health outcomes and instils confidence in patients about their long-term health prospects.

Vitality, which involves sufficient energy levels for daily activities, is another critical domain (Kudlová and Kočvarová 2020). Promoting energy-boosting interventions and lifestyle modifications can help patients remain engaged and active in their lives.

Social Functioning highlights the importance of meaningful relationships and social interactions (Costa et al. 2022). Health promotion can thus include social support networks and community engagement activities that help patients maintain their social well-being and foster a sense of belonging.

Role-Emotional addresses the emotional challenges associated with adapting to new limitations and changes in life roles (Vileikyte, Pouwer, and Gonzalez 2020). Health promotion must therefore include psychological support and counseling services that help patients navigate these emotional hurdles and improve their mental resilience.

Finally, Mental Health is pivotal in maintaining psychological well-being (Jiang et al. 2022). Ensuring that patients have access to mental health resources and support systems is crucial for helping them cope with the mental and emotional aspects of living with diabetes and post-surgical changes.

Bias on selecting and eliminating literatures to be used in this systematic review, should also be discussed, as this is an inherent issue in many types of research and can significantly affect the validity and reliability of study results (Kiani et al. 2022; Whelehan, Conlon, and Ridgway 2020). In critically appraising the eight studies using the AXIS tool for cross-sectional studies, the CONSORT checklist for randomized controlled trials, and the STROBE checklist for clinical trial observational studies, several biases were identified. Recognizing and addressing these biases is crucial for interpreting the findings accurately and understanding their implications for clinical practice and future research.

In the study by Byrnes et al. (2024), which employed a cross-sectional design and was appraised using the AXIS tool, potential biases included selection bias and recall bias. The study addressed a clearly focused issue and used an appropriate method, but the selection of participants may not have been entirely representative of the general population with diabetic foot ulcers. This could introduce selection bias, as those who volunteered to participate might have different characteristics compared to those who did not. Recall bias is also a concern in cross-sectional studies where participants self-report past health states or quality of life, potentially leading to inaccuracies in the data collected.

Álvaro-Afonso et al. (2023) also used a cross-sectional design and faced similar biases just like Byrnes et al. (2024). The study was strong in its clarity and methodology, but data collection from a suitable source was not fully established, raising questions about the representativeness of the sample. The study's design inherently limits the ability to establish causality, a common limitation in cross-sectional research. This could lead to confounding bias, where unmeasured variables affect both the exposure and outcome.

Mairghani et al. (2023), another cross-sectional study appraised with the AXIS tool, encountered issues with selection bias and potential information bias. The data source's suitability was uncertain, and while the study aimed to generalize findings to a broader population, the regional focus on the Kingdom of Bahrain might limit this applicability. Information bias could arise from inaccuracies in how participants reported their quality of life, influenced by cultural or personal factors.

Siracuse et al. (2023) utilized an observational study design within a clinical trial framework, evaluated using the STROBE checklist. This study faced potential confounding bias due to its observational nature, where uncontrolled variables could influence the outcomes. While the study made efforts to adjust for confounders, the complexity of real-world clinical settings means some biases are unavoidable. Additionally, selection bias could be present if the participants who underwent revascularization differed systematically from those who did not, affecting the study's internal validity.

Colas-Ribas et al. (2022) conducted an unblinded, randomized, controlled, cross-over study, appraised with the CONSORT checklist. The unblinded design introduces performance and detection bias, as participants and researchers knew which intervention was being administered, potentially influencing their behaviors and assessments. Although the cross-over design helps mitigate some individual differences, the lack of blinding remains a significant limitation. Additionally, there could be carry-over effects between the different intervention periods, impacting the study's internal validity.

Dehghan Nayeri et al. (2020) conducted a randomized clinical trial, also appraised using the CONSORT checklist. This study was strong in randomization and blinding, which helps reduce selection and performance biases. However, participant adherence and retention posed challenges,

introducing attrition bias. Participants dropping out or not following the intervention protocol as intended could skew the results, reducing the study's overall validity.

Gennai et al. (2021) performed a single-center randomized controlled trial, with its critical appraisal highlighting potential biases related to the single-blind design and the single-center setting. The single-blind nature of the study could lead to detection bias, as outcomes were assessed by individuals who might have known the participants' group assignments. The single-center setting limits the generalizability of the findings, introducing selection bias if the patient population at that center is not representative of the broader population.

Iversen et al. (2020) conducted a cluster randomized controlled trial, evaluated with the CONSORT extension for cluster trials. This study faced potential biases related to implementation fidelity across different clusters. Variations in how the telemedicine intervention was delivered and received could introduce performance bias. Additionally, the difficulty in blinding participants and personnel in telemedicine interventions poses a risk of performance and detection biases.

The critical appraisal of the 8 domains of the HRQOL revealed various biases inherent to their designs.

Cross-sectional studies frequently encountered selection, recall, and confounding biases. Observational studies faced challenges with confounding and selection biases. Randomized controlled trials, while generally more robust, were not immune to biases, particularly related to blinding and adherence.

5. Conclusion

In order for DFU patients' post-surgical amputations to enhance their HRQOL, health promotion must focus on several key areas of the 8 domains. By synthesizing knowledge from these 8 HRQoL domains, health promotion can be tailored to meet the comprehensive needs of diabetic patients. By addressing each domain effectively, health promotion not only enhances the HRQOL for diabetic patients' post-surgical amputation but also empowers them to lead healthier, more fulfilling lives.

Physical Functioning domain must provide health promotion to patients regarding their ability to perform physical tasks, ensuring that patients can engage in activities essential for daily living and maintain their independence.

Role-Physical domain must give must provide health promotion to patients regarding the impact on the physical ability to perform ADLs, highlighting the importance of managing and improving the physical limitations that patients may encounter.

Bodily Pain domain must provide health promotion to patients to manage and relieve pain severity, as effective pain management, crucial for overall comfort and quality of life.

General Health domain must provide health promotion to patients focusing on achieving a positive overall health prognosis, such as providing patients with a sense of well-being and optimism about their health outcomes.

Vitality domain must provide health promotion to patients regarding sufficient energy levels to support patients in their daily activities and overall engagement with life.

Social Functioning domain must provide health promotion to patients regarding good social interactions, instructing patients to maintain and foster meaningful relationships and participate in social activities that enhance their quality of life.

Role-Emotional domain must provide health promotion to patients regarding how to improve the emotional health concerning role limitations, addressing the emotional challenges and stresses that come with adapting to new limitations and changes in life roles.

Finally, Mental Health domain must provide health promotion to patients regarding maintenance of psychological well-being, ensuring that patients have the necessary support and resources to cope with the mental and emotional aspects of living with a diabetic condition and post-surgical changes.

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