


## Diabetic Foot Ulcers: Impact on Quality of Life and Instruments for Its Measurement

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### Abstract

Diabetic foot ulcers (DFUs) are a major complication of diabetes mellitus, significantly impacting patients' quality of life (QoL) due to the heightened risk of infection and amputation. Pharmacists play a crucial role in managing diabetes and its complications, and assessing QoL can be a valuable tool for monitoring treatment success and medication effectiveness. This review explores instruments used to measure QoL in patients with DFUs, encompassing both general and disease-specific tools. We examine the impact of DFUs on QoL and discuss various theoretical frameworks used to understand this complex relationship.

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## INTRODUCTION

Diabetes mellitus (DM) is a global health crisis, with an estimated 537 million people affected in 2021<sup>1</sup>. This number is projected to rise significantly in the coming decades. One of the most concerning complications of DM is diabetic foot ulcers (DFUs). These ulcers dramatically increase the risk of infection, amputation, and disability, leading to poor quality of life (QoL) and premature mortality<sup>2</sup>. Up to 34% of diabetic patients will experience foot ulcers during their lifetime<sup>3</sup>.

The underlying mechanisms of DFU development are not fully understood. Impaired immune function in diabetic individuals significantly increases their susceptibility to wound infections<sup>4</sup>. Studies have shown that DFU development is associated with a five-fold increase in mortality within the first year and a forty-two percent mortality rate within five years<sup>5</sup>. Additionally, patients with DFUs experience increased morbidity, lower health-related QoL, and poorer psychosocial well-being<sup>6</sup>.

Recognizing the significant impact of DFUs on QoL, healthcare professionals are increasingly emphasizing the importance of QoL assessment and monitoring as an essential outcome measure in diabetes care. A patient's QoL can significantly influence their self-care behaviors, which in turn, affect their diabetes control<sup>7</sup>. Pharmaceutical services play a crucial role in achieving positive treatment outcomes and improving patient QoL. Pharmacist-implemented pharmaceutical care programs, often in collaboration with other healthcare professionals, have been established worldwide to enhance clinical outcomes and health-related quality of life (HRQoL)<sup>8</sup>.

Quality of life can be measured using various instruments, categorized as generic or disease-specific. Generic instruments, like the SF-36 and EQ-5D, assess QoL as a multidimensional concept encompassing cultural, social, psychological, and physical health aspects<sup>9</sup>. Disease-specific instruments, also known as HRQoL measures, focus on specific areas of health and

QoL relevant to a particular disease or treatment<sup>10</sup>. This review explores various theories on DFU development, their impact on QoL, and compares different QoL measurement instruments.

## DEFINITION OF DIABETIC FOOT ULCERS

Diabetic foot ulcers represent a significant complication of diabetes mellitus, encompassing a spectrum of pathological conditions. The most common manifestation, a full-thickness skin breakdown extending into the dermis, is termed an ulcer<sup>11</sup>. However, DFUs can also present without overt skin compromise, manifesting as infections like cellulitis or osteomyelitis. Diabetic foot ulcers can be further categorized as acute or chronic. Chronic DFUs are particularly concerning, as they exhibit impaired healing and are strongly linked to adverse outcomes such as amputation<sup>12</sup>. Any wound persisting unhealed beyond four weeks warrants heightened clinical attention due to the increased risk of amputation<sup>13</sup>.

## PATHOPHYSIOLOGY OF DIABETIC FOOT ULCERS

Diabetic foot ulcers are a debilitating complication affecting a significant portion of the diabetic population. Several risk factors are well-established as predisposing individuals to DFU development, including poor glycemic control, peripheral neuropathy, peripheral vascular disease, and immunosuppression<sup>14</sup>. Peripheral neuropathy, in particular, leads to a series of events that contribute to ulcer formation. It causes intrinsic muscle atrophy, resulting in functional anatomical changes like hammer toe formation. These deformities create "high-pressure zones" on the plantar surface of the foot, particularly at the metatarsal heads (**Figure 1**)<sup>15</sup>. Repetitive microtrauma goes unnoticed due to decreased sensation and proprioception, further promoting skin injury. Additionally, atrophy and dislocation of the protective plantar fat pad can occur, leaving the underlying tissue vulnerable to ulceration and infection<sup>16</sup>.

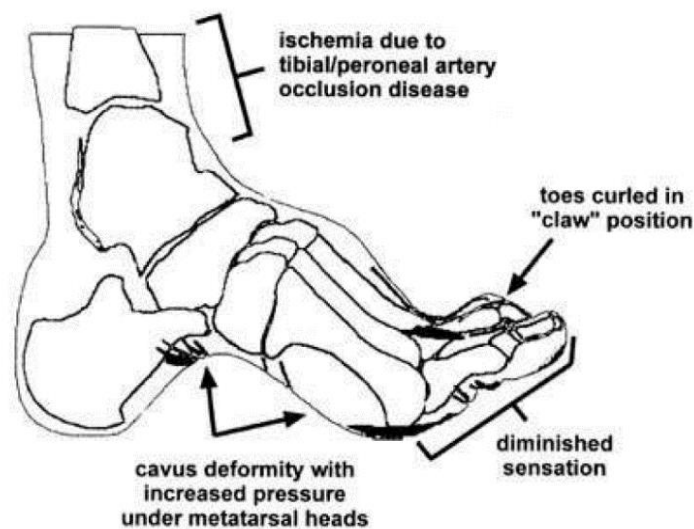
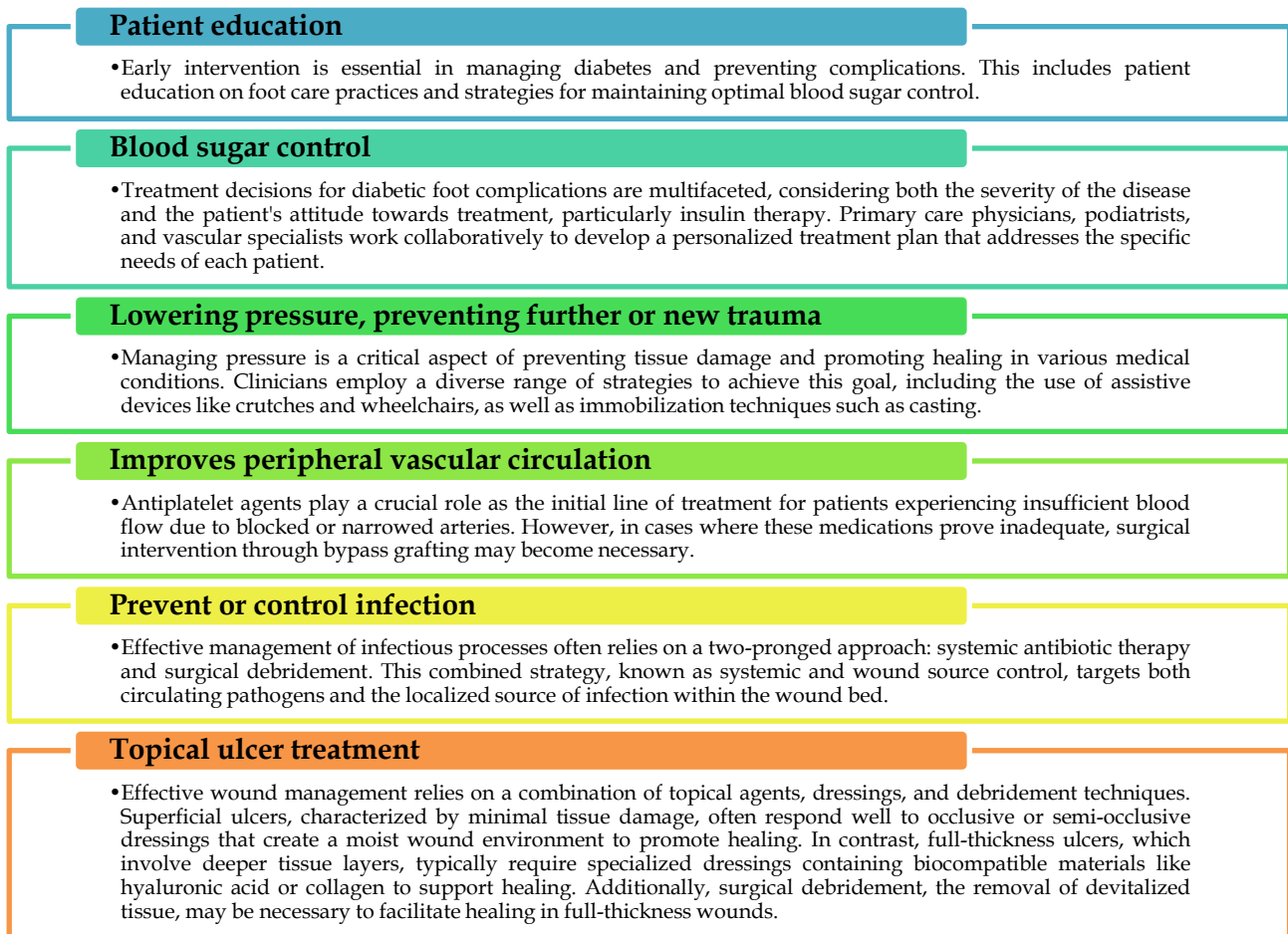


Figure 1. Mechanisms associated with the diabetic foot<sup>15</sup>.

Inadequate foot care practices further exacerbate the risk. Failure to use moisturizing creams or neglecting to promptly address early signs of dermal trauma (redness, blisters) can lead to ulceration and potentially, invasive soft tissue infections. Continued ambulation on an injured foot without prompt intervention allows tissue damage to progress<sup>17</sup>. Notably, the presence of neuropathy, foot deformity, or a history of toe amputation dramatically increases the risk of ulceration (by 32 times). In the most severe cases, the destructive process of trauma and infection can penetrate the deep fascia, allowing the spread of infection into the midfoot muscles, joints, and along tendon sheaths. This highlights the critical role of early intervention in preventing the devastating consequences of DFUs, including a significant contribution to lower extremity amputations in diabetic patients<sup>15,18</sup>.

## MANAGEMENT OF DIABETIC FOOT ULCERS

Diabetic foot ulcers are a serious complication affecting millions of people with diabetes worldwide. These chronic wounds can significantly impact a patient's QoL and pose a major healthcare burden. Effective management of DFUs requires a multidisciplinary approach that addresses the underlying causes, promotes wound healing, and prevents future complications. This includes optimizing blood sugar control, offloading pressure from the wound, proper wound care techniques, and potentially addressing vascular issues. Early intervention and a comprehensive treatment plan are crucial to minimize tissue damage, prevent amputation, and improve patient outcomes<sup>19</sup>. According to Giazcomozzi *et al.*<sup>20</sup>, management of DFUs explained in **Figure 2**.



**Figure 2.** Management of DFUs<sup>20</sup>.

## DEFINITION OF QUALITY OF LIFE

The concept of QoL goes beyond simply being alive. It encompasses a person's physical and mental well-being, their social connections, and their ability to live a fulfilling life according to their own values and goals. Quality of life is a subjective experience, meaning it varies greatly from person to person. Understanding and measuring QoL is crucial in various fields, including healthcare, social policy, and development studies. By examining factors that contribute to a good QoL, we can work towards improving individual and societal well-being<sup>21</sup>. The World Health Organization defines QoL as a person's perception of their position in life in the context of the value systems and culture in which they live and about their goals, expectations, standards, and concerns<sup>22</sup>. Nemcová *et al.*<sup>23</sup> describes QoL as the patient's level of physical and psychosocial well-being, independence, life satisfaction, and the experience of feelings of success in various areas of daily life.

## IMPACT OF DIABETIC FOOT ULCERS ON QUALITY OF LIFE

The presence of DFUs significantly impacts patients' HRQoL. Patients with DFUs experience a multitude of challenges, including disability, reduced mobility, and difficulty performing daily activities. These limitations have a profound negative effect on their physical, social, and psychological well-being<sup>24,25</sup>. Compared to diabetics without DFUs, individuals with these ulcers report higher levels of depression, lower life satisfaction, and poorer psychosocial adjustment to their illness<sup>26</sup>. The assessment of HRQoL is crucial for establishing evidence-based treatment protocols for DFUs<sup>27</sup>. Decreased mobility, a direct consequence of DFUs, significantly hinders patients' ability to perform daily tasks and participate in leisure activities<sup>28</sup>. Studies like Alrub *et al.*<sup>29</sup> support this notion, demonstrating that patients with DFUs have lower scores on physical and mental health components of HRQoL assessment scales.

Diabetic foot ulcers pose a significant physical and psychological burden on patients. Beyond the risk of lower limb amputation (nerve damage or deformity) and recurrent ulceration (39% in the first year, decreasing to 18% and 12.8% in the second and third years, respectively), DFUs can lead to permanent disability, particularly when complicated by infection<sup>30</sup>. The emotional toll of DFUs is substantial. Patients often experience fear of amputation and re-ulceration, contributing to negative mood and sleep disturbances<sup>31</sup>. Proper wound care is crucial to prevent amputation, but the associated costs can be a significant source of stress<sup>32</sup>. Job loss, reported in up to 50% of DFU patients, further diminishes self-esteem, particularly among younger individuals<sup>6</sup>. Compared to diabetic patients without DFUs, those with DFUs experience higher levels of anger, frustration, depression, and powerlessness<sup>33,34</sup>.

The financial burden of DFUs is substantial. Baroroh *et al.*<sup>35</sup> reported that the average monthly cost of managing type 2 diabetes with complications ranged from IDR 128,143 to IDR 1,174,342, with DFU medication costs alone reaching IDR 127,094 per day. Inpatient management focused on infection control with antibiotics, often injectables, further inflates medication costs.

## QUALITY OF LIFE MEASUREMENT INSTRUMENTS

### *Diabetic Foot Ulcer Scale-Short Form (DFS-SF)*

The diabetic foot ulcer scale (DFS) is a comprehensive instrument for assessing QoL in individuals with DFUs. It consists of 58 items categorized into 11 domains encompassing various aspects of well-being, such as leisure time, physical health, daily activities, and emotional well-being<sup>36</sup>. A shorter version, the diabetic foot ulcer scale-short form (DFS-SF), was developed with 29 items grouped into six subscales: leisure, daily life dependence, negative emotions, physical health, wound concerns, and wound care burden<sup>37</sup>. Both the DFS and DFS-SF have been psychometrically evaluated, demonstrating good validity and reliability. Each item utilizes a 5-point Likert scale, ranging from "not at all" or "never" (1) to "a lot," "always," or "very often" (5).

The DFS-SF's adaptability and validity have been established across diverse populations. For instance, a Brazilian study prospectively adapted and validated the DFS-SF for the Spanish-speaking population<sup>38</sup>. Similar validations have been conducted for Polish<sup>39</sup>, Greek<sup>40</sup>, Chinese<sup>41</sup>, Dutch<sup>42</sup>, Korean<sup>43</sup>, and Indian<sup>44</sup>. These translated versions consistently demonstrate good psychometric properties, highlighting the instrument's versatility for cross-cultural use.

### *Cardiff Wound Impact Scale (CWIS)*

The Cardiff wound impact schedule (CWIS) is a validated tool specifically designed to assess HRQoL in individuals with chronic wounds, such as leg ulcers and DFUs<sup>45</sup>. This 47-item questionnaire comprises four scales:

1. Demographic and clinical characteristics (3 items)
2. Global HRQoL (1 item)
3. Satisfaction with HRQoL (1 item)
4. Impact of the wound on lifestyle (42 items)

The last scale delves deeper into three key domains:

1. Social life (14 items): explores stress (7 items) and experiences (7 items) related to the wound.
2. Well-being (7 items)

3. Physical symptoms and everyday living (24 items): further divided into stress (12 items) and experience (12 items) associated with the wound.

All three domains utilize a 5-point Likert scale ranging from "not at all" to "always" for scoring. The total CWIS score ranges from 0 (indicating poorer HRQoL) to 100 (indicating higher HRQoL)<sup>46</sup>.

### **36-Item Short-Form Health Survey (SF-36)**

The 36-item short-form health survey (SF-36)<sup>47</sup> is a widely used generic instrument for assessing patient health status. This multicultural scale comprises 36 questions categorized into eight domains: physical functioning (PF; 10 items), general health (GH; 5 items), role limitations due to physical health (RP; 4 items), bodily pain (BP; 2 items), social functioning (SF; 2 items), vitality (VT; 4 items), role limitations due to emotional problems (RE; 3 items), and mental health (MH; 5 items). Each domain is scored on a 0-100 scale, with higher scores indicating better health.

### **EuroQoL 5D Health Utility Index (EQ-5D)**

The EuroQoL 5D health utility index (EQ-5D) instrument is a widely used and validated tool for assessing HRQoL in individuals with various chronic conditions<sup>48,49</sup>. It evaluates patients' physical, mental, and social functioning across five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension has three levels of severity: no problems, some problems, and extreme problems. A single index score (EQ-5D index value) is derived by combining these dimensions using established value sets, such as UK weights. Additionally, the EQ-5D incorporates a visual analog scale (VAS) where participants rate their current health status on a 0 (worst) to 100 (best) scale<sup>38</sup>. Three versions of the EQ-5D exist: EQ-5D-3L, EQ-5D-5L, and EQ-5D-y. The 5-level version (EQ-5D-5L) was introduced in 2009 by the EuroQoL Group to enhance the instrument's sensitivity and reduce ceiling effects compared to the earlier 3-level version<sup>50</sup>.

## **COMPARISON BETWEEN INSTRUMENTS MEASURING QUALITY OF LIFE**

Two main types of instruments are used to measure QoL: generic questionnaires and disease-specific questionnaires. Generic instruments assess the impact of various health conditions on overall health across different domains. They are particularly useful when patients have multiple chronic conditions or experience side effects from medications. Conversely, disease-specific questionnaires focus solely on aspects relevant to a particular disease, allowing for more sensitive detection of changes in QoL resulting from treatment or intervention<sup>51</sup>.

A study by Yordanova *et al.*<sup>52</sup> compared the EQ-5D and SF-36 instruments, finding the EQ-5D to be less responsive to variations in patient health status compared to the SF-36. Macioch *et al.*<sup>39</sup> reported that the Polish translation and validation of the DFS-SF instrument demonstrated superior psychometric performance compared to the SF-36. While the CWIS is not specifically designed for diabetic foot ulcers (DFUs), it can effectively discriminate between healed and unhealed ulcers. Additionally, Jeffcoate *et al.*<sup>53</sup> demonstrated the CWIS's sensitivity to wound healing in a randomized clinical trial evaluating different dressing types for DFUs. The heightened sensitivity of disease-specific instruments like the DFS-SF compared to generic instruments can be attributed, in part, to the extensive use of generic instruments in past QoL studies<sup>38</sup>.

## **CONCLUSION**

Diabetic foot ulcers significantly impact patients' QoL and are a major concern due to the increased risk of infection and morbidity. While established standards of care exist, assessing therapeutic outcomes beyond clinical success is crucial. This includes evaluating patient QoL and cost-effectiveness through pharmacoeconomic studies using cost-utility analysis (CUA). Our review highlights the trade-offs between generic and disease-specific patient-reported outcome measures (PROMs) used to assess QoL. Generic instruments offer the advantage of facilitating comparisons across diverse populations, conditions, and interventions. However, they may be less sensitive to specific aspects of a patient's experience. Conversely, disease-specific instruments demonstrate increased clinical sensitivity and responsiveness to changes in a patient's condition. However, their applicability is limited to specific patient groups and conditions.

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## AUTHORS' CONTRIBUTION

**Conceptualization:** Rani Sauriasari, Ratu Ayu Dewi Sartika

**Data curation:** -

**Formal analysis:** -

**Funding acquisition:** -

**Investigation:** -

**Methodology:** -

**Project administration:** -

**Resources:** -

**Software:** -

**Supervision:** -

**Validation:** -

**Visualization:** -

**Writing - original draft:** Khairunisa Qomariyanti

**Writing - review & editing:** Khairunisa Qomariyanti, Rani Sauriasari, Ratu Ayu Dewi Sartika

## DATA AVAILABILITY

None.

## CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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