The Impact of Underlying Conditions on Quality of Life Measurement Among Patients with Chronic Wounds as Measured by Utility Values

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Introduction

Quality of life (QoL), a popular patient-reported outcome measure (PROM), is a reflection of how patients with medical conditions feel about their treatment and outcomes. Wound-specific quality-of-life questionnaires aim to capture how the patient feels about the state of chronic wounds. The utility value of a given condition is another QoL concept represented on a scale of 0 (the state of death) to 1 (perfect health). In the late 20th century, utility values gained traction in quality-of-life research;[1] several methods have since been validated to calculate values from patients with a single medical condition. Such approaches help to measure the QoL of patients with chronic wounds, but we still do not fully understand how comorbidities may influence the patient's perception of their chronic wound and wound-related QoL. Underlying conditions that impair mobility, restrict lifestyle, cause pain, and negatively affect mental health can significantly lower QoL, but do they contribute to wound onset or are they caused by said wound?[2] Comorbid conditions may impair wound healing or bear more weight than the wound status (healed or active) in terms of QoL,[3] so that wound-related QoL tools are inappropriate and not practical in clinical practice.

This study aimed to demonstrate how we measure QoL in patients with chronic wounds and explain the limitations of QoL evaluations in patients with chronic wounds *and* serious comorbidities, illustrated by a detailed analysis of comorbidities and associated utility values in a large, real-world cohort of patients who responded to the Wound-QoL (W-QoL) questionnaire prior to wound care.

Box 1. Modified Wound-Quality of Life Questionnaire

Item No.	Occurring in the last 7 days…	Item No.	Occurring in the last 7 days…
1	my wound hurt	10[b]	I have been afraid of hitting the wound against something
2[a]	my wound had a bad smell	11	I have had trouble moving around because of the wound
3[a]	there was a disturbing discharge from the wound	12[b]	climbing stairs has been difficult because of the wound
4	the wound has affected my sleep	13	I have had trouble with everyday activities because of the wound
5[a]	the treatment of the wound has been a burden to me	14	the wound has limited my leisure activities
6	the wound has made me unhappy	15	the wound has forced me to limit my activities with others
7	I have felt frustrated because the wound is taking so long to heal	16	I have felt dependent on help from others because of the wound
8	I have felt worried about my wound	17[a,b]	the wound has been a financial burden to me
9	I have been afraid of the wound getting worse or of new wounds appearing	[a]Excluded from analysis for being wound-specific; [b]excluded, because excluded from refined questionnaire[4]	

Methods

This study reanalyzed a convenience sample of patients that was first used to assess the W-QoL tool from June 26, 2014 through March 10, 2016 at an outpatient wound center.[5] We included all patients able to answer the W-QoL tool using an electronic tablet during their first visit. Electronic tablets were programmed, so that the patients could answer the W-QoL questions separate from their electronic health records (EHRs). The W-QoL was modified for English translation (Box 1). W-QoL data were transmitted electronically to the U.S. Wound Registry (USWR), which merged those data with EHR data. Four W-QoL items were exclusive to wound status: No. 2 (smell), No. 3 (discharge), No. 5 (treatment burden), and No. 17. (financial burden). After initial data collection, the W-QoL authors simplified the tool, removing Nos. 10, 12, and 17;[4] we also excluded Nos. 2, 3, and 5 from analysis. We grouped W-QoL items by pain (No. 1), emotions/mental health (Nos. 6-9), sleep disturbance (No. 4), and limited activities, movement, and independence (Nos. 11,13-16).

There were 388 patients included; 6 (1.5%) patients had no comorbidities and were excluded, leaving 382 patients to be analyzed. The USWR generated a list of wounds and comorbidities with deidentified patient data for analysis. The Cost-Effectiveness Analysis Registry (CEAR) at the Center for the Evaluation of Value and Risk in Health Tufts Medical Center was searched for relevant utility values related to comorbidities and wounds.[6] PubMed was searched for newer utility values for wounds only among articles published from 2020 through March 2023. Utility value data were collected in an Excel spreadsheet; duplicate values were excluded, unless the condition descriptor changed. The median utility value was calculated to assign a value to each condition. Thirty-three distinct conditions lacking utility values were excluded; 81 conditions had proxy values imputed.

Methods *continued*

The number of patients with pain, mental health disorders, gait and mobility disturbances, and conditions that could cause sleep disturbances were counted. Descriptive statistics summarized patient demographic/clinical characteristics and utility values (SPSS [PASW 28], IBM, Armonk, NY). The subset of patients with comorbidities worse than wounds was counted. The 382 patients had 3,040 conditions in the final utility value dataset; 63 had no associated utility values and were deleted, leaving 2,997 comorbidities. Utility values using standard additive, multiplicative, and adjusted decrement estimator (ADE) approaches for each patient's set of comorbidities were derived.[7]

Table 1. Conditions that could have potentially negatively influenced response to Wound-Quality-of-Life (W-QoL) questions

Conditions that could have decreased QoL	No. of Patients (%)	W-QoL Variables Potentially Affected (Relevant W-QoL Item Numbers)
Chronic pain	129 (33.8)	• Pain (1) • Sleep disturbance (4) • Limited activities, movement, and independence (11,13-16)
Arthritis, any type	64 (16.8)	• Pain (1) • Sleep disturbance (4) • Limited activities, movement, and independence (11,13-16)
Depression/Anxiety	63 (16.5)	• Pain (1) • Emotions/mental health (6-9) • Sleep disturbance (4) • Limited activities, movement, and independence (11,13-16)
Posttraumatic Stress Disorder	4 (1)	• Pain (1) • Emotions/mental health (6-9) • Sleep disturbance (4) • Limited activities, movement, and independence (11,13-16)
Morbid obesity	65 (17.0)	• Sleep disturbance (4) • Limited activities, movement, and independence (11,13-16)
Obesity	65 (17.0)	• Sleep disturbance (4)
Heart failure	35 (9.2)	• Sleep disturbance (4)
Apnea	32 (8.4)	• Sleep disturbance (4)
Edema	135 (35.3)	• Sleep disturbance (4)
Uterine cancer	1 (0.3)	• Sleep disturbance (4)
COPD	24 (6.3)	• Sleep disturbance (4)
GERD	12 (3.1)	• Sleep disturbance (4)
Urinary/bowel incontinence	17 (4.4)	• Sleep disturbance (4)
Restless legs	6 (1.6)	• Sleep disturbance (4)
Gait and mobility disorder(s)	204 (53.4)	• Limited activities, movement, and independence (11,13-16)

COPD = chronic obstructive pulmonary disease; GERD = gastroesophageal reflux disease

Table 2. Utility values metrics derived from 382 patients and their associated conditions

Utility Method	Mean[b]	Median[b]	Range[b]
Utility value (mean)[a]	0.72	0.73	0.42-0.87
Utility value (median)[a]	0.73	0.76	0.42-0.95
Utility value (maximum)[a]	0.89	0.90	0.42-1
Utility value (minimum)	0.5	0.52	0.13-0.74
Utility value (additive)	-1.14	-1.02	-5.15-0.59
Utility value (multiplicative)	0.13	0.08	0-0.62
Utility value (ADE)	0.22	0.19	0-0.7

ADE = adjusted decrement estimator

[a]represents standard methods of calculating the mean, median, or largest value from a set of utility values for a **single** patient; [b]represents utility values derived from **all** patients in the dataset for the particular method use.

Results *continued*

Data from 382 patients (46.4% female, 172/369) were included. Their mean (SD) age was 64 years (16.4). They predominantly had chronic/complex wounds; 2.1% had uncomplicated acute wounds. The 3 most common wound types were VLUs in 23.6% of patients (n = 90), surgical wounds in 18.6% (n = 71), and PIs in 12.6% (n = 48). Patients each had a mean (SD; range) number of 8 (3.9; 2-26) conditions. They most commonly had hypertension (66.8%, n = 255), gait and mobility disorders (53.4%, n = 204), and edema (35.3%; n = 135). Comorbidities' utility values were worse than wounds' in 229 patients (59.9%).

In Table 1, preexisting conditions could have potentially influenced 10 (71.4%) of the refined W-QoL questions (i.e., the patient could have reported a lower score, because they already had pain, negative emotions/mental health, limited activities, and/or codependence). For example, a third of patients (n = 129) had preexisting chronic pain, which could have potentially influenced their response to 7 W-QoL questions related to pain, sleep disturbance, and limited activities, movement, and independence. The majority of patients had gait and mobility disorders, which would already have limited their movements: 20 (5.4%) had paralysis, paraplegia, quadriplegia, spinal cord injury, and/or were in wheelchair; 30 (7.9%) were bedridden; and 64 (16.8%) were morbidly obese. Sixty-three (16.5%) patients had depression/anxiety. More than one-third of patients (n = 135) likely had sleep disturbances due to edema.

In Table 2, the utility values obtained by standard approaches demonstrated a wide variety with mean values for the minimum, additive, multiplicative and ADE approaches of 0.5, -1.14, 0.13, and 0.22, respectively. Differences between means and median values for these standard approaches were minimal, while ranges were largest for the additive approach, and floor effects were observed for the multiplicative and ADE approaches.

Discussion and Conclusion

After the W-QoL instrument was shortened to make it easier for patient use,[4] the influence of wound comorbidities on QoL still remained unaddressed. Our real-world utility value analysis showed that the majority of patients (nearly 60%) had comorbidities that were worse than their wounds. This suggests that their QoL was already poor before wound onset. For example, 8% of patients were bedridden, which implies a state near death with a utility value of 0.13. Many comorbid conditions captured by this analysis negatively impact a patient's mental health, restrict their activities and independence, and cause pain and/or sleep disturbance, regardless of wound healing status (Table 2). Wounds still negatively affect the W-QoL domains and could make patients feel more pain, be more depressed, and have more trouble sleeping and moving around. However, outside of randomized controlled trials (RCTs) which use QoL as a surrogate for wound healing but tend to exclude impactful comorbidities,[8] the W-QoL tool does not have real-world practicality, because it does not distinctly capture wound impact, independent of the patient's general health status.

The more comorbidities the patient has, the more challenging it becomes to determine what the "true" utility value is for a given patient. For a given condition, utility values can vary widely, partly due to cultural values and how patients perceive different health-related issues.[9] Analyzing the utility of wound-care populations is especially limited by variance. For example, the median utility value for a DFU is 0.65, which decreases to 0.49 if ≥2 comorbidities are present. Likely, the more comorbidities (particularly severe comorbidities) the patient has, the less "value" they report feeling for their wound. It may not be possible for the patient to separate out and value the wound distinctly from their comorbidities. Utility value methods have additional limitations, particularly for comorbidities whose impact is intermittent (such as rheumatoid arthritis or episodes of depression)[10,11] or temporary, such as surgical wounds.[12] Consequently, while these values are very useful, they may only capture a "moment" of the entire spectrum of care.[13] Consequently, in our analysis, given that this patient population was very sick (with each patient having on average 8 conditions), the minimum utility value approach seems a reasonable compromise, meaning, the comorbidity associated with the lowest utility value is the one that could most influence their QoL at a particular point in time. This approach, however, had its limitations in our study, as we did not know the severity of the wounds or the patients' conditions, nor did we know how many wounds a patient had, and so, the effect of multiple wounds on QoL could not be measured. Further studies are needed to confirm this concept.

Thompson et al calculated health state utility values for up to 4 joint health conditions (JHCs) in a population of 929,565 patients in the United Kingdom, of which 30.5% had at least 2 conditions out of a possible 16.[7] Their state-of-the-art methodology found that the multiplicative approach was the best nonparametric estimator for 2 JHCs, but all the approaches except for the linear parametric estimator had substantial errors in the case of 4 JHCs. We found considerable variation using the different methods; we could not apply a parametric method, because the many JCH permutations resulted in a massive number of regression sets with a small number of samples.

Current wound-quality-of-life assessments are an inappropriate use of time and resource utilization in clinical practice. Determining the chronic wound contribution to overall QoL may in principle be useful, but it is quite limited for complex patients. In wound care research, we focus on the wound outcome, but wounds are more often a consequence of other conditions and not a root cause whose outcome is later affected by comorbidities. For example, a patient with paraplegia, an autoimmune disease, a heart disease, and diabetes may develop a chronic wound as a consequence of their overall health status. Additionally, many patients have multiple wounds (the impact of which is not known). Thus, among sicker patients with serious comorbidities, it may be unrealistic to expect a "wound-specific" QoL to be capable of measuring meaningful changes in response to wound outcomes. Alternatively, additional questions regarding wounds should be added to the tools used to calculate health utility values based on various comorbid conditions. PROMs, such as QoL, do not have a useful role in day-to-day wound management. Wound-quality-of-life assessments are not performed in clinical practice, nor are they useful outside the realms of RCTs. In a large proportion of cases, it is likely that QoL may be dominated by major underlying medical conditions which impact the patient even more than their chronic wound(s). More work is needed to create a PROM that can specifically measure response to treatment among patients with chronic wounds.

References

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