Quality of life: Venous leg ulcers

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BACKGROUND

Leg ulcers are one of those conditions wherein the patient distress is in much greater proportions to than what meets the eye on examination. Venous leg ulcers represent more than 80% of all chronic leg ulcers and chronic venous leg ulceration (CVLU) results in a significant decline in health related quality of life (HRQoL) for the patient. Hence, it is essential that the care delivered focuses on the factors that affect the HRQoL of the sufferer, in addition to the factors concentrating on the wound management. A holistic assessment of the needs of these patients suffering from CVLU is therefore recommended for optimal and cost-effective management.^[1]

FACTORS DETERMINING THE QUALITY OF LIFE IN LEG ULCERATION

Various factors play a role in determining the quality of life in leg ulceration. These factors relate to physical functioning, psychosocial functioning, and treatment aspects. Physical factors include pain, exudate and odor pertaining to the ulcer; effect on mobility, sleep and routine daily activities. Irrespective of the study design, pain emerged as the most significant factor affecting HRQoL (Level B).^[1] The chronic nature of leg ulcers, irrespective of the etiology is responsible for the various psychosocial and treatment aspects. Psychosocial parameters include social isolation, depression, feelings of regret, loss of power, and helplessness. Various studies have pointed out that patients with chronic wounds of the lower extremity often experience functional disability and emotional distress, which negatively affects patient quality of life, hence incorporating HRQoL measurements in clinical practice may improve understanding of chronic wound patients' healthcare needs.^[2] The treatment parameters include efficacy of treatment with respect to improvement of the wound, time taken for healing and cost-effectiveness of the therapy. In addition, the quality of life is also determined by the patient's concepts regarding wound hygiene, dressing and nursing care; and the quality of care being provided to them.^[3]

QUALITY OF LIFE INDICES/ INSTRUMENTS

Health-related quality of life can be defined as "the functional effect of an illness and its consequent therapy upon a patient, as perceived by the patient."^[4] Various generic and specific instruments have been used to evaluate QoL in leg ulcer patients. Pain scales have also been used in several studies, together with HRQoL instruments. An integrative review has been performed to analyze various generic and specific instruments (Level A).^[5] A brief outline of the various indices commonly used in leg ulcers has been outlined in Table 1.

Generic tools are widely available in various languages and have been frequently used since they are the most validated. Short form 36 (SF-36) and its adaptations are useful for establishing HRQoL in people with VLU compared with the general population. However, the responsiveness of the SF-36 to changes in wound status is unclear.^[6] EuroQol 5D (EQ-5D) is effective for economic and cost-effectiveness analysis.^[5] The generic tools have consistently demonstrated pain to be a significant problem for leg ulcer patients but are unable to accurately differentiate between pain that is directly related to leg ulceration and that experienced owing to comorbidities (Level B).[7] Hence, many studies incorporate generic tools along with pain scales for assessment. Generic instruments are also unable to identify changes in VLU in relation to the wound characteristics and its consequences, such as chronicity, recurrence, course of the disease, pain, odor, edema, exudation, mobility limitation, physical appearance, emotional, and

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Table 1: Generic and Specific Indices/ Instruments to evaluate quality of life

Generic HRQoL instruments

Medical outcome study SF-36 and its various adaptations SF-12, SF-6 NHP SIP

EQ-5D

QLI (Ferrans and Powers)

Leg ulcer specific HRQoL instruments

Hyland score CWIS Freiburger questionnaire of QoL in venous diseases (FLQA) CCVLUQ SPVU-5D Specific questionnaire for VLU (VLU-QoL)

Pain scales

VAS

SF-McGill pain questionnaire

PPI

Numerical rating scale, verbal description scale

QoL: Quality of life, HRQoL: Health related quality of life, NHP: Nottingham Health Profile, SIP: Sickness impact profile, EQ-5D: EuroQol 5D, CWIS: Cardiff Wound Impact Schedule, CCVLUQ: Charing Cross Venous Leg Ulcer Questionnaire, SPVU-5D: Sheffield Preference-based Venous Ulcer 5D, VLU-QoL: Venous Leg Ulcer-Quality of life, VAS: Visual analogue scale, PPI: Present pain intensity, QLI: Quality of life index, FLQA: Freiburg Life Quality Assessment, SF-36: Short form-36

social aspects and the effect of these on HRQoL measurement (Level B). $^{[\!\!4,5]}$

Specific tools have therefore been developed and these contribute to establishing clinical care based on individual needs. Hyland and Cardiff Wound Impact Schedule (CWIS) are applicable to all leg ulcers; whereas the other specific tools outlined in Table 1 are used for venous leg ulcers. Hyland has good reliability and ability to discriminate changes in VLU patients, by age, mobility, size, and duration of VLU, but is not a good tool to assess treatment responsiveness (Level C).[6,8] The CWIS is a good HRQoL measurement instrument for chronic wounds in general and can differentiate well between healed and non-healed states (Level C).^[9] Of the various specific tools, Charing Cross Venous Leg Ulcer (CCVLU) Questionnaire has a high reliability, validity and responsiveness and shows good correlation with SF-36 (Level B).[10] It is the most appropriate instrument for use with VLU patients, due to its disease-specific psychometric characteristics (Level B).^[4,5] Two new specific scores (SPVLU-5D and VLU-QoL) have shown great promise in measuring HRQoL in VLU patients, although more research is needed to establish their specific reliability and validity (Level C).^[5] A combination of generic and disease-specific QoL indices should be a standard measure in patients with chronic venous disease.[4]

DEVELOPMENT AND ASSESSMENT OF QUALITY OF LIFE INDEX

The implementation of a QoL index depends on the ease of application and the time taken for calculation. An ideal index should have high sensitivity and specificity. Larger number of questions increases the sensitivity but takes a lot of time; whereas lesser number of questions provides ease of implementation at the cost of sensitivity. It is important to assess the psychometric parameters of a QoL index by its reliability and validity. The process of development and validation of the specific measure CCVLU has been reviewed and the full text article is available online (Level B).[10] A validation study with two generic HRQoL indices (SF-12 and EQ-5D) and one specific CVLU (Hyland) validation study extending over a 1 year period has compared their discriminative and responsive characteristics (Level C).^[6] A VLU specific tool Freiburg Life Quality Assessment (German language questionnaire) was developed and validated and found suitable to assess QoL in both course and cross sectional studies (Level C).[11] Similarly, tools can be developed, translated into various languages with validation to suit the regional needs in the Indian context.

IMPLICATIONS IN CLINICAL PRACTICE AND RESEARCH

Quality of life indices in CVLU have been used in various clinical settings and are usually administered at intervals of 0, 3, 6, and 12 months. The selection of the tool may vary depending on the clinical or study based context, the number of questions and the time required to complete the questionnaire. SF-36, Nottingham Health Profile, CCVLU takes about 5-10 min to complete; whereas sickness impact profile is a long instrument with 136 items and may take approximately 30 min. A novel concept of a computerized questionnaire has been developed with patients filling the information in a touch screen interface kiosk. This is useful in a busy practice set up with easy availability of statistical analysis (Level C).^[2]

The clinical contexts in which QoL instruments are used include assessment of etiology of leg ulcers, correlation of clinical and social factors and evaluation of psychosocial aspects.^[12] The efficacy of health services delivering evidence based care to leg ulcer patients can also be documented using QoL instruments (Level C).^[3] These indices are used to assess various newer therapeutic interventions and their cost-effectiveness (Level B).^[13] QoL indices have been used to compare pain symptoms at initiation and end of therapy and assess the role of conservative versus surgical modalities. A study has demonstrated a statistically significant positive effect on QoL with surgical treatment of ulcers and reduction in pain with reduction of the ulcer area (Level C).^[6] The QoL tools are

now routinely used in various randomized controlled trials to measure and compare the therapeutic efficacy of various modalities (Level B).^[6,13,14]

CONCLUSION

Newer treatment modalities continue to emerge for treatment of CVLU, however pain and poor QoL in these patients leads to significant morbidity. Hence use of various generic and VLU specific QoL instruments should be incorporated in the management and care of these patients. These would help in planning treatment strategies, which would aim to provide a better quality of life for these patients.

RECOMMENDATION

Quality of life assessment should be an integral part in the management of CVLU patients. Use of a generic tool such as SF-36 and a specific tool such as CCVLU in cases of venous leg ulcers is recommended to assess QoL. Development, translation into various languages with validation of specific VLU-QoL instruments should be done to suit the regional needs in the Indian context.

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