IMPACT OF ULCER HEALING ON HEALTH RELATED QUALITY OF LIFE OF PATIENTS WITH DIABETIC LEG AND FOOT ULCERS

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INTRODUCTION

Complications of Diabetes Mellitus (DM) are known to be the most vital disease-specific determinant of health related quality of life (HRQoL). Diabetic foot ulcers adversely affect quality of life (QoL) and self-esteem of the patients. Common daily activities are restricted due to decreased physical mobility and functional capacities of patients. When compared to diabetic foot ulcer (DFU) patients, both with the general population and those with DM, DFU patients have lower HRQoL. Poorer HRQoL was reported in patients with active ulceration than those who have undergone minor amputation (Hogg *et al.,* 2012) indicating a comparatively better psychological status of mobile amputees than DFU patients. Number of ulcers and severity of ulcers (Valensi *et al.,* 2005) have shown to be associated with impairment in HRQoL. HRQoL has been found to be lower in those living alone, those who are not employed, those with low educational level, and those having at least one complication of DM (Javanbakht *et al.,* 2012; Yekta *et al.,* 2011). Better QoL is reported in men than women with DM but not with diabetic foot ulcers (Javanbakht *et al.,* 2012).

In Sri Lanka, limited studies have reported HRQoL of patients. A recent study which was conducted to establish population norms for HRQoL in healthy individuals in four districts reported lower HRQoL in socioeconomically disadvantaged people (Kularatna *et al.,* 2014). No studies exist in HRQoL of patients with DFU. Therefore, the purpose of the present study was to evaluate HRQoL of patients with diabetic leg and foot ulcers, to examine associations between HRQoL and socio demographic and clinical characteristics, and to compare HRQoL of patients with non-healed vs. healed status of ulcers.

METHODOLOGY

The study is a part of a large descriptive cross-sectional study conducted at the Colombo North Teaching Hospital during the period from June to December 2014. Adult diabetic leg and foot ulcer patients admitted to the surgical wards with wound duration of more than two weeks were recruited purposefully for the study. Acutely ill and those with cognitive impairment were excluded. Data were collected by an interviwer from patients who gave written informed consent. This study was approved by the Ethics Review Committee of University of Sri Jayewardenepura and permission to conduct the study was obtained from hospital authorities.

Data on socio-demographic and clinical characteristics including age, gender, marital status, educational level, duration and family history of DM, duration of ulcer and site of ulcer (foot or leg), history of previous ulceration and amputations were obtained through interviewing the patients**.** To assess HRQoL, Short form Health Survey (SF-36) questionnaires were completed in respect of 50 patients at baseline and after three months when the ulcer is healed. Scores of each subscale of the SF-36 obtained for patients with a healed ulcer was compared with their own scores obtained when they had the unhealed ulcer to discriminate QoL between non-healed versus healed status. The SF-36 instrument consists of 36 questions that grouped into eight conceptual domains (physical functioning, role limitation due to

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physical health, bodily pain, general health perceptions, vitality, social functioning, role limitation due to emotional problems and mental health). A two-factored model has been developed by aggregating first four domains into physical component score (PCS) and latter four domains into mental component score (MCS). Each question is scored on a scale of a zero to 100 and aggregate percentage scores are calculated for each domain. High scores denote high QoL and low scores denote low QoL. In this study, QoL was measured according to two-factored model; MCS and PCS, eight domains, and aggregated all domains to count total QoL.

Statistical analysis: Demographic and clinical characteristics of the patients were presented using descriptive statistics. Associations between variables were determined using Mann-Whitney U test. Scores of each domain of the SF-36 obtained for patients with a healed ulcer was compared with their own scores obtained when they had the unhealed ulcer using paired t-test. Significance was accepted at alpha <0.05. Data were analyzed using SPSS version 21.

RESULTS AND DISCUSSION

A total of 50 patients were studied. Demographic and clinical characteristics of the patients are shown in Table 1.

Table 1. Demographic and clinical characteristics associated with HRQoL

Variable	Category	n	%
Gender	Men	32	64.0
	Women	18	36.0
Age	≤60	30	60.0
	>60	20	40.0
DM duration	≤10 years	31	62.0
	> 10yrs	19	38.0
Family history of DM	Yes	22	44.0
	No	24	48.0
Ulcer site	Foot	42	84.0
	Leg	8	16.0
Re-ulceration history	Yes	8	16.0
	No	42	84.0

DM, diabetes mellitus; HRQoL, health related quality of life

Our findings indicated that HRQoL measured using SF-36 questionnaire is low in the study cohort (Table 2). The total HRQoL score was 49.04±19.8 (range 20.45 - 89.02) and 61.7% (n=29) patients had a total score of less than 50%. The scores were low for all eight domains. The scores remained low even when the domains were separated to physical (PCS; 44.73±19.8) and mental (MCS; 53.13±18.7) components. Similarly, previous studies in France (Valensi *et al*., 2005), Iran (Yekta *et al*., 2011) have shown poor HRQoL in patients with diabetic ulcers. A Malaysian study (Mazlina *et al.*, 2011) has reported scores similar to our study in physical (PCS; mean 41.05) component, but comparatively higher scores for mental (MCS; mean 63.48) component.

According to the current study, when compared to men, women obtained lower scores for each domain (except role limitation-emotional) as well as for total QoL, PCS and MCS. However, these scores did not show statistically differences except for scores obtained for domains of vitality (p=0.041) (Table 3). Yekta *et al*., (2011) has also shown significantly higher HRQoL scores in diabetic men compared to diabetic women with no foot ulcers. Likewise, when DFU patients were compared with the general population, DFU patients had lower HRQoL and significant difference was seen on domains of physical functioning, role limitation, physical (Mazlina,*et al*., 2011) and general health. Present findings also indicated that the scores obtained for vitality were significantly lower in patients who have longer DM duration (>10 years) when compared to scores of patients DM duration of ≤10 years (mean 39.16 vs. 48.44, p=0.025). Similarly, previous findings have shown lower scores for domains of vitality in the sample they studied (Bardage and Isacson, 2001; Trevisol *et al*, 2011).

Table 2. The scores for eight SF-36 domains, two summary components and overall QoL in the healed vs. non healed status of ulcers of patients

	Non Healed (n=50)		(Healed n=50)		p –value (Paired t-test)
	Mean	SD	Mean	SD	
Physical function	52.18	33.0	66.60	28.4	0.015
Role limitation (physical health)	28.06	39.9	72.44	38.1	<0.0001
Role limitation (emotional problems)	29.93	43.1	78.00	38.7	<0.0001
Vitality	61.73	18.2	80.12	17.2	<0.0001
Mental health	61.93	22.3	84.80	13.1	<0.0001
Social function	48.72	31.8	74.00	25.2	<0.0001
Pain	41.58	24.5	80.00	19.8	<0.0001
General health	44.89	24.7	54.70	15.9	0.004
MCS	53.13	18.7	80.46	16.6	<0.0001
PCS	44.73	22.9	71.04	26.3	<0.0001
Overall QoL	49.04	19.8	75.12	20.5	<0.0001

SD, standard deviation; PCS, physical component score; MCS, mental component score; QoL, quality of life; significant at $\alpha<0.05$

Scores for role limitation due to physical health (mean 28.06) and role limitation due to emotional problems (mean 29.06) were very low in our study cohort than studies reported elsewhere (Yekta *et al*., 2011). Role limitation due to physical health was significantly different among patients with history of re-ulceration than those with no history of re-ulceration (mean 10.00 vs. 33.53, p=0.016). Role limitation due to emotional health was significantly different in patients with a history of toe amputation than those with no amputation (mean 59.52 vs. 84.79, p=0.031) in healed status of ulcer. Previous evidence also indicates that better QoL of patients who have undergone successful minor amputations than those with active ulcerations (Hogg *et al*., 2012).

Table 3. Comparison of SF-36 domains, two summary components and overall QoL for gender difference

Gender	Female	Male
Physical function	43.33	57.50
Role (physical	23.61	30.64
Role (emotional	79.62	77.08
Vitality	54.16	66.12*
Mental health	56.11	65.32
Social function	40.97	53.22
Bodily pain	34.02	45.96
General health	44.70	45.00
PCS	39.51	47.97
MCS	48.51	55.81
Total QoL	44.01	51.63

PCS, physical component score; MCS, mental component score; QoL, quality of life; * p=0.041

When the ulcer site was considered, significantly lower scores were found in patients with leg ulcers compared to the once with foot ulcers across scores of social function (mean 20.31 vs. 54.26, p=0.004) and bodily pain (mean 25.00 vs. 44.8, p=0.030) indicating poorer health status among patients with leg ulcers. A previous study has reported a negative impact of leg ulceration on QoL of patients without diabetes (Herber *et al*., 2007). Further, the numbers of ulcers and severity of foot ulcers have shown to be associated with poor HRQoL (Valensi *et al.,* 2005; Yekta *et* al., 2011).

Comparison of scores of eight SF-36 domains, PCS and MCS and overall QoL of non-healed (scores obtained at baseline) vs. healed status of ulcers showed that mean scores at healed stage were significantly higher (p<0.0001) compared to non-healed stage (Table 3) indicating better HRQoL in healed status of ulcers. In agreeable with this finding, Nabuurs-Franssen *et al*., (2005) have shown higher HRQoL for patients with healed ulcers than persisting ulcers. Ribu *et al*., 2007) indicating significant improvement of HRQoL in social functioning and mental health with healing of ulcers. Similarly, another study (Hogg *et al.,* 2012) has reported poorer QoL for patients with active ulcers.

CONCLUSIONS/RECOMMENDATIONS

Findings of this study provide useful information to health care workers and researchers regarding HRQoL of patients with diabetic leg and foot ulcers. Diabetic leg and foot ulcers were shown to have a negative impact on HRQoL with both physical health and mental health being affected. Scores of eight domains, total SF-36, PCS and MCS were consistently lower in the study cohort in non-healed status of ulcer. HRQoL was significantly improved when ulcers were healed. HRQoL was worse in women than in men and in patients with leg ulcers compared to those with foot ulcers. This study recommends considering the physical and mental health status when planning, evaluating and managing the patients with diabetic ulcers. Steps should be taken to actively minimize the duration of ulcer healing in order to improve the HRQoL of these patients.

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