Quality of life of diabetes amputees following major and minor lower limb amputations

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ABSTRACT

Introduction: Minor amputation was performed as a salvage procedure because most of the patients were not able to ambulate and become dependent following major amputation. Minor amputation is defined as amputation at the level of ankle joint and below while major amputation is defines by amputation above the ankle joint. The aim of this study was to compare the quality of life among diabetes patients following major and minor amputations.

Methods: A total of 94 diabetes patients were reviewed six months following amputation. Their walking ability, dependency status and quality of life were evaluated, using the Malay translated version of the Short Form Health Survey 36 (SF-36) questionnaire.

Results: During the follow up only three patients (8.3%) following major amputation were dependant compared to 30 patients (51.7%) following minor amputation. Forty-nine (84.5%) of minor amputation and only 15 (41.7%) of major amputation patients were ambulating independently. Patients with minor amputation have significantly better Physical functioning, Role - physical, General health, Role – emotional, and Mental health score (p<0.001). However, they have worse BP and SF score than those following major amputation (p<0.001). The VT score of both groups were not significantly different.

Conclusion: Patients with minor amputation are more independent, ambulatory and had better quality of life than those with major amputation. Despite the risk of persistent infection and amputation stump complication, minor amputation should be attempted in diabetes patients.

KEY WORDS:
Diabetes mellitus, amputation, health related quality of life

INTRODUCTION

The prevalence of diabetes in Malaysia has significantly increased from 11.6% in 2006 to 15.2% in 2011. Conversely, the prevalence of diabetes-related amputations has reduced from 4.3% to 0.9%.[1,2] Up to 50% of patients who had major amputation are wheelchair-dependant and 37% require long term placement in nursing facility.[3] A recent local study found that only 80% of the amputees interviewed had prostheses and among those, only 80% of them actually used them. Nearly half of them reported their prostheses were uncomfortable. Furthermore, walking with prosthesis required more energy for these mostly frail patients.[4] To overcome these problems, limb salvage surgery in the form of minor amputation has been suggested. Minor amputation is defined as amputation at the level of the ankle joint and below while major amputation is defined as amputation above that level.[3,5-7] Studies have shown that patients with diabetes who had minor amputation were not significantly impaired when compared to those who had no amputation.8 Primary major amputation is still indicated in patients with poor general health status and extensive disease beyond the minor amputation level.[3] Minor amputation will sometimes result in non-healing stump and creeping amputation in patients with severe peripheral vascular disease.

Unlike functional outcome which measures only the physical activities, quality of life outcome measures both the physical and mental domains. The latter therefore gives a more holistic picture. Study comparing quality of life between diabetes patients with foot problems and those without showed a significant difference in their quality of life for both mental and physical components.[9] Comparison of the quality of life between diabetes patients who had major and minor amputations has yet to be studied. Hence, the objective of this study was to compare the quality of life between these two groups. We hypothesized that the quality of life of those with minor amputation is better than those with major amputation.

METHODOLOGY

Study design

This was a cross-sectional study, conducted between January 2012 and July 2013, at Tengku Ampuan Afzan Hospital (HTAA), Kuantan. HTAA is a tertiary referral centre for the state of Pahang. It receives referrals from the nearby districts of Kuantan, Rompin, Pekan and Maran.

Ethics statement

The study was approved by the International Islamic University Malaysia Research Working Committee on the 5th April 2012 and awarded Research Endowment Grant (EDW B

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12-368-0846). The permission to use the SF-36 survey has also been obtained (licence number QM039808).

Sample size and sampling technique
The sample size was calculated based on the difference on mean SF-36 T-score of 25 and 40 for major and minor amputation; with the estimated standard deviation of 25. At 95% confidence interval and to achieve 80% power, with ratio of 1:2, the minimum sample size required were 33 and 66 respectively.

Selection criteria
All patients with diabetes who were admitted to the orthopaedic wards in HTAA and planned for amputation from January to December 2012 were included in the study. The questionnaires were administered in Bahasa and English language. Patients who were unable to understand the language were excluded. In addition, patients who were cognitively impaired and unable to give written consent were also excluded.

Subjects
Out of the 124 potential patients, 104 (83.0 %) consented to enter the study and they were interviewed whilst in the ward. Out of the 104 patients, only 94 (90.38%) turned up for follow up. Out of the 10 non-attenders, three had died and four had cerebrovascular accident.

Baseline data
Demographic data including age, sex, ethnic group, educational level, employment status, house income, location of residence and type of house were recorded. Clinical variables, including smoking habit, alcohol consumption, duration of diabetes, type of medication, type of amputation, side of amputation, and frequency of surgery were also recorded.

The patients were reviewed six months following the surgery to assess their dependency status and walking ability. They were also required to complete the validated Malay-translated version of the Short Form Health Survey 36 (SF-36) questionnaire to measure their health-related quality of life (HrQOL).[10,11]

Study instruments
The walking ability is categorised into walking without aids, walking with aids, walking with one person assisting, and unable to walk. The walking ability is one of the outcome variables taken from the International Classification of Impairments, Disabilities and Handicaps (ICIDH) questionnaire.[12] Dependency status is categorised as independent when they do not require anybody to look after them at home. Patients are considered dependent when they require a guardian to look after them at home or need to be placed in a care centre. The walking ability and dependency status questionnaires were not validated.

The SF-36 questionnaire consists of eight important health concepts based on the Medical Outcomes Study (MOS), i.e., physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE) and mental health (MH). The items and scales are constructed using the Likert methods of summated rating. The scoring procedure followed the guideline from the User's Manual for the SF-36v2 Health Survey, Third Edition. First, the data is entered and recoded. Then the total raw score of SF-36 was transformed to 0-100 score. Next, it was transformed to z-scores based on the 2003 Malaysian general population data. Then the z-scores were transformed to T-score. The T score had a mean of 50 and standard deviation of 10 of the Malaysian population norm. The SF-36 had been validated locally and the psychometric properties of the Malay or translated version is good. Cronbach's as for all scales exceeded the recommended 0.70 level, except for SF.[10,11]

Statistics
Data obtained from the questionnaire was analysed using the IBM SPSS Statistics version 22 (IBM Corp., Armonk, NY), while the SF-36 scoring was calculated using Microsoft Excel 2010. Since the T-scores were not normally distributed, the distribution between minor and major amputations was done using Mann-Whitney U test. Data significance was considered when $p<0.05$.

RESULTS

Patients age ranged from 38 to 85 years old (median 55, interquartile range 11) with 52 (55.3%) of the patients were male. Nearly 54% of the patients were unemployed. Majority of the patients were Malays (89.4%), followed by Indians (7.4%), Chinese (2.1%) and others (1.1%). Majority of the patients did not study up to secondary education, and 57% were unemployed. In all 54% patients came from the rural areas and were staying in a single-storey house (46.8%). Only 19% were smokers and three of them also consumed alcohol. In all 39 patients (41.2%) had suffered from diabetes mellitus for more than 10 years, with majority of them (84.0%) were on insulin injection. More than half (61.7%) have had an operation before. There was no significant difference in the age, gender, ethnic group, education level employment status, location of residence and type of houses between those with minor or major amputations. However, the income of those with minor amputation was slightly more than those with major amputation. There was no significant difference in the smoking habit, alcohol consumption, duration of diabetes, type of medication and number of operations between those with major and minor amputations. (Table I)

During the six-monthly follow up, only three patients (8.3%) with major amputation were independent compared to 30 patients (51.7%) with minor amputation. Forty-nine (84.5%) of minor amputees and only 15 (41.7%) of major amputees were ambulating independently. The patients with minor amputation were significantly more independent and ambulatory compared with patients with major amputation. ($p<0.001$) (Table II).

The results also show that patients with minor amputation have significantly better PF, RP, GH, RE and MH scores ($p<0.001$) six months after the surgery. However, they have worse BP and SF scores than those following major amputation ($p<0.001$). The VT scores of both groups were not significantly different. (Table III)

Table I: Baseline characteristics between major and minor amputees

	Major		Minor		P
	N	%	N	%	
Age	36	56 (13)*	58	53 (10)*	0.346
Sex					
Male	20	55.6	32	55.2	0.971
Female	16	44.4	26	44.8	
Race					
Malay	30	83.3	54	93.1	0.135
Non Malay	6	16.7	4	6.9	
Education Level					
Nil	9	25.0	11	19.0	0.106
Primary	26	72.2	35	60.3	
Secondary	1	2.8	9	15.5	
Tertiary	0	0.0	3	5.2	
Occupation					
Yes	12	33.3	28	48.3	0.154
No	24	66.7	30	51.7	
Monthly household income (in RM)	36	1000 (750)*	58	1100 (1100)*	0.024
Location of Residence					
Rural	23	63.9	28	48.3	0.14
Urban	13	36.1	30	51.7	
Type of House					
Terrace	18	50.0	26	44.8	0.282
Bungalow	0	0.0	6	10.3	
Semi-detached	1	2.8	4	6.9	
Traditional house	15	41.7	19	32.8	
Others	2	5.6	3	5.2	
Smoking					
Yes	8	22.2	10	17.2	0.551
No	28	77.8	48	82.8	
Alcohol Consumption					
Yes	1	2.8	2	3.4	0.857
No	35	97.2	56	96.6	
Duration of diabetes mellitus					
< 10 years	20	55.6	35	60.3	0.647
10 years or more	16	44.4	23	39.7	
Diabetes mellitus treatment					
Nil	0	0.0	2	3.4	0.512
Diet	0	0.0	3	5.2	
Traditional Medicine	0	0.0	0	0.0	
OHA	4	11.1	6	10.3	
Insulin	26	72.2	38	65.5	
OHA + Insulin	6	16.7	9	15.5	
Side of Amputation					
Left	10	27.8	29	50.0	0.089
Right	22	61.1	26	44.8	
Both	4	11.1	3	5.2	
Numbers of operation					
1	12	33.3	24	41.4	0.435
> 1	24	66.7	34	58.6	

* Median (Inter-quartile range), OHA – Oral hypoglycaemic agent

Table II: Functional outcomes between major and minor amputees

	Major		Minor		P
	N	%	N	%	
Dependency					
Independent	3	8.3	30	51.7	< 0.001
Dependent	33	91.7	28	48.3	
Walking ability					
Regularly walked without aids	0	0.0	34	58.6	< 0.001
Regularly walked with walking stick	15	41.7	15	25.9	
Regularly walked with other person help	7	19.4	7	12.1	
Unable to walk	14	38.9	2	3.4	

Table III: T-scores for eight SF36 domains between major and minor amputees

	Major			Minor			P
	N	Median	IQR	N	Median	IQR	
PF	36	5.3	6.4	58	28.2	28.0	< 0.001
RP	36	23.2	0.0	58	23.2	15.6	0.006
BP	36	48.1	12.6	58	29.2	19.0	< 0.001
GH	36	47.9	10.9	58	57.3	12.5	< 0.001
VT	36	42.3	10.6	58	44.0	10.6	0.897
SF	36	45.5	25.9	58	19.5	13.0	< 0.001
RE	36	27.9	0.0	58	27.9	27.8	< 0.001
MH	36	35.7	14.5	58	41.5	8.7	0.011

IQR – Inter-quartile range

DISCUSSION

In this study, 51.7% of our patients who had minor amputation were independent, compared to just 8% for those with major amputation. Van Damme et al., also observed similar findings where nearly 40 % of their patients with major amputation required long term nursing care, compared to only 15 % with minor amputation.[3] An eastern population study found that only 44% of patients with major amputation could live with their family six months after the surgery.[13]

Most of the patients with minor amputation (84.5%) were able to walk independently compared to just 41.7% of with major amputation. A study in Hong Kong reported that only 15% of their patients were able to walk independently following major amputation. However, their population cohort was much older than ours.

Amputation affects both the physical and mental health of our patients with diabetes as shown by the low T scores. Only the GH score was comparable to normal population with T score of 57.43 following minor amputation. De Godoy et al., compared the HrQOL between amputees and control normal subjects and have found that the amputees were worse in all the physical domain (PF, RP, BP and GH). However, their MH and VT were similar to normal subjects.[14]

As expected, the impact of amputation is worse following major amputation. It affects the ability of patients to perform physical activity and their work, as evidenced by the lower PF and RP scores. Subsequently the amputation also affects their emotion, as evidenced by the lower RE and MH scores. However, the energy level or vitality of patients with minor and major amputation was not significantly different.

Patients with major amputation experience less pain and exhibit better social function compared with those with minor amputation. It is possible that stump healing problems in minor amputation is a factor for this. Barceli et al., found that healing problems following minor amputation was very high (up to 70%). They also found that prolonged healing time following minor amputations ranging from one to five months, with 30% of their patients progress to major amputation, three years after the surgery.[15]

Pain does not negatively affect the walking ability among our patients. Similarly, Greive and Lankhorst using the Sickness Impact Profile (SIP) scores also found that stump pain does not affect the functional status of their amputees.[12]

Peters et al., observed that only the physical function was significantly affected when they compared between diabetes patients who had amputation and those had not, using the SIP. The psychosocial function however was not significantly different between the two groups. They also found that the physical and psychosocial scores of patients with minor amputation were not significantly different from those without amputation. In contrast, patients with major amputation have significantly poorer total functional score compared with the control group.[8] This difference could be due to the better rehabilitation and support services in their country than in Malaysia.

There are a few limitations in this study. Firstly, the quality of life of our subjects prior to the surgery was not measured. The baseline measurements would give a clearer evidence to suggest that patients, who had major amputation, were already in a bad condition even before the surgery. The questionnaire that we used was the standard SF-36 form which requires patients to recall their condition over the

earlier four weeks. We feel that the questionnaire we used was not suitable for our cohort of patients since we could only identify them immediately after the amputation. Secondly, the six-month follow up period in our cohort was rather short. However, a study on quality of life following amputation by Fortington et al., noted that most changes occur 6 months after the amputation and is not much change thereafter.[15] Thirdly, we did not include in the analysis other possible confounders or comorbidities such as hypertension, renal diseases and stroke. Lastly, the questionnaires used to obtain the walking ability and dependency status had not been validated.

CONCLUSION

As expected, the walking ability and dependency of patients with diabetes following minor amputation are better than those following major amputation at six months. The quality of life of patients with minor amputation is better than those with major amputation in the PF, RP, GH, RE and MH domains. However, patients with minor amputation have more pain and poorer social function than those with major amputation. Despite the risk of persistent infection and stump complications, minor amputation should be attempted in suitable patients with diabetes.

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