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Research Article

Major limb-sparing treatment results following foot and ankle infection in patients with and without diabetes mellitus

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Abstract

Background: Little is known about the outcomes following major limb-sparing treatment (treatments avoiding below-knee amputation) in diabetic or non-diabetic patients with foot and ankle infection. This study was to compare patient-reported outcomes (PROs) and health-related quality of life (HrQoL) of diabetic and non-diabetic patients with foot and ankle infections in both pre-and post-treatment (major limb-sparing treatment) periods.

Methods: This study included a total number of twenty-six patients who were divided as 15 patients with diabetic-related foot and ankle infection and 11 patients who had foot and ankle infections without diabetes mellitus (DM). Baseline characteristics including site of infection, PROs via visual analogue scale foot and ankle (VASFA) score, and HrQoL via Short-Form (SF)-36 score were recorded in each patient. VASFA and SF-36 scores were compared between the two groups in both pre-and post-treatment periods.

Results: Mean follow-up time was 11.1 months. There were significant improvements of the VASFA score and SF-36 score regarding the pre-and post-treatment periods ($p<0.001$). The correlations between the VASFA score and SF-36 score were significant in both the pre-($r = 0.469$; $p = 0.024$) and post-treatment periods ($r = 0.772$; $p<0.001$). The variables as height, weight, body mass index (BMI) included pre-and post-treatment VASFA scores and SF-36 scores were no significant differences ($p>0.05$).

Conclusions: Regarding foot and ankle infection, the patients with and without DM could undergo the comparable results via patients' PROs and HrQoL assessment following the major limb-sparing treatments.

Keywords: Diabetes mellitus, Major limb-sparing, Foot-ankle, Infection, Ulcer

INTRODUCTION

Foot infections in diabetic patients are well established as a serious complication of this metabolic disorder. It is associated with longer and more frequent hospital stays [1] and is a major risk factor for amputation [2]. When compared to the general population, patients with diabetic foot ulcers have a poorer health-related quality of life [3]. The alteration of quality of life in patients with diabetes-related foot complications has been also reported in a previous study [4]. However, little is known about the different outcomes in diabetic or non-diabetic patients with foot and ankle infection following the major limb-sparing treatment (treatments avoiding below-knee amputation). The purpose of this study was to compare the patient-reported outcomes (PROs) and health-related quality of life (HrQoL) of diabetic and non-diabetic patients with foot and ankle infections in both pre-and post-treatment (major limb-sparing treatment) periods.

MATERIALS AND METHODS

This study included a total number of twenty-six patients. Fifteen patients presented with diabetic-related foot and ankle infection. The remaining eleven patients had foot and ankle infections without an underlying disease as diabetes mellitus (DM). In diabetic patients, the diabetic foot or ankle ulcer was defined as an open wound with discharge and/or signs of infection such as redness, warmth, and swelling. The site of diabetic ulcer could be occurred at the abnormal pressure area or the area with other bony prominence due to complication of diabetes mellitus such as Charcot arthropathy. The main purposes of treatment were infection clearance, ulcer healing, functional restoration, and plantigrade positioning of foot. The surgical debridement was decided to perform in each patient as necessary in the present study. All patients underwent the successful major limb-sparing treatment (treatments avoiding below-knee amputation). The baseline characteristics including height, weight, body mass index (BMI), and site of infection were collected in the study. The variables included the levels of fasting blood glucose, levels of Hemoglobin A1c (HbA1c), diagnoses of retinopathy, nephropathy, neuropathy, macroangiopathy, and the duration of DM were collected in the patients with the DM diagnosis. The PROs via validated visual analogue scale foot and ankle (VASFA) score [5], and HrQoLvia validated Short-Form (SF)-36 score [6] were recorded in each patient. The VASFA [5] and SF-36 scores [6] were compared between the two groups in both pre-and post-treatment periods. An institutional review board approval was obtained in this study. The informed consent was obtained from all patients.

STATISTICAL ANALYSES

Outcome measures before and after treatments were compared using T-test, ANOVA for continuous variables and Chi-square or Fisher's exact test for categorical variables. Pearson correlation analysis was used to determine the Pearson's R correlation (r) among the continuous variables.

RESULTS

The mean age of patient was 51.9 ± 15.9 years. There were men as 69.2% and women as 30.8%. There were no significant differences between the two groups in terms of mean age and sex ratio ($p>0.05$). The mean follow-up time was 11.1 months. There were no significant differences of patients' height, weight, and BMI between the two groups ($p>0.05$). Other baseline data of DM group was shown in a Table 1. The diagnoses of retinopathy, nephropathy, neuropathy, and macroangiopathy in diabetic group were 7 (46.7%), 11 (73.3%), 13 (86.7%), and 2 (13.3%) patients, respectively. There was no significant difference of the site of infection between the two groups ($p=0.505$) (Table 2). There were significant improvements of the VASFA score [5] and SF-36 score [6] regarding the pre-and post-treatment periods ($p<0.001$) (Table 3). The correlations between the VASFA score [5] and SF-36 score

Table 1. The baseline data in DM group.

Diagnosis		DM duration (years)	Fasting Blood Glucose (mg/ dL)	HbA1C (%)
DM	Mean	16.133	230.3000	8.7107
	Number*	15	15	14
	S.D.	7.9450	130.22231	2.12858

*Number of patients with completed data
S.D.: Standard Deviation

Table 2. The site of infections.

Diagnosis		Site of Infections								Total
		Open ankle injury-infection	Open forefoot wound	Open midfoot wound	Open hindfoot wound	Open combined wound	Closed ankle infection	Closed combined infection	Closed forefoot infection	
Non-DM DM	Number	4	2	1	1	1	1	1	0	11
	%	36.4%	18.2%	9.1%	9.1%	9.1%	9.1%	9.1%	0.0%	100.0%
	Number	1	6	2	2	0	1	1	2	15
	%	6.7%	40.0%	13.3%	13.3%	0.0%	6.7%	6.7%	13.3%	100.0%
Total	Number	5	8	3	3	1	2	2	2	26
	%	19.2%	30.8%	11.5%	11.5%	3.8%	7.7%	7.7%	7.7%	100.0%

Table 3. The visual analogue scale foot and ankle (VASFA) score [5] and Short-Form (SF)-36 score [6] in the pre-and post-treatment periods.

Scores		Mean	Number*	S.D.	P-value
Pair 1	VASFA post-treatment	73.19	19	22.06	<0.001**
	VASFA pre-treatment	36.18	19	21.94	
Pair 2	SF post-treatment	72.26	19	19.25	< 0.001**
	SF pre-treatment	43.53	19	20.95	

*Number of patients with completed data
**Significant differences
S.D.: Standard Deviation

Table 4. The visual analogue scale foot and ankle (VASFA) score [5] and the Short-Form (SF)-36 score [6] in each group.

Diagnosis		VASFA pre-treatment	VASFA post-treatment	SF pre-treatment	SF post-treatment
No DM	Mean	34.3636	75.0500	36.4935	72.9571
	N	11	10	11	10
	S.D.	20.90705	21.33913	16.18999	21.71836
	Minimum	5.00	31.50	15.71	27.00
	Maximum	58.00	100.00	58.86	96.43
DM	Mean	38.4167	71.6758	50.6310	71.3694
	N	12	12	12	12
	S.D.	21.16798	21.60267	21.21114	16.37486
	Minimum	5.00	37.50	23.57	44.43
	Maximum	75.50	100.00	92.86	99.29
P-value		0.649	0.718	0.089	0.847
Total	Mean	36.4783	73.2095	43.8696	72.0911
	N	23	22	23	22
	S.D.	20.66424	21.03711	19.90576	18.52724
	Minimum	5.00	31.50	15.71	27.00
	Maximum	75.50	100.00	92.86	99.29

*Number of patients with completed data
S.D.: Standard Deviation

[6] were significant in both the pre-(r=0.469; p=0.024) and post-treatment periods (r=0.772; p<0.001).

There were insignificantly different scores of pre-and post-treatment VASFA and SF-36 between the diabetic group and non-diabetic group (Table 4).

DISCUSSION

The importance of this study concerns the health-related quality of life in patients with diabetic foot infections. This study is of particular importance because even though there are numerous studies concerning diabetic foot ulcers and quality of life [7,8], there are few studies that directly investigate the impact of foot infections and diabetic foot ulcers [9]. The present study also highlights the outcomes following the major limb-sparing treatments or treatments avoiding below-knee amputation in the diabetic or non-diabetic patients with foot and ankle infection.

The pre-treatment and post-treatment outcomes were measured using the VASFA score [5] and SF-36 score [6] in patients with and without DM. The two surveys have been used previously in support of each other [10]. SF-36 is used in order to supplement the results of VASFA because of its focus on HrQoL questions. VASFA additionally was chosen because of a previous research showing normative results across different pathologies [11] and would be a proper choice for methodology. The present evidence demonstrated that patients with DM had no significantly inferior results via VASFA score [5] and SF-36 score [6] assessment than non-diabetic groups in both pre-and post-treatment (major limb-sparing treatment) periods. These results were consistent with the results in a previous study as the proper treatment of diabetic foot infection could significantly improve quality of life and lower-extremity functioning in select patients with non-functional lower extremities [4]. The present study also highlights the merit of major limb-sparing treatment in the diabetic patients with foot and ankle infection who underwent the comparable results of foot and ankle score and quality of life as the non-diabetic patients. These results show the similar trend with the evidence of the previous study regarding the using a limb salvage protocol which demonstrates the improved outcomes [12]. The present evidence also supports the holistic treatment with patient-centered care as the patients should have the opportunity to undergo the attempts to salvage their major limbs before the below-knee amputation (BKA). Most patients preferred to undergo multiple procedures to save the limb from diabetic foot infection even if it eventually concluded with a BKA [13].

One limitation of this study was a low number of patients in both cohorts, which could skew the data because of a small sample size. Another limitation was a retrospective study design with incomplete data in some patients. Follow-up time on patients before taking post-operative data is short, and results of HrQoL could change over many years. However, the present study could be the early platform to distribute the knowledge regarding the outcomes following the major limb-sparing treatment (treatments avoiding BKA) for further study with larger populations and longer follow-up time. The role of DM is also necessary to be clarified to find the way to improve caring of the patients with diabetic-related foot and ankle infections in the future.

CONCLUSION

Regarding foot and ankle infection, the patients with and without DM could undergo the comparable results via patients' PROs and HrQoL assessment following the major limb-sparing treatments.

CONFLICT OF INTEREST

The author reports personal fees from Amgen, personal fees from Novatec healthcare (Thailand), personal fees from Device Innovation, personal fees from Phoenix surgical equipment (Thailand), personal fees from Pfizer, personal fees from Eisai (Thailand), personal fees from Symgens, personal fees from Smith and Nephew, personal fees from Bangkok Unitrade, outside the submitted work.

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