Remote Care of Lower Extremities Ulcers: An Observational Pilot Study

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ABSTRACT: **Background:** Lower extremities ulcers (LEU) are associated with considerable morbidity and mortality. With longer life expectancy, the prevalence of LEU in developed countries is assumed to grow, necessitating an increased demand for treatment by specialists.

Objectives: To compare the effectiveness of a telemedicine video conferencing modality with the conventional face-to-face treatment of LEU.

Methods: The study was conducted at a 2-million-member health organization in Israel (Maccabi Healthcare Services). Consecutive visits of patients to wound care specialists during a 12-month observational period in 2015 were reviewed. A nurse-assisted setting was implemented during all treatment sessions. The same specialist supervised patients in both modalities.

Results: A sample of 111 patients (n=55 in the telemedicine group; n=56 in the face-to-face group) with 593 visits was analyzed. No significant difference in healing of LEU (78.2% in telemedicine vs. 75.0% in face-to-face) was detected, $P = 0.823$. A reduced number of visits in telemedicine (4.36 ± 2.36) compared to the face-to-face care (6.32 ± 4.17) was shown, $P = 0.003$. Non-inferiority of telemedicine demonstrated within the $\Delta = 15\%$ range limits and 80% statistical power was demonstrated.

Conclusions: Compared to the usual face-to-face method, synchronous video conferencing-based telemedicine may be a feasible and efficient method for LEU management.

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KEY WORDS: foot and leg ulcer, lower extremities ulcers (LEU), Maccabi Healthcare Services, synchronous telemedicine, wound therapy

Access to healthcare services is one of the largest concerns in modern and developing societies. Two Israeli laws, the National Health Insurance Law (1995) and the Patient's Rights Law (1996), defined a strategy to ensure equality in quality and efficiency of health services for populations living in the central urban areas as well as in the periphery.

Integration of telemedicine, as well as information and communications technologies, may yield several advantages for patient treatment, including better distribution of medical services within a single country or worldwide. In addition, immediate availability of medical information may be achieved. Synchronous video telemedicine is aimed at facilitating the virtual realization of the doctor–patient interaction over distances [1-8]. Such technology may contribute to a patient's medical education and equality in medical services provision [9-11].

The estimated annual prevalence of foot and leg ulcers varies from 0.12% to 3.1%, while their annual incidence rate is estimated to be approximately 1.2% to 3.0% [12-14]. People in most developed countries have a longer life expectancy. Consequently, the prevalence of foot and leg ulcers may increase, which in turn could have an impact on treatment resources and follow-up care [3,9,10,12-14]. Lower extremities ulcers (LEU) impose a heavy burden on individuals as well as on the healthcare system [6,12]. Furthermore, an almost two-fold mortality rate was demonstrated in patients with diabetic foot ulcers compared to a healthy cohort [15]. Appropriate treatment and follow-up care may, therefore, be required to improve life expectancy and quality of life of patients [15-17].

Recent achievements in synchronous video conferencing-based telemedicine technology, such as evaluated in our study, enable patients and doctors to use a high-resolution video for clear displays of wound edges and color separation [7,16,17]. Compared to asynchronous telemedicine systems, the synchronous video technology may have some advantages for patients and physicians by enabling an interactive, life-like intervention. Video conferencing implementation in telemedicine, especially in LEU, may thus be considered where such high-quality technical infrastructures are present [16].

Several major issues of effectiveness, settings, and economics have to be assessed for implementation of telemedicine for a particular medical condition. The approach to these issues may vary according to the medical services policies, telecommunication options, transportation choices, availability of information infrastructure, and population distribution (particularly with chronic diseases). Other social, demographic, and economic considerations as well as clinical conditions must be assessed [3-6,11,18-20]. Our study addresses the technology and treatment effectiveness challenges.

The purpose of this study was to compare synchronous video conferencing-based telemedicine to the standard face-to-face treatment of LEU in remote outpatient clinic environments throughout Israel.

STUDY HYPOTHESES

The null hypothesis assumed no difference between the two methods (telemedicine and face-to-face) for all outcomes, including ulcers status and number of visits.

The non-inferiority hypothesis assumed that the telemedicine method was inferior to the face-to-face design by at least a predefined difference in the effect [21-24]. The null hypothesis defined telemedicine as being inferior to the face-to-face method with the difference exceeding the adopted difference. The alternative hypothesis stated that the difference in effect size is less than a predefined value.

PATIENTS AND METHODS

SETTING

This observational cohort study was performed using electronic medical records data from Maccabi Healthcare Services. The time frame of the study was from 1 January 2015 to 31 December 2015. The face-to-face interventions took place in three northern district centers serving members of Maccabi Healthcare Services, a two-million member healthcare organization in Israel, which were closest to where the patients lived. The telemedicine cohort included patients from two outpatient clinics corresponding to identical telecommunications, information technologies, and video-conferencing infrastructures. All patients were treated by the same nurse at each location and by the same specialist for both modalities.

INCLUSION CRITERIA

Patients older than the age of 18 years with ulceration history longer than 6 weeks were included in the study.

EXCLUSION CRITERIA

Patient records with fewer than two interventions were excluded, as were records with irrelevant data.

INFRASTRUCTURE

The study was based on a commercial video conferencing system (Lifesize Inc, Austin, Texas, USA) and Maccabi Healthcare Services internal telecommunications network with high availability access and at least 1 Mbps (megabits per second) trunk capacity. The quality of service functionality, facilitating permanent communications bandwidth, was enabled. The internal telecommunications infrastructure, which is a secure, low-latency network connecting all Maccabi Healthcare Services sites in Israel, was used for the video conferencing interventions. The communications protocol H.232 and H.264 video compression techniques were deployed. Two different video conferencing setups were enabled: one for the specialist site at the central clinic and the other for the remote outpatient clinic. At the specialist facility, a high quality 21-inch video screen with built-in communications, video conferencing equipment, and an additional stationary high definition (resolution 1280 × 720) Sony video camera (HDR-CX440 HD Handycam®, Sony Mobile Communications Inc., Japan) was available. A special purpose ruggedized cart was manufactured (S.L.G. Ltd., Israel) for the remote site communications equipment, which included a 21-inch screen monitor, microphones, and video cameras.

Both telemedicine and face-to-face modalities were implemented in a similar setting with the same nurse at each location present during all treatment sessions. For the first consultation stage (anamnesis), the patient sat in front of the screen and camera. The patient's wound was monitored using an additional video camera installed on the adjustable arm, which was specially designed for this purpose. The patient could stand or lay down according to the medical condition and the location of the wound. The camera was controlled by the nurse, as instructed by the physician. Patient medical records were available to the specialist for reviewing and updated throughout the session.

STUDY VARIABLES

The ulcers were grouped into two categories according to their underlying diseases: diabetes mellitus ulcers and non-diabetic chronic wounds such as pressure sores, venous insufficiency, and other traumatic, oncologic, and postoperative ulcers.

Two types of outcome variables were defined and grouped in cohorts indicating ulcer conditions based on a medical evaluation of wound treatment results: negative outcomes and positive outcomes. Positive outcomes indicated closed ulcers and at least 50% of the ulcer closure with granulation tissue appearance. Negative outcomes indicated deterioration in ulcer conditions of at least 10% in size, or those in which no positive change occurred.

STUDY SAMPLE SIZE CONSIDERATIONS

The required sample size of n=45 in each group was calculated to satisfy an 80% power value for 0.2 difference [25].

STATISTICAL ANALYSIS

Population similarities in both modalities for age group and gender were tested using chi-square (cross-tabulation). Binary data (dichotomous) were cross-tabulated, while numerical data (number of visits and treatment duration) were calculated using the Student *t*-test method. The non-inferiority trial based on the assessment that a new modality could be inferior to the usual face-to-face method by 0.15 was adopted from previously published studies [23,24]. A logistic regression model was used to demonstrate the statistical inferences on potential confounding effect. A statistical significance level of 0.05 was assumed throughout the study. Statistical analyses were performed using IBM Statistical Package for the Social Sciences statistics software, version 22 (SPSS, IBM Corp, Armonk, NY, USA).

ETHICS APPROVAL

Maccabi Healthcare Services ethical committee approved the study in accordance with the 1964 Helsinki Declaration, permission number 42/2015.

RESULTS

The final sample size was 111, with 55 patients in the telemedicine group and 56 in the face-to-face group. The actual study sample size was larger than that required for 80% statistical power. The final analyses included 593 interventions.

Descriptive data for the study samples of demographic and clinical conditions are shown in Table 1. The data were presented in quantity and relative proportions, while treatment duration and number of visits were presented as mean values. The probability of male population predominance in all types of ulcers was noticed. Our sample included 61.3% men and 31.1% women.

The population distribution between telemedicine and face-to-face cohorts demonstrated a probable homogeneity of the cohorts. Type of ulcer, age, and gender groups cross-tabulation results demonstrated a similarity in the population data distribution with 95% confidence interval (95%CI) 0.938–4.297, 0.242–1.194, and 0.279–1.304, respectively. The treatment duration and number of visits needed until a positive outcome was achieved were defined as the time needed to treat the ulcer until a positive result was achieved. The average healing time of ulcers for positive outcomes in the face-to-face cohort was 74.1 ± 59.3 days compared to telemedicine 96.4 ± 60.1 days, *P* = 0.090. The mean number of visits until the positive outcome in telemedicine modality was 4.4 ± 2.4 days, which was substantially lower (*P* = 0.003) compared to face-to-face with 6.3 ± 4.2 days.

Non-inferiority of telemedicine to face-to-face was assessed by evaluating the lower left border of 95%CI, which was 0.144 under the zero-inferiority level, satisfying the adopted D = 0.15 value and statistical power of 80%. Binary logistic regression was performed for the confounding effect testing for age, gender, and ulcer type, with a positive outcome being a dependent variable [Table 2]. The Hosmer–Lemeshow test (chi square = 3.47) indicated a good fit of the logistic model (*P* = 0.483).

Table 1. Patient characteristics and outcome distribution in telemedicine and face-to-face treatment modalities

Samples data	Telemedicine n (%)	Face-to-face n (%)	Total	*P* value
Number of patients	55 (49.5)	56 (50.5)	111	
Gender				
Female	18 (32.7)	25 (44.6)	43	
Male	37 (67.3)	31 (55.4)	68	0.244
Age group				
≤ 60 years	16 (29.1)	23 (41.1)	39	
> 60 years	39 (70.9)	33 (58.9)	72	0.162
Ulcer type				
Diabetic	29 (52.7)	20 (35.7)	49	
Non-diabetic	26 (47.3)	36 (64.3)	62	0.087
Outcomes				
Positive*	43 (78.2)	42 (75.0)	85	
Negative	12 (21.8)	14 (25.0)	26	0.823

*Implies complete healing or improvement of more than 50% of tissue granulation

DISCUSSION

Our study demonstrated that video conferencing-based telemedicine technology has no disadvantages compared to face-to-face in LEU treatment in an outpatient clinic environment. This effect is consistent with previously published reports comparing telemedicine and face-to-face treatment modalities in different settings [3,4,6,7,12-16,18].

Demographic parameters were similar in both cohorts. There was, however, a trend for male preponderance in the telemedicine group as well as a higher proportion of older patients. These parameters could indicate a clinical plausibility of more co-morbidities in the telemedicine cohort, with male gender and older age being associated with the higher prevalence of ulcerations in the general population [14,20]. Fewer visits in the telemedicine cohort was demonstrated, similar to the previously published reports [3,6,19]. This difference could be due to some difficulties in conducting telemedicine interactions or that telemedicine was more effective in managing these conditions than face-to-face meetings.

The treatment time "until positive outcome" was shorter in the face-to-face cohort; however, the variation was within the limits of a significant difference. Non-inferiority of the telemedicine modality was within the 15% range. Similar margins (15–20%) were reported in previous studies [21,23,24]. The non-inferiority assessment requires a definition of an agreed

Table 2. Binary logistic regression testing for potential confounding effect in positive outcomes

Models	Predictors	Odds ratio	95% confidence interval	*P* value
Model 1: Telemedicine modality without demographic data	Constant	3.583		< 0.001
Model 2: Telemedicine modality including demographic data	Constant	4.083		0.001
	Age (< 60 years)	1.047	0.273–5.328	0.805
	Gender (female)	1.201	0.240–6.005	0.824
	Ulcer type (diabetic ulcers)	0.522	0.118–2.313	0.392

margin of difference; however, the margin for the telemedicine non-inferiority as a LEU management method has not yet been defined as a standard practice [3,20,23,24].

Since 2010, the capacity and quality of video conferencing technology and telecommunication infrastructures have enabled their implementation in telemedicine, particularly in wound therapy [7,24]. The current video conferencing systems have high-resolution cameras, autofocus technologies, and automatic white balance as required for a proper color transmission. This technology should be considered as a gold standard for the minimal quality infrastructure required for the implementation of telemedicine. The expertise in using high-resolution video conferencing facilities should, therefore, be investigated based on a technological quality of the compatibility to the disease [21]. Medical expertise and technological advances that are suitable for implementation are an essential parameter. Acceptance by practitioners and organizations, policies at medical facilities, and legislation are other determinants for successful implementation of telemedicine [16].

Further studies of telemedicine implementation in wound therapy in Western societies and less developed countries are needed, particularly for follow-up treatment of foot and leg ulcers [1,2,5,6,14,22].

LIMITATIONS

A possible generalization bias could be due to potential differences among populations in different parts of the country. The fact that a single specialist managed all interventions could have resulted in an observer bias. However, this factor could be both a strength and a weakness of this study. While the same clinical knowledge was applied to both cohorts, the interpretation of the results could be influenced by personal beliefs of the physician or may be influenced by certain doubts about the technology-based treatment compared to the usual face-to-face treatment.

CONCLUSIONS

Our study demonstrated telemedicine non-inferiority to the existing face-to-face practice in outcomes measured in healing parameters as well as a significant reduction in the number of visits via the telemedicine modality. Video conferencing technologies may prove to be a valuable tool for the treatment of foot and leg ulcers for both patients and healthcare organizations. A video conferencing method in telemedicine modalities thus could be considered to be a prime candidate for wound therapy.

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"A sad soul can kill quicker than a germ"

John Ernst Steinbeck, Jr. (1902–1968), American novelist