

Telemedicine in diabetic ulcer management: A pilot study with exploration of medico-legal aspects

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Abstract *Background and aims:* This study aimed to evaluate the quality and efficiency of telemedicine in managing patients with chronic diabetic ulcers and provide an overview of the main medico-legal implications associated with telemedicine management of diabetic foot complications.

Methods and results: A total of 50 patients with type 2 diabetes mellitus were enrolled from a diabetic foot outpatient clinic in Cyprus between March and May 2022. Participants completed a survey concerning telemedicine services, and the demographic variables and average responses to the PACIC (Patient Assessment of Chronic Illness Care) questions were examined using descriptive analysis. The majority of patients (84%) were male, with a mean age of 60.9 ± 13.05 years. The average PACIC score was 4.42 (min. 2.7 and max. 5.0). Voice calls were the most preferred method of telemedicine delivery, accounting for 53% of all services.

Conclusion: Telemedicine can effectively manage chronic patients, such as those with diabetic ulcers, by reducing the burden on resources and maintaining service quality. However, healthcare professionals must be well-versed in medico-legal implications to adhere to legal and ethical guidelines, protect patient privacy, and maintain high standards of care while using telemedicine for chronic condition treatment.

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1. Introduction

Diabetes is a common chronic disease that occurs due to the lack of pancreas producing enough insulin, or the ineffectiveness of the body itself to use the insulin produced. The hyperglycemia is a common side effect of uncontrolled diabetes that in turn causes many diseases including neuropathies, angiopathies, ulcers, retinopathies,

nephropathies, and cardiovascular diseases. Diabetes is the principal cause of millions of premature deaths every year, both in developing and developed countries according to the World Health Organization [1]. Various prevention strategies are suggested by both private and public organizations to minimize these catastrophic public health burden. The most important modification factors that need to be addressed are lifestyle factors including eating habits, alcohol, stress, and lack of exercise [2,3]. Exercise is proven through many studies that improves glucose levels and aids the reduction of cardiovascular disease risk and mortality in diabetic patients [4,5]. Well-designed longitudinal

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studies that focus on daily activities as part of physical exercise are lacking at the moment. However, non-exercise activity thermogenesis (NEAT), like walking to work, typing, gardening, is associated with reduction in diabetic risk, obesity, and mortality [6–8].

In Cyprus, diabetes is one of the five most common causes of death. It is estimated that one in every 10 Cypriots over 20 years of age suffer from diabetes, a percentage that is higher than the European average of 6.3% [9–11]. The main reason is the lack of exercise and diet habits of the Cypriot population. Small and steady measures to address the risk factors and aid in the decrease of diabetic trends in Cyprus are in practice in the last decade [12–14]. The Republic of Cyprus in 2013 appointed the Cyprus National Diabetes Committee, as a compulsory need to manage this upcoming public health disease [15]. Their strategy plan has the primary goal to be the first wheel in the coordination of public and private health sector in promoting more efficient and effective programs in association with the management of diabetes. This multidimensional approach is based on 5 main axons: prevention, early diagnosis-care, recovery-palliative care, study, record archives. The aim of the 5-step approach is the prevention of diabetes and management of its complications through a holistic approach.

Therefore, to observe the efficacy of the above steps, we decided to set a pilot study aimed at evaluating the specialized management provided to patients with type 2 diabetes mellitus, treatment plans and goals set. This study aimed to provide evidence-based information to health centers in the country in terms of the application of treatment goal protocols that can aid in the management and treatment of diabetic patients. Furthermore, the aim of this pilot study was to investigate possible strategies to be taken for the care and management of diabetic patients in emergency situations such as a pandemic lockdown, as well as the medico-legal implications of these modification strategies in order to secure correct ethical and legal standards of healthcare in respect to the patient and the doctor himself.

2. Methods

Patients were recruited from the outpatient clinic at the diabetic foot department. They were invited to voluntarily participate in this study while maintaining anonymity. After providing informed consent, they were asked to complete a survey about their experience with telemedicine and remote management of their condition and its associated complications. The survey was divided into three sections.

1. Section 1: demographic data (gender and age) and characteristics of diabetic pathology (type of diabetes, type and extent of complications).
2. Section 2: Patient Assessment Chronic Illness Care (PACIC) [16] questions. The level of agreement regarding the statements was rated with Likert scale

1–5 (1: strongly disagree, 2: disagree, 3: neither agree nor disagree, 4: agree, 5: strongly agree) [17].

3. Section 3: questions regarding telemedicine services and quality of distant care. These were rated with Likert scale 1–10, in order to have a bigger range of answers and therefore a broader understanding of the patients' needs and expectations.

Between March 2022 and May 2022, we gathered patient data through surveys at our outpatient clinic, which we subsequently digitized for analysis. This survey served as an observational evaluation of the services provided by the clinic, treatment plans and objectives, as well as inquiries into telemedicine and the quality of remote care. The Department of Plastic Surgery collaborated with doctors, hospital nurses, outpatient clinic nurses, and home healthcare nurses to develop this comprehensive survey. Significant attention was given to treatment plans, chronic care models, and patient goals, as well as the effectiveness of telemedicine services, to ensure the creation of a robust and efficient assessment tool [18,19].

The PACIC questionnaire, which constituted the second section of the survey, was chosen for the primary portion of the study, utilizing a Likert scale ranging from 1 (almost never) to 5 (almost always). The questionnaire was divided into five main sections. Statements 1–3 focused on patient involvement and activation. Statements 4–6 addressed the design of the delivery system and patient decision support. Statements 7–11 pertained to the establishment and customization of treatment plans and goals. Statements 12–15 involved contextual problem-solving aspects. Finally, statements 16–20 encompassed coordination with other specialists and follow-up care.

The third and final section of the survey involved 10 specific questions regarding telemedicine and quality of service care through distant services. The main objective of the third section was to identify any means of telemedicine used by the patients, the process and ease of use as well as their satisfaction regarding this type of service, if used at all.

It is worth mentioning here that patients that are referred to the diabetic foot outpatient clinic and were included in this study were patients that were referred to by their general practitioners and they are patients with an advanced foot lesions (Wagner classification Grade III (deep abscess/osteomyelitis)-V (extensive gangrene)). Early lesions are managed by general practitioners through glycemic control and basic wound management in order to avoid the crowding of the surgical outpatient departments and manage in this way the patients in two sections for better control and organization.

2.1. Subjects

A total of 50 patients were included in our study, comprising 42 males and 8 females who all had type 2 diabetes mellitus. The male patients ranged in age from 34 to 88, while the female patients ranged in age from 48 to 80. The mean age of study participants was 60.9 ± 13.05 .

The average age of male and female patients was 59.86 ± 13.39 and 66.38 ± 9.72 , respectively.

3. Results

The second section of the survey consisted of 20 PACIC statements, responded to using a Likert scale ranging from one to five. Below are the statements that were used.

1. The doctor asked for my ideas when we made a treatment plan
2. The doctor gave me choices about my treatment plan and alternative suggestions.
3. The doctor talked about any problems with my medication and/or treatment regime.
4. The doctor gave me a written list of the steps necessary to improve my condition
5. I am satisfied with the list of care steps that need to be undertaken.
6. I have been shown how what I did to take care of my illness influenced my condition.
7. The doctor asked me to talk about my goals in caring my condition.
8. The doctor helped me to set specific goals to improve my condition.
9. The doctor gave me a copy of my treatment plan
10. The doctor encouraged me to attend local programs to help me with my condition.
11. The doctor asked questions about my health habits.
12. The doctor thought about my values and traditions before setting a plan.
13. The doctor helped to make a viable treatment plan to align with my daily life.
14. The doctor helped me to plan ahead, so I could take care of my illness if things worsen.
15. The doctor asked my how my chronic illness affects my everyday quality of life.
16. The doctor referred me to a dietician, diabetologist, or a counselling specialist.

17. The doctor explained how my visits to other specialized doctors will help with my condition.
18. The doctor asked how my visits with the other specialized doctors were going
19. I have been advised to keep a diary record of my progress
20. I was told how important is to take care of my comorbidities regarding my overall health.

In Fig. 1, a graph is depicted illustrating the average Likert scale scores obtained for each of the 20 statements in the PACIC questionnaire.

The study cohort yielded an average score of 4.42 on the 20-statements PACIC survey. The four statements with the highest average scores were number 3 (“The doctor talked about any problems with my medication and/or treatment regime”), with an average score of 4.96, number 4 (“The doctor gave me a written list of the steps necessary to improve my condition”), with an average score of 5.0, number 8 (“The doctor helped me to set specific goals to improve my condition”), with an average score of 4.96, and number 9 (“The doctor gave me a copy of my treatment plan”), with an average score of 5.0. Conversely, the statements with the lowest scores were number 10 (“The doctor encouraged me to attend local programs to help me with my condition”), with an average score of 2.66, and number 12 (“The doctor thought about my values and traditions before setting a plan”), with an average score of 2.8. Based on these results, we can infer that the cohort study emphasized the clinical aspects of therapeutic plans more than the socio-health components of disease management. Overall, the results of all statements are satisfactory, with some areas for improvement, particularly concerning patient satisfaction with the services provided according to their needs and educational strategies to enhance their condition.

The third and final section of the survey involved 10 specific questions regarding telemedicine and quality of service care through distant services (Table 1). Among the



Figure 1 Average scores obtained for each of the 20 statements in the PACIC questionnaire (minimum score: 1, maximum score: 5).

Table 1 Section 3 of the survey: telemedicine questions.

1	Have you ever used any telemedicine service?	Yes No
<i>If YES, continue to questions 2–10</i>		
2	What means of telemedicine was used?	Email Voice call Videocall Text Message
3	Why did you use telemedicine services?	After my general practitioner's advice After my plastic surgeon's advice in the outpatient clinic With my own innovative Due to movement difficulties Due to easiest and fastest service
<i>Answer questions 4–10 in a scale of 1–10 (1: strongly disagree to 10: strongly agree)</i>		
4	The information provided was sufficient	
5	How easy was the communication?	
	According to the way of examination, how would you rate:	
6.1	History taking?	
6.2	The questions regarding your problem?	
6.3	The information provided regarding your treatment plan?	
6.4	The information regarding your medication drugs and consumables?	
	According to your experience:	
7.1	Are you satisfied with the service provided?	
7.2	I understood fully the information provided	
7.3	I feel safe with the tele visit and do not require a physical visit	
8	Would you be interested in training regarding telemedicine services?	
9	Would you recommend telemedicine to other patients with same problems?	
10	Would you use again in the future telemedicine services?	

34 patients who selected 'YES' in response to the first question ("Have you ever used any telemedicine service?"), the results of the third and final section were based on their input. The most popular mode of telemedicine services was voice calls, with 53% of respondents preferring this method. The primary reasons for this preference were ease of use, the inexperience of older individuals with technology, and the lack of a smart device for some participants. Of the remaining 47%, 23% of participants preferred video calls, 18% preferred text messaging, and 6% favored e-mails.

Most patients (12) were advised to use telemedicine services by their outpatient clinic doctors. Out of these, 9 chose to utilize teleservices because of mobility issues, while 9 patients considered it the most convenient and quickest option compared to physically visiting the outpatient clinic. The remaining 7 patients chose to resort to telemedicine services because they were attracted by the innovative nature of the practice. Questions 4–10 of the third and final section of the survey (shown in [Table 1](#)) were scored with Likert scale 1–10. We chose to utilize a more extensive scale for this section of the questionnaire simply because we aimed to gather a broader array of responses, allowing us to better comprehend the needs and expectations of the patients. [Fig. 2](#) displays the average scores for questions 4–10 in the survey's third section.

The statements/questions that obtained the lowest scores were number 7.3 ("I feel safe with the televisit and do not require a physical visit") and number 9 ("Would you recommend telemedicine to other patients with same problems?"). This hesitation to utilize telemedicine services is likely due to the age of the patients, who are often unwilling to learn about new technological advancements.

Consequently, this reluctance is passed on to their mindset of not recommending these services to their peers. This issue can be addressed through educational programs on telemedicine targeted at the elderly population, delivered by community nurses or within specialized hospital settings.

4. Discussion

4.1. Interpreting the findings

The results of our pilot study keep up with similar studies performed in other countries [20,21]. The use of telemedicine services needs to be employed wherever possible in the healthcare system. The advantages of telemedicine are much more than the drawbacks. Telemedicine services have the potential to significantly reduce the physical burden on healthcare facilities. Through these services, doctors can determine whether a patient requires an in-person visit or if they can be advised on their treatment plan remotely, eliminating the need for travel to a physical healthcare center. This not only reduces the number of physical visits, but also allows doctors to allocate more time to patients who genuinely need in-person consultations.

From the patient's perspective, telemedicine saves time and effort, especially for those with chronic conditions who may have difficulty moving around. Treatment plans can be explained to a patient's relative or a home nurse to ensure proper understanding of medications and wound care, particularly when the patient is unable to comprehend instructions. Based on the final section of our survey, we can infer that patients remain somewhat hesitant to

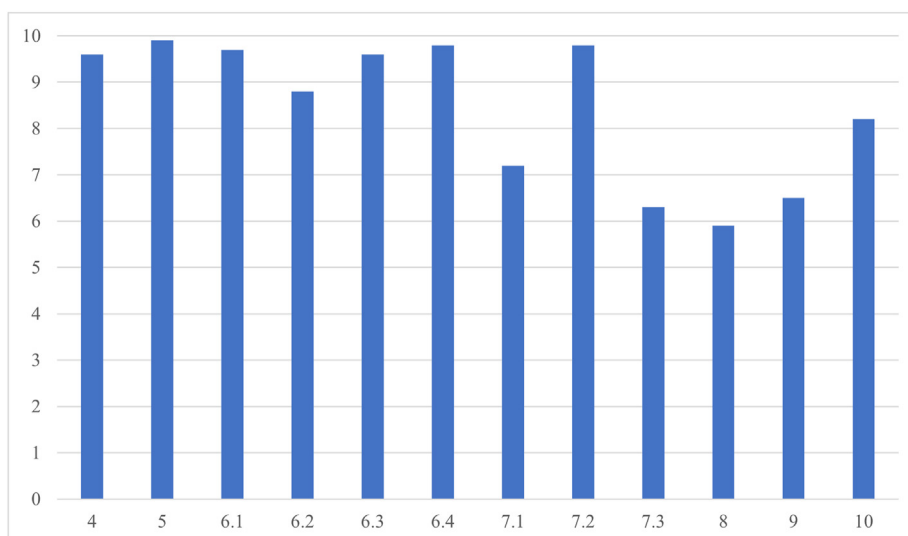


Figure 2 Mean scores of questions 4–10 of the third section of the survey (minimum score: 1, maximum score: 10).

use telemedicine services or feel that remote care is inadequate, which can be seen as limitations in our study. Addressing these concerns may involve providing thorough explanations and education to both patients and their relatives about the ease and benefits of using telemedicine compared to traditional in-person visits to outpatient clinics. This reassurance can help them understand that the quality of care remains consistent. Regular telemedicine follow-up visits can enable easy monitoring of chronic diabetic patients, allowing for early detection and management of complications or worsening symptoms.

Another limitation of our study is the discrepancy between male and female participants, as well as the smaller number of younger patients compared to older ones. This is primarily due to the higher percentage of male diabetes patients in the country where the study was conducted and the fact that female patients often manage their glucose levels without requiring extensive monitoring at an outpatient clinic within our department. Instead, they tend to follow up with their general practitioners.

The study's time frame may also be considered a limitation. However, given the small population size of Cyprus, the three-month time frame was deemed sufficient for following up with nearly all of our patients in the clinic and offering them the opportunity to participate in our study.

4.2. Medico-legal implications

One of the primary medico-legal concerns in telemedicine in the monitoring and management of diabetic foot is the issue of patient privacy and confidentiality. Traditionally, medical professionals have been obligated to maintain patient confidentiality, as breaches in this area can lead to severe legal consequences. The Health Insurance Portability and Accountability Act (HIPAA) outlines strict

guidelines for protecting patient information in the United States, while in Europe, a similar level of protection is governed by the General Data Protection Regulation (GDPR). The GDPR sets comprehensive rules for the collection, processing, and storage of personal data, including health-related information, within the European Union. Both HIPAA and GDPR aim to safeguard individuals' privacy rights and ensure the security of their sensitive data in the healthcare context [22]. With telemedicine, sensitive patient data is transferred electronically between healthcare providers, patients, and third-party service providers, which increases the risk of data breaches and unauthorized access to personal health information. Healthcare providers must ensure that they employ secure electronic communication channels and robust data encryption methods to protect patient data and comply with privacy laws [23].

Another medico-legal implication of telemedicine in monitoring diabetic foot is the matter of informed consent. Informed consent is a fundamental principle in medical practice, where patients must be provided with adequate information about their condition, treatment options, and potential risks associated with a specific treatment plan [24]. In telemedicine, obtaining informed consent from patients can be challenging due to the lack of face-to-face interaction between patients and healthcare providers [25]. To address this issue, healthcare providers may resort to using electronic consent forms and video conferencing tools to ensure that patients fully understand their treatment options and the implications of telemedicine services.

Telemedicine also raises concerns related to the standard of care provided by healthcare professionals. The standard of care is a legal concept that requires medical professionals to provide treatment that meets the generally accepted practices and guidelines within their profession [26]. When telemedicine is used to monitor

diabetic foot, the standard of care must be maintained, despite the remote nature of the services provided. Healthcare professionals must ensure that they have the appropriate training, certifications, and licensure to provide telemedicine services. Moreover, they must stay up to date with advancements in technology and medical knowledge to ensure that patients receive the highest standard of care possible. Specifically, in order to maintain the standard of care in telemedicine diabetic foot treatment, healthcare providers should take several steps: utilizing high-quality video and audio equipment to ensure clear communication and accurate visual assessment of the patient's foot; developing protocols for remote physical examination and wound assessment, including patient self-examination and the use of remote monitoring devices; collaborating with other healthcare providers, such as local wound care specialists, to ensure comprehensive care and appropriate follow-up; maintaining continuous medical education and training in telemedicine best practices, diabetic foot care, and relevant medical-legal issues.

Liability issues are another significant medico-legal concern in telemedicine. Medical malpractice claims can arise when a healthcare professional's negligence results in harm to a patient. In the context of telemedicine, determining liability can be complex due to the involvement of multiple parties, including healthcare providers, patients, and third-party service providers [27]. Additionally, the use of technology in telemedicine may result in technical errors or equipment malfunctions that could lead to adverse patient outcomes. Healthcare providers must be vigilant in ensuring that telemedicine services are provided with the utmost care and diligence to minimize the risk of liability.

With particular reference to the treatment of the diabetic foot, we recommend the following practices: adhering to established guidelines and best practices for telemedicine and diabetic foot care; maintaining comprehensive and accurate documentation of telemedicine encounters, including medical history, examination findings, and treatment plans; communicating clearly and effectively with patients and other healthcare providers involved in the patient's care; ensuring that telemedicine services are provided in a manner consistent with the standard of care for in-person consultations.

Jurisdiction is another medico-legal challenge associated with telemedicine. Although in this study both doctors and patients were located in the same country (Cyprus), the practice of telemedicine often transcends geographical boundaries, allowing healthcare providers to treat patients in different states or countries. Consequently, healthcare professionals must grapple with the complexities of navigating different legal and regulatory frameworks that govern medical practice in various jurisdictions [28]. This issue is particularly pertinent in cases where healthcare professionals are licensed to practice medicine in one jurisdiction but provide telemedicine services to patients in another jurisdiction. To mitigate this challenge, healthcare providers should familiarize

themselves with the medical regulations and licensure requirements in the jurisdictions where they intend to provide telemedicine services.

Telemedicine also brings forth ethical considerations that have medico-legal implications [29]. Equity in access to telemedicine is a significant concern, as not all patients have access to the necessary technology or internet connectivity to benefit from telemedicine services. Additionally, some patients may face language barriers or have limited health literacy, which could hinder their ability to effectively use telemedicine services. Healthcare providers must be mindful of these issues and take steps to ensure that telemedicine services are accessible and equitable for all patients, regardless of their socio-economic status, geographical location, or other factors.

5. Conclusions

In conclusion, telemedicine has the potential to significantly alleviate the burden on healthcare systems globally, including in Cyprus. By comprehending and effectively utilizing telemedicine services, both physicians and patients can reap the benefits of an enhanced healthcare system and a more equitable distribution of resources. However, this healthcare approach is accompanied by numerous medico-legal implications. Healthcare providers must diligently consider, and address matters related to patient privacy and confidentiality, informed consent, standard of care, liability, jurisdiction, and ethical concerns to ensure that telemedicine services are delivered safely, efficiently, and in accordance with relevant laws and regulations. By proactively tackling these medico-legal challenges, healthcare providers can easily harness the power of telemedicine in improving the lives of patients with diabetic foot, and in this way relieve a big physical burden from physical centers without altering the quality of services provided.

Contributors

GN conceived the original idea and drafted the initial version of the paper; DS developed the survey and personally observed and collected the data; GR, FG, PB, and FA delved into the medico-legal issues and wrote the corresponding section of the article; DDL provided overall supervision of the work and conducted the final review.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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