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Telehealth has comparable outcomes to in-person diabetic foot care during the COVID-19 pandemic.

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Abstract

BACKGROUND

The COVID-19 pandemic has posed obstacles to the delivery of diabetic foot care. In response to this remote healthcare services have been deployed offering monitoring, follow-up, and referral services to patients with diabetic foot ulcers and related conditions. Although, remote diabetic foot care has been studied before the COVID-19 pandemic as an alternative to in-person care, the peculiar situation of the pandemic, which dictates that remote care would be the sole available option for healthcare practitioners and patients, necessitates an evaluation of the relevant knowledge obtained since the beginning of the SARS-CoV-2 outbreak.

AIM

To perform a thorough search in Pubmed/Medline and Cochrane to identify original records on the topic.

METHODS

To identify relevant peer-reviewed publications and gray literature, the authors searched PubMed-Medline and Cochrane Library– Cochrane Central Register of Controlled Trials (CENTRAL) starting September 27 till October 31, 2021. The reference

lists of the selected sources and relevant systematic reviews were also hand–searched to identify potentially relevant resources.

RESULTS

A number of randomized prospective studies, case series, and case reports have shown that the effectiveness of remote care is comparable to in-person care in terms of hospitalizations, amputations, and mortality. The level of satisfaction of patients' receiving this type of care was high. The cost of remote healthcare was not significantly lower than in - person care though.

CONCLUSION

It is noteworthy that remote care during the COVID-19 pandemic appeared to be more effective and well - received than remote care in the past. Nevertheless, larger studies spanning over longer time intervals are necessary in order to validate these results and provide additional insights.

Key Words: Diabetes; Diabetic foot; telehealth; telemedicine; COVID-19; SARS-CoV-2.

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Core Tip: Telehealth has a major potential to sustain and improve diabetic foot care during the COVID-19 pandemic. Studies reporting the experience of healthcare providers and patients around the globe are encouraging. These findings need to be validated with larger and long – term studies. In the post COVID era, the knowledge and experience obtained can serve as the standpoint of a hybrid approach of telemedicine and in-person care oriented towards delivering fast, efficient and cost-effective care to the patients.

INTRODUCTION

During the COVID-19 pandemic, access to healthcare has been hampered by restrictions on citizen movement applied by governments globally as well as people in vulnerable demographics avoiding or delaying visiting healthcare facilities due to health concerns. Internal hospital rearrangements in order to prioritize COVID-19-centered care, especially relevant from our experience in the Diabetes Center of Tzaneio General Hospital of Piraeus in Greece, result in debilitation of the health systems' capacity to assess patients in need in a timely manner [1]. Patients with diabetes mellitus (DM) have been greatly affected by this. In addition to being a high-risk group, they need to consult their treating physicians often to maintain DM and its complications under control [2]. This need has remained unmet on many occasions. The repercussions of this have been evident particularly with regard to diabetic foot ulcerations, where lockdown periods have been followed by an increased rate of emergency hospitalizations and limb amputations [3].

Diabetic foot (DF), as defined by the International Working Group on the Diabetic Foot, is infection, ulceration or destruction of tissues of the foot associated with neuropathy and/or peripheral artery disease in the lower extremity of a person with (a history of) diabetes mellitus [4]. On a global scale, according to Global Burden of Disease an estimate of 131 million (1.8% of the population) people had developed a diabetes related lower extremity complication, chief among them being foot ulcers [5]. DF amounts for a significant amount of healthcare spending, as it is estimated to account for one third of diabetes spending which was $237 billion in 2017 in the United States, increasing by 26% from 2012 [6] [7]. As a result, this is a disease which rivals cancer cost ($80.2B in 2015) [7]. We should also take into account indirect costs which include absenteeism from work or reduced productivity and even early mortality, which accounted for $90B [8].

While DF is one of the many diabetes sequelae, it is the one responsible for the most hospitalizations [5]. All diabetic patients have been estimated to have a 25% risk of

developing a DF ulcer, with type 2 diabetics having a slightly higher chance [9] [10]. Almost 50% of them are expected to become infected and in moderate to severe cases of infection about 20% will require to be amputated [11]. In fact, diabetes dominates nontraumatic lower extremity amputations, accounting for 85% of these operations.

To better understand the challenges of providing appropriate care and preventing amputations in patients with DF, one should consider this condition as a culmination of vascular disease, neuropathy and oftentimes disrupted immunity, vision impairment, debilitating comorbid conditions and frailty [12]. DF care requires frequent visualization, measurement and assessment of the wound by a specialist in addition to diverse treatment strategies including the use of medications, debridement patches and surgical cleaning of the wound. Having all this in mind, we can see how limited healthcare access directly affects the care of these individuals. The potential of remote care to patients unable to access healthcare facilities to stave off this highly morbid disease has been acknowledged before the pandemic. During the pandemic, the need to decrease the DF related burden of secondary and tertiary healthcare facilities, prevent hospitalizations and protect the patients from life-changing complications became even more evident. Although there is abundant research about remote diabetes care before and during the pandemic, there is limited evidence focusing specifically on DF care under these circumstances.

The authors summarize primary research focusing on digital health and remote care for DF, its precipitating factors and sequelae and identify relevant research gaps and fields of action.

MATERIALS AND METHODS

To identify relevant peer-reviewed publications and gray literature, the authors searched PubMed-Medline and Cochrane Library– Cochrane Central Register of Controlled Trials (CENTRAL) starting September 27 till October 31, 2021. The reference lists of the selected sources and relevant systematic reviews were also hand–searched to identify potentially relevant resources. The search terms: (“Digital health” OR “Remote

Healthcare" OR "Telemedicine") AND ("Diabetic Foot"[MeSH] OR "Diabetic Angiopathies"[MeSH] OR "Foot Ulcer [MeSH]" OR "Diabetic Neuropathies"[MeSH]) AND "COVID-19"[MeSH] were used. Studies were included if they fulfilled all the following eligibility criteria: (1) ongoing or published clinical studies reporting on digital and remote healthcare applications in the prevention or management of DF, its risk factors and sequelae, and (2) epidemiological analyses and reports. A study was excluded if it met at least one of the following criteria: (1) non-English publication language, (2) study types: editorials, opinion articles, perspectives, letters to the editor. No sample size restriction was applied when screening for eligible studies. Disputes in the selection of relevant studies were discussed between the two primary authors and a senior author until a consensus was reached. The literature was searched and reported according to the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) extension for Scoping Reviews (PRISMASc).

RESULTS

The initial search yielded 29 relevant publications, following the exclusion of non - primary sources from the database search and the deletion of duplicates. After screening titles and abstracts (n = 29) and excluding 12 records on the grounds of irrelevance to the topic, the full texts of 17 articles were assessed. 12 studies were eventually included in the present review (Figure 1).

A detailed overview of the included studies' characteristics is presented in Table 1.

Eight clinical studies reported on the utilization of telehealth services during the COVID-19 pandemic in the US, Europe, the UK, Turkey and India (2020-21). Four clinical studies with similar design and outcomes that were conducted before the pandemic were included. These studies serve as control when compared to studies conducted during the COVID-19 pandemic. The majority of the studies presented observational data from cohorts, case series or sole case reports, fewer studies were designed as randomized clinical trials and one was based on a cross sectional survey.

The existing evidence focused on the effectiveness of remote DF care and touched upon patients' experience and satisfaction and cost evaluation

Effectiveness of remote DF care

Studies regarding the effectiveness of various models of remote DF care during the COVID-19 pandemic paint a mostly positive picture. Utilizing a regime of virtual triage and consultations for a group of patients and comparing the outcomes with standard care from before the pandemic, Rastogi *et al* [13] concluded similar ulcer and limb outcomes in both groups, in a total of 1199 patients. In a randomized control trial (RCT) by Téot *et al* [14] in France that examined 173 patients, healing was insignificantly slower in the telehealth group, while both groups showed similar mortality rates. In an observational cohort study in Italy, Meloni *et al* [15] found telemedical care to be similarly as effective as outpatient care, while neutralizing healthcare setting transmission risk of COVID-19. Moving on to smaller scale studies, case report studies by Shankhdhar *et al* [16], Kavitha *et al* [17] and Ratliff *et al* [18], in India, India and USA respectively, report a positive healing outcome in an ulcer treated exclusively with telemedicine, effective assessment and follow-up of lower risk diabetic foot ulcer (DFU) cases and enhanced healing outcomes with telemedicine utilization respectively. Examining pre-pandemic literature on this topic we can derive that during recent years there has been a rise in interest in modernizing DFU care, although not without some potentially concerning findings. Interestingly studies before the pandemic report higher mortality in telehealth or inadequacy of remote care means like mobile photos - *e.g.* Rasmussen, 2015 [19]; van Netten, 2017 [20]. In an RCT by Rasmussen *et al* in 2015 [19], comparing outpatient *vs* telemedical monitoring in DFU, similar healing and amputation rates were found in both groups of 401 patients, but with an inexplicable higher mortality rate in the second group. Van Netten *et al* [20], while observing a cohort of 50 patients regarding the reliability of DFU ulcer using mobile phone images concluded it to be an unreliable method of remote assessment. Finally, standard medicine was found comparable to telemedicine in terms of outcome and patient satisfaction in a cluster RCT in Norway by

Smith-Strøm [21], and notably, there were significantly less amputations in the telemedicine group.

Patients' perceptions and cost evaluation

As with any implementation in healthcare, it is of vital importance to gauge patient experience and perception. In a randomized pilot study in Turkey by Kilic *et al* [22], a novel mobile application was developed as a way for patients to submit their blood glucose measurements and potentially pictures as well. This was compared to receiving 30-minutes of training once by a healthcare professional. After 6 mo, patient education and behavior had improved, and overall increased self-efficacy was found. Patients reported, in their majority, that they appreciated this portal of communication with the specialists and overall thought this was an effective contribution to their DFU care. In another similar study by Iacopi *et al* in Italy [23], 206 patients' opinions regarding their telemedicine consultations for DFU during the pandemic were assessed, as well as their anxiety regarding both COVID-19 and DFU. Patients were found to be very positive about their experience with telemedicine, finding it both very useful and a potential modality to keep using after the experiment. DFU patients seemed to be significantly more anxious regarding their existing DF disease compared to COVID-19, a result that was more apparent in the subgroup of patients with a history of ulceration, and even more prevalent in a subgroup that had undergone amputation. Regarding cost-effectiveness evaluation, in a study by Fasterholdt *et al* [24], the telemedical approach to treatment and monitoring of DFUs was not statistically significantly cheaper, although being cheaper by 2039 euros per patient. Some limitations of this study are the fact that it was conducted in Denmark in a highly urban setting which reasonably translates to a smaller distance between the patient's setting and the care center in comparison to more rural areas. Furthermore, it did not take into account costs regarding personnel training and telemedicine implementation that would be required in order to apply this remote care modality.

Overall, available evidence suggests that remote DFU care has approximately similar or better outcomes to standard therapy regarding healing time and amputations. There is potential in utilizing telehealth methods in order to triage and consult patients without inconveniencing them with unnecessary and potentially hazardous trips to the physician's office. In the study from Rasmussen *et al* [19] it was concerning that mortality was statistically significantly higher in the telehealth group, but without a concrete accountable reason, more large-scale studies are needed to justify this result. Finally, patients seemed to be content with telehealth applications, can recognize their usefulness and would be open to adding a telehealth element to their treatment regime. It is unfortunate that evidence regarding patient satisfaction is scarce up to this point, but with a more patient-centered healthcare approach undertaken globally, it would be reasonable to expect additional literature in the upcoming years.

DISCUSSION

Overall, it appears that telehealth services for DF remote care during the COVID-19 pandemic have been described in a number of studies, primarily during the first months of 2020. Remote DF care had already been developed before the pandemic, but its use was limited. This can be linked to studies showing increased mortality among telehealth services recipients [19]. It seems that remote DF care during the COVID-19 pandemic became more effective than before, as shown in a study done in Australia examining the adherence to national DF guidelines and treatment efficacy using telemedicine [25]. This can be attributed to the accumulated knowledge that helped physicians to avoid mistakes of the past, to the increased familiarization of physicians, patients and caregivers with telehealth during the last two years and to the relatively short - term monitoring time of the studies in comparison with previous research. Perhaps, monitoring these patients for a longer time would still reveal adverse

outcomes that have not become evident to date. This interpretation is subject to a number of factors.

Firstly, one should acknowledge the geographical variation scarcity of the literature. Studies that we reviewed come from Europe (Norway, Denmark, Italy, France, UK), USA, India and Turkey. Suffice it to say that there's a whole unknown world out there in terms of research on this subject, with large geographical regions not being represented as is. There is no literature regarding regions such as South America, Russia, Central Asia, Asia-Pacific and Africa, among others which inevitably lead to some level of bias. For example, the studies were done in countries and people that had access to remote healthcare services. This is best exemplified by the example of some developing countries, where it's estimated that about one third of the population has access to the internet, the principal foundation of telehealth in DFU. In addition, even in more developed countries there is often a shortage of tech-savvy physicians and lack of appropriate equipment. In our experience in public hospitals in Greece, for example, before the pandemic few web-cameras were available to use by the staff, a problem that thankfully was fixed on time.

There are certainly a number of knowledge gaps with regard to the matter. On top of those implied before. A considerable gap stems from the lack of cost effectiveness data in comparison to the pre-pandemic era. which necessitates further assessment, given that a non - cost effective model of remote care has lower likelihood to survive after the pandemic. Furthermore, there is no data in regard to the physician's perception of remote care, the level of physicians' digital literacy, accountability and financial compensation. Again, judging from the authors' experience, there is a lack of familiarity with concurrent technology that's proportional to the personnel's age, mostly affecting the most senior members of the staff. In regards to the economics of telehealth, it is unclear whether state and private insurance have a homogenous stance of compensating remote care and whether they compensate at the same rate as in-person care, which, as expected, could stress medical staff. Last but not least, it is

necessary to mention that the reported studies involved limited numbers of patients monitored for a number of weeks or months.

Future research needs to address the above limitations in the form of large scale and long-term studies providing - wherever necessary - head-to-head comparisons between patients treated in physical and remote settings. Studies evaluating patients and healthcare professionals' digital literacy can also help make digital health applications more relevant and improve the quality of the provided services. The latter calls for multidisciplinary research and initiatives involving digital health and network specialists apart from healthcare professionals, patients and caregivers.

CONCLUSION

Current evidence seems to favor the implementation of telehealth approaches to DF care. The encouraging results that have been reported thus far need to be monitored and reevaluated in the long term. Likewise, research needs to expand by getting more diverse and inclusive of a greater spectrum of socio-political landscapes. A good example of that is a recent study by Em Yunir *et al* [26] in Indonesia. We believe the conditions of the pandemic will inevitably contribute to the rapid development of the means of this method, either in the form of new software or patient and physician digital education and familiarization. This could serve as an excellent transition to the post-COVID era, as examined by Roberto Anichini *et al* [27], where a hybrid approach of telemedicine and in-person care will work best for all parties involved, delivering fast, efficient and cost-effective care to the patients.

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