#### ORIGINAL ARTICLE



# Effects of the COVID-19 pandemic on the outcome and mortality of patients with diabetic foot ulcer

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Revised: 22 April 2022

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## Abstract

The outbreak of the coronavirus disease 2019 (COVID-19) led to events that significantly impaired the treatment and management of patients with chronic diabetes. Therefore, elective treatments at hospitals were cancelled and patients with chronic ailments were instructed to stay at home and minimise the time spent in public areas. The second was due to COVID-19-induced anxiety that deterred many patients from seeking care and adhering to periodic out-patient visits. In this study, we examined the short-term effects of the COVID-19 pandemic on patients with chronic diabetes who suffered from contaminated diabetic ulcers. We conducted a retrospective study with patients who had undergone amputations following diabetic ulcers during 2019-2020. The research group included diabetic amputees during the COVID-19 outbreak period ranging from March 2020 to December 2020. The control group included diabetic amputees from the corresponding period in 2019. Using the Wagner Scale, we measured the difference in the severity of ulcers upon the patient's initial admission. Additionally, we examined patient survival rates based on the size of amputations, by specifically focusing on the period between 1- and 6-months post-surgery. The results failed to suggest a clear and statistically significant worsening trend in the condition of patients in the research and control groups. Due to public lockdowns, transportation restrictions, scarcity of healthcare staff, and reduced adherence to exposure anxiety, patients with diabetic foot ulcers received inferior medical care during the COVID-19 pandemic. However, this study could not find a statistically significant difference in the mortality and major amputation rates in patients with diabetic ulcer before and during the pandemic. The health system should incorporate the existing institutional and technological recommendations to facilitate care and follow-up of patients with diabetic foot ulcers during the current and future pandemics.

Guy Rubin and Guy Feldman contributed equally to this study.

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#### K E Y W O R D S

corona-phobia, COVID-19, diabetes mellitus, diabetic ulcers, SARS, Wagner scale

### **Key Messages**

- patients with diabetic foot ulcers received inferior medical care during the COVID-19 pandemic
- the health system should incorporate the existing institutional and technological recommendations

# 1 | BACKGROUND

The COVID-19 pandemic has significantly affected our daily routine due to the lockdown strategy recommended by the World Health Organization on 14 March 2020. Public gatherings were banned, travel was restricted, unessential businesses were closed, and the educational system moved to online platforms. For the general population, elective surgeries at public hospitals were cancelled and patients were instructed to remain indoors unless they developed respiratory instability. At the psychological level, increased population anxiety among other psychological difficulties was described.<sup>1</sup> These factors hampered the community health quality as patients could not undergo regular medical assessment and follow-up by primary care physicians. The avoidance of public health facilities and fear of exposure delayed the diagnosis and treatment of acute illnesses. For instance, Snapiri et al reported a case series of diagnostic delays in patients with appendicitis.<sup>2</sup>

Diabetes care is not an exception, especially as patients frequently require medical attention for glucose control, renal and vision assessment, and diabetic foot monitoring. For example, Lazzerini et al reported a case series of 12 children with delayed presentation of diabetic ketoacidosis.<sup>3</sup> A study conducted in Brazil identified impaired sugar balance in adults suffering from type 1 and 2 diabetes mellitus due to cancellation of clinic sessions and avoidance of primary care visits following the COVID-19 lockdown.<sup>4</sup>

Further, the incidence of obesity also increased during the lockdown. A prospective study by Rundle et al identified increased obesity in children due to the absence of educational frameworks and restrictions on social interactions.<sup>5</sup> There has been a significant increase in the consumption of high-calorie foods, such as potato chips, sugary drinks, and red meat in Italy. Additionally, there has been an increase in children's screen time and a decrease in sleep hours and sports activities.<sup>6</sup> Moreover, the COVID-19 lockdown affected patients with diabetes at the medical, social, and psychological levels. Therefore, we considered the COVID-19 lockdown period as a unique opportunity to investigate the effects of such changes on the outcome in patients with diabetic foot.

The development of diabetic foot ulcers is one of the most common complications and causes of hospitalizations in patients with diabetes in the United States.<sup>7</sup> The ulcers are formed secondary to diabetic neuropathy, and small and large vessel vasculopathies. The wound healing mechanisms are inadequate and any minor trauma may lead to unhealed ulcer and subsequent complications, such as osteomyelitis and ischemia. Each year, more than a million patients with diabetes have to get their legs amputated due to complications of the disease and diabetic foot ulcers.<sup>8</sup> A meta-analysis by Woods et al predicted that approximately 40% of the foot ulcers may get infected, of which 8% may need amputation, and lead to a five-year mortality rate of 74%.<sup>9</sup> Patients suffering from diabetic foot need strict and continuous outpatient follow-up. A study by Shin et al suggested a 50% reduction in the number of visits to foot clinics in Manchester, England, in 2020 than those in 2019.<sup>10</sup> A similar study by Liu et al reported an approximately 70% decrease in the number of visits to foot clinics in Los Angeles, the United States.<sup>11</sup> A reduction in the number of visits was also noted during the lockdown period.<sup>12</sup>

This study aimed to examine the consequences of the COVID-19 pandemic on diabetic foot ulcer care, outcome, and mortality.

# 2 | MATERIALS AND METHODS

This study was conducted at a level 2 medical center. The study was approved by the Institutional Helsinki Committee. A retrospective search was performed to locate patients aged  $\geq$ 18 years who underwent amputation during 2019 and 2020. We excluded patients aged <18 years, who underwent amputations due to failed vascular surgery or had peripheral vascular disease, who underwent traumatic amputations, and who

	2019 (n = 64)	2020 (n = 58)	Total (n = 122)	P value
Age average	67.41 (13.69)	62.91 (12.35)	65.27 (13.21)	.0602
Age median	70.5	62	64	
Gender				.7591
Male	47 (73.4%)	44 (75.9%)	91 (74.6%)	
Female	17 (26.6%)	14 (24.1%)	31 (25.4%)	
Diabetes				.3391
0	1 (1.6%)	0 (0.0%)	1 (0.8%)	
1	63 (98.4%)	58 (100.0%)	121 (99.2%)	
Renal failure				.0071
0	24 (37.5%)	36 (62.1%)	60 (49.2%)	
1	40 (62.5%)	22 (37.9%)	62 (50.8%)	
Ischemic heart	disease			.4681
0	30 (46.9%)	31 (53.4%)	61 (50.0%)	
1	34 (53.1%)	27 (46.6%)	61 (50.0%)	
Peripheral vasc	ular disease			.8491
0	32 (50.0%)	28 (48.3%)	60 (49.2%)	
1	32 (50.0%)	30 (51.7%)	62 (50.8%)	
Retinopathy				.8671
0	41 (64.1%)	38 (65.5%)	79 (64.8%)	
1	23 (35.9%)	20 (34.5%)	43 (35.2%)	
Hypertension				.1211
0	14 (21.9%)	20 (34.5%)	34 (27.9%)	
1	50 (78.1%)	38 (65.5%)	88 (72.1%)	
Cerebral vascul	ar attach			.0321
0	42 (65.6%)	48 (82.8%)	90 (73.8%)	
1	22 (34.4%)	10 (17.2%)	32 (26.2%)	
Smoke				.2381
0	42 (65.6%)	32 (55.2%)	74 (60.7%)	
1	22 (34.4%)	26 (44.8%)	48 (39.3%)	

# TABLE 1 Patient's demographic

and medical characteristics

underwent amputations of the upper limb. In cases of multiple surgeries performed for the same patient, we considered it as a single case. The research group included diabetic amputees during the COVID-19 outbreak period ranging from March 2020 to December 2020. The control group included diabetic amputees from the corresponding period in 2019.

Data was collected from computerised patient files that included: demographics and medical history; the number and type of amputations—above knee amputation (AKA) and below knee amputation were defined as major amputations, while the Toe, Ray, and Transmetatarsal amputations were defined as minor amputation; mortality following amputation after 1 and 5 months; severity of ulcers described using the Wagner diabetic wound classification system<sup>13</sup>; and preliminary laboratory data.

## 2.1 | Statistical analyses

For the purpose of analysing results, if the same patient was operated on during the two study periods, we counted them as two separate cases. Statistical analyses were performed using SPSS software version 24.0. A P < .05 was considered to be statistically significant.

## 3 | RESULTS

A total of 122 patients had undergone amputation due to diabetic foot ulcers—58 and 64 in the research and control groups, respectively. During the study period, 28, 6, and 1 patient underwent a second, third, and fourth surgery, respectively. The demographics were similar in

#### **TABLE 2**Operation type

Period	3-12/2019 (n = 64)	3-12/2020 (n = 58)	Total (n = 122)	P value
First operation				.7481
AKA	17 (26.6%)	17 (29.3%)	34 (27.9%)	
BKA	12 (18.8%)	8 (13.8%)	20 (16.4%)	
Ray amputation	2 (3.1%)	4 (6.9%)	6 (4.9%)	
TMT amputation	1 (1.6%)	2 (3.4%)	3 (2.5%)	
Toe amputation	32 (50.0%)	27 (46.6%)	59 (48.4%)	
Second operation				.2851
AKA	6 (40.0%)	3 (23.1%)	9 (32.1%)	
BKA	1 (6.7%)	3 (23.1%)	4 (14.3%)	
DEBRIDEMENT	0 (0.0%)	1 (7.7%)	1 (3.6%)	
Ray amputation	2 (13.3%)	4 (30.8%)	6 (21.4%)	
TMT amputation	2 (13.3%)	0 (0.0%)	2 (7.1%)	
Toe amputation	4 (26.7%)	2 (15.4%)	6 (21.4%)	

Abbreviations: AKA, above knee amputation; BKA, below knee amputation; TMT, trans metatarsal.

#### TABLE 3 Major vs minor amputation

		3-12/2020 (n = 58)	Total (n = 122)	P value
First operation				.8061
Major amputation	35 (54.7%)	33 (56.9%)	68 (55.7%)	
Minor amputation	29 (45.3%)	25 (43.1%)	54 (44.3%)	
Second operation				.9781
Major amputation	8 (53.3%)	7 (53.8%)	15 (53.6%)	
Minor amputation	7 (46.7%)	6 (46.2%)	13 (46.4%)	

terms of age, sex, origin, place of residence, and education level in both the groups (Table 1). During the pandemic, fewer patients with prior stroke and renal failure needed amputation than patients with other morbidities (Table 1). This difference may be due to measurement bias, as patients in the control group had a longer followup time than those in the research group. However, the two groups had a similar distribution of amputation levels (Table 2).

The parameters measured were as follows:

- 1. Amputation level: The difference in amputation levels was not statistically significant (P = .8061) between the groups. There was no change between the groups in individuals who underwent two procedures (Table 3).
- 2. Mortality: The difference in mortality rates was not statistically significant (P = .531) between the groups

#### TABLE 4 Mortality cases

	2019	2020	Total	P value
Death 1 month	4 (6.2%)	0 (0.0%)	4 (3.3%)	.0531
Death 6 month				.2352
n	23	13	36	
Mean (SD)	150.04	87.92	127.61	
Median	79	80	79.5	

#### TABLE 5 Wagner score at admission

Wagner Score				0.366
2	0 (0.0%)	0 (0.0%)	0 (0.0%)	
3	26 (40.6%)	20 (34.5%)	46 (37.7%)	
4	22 (34.4%)	20 (34.5%)	42 (34.4%)	
5	16 (25.0%)	18 (31.0%)	34 (27.9%)	

(Table 4). During the first month, four patients in the control group died as opposed to 0 in the research group. During the first 6 months after amputation, the mortality rate was not statistically different (P = .2352). The average duration between surgery and death in the control group was 150 days as opposed to 88 (median 80) days in the research group.

3. Wound severity: The distribution of wounds according to the Wagner classification during admission was not statistically different between the two groups (Table 5). Moreover, patients with a Wagner rating of <3 were not admitted.

## 4 | DISCUSSION

This study failed to identify a significant difference in mortality and amputation level following complicated diabetic foot ulcers during and before the COVID-19 pandemic. Both the research and control groups had similar demographic characteristics, except for a higher pre-amputation stroke and renal failure disease in the control than those in the research group. However, due to technical problems in the database, we could not confirm when these were diagnosed, and thus, the results may be skewed due to measurement bias. It is known that diabetes increases the risk of stroke<sup>14</sup> and diabetic kidney disease<sup>15</sup>; therefore patients in the control group had longer follow-up duration and higher chances of diabetic complications than those in the research group.

The study findings disprove the original hypothesis that the pandemic restrictions and social, economic, and psychological burden would increase morbidity and mortality following diabetic ulcer disease. The latter could be due to the small sample size. Moreover, the short 9-month follow-up may have contributed to the absence of difference in mortality between the groups.

In contrast to the fact that there was no statistically significant difference in the mortality rate and amputation level between the groups, we believe that the effects of the COVID-19 pandemic on diabetic ulcers could be more pronounced in the future. Therefore, as healthcare providers, we should adapt to the pandemic restrictions and facilitate diabetic foot care. In a previous study, we formulated a set of recommendations for orthopaedic surgeons during the COVID-19 pandemic<sup>16</sup>: monitoring of patients and visitors, enhanced use of personal protection equipment, redesigning wards and operative rooms, and providing virtual monitoring and video-assisted follow-ups for outpatients. The latter should be incorporated to reduce future morbidity and facilitate diabetic foot ulcer care.

In conclusion, patients with diabetic foot ulcers could possibly receive inferior medical care during the COVID-19 pandemic, possibly because of lockdown, transportation restrictions, lack of staff, and reduced adherence to treatment due to exposure anxiety. However, the study failed to find a statistically significant difference in the mortality and major amputation rates in patients with diabetic ulcers before and during the COVID-19 pandemic. Nevertheless, the healthcare system should incorporate the existing technological recommendations to facilitate unhindered care and follow-up of patients with diabetic foot ulcers during the current and future pandemics.

## **AUTHOR CONTRIBUTIONS**

**Guy Rubin**: Conception and design; acquisition of data; analysis and interpretation of data; drafting of the article; final approval; read and approved the final manuscript. **Guy Feldman**: Analysis and interpretation of data; revising the article; final approval; read and approved the final manuscript. ID, Acquisition of data; revising the article; final approval; read and approved the final manuscript. **Arthur Shapiro**: Acquisition of data; revising the article; final approval; read and approved the final manuscript. **Nimrod Rozen**: Conception and design; acquisition of data; revising the article; final approval; read and approved the final manuscript. **Inon Dimri**: read and approved the final manuscript.

## DATA AVAILABILITY STATEMENT

Data available on request due to privacy/ethical restrictions.

## ETHICS STATEMENT

The study and all experimental protocols were approved by the Emek ethical committee. All methods were carried out in accordance with relevant guidelines and regulations. Written informed consent was not obtained from all participants because it is a retrospective study. The study was approved by the local ethical committee.

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**How to cite this article:** Rubin G, Feldman G, Dimri I, Shapiro A, Rozen N. Effects of the COVID-19 pandemic on the outcome and mortality of patients with diabetic foot ulcer. *Int Wound J.* 2022;1-6. doi:10.1111/iwj.13837