

Effect of COVID- 19 pandemic on patients with diabetic foot ulcer

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ABSTRACT

Introduction: The COVID-19 pandemic disrupted the basic functioning and delivery of hospital care. The strict lockdown policies across the globe, the lack of hospital follow-up, scare of COVID-19 and its complications along with relative unexplored field of telemedicine lead to patients of diabetic foot ulcer to present with more severe conditions and thereby a poorer prognosis

Aim: To evaluate the effect of the COVID-19 pandemic on patients with Diabetic foot Ulcer.

Methods and Materials: A retrospective study was conducted at Nair hospital between April 2020 and October 2020. These patients admitted between April 2020 and October 2020 were enrolled as the Study group. The sample size was 58 patients. The patients admitted between April 2019 and September 2019 were enrolled as the control group. The sample size was 123 patients. The parameters assessed included demographics, medical history, severity of current infection consisting of Wagner's grading and mean sugar levels, medical or surgical management and mortality. Data was collected and stored on Microsoft Excel. Continuous variables were compared with chi-square test with 95% Confidence limit.

Results: The study group consisted of patients presenting with a higher Wagner's grade as compared to the control group. The study group also had a more significant (p-value=0.025) number of amputations with respect to the control group. There was no statistical significance between the two groups with regards to mean sugar level, vasculopathy, neuropathy and mortality.

Conclusions: The study demonstrated more severe infections and higher rate of amputation during the pandemic, reconfirming the importance of preventive care.

Key-words: Diabetes Mellitus, Novel Coronavirus, Wagner's Classification, Ulcer, Gangrene

INTRODUCTION

The novel Coronavirus (2019-nCoV) crisis started in Wuhan, China in December 2019 ^[1] and has spread globally. It was declared a public health emergency of international concern (PHEIC) by the World Health Organization (WHO) on January 30, 2020 ^[2]. The Indian Government announced a countrywide lockdown. ^[3] The civic-run Nair Hospital in Mumbai which is attached to a medical college, was the city's first major tertiary care Centre converted into a COVID-only facility on 19 April 2020. Authorities had advised immediate discharge of all medically fit non-COVID patients, instructed the suspension of OPD services and all elective surgeries. These measures were intended to maximize the critical care capacity in order to mitigate the anticipated sharp rise of COVID cases ^[4]. Diabetic Foot was defined as 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 ^[5]. These changes in the health system had affected patients with chronic diseases ^[6] which included diabetics and diabetic foot ulcers (DFU).

The impact of the pandemic is uncertain and continues to evolve. The study from Hangzhou reported that the COVID-19 outbreak had a negative impact on the delivery of Hospital care for patients with DFUs. ^[7] Urbancic – Rován reported severe logistic problems during their study on patients with DFU ^[8]. Various studies ^[7,9-12] suggested the use of telemedicine and triage methods for delivering care to patients with DFU.

India was the second worst affected country during the ongoing pandemic ^[13] and is the capital for patients with Diabetes mellitus. Nearly 62 million diabetics were present in India in the year 2016, out of which 25% may develop diabetic foot ulcers resulting in around 100,000 associated leg amputations a year ^[14]. This defines the significance of the burden of this disease. Various factors increased the risk of developing the DFU during lockdown ^[15]. These factors were reduced physical activity, poor dietary control and interruption of health care facilities, which are known risk factors for diabetic foot ulceration ^[16]. A higher rate of amputations and a more severe infection was observed in patients of DFU during the lockdown, as compared to the time period prior to the lockdown ^[10]. Nair hospital, being a dedicated COVID-19 hospital, had access to only Covid-19 patients with co associated medical and surgical conditions, due to which the data to study the effect of COVID-19 on Patients with DFU as compared to the pre COVID-19 era was available. The need and novelty in the study was to study the reason for the above and if Coronavirus itself acted as a confounding factor.

The aim of this study was to evaluate the effect of the COVID-19 pandemic on patients with DFU admitted at a tertiary care center and compare the clinical profile and outcome of the patients during and before the pandemic.

MATERIALS AND METHODS

A retrospective observational study was conducted in Nair Hospital from June 2021 to September 2021. Data was collected from April to October 2019 (Before Pandemic) and 19 April 2020 to 31 October 2020 (during Pandemic). Study Sample Size was 171 Patients. A total of 58 patients were enrolled in the study group, whereas 123 patients were enrolled in the control group.

Inclusion Criteria

1. Patients with Reverse transcription polymerase chain reaction (RTPCR) Positive reports for SARS-CoV2 who were being referred and transferred from other peripheral as well as non-COVID hospitals to Nair Hospital with Diabetic Foot Ulcer (DFU).

Exclusion Criteria

1. All pregnant females
2. Children below 18 years.
3. All other causes of lower limb ulcer not associated with diabetes such as Peripheral vascular disease, necrotizing fasciitis, traumatic amputation.

Parameters compared

All patients with Diabetic foot and DFU who were admitted from 19 April 2020 to 31 October 2020 (during Pandemic) were considered as a study group. Patients with Reverse transcription polymerase chain reaction (RTPCR) Positive reports for SARS-CoV2 were being referred and transferred from other peripheral as well as non-COVID hospitals to Nair Hospital. This group was compared with a control group, which consisted of patients admitted for diabetic foot and DFU from April to October 2019 (Before Pandemic).

Data about the demographic profile consisting of age, gender, clinical, and biochemical parameters comprising of Wagner's grading ^[17], sugar levels at admission, and presence of neuropathy and vasculopathy and DFU treatments were collected from the medical records. Both groups were compared on blood sugar levels at admission, severity of lesions as per Wagner's Classification ^[17], associated vascular compromise and or neuropathy. Wagner class 1 and 2 was termed, as superficial infection and class 3, 4 & 5 were included in deep infection. Outcome of the study was measured in terms of amputation rate and in hospital mortality.

Statistical analysis

Variables were compared with standard deviation between two means and Chi Square test according to their distribution with 95% Confidence limit and were compared for their significance. Different incidences and proportions were calculated of both groups and compared with each other for tests for significance.

RESULTS

Out of 58 patients, the most common age group of presentation was the 6th decade of life with mean age being 54.60 years. There was a male preponderance of 42 (72.41%) patients as compared to 16 (27.59%) females. Majority of the patients (26 patients (44.82%)) presented with DFU of Wagner's staging grade 3. A total of 25 patients underwent amputations, whereas the remaining 33 were subject to single or multiple debridement. A total of 7 patients had succumbed in their postoperative period.

Control group revealed the following statistics: Out of 123 patients, the most common age group of presentation was the 6th decade of life with mean age being 55.50 years. There was a male preponderance of 79 (64.23%) patients as compared to 44 (35.77%) females. Majority of the patients (58 patients (47.15%)) presented with Wagner's staging grade 2. A total of 32 patients underwent amputations, whereas the remaining 91 were subjected to debridement. A total of 11 patients had succumbed in their postoperative period.

There were no significant differences between groups in age and gender. In both groups the majority of patients were in the age group of 50-60 years and with male predominance. At the time of presentation, a higher prevalence was found in study group as compared with the control group for Wagner's grade 3 and 4. There was no statistical significance in the mean sugar levels on admission, presence of neuropathy and presence of Peripheral Vascular Disease between the 2 groups (Table 1).

On comparison of the rate of amputations of the above 2 studies, using Chi Square test with 95% CL, the calculated value for z was 2.24 (>1.96), which was significant (p=0.025). Hence, there were significantly more amputations in the study group as compared to 2019.

On comparison of the mortality the calculated value for z was 0.63 (<1.96), which was not significant. Hence, there was no significant (p=0.529) increase in mortality in 2020 as compared to 2019.

Table 1: Demographic Details, Clinical Profile and Outcome

		Study Group	Control Group	P value
Participants	n	58	123	
Gender	Male	42 (72.41%)	79 (64.23%)	0.263
	Female	16 (27.59%)	44 (35.77%)	
Age	Mean age +/- SD	54.60 Years +/- 11.4	55.50 Years +/- 10.3	0.597 [#]
Severity of Lesion	Wagner's Grade 1, 2	19 (32.75%)	69 (56.09%)	0.002
	Wagner's Grade 3, 4, 5	39 (67.25%)	54 (43.91%)	
Findings on admission	Mean Sugar Level on Admission (mg/dl)	226.6 +/- 64.6	208.4 +/- 57.8	0.074 [#]
	Absence of Sensations	11 (18.96%)	13 (10.56%)	0.063 ^{\$}

	Absence of Pulsations	9 (15.52%)	8 (6.51%)	0.085 ^{\$}
Outcome	Amputations	25 (43.10%)	32 (26.01%)	0.025 ^{\$}
	Mortality	7 (12.07%)	11 (8.94%)	0.529 ^{\$}

(P value calculated using # - Comparison between two means and \$ - Chi Square test)

DISCUSSION

Table 2: Comparison of this study with the study of Caruso et al and Schuivens et al

	This study			Caruso et al			Schuivens et al		
	Study Group	Control Group	P value	Study Group	Control Group (2019)	P value	Study Group (2020)	Control Group (2019)	P value
n	58	123		38	29		25	38	
Male	42 (72.41%)	79 (64.23%)	0.263	26 (68.42%)	22 (75.86%)	0.485	21 (84.00%)	23 (60.53%)	
Female	16 (27.59%)	44 (35.77%)		12 (31.58%)	7 (24.14%)		4 (16.00%)	15 (39.47%)	
Mean age +/- SD	54.60 Years +/- 11.4	55.50 Years +/- 10.3	0.597	71	69		62.6 +/- 11.1	65.4 +/- 16.8	0.466
Amputations	25 (43.10%)	32 (26.01%)	0.025	4 (10.53%)	6 (20.70%)	0.724, 0.431	15 (60.00%)	7 (18.42%)	0.001

On comparing data from this study, the study group showed a more deranged mean sugar level, a more severe infection, more vascular involvement, and a higher rate of amputation as compared to the control group. An Increased severity of lesion and a higher rate of amputation were statistically significant in the study, whereas vascular involvement and mortality, although higher, were not statistically significant.

A study in Italy found similar findings, correlating with rapid and critical worsening of diabetic foot infections ^[18].

A study in the Netherlands suggested that there were significantly more major amputations in patients with critical limb-threatening ischemia in 2020 than in the previous 2 years ^[19].

With a threefold increase in major amputations from pre-pandemic levels, Lancaster and colleagues saw a similar increase in foot infections and an increase in the ratio of major to minor amputations ^[20]. Mortality rate in the study group was 12.07% and that of the control Group was 8.94%. Mortality rate was not clinically significant.

A global pandemic disrupts equilibrium between patients and all aspects of the health care system. Diabetic foot ulcers do require supervised care. In absence of public transport during lockdown, Diabetic foot patients were finding it difficult to reach hospital. The cancellation of routine procedures, lack of information on preventive diabetic foot care and patient’s perception

of safety of care during the COVID-19 pandemic led to the initial neglect of a superficial ulcer leading to severe infections and hospitalizations. If Diabetic foot ulcers neglected or left untreated can worsen ulcer severity and lead to an increase in amputation [21,22].

The study group revealed a more deranged level of mean sugar levels at admission as compared to that of the control group. Elevated sugar levels may be because of reduction of physical activity, inability to visit healthcare facilities to test their glycemic control and poor dietary habits. Persistent elevated sugar level is known to cause neuropathy and peripheral arterial changes [23-26]. COVID-19 in turn, itself induced hyperglycemia in patients regardless of their diabetic history, secondary to infection, which increased the risk of critical disease [27,28]. The above factors in combination with each other, lead to increase in the severity of diabetic foot lesions. This was reflected in the study by higher prevalence of Wagner's grade 3 and 4 amongst the study group as compared to the control group.

Outcome of DFU was measured in terms of amputation rate and mortality. The study revealed that the rate of amputation was significantly high in the study group (43.10%) as compared to the control group. According to literature, patients with COVID-19 are subjected to a severe systemic inflammatory response associated with hypercoagulability that further compromises the blood supply to the ulcer which adds additional burden to the ongoing infection by prolonging the inflammation and delaying wound healing, hence worsening the DFU outcome [23].

LIMITATIONS

We recognize that the study had several limitations. Only interpretations are made due to the retrospective nature of the study. Because this study examines only one institution and caters to only the lower extremity, the sample size is not as large as those in the literature. Vascular compromises although present at the time of admission, were not further evaluated and no interventional vascular imaging was done. Moreover, there was no clear demarcation as to which patients were admitted on an elective basis in the control group. The Study Group was consistent with only emergency and patients with incidental findings, since Nair hospital was a Dedicated COVID-19 hospital, accepting only emergency admissions. Being a retrospective study, we had not kept a long term follow up of the patients who had been discharged from either group. The Ministry of Health and Family Welfare (MOHFW) had issued the guidelines that state-registered medical practitioners are eligible to practice using telemedicine [29,30], which had been proven beneficial in caring services during the Covid-19 Pandemic. However, this facility was not available in our institution.

CONCLUSION

The study showed more uncontrolled sugar levels, more severe infections, and higher rates of amputation during the pandemic, reconfirming the importance of preventive care. These observations made in the study could perhaps be due to the effect of total lockdown-affecting patients' main preventive care i.e., diet, drugs, and exercise. It could also have been due to the effect of COVID-19 infection which was known to cause hyperglycemia and vascular occlusion.

More studies are required to ascertain the above observations. Preventive care which intends following proper foot care principles, strict dietary control, and use of telemedicine to avoid severe infection and amputation can be applied. Though the pandemic affected the normal functioning health care systems at multiple facets, our goal was to identify these facets and find the appropriate solution for it. Many changes in providing healthcare to decrease exposure to the virus such use of Telemedicine and adoption of Triage systems have been implemented and we should accept these changes as a new normal in our approach in the management of those with DFUs indicating a paradigm shift in clinical management.

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