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ORIGINAL ARTICLE

Diabetes-Related Major and Minor Amputation Risk Increased During the COVID-19 Pandemic

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Background: Along with significant case transmission, hospitalizations, and mortality experienced during the global Sars-CoV-2 (COVID-19) pandemic, there existed a disruption in the delivery of health care across multiple specialties. We studied the effect of the pandemic on inpatients with diabetic foot problems in a level-one trauma center in Central Ohio.

Methods: A retrospective chart review of patients necessitating a consultation by the foot and ankle surgery service were reviewed from the first 8 months of 2020. A total of 270 patients met the inclusion criteria and divided into pre-pandemic (n = 120) and pandemic groups (n = 150). Demographics, medical history, severity of current infection, and medical or surgical management were collected and analyzed.

Results: The odds of undergoing any level of amputation was 10.8 times higher during the pandemic versus before the pandemic. The risk of major amputations (below-the-knee or higher) likewise increased with an odds ratio of 12.5 among all patients in the foot and ankle service during the pandemic. Of the patients undergoing any amputation, the odds for receiving a major amputation was 3.1 times higher than before the pandemic. Additionally, the severity of infections increased during the pandemic and a larger proportion of the cases were classified as emergent in the pandemic group compared to the pre-pandemic group.

Conclusions: The effect of the pandemic on the health-care system has had a deleterious effect on people with diabetes-related foot problems resulting in more severe infections, more emergencies, and necessitating more amputations. When an amputation was performed, the likelihood it was a major amputation also increased.

The Severe Acute Respiratory Syndrome Coronavirus 2 pandemic (SARS-CoV-2), colloquially recognized as COVID-19, stressed health-care systems across the globe from the end of 2019 through 2020. As of October 2020, more than 42 million cases have been

reported globally, with more than one million deaths from the continuing disease .[1] As the international community suspended societal norms to reduce the spread of the predominantly respiratory virus, traditional means of health care similarly adjusted. In March of 2020, hospitals around the United States of America suspended elective procedures to conserve personal protective equipment (PPE), ventilators, and potential hospital beds in anticipation of surges that would overwhelm individual health systems.[2-4] In an effort to reduce the exposure of patients at risk for developing severe symptoms of the illness, physicians turned to telehealth for patient encounters.[5]

As the utility of telehealth in the outpatient and inpatient setting varies, several manifestations continue to require in-person follow-up due to the nature of the pathology. Specifically, postoperative follow-up appointments and diabetic–foot-wound checks posed a challenge as several parameters of evaluation become difficult to assess over the digital medium. Despite this disturbance in traditional care, outpatient care continued with attention to minimizing exposure risk as outlined in the pandemic Diabetic Foot Triage System.[6] Even with the adoption of telehealth, home health visits, and reduced in-person clinic hours, care of patients was significantly disrupted.

Our primary aim is to perform a descriptive, secondary analysis, of an inpatient population requiring foot and ankle services in a level-one trauma center in the US Midwest during the COVID-19 pandemic through September 2020. Our secondary aim is to illustrate changes in this inpatient population in terms of both volume and infection

severity in relation to identified time points during the pandemic, specifically in those with diabetes.

Materials and Methods

We reviewed the electronic charts of inpatients admitted to and consulted by the foot and ankle surgery service between January 1 and August 31, 2020. Inclusion exclusion criteria, as shown in Figure 1, allowed for the identification of patients that were admitted to Grant Medical Center (GMC) from January 1 through August 31, 2020 by the foot and ankle surgery service or consulted by the service. The group was divided into pre-pandemic (January 1, 2020–March 17, 2020) and pandemic (March 18, 2020–August 31, 2020). Patients who were admitted pre- or postoperatively for an outpatient, elective procedure as well as those aged younger than 18 were excluded. Key dates in the timeline of the pandemic are shown in Table 1 and provide context for changes in health-care delivery or other social circumstances.

Demographics including age, gender, height, weight, body mass index (BMI), and race were collected. Medical history consisted of history of smoking, diabetes status, hypertension, end-stage renal disease, peripheral vascular disease, COVID-19 status, and previous wound/amputation. Severity of infection in the diabetic population was identified by laterality of infection, the International Working Group on the Diabetic Foot (IWGDF) classification, final level of amputation, and length of stay.[7] Patient data was accessed retrospectively via electronic medical record (EMR) and entered into Research Electronic

Data Capture (REDCap).[8-9] Descriptive statistics were used to describe demographics and variables for the pre-pandemic and pandemic groups. Student's *t*-test, Fisher's exact test, and χ^2 test were used to analyze variables between these groups. An odds ratio with 95% confidence interval (CI) was used to show the relationship of minor and major amputation rate from before and during the pandemic. Statistical significance was set at $P \leq 0.05$. This study was approved by the OhioHealth GMC IRB (#1638958-3).

Results

Patient Characteristics

A total of 370 patients were included in the final analysis as shown in the consortium flowchart (Fig. 1). There were 100 nondiabetic (non-DM) patients and 270 diabetic (DM) patients, of which most were diagnosed with Type II diabetes (Type I: 10 patients; Type II: 260 patients) as reported in Table 2. The demographics of the DM group were not statistically significantly different between the pre-pandemic DM group and the pandemic DM group except for age, history of hypertension, and history of peripheral artery disease. Of the 123 patients tested for COVID-19 in the DM group, 4 (3.25%) tested positive at least once upon admission. Figure 2 illustrates the number of admission or consultations to the GMC foot and ankle surgery service for all patients with the DM group overlaid with the number of COVID-19 cases in Franklin County, Ohio by calendar week. The labeled vertical lines denote important dates (Table 1) regarding State of Ohio orders, such as closing and

opening services denoted by the labeled vertical lines. (Note: Weeks calculated as starting Mondays and ending Sundays).

Infection Severity

Diabetes type, presenting pathology, and level of amputation were not statistically significantly different between the groups as shown in Table 3. Laterality was statistically significantly different between the two periods with more bilateral presentation in the pre-pandemic group (14.7%) than in the pandemic group (5.33%) ($P = 0.043$). The infection severity differed between groups as well with more uninfected cases occurring in the pre-pandemic group (18.26%) than the pandemic group (7.48%) ($P = 0.04$) (Fig. 3). More mild and severe cases occurred in the pandemic group (35.37% and 14.97%, respectively) than in the pre-pandemic group (29.57% and 9.57%, respectively). The odds of receiving any level of amputation during the pandemic period were 10.8 times higher ($P < 0.0001$; 95%, CI: 6.5–17.8) compared to the pre-pandemic period. Though the extent of surgery and length of stay were not statistically significantly different between the groups (Table 4), the odds ratio of receiving a major amputation during the pandemic period was 12.5 ($P <0.001$; 95%CI: 4.2–37.7) compared to the pre-pandemic period. Of the patients who did require an amputation, the odds of that being a major amputation was 3.1 times higher ($P = 0.028$; 95%CI: 0.98–9.7) than before the pandemic. A larger proportion of emergent cases

occurred in the pandemic group (6.00%) compared to the pre-pandemic group (0.83%; P = 0.046).

Discussion

COVID-19 manifested itself in a number of pathologies where exposed individuals expressed both the initial traditional fever, dry cough, and respiratory distress as well as unique symptoms, such as delirium, anosmia, and gastrointestinal illness.[10-12] In the lower extremity, sequelae of the virus has been reported to include a dermatologic appearance of "COVID-toes" or chilblain-like lesions, though information continues to evolve.[13-16] Impacts of the pandemic indirectly linked to the virus because of fear of contracting the illness lead to neglect and an initial decrease in admission for illnesses such as acute coronary syndrome followed by a mortality increase.[17] Similarly, the Centers for Disease Control and Prevention reported a 23% decrease in heart attack, 20% decrease in stroke, and 10% decrease in uncontrolled glycemic control emergency department visits within 10 weeks of the national emergency declared following COVID-19, though limited data examines similar effects on diabetic foot infections.[18] Our study includes data for lower-extremity infection admissions at GMC from January 1, 2020 to August 31, 2020, with Figure 2 highlighting the steep and steady decline in the number of admissions following stay-at-home orders and the cancellation of elective procedures around week 10 followed by a return to baseline number of weekly admissions after reopening of businesses and medical facilities (Fig. 2B and 2E).

Weeks after widespread shutdown, we found that our hospital experienced a higher proportion of patients with mild and severe infections during the pandemic compared to the pre-pandemic period. Moreover, the number of emergent surgeries was greater in the pandemic period, a time when the odds of undergoing a minor or major amputation was significantly greater compared to the pre-pandemic period. We speculate that the increased severity of diabetic foot infections and major amputations were attributable to an abrupt interruption of and limited accessibility to diabetic–foot-wound care and limb preservation, as well as a patient's perception of safety of care during the COVID-19 pandemic. Similar findings were noted in Italy, correlating with rapid and critical worsening of diabetic foot infections, as well as in the Netherlands where significantly more major amputations occurred in 2020 than in the previous 2 years in patients with critical limb-threatening ischemia.[19,20] Lancaster and colleagues[21] saw a similar increase in foot infections and an increase in the ratio of major to minor amputations, with a threefold increase in major amputations from pre-pandemic levels.

The sequelae of COVID-19 on patients with diabetic foot disease support the need for further investigation into methods of health-care delivery such as telemedicine to assess and treat this vulnerable patient population.[22] Current literature assists in the management of the diabetic foot, emphasizing triaging patients to dictate the appropriate site and urgency of care needed to limit diabetic–foot-related hospitalizations.[6] Similarly, the strategies to reduce severe diabetic foot infections and complications (STRIDE) protocol, demonstrated efficacy in triaging patients, resulting in similar rates of diabetic

foot–ulcer-related hospitalizations and minor amputation rates during the pandemic compared to the same study period 1 year prior. [23] Overall, the restrictions of patient encounters during the pandemic reinforce the importance of clinical observation and as Shi and colleagues[24] noted, will result in a paradigm shift in the management of diabetic foot ulcers with emphasis on alternatives such as larval therapy for at-home wound debridements or oral antibiotics to treat osteomyelitis that would have otherwise necessitated resection.[24]

We recognize that our study has several limitations, and due to its retrospective nature, we can only make correlational claims. Notably, patients were not analyzed for rates of direct admission or scheduled admission from an outpatient setting during pre-pandemic and during pandemic settings. Our study was limited to patients from the foot and ankle surgery service roster. We did not account for patients with infection severity deemed beyond salvageable and those who did not receive a consultation from our service. Because this study examines only one institution, the sample size is not as large as those publications using databases across multiple hospitals. Thus, the present study focuses only on lower-extremity infections in patients who presented to the hospital during this initial period. We plan to continue the investigation through the end of the pandemic.

Conclusions

In conclusion, the results of this study illustrate the initial decrease followed by increase in lower-extremity infection hospitalizations during the COVID-19 pandemic, an experience

shared across medical specialties during this period. Moreover, the rise in severity of infections further shows the indirect toll the pandemic placed on patients at risk for limb loss as their neglected care and follow-up for fear of contracting the virus lead to more proximal amputations. The findings in this investigation show the vital role podiatrists play from routine follow-ups to limb salvage for at-risks populations. Furthermore, as this pandemic continues, this study shows the need for effectively triaging patients at risk of limb loss, specifically in instances where face-to-face encounters have been replaced by telemedicine. We will continue to collect data through the remainder of the pandemic and report future trends in lower-extremity infections, amputations, and other complications to understand the full impact that COVID-19 placed on our patients.

Financial Disclosures: None reported.

Conflict of Interest: None reported.

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278 **Table 1. Key dates associated with restrictions or reopenings.**

Key Date	Restriction/Reopening
March 18, 2020	Cancellation of elective procedures
March 20, 2020	First COVID– 19 death reported in Ohio
March 22, 2020	Stay-at-home order is issued
May 1, 2020	Hospital, medical, dental and veterinary services that don't require an overnight hospital stay were able to be performed
May 12, 2020	Consumer, retail and service businesses reopened
May 26, 2020	Gyms, fitness centers, pools, and sports leagues (only for sports involving limited or no contact) reopened
June 8, 2020	Assisted living facilities and intermediate care facilities for people with developmental disabilities allowed outside visitation

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280 **Table 2: Demographics and Medical History (All and Diabetic Patients)**

Characteristic	Overall (N = 370)	Diabetes Mellitus Group (n = 270)
Age (mean ± SD [range] (years)	58.55 ± 13.35 [22–97]	58.59 ± 11.46 [29–88]
Race (No. [%])		
Asian	2 (0.54)	2 (0.74)
Black	89 (24.05)	61 (22.59)
Caucasian	272 (73.51)	201 (74.44)
Hispanic or Latino	4 (1.08)	3 (1.11)
Declined/Unknown	3 (0.81)	3 (1.11)
Gender (No. [%])		
Female	131 (35.41)	89 (32.96)
Male	239 (64.59)	181 (67.04)
Weight (mean ± SD [range] (pounds)	210.50 ± 63.86 [81–563]	224.2 ± 59.71 [81–424]
Height (mean ± SD [range] (inches)	68.97 ± 4.24 [53–84]	69.30 ± 4.34 [53–84]
Body Mass Index (mean ± SD [range] (kg/m^2)	30.99 ± 8.57 [14.3–68.5]	32.80 ± 8.16 [14.3–62.6]
Smoking (No. [%])		
Yes	228 (61.62)	169 (62.59)
No	142 (38.38)	101 (37.41)
Hypertension (No. [%])		
Yes	284 (76.76)	221 (81.85)
No	86 (23.24)	49 (18.15)
End Stage Renal Disease (No. [%])		
Yes	46 (12.43)	39 (14.44)
No	324 (87.57)	231 (85.56)
Peripheral Vascular Disease (No. [%])		
Yes	145 (39.19)	116 (42.96)
No	225 (60.81)	154 (57.04)
Covid-19 Test (No. [%])		

Not Tested	211 (57.03)	147 (54.44)
Yes-once negative	152 (41.08)	117 (43.33)
Yes-once positive	3 (0.81)	2 (0.74)
Multiple negative	2 (0.54)	2 (0.74)
Multiple positive	2 (0.54)	2 (0.74)
Time of Admission (No. [%])		
Pre-closure	158 (42.70)	120 (44.44)
Pandemic	212 (57.30)	150 (55.56)

288 **Table 3. Pathology and final level of amputation of the DM Group (pre-pandemic versus**

289 **pandemic)**

Characteristic	Pre-pandemic (n = 120)	Pandemic (n =150)	*P* value
Diabetes (No. [%])[a]			
Type 1	4 (3.33)	6 (4.00)	
Type 2	116 (96.67)	144 (96.00)	
Presenting Pathology (No. [%])[a]			0.524
Diabetic Foot Infection	111 (92.50)	137 (90.73)	
Post-operative complication	5 (4.17)	8 (5.33)	
Traumatic Foot Injury	2 (1.67)	4 (2.67)	
Intravenous Drug Use Infection	0 (0.00)	1 (0.67)	
Other	2 (1.67)	0 (0.00)	
Laterality (No. [%])[b]			0.043
Left	48 (40.00)	69 (46.00)	
Right	55 (45.83)	73 (48.67)	
Bilateral	17 (14.17)	8 (5.33)	
Most proximal level of amputation of the side of presenting illness (No. [%])[a]			0.06
Digital	18 (34.62)	27 (54.00)	
Forefoot	21 (40.38)	19 (38.00)	
Midfoot	11 (21.15)	4 (8.00)	
Rearfoot	2 (3.85)	0 (0.00)	
NA	68	100	

290 Abbreviation: NA, not applicable
291 [a]Fisher's test
292 [b] χ^2 test
293
294

Table 4. Surgery-related variables for the DM group (pre-pandemic versus pandemic)

Variable	Pre-pandemic (n=120)	Pandemic (n = 150)	*P* value
Extent of surgery/final level of amputation (No. [%])[a]			0.093
0 - soft tissue/bone debridement	13 (22.41)	24 (22.64)	
1 - digital amputation	19 (32.76)	22 (20.75)	
2 - Forefoot Amputation	19 (32.76)	38 (35.85)	
3 - Midfoot (Lisfranc) Amputation	0 (0.00)	2 (1.89)	
4 - Rearfoot (Chopart) Amputation	3 (5.17)	1 (0.94)	
5 – Below/Above the Knee Amputation	4 (6.90)	19 (17.92)	
NA	62	44	
Number of emergent cases (No. [%])[a]			**0.046**
Yes	1 (0.83)	9 (6.00)	
No	119 (99.17)	141 (94.00)	
Length of stay (mean ± SD [range])[c]	7.1 ± 6.28 (0–35)	6.30 ± 4.65 (0–22)	0.246

Abbreviation: NA, not applicable.
[a]Fisher's test
[b] χ^2 test
[c]*t*-test

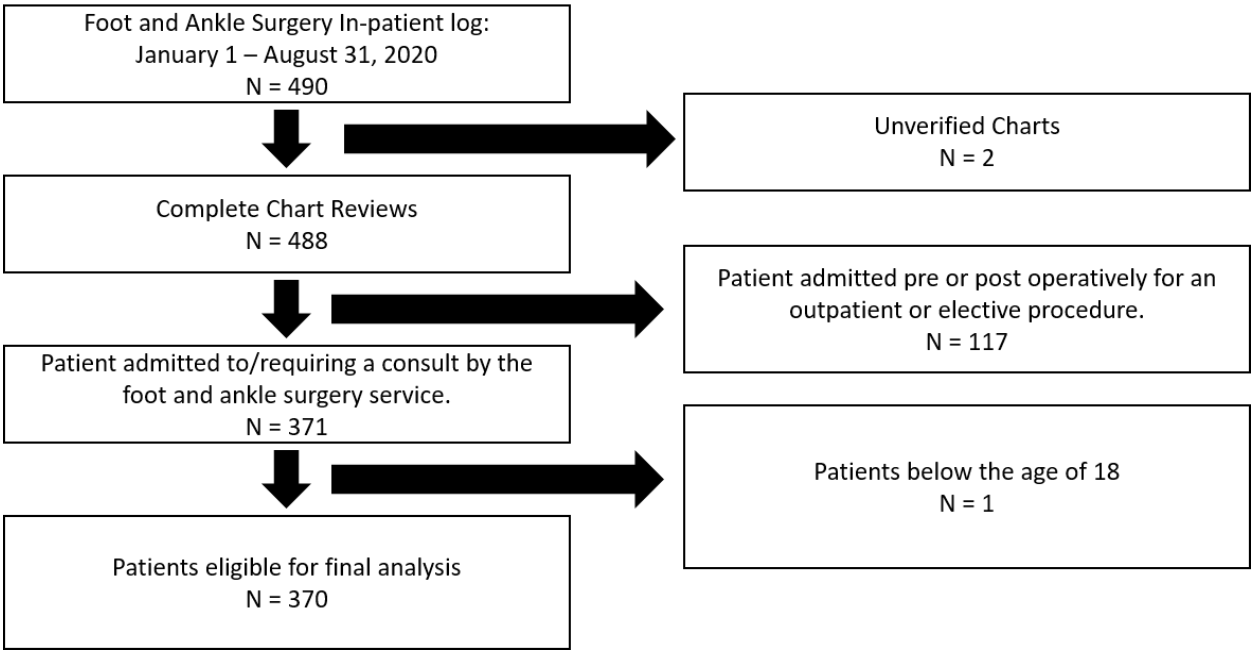

Figure 1: Inclusion and exclusion criteria applied during data collection.

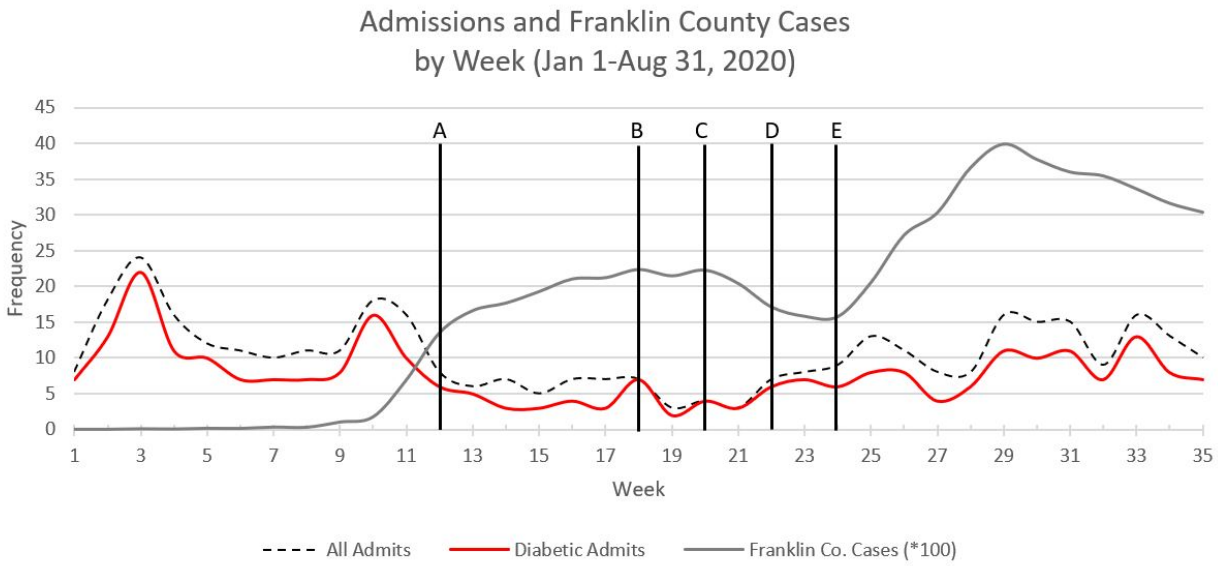

Figure 2: Franklin County COVID-19 Cases and lower extremity infection admissions with respect to (A) Cancellation of elective procedures **(B)** Hospital, medical, dental and veterinary services that don't require an overnight hospital stay were able to be performed **(C)** Consumer, retail, and service businesses reopened **(D)** Gyms, fitness centers, pools, and sports leagues (only for sports involving limited or no contact) reopened **(E)** Assisted living facilities and intermediate care facilities for people with developmental disabilities allowed outside visitation

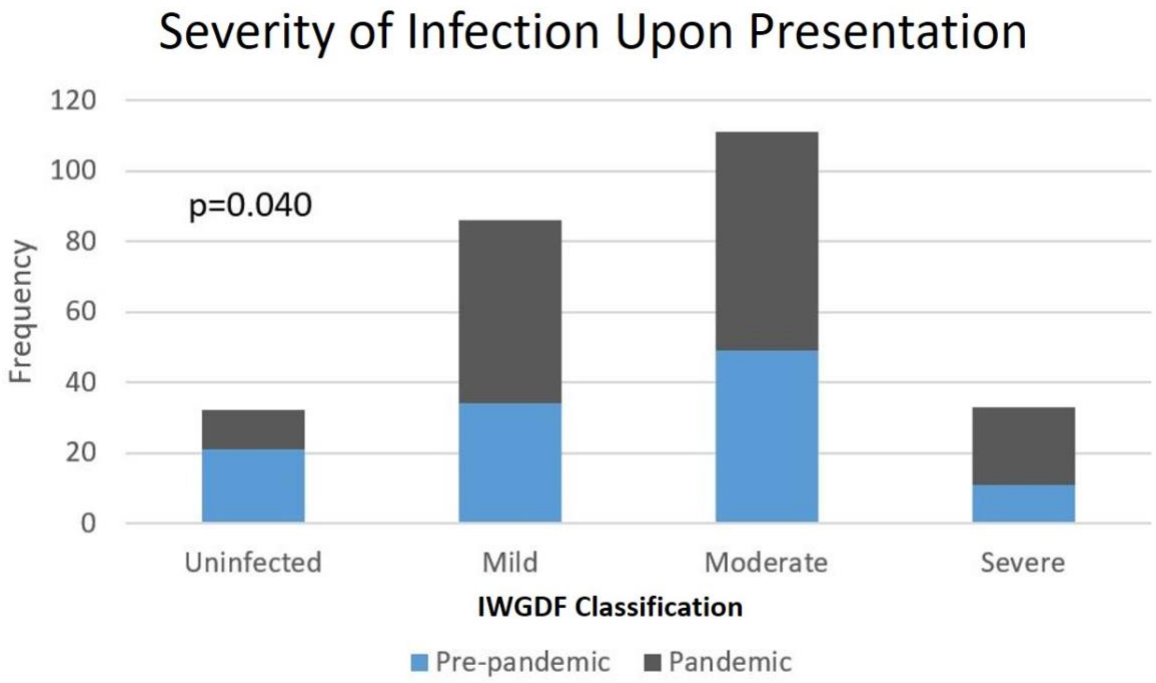

Figure 3: Severity of Infection Upon Presentation of patients between pre-pandemic and pandemic periods.