Evaluating the effects of the COVID-19 pandemic on patient management of Type 2 Diabetes Mellitus in a rural population

Shelby B E Wildish, Ric Bonnell MD

Scholarly Pursuit and Thesis
Anne Burnett Marion School of Medicine
Texas Christian University

ABSTRACT

Research Question: This research project compares patient's Hemoglobin A1C (HbA1c), Weight and Body Mass Index (BMI) pre- vs. post-COVID-19 pandemic to investigate whether the COVID-19 pandemic affected the patient's management of type 2 diabetes mellitus (T2DM). **Background**: On March 11, 2020, Coronavirus disease 2019 (COVID-19) was declared as a global pandemic. As a consequence, many countries implemented "lockdown" or quarantining regulations, which resulted in extended periods at home. In this study, we aim to assess the impact of quarantine periods on patient's management of T2DM. **Material and methods**: A chart review was conducted using paper charts of patients above 18 years at Ruth's Place Clinic in Granbury, Texas. The pre and post COVID-19 lockdown data of 55 patients with T2DM was documented. The variables recorded included demographic data, HbA1c, body weight, past medical history and current anti-diabetic medications. **Results**: The study found p values > 0.05 when comparing both pre and post COVID-19 mean HbA1c and pre and post COVID-19 calculated BMI. There was a significant correlation between both pre and post COVID-19 HbA1c and pre and post COVID-19 calculated BMI. Although, no significant correlation was found between the calculated difference of pre and post COVID-19 mean HbA1c and the difference of pre and post COVID-19 BMI. **Conclusions**: The quarantine regulations implemented during COVID-19 did not cause a major disruption in patients' glycemic control and management of T2DM in our population.

RESEARCH QUESTIONS

Specific Aim One: *In adult patients with Type 2 Diabetes Mellitus who utilize free clinics for longitudinal primary care, has there been a clinically significant change of at least 0.5%*[1,2] *in patient's Hemoglobin A1C levels pre- vs. post- COVID-19 pandemic?*

This research project aims to examine the effects of the COVID-19 pandemic on patient management of Type 2 Diabetes Mellitus (T2DM). The effectiveness of patient individual management will be measured by examining Hemoglobin A1C (HbA1c) levels pre- vs. post-COVID-19 pandemic. It is hypothesized that patient's post- COVID-19 HbA1c levels will be increased when compared to pre-COVID-19 HbA1c levels.

Specific Aim Two: *Is there a clinically significant change of at least 5%*[3,4,5] *in the patient's calculated Body Mass Index pre- vs. post COVID-19 pandemic?*

This research project aims at examining the effects of the COVID-19 pandemic on patient weight, a factor known to affect patient's management of Type 2 Diabetes Mellitus (T2DM). Patient's body mass index (BMI) will be calculated based on record weight and height in clinical charts dating pre vs. post COVID-19 pandemic. It is hypothesized that the patient's post COVID-19 body weight, and thus BMI, will be increased when compared to pre-COVID-19 period.

Specific Aim Three: *Is there a correlation between changes in HbA1c levels and patient's Body Mass Index pre- vs. post- COVID-19 pandemic?*

This project will also examine the possible relationship between a patient's HbA1c levels and their BMI in pre- vs. post- COVID-19 pandemic time periods. It is hypothesized that both HbA1c levels and BMI measurements will increase proportionally in post- COVID-19 data sets as compared to pre-COVID-19 time period.

INTRODUCTION, SIGNIFICANCE, AND RATIONALE

COVID-19 Pandemic

On March 11, 2020, the WHO declared Coronavirus disease 2019 (COVID-19), caused by the severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), as a global pandemic.[6] Due to its rapid transmission, it is reported that the COVID-19 virus has infected more than 34 million people and killed more than 1 million people worldwide as of October 1, 2020, nearly six months after the pandemic was declared.[6]

As a consequence of the COVID-19 pandemic, many countries implemented "lockdown," or quarantining regulations, to help mediate the virus spread. In Texas, on March 13, 2020, the Governor of the State of Texas issued a statement to the public declaring a state of disaster for all counties in Texas due to COVID-19.[7] This declaration resulted in extended periods at home for residents. Prolonged homestays have shown to have undesirable consequences, such as physical inactivity, weight gain and increased risks of many pathologies such as type 2 diabetes mellitus (T2DM).[8]

On March 2nd 2021, Governor Greg Abbott issued an executive order (GA-34) which lifted the quarantining regulations, mask mandates and facility capacity restrictions which were first implemented in Texas for the pandemic.[9] This new executive order allowed Texans to resume normal life, including the various physical activities they used to maintain a healthy lifestyle.

Rural Communities and Ruth's Place Clinic

Many rural communities in the US are at a disadvantage in terms of healthcare accessibility and availability, with limited hospitals within their area.[10] As compared to urban communities, rural residents tend to be older and have more chronic underlying conditions, which are known risk factors for adverse effects of COVID-19.[11] Higher COVID-19 rates have been recorded in certain minority populations, including Hispanics/Latinos, who tend to live in rural communities.[12] According to a 2021 census, Granbury Texas has an estimated population of 11,424, of which 8.6% are Hispanic.[13]

Operating in Granbury Texas, Ruth's Place Clinic provides free medical care, laboratory services, medications, immunizations and social services to underserved patients, all of whom are residents of Hood County, a large majority of which are Hispanic. Due to the county and state regulations, Ruth's Place Clinic stopped seeing new patients and moved all patient visits to telehealth on March 13, 2020. This further limited patient's access to healthcare during the COVID-19 for management of known chronic conditions, like that of T2DM.

Type 2 Diabetes Mellitus (T2DM)

Type 2 Diabetes Mellitus (T2DM) is ranked as the seventh leading cause of death in the United states, with an estimated 34.2 million people or 10.5% with T2DM in 2020.[9] Of those thought to have T2DM, 7.2 million people or 21.4% are undiagnosed.[9] Texas was found to have an increased prevalence of T2DM as compared to the US. It is projected that by 2040, Texas will have nearly 8 million people with T2DM with a prevalence rate increase from one in nine adults to one in five adults.[14] In Texas, T2DM disproportionately impacts the racial/ethnic minorities, elderly and undereducated throughout the population. Non-Hispanic Blacks and Hispanics are found to have a higher occurrence of T2DM throughout Texas as compared to other races.[15] In a study by Baek and Lee, Texas rurality was found to be highly associated with T2DM prevalence at the county level. Hood County, a rural county in Texas, has an 8.8%-9.7% prevalence of T2DM.[16]

According to the CDC, T2DM is the second most common underlying health condition associated with severe outcomes in COVID-19 patients.[17] In Chinese studies, it was found that among COVID-19 patients the proportion with comorbid T2DM was 16.2% in one study of 1,099 patients[18], 22% in another cohort of 191 patients[19] and, of 72,314 patients, a higher mortality was found in diabetic patients (7.3% vs. 2.3% overall).[20]

The Hemoglobin A1C Test

The hemoglobin A1C (HbA1c) test the estimated average blood glucose levels over the past three months, elevated levels serving as a marker for T2DM. HbA1c testing is an important tool in assessing glycemic control and is known to have strong predictive value for T2DM. According to the American Diabetes Association, criteria for diagnosis of T2DM is an HbA1c ≥ 6.5%, with 50% of patients found to have diabetes-related complications to have HbA1c values 7.0% or higher.[21] HbA1c is known to be a more advantageous screening tool compared with fasting plasma glucose and oral glucose tolerance testing due to the less day-to-day impacts of stress, illness or diet.[22] HbA1c testing does not require fasting, resulting in a more convenient and versatile testing platform.

Body Mass Index

The Body Mass Index (BMI) is defined as weight in kilograms divided by the square of the height in meters.

$$\text{BMI} = \frac{\text{weight (kg)}}{\text{height (m}^2\text{)}}$$

This equation was first created by Adolphe Quetelet, a belgium mathematician, in the early 19th century. It has since become a quick way to determine the degree of obesity in an individual. Due to its generalized use and standardization, it serves as a reliable marker for understanding a patient's weight, and possible impact on chronic medical problems.

Currently, there is little research that assesses the impact of the COVID-19 pandemic on patient's management of T2DM. This study will allow for a better understanding on the consequences that extended periods of "lockdown" have on chronic illnesses like T2DM.

RESEARCH MATERIALS AND METHODS

Location and Subject Population

Operating in Granbury Texas, Ruth's Place Clinic provides free medical care, laboratory services, medications, immunizations and social services to underserved patients, all of whom are residents of Hood County.

Subjects, all of whom will be at least 18 years old, are selected based on (1) being a current registered patient at Ruth's Place Clinic and (2) a diagnosis of T2DM prior to March 13, 2020. Further subject eligibility included at least one HbA1c and weight documented in the patients charts prior to March 13, 2020 and at least one HbA1c and weight documented between March 13, 2020 and May 5, 2022. March 13th is defined as the start of post-COVID time period as this is the date that Ruth's Place Clinic stopped seeing new patients and went entirely to telehealth visits due to the COVID-19 pandemic. January 1st, 2019 to March 13th, 2020 is the time period used for pre-COVID19 period to give adequate opportunity for a patient to have been seen in the clinic. March 13, 2020 to May 1, 2022 is used as post COVID-19 period to mirror the time period given for pre COVID-19 period. To allow for statistically significant data analysis, the study aimed to recruit a minimum of 100 participants.

Study Eligibility Criteria
1. Adult (≥ 18) 2. Currently registered patient at Ruth's Place Clinic prior to March 13, 2020 3. Patients diagnosed with Type 2 Diabetes Mellitus prior to March 13, 2020 4. Patients with at least one laboratory HbA1c measurement and at least one weight measurement between Jan. 01, 2019, and March 13, 2020. 5. Patients with at least one laboratory HbA1c measurement and at least one weight measurement between March 13, 2020 and May 01, 2022.

Since this study is a retrospective chart analysis, there was no recruitment of participants. All data was obtained from pre-existing patient charts at Ruth's Place Clinic. No compensation was offered to participants. Since there was no direct contact with participants, there were no potential risks for participants.

Data Collection

The researchers examined Ruth's Place Clinic patient registry of current patients to identify individuals that meet the study eligibility criteria discussed above. To ensure anonymity of participants, upon identifying patients who meet the study eligibility criteria, data collected was de-identified. Each patient chart was assigned an Identification (ID) number which will correlate to the recorded data points. A master list was generated that matched patient names with ID numbers. This master list was stored as both an electric copy and printed copy at Ruth's Place Clinic. The printed copy was stored in a locked filing cabinet in the principal investigator's office at the Clinic.

The data that was collected included demographic markers of age, sex, race, ethnicity and height and health markers of weight, HbA1c and previously prescribed anti-diabetic medications. Although the patient's HbA1c levels and BMI served as the defining research markers, other health and social data were recorded to allow for a better understanding of the patient population in this community.

Study Data Points	
Demographic Markers	Health Markers
- Age - Sex - Race - Ethnicity - Height	- Weight - Calculated BMI - HbA1c levels - Previously prescribed anti-diabetic medications

Two hundred and fifty-two paper patient charts were examined. Of the 252, 81 patients met the pre COVID-19 criteria previously mentioned above. Of the 81 patients, 55 patients met both the pre COVID-19 and post COVID-19 criteria.

Data Analyses

Data Summary	
Total Number of Patient Charts examined	252
Number of patient's qualify for pre COVID-19 requirements	81
Number of patient's that meet both pre COVID-19 and post COVID-19 requirements	55

Figure 2. Summary of data collection and qualification utilized during research data analysis.

IBM SPSS Statistics database was utilized for all data analyses. To examine the first hypothesis, a dependent sample t-test was conducted between the patient's pre-test HbA1c scores and post-test HbA1c scores. Likewise, the same analysis was compiled for pre-weight to post-weight measurements to assess the second hypothesis. To evaluate the third hypothesis, bivariant correlation was computed to look at the linear relations between pre-test HbA1c and BMI and post-test HbA1c and BMI.

RESULTS

Demographics and Characteristics of the Study Population

Of the 55 cases included in this study (Figure 1), 18 patients (32.7%) were male and 37 (67.3%) were female. The mean age was 54 years, ranging between 35-68 years. 35 patients (63.6%) were Hispanic, 19 patients (34.5%) were Caucasian and 1 patient (1.9%) was Asian. There were 32 patients (58.2%) who had a known history of hypertension, 33 patients (60.0%) with a known history of hyperlipidemia and 21 patients (38.2%) with a known history of both hypertension and hyperlipidemia.

Patient Demographics

Category	Number of Patients (n=55)	Percentage of total (%)
Age (years)		
Mean	54	
Range	35 – 68	
Sex		
Male	18	32.7
Female	37	67.3
Race		
Hispanic	35	63.6
Caucasian	19	34.5
Asian	1	1.9
Past Medical History		
History of Hypertension (HTN)	32	58.2
History of Hyperlipidemia (HLD)	33	60
Both HTN & HLD	21	38.2
Medications		
Currently on anti-diabetic medications	52	94.5
Only Oral medications	43	78.2
One medication	31	56.4
> One medication	12	21.8
Only Insulin	5	9.1
Both Oral medications and Insulin	4	7.3
One oral medication	1	1.9
> One medication	3	5.5
Not currently on anti-diabetic medications	3	5.5

Figure 1.

Anti-diabetic Medications Utilized by Study Population

52 patients (94.5%) were currently on an anti-diabetic medication at the time of the research study (Figure 1). Of these 52 patients, 43 patients (78.2%) were only using an oral medication, with 31 patients (56.4%) on one medication and 12 patients (21.8%) on more than one oral medication. There were 5 patients (9.1%) only taking insulin and 4 patients (7.3%) taking both insulin and an oral medication. Of these 4 patients, 1 patient (1.9%) was taking only one oral medication and 3 patients (5.5%) were taking more than one oral medication. 3 patients (5.5%) were not currently on an anti-diabetic medication.

Of the 47 patients taking one or more oral medications (Figure 2), 39 patients (75%) were taking Metformin, 21 patients (40.4%) were taking a type of Sulfonylureas and 2 patients (3.8%) were taking a type of Thiazolidinediones. There was 1 patient (1.9%) taking a short acting insulin, 4 patients (7.7%) taking a long acting insulin and 4 patients (7.7%) taking a pre-mixed insulin.

Anti-Diabetic Medications

Category	Number of patients (n=52)	Percentage of total (%)
Oral Medications		
Metformin	39	75
Sulfonylureas	21	40.4
Thiazolidinediones	2	3.8
Insulin		
Rapid Acting	0	0
Short Acting	1	1.9
Intermediate Acting	0	0
Long Acting	4	7.7
Pre-Mixed	4	7.7

Figure 2.

Descriptive Statistics of Data Collected

55 patients qualified for the research study. Of the 55 patients (Table 1), the mean pre COVID-19 Hemoglobin A1c (HbA1c) was 7.3 (SD ±1.855) and mean pre COVID-19 calculated BMI was 36.1 (SD±10.2). The mean post COVID-19 HbA1c was found to be 8.25 (SD±2.1) and mean post COVID-19 calculated BMI was 35.91 (SD±10.6). The calculated difference between mean pre COVID-19 HbA1c and post COVID-19 HbA1c is -0.321. The calculated difference between mean pre COVID-19 BMI and post COVID-19 BMI is 0.23.

Descriptive Statistics of Data Collected

	Mean	Std. Deviation	N
Mean pre COVID19 HbA1c	7.929	1.855174	54
pre COVID19 BMI	36.14	10.20072	55
Mean post COVID19 HbA1c	8.250	2.115350	55
post COVID19 BMI	35.91	10.62529	55

Difference between mean pre COVID19 HbA1c and post COVID19 HbA1c	-0.321
Difference between mean pre COVID19 BMI and post COVID19 BMI	.23

Results table 1. Summary of data.

Specific Aim One: Comparing pre COVID-19 HbA1c to post COVID-19 HbA1c

A dependent sample t-test between pre COVID-19 HbA1c and post COVID-19 HbA1c found a mean of -0.274 (SD±1.4, CI -0.658-0.1093) with a one-sided p value of 0.079 and a two-sided p value of 0.157 (Table 2).

Comparing Pre COVID-19 HbA1c to Post COVID-19 HbA1c

		Paired Differences					t	df	Significance	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			One-Sided p	Two-Sided p
Specific Aim One	Mean Pre COVID-19 HbA1c vs Mean Post COVID-19 HbA1c	-.274	1.405000	.191	-.658	.1093	-1.434	53	.079	.157

Table 2. A dependent sampe t-test comparing the patient's average pre COVID-19 HbA1c scores to post COVID-19 HbA1c scores. Pre COVID-19 data collected and mean calculated for up to three HbA1c measurements at clinic visits between January 01, 2019 and March 13, 2020. Post COVID-19 data collected and mean calculated for up to three HbA1c measurements at clinic visits between March 13, 2020 and May 01, 2022. Results found a p-value of 0.079 (>0.05).

Specific Aim Two: Comparing average pre COVID-19 weights to average post COVID-19 weights

A dependent sample t-test between pre COVID-19 weights and post COVID-19 weighs found a mean of 1.2487 (SD±11.73, CI -2.018-4.516) with a one-sided p value of 0.223 and a two-sided p value of 0.446 (Table 3).

Comparing Pre COVID-19 Weights to Post COVID-19 Weights

		Paired Differences					t	df	Significance	
		Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference Lower	Upper			One-Sided p	Two-Sided p
Specific Aim Two	Mean Pre COVID-19 Weight vs Mean Post COVID-19 Weight	1.2487	11.73485	1.627	-2.018	4.516	.767	51	.223	.446

Table 3. A dependent sample t-test comparing the patient's average pre COVID-19 weight to post COVID-19 weight. Pre COVID-19 data collected and mean calculated from up to three weights measured at clinic visits between January 01, 2019 and March 13, 2020. Post COVID-19 data collect and mean calculated for up to three weights measured at clinic visits between March 13, 2020 and May 01, 2022. Results found a p-value of 0.223 (>0.07).

A dependent sample t-test between pre COVID-19 calculated BMI and post COVID-19 calculated BMI found a mean of -1.528 (SD±10.2018, CI -4.286-1.230) with a one-sided p value of 0.136 and a two-sided p value of 0.272 (Table 4).

Comparing calculated pre COVID-19 BMI vs post COVID-19 BMI									
	Paired Differences							Significance	
				95% Confidence Interval of the ...					
	Mean	Std. Deviation	Std. Error Mean	Lower	Upper	t	df	One-Sided p	Two-Sided p
Pre COVID-19 BMI vs Post COVID-19 BMI	-1.528	10.2018	1.37561	-4.286	1.230	-1.1	54	.136	.272

Table 4. A depended sample t-test comparing calculated pre COVID-19 BMI to calculated post COVID-19 BMI. BMI was calculated using first recorded height in clinical medical records and calculated average weights pre COVID-19 and post COVID-19. Results found p-value of 0.136 (>0.05).

Specific Aim Three: Correlations between changes in HbA1c levels and patient's BMI pre vs. post COVID-19 pandemic

A bivariant Pearson correlation (Table 5) was used to look at the linear relations between pre-test HbA1c and BMI and post-test HbA1c and BMI. The mean pre COVID-19 HbA1c was found to have a correlation of -0.258 (p-value of 0.06) to pre COVID-19 BMI, a correlation of 0.755 (p-value of <0.001) to mean post COVID-19 HbA1c and a correlation of -0.249 (p-value of 0.069) to post COVID-19 BMI. The pre COVID-19 BMI was found to have a correlation of -0.258 (p-value of 0.06) to mean pre COVID-19 HbA1c, a correlation of -0.192 (p-value 0.161) to mean post COVID-19 HbA1c and a correlation of 0.981 (p-value of <0.001) to post COVID-19 BMI. T mean post COVID-19 HbA1c was found to have a correlation of 0.755 (p-value of <0.001) to mean pre COVID-19 HbA1c, a correlation of -0.192 (p-value of 0.161) to pre COVID-19 BMI and a correlation of -0.194 (p-value of 0.157) to post COVID-19 BMI. The post COVID-19 BMI was found to have a correlation of -0.249 (p-value of 0.069) to mean pre COVID-19 HbA1c, a correlation of 0.981 (p-value of <0.001) to pre COVID-19 BMI and a correlation of -0.194 (p-value of 0.157) to mean post COVID-19 HbA1c.

Correlations between HbA1c levels and patient's BMI pre- vs. post-COVID10 pandemic

		Mean pre COVID19 HbA1c	pre COVID19 BMI	Mean post COVID19 HbA1c	post COVID19 BMI
Mean pre COVID19 HbA1c	Pearson Correlation	1	-.258	.755**	-.249
	Sig. (2-tailed)		.060	<.001	.069
	N	54	54	54	54
pre COVID19 BMI	Pearson Correlation	-.258	1	-.192	.981**
	Sig. (2-tailed)	.060		.161	<.001
	N	54	55	55	55
Mean post COVID19 HbA1c	Pearson Correlation	.755**	-.192	1	-.194
	Sig. (2-tailed)	<.001	.161		.157
	N	54	55	55	55
post COVID19 BMI	Pearson Correlation	-.249	.981**	-.194	1
	Sig. (2-tailed)	.069	<.001	.157	
	N	54	55	55	55

Results table 5. Bivariant correlation used to examine the linear relations between averaged pre COVID19 HbA1c and BMI and post COVID19 HbA1c and BMI. Correlation is significant at the 0.01 level for mean pre COVID19 HbA1c and mean post COVID19 HbA1c (<0.001).

**. Correlation is significant at the 0.01 level (2-tailed).

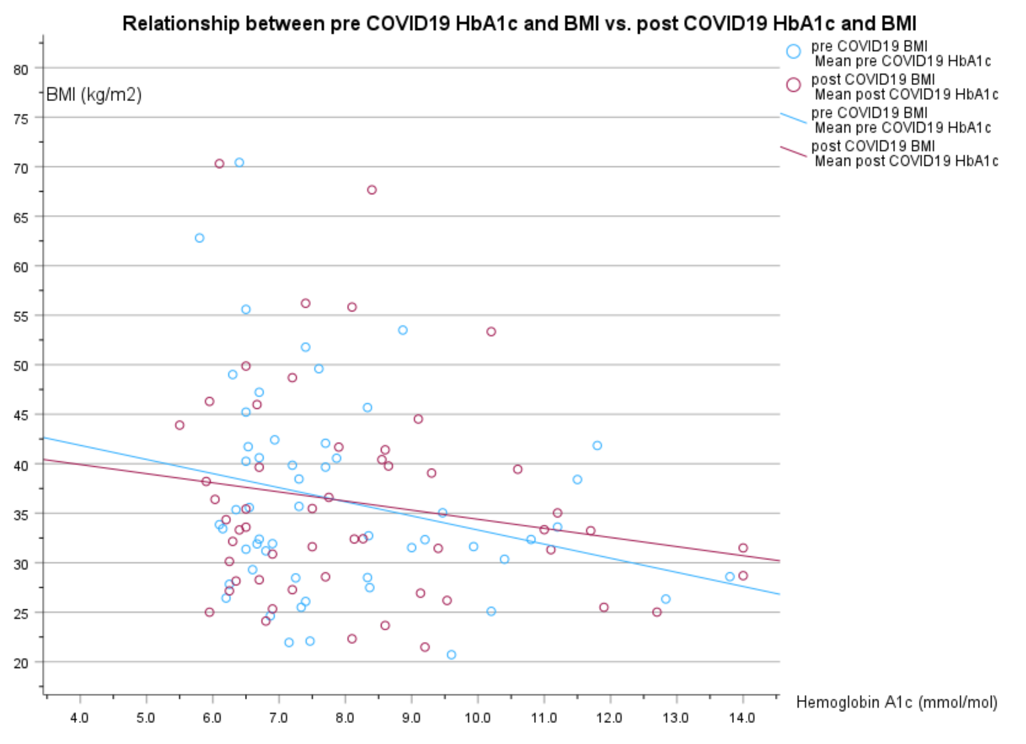
A correlation analysis between the calculated difference of pre and post COVID-19 mean HbA1c and the difference of pre and post COVID-19 BMI is shown in Results table 6. A correlation of -0.072 is found between these two variables.

Correlations Analysis of the calculated difference between pre and post COVID-19 mean HbA1cand BMI

Variable	Variable2	Correlation	Count	Lower C.I.	Upper C.I.	N
				Statistic		
Difference between mean pre COVID-19 HbA1c and mean post COVID-19 HbA1c	Difference between pre COVID-19 BMI and post COVID-19 BMI	-.072	55	-.331	.197	0.600

Results table 6. Correlation analysis of the relationship between the difference of pre and post COVID-19 mean HbA1c vs. the difference of pre and post COVID-19 BMI

The relationship between pre COVID-19 HbA1c and BMI versus post COVID-19 HbA1c and BMI is documented on Graph 1.



Results Graph 1. relationship between pre COVID19 HbA1c and BMI and post COVID19 HbA1c and BMI.

DISCUSSION

Few research studies have looked at the effect of long term quarantining due to the COVID-19 pandemic and its impact on patient management of type 2 Diabetes Mellitus. Our study population looked at 55 patients above the age of 18 who utilize a free clinic in Granbury, Texas with a known diagnosis of T2DM prior to March 15, 2020. The majority of the study population was on at least one anti-diabetic medication. With the mean age of 54, more than half the study population had a history of either hypertension or hyperlipidemia, with nearly one third having both hypertension and hyperlipidemia. Over sixty percent of the patients were Hispanic race, the remaining being Caucasian or Asian. A female predominance of 67.3% was noted in our study.

Adequate glycemic control is important in reducing diabetes related complications, with sufficient control defined by maintaining an hemoglobin A1C < 7.0%[23]. Limited physical activity, as seen during COVID-19 related lockdown periods, increases risks and severity of T2DM.[24]

Interpretation of Results

Our study found a clinically relevant increase in mean HbA1c of 0.321 in the patient population pre versus post COVID-19 pandemic. Yet, the study found a decrease in calculated mean BMI of 0.23 in the pre versus post pandemic period. Unlike other research studies that found a significant worsening of glycemic control secondary to COVID-19 quarantine regulations,[25] our study found no significant changes in the HbA1c and BMI. For changes in both HbA1c and BMI to be deemed significant, there must be a change of more than 5%[26,27]. The results of our study were unable to reject the null hypothesis of both specific aim one and specific aim two, which look at changes in HbA1c and BMI pre vs. post COVID-19 pandemic.

When looking at the relationship between changes in HbA1c and BMI, our study found a significant correlation between the mean pre COVID-19 HbA1c and the mean post COVID-19 HbA1c. There was also a significant correlation between the mean pre COVID-19 BMI and the mean post COVID-19 BMI. Although, there was not a significant correlation between the calculated difference of pre and post COVID-19 mean HbA1c and the difference of pre and post COVID-19 BMI.

Strengths of the Study

The strengths of our study are that we had direct examination of patient charts compared to gaining data via face to face interviews. This is especially important when documenting values such as body weight, height, HbA1c and current medications, which can be erroneously remembered or reported by patients. There are few research groups that have examined the changes in HbA1c and BMI before and after the COVID-19 pandemic quarantine mandates. Our study serves as a source of understanding the real effects of extended periods of lockdown on patients with T2DM.

Limitations of the Study

There are several limitations of our study that are worth noting. One of the main limitations of this study is the small sample size, which makes it difficult to determine if the study outcomes are a true and accurate finding. Our small sample size could result in a type II error, falsely accepting the null hypothesis due to limited data points. This study also only looks at patients at a single clinic, which may not represent the general population. The single-center free clinic is used predominantly by the low income minority populations. Thus, our patients belong to the lower socioeconomic strata, which were disproportionately affected by the COVID-19 pandemic regarding continuity of care due to limited access to telemedicine.[28] This confounding variable of accessibility was not accounted for in our patient population.

FUTURE DIRECTIONS

For many Texans, managing their type 2 Diabetes Mellitus is a part of their day to day lives. It is important to examine the needs of these patients and understand different social variables that may affect their ability to manage this condition. In our study, we looked at the impact of COVID-19 "lockdown" protocols on glycemic control through a patient's HbA1c and weight. Yet, our study did not look at various confounding elements that could also play a role.

One area that could benefit from further examination is looking at the patient's lifestyle habits and if the COVID-19 pandemic impacted these habits. Patients with T2DM benefit from following healthy lifestyle habits of balanced diet, healthy mental state and regular exercise. Our study did not account for these elements when looking at the patient's management of T2DM. It would be beneficial to understand if and how the COVID-19 lockdown limits or changes a patient's habits.

Secondly, one study was limited by small sample size and patients from one geography location. Going forward, a larger study with differing geographic locations could shine light on a better understanding of the impact COVID-19 lockdowns have had on patients with T2DM. Ultimately, the overall goal of this study and future studies should be to gain insight on how best the community, medical facilities and government can help manage T2DM during future pandemics.

CONCLUSIONS

This research study is one of the few that looks at the effect of long term periods of "lockdown" during COVID-19 pandemic on a patient's management of T2DM. The study focused on adult patients with a known diagnosis of T2DM who utilize Ruth's Place free Clinic in Granbury, Texas. Our study found no significant changes in the HbA1c and BMI secondary to COVID-19 quarantining regulations, indicating that these regulations did not cause a major disruption in patients' glycemic control and management of T2DM in our study population. This understanding can serve as the starting point for health systems embarking on post COVID-19 recovery plans, and ultimately can aid in improving medical preparedness for periods of extended homestay or future pandemics.

COMPLIANCE

Conflict of Interest: The authors declare that they have no conflict of interest.

Ethical Approval: This study has been approved by the TCU Institutional Review Board (IRB) on November 16, 2020, #1920-322.

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