Impact of Optimum Diabetes Care on the Safety of Fasting in Ramadan in Adult and Adolescent Patients with Type 1 Diabetes Mellitus

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Introduction

Management of diabetes during Ramadan and fasting is a challenge faced by healthcare professionals and patients worldwide. It is estimated that around 1.8 billion, or a quarter of the world's population are Muslim (1). Fasting during the month of Ramadan is obligatory for all adolescent and adult Muslims whereby abstinence from both eating and drinking is observed between dawn and sunset. Although Islamic law exempts patients with chronic illnesses or poor health from fasting, many patients are eager to fast against medical advice and religious exemption.

Current recommendations from the International Diabetes Federation (IDF) and Diabetes and Ramadan (DAR) Alliance Group stratify patients with type 1 diabetes mellitus as high-risk to very high-risk for fasting; and are advised against fasting (2). The risks of fasting posed in those with diabetes include the potential for hypoglycemia, hyperglycemia, dehydration and diabetic ketoacidosis (3, 4). However, a significant number of patients choose to fast. In the EPIDIAR study, 42.8% of the 1,070 patients with type 1 diabetes mellitus who participated in the retrospective survey conducted across 13 countries, were willing to and able to fast at least 15 days of Ramadan (5).

As one of the main challenges in the management of type 1 diabetes is control of glycemic variability and glycemic extremes of hypoglycemia and hyperglycemia; these issues become especially concerning during days of fasting when prolonged hours without food intake in the daytime is followed by excess intake of carbohydrate and sugar-rich foods in the evening. The advent of more accessible continuous glucose monitoring in the past few years has been of great clinical utility in improving compliance with monitoring of blood glucose through the convenience of regular interval glucose sensing without the need for invasive pin pricking. Insulin and diet adjustments based on glucose readings aid in reducing glycemic variability, despite possible inaccuracies in readings (6-8).

Several studies in recent years have looked at the trend of glycemic variability in patients with type 1 diabetes during Ramadan fasting, as well as the utility of continuous glucose monitoring in improving glycemic control and safety during fasting. The majority of these studies were done with children and adolescents (9-16).

One of the questions that arise regarding the safety of fasting in type 1 diabetes, is whether the type of insulin regimen or dose adjustments would reduce hypoglycemia and glucose variability.

Alamoudi et al. studied 156 patients with type 1 diabetes during Ramadan fasting and found that there was no difference between the use of Continuous Subcutaneous Insulin Infusion (CSII) and Multiple Daily Injections (MDI) in terms of rates of hypoglycemia and hyperglycemia, but there was significantly less glycemic variability in patients using CSII (9). Other studies looked at whether a reduction of insulin dosing - specifically long acting insulin - during fasting, reduced hypoglycemic events and found no benefit in insulin reduction in lowering the rate of hypoglycemia (10, 11).

Al Agha et al. reported in their study of 51 children and adolescents with type 1 diabetes who fasted Ramadan, that the use of flash glucose monitoring helped prevent severe hypoglycemia requiring assistance and severe diabetic ketoacidosis (DKA) during Ramadan, while asymptomatic hypoglycemia occurred in 10% of cases (13).

Asymptomatic hypoglycemia is frequently encountered in Ramadan studies using any type of continuous glucose monitoring, including flash glucose monitoring. There is no clear explanation for this. One thought is that it may be due to the technology used, as it relies on interstitial fluid glucose detection. Sampling frequency accuracy variation may be expected with a mean absolute relative difference (MARD) of 12.3% in the Abbott Freestyle Libre sensor (6). In their study of 21 adolescent patients with type 1 diabetes fasting Ramadan, Kaplan et al. reported no severe hypoglycemia or DKA admissions, but a significant increase in hypoglycemia rates in fasting hours compared to eating hours (14.2% vs 2.5%, $p=<0.05$). There was a wide fluctuation in glycemic readings throughout the day and frequent episodes of unreported hypoglycemia. The CGM systems in use were the Medtronic iPro and Guardian REAL-Time systems (14).

Although most trials looked at hypoglycemia rates within Ramadan, a few compared the variation in rates in and out of Ramadan. A small study of 14 adolescent patients in Al Ain, the UAE compared rates of hypoglycemia pre Ramadan and during Ramadan using CGM and found no significant difference in interstitial glucose mean values, nor in the duration of hypoglycemia and hyperglycemia in and out of Ramadan (15).

The use of CGM technology in most trials done in type 1 diabetes during Ramadan did not always have a beneficial effect in improving glycemic control and reducing hypoglycemia. The positive role of education in the management of diabetes during Ramadan has been supported by several studies (17-21).

The current study differs from the previously mentioned studies in that it has been mainly done with adult patients rather than children and adolescents. It is a prospective study that followed patients prior to Ramadan and during Ramadan with a comprehensive duration of time that CGM data was obtained from. This allowed a detailed insight into glycemic variability and to highlight differences in rates of hypoglycemia and hyperglycemia not only between fasting and eating hours, but also in and out of Ramadan. As the patients had all received specific Ramadan-focused education and instructions on target glucose readings, insulin dose adjustments, diet control and indications for breaking the fast in addition to the CGM sensor and reader, consequently, this

study looks at the effect of optimum care which includes Ramadan focused education, flash glucose monitoring and treatment adjustment in type 1 diabetes, aiming at improving safety in fasting.

Methodology

Subjects and Procedure:

This is a prospective interventional, single-center trial assessing the safety of fasting in patients with type 1 diabetes mellitus during the month of Ramadan. We included patients 14-75 years of age, with a known diagnosis of type 1 diabetes mellitus attending the Adult Endocrinology Clinic at Dubai Hospital. All patients were advised not to fast, however those who insisted were offered enrolment. Participants were selected at convenience 1 to 2 months before Ramadan in 2016, counselled, and asked to sign an informed consent. Patients with type 2 diabetes, concurrent renal disease, ischemic heart disease, pregnancy or any recent hospitalization in the preceding 3 months were excluded. All patients received a 60-minute Ramadan-focused educational session (DAR SaFa) which included information on lifestyle and treatment modifications, and on indications for breaking the fast as well as advice on diet and fluid intake during Ramadan. The Freestyle Libre flash sensor insertion was done for continuous glucose monitoring at the initial visit after consent was obtained, and patients were instructed on the use of the sensor and monitor. The biophysical and biochemical profile was collected 2 to 4 weeks before and after Ramadan. We recorded diabetes related emergency visits or hospitalization, change in weight, systolic and diastolic blood pressure, lipids profile, renal function, HBA1c, and urine microalbumin/creatinine ratio.

Aim of the Study:

Primary Objective:

Evaluate the safety of fasting Ramadan for patients with type 1 diabetes mellitus by assessing the biochemical parameters as well as flash glucose monitoring data including hypoglycemia (glucose level <70mg/dl with or without symptoms) and hyperglycemia pre- Ramadan compared to during and/or post Ramadan.

Secondary Objectives:

- To compare the severity and duration of hypoglycemia, hospital admissions, and biochemical parameters, during and outside of Ramadan.
- To assess frequency of breaking the fast when hypoglycemia develops and the total number of days that patients were able to fast during Ramadan.
- To determine the influence of focused diabetes and Ramadan education on improving the safety of fasting Ramadan in patients with type 1 diabetes.

Ethical Approvals:

The study has been approved by the ethical committee of Dubai Health Authority.

Funding: This study was funded by a grant from Al-Jalila Foundation of Dubai after competing for research grants by the foundation.

Definitions:
According to diabetes and Ramadan guidelines, hypoglycemia was recognized when blood glucose was less than 70 mg/dL with or without symptoms. Severe hypoglycemia occurred if the person required third-party assistance or admission to an emergency room or hospitalization.

Data Collection and Analysis:
All data was then entered in an Excel sheet and was prepared for analysis. Paired Student's t-tests were used to test the significance of differences between values for continuous variables measured at baseline and at various time points. Independent t test, one-way analysis of variance (ANOVA) and Chi square tests were used to assess the significance of differences between the groups. Continuous data are presented as the mean. Standard deviation (SD) and categorical data are presented as frequencies and percentages. Differences with P-values ≤ 0.05 were considered to be statistically significant. Analyses were performed using Statistical Package for the Social Sciences (SPSS) version 23 (IBM Corp, New York, USA).

Results

A total of 30 patients with type 1 diabetes were recruited. 4 patients had dropped out of the study during the pre-Ramadan phase; 1 was due to a hospitalization with diabetic ketoacidosis early during Ramadan. A few patients did not complete the full protocol as they only had one sensor during or out of Ramadan. There were 24 patients in total with CGM data available. 53% were male and 47% female with a mean age of 23.3 years ± 7.85. The average duration of diabetes was 8.6 years. Patient demographic data can be found in Table 1. The majority of patients were on basal bolus insulin with the exception of 2 who were on an insulin pump. 21% reported fasting the entire month of Ramadan with 24 days being the average number of days fasted. 95% of patients reported satisfaction with the pre-Ramadan educational session in terms of learning benefits. 63% reported making insulin dose adjustments in Ramadan.
A total of 258 days of non-fasting data was recorded (47%) with an average data capture rate of 72% and a total of 289 days of fasting data was recorded in Ramadan (53%) with an average data capture rate of 78%.

Hypoglycemic Events:
The mean total number of hypoglycemic events recorded by the sensor before Ramadan among all patients was slightly higher than during Ramadan, but the difference was not statistically significant (see Table 1b). The average duration of hypoglycemic episodes was slightly longer during Ramadan with a mean of 98.50 minutes ± 62.55 compared to 96.33 minutes ± 49.32 in the non-fasting period. 79% of patients had a glucose reading below 49 mg/dl in the non-fasting period compared to 66.7% who had a similar reading during Ramadan. There was no statistically significant difference in the severity of hypoglycemic episodes occurring before and during Ramadan in terms of the lowest blood glucose value obtained.
Based on the CGM data, 46.7% of patients had frequent hypoglycemic events of more than 10 episodes in the 2 weeks of sensor data captured during the non-fasting period compared to 29.2% who had a similar frequency of hypoglycemia during Ramadan. There was no difference

between the percentage of patients who had between 1 to 9 episodes of hypoglycemia comparing the non-fasting sensor data with the Ramadan data. There were more patients who had no episodes of hypoglycemia recorded at all on CGM in the Ramadan group compared to the non-fasting period (see Figure 1). 62% of patients had less hypoglycemic episodes during Ramadan compared to non-fasting days (see Figure 2), however, this was statistically not significant.

Most hypoglycemic events occurred between 00:00 to 06:00 and the least number of hypoglycemic events occurred between 06:00 to 12:00 in the non-fasting period. During Ramadan, most hypoglycemic events occurred between 00:00 to 06:00 and the least number of events occurred between 12:00 to 18:00 (see Figure 3).

Glycemic Control:

The peak glucose value before and during Ramadan was similar at 403.0 ± 77.2 and 394.8 ± 68.2, respectively. The mean average glucose around Iftar (breaking fast) time was 181.1 mg/dl ± 58 and the mean glucose 2 hours later was 231.0 mg/dl ± 66.

The average laboratory HbA1c prior to Ramadan was 8.23% and it reduced to 7.89% post Ramadan. However, the average sensor estimated HbA1c was 7.93% prior to Ramadan and increased to 8.52% in Ramadan. Differences between the estimated duration of time when glucose value was within, above and below target range is highlighted in Figure 4.

Safety Profile:

There was one admission with diabetic ketoacidosis in a patient occurring on the first day of Ramadan, which was not related to fasting. There were no hospital admissions with hypoglycemia or hyperglycemia, otherwise.

Biometric and Metabolic Parameters:

The mean weight before Ramadan was 70.16 kg ± 17.92 and 69.61 kg ± 16.70 after Ramadan. Systolic blood pressure was 116.31 mmHg ± 15.45 before Ramadan and 116.13 mmHg ± 12.25 after Ramadan. Diastolic blood pressure was 69.7 mmHg ± 7.46 before Ramadan and 66.31 mmHg ± 10.1 after Ramadan. None of the biometric or biochemical data changes were statistically significant (see Table 2).

Discussion

Attainment of a stable glycemic profile, void of any major fluctuations leading to potential severe hypoglycemia, or hyperglycemia and diabetic ketoacidosis, is a cornerstone in the management of patients with type 1 diabetes mellitus. The dietary constraints imposed by fasting and associated lifestyle changes during Ramadan combined with intensive insulin treatment make this group especially challenging in glycemic management and are thus classified as high-risk to very high-risk for fasting.

Our study has shown that it may be possible for selective patients with type 1 diabetes with no major diabetes related complications, to fast Ramadan safely if optimum care is available. The care provided to participants in this study was in the availability of a flash glucose sensor and

monitor, access to an educator and physician if required, regular follow up at clinic and Ramadan-focused education. It remains to be known whether any specific aspect of care had a major impact in reducing acute complications; certainly, the convenience of non-invasive glucose monitoring is of great clinical utility. However, as per the Joint Statement of the European Association for the Study of Diabetes (EASD) and the American Diabetes Association (ADA) Diabetes Technology Working Group on improving the clinical utility of CGM, there is no advantage in using this diagnostic tool without appropriate training and education in its use and in methods of dealing with variable glucose readings (22). The READ study in type 2 diabetes and others have supported the role of focused education in improving safety of fasting in Ramadan (17, 18, 20, 21). In a recent single blinded randomized control trial of the Dar Safa pre-Ramadan structured education program, as was used in our current study, Mohamed et. al described a reduction of more than 50% in post intervention hypoglycemia in the study group who received education compared to controls ($p<0.003$) (19).

As patients were able to act on their glucose readings and were aware of indications for breaking of their fast, only 21% of patients reported having fasted the whole month of Ramadan. This indicates that even well-controlled and motivated patients with optimum resources, may find the prospect of fasting the entire month challenging and would rather opt to fast on select days. However, the average number of days fasted was high at 24 days. The self-reported rate of satisfaction of patients with the Ramadan-focused educational session in terms of learning benefits was 95%; indeed, demonstrating that despite years of experience in dealing with diabetes as patients, the majority were not fully informed of key safety concepts in managing diabetes during Ramadan.

Comparing our study to others done in patients with type 1 diabetes during Ramadan, we note that we had an overall reduction in the frequency of hypoglycemic episodes during Ramadan. Although 63% of our patients reported making dose adjustments to their insulin during Ramadan based on either healthcare provider recommendations or their diet and glycemic profile; we can not attribute the improvement purely to this. Deeb et al. had shown no improvement with a reduction in insulin glargine dose in Ramadan and Alamoudi et al. demonstrated no difference between CSII and MDI regimens in reducing the frequency of hypoglycemia (9, 10). Unfortunately, we do not have data on the specific dose adjustments made by patients in our cohort.

With regards to the timing of hypoglycemia, Kaplan et al. reported that 69% of patients with type 1 diabetes using CGM experienced hypoglycemia between 11.00 and 19.00 during Ramadan. The recommendation was to reduce basal insulin dosing which may lead to hypoglycemia during fasting hours (11). However, our data showed that the time immediately prior to breaking the fast (12.00 to 18.00) had the least frequency of hypoglycemic episodes during Ramadan. Most of the hypoglycemic episodes occurred at night between 00.00 and 06.00. This may point to inappropriate carbohydrate counting during meals in the evening at Ramadan, leading to night time hypoglycemia. The basal insulin dose in our group would have been more appropriate for the daytime. Although the overall frequency of hypoglycemia was less in Ramadan compared to pre-Ramadan, this was not statistically significant, and a similar finding was also reported by Kaplan et al. in another study of adolescents using CGM in Ramadan for an average of 2.5 days prior to and during Ramadan (15). Afandi et al., however, suggested that poor pre-Ramadan glycemic control was associated with more frequent hypoglycemia and glycemic variability during

Ramadan (12). Al Agha et al., demonstrated that there were no cases of severe hypoglycemia and DKA in pediatric patients with the use of CGM during Ramadan, however there was no comparator data from prior to Ramadan to assess for any differences (13).
The latter study had found asymptomatic hypoglycemia in 10% of patients. We also noted that the frequency of hypoglycemia per day appeared to be quite high from the CGM readings in our study, with a significant number of patients having more than 10 episodes of hypoglycemia in the timeframe of wearing the sensor (a maximum of 2 weeks). This may be related to inaccuracies in interstitial glucose detection resulting in exaggerated low glucose values (6, 23). However, despite this, there was still a reduction in the percentage of patients having >10 recorded episodes of hypoglycemia during Ramadan (29.2%) compared to prior to Ramadan (41.7%).

This study has its limitations in its design as an observational trial aiming to understand the issues facing patients with type 1 diabetes during Ramadan fasting, rather than to intervene. Ideally, these findings would have to be re-examined in a larger, randomized controlled trial. The data can not be generalized as patients enrolled in the study received specialized care in the form of access to flash glucose monitoring, Ramadan-focused education and supervision by specialized healthcare providers at a tertiary referral center with experience in the management of diabetes during Ramadan. There was no data available on details of insulin dose adjustments made by patients, which would be helpful to ascertain the impact of basal dose reduction or prandial dose mismatch.

Our study, nevertheless, is one of the first looking at glycemic control in adult patients with type 1 diabetes during Ramadan. It also provides comparator data from before and during Ramadan covering an extensive duration of time of around 2 weeks each, respectively, which demonstrates the differences in glycemic control in Ramadan from baseline. This provides a great insight into the safety of fasting of selective patients, provided they receive optimum care and match the prandial dose of insulin.

Conclusion

Optimal care of selective patients with type 1 diabetes may allow for safe Ramadan fasting with a low complication rate, less hypoglycemia and glycemic variability with stable biometric and metabolic parameters. This can be achieved by following a comprehensive approach of individualized care, provision of flash glucose monitoring, structured Ramadan and diabetes education sessions and access to a specialist diabetes center. Larger, randomized controlled trials are required to be able to generalize this as a recommendation.

Tables and Graphs

Table 1			
a) Baseline Characteristics			
Total number of patients	24		
Gender	Male = 46.7% Female = 53.3%		
Average duration of type 1 diabetes	8.6 years		
Mean Age	23.3 +/- 7.85 years		
Age Groups	<18 years = 20% 18 to 24 years = 50% 25 to 30 years = 16.6% >30 years = 13.3%		
Ethnicity	Emirati = 76.6% Arab Nationals = 23.3%		
b) Hypoglycemic Events			
Number of hypoglycemic events	Non-Fasting 8.7 ± 6.3	Fasting 6.8 ± 5.2	P value = 0.502
Total duration of hypoglycemic events (minutes)	Non-Fasting 96.3 ± 49.3	Fasting 98.5 ± 62.6	P value = 0.909
Lowest blood glucose value (mg/dl)	Non-Fasting 46.0 ± 10.4	Fasting 50.5 ± 13.7	P value = 0.177

Table 2: Changes in Biometric and Metabolic Parameters Before and After Ramadan				
	n	**Before Ramadan**	**After Ramadan**	**P value**
Weight	18	70.2 ± 17.9	69.6 ± 16.7	0.632
Systolic Blood Pressure	16	116.3 ± 15.4	116.1 ± 12.3	0.955
Diastolic Blood Pressure	16	69.7 ± 7.5	66.3 ± 10.1	0.207
HbA1c	21	8.2 ± 1	7.9 ± 0.9	0.010
LDL	18	66.3 ± 10.1	103.5 ± 36.7	0.687
Triglycerides	18	76.7 ± 34.8	83.1 ± 27.9	0.058
Total Cholesterol	18	179.3 ± 36.4	181.8 ± 42.3	0.602
HDL	18	60.6 ± 17.2	61.7 ± 13.9	0.705
Creatinine	7	0.71 ± 0.34	0.67 ± 0.32	0.180
EGFR	5	109.5 ± 30.1	116.1 ± 29.7	0.180
Microalbuminuria	9	4.6 ± 3.2	28.4 ± 69.3	0.123

Figure 1: Frequency of Hypoglycemic Episodes Per Patient Per Sensor Duration

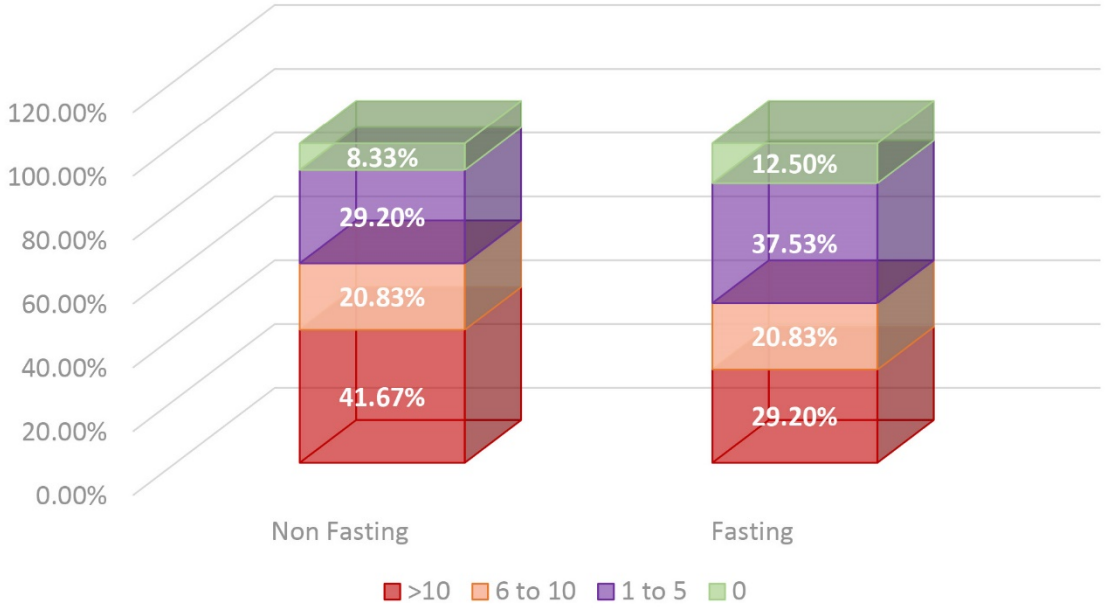


Figure 2: Comparison of Average Frequency of Hypoglycemic Episodes Per Day In and Out of Ramadan

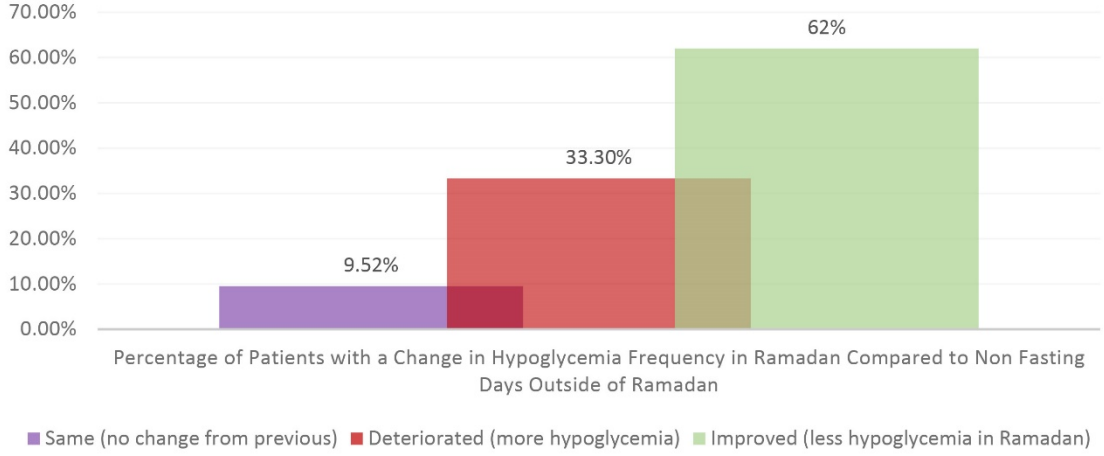


Figure 3: Number of Hypoglycemic Events Per Sensor Day at Different Timings in Non-Fasting vs Fasting Days

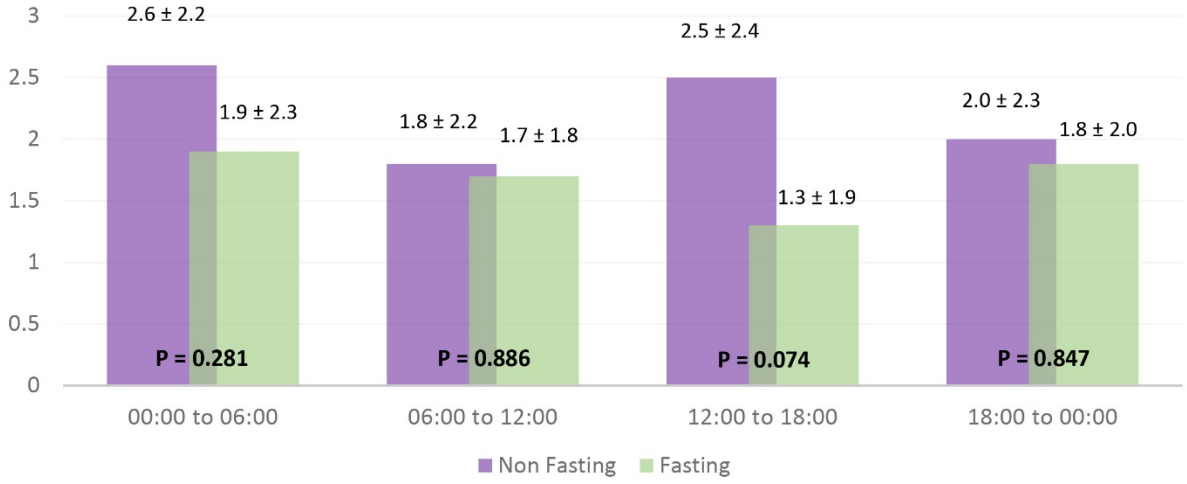
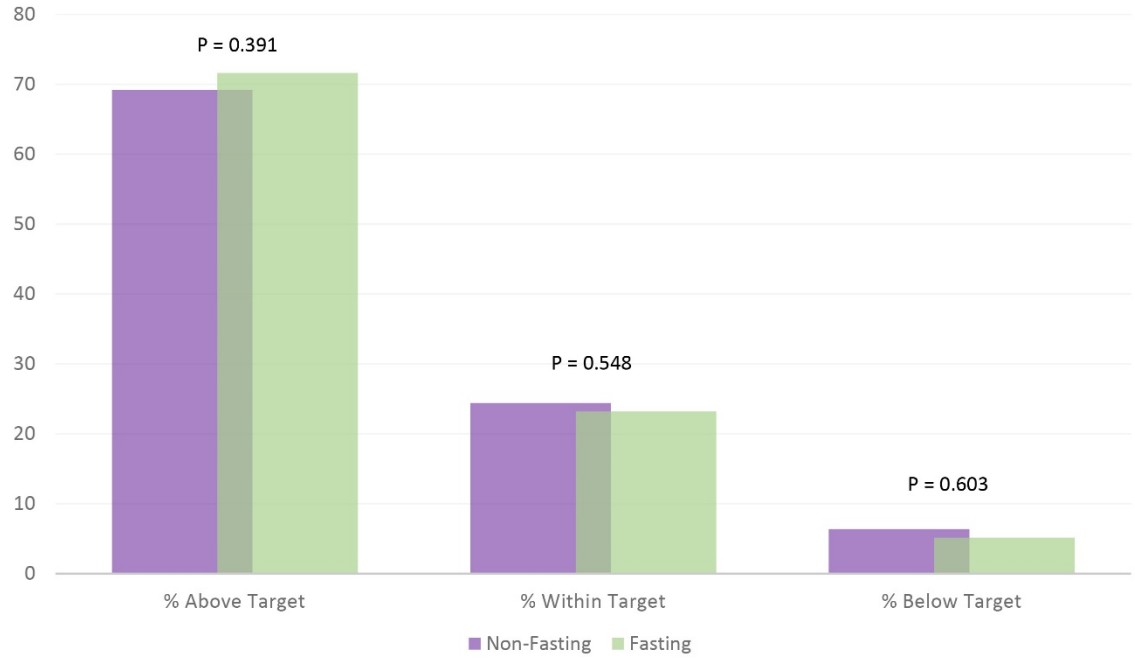


Figure 4: Sensor Data Comparing Percentage of Blood Glucose Readings Above, Within and Below Targets in Non-Fasting Days and Fasting Days



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