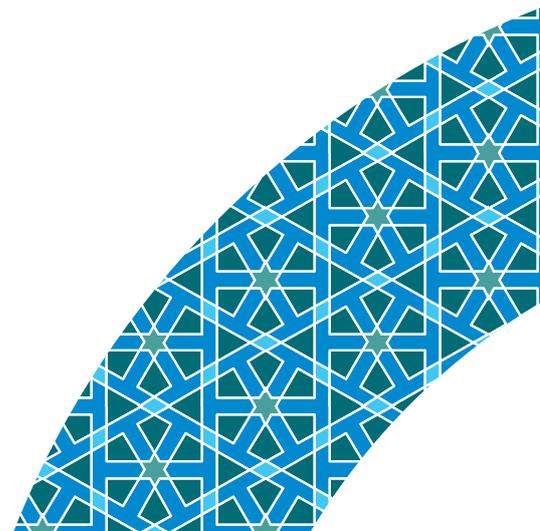


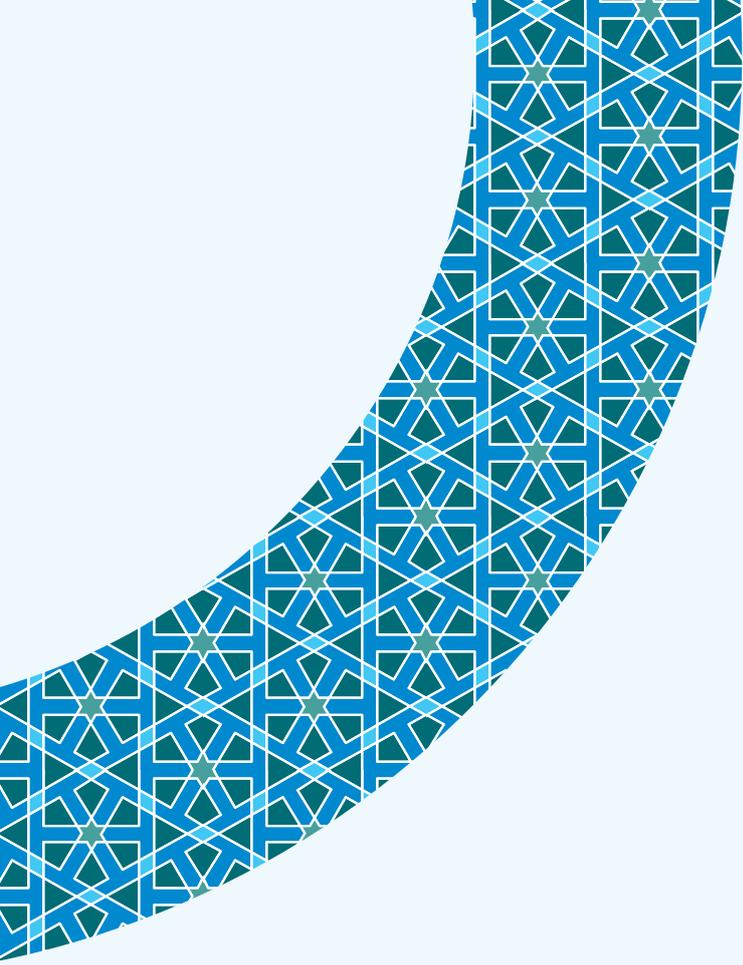
CHAPTER 5

Risk stratification of people with diabetes before Ramadan

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WHAT IS KNOWN?

- Different factors are used to classify people with diabetes into risk categories.
- Physicians may weight the risk factors differently.
- There is broad variation in risk stratification.
- Many high risk people with diabetes still insist on fasting.

WHAT IS NEW?

- Care must be highly individualised.
- A risk calculator with various risk variables is introduced.
 - There is flexibility in calculating an individual's risk.
 - This empowers physicians from all specialties to help categorise individuals that seek to fast.

WHAT IS MISSING?

- More research on the impact of different risk factors on the safety of fasting during Ramadan.
- Further research on the quality of life or patient reported outcomes of individuals that fast.
- An accessible easy to use tool to implement the use of this risk calculator.
- Prospective clinical trials on the effects of hypoglycaemia and hyperglycaemia during Ramadan on an individual's wellbeing.

1. RISKS ASSOCIATED WITH FASTING IN PEOPLE WITH DIABETES

Fasting during Ramadan for people with diabetes carries considerable challenges. However, despite these challenges many still insist on fasting [1]. The main risks reported with fasting are hypoglycaemia and hyperglycaemia [2]. Summer fasting periods can last between 15–18 hours per day and are often undertaken in hot and humid conditions which can lead to complications such as dehydration [3].

The major risks, hypoglycaemia and hyperglycaemia, are faced by people with diabetes on a daily basis; however, studies have shown that fasting may increase the chances of these events occurring [4-6]. Recently, the Diabetes and Ramadan-Middle East and North Africa (DAR-MENA) Type 1 Diabetes Mellitus (T1DM) study reported that 48.5% of participants fasted for the full month of Ramadan. The incidence of confirmed and severe hypoglycaemia was similar to that prior to Ramadan [7]. While in the DAR-MENA Type 2 Diabetes Mellitus (T2DM) study, it was shown that hypoglycaemia increased significantly during Ramadan when compared to before Ramadan, 10.4% - 4.9% respectively [8].

Many Muslims with diabetes who decide to fast during Ramadan face a number of challenges. Despite these challenges many still insist on fasting.

Similarly, higher hyperglycaemia rates have been reported during Ramadan. The EPIDIAR study showed that people with T2DM, with or without diabetic ketoacidosis (DKA), could have their rates of hyperglycaemia increase 5-fold [4]. Ahmedani *et al.*, found symptomatic hyperglycaemia in 33.3% and 15.4% of individuals with T1DM and T2DM, respectively [5]. The risk of these complications appears to be particularly high in people with T1DM. A recent global survey of 1054 individuals with type 1 diabetes found that 27% were able to fast for the whole of Ramadan and 39% reported no episodes of hypoglycaemia. Conversely, the study reported that 28% fasted 21 days or less due to diabetes related illnesses. The survey also found that 45% and 60% reported the incidence of hyperglycaemia and hypoglycaemia respectively, and 7% needed hospital admissions [9].

The incidence of DKA seems to be higher during Ramadan as observed in the EPIDIAR study as well as others [4, 10]. However, Beshyah *et al.* found DKA rates during Ramadan to be similar to that of other months [11].

In a narrative review, Afandi *et al.* discussed the individualised management of people with diabetes during Ramadan fasting and factors that influence the development of personalised care are shown in **Table 1** [12].



TABLE 1: RECOGNISED FACTORS THAT MAY INFLUENCE THE DEVELOPMENT OF PERSONALISED CARE FOR PEOPLE WITH DIABETES THAT FAST DURING RAMADAN

Ramadan related factors	Diabetes related factors	Factors concerning the individual
Length of fasting hours	Type of diabetes	Age (adolescents and elderly)
Season of fasting	Duration of diabetes	Gender
Weather	Diabetic complications	Occupation
Geographical location	Antidiabetic therapies	Pregnancy/Lactation
Social changes	Previous control	Meal pattern
Past experiences	Proneness to hypoglycaemia	Exercise nature/timing
	Hypoglycaemic unawareness	Motivation
	Access to care	Personal preferences

All of the factors mentioned in **Table 1** are thoroughly discussed in the various chapters of these guidelines. Healthcare professionals (HCPs) must be conscious of the potential dangers of fasting for some individuals with diabetes and should quantify and stratify the risks for every person individually in order to provide the best possible care.

Taking into account all the risks encountered during Ramadan it is easy to see why religious permissions and regulations, as well as medical recommendations, exist that allow exemption from fasting for some people with diabetes [2, 13-15]. However, for many it is a deeply spiritual experience, and they will insist on fasting, perhaps unaware of the risks they are taking.

HCPs managing high risk individuals that insist on fasting must be conscious of the potential dangers and should quantify and stratify the risks for every person on an individual basis.

2. RISK STRATIFICATION

Risk stratification is an essential aspect of all diabetes and Ramadan recommendations. Indeed, this has gradually evolved from the 4 tier categories in the 2005 and 2010 American Diabetes Association (ADA) recommendations to the three tier traffic light system in the IDF-DAR guidelines in 2016 as well as the recommendations of many other groups or diabetes societies [1, 12, 13], and guidelines including the Canadian guidelines [16] and the BMJ guidelines 2010 [17], IDF-DAR 2016 [18]. Furthermore, some of these recommendations have been endorsed by religious authorities such as the Islamic Organisation for Medical Sciences and the International Islamic Fiqh Academy who published a decree accepting and approving the ADA's risk categories, or the Mofty of Egypt where their recommendation was an integral part of the IDF-DAR guidelines of 2016. In general, the religious authorities gave their opinion according to medical advice [15].

Despite, all these recommendations, many people with diabetes that are categorised as high risk were still fasting. HCPs welcomed the guidelines and stated that it was their go to source of advice [6]. In the CREED study, 62.6% of physicians referred to guidelines for the management of fasting and of these 39.0% reported using the ADA 2005 recommendations and 41.2% consulted the 2010 guidelines [6]. However, in light of emerging evidence highlighting the ability of some high risk individuals to fast when provided with the right circumstances, many felt that the current scoring system was too rigid. Surprisingly, the numbers of days fasted by the highest and the lowest risk group only differed by 3 days. There is a clear need to reconsider the risk categories and to provide a flexible means of taking into account an individual's circumstances and an individualised plan that would help people with diabetes and their HCPs to make better decisions about fasting during Ramadan.

For instance, almost all guidelines categorise people with T1DM as high risk, however, as mentioned earlier, several studies have demonstrated that some individuals with T1DM are able to fast safely and, indeed, others are more prone to developing hypoglycaemia or hyperglycaemia necessitating Emergency Room (ER) or hospital admission. This sort of blanket grouping needs to be disaggregated.

Consequently, in this chapter we have looked into the various risks in people with diabetes that choose to fast during Ramadan and have assigned a score for every risk element in accordance with the available evidence in the literature and from our clinical judgement. Furthermore, we have developed several clinical case scenarios and have presented them in a survey to 300 experienced physicians from across many countries within the regions of North Africa, Middle East, South Africa, Gulf region, Indian subcontinent, South East Asia and UK. The case scenarios were purely focused on the risk categories in relation to fasting during Ramadan. Details of this survey will be published soon, however, preliminary results from the survey indicate a wide variation in practices among physicians even from within the same country. This is perhaps due to a difficulty in quantifying some risk factors or in part due to differences in experience and resources or cultural factors. Indeed, this is also evident in the wider variations of fasting practices among many countries. It should be remembered that, while medical based evidence is scarce in the field of risk categorisation in relation to fasting during Ramadan, the safety of the individual with diabetes is of the utmost importance. Further, this approach matches the essence of the religious regulations of Islam.

The scoring system was designed considering the various factors that were deemed to influence fasting (**Table 2**). Some of the factors are discussed in **4.1** whereas the other factors are discussed in the other chapters of these guidelines.

For a given individual, each risk element should be assessed, and the score should be totalled. The resulting score will determine the overall risk level for an individual with diabetes that is seeking to fast during Ramadan (see **Figure 1**).

The following table includes the new IDF-DAR elements for risk calculation and the relevant risk score.



TABLE 2: ELEMENTS FOR RISK CALCULATION AND SUGGESTED RISK SCORE FOR PEOPLE WITH DIABETES MELLITUS (DM) THAT SEEK TO FAST DURING RAMADAN

Risk Element	Risk Score	Risk Element	Risk Score
1. Diabetes type and duration		8. MVD Complications/Comorbidities	
Type 1 diabetes	1	Unstable MVD	6.5
Type 2 diabetes	0	Stable MVD	2
2. Duration of Diabetes (years)		No MVD	0
A duration of ≥ 10	1	9. Renal Complications/Comorbidities	
A duration of < 10	0	eGFR < 30 mL/min	6.5
3. Presence of hypoglycaemia		eGFR 30–45 mL/min	4
Hypoglycaemia unawareness	6.5	eGFR 45–60 mL/min	2
Recent Severe hypoglycaemia	5.5	eGFR >60 mL/min	0
Multiple weekly Hypoglycaemia	3.5	10. Pregnancy*	
Hypoglycaemia less than 1 time per week	1	Pregnant not within targets*	6.5
No hypoglycaemia	0	Pregnant within targets*	3.5
4. Level of glycaemic control		Not pregnant	0
HbA1c levels > 9% (11.7 mmol/L)	2	11. Frailty and Cognitive function	
HbA1c levels 7.5–9% (9.4–11.7 mmol/L)	1	Impaired cognitive function or Frail	6.5
HbA1c levels < 7.5% (9.4 mmol/L)	0	> 70 years old with no home support	3.5
5. Type of treatment		No frailty or loss in cognitive function	0
Multiple daily mixed insulin Injections	3	12. Physical Labour	
Basal Bolus/Insulin pump	2.5	Highly Intense physical labour	4
Once daily Mixed insulin	2	Moderate Intense Physical Labour	2
Basal Insulin	1.5	No physical labour	0
Glibenclamide	1	13. Previous Ramadan Experience	
Gliclazide/MR or Glimepride or Repeganide	0.5	Overall negative experience	1
Other therapy not including SU or Insulin	0	No negative or positive experience	0
6. Self-Monitoring of Blood Glucose (SMBG)		14. Fasting hours (location)	
Indicated but not conducted	2	≥ 16 hours	1
Indicated but conducted sub-optimally	1	< 16 hours	0
Conducted as indicated	0		
7. Acute complications			
DKA/ HONC in the last 3 months	3		
DKA/ HONC in the last 6 months	2		
DKA/ HONC in the last 12 months	1		
No DKA or HONC	0		

DKA — Diabetic Ketoacidosis
HONC — Hyperglycaemic Hyperosmolar Nonketotic Coma
eGFR — Estimated glomerular filtration rate
MVD — Macrovascular disease

*Pregnant and breastfeeding women have the right to not fast regardless of whether they have diabetes



FIGURE 1
Risk score and risk categories

The risk factors were graded in relation to safety during the fast as follows:

Low risk was a score 0 to 3; moderate risk if they score 3.5 to 6; and high risk when they score > 6. It should be noted that individuals previously deemed “very high risk” have the same recommendations as those that were categorised as high risk.

The strategies to ensure the safety of individuals that are fasting in all risk categories include:

- Ramadan focused medical education
- A pre-Ramadan medical assessment, including a robust assessment of hypoglycaemia awareness
- Following of a healthy diet and a physically active lifestyle
- Frequent SMBG or continuous glucose monitoring (CGM)
- Modifications to treatment regimens

3. RISK LEVELS AND ASSOCIATED RECOMMENDATIONS

It is worth highlighting that the initial risk assessment can change, for example if the risk is modifiable such as glycaemic control, frequency of SMBG or with the development of a new complication; in these circumstances the risk level will need to be adjusted accordingly. An individual’s Ramadan experience may vary every year and, therefore, there is a need for a renewed risk stratification annually to make it a safe and happy experience for all.

Individuals who are in the high risk category should not fast.

These individuals are of high-very high risk of developing complications when fasting during Ramadan. We recommend that these individuals do not fast. If they do still insist on fasting the utmost care and monitoring should be provided alongside the strategies and recommendations mentioned above and in the other chapters of these guidelines.

Those at the moderate risk level are advised not to fast.

As previously mentioned, many of these patients will choose to fast anyway. This important personal decision should be made after consideration of the associated risks in consultation with HCPs. They also need to be aware of the techniques or strategies to decrease this risk. If individuals choose to fast, then they would need to be cautious and discontinue fasting if any problems arise.

Those at the low risk level should be able to fast.

These individuals are at a lower risk of in terms of complications arising when fasting during Ramadan. However as mentioned, circumstances can change leading to a change in the risk scoring. Therefore, risk stratification should be conducted annually to review the level of risk in advance of Ramadan.



SUMMARY

- The risks of fasting include hypoglycaemia, hyperglycaemia, DKA and dehydration.
- Physicians must quantify these risks and stratify each individual accordingly.
- With the correct guidance, many people with diabetes can fast during Ramadan safely but they must be under the close supervision of HCPs and made aware of the risks of fasting.
- The new IDF-DAR risk stratification defines three risk categories and provides a risk score that includes multiple factors that plays an important role in the fasting decision recommended for each.
- Individuals who fast against the advice provided by their healthcare professionals should follow expert and detailed guidance to avoid the development of serious complications.

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