AN INTRODUCTION TO THE DIABETES AND RAMADAN PRACTICAL GUIDELINES FROM THE IDF-DAR ALLIANCE

Neha Verma, MD, and Mohamed Hassanein, MB CHB, FRCP (Lon), FRCP (Edin), MPhil

Ramadan is a holy period in the Muslim calendar during which healthy Muslim adults follow daylight fasting. Although this is recommended for healthy adults, practicing Muslims view fasting as a deeply meaningful, spiritual experience, and most will participate, sometimes against medical advice. It is a challenging duty for a patient with diabetes to perform safely without significant hypoglycemia or hyperglycemia. Several organizations have developed methods and guidelines to help patients with diabetes fast while minimizing risk of complications. Along with education for the patients, in this paper, we summarize International Diabetes Federation (IDF)-Diabetes and Ramadan (DAR) collaborative recommendations for health-care providers managing patients with diabetes during Ramadan.

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The year 2016 was pivotal in the field of diabetes and psychosocial support. The American Diabetes Association (ADA) revised its annual guidelines to include a position statement on the psychosocial care for people living with diabetes. Regardless of the type of diabetes, lifestyle change is required for effective management. Diabetes educators’ unique training and expertise put them in a good position to help people with diabetes manage most aspects of living with the condition. Even with the best technologies and numerous resources, it is often the psychosocial barriers that keep people from initiating and sustaining behavior change.

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Ramadan is a holy period in the Muslim calendar during which healthy Muslim adults follow daylight fasting. Although this is recommended for healthy adults, practicing Muslims view fasting as a deeply meaningful, spiritual experience, and most will participate, sometimes against medical advice. It is a challenging duty for a patient with diabetes to perform safely without significant hypoglycemia or hyperglycemia. Several organizations have developed methods and guidelines to help patients with diabetes fast while minimizing risk of complications. Along with education for the patients, in this paper, we summarize International Diabetes Federation (IDF)-Diabetes and Ramadan (DAR) collaborative recommendations for health-care providers (HCPs) managing patients with diabetes during Ramadan.

Epidemiology and structure of Ramadan
Ramadan is a month-long (29 to 30 days) time of spiritual contemplation and seeking nearness to God during which fasting is obligatory for all healthy Muslims who have reached puberty. Followers must refrain from eating and drinking between dawn and sunset and must also abstain from using oral medications, sexual activity and smoking. It is believed that spiritual rewards for good deeds are multiplied during Ramadan, and there is an intense desire to participate in fasting, even among those who could seek exemption such as the elderly, children, the infirm and pregnant women. Missed fasts should be completed at other times, for example, when health is restored or after the delivery of a baby. Fasting outside of Ramadan (when the rest of the community is not observing a fast) can be challenging, and this may discourage people from taking advantage of granted exemptions. Those who are permanently incapacitated can compensate by Fidya, a donation of food or money to the poor, for each day’s fast that is missed.

The timing of Ramadan is based on the lunar calendar (355 days per lunar year), which is shorter...
### Assessment

#### Table 1

**IDF-Dar Risk Categories for Patients with Diabetes Who Fast During Ramadan**

<table>
<thead>
<tr>
<th>Risk category</th>
<th>Patient characteristics</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Category 1: Very high risk</strong></td>
<td>One or more of the following: • Severe hypoglycemia within the 3 months prior to Ramadan • DKA within the 3 months prior to Ramadan • Hyperosmolar hyperglycemic coma within the 3 months prior to Ramadan • History of recurrent hypoglycemia • History of hypoglycemia unawareness • Poorly controlled T1DM • Acute illness • Pregnancy in pre-existing diabetes, or GDM treated with insulin or SUs • Chronic dialysis or CKD stage 4 and 5 • Advanced macrovascular complications • Old age with ill health</td>
<td>If patients insist on fasting then they should: • Receive structured education • Be followed by a qualified diabetes team • Check their blood glucose regularly (SMBG) • Adjust medication dose as per recommendations • Be prepared to break the fast in case of hypo- or hyperglycemia • Be prepared to stop the fast in case of frequent hypo- or hyperglycemia or worsening of other related medical conditions</td>
</tr>
<tr>
<td><strong>Category 2: High risk</strong></td>
<td>One or more of the following: • T2DM with sustained poor glycemic control* • Well-controlled T1DM • Well-controlled T2DM on MDI or mixed insulin • Pregnant T2DM or GDM controlled by diet only or metformin • CKD stage 3 • Stable macrovascular complications • Patients with comorbid conditions that present additional risk factors • People with diabetes performing intense physical labor • Treatment with drugs that may affect cognitive function</td>
<td></td>
</tr>
<tr>
<td><strong>Category 3: Moderate / low risk</strong></td>
<td>Well-controlled T2DM treated with one or more of the following: • Lifestyle therapy • Metformin • Acarbose • Thiazolidinediones • Second-generation SUs • Incretin-based therapy • SGLT-2 inhibitors • Basal Insulin</td>
<td>Patients who fast should: • Receive structured education • Check their blood glucose regularly (SMBG) • Adjust medication dose as per recommendations</td>
</tr>
</tbody>
</table>

* The level of glycemic control is to be agreed upon between doctor and patient according to a multitude of factors.

CKD, chronic kidney disease; DAR, Diabetes and Ramadan International Alliance; DKA, diabetic ketoacidosis; GDM, gestational diabetes mellitus; IDF, International Diabetes Federation; MDI, multiple dose insulin; SGLT-2, sodium-glucose co-transporter-2; SMBG, self-monitoring of blood glucose; SU, sulfonylurea; T1DM, Type 1 diabetes mellitus; T2DM, Type 2 diabetes mellitus.
than the Gregorian (Western) calendar. Therefore, Ramadan occurs 10 to 11 days earlier every year. This means that the duration of daylight fasting varies according to the time of year in which Ramadan falls.

Figure 3 compares sleep and meal patterns during Ramadan and non-Ramadan days. Two meals are consumed during Ramadan. The first, eaten before dawn, is called Suhoor, and the second, after sunset, is Iftar.

A recent survey in 39 countries involving more than 38,000 Muslims reported that a median of 93% fasted during Ramadan. The Epidemiology of Diabetes and Ramadan (EPIDIAR) study performed in 2001 found that 42.8% of patients with Type 1 diabetes and 78.7% of those with Type 2 diabetes fasted for at least 15 days during Ramadan. More recently, the 2010 CREED study reported that 94.2% of patients with Type 2 diabetes enrolled in the study fasted for at least 15 days, and 63.6% fasted every day. Therefore, Ramadan has a major impact on the management of diabetes in the Muslim population. With so many Muslims with diabetes fasting, the importance of practical diabetes and Ramadan guidance becomes evident.

Pre-Ramadan diabetes patient education overview
A cornerstone of Ramadan diabetes management is patient education on risks, glucose monitoring,
nutrition, exercise and medication, including when to break the fast to protect one’s health. Studies have shown that pre-Ramadan counselling reduces the incidence of hypoglycemia, while recent reports from the United Kingdom and Pakistan show that HCPs can provide effective education. Bravis et al. in 2009 reported a significant decrease in hypoglycemia in a group receiving education compared to a group without Ramadan-focused diabetes education.

Pre-Ramadan education provides a platform to remind patients about the importance of diet and exercise and that regular glucose monitoring is essential to avoid complications (while reassuring them that this does not invalidate the fast). See Figure 2 for some of the key aspects of pre-Ramadan patient education.

Risk quantification begins before the month of Ramadan with the patient and HCP. This meeting should address the patient’s current diabetes control, ability to recognize symptoms of hypoglycemia and hyperglycemia and comorbid conditions such as kidney disease. HCP can use the risk stratification to determine whether it is safe for the patient to fast.

Patients should be reminded that insulin does not have any nutritional value and administration does not invalidate the fast. Similarly, point of care (POC) testing for blood does not break the fast per the IDF-DAR guidelines. Masood et al. in 2014 conducted a retrospective observational study to assess beliefs of people with diabetes regarding skin prick during Ramadan for glucose testing. In their study, they found 77% did not perform blood glucose monitoring despite the 57% literacy level in that group. Therefore, reviewing POC and insulin administration during education is essential.

The ability to monitor blood glucose and methods to troubleshoot such as consuming 15 grams of carbohydrates for hypoglycemia should also be reviewed with the patients. Also, review triggers for breaking the fast (Figure 4).

Nutrition therapy plays a vital role in diabetes management, and an individual’s religion and culture should be considered when preparing his or her diet plan. The diet of a person with diabetes during Ramadan should be comparable to that followed during the rest of the year. However, Ramadan can result in an extra burden of calories. Iftar, the meal taken when the fast is broken at sunset, often turns into a celebration, with huge volumes of sugar- and carbohydrate-laden foods. Regional variations exist in the timing of meals during Ramadan.

The Ramadan Nutrition Plan (RNP), a mobile and web-based application, aims to provide HCPs with information to help them individualize medical nutrition therapy for patients with diabetes during Ramadan. The app includes sample meal plans for different countries and regions, along with country-specific best-practice recommendations. Chapter 7 of the IDF-DAR guidelines [Ramadan Nutrition Plan (RNP) for Patients with Diabetes] offers a full description of the RNP.

Patient should be encouraged to follow a healthy balanced diet during Ramadan. Table 1 depicts a general dietary plan for a patient planning to fast for Ramadan.

### Table 2

**Balanced meal recommendations for patients with diabetes during Ramadan**

- Divide daily calories between Suhoor and Iftar, plus 1-2 snacks if necessary
- Ensure meals are well balanced
  - 45-50% carbohydrate
  - 20-30% protein
  - <35% fat (preferably mono- and polyunsaturated)
- Include low-glycemic-index, high-fiber foods that release energy slowly before and after fasting (e.g., granary bread, beans, rice)
- Include plenty of fruit, vegetables and salads
- Minimize foods that are high in saturated fats (e.g., ghee, samosas, pakoras)
- Avoid sugary desserts
- Use small amounts of oil when cooking (e.g., olive, grapeseed)
- Keep hydrated between sunset and sunrise by drinking water or other non-sweetened beverages
- Avoid caffeinated and sweetened drinks
Patient Education Tools

Key components of a Ramadan-focused educational program

- **Risk quantification**
- **When to break the fast**
- **Blood glucose monitoring**
- **Fluids and dietary advice**
- **Medication adjustments**
- **Exercise advice**

**Figure 3**
Sleep and meal comparison between Ramadan and non-Ramadan days

**Figure 4**
Triggers for breaking the fast

**All patients should break their fast if:**
- Blood glucose <70 mg/dl (3.9 mmol/L)
- Re-check within 1 h if blood glucose 70-90 mg/dl (3.9-5.0 mmol/L)
- Blood glucose >300 mg/dl (16.6 mmol/L)*
- Symptoms of hypoglycemia, hyperglycemia, dehydration or acute illness occur

**Hypoglycemia**
- Trembling
- Sweating / chills
- Palpitations
- Hunger
- Altered mental status
- Confusion
- Headache

**Hyperglycemia**
- Extreme thirst
- Hunger
- Frequent urination
- Fatigue
- Confusion
- Nausea / vomiting
- Abdominal pain

*Consider individualized care.
Adjusting Diabetes Treatments

Table 3

Insulin dosing adjustments

<table>
<thead>
<tr>
<th>Changes to long- and short-acting insulin dosing during Ramadan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long/intermediate-acting (basal) insulin</td>
</tr>
<tr>
<td>NPH/detemir/glargine/degludec once-daily</td>
</tr>
<tr>
<td>Reduce dose by 15–30%</td>
</tr>
<tr>
<td>Take at Iftar</td>
</tr>
<tr>
<td>NPH/detemir/glargine twice-daily</td>
</tr>
<tr>
<td>Take usual morning dose at Iftar</td>
</tr>
<tr>
<td>Reduce evening dose by 50% and take at Suhoor</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fasting/pre-Iftar/pre-Suhoor blood glucose</th>
<th>Pre-Iftar*</th>
<th>Post-Iftar*/post-Suhoor**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basal insulin</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;70 mg/dL (3.9 mmol/L) or symptoms</td>
<td>Reduce by 4 units</td>
<td>Reduce by 4 units</td>
</tr>
<tr>
<td>70–90 mg/dL (3.9–5.0 mmol/L)</td>
<td>Reduce by 2 units</td>
<td>Reduce by 2 units</td>
</tr>
<tr>
<td>90–130 mg/dL (5.0–7.2 mmol/L)</td>
<td>No change required</td>
<td>No change required</td>
</tr>
<tr>
<td>130–200 mg/dL (7.2–11.1 mmol/L)</td>
<td>Increase by 2 units</td>
<td>Increase by 2 units</td>
</tr>
<tr>
<td>&gt;200 mg/dL (11.1 mmol/L)</td>
<td>Increase by 4 units</td>
<td>Increase by 4 units</td>
</tr>
</tbody>
</table>

*These recommendations also apply to adolescents with T1DM.
**Adjust the insulin dose taken before Suhoor.
NPH, neutral protamine Hagedorn

Changes to premixed insulin dosing during Ramadan

<table>
<thead>
<tr>
<th>Fasting/pre-Iftar/pre-Suhoor blood glucose</th>
<th>Premixed insulin modification</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;70 mg/dL (3.9 mmol/L) or symptoms</td>
<td>Reduce by 4 units</td>
</tr>
<tr>
<td>70–90 mg/dL (3.9–5.0 mmol/L)</td>
<td>Reduce by 2 units</td>
</tr>
<tr>
<td>90–126 mg/dL (5.0–7.2 mmol/L)</td>
<td>No change required</td>
</tr>
<tr>
<td>126–200 mg/dL (7.0–11.1 mmol/L)</td>
<td>Increase by 2 units</td>
</tr>
<tr>
<td>&gt;200 mg/dL (11.1 mmol/L)</td>
<td>Increase by 4 units</td>
</tr>
</tbody>
</table>

Changes to insulin pump use during Ramadan

<table>
<thead>
<tr>
<th>Basal rate</th>
<th>Bolus rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce dose by 20–40% in the last 3–4 hours of fasting</td>
<td>Normal carbohydrate counting and insulin sensitivity principles apply</td>
</tr>
<tr>
<td>Increase dose by 0–30% early after Iftar</td>
<td></td>
</tr>
</tbody>
</table>

Changes to MDI dosing for adolescents during Ramadan

<table>
<thead>
<tr>
<th>Long/intermediate-acting insulin</th>
<th>Short-acting insulin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reduce dose by 30–40% Take at Iftar</td>
<td>Normal dose at Iftar</td>
</tr>
<tr>
<td>Reduce Suhoor dose by 25–50%</td>
<td></td>
</tr>
</tbody>
</table>

These recommendations also apply to adolescents with T1DM and patients with T2DM.
MDI, multiple daily injections
IDF-DAR recommends against strenuous exercise due to increased risk of hypoglycemia and to avoid dehydration. Advise patients to stay hydrated through fluid intake at Iftar and Suhoor. Remind patients that their Tarawih prayers, which involve kneeling, bowing and rising for up to 1-2 hours daily, can be considered light exercise.

In addition to the patients, education of physicians, especially in Muslim-minority countries, is needed. A study in France found that among general practitioners, medical understanding of fasting in patients with diabetes during Ramadan was lacking and resulted in suboptimal advice.12 In the U.S., a study reported that while 67% of patients with diabetes consulted HCPs before Ramadan, the majority did not receive relevant advice regarding risks, breaking the fast, diet, exercise or medications.13

Risk stratification
To help HCPs deliver the best possible advice, individuals with diabetes can be stratified into different groups according to the risk fasting would impose. Factors such as the type of diabetes, level of glycemic control, medication, presence of comorbidities and personal circumstances can be used to assess individual risk. Medical experts and religious leaders have previously agreed on four categories of risk from very high to low.6,7 Table 1 describes a new risk stratification strategy provided by the IDF-DAR Practical Guidelines and defines three risk categories.

Therapy and dose adjustments for Ramadan in patients with Type 2 diabetes
Before Ramadan, the HCP should carefully review a patient’s diabetes regimen because it may need adjustment. Following is a summary of recommendations based on the IDF-DAR and American Diabetes Association guidelines.

**Oral agents.** Metformin is safe to use in Ramadan due to its low risk of hypoglycemia. However, this is not the case with secretagogues such as sulfonylureas and meglitinides. Therefore, caution needs to be used when working with these agents and, in certain cases, dose adjustment may be necessary. Studies have shown it is safe to redistribute the doses of short-acting secretagogues, taking them with Suhoor and Iftar instead of the usual three-meal dosing schedule. Sulfonylureas can be used during Ramadan but may require dose reduction in some individuals who have well-controlled pre-Ramadan blood glucose. See Table 4 for IDF-DAR guidelines on metformin and sulfonylureas dose adjustment.

Data regarding use of Acarbose during fasting periods are scarce. If used, thiazolidinediones should be started months before Ramadan to exert their full effect on glycemic control.

DPP-4 inhibitors have very low risk of hypoglycemia due to their glucose-dependent insulin secretion and delayed gastric emptying. DPP-4 can be one of the safer agents during Ramadan, as noted in the VECTOR study. Al Sifiri et al. in 2011 compared sitagliptin with various sulfonylureas (glimipiride, gliclazide and glibenclamide) and noted significantly less hypoglycemia in the sitagliptin group compared to sulfonylureas during Ramadan.25 Studies on GLP-1 agonists have yielded similar results as DPP-4 inhibitors, so their use is favored during Ramadan.21

Due to the low risk of hypoglycemia, SGLT-2 inhibitors can be favorable, but dehydration is a concern because of the mechanism of action. Wan Juani et al. showed significantly less hypoglycemia with dapagliflozin compared with sulfonylurea use dur-
ing Ramadan. In this study, a higher rate of postural hypotension was noted in the SGLT-2 group, but it did not reach statistical significance.26 There was no increased risk of dehydration observed in the group using dapagliflozin.27 More recently, Hasaanein et al. found that the risk of hypoglycemia with canagliflozin was statistically lower than with sulfonylureas, while dehydration symptoms were higher. Canagliflozin in this study was well tolerated and associated with very low rates of discontinuation or missed doses.28 IDF-DAR recommends use of SGLT-2 inhibitors with caution during Ramadan in select patients who have high risk of dehydration at baseline. No dose adjustment is needed for SGLT-2 inhibitors, and these medications should be taken with Iftar.

Insulin doses. Insulin doses should be adjusted for both Type 1 and Type 2 diabetes patients during Ramadan. Basal and bolus regimens have lower risk of hypoglycemia compared to premixed insulin formulations.22 Decrease in basal dose of insulin should be considered in both Type 1 and Type 2 diabetes patients.22 In terms of correction factor and carbohydrate ratio, the pre-dawn dose before Suhoor should be decreased to avoid daytime hypoglycemia. See Table 3 for summaries of insulin adjustment for patients with Type 2 diabetes during Ramadan.

Patients with Type 1 diabetes are at higher risk of complications compared to those with Type 2 diabetes and therefore should be advised to not fast per the IDF-DAR guidelines. Especially those with history of recurrent hypoglycemia, hypoglycemia unawareness, poor diabetes control, or simply non-compliance with medical regimen or glucose monitoring should be strongly advised against fasting for Ramadan. Patients who insist on fasting may require less basal insulin. Mucha et al. and Benbarka et al. both showed decreased glargine and basal pump infusion requirements during Ramadan.23,24 See Table 3 for dose adjustment recommendations in patients with Type 1 diabetes who are fasting for Ramadan.

Lastly, patients should be advised to monitor their blood glucose regularly to prevent and detect hypoglycemia and avoid recurrent hyperglycemia.

Conclusion
Fasting during Ramadan can be challenging for patients with diabetes and can increase risk of health complications. Therefore, it is essential to educate patients regarding the importance of blood glucose monitoring, maintaining balanced diet and avoiding strenuous exercise. HCPs should certainly review and optimize patients’ diabetes regimens for prolonged fasting during Ramadan (Figure 5). With the guidelines from IDF-DAR, patients with diabetes can participate in the holy month of Ramadan without increased risk of complications from diabetes management.1

REFERENCES
Read all of this issue’s references online at bit.ly/2DxxSMA
Transcultural awareness is an important topic that is best planned for in advance rather than learning from your mistakes.

How many times have you asked a patient how he or she plans to adjust medications for Ramadan? How many times has a patient asked for assistance in planning for Ramadan? Have you ever told a patient that he or she should not fast for Ramadan due to medical conditions? And did that patient agree to do so, or did he or she proceed with the daily fasting in spite of your advice?

The article in this issue by Drs. Verma and Hassanein describes the Diabetes and Ramadan Guidelines from the IDF-DAR Alliance that were published in April 2016.

The Diabetes and Ramadan Alliance
The Diabetes and Ramadan (DAR) Alliance was formed in January 2013 following an International Diabetes Federation-Middle East and North Africa Region (IDF-MENA region) meeting. The primary goal of the DAR Alliance is to provide a better understanding of the best strategies to manage diabetes during the month of Ramadan and provide a central location for people with an interest in diabetes and Ramadan to concentrate their efforts, including health-care professionals, patient associations, Muslim societies, and public and private stakeholders.

The IDF-DAR Guidelines are very practical and address the following issues:

- epidemiology of diabetes and Ramadan fasting;
- physiology of Ramadan fasting;
- risk stratification of individuals with diabetes before Ramadan;
- diabetes and Ramadan: a medico-religious perspective;
- pre-Ramadan education;
- Ramadan Nutrition Plan (RNP) for patients with diabetes;
- management of diabetes during Ramadan; and
- identifying and overcoming barriers to guideline implementation.

Before you start asking patients about their plans for diabetes management during Ramadan, review some of the history of Ramadan and familiarize yourself with the timing and duration.

What is Ramadan?
The word “Ramadan” comes from the Arabic root “ramiḍa” or “ar-ramaḍ,” which means scorching heat or dryness. Fasting during the month of Ramadan was made obligatory in the second year after the Muslims migrated from Mecca to Medina. The fast starts at sunrise (Suhoor) and ends at sunset (Iftar).

Ramadan, the ninth month of the Islamic calendar, is observed by Muslims worldwide as a month of fasting to commemorate the first revelation of the Quran to Muhammad. This annual observance is one of the Five Pillars of Islam. The month lasts 29 to 30 days, based on the visual sightings of the crescent moon. The end of Ramadan occurs after another crescent new moon has been sighted or the completion of 30 days of fasting if no visual sighting is possible due to weather conditions. The day after Ramadan ends, Shawwal, is the first day of the next lunar month and is called Eid al-Fitr, which is celebrated as a holiday. Fasting is not permitted on this day.

Who should fast?
Fasting is obligatory for adult Muslims, except those who are suffering from an illness, travelling, elderly, pregnant, breast-feeding, diabetic, chronically ill or menstruating. Those unable to fast make up the days missed later. This leads to many patients fasting once or twice a week throughout the year. Although fasting is not obligatory until after puberty, many children fast intermittently during Ramadan as preparation for when they will be adults.

While fasting, Muslims refrain from consuming food, drinking liquids, smoking, sexual activity and any sinful behavior that may negate the reward of fasting, such as false speech (insulting, backbiting, cursing, lying, etc.) and fighting, except in self-defense.

The fast is broken at sunset with the meal called Iftar. According to tradition, Muhammad broke his fast with three dates, so dates are usually the first food consumed. Social gatherings of family and friends are common at Iftar, which may be small or a large community banquet.

Planning for medication management during Ramadan
It is important to discuss all medical conditions with your Muslim patients to ensure they have made plans to adjust the timing of their medications. Fasting patients will not be able to take any medications or injections between sunrise and sunset. It is also important to keep in mind that Iftar, the meal just after sunset, is also a social event, so it will not be a small meal that is eaten quickly. For example, when will a patient take levothyroxine to ensure that it is

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not within two to four hours of a meal? Or what will be the timing for a blood pressure medication that is usually taken twice daily?

Planning for diabetes management during Ramadan

Although patients with diabetes are excused from fasting, many still plan to fast, so it is imperative to discuss timing and dosing of medication. Although many medications, such as sulfonylureas and rapid-acting insulin, are taken prior to meals, one cannot take a pill or injection until after the fast is broken, when the patient will not likely be in a setting in which he or she can then wait 15 to 30 minutes before starting a meal. Planning the timing of subsequent medication doses can be a challenge because the patient may be eating throughout the night (i.e., “grazing”). Lastly, one has to consider the safety of taking medication just prior to sunrise to avoid developing hypoglycemia while fasting.

Although one always hopes to complete the fast without hypoglycemia, it is necessary to discuss how to manage such events. This starts with determining what symptoms would lead the patient to check blood sugar and reviewing treatment at different glucose levels and when glucagon administration would be recommended. Involvement of family members in this discussion may be crucial. It is also important to remind the patient that if the fast must be broken for hypoglycemia, he or she may want to contact the clinic to discuss the events to devise a plan for the next day so it does not recur.

Initiating a discussion about Ramadan

Opening a dialogue related to religious issues is always sensitive. From experience, I can tell you that most patients are very happy that you are interested enough to raise this topic. It is important to plan to open the discussion well in advance, especially since we typically see patients every three to six months, so we will only see them two to three times between the end of Ramadan one year and the start the next year.

If you have had prior discussions about general Muslim dietary guidelines, the topic of Ramadan is easy to bring up. Otherwise, you will want to think creatively within your clinic structure for strategies to increase awareness of this topic. This may include having a diabetes education class focused on different religions that is offered throughout the year that can be advertised in all the exam rooms and on the TV in the waiting room. You could also put an information piece related to the IDF-DAR guidelines on your website with a link to the DAR Alliance (www.daralliance.org). The key is to be proactive in letting patients and their families know that your clinic is aware of the significance of Ramadan and that you are open to reviewing plans for management during that time each year.

Summary

The IDF-DAR guidelines are a very important document in that they provide a framework to think about Ramadan and to discuss it with patients and families. Throughout the guidelines, the importance of individualization and education within a diabetes management plan is a fundamental theme that cannot be emphasized enough. Ongoing studies are looking at implementation of these guidelines as well as testing new diabetes medications within this framework.
CONTINUOUS GLUCOSE MONITORING AND RISK OF HYPOGLYCEMIA

These papers published in the December 2017 issue of Diabetes Care summarize the recent progress in continuous glucose monitoring (CGM) measurements and interpretation, describe the properties and limitations of available CGM systems, propose minimum standards for these systems, address practical issues related to daily use and discuss proposed measures of glycemic control other than A1C, including categories of hypoglycemia and proportions of time in glucose target ranges during CGM.

Reading the editorial first and then the position statements in any order followed by reading the editorial again would be a reasonable strategy to tackle these valuable but complex issues.

EDITORIAL

Maturation of CGM and Glycemic Measurements Beyond HbA1c—A Turning Point in Research and Clinical Decisions


POSITION STATEMENTS


Title: Efficacy and Safety of Semaglutide versus Dulaglutide as Add-on to Metformin in Subjects with Type 2 Diabetes

Study Title Acronym: SUSTAIN 7

ClinicalTrials.gov Identifier: NCT02648204

References (related):


Sponsor: Novo Nordisk A/S

Study Design: Randomized, parallel assignment, open label, enrolling 1201 participants

Intervention: Patients were randomly assigned (1:1:1:1) by use of an interactive web-response system to once a week treatment with either semaglutide 0.5 mg, dulaglutide 0.75 mg, semaglutide 1.0 mg, or dulaglutide 1.5 mg subcutaneously.

Primary Outcome Measure: Change in A1C at week 40

Secondary Outcome Measures:
1. change in body weight (kg) at week 40;
2. change in fasting plasma glucose at week 40;
3. change in systolic and diastolic blood pressure at week 40;
4. change in overall scores for Diabetes Treatment Satisfaction Questionnaire at week 40; and
5. A1C below or equal to 6.5% at week 40.

Results: 1201 patients were randomized, with 94% completing the trial. The mean A1C change was compared between the low doses and high doses.

Low:
- semaglutide 0.5 mg: -1.5% (SE 0.06)
- dulaglutide 0.75 mg: -1.1% (SE 0.05)
estimated treatment difference: -0.40% [95% CI -0.55 to -0.25]; p<0.0001

High
- semaglutide 1.0 mg: -1.8 (SE 0.06)
- dulaglutide 1.5 mg: -1.4% (SE 0.06)
estimated treatment difference: -0.41% [95% CI -0.57 to -0.25]; p<0.0001

Mean bodyweight change was compared between the low doses and the high doses.

Low:
- semaglutide 0.5 mg: 4.6 kg (SE 0.28)
- dulaglutide 0.75 mg: 2.3 kg (0.27)
estimated treatment difference: -2.26 kg [-3.02 to -1.51]; p<0.0001

High
- semaglutide 1.0 mg: 6.5 kg (0.28)
- dulaglutide 1.5 mg: 3.0 kg (0.27)
estimated treatment difference: -3.55 kg [-4.32 to -2.78]; p<0.0001

Summary
This study demonstrates that when directly comparing low and high doses of semaglutide to dulaglutide, the improvements in A1C and body weight are statistically significantly better with semaglutide, with similar safety profiles.

Semaglutide is the newest GLP-1 to become available to the U.S. market. These data suggest that we may be able to get patients with A1Cs of 8.5-8.8% to goal by adding semaglutide with a concomitant weight loss of at least 10 lbs.

Title: Efficacy and Safety of Semaglutide Once-weekly versus Exenatide ER 2.0 mg Once-weekly as Add-on to 1-2 Oral Antidiabetic Drugs (OADs) in Subjects with Type 2 Diabetes (SUSTAIN™ 3 - versus QW GLP-1)

Study Title Acronym: SUSTAIN 3

ClinicalTrials.gov Identifier: NCT01885208

References (related):

Sponsor: Novo Nordisk A/S

Study Design: Randomized, parallel assignment, open label

Intervention: 1.0 mg semaglutide or 2.0 mg exenatide ER once weekly

Primary Outcome Measure: Change from baseline in A1C at week 56
Secondary Outcome Measures:
1. change from baseline in body weight at week 56;
2. change from baseline in fasting plasma glucose (FPG) at week 56;
3. change from baseline in systolic and diastolic blood at week 56;
4. change from baseline in Diabetes Treatment Satisfaction Questionnaire status (DTSQs) at week 56; and
5. subjects who achieve A1C equal to or below 6.5% at week 56.

Results: In all, 813 participants were randomized to 56 weekly treatments of semaglutide or exenatide ER.

Mean baseline A1C of 8.3% was reduced by 1.5% with semaglutide and 0.9% with exenatide ER. The estimated treatment difference for semaglutide versus exenatide ER was -0.62% [95% CI -0.80, -0.44] P < 0.0001 for noninferiority and superiority. In all, 67% of the subjects treated with semaglutide achieved A1C <7.0% versus 40% of those taking exenatide ER.

Mean body weight of 95.8 kg at baseline was reduced by 5.6 kg with semaglutide and 1.9 kg with exenatide ER for an estimated treatment difference of -3.78 kg [95% CI -4.58, -2.98]; P < 0.0001).

Summary
This study compared semaglutide directly with the once-weekly formulation of exenatide. It found that semaglutide at a dose of 1.0 mg weekly was superior to the current weekly exenatide ER dose (2.0 mg/week) at improving glycemic control and reducing body weight after 56 weeks of treatment. Safety profiles were similar between the two drugs.

This study provides more evidence of the efficacy of the newest GLP-1 and allows us to compare it to exenatide, which has been available in the U.S. since 2012. The 1.5% decrease in A1C shows that we could anticipate getting A1C to goal by adding semaglutide if a patient has an A1C of 8.5% or less on his or her current regimen. PD

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INCORPORATION OF ADA’S PSYCHOSOCIAL CARE POSITION STATEMENT INTO EVERYDAY CLINICAL PRACTICE

The year 2016 was pivotal in the field of diabetes and psychosocial support. The American Diabetes Association (ADA) revised its annual guidelines to include a position statement on the psychosocial care for people living with diabetes. Regardless of the type of diabetes, lifestyle change is required for effective management. Diabetes educators’ unique training and expertise put them in a good position to help people with diabetes manage most aspects of living with the condition. Even with the best technologies and numerous resources, it is often the psychosocial barriers that keep people from initiating and sustaining behavior change.

The general considerations for psychosocial care published by the ADA include “monitoring patient performance of self-management behaviors as well as psychosocial factors impacting the person’s self-management.”

Psychosocial needs should be addressed throughout the lives of people living with diabetes. This typically occurs during the initial diagnosis phase or if a serious complication develops, but can be neglected at other times. It is important not to forget that psychosocial needs reach outside of the realm of diabetes, too. Health-care professionals can become so preoccupied with modifying medications and discussing diet and nutrition that the patient’s beliefs and behaviors are forgotten. Measuring the patient's willingness and readiness to change is vital. This can occur with a conversation about their willingness to change and motivation to initiate change and sustain it. Finding internal motivation can help with longer-lasting behavior change.

“Consider assessment of life circumstances that can affect physical and psychological health outcomes and their incorporation into intervention strategies.”

Although managing diabetes is a 24/7 job, patients deal with other positive and negative stressors every day. Buying a house, having a family member move in, going on vacation, financial struggles and caring for a loved one can all lower the priority of managing diabetes. A physician who is a good listener can help patients prioritize steps to change. Diabetes educators often assume that diabetes self-management is the number one priority, but that is rarely the case, regardless of type of diabetes and the presence of diabetes-related complications. Other circumstances can trump managing diabetes. Knowing the appropriate time and which diabetes-related behavior to address first is important. Once patients at least somewhat improve stress management, their diabetes-related behaviors can be addressed. Be sure to consider lifestyle when helping people reach diabetes-related goals.

“Providers should consider an assessment of symptoms of diabetes distress, depression, anxiety, and disordered eating and of cognitive capacities using patient-appropriate standardized/validated tools at the initial visit, at periodic intervals, and when there is a change in disease, treatment, or life circumstance. Including caregivers and family members in this assessment is recommended.

“Addressing psychosocial problems upon identification is recommended. If an intervention cannot be initiated during the visit when the problem is identified, a follow-up visit or referral to a qualified behavioral health care provider may be scheduled during that visit.”

Most diabetes educators, regardless of discipline, have a basic understanding of psychological concerns. Each phase of living with diabetes is associated with various psychological conditions. Young-Hyman et al. suggest that there is a delineation of “nonclinical/normative” behaviors and clinical symptoms at each phase of living with diabetes to include pre-diagnosis, diagnosis of diabetes, learning stage, maintenance of behavior change, life transitions affecting the sustainment of behavior change, the influence of complications and disease progression on maintenance, and the influence of aging on behavior change. Reactions such as sadness, nervousness, changes in sleep, worrying, hopelessness and feelings of being overwhelmed are all considered normal when a person is diagnosed with a chronic condition or upon change in health status. When the psychological reactions cross over to the clinical side of the spectrum, including a behavioral health specialist such as a psychologist or psychiatrist is recommended. Ideally, this would include...
a behavioral health-care provider familiar with the daily challenges of living with diabetes.

A diabetes educator should have many tools on hand to help him or her decide when to refer a client to a behavioral health-care provider. Young-Hyman et al. provide a comprehensive list of measures for assessing psychosocial variables. The Patient Health Questionnaire (PHQ-9) is a popular nine-item screening tool used for monitoring general depressive symptoms. The MacArthur Foundation Initiative developed a toolkit to help primary care physicians evaluate and determine the best treatment plan for those who score highly on the screening instruments. Although developed for physicians, it is a good resource for other health-care providers. The MacArthur Foundation Initiative also distributes patient handouts and documents on monitoring depression symptoms as well as templates for communicating with primary care physicians. The Child Depression Inventory (CDI-2) is an assessment tool for depression in those ages 7-17. The Geriatric Depression Scale (GDS) is a similar instrument for those 55-85 years old. For anxiety, the Beck Anxiety Inventory is empirically validated, although it must be purchased from its publisher. The Diabetes Distress Scale and Problem Areas in Diabetes (PAID) measure diabetes-specific distress, with PAID versions for children, teenagers, parents and adults. Measures such as these can provide great assistance in determining when a referral to a behavioral health-care provider is warranted.

Including family members and friends of diabetes patients is essential because diabetes educators rely on self-reporting in assessing psychological distress, which has flaws, including under- and over-representation of symptoms. Including others in the assessment/interview can provide a more accurate picture of what is truly going on in the lives of people living with diabetes. It is important to judge whether you can get truthful answers from a family member when the person living with diabetes is present or if a phone call or private meeting with the family member or friend will be more valid. Adequate management of psychological concerns will yield better diabetes self-management in the long run.

People living with diabetes are far from exempt from struggling with psychological/psychiatric disorders listed in the most recent version of the Diagnostic and Statistical Manual of Mental Disorder, 5th edition (DSM-5), published in 2013. Common conditions in those living with diabetes include adjustment disorders, depressive disorders, anxiety disorders, obsessive-compulsive disorders, feeding and eating disorders, impulse control disorders and neurocognitive disorders. Symptoms of these conditions negatively influence one’s ability to monitor and manage diabetes. Noting the severity of these symptoms and the degree to which they are causing impairment in social, occupational and other important activities is essential. Without substantial impairment, one cannot be diagnosed with a disorder listed in the DSM-5. It is important to distinguish if these conditions are present in all situations or only when there are diabetes-related concerns, such as limiting food choices due to fear of not knowing an accurate carbohydrate count or refusing to have blood glucose levels under a certain range (for example <150 mg/dL) due to an irrational fear of having a hypoglycemic-induced seizure. The rationale and motivation for engaging in certain behaviors need to be discussed. If a person is being treated for a serious mental illness such as schizophrenia or bipolar disorder, then adequate medical management of these conditions is essential to expect one to engage in healthy diabetes self-management behaviors. The side effects of psychiatric medications, which can confound symptoms of diabetes, need to be considered when working with an individual with diabetes. It may be necessary to consult with the managing psychiatric provider, who may be a primary care physician, regarding an educator’s concerns about side effects of medications to determine if there are better alternatives that would not compromise the treatment of the psychiatric condition. If this is a psychiatric crisis, then that must be resolved before diabetes self-management can be expected.

Diabetes educators have many roles in working with people with diabetes. Incorporating the person living with diabetes and his or her loved ones in treatment planning is essential. Reinforcing positive behaviors, instead of focusing on what the individual is or is not doing, is helpful to maintain motivation and increase self-esteem and self-efficacy. Recognizing small goals and verbalizing them can help with motivation as well. Something as simple as validating how difficult switching to a sugar-free beverage must have been for the individual provides positive reinforcement.

Establishing rapport with an individual living with diabetes is extremely important. This can set the stage for future appointments. Educators who are warm, non-threatening, caring, non-judgmental and active listeners are usually the most successful. At times, it may be necessary to refer an individual to a mental health professional. Normalizing this process and introducing the mental health professional as part of the team can help reduce stigma associated with seeing this type of provider. A mental health professional who is knowledgeable about aspects of living with diabetes is helpful when diabetes-specific behaviors are causing a lot of the psychological distress. Delegating these types of difficult conversations to another trusted professional can help to ensure that the person living with diabetes is able to get as many of these needs met as possible to enhance quality of life.
A New Device for Foot Ulcers
The U.S. Food and Drug Administration (FDA) recently approved the marketing of the dermaPACE system, the first shockwave device for foot ulcers. Its development was based on the previous use of shockwave technology to shatter kidney stones, which led to the development of Pulsed Acoustic Cellular Expression, or PACE. The dermaPACE device is the first to employ PACE technology for wound treatment. Using energy pulses to stimulate wounds, it is intended for diabetes patients aged 22 and older who have chronic (more than 30 days), full-thickness diabetic foot ulcers that are no larger than 16 sq. cm. and that extend through the epidermis, dermis, tendon or capsule but do not involve bone exposure.

The FDA approved the device after reviewing the results of two multicenter randomized, double-blind studies. Forty-four percent of those studied experienced wound closure while receiving the PACE treatment.

A New Lyrica
The pharmaceutical company Pfizer has announced that the FDA has approved a new formulation of the drug Lyrica (pregabalin). Lyrica CR is a longer-lasting version of the original medication; unlike the previous version, Lyrica CR is taken just once a day. The FDA approval is for the management of neuropathic pain associated with diabetic peripheral neuropathy (pDPN) and the management of postherpetic neuralgia (PHN).

The efficacy and safety of the medication in PHN were determined in a randomized placebo-controlled clinical trial involving 801 patients with PHN who entered single-blind treatment. Because both pDPN and PHN are peripheral neuropathic pain conditions, the PHN data supported both the pDPN and PHN indications.

Introducing the "Sugar Sponge"
Scientists at Tongji University in Shanghai recently reported on their development of a "sugar sponge." Injected into the bloodstream of diabetes patients, the sponges are meant to soak up glucose. The sugar sponge is a lectin-bound glycopolymersome that can regulate glucose due to the dynamic recognition between the lectin and different carbohydrates. It acts as a glucose storage unit—the lectin in the sponge binds and stores the glucose from its surrounding solution when the glucose concentration is too high and releases it when the concentration is too low. In testing on mice, the sugar sponge showed an excellent antidiabetic effect, although it wore off after two days. The researchers’ next goal is to prolong the effect of the sugar sponges, perhaps to as long as a month.

Perspiration Perspectives
Researchers at the University of Texas have announced the development of a wearable device that can measure diabetes-related compounds in tiny amounts of sweat. The monitor detects amounts of cortisol, glucose and interleukin-6 (IL-6).

The device requires 1 to 3 microliters of sweat for testing. Because the device is worn continually, it gives constant readings, unlike devices that test once before being discarded. The developers expect that a wearer can use it for about a week before replacing and intend it to be affordable enough to be used in developing countries. They expect soon to have a mobile app that will enable wearers to retrieve information that will allow them to determine how habits and activities affect their diabetes management.

Victoza and Heart Health
The FDA has granted a new indication for the drug Victoza (liraglutide). Already used to control blood glucose, it is now approved for reducing the risk of major cardiovascular events in adults who have both Type 2 diabetes and cardiovascular disease.

The approval was based on the results of an international trial that studied the effect of liraglutide on 9,340 diabetes patients for a period ranging from 3½ to 5 years. The results showed a 13 percent reduction in the risk of a composite of cardiovascular death, non-fatal heart attack and non-fatal stroke compared to a placebo.

Liraglutide is the second diabetes medication to be granted a cardiovascular indication. The first was Jardiance (emagliflozin), but Victoza is the only one indicated to reduce the risk of three major adverse cardiovascular effects (heart attack, stroke and cardiovascular death).
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REFERENCES

AN INTRODUCTION TO THE DIABETES AND RAMADAN PRACTICAL GUIDELINES FROM THE IDF-DAR ALLIANCE


REFERENCES

INCORPORATION OF ADA’S PSYCHOSOCIAL CARE POSITION STATEMENT INTO EVERYDAY CLINICAL PRACTICE


