# Updates in the Management of T2DM during Ramadan

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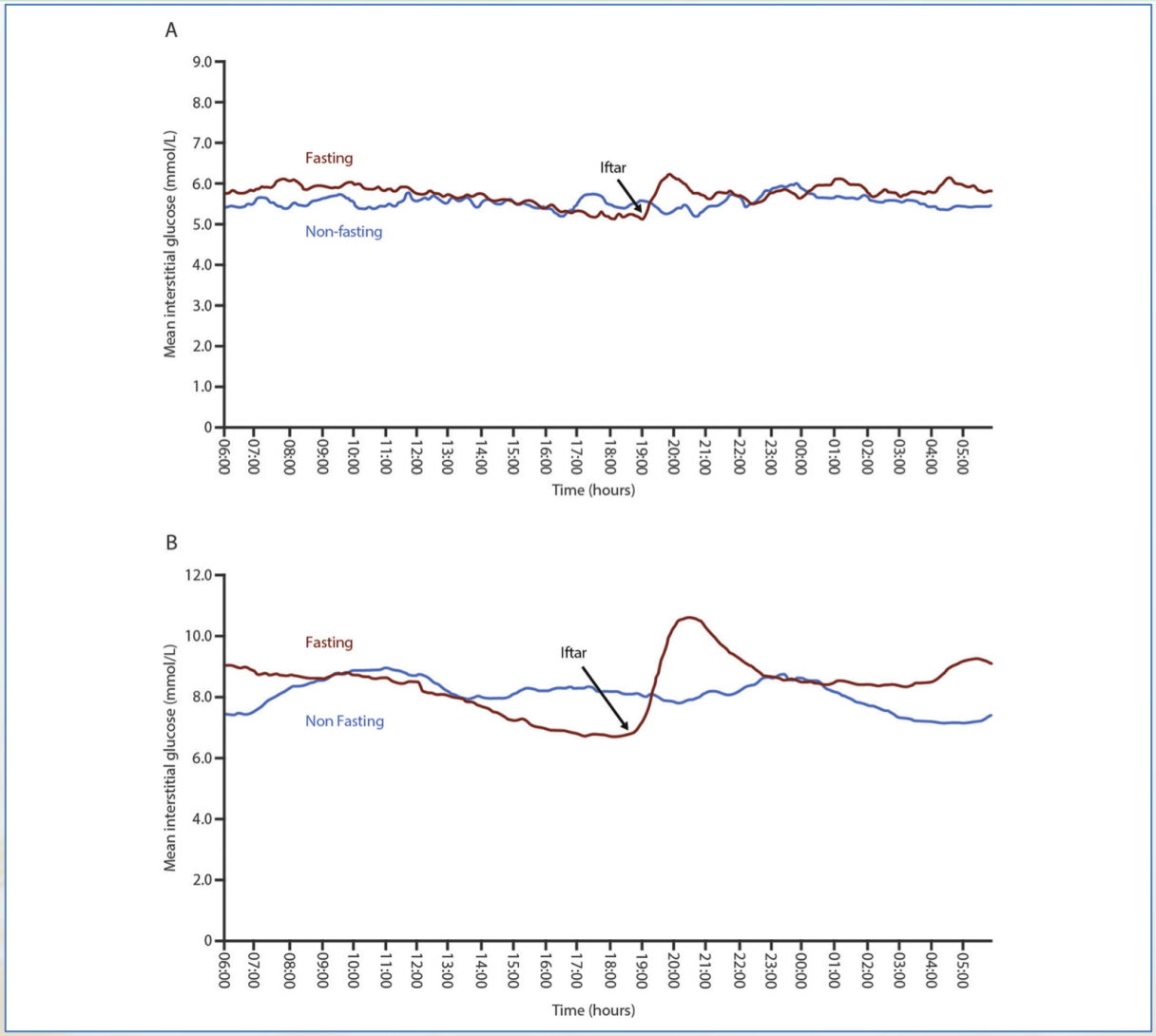
# Blood Glucose Fluctuations during Ramadan




**Fasting during Ramadan - Continuous glucose Monitoring (CGM)**
**24 hour profile**

A. **Nondiabetic**
B. **Diabetic**

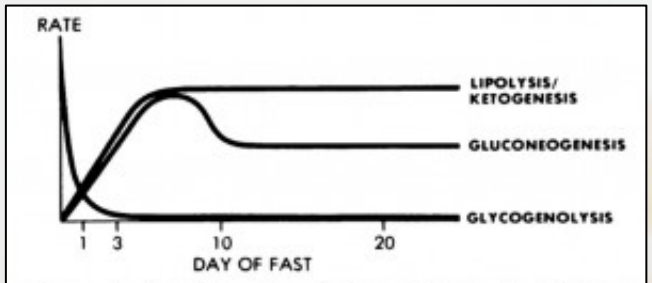



**Figure 3.**—A schematic of the changes in rates of glycogenolysis, gluconeogenesis, lipolysis and ketogenesis that are required to maintain caloric homeostasis during the transition from brief to prolonged fasting.

# Risks associated with Ramadan Fasting in Diabetics

## Hypoglycaemia

- Increase in hospitalisation due to hypoglycaemia[1]
- **Diabetics with HbA1c <8% and the elderly have more than twice the risk of developing hypoglycaemia during the fasting month[2]**

**Type 1 DM – 4.7 fold increase in Severe Hypos**

**Type 2 DM – 7.5 fold increase in Severe Hypos**
**(EPIDIAR study)**

## Hyperglycaemia/ ketoacidosis

- Increase in hospitalisation due to hyperglycaemia[1]
- **Patients who are poorly controlled before Ramadan are at an increased risk of diabetic ketoacidosis (DKA)[3]**

**Type 1 DM – 3 fold increase in Ketoacidosis**

**Type 2 DM – 5 fold increase in Ketoacidosis**
**(EPIDIAR study)**

## Dehydration

- Occurs due to limitation in fluid intake (prolonged fasting and those who perform hard and physical labour)[3]
- **Orthostatic hypotension may occur leading to syncope, falls, injuries and fractures[3]**
- 
- Hypercoagulable state in diabetes might be exacerbated, enhancing the risk of **thrombosis and stroke[3]**


**References:**

1. Salti I, Bénard E, Detournay B, et al A population-based study of diabetes and its characteristics during the fasting month of Ramadan in 13 countries: results of the epidemiology of diabetes and Ramadan 1422/2001 (EPIDIAR) study. *Diabetes Care*. 2004; 27(10): 2306-2311.
2. Loke SC, Rahim KF, Kanesvaran R, et al. A prospective cohort study on the effect of various risk factors on hypoglycaemia in diabetics who fast during Ramadan. *Med J Malaysia*. 2010; 65(1): 3-6.
3. Ministry of Health Malaysia. Practical guide to Insulin Therapy in Type 2 Diabetes Mellitus. 2010.

# Benefits of Fasting for Diabetics

- Decrease in body weight
- Improved lipid profile
- Improved glycaemic control
- Decrease in daytime average SBP and DBP in HPT
- Reduced CV disease markers – hs-CRP, PAI-1

# Pre Ramadan Assessment and Education

**Pre-Ramadan medical review**
- Performed 1-2 months before Ramadan
- Approach should be individualised
- Assessment of glycaemic control, blood pressure, and lipids

**Evaluate risk of developing complications during Ramadan**

- **Moderate risk**
- **Low risk**

**Structured Ramadan-focused patient education**
- Meal planning and dietary advice with a dietitian
- Appropriate timing and intensity of exercise
- Blood glucose monitoring
- Knowing when to end the fast
- Recognising and managing acute complications

**Treatment adjustments**

Changes to diabetes medication regimes:
- Treatment choice
- Timing and frequency of dosing
- Dosage adjustments

- **Very high risk**
- **High risk**

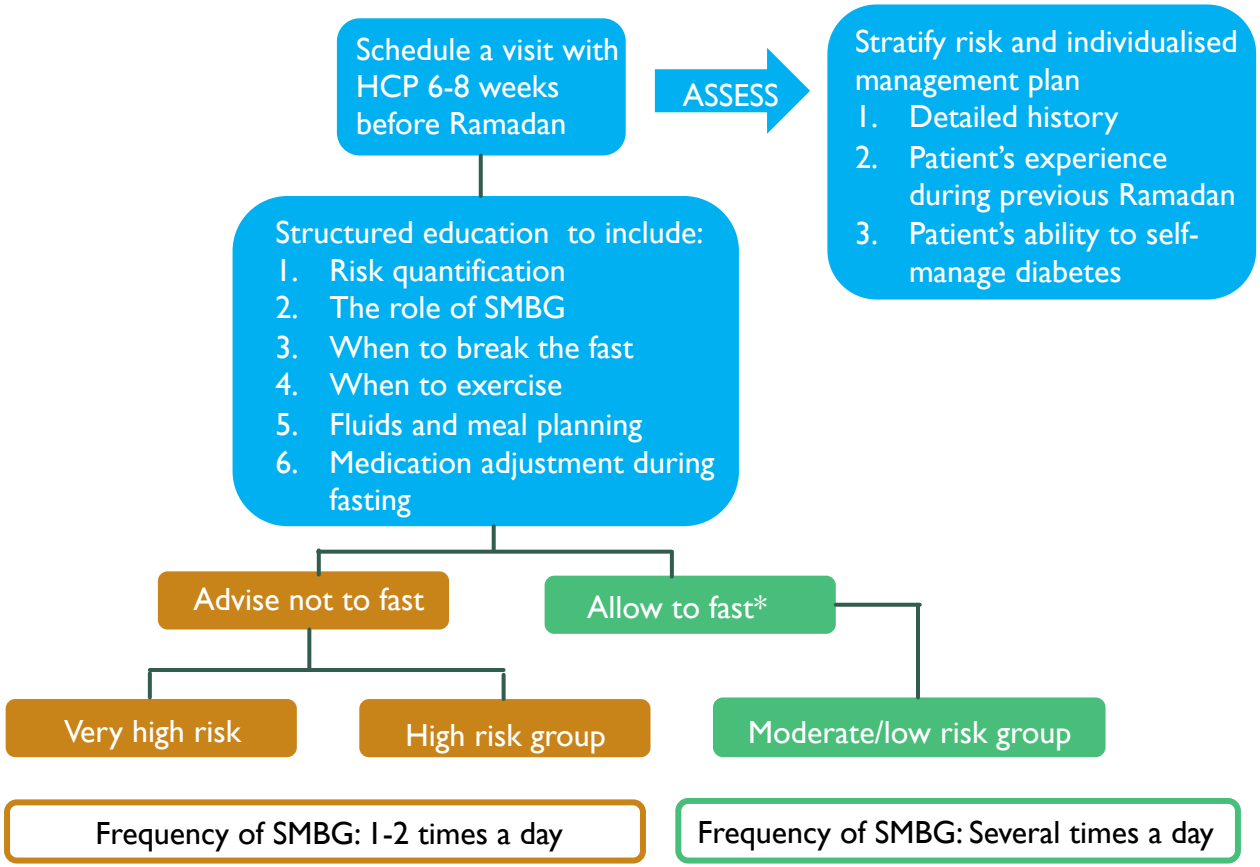
**Advised to abstain from fasting**

**Follow-up is essential after Ramadan**
- HbA1c, blood pressure, lipids
- Readjustment of medications where appropriate
- Revert back to pre-Ramadan treatment regimen

**Reference:**

1. **Ministry of Health (MOH) Malaysia. Practical Guide to Diabetes Management in Ramadan 2015.**

# Patient assessment flow




All patients should break their fast if:

- Blood glucose < 3.9 mmol/L
- Re-check blood glucose of if BG 3.9-5.0 mmol/L
- Blood glucose > 16.7 mmol/L**
- Symptoms of hypoglycaemia or acute illness occur

*Decision to fast based on medical opinion and ability of the individual to tolerate fast;
**Consider individualisation of care

*HCP, healthcare professional; SMBG, self-monitoring of blood glucose

## Metformin

- Most commonly used first-line oral anti-diabetic drug (OAD)
- It works by suppressing hepatic glucose production, enhances insulin sensitivity, enhances peripheral glucose uptake.
- No RCT on metformin use in T2DM patient during Ramadan.
- However, it is considered safe as the **likelihood of hypoglycaemia is low.**

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# Adjustment of oral anti-diabetic therapy during Ramadan.

| Regimen | | Sunset meal (*iftar*) | Pre-dawn meal (*sahur*) |
|---|---|---|---|
| **Biguanides (Metformin)** | **Immediate-release** | | |
| | Twice daily | **No changes** | **No changes** |
| | Thrice daily | **Two third of dose** | **One third of dose** |
| | **Extended-release** | **Full dose** | **None** |
| α-glucosidase inhibitors | | No changes | No changes |
| Sulphonylurea | Glibenclamide, Gliclazide | No changes | Reduce / Omit |
| | Gliclazide MR, Glimepiride | | Sunset meal dosing |
| Meglitinides | | No changes | No changes |
| Thiazolidinediones | | No changes | None |
| Dipeptidyl peptidase-4 inhibitors | | No changes | No changes |
| Sodium glucose co-transporter 2 inhibitors* | | No changes | Sunset meal dosing |

* Based on expert opinion

1. Almaatouq MA. *Diabetes Metab Syndr Obes.* 2012; 5: 109-119.

## Acarbose

- It inhibits the actions of alpha-glucosidase, thereby slowing down the absorption of glucose and modifying insulin secretion.
- No dose adjustment of acarbose is needed during Ramadan as the risk of **hypoglycaemia is low.**

Aravind S, et al. Curr Med Res Opin 2011;27:1237-42

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| | Immediate-release Thrice daily | | |
| | Extended-release | Full dose | None |
| α-glucosidase inhibitors | | No changes | No changes |
| Sulphonylurea | Glibenclamide, Gliclazide | No changes | Reduce / Omit |
| | Gliclazide MR, Glimepiride | | Sunset meal dosing |
| Meglitinides | | No changes | No changes |
| Thiazolidinediones | | No changes | None |
| Dipeptidyl peptidase-4 inhibitors | | No changes | No changes |
| Sodium glucose co-transporter 2 inhibitors* | | No changes | Sunset meal dosing |

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1. Almaatouq MA. *Diabetes Metab Syndr Obes.* 2012; 5: 109-119.

## Sulphonylurea

- It stimulates insulin secretion from pancreatic β cells in a glucose-independent process.
- Widely used in T2DM patients.
- Higher risk of hypoglycaemia.
- The risk increases exponentially in **elderly patients** and patients with **renal failure and medical illnesses** treated with sulfonylureas.
- **Glimepiride, glipizide and gliclazide have more favourable safety profile in terms of hypoglycaemia.**
- Patients with T2DM may continue to use 2nd SUs and fast safely during Ramadan.
- **Glibenclamide should be avoided**

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## Changes to SU dosing during Ramadan

| Once-daily dosing | Twice-daily dosing | Older drugs in the class |
|---|---|---|
| Take at iftar | Iftar dose remains the same | Glibenclamide carry a higher risk of hypoglycaemia and should be avoided |
| In patients with well-controlled BG levels, the dose may be reduced | In patients with well-controlled BG levels, the suhoor dose should be reduced | 2nd - generation SUs (gliclazide glimepiride) should be used in preference |

BG, blood glucose; SU, sulphonylurea

| | | | |
|---|---|---|---|
| **Sulphonylurea** | Glibenclamide, Gliclazide | No changes | Reduce / Omit |
| | Gliclazide MR, Glimepiride | | Sunset meal dosing |
| Meglitinides | | No changes | No changes |
| Thiazolidinediones | | No changes | None |
| Dipeptidyl peptidase-4 inhibitors | | No changes | No changes |
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| | Thrice daily | Two third of dose | One third of dose |
| | Extended-release | Full dose | None |
| α-glucosidase inhibitors | | No changes | No changes |
| Sulphonylurea | Glibenclamide, Gliclazide | No changes | Reduce / Omit |
| | Gliclazide MR, Glimepiride | | Sunset meal dosing |
| **Meglitinides (repaglinide, nateglinide)** | | No changes | No changes |
| Thiazolidinediones | | No changes | None |
| Dipeptidyl peptidase-4 inhibitors | | No changes | No changes |
| Sodium glucose co-transporter 2 inhibitors* | | No changes | Sunset meal dosing |

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| Sulphonylurea | Glibenclamide, Gliclazide | No changes | Reduce / Omit |
| | Gliclazide MR, Glimepiride | | Sunset meal dosing |
| Meglitinides | | No changes | No changes |
| **Thiazolidinediones (pioglitazone)** | | No changes | None |
| Dipeptidyl peptidase-4 inhibitors | | No changes | No changes |
| Sodium glucose co-transporter 2 inhibitors* | | No changes | Sunset meal dosing |

* Based on expert opinion

1. Almaatouq MA. *Diabetes Metab Syndr Obes.* 2012; 5: 109-119.

## Dipeptidyl peptidase-4 (DPP-4) inhibitors

- It inhibit the DPP-4 enzyme responsible for the degradation of endogenous GLP-1, effectively increase the circulating levels of GLP-1, which in turn stimulates insulin secretion in a glucose-dependent manner.
- **Low risk of hypoglycaemia**
- No treatment dose modification during Ramadan.
- Studies for Sitagliptin and Vildagliptin in Ramadan compared to SU – less hypoglycaemia

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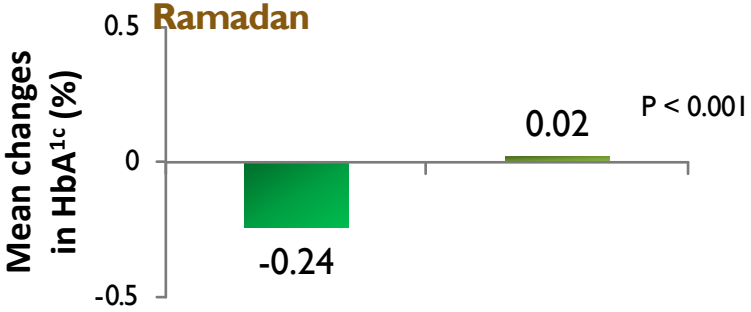
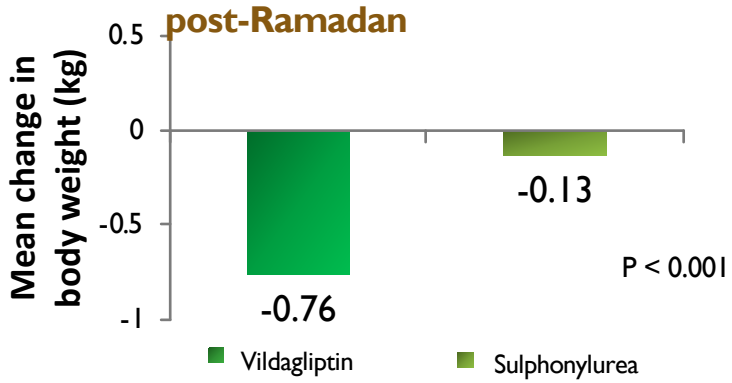
# VIRTUE STUDY: Safety and Efficacy of Vildagliptin during Ramadan.

Fewer patients experienced hypoglycaemia in the vildagliptin therapy compared to SU therapy.

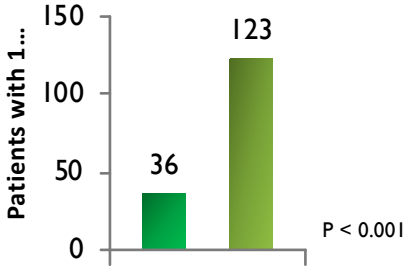
**Mean change HbA1c pre- to post-Ramadan**

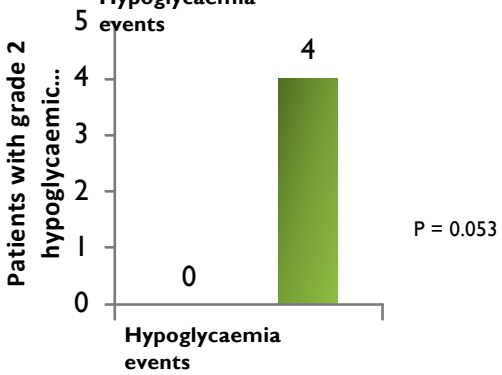



**Mean change body weight pre- to post-Ramadan**



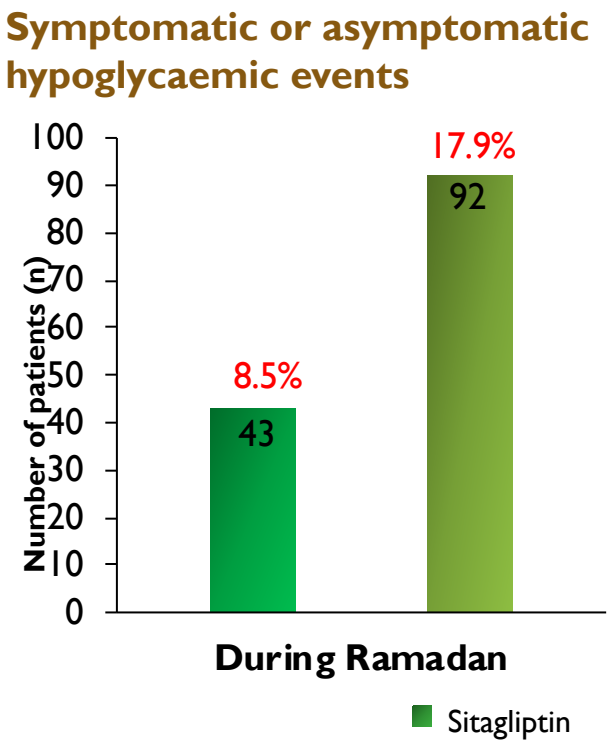

**Number of patients with hypoglycaemic events during Ramadan**

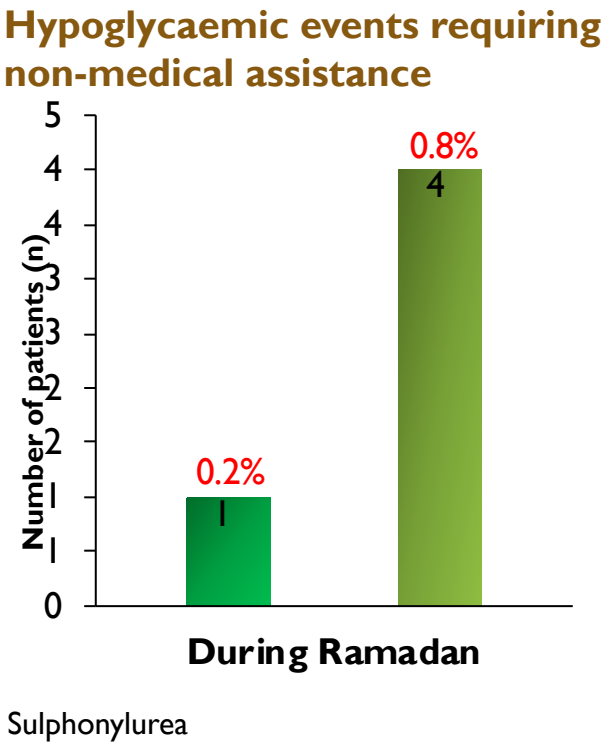



Al-Arouj M et al. The VIRTUE study. *Int J Clin Pract.* 2013; 67(10): 957-963.

# In T2DM patients, switching treatment to Sitagliptin reduces the risk of hypoglycaemia compared to sulphonylurea during Ramadan.




1. Al Sifri, Basiounny A et al. *Int J Clin Pract.* 2011; 65(11): 1132-1140.

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| **Dipeptidyl peptidase-4 inhibitors** | | No changes | No changes |
| Sodium glucose co-transporter 2 inhibitors* | | No changes | Sunset meal dosing |

* Based on expert opinion

1. Almaatouq MA. *Diabetes Metab Syndr Obes.* 2012; 5: 109-119.

## Sodium-glucose co-transporter-2 (SGLT2) inhibitors

- It increases excretion of glucose by the kidneys by **reducing reabsorption in the proximal tubule**, consequently decreasing blood glucose.
- It has low risk of hypoglycaemia.
- A survey of physicians' view (70.6%) reported that SGLT2 inhibitors is suitable and safe for some patients during Ramadan.
- Patients that are at risk of complications such as the elderly, patients with renal impairment, hypotensive individuals, those at risk of dehydration or those taking diuretics should not be treated with SGLT2 inhibitors.
- SGLT2 inhibitors should be taken with iftar and the importance of taking on extra fluids during the evening after a fast.

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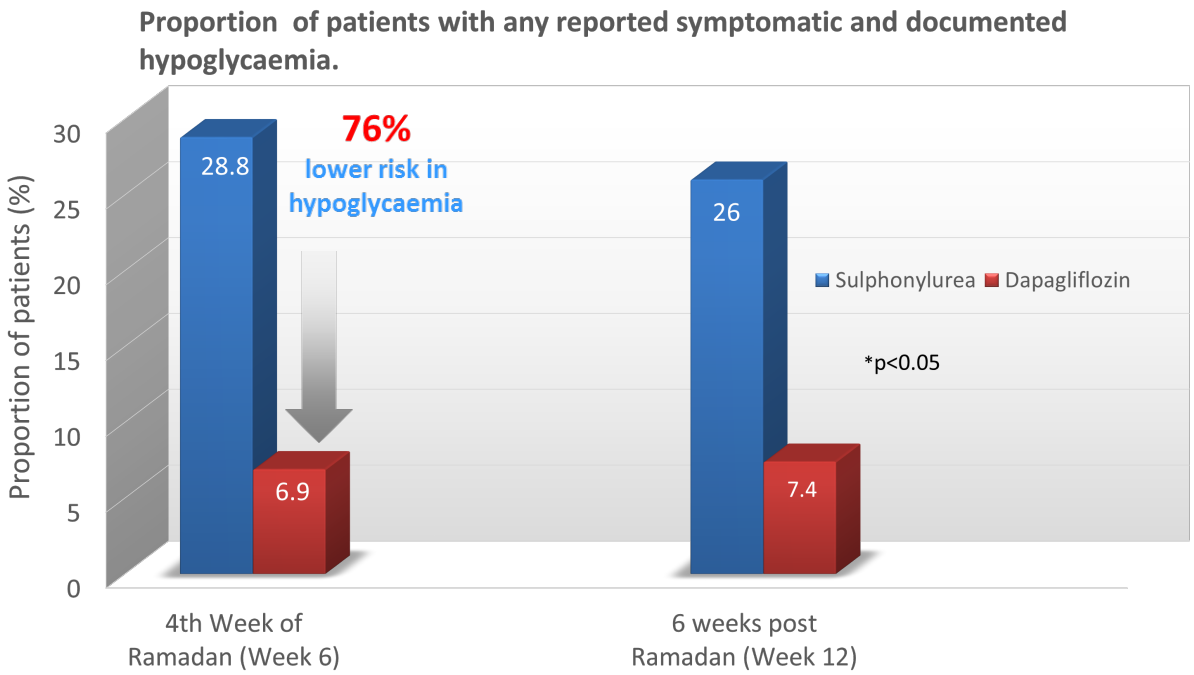
# Patients switched from Sulphonylurea to SGLT2 inhibitor have 76% lower risk in hypoglycaemia during Ramadan.




*Level of significance p<0.05 between dapagliflozin and SU.

*Wan Juani WS et al* Diabetes, Obesity and Metabolism 2016.

**Safety And Tolerability Of Dapagliflozin And Sulphonylurea.**

| | Week 6 | | Week 12 | |
|---|---|---|---|---|
| | Dapagliflozin + Metformin (n=58) | Sulphonylurea + Metformin (n=52) | Dapagliflozin + Metformin (n=54) | Sulphonylurea + Metforminn (n=50) |
| One or more adverse events (AE) | 20 (34.5) | 18 (34.6) | 16 (29.6) | 11 (22.0) |
| Symptomatic hypoglycaemia† | 2 (3.4) | 10 (19.2) | 4 (6.9) | 9 (17.3) |
| Documented hypoglycaemia.* | 4 (7.3) | 13 (27.1) | 1 (1.9) | 7 (15.2) |
| Urinary Tract Infection | 6 (10.3) | 2 (3.8) | 6 (11.1) | 3 (6) |
| Genital Tract Infection | 3 (5.2) | 3 (5.8) | 1 (1.9) | 2 (4.0) |
| Postural Hypotension | 8 (13.8) | 3 (5.8) | 3 (5.7) | 2 (4.0) |
| Others‡* | 7 (12.1) | | 6 (11.1) | |
| Serious adverse events (SAE) | 1 (1.7) | | 0 (0) | |
| Any hospital admission~ | 1 (1.7) | | 0 (0) | |

- Polyuria (1.7%)
- Thirst Sensation (3.4%)
- Itchiness (1.7%)
- Dry skin (1.7%)
- Nausea (1.7%)
- Lethargy (1.7%)

- Thirst sensation (5.6%)
- Itchiness (1.8)
- Vagina dryness (1.8%)
- Lethargy (1.8)

*level of significance p<0.05 between groups at week 6 and 12. †p< … uded adverse events such as polyuria, excessive thirst, itchiness, skin dryness, nausea, lethargy and vaginal dryness.~hospita… …ia.

- **No difference in overall adverse events** between the two groups.
- More urinary tract infections were reported in patients receiving dapagliflozin.
- Other adverse events were mild and self-limiting.
- No hospital admission for hypoglycaemia, uncontrolled DM or DKA.

*Wan Juani WS et al* Diabetes, Obesity and Metabolism 2016.

## Sodium-glucose co-transporter-2 (SGLT2) inhibitors

- A survey of physicians' view (70.6%) reported that SGLT2 inhibitors is suitable and safe for some patients during Ramadan.
- Patients that are at risk of complications such as the elderly, patients with renal impairment, hypotensive individuals, those at risk of dehydration or those taking diuretics **should not** be treated with SGLT2 inhibitors.
- **SGLT2 inhibitors should be taken with iftar and the importance of taking on extra fluids during the evening after a fast**.

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| | Extended-release | Full dose | None |
| α-glucosidase inhibitors | | No changes | No changes |
| Sulphonylurea | Glibenclamide, Gliclazide | No changes | Reduce / Omit |
| | Gliclazide MR, Glimepiride | | Sunset meal dosing |
| Meglitinides | | No changes | No changes |
| Thiazolidinediones | | No changes | None |
| Dipeptidyl peptidase-4 inhibitors | | No changes | No changes |
| **Sodium glucose co-transporter 2 inhibitors*** | | No changes | Sunset meal dosing |

* Based on expert opinion

1. Almaatouq MA. *Diabetes Metab Syndr Obes.* 2012; 5: 109-119.

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| **Thiazolidinediones** | | No changes | None |
| **Dipeptidyl peptidase-4 inhibitors** | | No changes | No changes |
| **Sodium glucose co-transporter 2 inhibitors*** | | No changes | Sunset meal dosing |

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# GLP1- Receptor Analogues / Agonists

- Injectable incretin therapies
- Daily or weekly subcutaneous injections
- Increase GLP-1 levels to supraphysiological levels – promote endogenous meal related insulin secretion and inhibit glucagon secretion
- Low risk of hypoglycaemia
- Best not to initiate just before / during Ramadan as GI side effects in first few weeks of therapy
- Those on stable doses, should continue with no need for adjustment

Liraglutide – once daily

Dulaglutide, Exenatide QW, Semaglutide – once weekly

# Insulin Adjustment during Ramadan – Basal Insulin

| Insulin regimen | Type 1 diabetes mellitus | Type 2 diabetes mellitus |
|---|---|---|
| **Basal insulin only[1-4]** | | |
| | Not applicable. | Taken at bedtime or any time after *iftar* meals.<br>May require dose reduction if there is risk of daytime hypoglycaemia. |

- Insulin glargine can be given once daily any time after *iftar.*
- Insulin levemir and NPH insulin can be given either once daily at bedtime or divided into twice daily during pre-dawn meal (*sahur*) and *iftar*.[1]


References:

1. Al-Arouj M, Assaad-Khalil S, Buse J, et al. Recommendations for management of diabetes during Ramadan: update. 2010. Diabetes Care. 2010; 33(8): 1895-902.
2. Ministry of Health Malaysia. Practical guide to Insulin Therapy in Type 2 Diabetes Mellitus. 2010.
3. Pathan MF, Sahay RK, Zargar AH, South Asian Consensus Guideline: Use of insulin in diabetes during Ramadan. Indian J Endocrinol Metab. 2012; 16(4): 499-502.
4. Hui E, Devendra D. Diabetes and fasting during Ramadan. Diabetes Metab Res Rev. 2010; 26(8): 606-610.

# Insulin Adjustment during Ramadan – Premixed Insulin

| Insulin regimen | Type 1 diabetes mellitus | Type 2 diabetes mellitus |
|---|---|---|
| **Premixed insulin once daily[1-4]** | | |
| | Not applicable. | Inject usual dose at *iftar* meals. |
| **Premixed insulin twice daily[1-5]** | | |
| | **Reverse doses**<br>Morning dose given at *iftar* and evening dose given at *sahur.* | |
| *Sahur* | Insulin dose reduced by 20-50% to prevent daytime hypoglycaemia. | Insulin dose reduced by 20-50% to prevent daytime hypoglycaemia.<br>OR<br>Change to short/rapid acting.*<br>* Late afternoon hypoglycaemia may occur |
| *Iftar* | Switch to mid/high premixed (ie. Mix50) insulin | |


References:
1. Al-Arouj M, Assaad-Khalil S, Buse J, et al. Recommendations for management of diabetes during Ramadan: update. 2010. Diabetes Care. 2010; 33(8): 1895-902.
2. Ministry of Health Malaysia. Practical guide to Insulin Therapy in Type 2 Diabetes Mellitus. 2010.
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4. Hui E, Devendra D. Diabetes and fasting during Ramadan. Diabetes Metab Res Rev. 2010; 26(8): 606-610.
5. Hui E, Bravis V, Salih S, et al. Comparison of Humalog Mix 50 with human insulin Mix 30 in type 2 diabetes patients during Ramadan. Int J Clin Pract. 2010; 64(8): 1095–1099.

# Insulin Adjustment during Ramadan – Basal Bolus Insulin and Insulin Pump

| Insulin regimen | Type 1 diabetes mellitus | Type 2 diabetes mellitus |
|---|---|---|
| **Basal bolus insulin[1-4]** | | |
| **Basal insulin** | Taken at bedtime or any time after *iftar* meals. May require dose reduction if there is daytime hypoglycaemia. | |
| **Bolus/Prandial insulin**<br>*Sahur* | Usual pre-Ramadan breakfast or lunch dose. May require dose reduction to avoid daytime hypoglycaemia.<br><br>Omit. | |
| Lunch<br><br>*Iftar* | Usual pre-Ramadan dinner dose. May require dose increment.<br>* Total insulin requirement for Type 1 diabetics who are on basal bolus insulin regimen while fasting during Ramadan may require dose reduction 15–30% of their pre-Ramadan dose requirements. | |
| **Insulin pump[5-7]** | | |
| Basal insulin rate | Unchanged or may require reduction of up to 25%. | |
| Prandial bolus | According to individualised insulin to carbohydrate ratio (ICR). | |


**References:**

1. Al-Arouj M, Assaad-Khalil S, Buse J, et al. Recommendations for management of diabetes during Ramadan: update. 2010. Diabetes Care. 2010; 33(8): 1895-902.
2. Ministry of Health Malaysia. Practical guide to Insulin Therapy in Type 2 Diabetes Mellitus. 2010.
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4. Hui E, Devendra D. Diabetes and fasting during Ramadan. Diabetes Metab Res Rev. 2010; 26(8): 606-610.
5. Bin-Abbas BS. Insulin pump therapy during Ramadan fasting in Type 1 diabetic adolescents. Ann Saudi Med. 2008; 28(4): 305-306.
6. Hawli YM, Zantout MS, Azar ST. Adjusting the basal insulin regimen of patients with Type 1 diabetes mellitus receiving insulin pump

# CONCLUSION

- A **pre-Ramadan assessment is vital** for any patient with diabetes who intends to fast to evaluate the risks, education on self-management of the condition during Ramadan and to produce a patient-specific treatment plan.

- Patients taking **short-acting insulin secretagogues and SUs** will need to make adjustments to dose and or timings to reduce the risk of hypoglycaemia while maintaining good glycaemic control.

- **Newer OADs** including **incretin-based therapies** are associated with a **lower risk of hypoglycaemia** and may be preferable for use during Ramadan.

- **SGLT2 inhibitors** are probably safe but should be used with caution in some patients. More data regarding the use of SGLT2 inhibitors during Ramadan are required.

- **With the correct advice and support from HCPs most people with T2DM can fast safely during Ramadan.**