



Review

The effect of Ramadan fasting on glycaemic control in insulin dependent diabetic patients: A literature review

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ABSTRACT

Background: Ramadan fasting is one of the five pillars of Islam. People with diabetes are exempted from fasting according to Islamic rules. However, many people with diabetes wish to fast. Physicians are asked frequently by their patients about their ability to fast and the possible impact of fasting on their glycaemic control. Studies about the effect of Ramadan on people with insulin-treated diabetes are scarce. This review aims to provide clinicians with the best recommendations for their patients with insulin-treated diabetes who wish to fast.

Methods: Four databases (Medline, EMBASE, Scopus and PubMed) were searched using the following MeSH terms and keywords: “insulin dependent diabetes mellitus”, “type 1 diabetes mellitus”, ‘Ramadan’ “and” “fasting”. In addition, a hand search of key journals and reference lists was performed. Sixteen full text articles were selected for review and critical analysis.

Results: All of the included studies except one found improvement or no change in glycaemic control parameters during Ramadan fasting. The incidence of major complications were negligible. Minor hypoglycaemic events were reported in some studies but did not adversely affect fasting. Postprandial hyperglycaemia was a major concern in other studies. However, the incidence of severe hyperglycaemia and diabetic ketoacidosis were trivial.

Conclusion: Ramadan fasting is feasible for insulin dependent diabetic patient who wish to fast. Clinicians should advise their patients about the importance of adequate glycaemic control before Ramadan and frequent glucose monitoring during fasting. Certain types of Insulin seem to be more beneficial than other.

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1. Introduction

Ramadan fasting is one of the five pillars of Islam [1]. Every healthy adult Muslim must abstain from food and drink during the lunar month of Ramadan from sunrise to sunset. They can eat and

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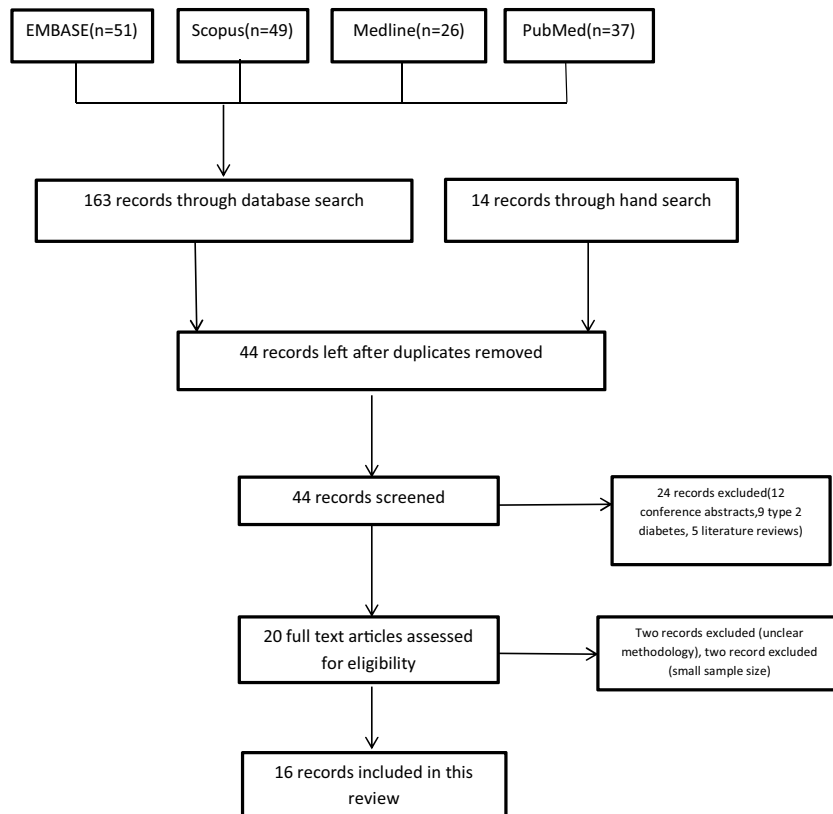
drink freely during night hours. There are two main meals; one small and low caloric meal before sunrise at dawn (sohur) and another large high caloric meal just after sunset (iftar) [2]. This change in dietary habit represents a challenge to both patients and their caring clinicians and may affect glycaemic control adversely leading to major complications like hypoglycaemia, hyperglycaemia and diabetic ketoacidosis (DKA) [2]. Despite the fact that Islamic rules have exempted unhealthy Muslims from fasting including those with diabetes mellitus, many wish to fast and feel guilty if do not. The number of diabetic Muslims who fast is estimated to be 50 million annually [3]. In addition, approximately half of type 1 diabetic Muslims fast every year [4]. Those patients feel obliged to fast during Ramadan and this obligation must be respected by physicians [5]. In countries where Muslims are in preponderance, physicians are always challenged by their patients' inquiries about their ability to fast and the effect of fasting on their plasma glucose control. Physicians should provide clear and evidence-based advice to their patients who intend to fast [6]. Type 1 diabetes has been identified by the American Diabetes Association and the International Consensus Meeting on diabetes and Ramadan (held in Morocco in 1995) as one of the major risk factors for hypoglycaemia in patients who fast based mostly on

Table 1
EMBASE search strategy.

1. [ramadan.mp](#)
2. insulin dependent diabetes mellitus/
3. 1 and 2
4. limit 3 to human
5. limit 4 to English language

2. Methods

Four databases (Medline, EMBASE, Scopus and PubMed) were searched using the following MeSH terms and keywords: "insulin dependent diabetes mellitus", "type 1 diabetes mellitus", 'Ramadan' "and" "fasting". A detailed search strategy of EMBASE is shown in Table 1. In addition, a hand search of key journals and reference lists was performed. Duplicates were removed and only full text, English articles, systematic reviews, randomized controlled trials, cohort, case controlled studies and some case series that included in its methodology insulin dependent diabetic patients who fasted Ramadan partially or completely were included. On the other hand, reviews and conference abstracts were excluded. A flow diagram showing the search result is shown below. Ultimately, sixteen



experts' opinion at that time [4,7]. Reviews about the effect of Ramadan fasting on glycaemic control in insulin dependent diabetes mellitus are scarce. This review will discuss the effect of Ramadan fasting on glycaemic control and the incidence of complications like hypoglycaemia, hyperglycaemia and DKA in insulin dependent diabetic patients who fast. This review aims to provide clinicians with the best recommendations for their patients in this regard.

relevant studies were included in this narrative review. Most of the studies were observational except for two case-control studies [2,8] and two randomized trials [9,10]. Two studies were conducted on children [2,5] and one study was on pregnant women [9]. All of the studies except one [4] had small sample sizes. Eight out of the sixteen studies included insulin dependent diabetics exclusively [5,9–15]. Data related to insulin management was reviewed from the remaining studies.

3. Results

The following data were extracted from the selected 16 articles: authors, year, country, study design, sample size and results' summary as shown in Table 2. Three studies found Ramadan fasting resulted in significant improvement in glycaemic parameters such as fructosamine and glycated haemoglobin (HbA1c) [11–14]. Three recorded severe complications such as severe hypoglycaemia (defined as hypoglycaemia necessitating help from others), severe hyperglycaemia and DKA in insulin dependent patients who fast during Ramadan [2,5,8,9,11–17]. However two studies found the incidence of major complications was negligible [1,3]. In one study, the incidence of severe hypoglycaemia in insulin

dependent patients was 0.14 episode/month during Ramadan versus 0.03 episode/month before Ramadan, ($p=0.0174$) [4]. Comparison of different forms of insulin was studied in five studies [5,9,10,13,16]. None of the five studies recorded severe complications. The effect of Ramadan on glycaemic control, hypoglycaemia and hyperglycaemia rates will be discussed in more details in the following paragraphs.

3.1. Effect of Ramadan fasting on glycaemic control

There are several means to gauge glycaemic control. These include mean blood glucose, HbA1c, fructosamine, mean interstitial glucose (measured by a continuous glucose monitoring probe

Table 2
The characteristics of the included studies.

first author (year)	Country	Design	sample size	Results
Ahmadani (2008) [6]	Pakistan	Retrospective survey	132	4% major hypoglycaemia, 8% hyperglycaemia.
Ahmedani (2014) [7]	Pakistan	Prospective pre and post-Ramadan interview	335	No DKA or severe hypoglycaemia.
Ahmedani (2012) [8]	Pakistan	Prospective study	74	No DKA, one severe hypoglycaemia. MBG reduced from 12.47 ± 3.94 mmol/L to 8.67 ± 1.92 mmol/L; $p < 0.000$.
Alalwan (2010) [9]	Saudi Arabia	Case-control (fasting vs non-fasting) (children)	20	No difference in HbA1c ($p=0.9$)
Al-Khawari (2010) [1]	UK	Prospective observational (children)	22	Hypoglycaemia and hyperglycaemia were more in premixed than basal-bolus insulin.
Benbaraka (2010) [10]	UAE	Prospective observational (two weeks before and two weeks after Ramadan)	49	Fructosamine reduced from 4.0 ± 0.6 before Ramadan to 3.6 ± 0.6 mmol/L after Ramadan ($P=0.007$).
Bin-Abbas (2007) [2]	Saudi Arabia	Observational study (CSII vs CI)	9	HbA1c 7.8% (7.1–8.9%) in CSII vs. 9.1% (8.3–10.6%) in CI ($p < 0.001$). MBG 123 mg/dl (72–201) in CSII vs. 192 (122–394) in CI ($p < 0.001$). Hypoglycaemia 16 episodes in CSII vs. 29 episodes in CI ($p < 0.002$).
Cesur (2004) [11]	Turkey	Open-label, prospective, observational study	10	No statistically significant difference in HbA1c .
Hui (2010) [3]	UK	Prospective observational study (Humalog Mix 50 vs human insulin Mix 30)	52	HbA1c reduced from $9.05 \pm 0.43\%$ before Ramadan to $8.56 \pm 0.62\%$ post-Ramadan ($p 0.0004$) in the Humalog Mix 50 group.
Kadiri (2001) [4]	Saudi Arabia, UAE, Egypt, Kuwait, Pakistan and Morocco	Open label randomized cross-over trial (Lispro vs regular insulin)	64	Hypoglycaemia frequency/patient 0.70 ± 0.19 in Lispro vs. 2.25 ± 0.36 in regular insulin ($p < 0.001$)
Khalil (2012) [12]	UAE	Prospective observational study (insulin pump)	21	No changes in HbA1c or average blood glucose. No major hypoglycaemic episode.
Kassem (2005) [13]	Lebanon	Prospective observational (ultralente insulin)	17	No change in HbA1c or hypoglycaemic episode.
Lessan (2015) [14]	UAE	Case-control study (continuous glucose monitoring over two days)	13	MAGE 9.8 ± 3.4 in fasting vs. 7.4 ± 4.0 (mmol/L) in non-fasting.
Mattoo (2003) [5]	India, Pakistan, Malaysia, Singapore, Egypt, Morocco and South Africa	Open label, randomized, crossover study. (Insulin Lispro mix 25 vs human insulin 30/70)	151	2 h PPG excursion post-iftar in Lispro Mix 30 (3.4 ± 2.4 mmol/L) compared to Human insulin 30/70 (4.0 ± 3.2 mmol/L), $p=0.007$. The average daily BG in Lispro Mix 25 9.5 ± 2.4 mmol/L compared to 10.1 ± 0.5 mmol/L in human insulin 30/70, $p=0.004$.
Nor Azlin (2011) [15]	Malaysia	Prospective cohort (pregnant women in second trimester on twice daily NPH insulin)	24	Mean FBS 6.16 mmol/L before Ramadan vs. 5.34 mmol/L after Ramadan ($P=0.001$); HbA1c $6.70\% \pm 0.91$ before Ramadan vs. $6.64\% \pm 0.96$ after Ramadan ($P=0.001$); fructosamine 232.4 mmol/L ± 24.0 before Ramadan vs. 217.0 mmol/L ± 24.3 after Ramadan ($P=0.001$).
Salti (2004) ^a [16]	13 countries ^b	Retrospective transversal survey	1070	Severe hypoglycaemia 0.14 episode/month during Ramadan vs. 0.03 episode/month before Ramadan ($P=0.0174$).

BG: blood glucose, CI: conventional insulin, CSII: continuous subcutaneous insulin infusion, FBS: fasting blood sugar, MAGE: mean amplitude of glucose excursions, PPG: post prandial glucose, vs.: versus.

^a EPIDIAR study: Epidemiology of Diabetes and Ramadan study.

^b Algeria, Bangladesh, Egypt, India, Indonesia, Jordan, Lebanon, Malaysia, Morocco, Pakistan, Saudi Arabia, Tunisia and Turkey.

inserted in the interstitial tissue), MAGE (a measure of blood glucose volatility) and mean continuous glucose monitoring. Unlike HbA1c which reflects the average plasma glucose level over a period of 12–16 weeks, fructosamine reflects the average plasma glucose over a period of 2–3 weeks only [18]. This suggests that the latter may be a more reliable indicator of glycaemic control for short periods of fasting in Ramadan.

Two studies found serum fructosamine level reduced significantly after Ramadan (from 4.0 ± 0.6 mmole/L to 3.6 ± 0.6 mmole/L, $p=0.007$, and from 232.4 ± 24 mg/dl to 217 ± 24.3 mg/dl, $p=0.001$, respectively) [11,14]. The first study involved 49 patients on insulin infusion pump; nearly half of them had reduced their pre-fasting basal Insulin dose by 5–50% during Ramadan [11]. Cesur et al. compared two oral hypoglycaemic drugs versus Insulin glargine found a non-significant rise of fructosamine from 266.4 ± 35.2 mg/dl to 268.8 ± 41.1 mg/dl immediately after Ramadan in the glargine group; however, this increment was statistically insignificant [12]. This study was underpowered by the small sample size (10 patients).

Measuring HbA1c at one month interval is not an ideal method to assess glycaemic control [12]. However, Nor Azlin et al. found HbA1c significantly reduced from 6.70 ± 0.91 before Ramadan to 6.64 ± 0.96 after (95% CI=0.15 to 0.43; $p=0.001$) in 24 pregnant women in their second trimester on neutral protamine hagedron insulin (NPH) [14]. Similarly, Hui et al. compared the effect of Humalog Mix 50 (50% Lispro and 50% neutral Protamine Lispro) to Human insulin Mix 30 (30% Human insulin and 70% NPH) on 52 type 2 diabetics and found that HbA1c significantly reduced from $9.05 \pm 0.43\%$ before Ramadan to $8.56 \pm 0.62\%$ after Ramadan ($p=0.0004$) in the Humalog Mix 50 group [13]. The mean blood glucose level (MBG) was significantly reduced during Ramadan in Nor Azlin et al. study and Ahmedani et al. study (from 6.16 mmol/L to 5.34 mmol/L; $p=0.001$ and from 12.47 ± 3.94 mmol/L to 8.67 ± 1.92 mmol/L; $p<0.000$ respectively) [3,14].

Three studies (Kassem et al., Cesur et al. and AlAlwan et al.) demonstrated that Ramadan fasting has no effect on HbA1c [2,12,17]. The small sample size (17 and 10 respectively) and the measurement of HbA1c twice within 30 days are the major weaknesses of the first two studies. The third study had selection bias because it was not randomized. In contrast to the above studies, Lessan et al. study demonstrated that MAGE was significantly higher in the insulin group compared to other medication (9.8 ± 3.4 ; $p<0.05$) (the higher the MAGE values, the more the glycaemic excursions and the poorer the glycaemic control) [14]. However, the small sample size (13 patients) and the design of this study (continuous glucose monitoring over two days in Ramadan only) had affected the strength of its results.

Other studies discussed the use of certain types of insulin over another. One study found the use of CSII improved glycaemic control over conventional insulin (CI). Mean HbA1c was 7.8% (7.1–8.9%) in CSII group compared to 9.1% (8.3–10.6%) in CI group ($p<0.001$) [2]. However, the small sample size was small (9 patients). Another study showed that glucose excursion two hours after iftar was significantly lower with Lispro than with regular insulin (2.50 ± 0.46 mmol/L and 3.47 ± 0.49 respectively; $p=0.026$) [9]. Mattoo et al. showed that use of Lispro Mix 30 was associated with significantly lower glucose excursion (3.4 ± 2.4 mmol/L) compared to Human insulin 30/70 (4.0 ± 3.2 mmol/L) ($p=0.007$). This study was an open label, randomized, crossover study with good design and reasonable sample size conducted in 13 centres in 7 different countries.

The overall results suggest that glycaemic control may be improved or at least will not deteriorate through Ramadan fasting in insulin dependent diabetics. The use of CSII or insulin pump enhanced by continuous glucose monitoring, especially with the newly added features of sensing and automatically suspending

infusion in the presence of hypoglycaemia, provides flexibility and safety of using insulin during Ramadan. Insulin pump may be the best option for those who intend to fast. If pump is unfeasible, then Lispro containing insulin formations such as Lispro Mix 50, Mix 25 or pure Lispro are the preferable options. The rapid onset of action of Lispro (5–15 min) compared to 30–60 min of Human regular insulin may make control of glucose more precise during Ramadan.

3.2. Hypoglycaemia in Ramadan

As Ramadan is a lunar month, it starts 11 days earlier each year and coincides with a different season every nine years [17]. Therefore duration of the fast may last from 11 to 19 h relying on geographical location and season of year when Ramadan falls [13]. One of the major complications that can occur in Ramadan is hypoglycaemia due to the prolonged fasting hours especially in Ramadan occurs during summer season [13]. Several studies in this review found the incidence of severe hypoglycaemia was negligible during Ramadan [2,3,7,10,12,13]. The prevalence of minor hypoglycaemic episodes was 33 during the whole month in the 21 patients who were on insulin pump. None of them break their fast prematurely and there were no statistical significance between the hypoglycaemic episodes before and during Ramadan [12]. The incidence also decreased toward the end of the month [13].

In contrast, Lessan et al. study stated that hypoglycaemia risk was significantly increased in the insulin group as reflected by the low blood glucose index of 3.4 ± 3.9 ($p<0.05$) [14]. However, this study had many limitations as mentioned previously. Similarly, the EPIDIAR study which was conducted on 1070 patients from 13 countries showed that severe hypoglycaemia was significantly higher in the insulin group (0.14 episodes/month in Ramadan vs. 0.03 episodes/month in other month; $P=0.0174$) [16]. The large sample size and diversity of study centres are strengths for this study. Nevertheless, two thirds of patients in the EPIDIAR study had recall bias and had either maintained or increased their insulin dose during Ramadan which may explain the higher rate of severe hypoglycaemia.

Expert consensus recommends reducing total daily dose of insulin during Ramadan by 20–50% to reduce incidence of hypoglycaemia [17]. Most hypoglycaemic episodes occur before iftar as expected [4]. Hypoglycaemia occurs less with CSII than CI [2], with Lispro than regular insulin [4], with basal-bolus than premixed insulin [1] and with Humalog Mix 50 than with Human insulin Mix 30 [3]. Severe hypoglycaemia can also be avoided by frequent monitoring of capillary glucose during fasting. Patients at high risk of hypoglycaemia such as those with advanced renal or hepatic impairment, severe comorbid diseases and those with frequent hypoglycaemic episodes or hypoglycaemia unawareness should be actively discouraged from fasting.

3.3. Hyperglycaemia in Ramadan

The main meal in Ramadan is iftar which is often a high caloric meal rich in carbohydrates [9]. Therefore hyperglycaemia is expected to occur shortly after this meal. Post-iftar hyperglycaemia was examined in two studies [1,14]. Ahmedani et al. study found hyperglycaemia to occur more in the pre-sohur period [8]. No diabetic ketoacidotic episodes were documented in any of the reviewed articles. Hyperglycaemia occurred more frequently than hypoglycaemia in two studies [6,7]. The first study by Ahmedani et al. was a retrospective survey with recall bias and small sample size [6]. The second study had a high dropout rate [7].

Lessan et al. study found hyperglycaemia more commonly encountered in the insulin group (13.9 ± 7.7 mmol/L compared to 8.1 ± 6.3 mmol/L in the non-fasting group; $p<0.04$) [14]. This may reflect increased hypoglycaemia in insulin group and therefore

correction-related hypoglycaemia. Khalil et al. reported 801 episodes of postprandial hyperglycaemia in the 21 patients observed in their study whilst on insulin pump [12]. However, there was no active comparator control group and there were no mentions of severe hyperglycaemia incidence [12]. Al-Khawari et al. found that basal-bolus was better than premixed insulin [1] as did insulin Lispro, compared to regular insulin (Kadiri et al. randomised trial) [4] in reducing hyperglycaemic episodes. However, these studies did not have uniform definitions for hyperglycaemia.

4. Conclusion

The paucity of good quality studies examining hyperglycaemia and hypoglycaemia complications in Ramadan fasting does not guide a diabetes physician in consistently recommending an appropriate insulin regimen for a Muslim diabetes patients who fast during Ramadan. However, this review suggests that Ramadan fasting can be feasible for insulin dependent diabetic patients. Islamic rules exempt insulin dependent diabetics patient from fasting. Nevertheless, if patients wish to fast, they should be allowed to do so after comprehensive explanation of the possible complications and the required dietary and therapeutic modifications before and during fasting. Optimal insulin regimens may be CSII or insulin infusion pump enhanced by CGM which measures glucose level in the subcutaneous tissue. Use of short acting insulin analogues like Lispro pre-meals may be advantageous because of rapid onset of action, which may be as short as 5 min. This will help in the postprandial control of glucose as well as providing flexibility to adjust the insulin dose. Lispro containing premixed insulin preparations may be superior to premixed human insulin. If insulin analogues are not available, ultralente insulin at night may be a reasonable alternative. Frequent monitoring of blood glucose during fasting is important. Patients should be encouraged to drink adequate fluids after breaking fast and avoid excessive physical activity during fasting. They should be advised to discontinue their fast if they fell unwell.

Most of the reviewed studies are observational studies with small sample sizes. They have excluded high risk patients with comorbidities and brittle diabetes. Hence, the results cannot be applied to the high risk diabetics. Diabetic patients with severe comorbidities and advanced diabetic complications including those at risk of hypoglycaemia should be discouraged from fasting. Future well-designed, large, multi-centre observational cohort studies are needed to explore the effect of Ramadan fasting on insulin dependent diabetics. These studies should consider the effect of different variables such as length of fasting, physical activity, type and dosing of insulin, including novel insulin analogues like Degludec or Peglispro, dietary habits and length of sleeping hours. They should enrol patients with advanced comorbidities or brittle diabetes in their design if possible.

Conflicts of interest

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