ABSTRACT

Introduction Ramadan fasting is globally observed and a great majority of the residents of Islamic countries and elsewhere fast during Ramadan all across the world every year. Many patients with type 1 diabetes fast during Ramadan according to (or against) medical and jurisprudence advice. Nonetheless, there is a paucity of scientific evidence regarding the risks patients with diabetes who fast may be confronted with. The current scoping review protocol aims at systematic analysis and mapping of existing literature in the field and highlighting scientific gaps.

Methods and analyses This scoping review will be conducted based on the Arksey and O’Malley’s methodological framework with consideration of later modifications and amendments. Three major scientific databases, namely PubMed, Scopus and Embase up to February 2022 will be systematically searched by expert researchers in collaboration with a medical librarian. Considering the fact that Ramadan Fasting is a cultural-dependent subject, which may be studied in the Middle Eastern and Islamic Countries in languages other than English, local Persian and Arabic Databases will also be included. Grey literature will be sought too, and unpublished works such as conference proceedings and academic degree dissertation will be considered. Subsequently, one author will screen and record all abstracts, and two reviewers will independently screen and retrieve eligible full texts. A third reviewer will then be designated to resolve potential discrepancies. Standardised data charts and forms will be used for information extraction and reporting of the outcomes.

Ethics and dissemination No ethical considerations apply to this research. Results will be published and presented in academic journals and scientific events.

INTRODUCTION

Globally, 460 million patients with diabetes lived in 2019, and this number is forecast to rise by 51% increase to 700 million in 2045.

In 2045, in the Islamic countries where many fast every year in Ramadan from dawn to dusk for an entire month, the number of patients living with diabetes is predicted to rise approximately twofold. Therefore, considering high prevalence of diabetes among Muslims and the significant number of people who observe the ritual of fasting every year, it is imperative that credible evidence about Ramadan fasting and diabetes should be systematically compiled and analysed so that informative and evidence-based guidelines on the subject can be developed. The scoping review, which is planned to be developed based on this protocol, can be of immense benefit in terms of systematic analysis of the existing knowledge in this field, and guideline-developing teams can enormously benefit from it.

Type 1 diabetes is a metabolic disease inflicting various organs, and patients with the disease who fast are at high risk for development of a wide range of fasting-related complications such as dehydration, hypoglycaemia, hyperglycaemia and diabetic ketoacidosis. Generally, people with type 1 diabetes are vulnerable to two major risks, that is, hypoglycaemia and hyperglycaemia, and fasting can remarkably increase the probability of both. It should be mentioned, however, that fasting can be wholesome for a group of patients with type 1 diabetes provided that they strictly follow evidence-based guidelines and recommendations. Indeed, Ramadan fasting might even be an opportunity for adjustment of insulin provision for fasting
and postprandial insulin adjustments. As Ramadan fasting imposes a fasting-feeding cycle, patients with diabetes are exposed to the risk of hypoglycaemia when fasting during the day and hyperglycaemia after iftar at night. Moreover, in most Islamic cultures, high-calorie, high-fat, and carbohydrate-rich meals, confectionaries, and beverages are consumed before and after fasting, and this can dramatically increase blood glucose levels and expose patients to the risk of hyperglycaemia and related complications.

Notwithstanding all the risks involved, many people with diabetes for whom fasting is religiously prohibited due to their health conditions choose to fast in Ramadan. For instance, many pregnant women with type 1 diabetes who should not observe the ritual of fasting from a jurisprudence viewpoint do fast in Ramadan. It should be mentioned, however, that in high-risk patients with diabetes, good glycaemic control is not elusive if they strictly follow evidence-based guidelines. Therefore, high-risk individuals who choose to fast against jurisprudence and medical advice should have access to evidence-based information and support so that the risks can be minimised. Moreover, as the intake of total daily calories as one or two meals requires change in insulin doses, fat, protein and carbohydrate consumption and their effect on gastric emptying should be taken into account content.

Development of diabetes-care technology has revolutionised glycaemic control in patients with type 1 diabetes. Compilation and analysis of the benefits novel diabetes-control technology provide for people with diabetes who fast is of great importance. For instance, there is credible evidence indicating that in patients with type 1 diabetes who fast, continuous subcutaneous insulin infusion can be advantageous over the traditional insulin injection regimens to minimise the risk of hypoglycaemia. Moreover, low-glucose suspend feature of insulin pumps can be quite effective in glycaemic management of patients with type 1 diabetes who fast. Nonetheless, it is not clear whether the usual basal rate profile is suitable or they should be changed, and in which way. In this regard, more evidence on ‘low-glucose-suspend’ functions and closed-loop devices should be provided.

Therefore, it is imperative that Ramadan fasting guidelines for patients with type 1 diabetes mellitus should be developed so that this group of patients can safely fast and the risks involved could be minimised. The current scoping review can be a significant contribution to the literature so that the scattered information about the subject can be compiled and evidence-based recommendation for management of patients with type 1 diabetes who fast could be developed. We propose to conduct this scoping review to investigate into the existing literature on patients with type 1 diabetes who fast from all age groups, including children and adolescents. In this manner, the knowledge gaps on this topic can be identified and highlighted, and recommendations for future research can be developed.

**METHODS**

The current protocol is designed primarily based on Arksey and O’Malley’s five-stage methodological framework, and amendments later proposed later by the Joanna Briggs Institute (JBI) are considered. The protocol follows the Preferred Reporting Items for Systematic Review and Meta-analysis protocols (PRISMA) 2020 checklist when it is considered relevant.

The process of development of the ultimate scoping review will include the five following stages:

- Stage 1: Defining the research question.
- Stage 2: Identification of relevant studies.
- Stage 3: Selection of the studies.
- Stage 4: Organisation and tabulation of the data.
- Stage 5: Summarisation, compilation and documentation of the results.

The final scoping review will be developed based on the PRISMA extension for Scoping Reviews checklist. These stages are planned to be carried out as follows:

**Stage 1: identification of the research questions**

As the initial stage, the research questions were defined based on a narrative review published by the authors in 2021. The primary aim of publication of this narrative review of literature was to investigate into diabetes management in patients with diabetes (both type 1 and type 2) who fast in Ramadan. Based on the experience of this publication, in the current project, the authors aim to systematically search related literature and compile, analyse and report published evidence about management of type 1 diabetes in fasting individuals in Ramadan. Unlike the previous narrative review, in the current scoping review, authors will only focus on the management of type 1 diabetes in the holy month of Ramadan. In this regard, different aspects of the issue, including education, medications and contraindications of fasting for patients with type 1 diabetes will be investigated and reported. To the best of the knowledge of the authors, the current scoping review will be the first study to systematically search the literature and report the existing evidence and research gaps pertaining to the management of type 1 diabetes in those who fast according to (or against) medical and jurisprudence advise. Moreover, this scoping review will lead to provision of the evidence-based information physicians (and clerics) need for making a decision whether a particular patient should be allowed to fast in Ramadan or not. In addition, our findings will update physicians’ knowledge and provide them with evidence-based information they need in their daily practice to optimise diabetes management in fasting individuals in Ramadan. In addition, as postpubertal children and adolescents are also required to fast according to Islamic jurisprudence principles, this review can be of great application in terms of the management of juniors with type 1 diabetes who choose to fast regardless of their health condition and medical advice. At this stage, the following indicative research questions were developed:
Inclusion criteria

P-population.
Studies will be considered if they assess.
Adults, adolescents and children who are diagnosed with type 1 diabetes.

C-concept
Studies will be considered if they investigate children or adults with type 1 diabetes who:

⇒ Identify themselves as Muslims.
⇒ Practice Islamic fasting only for fulfilment of their obligation to the divinity as Muslims.
⇒ Abstain from eating, drinking, smoking or other means of breaking fasting defined by the Sharia Law from dawn to dusk.

C-context
⇒ Islamic countries and Muslim communities living elsewhere.

Type of evidence sources
⇒ Original studies, systematic reviews, scoping reviews, expert opinion papers, clinical guidelines and any published or unpublished material on the subject of management of type 1 diabetes in Ramadan fasting.

Stage 2: identiﬁcation of the relevant literature

This stage of the development of the current scoping review includes the process of selection of studies and papers authors deem appropriate for development of the current scoping review. In order for this to be realised, the authors have developed a set of inclusion criteria based on the ‘Population–Concept–Context’ (PCC) framework proposed by JBI for conducting scoping review studies.

A summarised form of the PCC inclusion criteria for the current study is tabulated in box 1.

Inclusion criteria

Articles and other types of material will be deemed as suitable by the authors if they have dealt with children, adolescents and adults who:

⇒ Are required to practise Ramadan Fasting as a compulsory religious obligation?
⇒ Have practised fasting for any number of days in Ramadan?
⇒ Have been diagnosed with type 1 diabetes according to the criteria elaborated later in details?

In short, studies will be included if they have dealt with the topic of diabetes management in Muslims who practise Ramadan fasting. The diagnosis of type 1 diabetes should have been made by a physician or any valid documentation such as medical records, registries or self-administered reports.

We have defined diagnosis of diabetes according to American Diabetes Association definition and one the following criteria:

⇒ Fasting plasma glucose ≥126 mg/dL (7.0 mmol/L). Fasting is deﬁned as no caloric intake for at least 8 hours.
⇒ Two-hour plasma Glucose (PG) ≥200 mg/dL (11.1 mmol/L) during OGTT (Oral Glucose Tolerance Test). The test should have been performed as described by the WHO (using a glucose load containing the equivalent of 75 g anhydrous glucose dissolved in water).
⇒ A1C ≥6.5% (48 mmol/mol). The test should have been performed in a laboratory using an NGSP (National Glycohemoglobin Standardization Program) certiﬁed method according to standardised to the DCCT (Diabetes Control and Complications Trial) assay.
⇒ In a patient with classic symptoms of hyperglycaemia or hyperglycaemic crisis, a random PG ≥200 mg/dL (11.1 mmol/L) should have been recorded.

Confirmation of type 1 diabetes should have made as follows:
⇒ Type 1 diabetes diagnosis should be made by one or more autoimmune markers of the disease.
⇒ Persistence of two or more autoantibodies conﬁrms diagnosis of type 1 diabetes.
⇒ Diagnosis of type 1 diabetes should be ideally conﬁrmed with a panel of autoantibodies.
⇒ Plasma blood glucose rather than A1C should be used to diagnose the acute onset of type 1 diabetes in persons with symptoms of hyperglycaemia.

In our search, no language restrictions will be set and all studies matching our criteria published up to 18 February 2022 were considered in the final search which was carried out on 18 February 2022. Studies in Arabic or Persian languages will be considered so that the search can be as inclusive as possible. Only peer-reviewed articles and document intended to be presented in scientiﬁc assemblies and journal will be considered and other published material will be excluded. Grey literature will be considered whenever they are judged as relevant, and all studies considering type 2 or any other type of diabetes other than type 1 will be excluded.

Search strategy

A primary and inclusive search strategy has been developed for identification of relevant articles and academic manuscripts (online supplemental appendix 1). This
preliminary syntax is designed to be used on the PubMed and will consist the foundation of the search strategies to be later adapted for the two other databases (Embase and Web of Science). This process will be strictly based on recommendations by the JBI. This syntax is developed and expanded following a comprehensive search on different databases such as PubMed, PROSPERO, Embase, Google Scholar and the Cochrane Database of Systematic Reviews.

All search terms were selected after consultation with an academic librarian (RA) based on a previous narrative review published by the authors. More specifically, initially, a list of relevant search terms was developed based on the comprehensive search carried out for publication of this narrative review. All references used for drafting it were handsearched for detection of any relevant keywords or prominent guidelines and papers published about management type 1 diabetes in Ramadan fasting. Subsequently, this primary list was elaborated by the Medical Subject Headings (MeSH) and keywords in the PubMed database. All processes were conducted in accordance to the Peer Review of Electronic Search Strategies checklist.

Ultimately, the final syntax and search strategy will be amended as deemed necessary by the authors. Additional keywords may be added and Boolean operators (OR, AND), and tags (tiab, ti, tw…) will be applied so that the search strategy can be as inclusive as possible with the desired number needed to read.

Grey literature will be obtained through different means, such a simple search on Google. This stage will be followed by a ‘snowballing’ methods, which include searching references of the selected papers, citation tracking and exploitation of existing networks on the subject. The published scoping review will provide complete details about the final search strategy and results, including the date of all searches and any search limitations or filters applied. We shall also contact famous authors in the field and any input from prominent researchers known to the authors whose field of research includes Ramadan fasting will be appreciated, considered and acknowledged in the published manuscript.

Stage 3: study selection

Results obtained from different searches will be compiled and merged, and duplicate records will be omitted from the ultimate list. The primary reference-management software will be Endnote, but other research facilitating pieces of software and networks such as Covidence may also employ to foster collaboration among the authors. Titles and abstracts of the retrieved articles will be screened by two reviewers, and non-relevant records will be excluded according to the PCC inclusion criteria (box 1).

Remaining articles which will be considered as relevant will be finalised, the corresponding full-text articles will be procured and analysed by the reviewers so that we can ensure full adherence to the PCC inclusion criteria. The two authors will discuss any possible differences of opinions regarding suitability of the manuscripts, and a more
experienced third author who is considered expert in this field will make the final decision in this regard. This final collection of full-text articles will be once again checked according to the PCC inclusion criteria, and the principal author will declare his ultimate approval.

Stage 4: charting the data
The authors will use a charting form (based on the JBI template source of evidence details, characteristics and results extraction instrument) to address the study questions. Relevant information procured from observational studies or grey literature will be extracted and tabulated using this charting form (table 1). If the authors think it necessary, they may also use the data obtained from the original studies for spotlighting relevant review articles. The main objective of development of the charting form will be to present basic citation information, information about PCC, methodology of the studies, main findings, summary of the results, strengths and limitations of the studies, and research gaps proposed by the authors. The charting form will be developed by two authors so that we can ensure addressing the research questions. For this purpose, two reviewers will discretely and independently harvest corresponding information from the identified articles, and confirm them under direct supervision of the appointed senior author. Subsequently, these two reviewers will collaboratively tabulate the information in a manner that one procures the information and the other will check and confirm them, and as such potential shortcomings and mistakes can be addressed. Should any uncertainty emerge, corresponding authors of the selected articles may be contacted for procurement of information or explanation. During this time, publication of any potential novel articles, which may influence the design of our scoping review, will be diligently monitored by the authors and the issue will be discussed among them and they will modify the process accordingly. As such, the proposed charting form in this protocol is preliminary and it may be amended as the scoping review progresses. Ultimately, the final text of the scoping review will be read and confirmed by all authors.

Stage 5: collating, summarising and reporting the results
The outcome of the study will be published as a scoping review article containing texts, flow charts and tables. The flow chart will present different processes of search strategy and study selection. Besides presentation in tables, identification and findings of the selected articles studies will be elaborated in the main body of the article. Moreover, the research questions will be addressed using the main findings. Accordingly, limitations, knowledge gaps and areas which require further research will be spotlighted.

Patient and public involvement
No patient involved

DISCUSSION
It is envisaged that the proposed scoping review article will substantially contribute to the expansion of the literature about management of type 1 diabetes in Ramadan fasting. This will be realised by systematically reviewing published and unpublished works on the subject. Findings of this scoping review are expected to substantially expand available evidence on this important topic and guide and facilitate future primary and secondary research projects such as preclinical, clinical, systematic reviews and meta-analyses works on the subject.

Another potential invaluable outcome of publication of this scoping review will be illumination of the risks involved in practising Ramadan fasting in patients with type 1 diabetes for whom observation of the ritual is prohibited from a jurisprudence viewpoint. The evidence synthesised by this scoping review can also lead to development of evidence-based guidelines for management of high-risk patients with type 1 diabetes who insist to fast against medical advice. The ultimate scoping review will be submitted for publication in a peer-reviewed academic journal. Moreover, the findings may be presented at conferences and other scientific assemblies and events. As for potential obstacles and limitations, it is predictable that the included studies may be quite heterogenous and methodologically differ in terms of means of diagnosis of type 1 diabetes, age group of the people included, and usual deficiencies and primary and secondary research. Nonetheless, we believe that a scoping review methodology will be the most suitable design for spotlighting the existing evidence and illuminating obscure aspects of the subject, especially considering the fact that this topic is comparatively ill researched and new evidence emerges on an ongoing basis. Ultimately, a list of strengths and limitations of the included studies will be developed, but critical appraisal of the selected studies will not be conducted. Naturally, considering the secondary research quality of this research, no ethical approval is needed for this article.

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