Ramadan and diabetes: Holistic trial design
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Abstract
Extensive work has been done to analyze the safety of various modern glucose-lowering drugs during Ramadan fasting. This editorial suggests the use of validated scales of religiosity/spirituality as an adjunct to pre-Ramadan counselling and risk stratification. The editors also propose a holistic trial design for future trials on glycaemic management during Ramadan. Such a design should include both spiritual and biomedical endpoints, while trying to assess correlation between religiosity/spirituality and biomedical outcomes after Ramadan fasting. Integration of validated instruments to screen and monitor spirituality will help achieve the holistic health in devout Muslims who wish to observe Ramadan.

Keywords: Counselling, Diabetes, Person centered care, Ramadan, Spirituality.

Introduction
Science and religion are two pillars of human society which are often in conflict with each other.1 Rarely do they achieve integration into one field. One situation where science and religion integrate seamlessly is during the Holy month of Ramadan. Devout adult, healthy Muslims fast from dawn to dusk during this month, as an obligation of religion and to achieve a sense of spiritual well being. Exemptions laid down in the Holy Koran, such as for children, antenatal and menstruating women, the sick, and travelers, prevent believers from harming themselves through medically unwarranted fasting.2 Despite this, many believers with diabetes insist upon fasting during Ramadan.

Non-Insulin Management
Management of glycaemia, in people with type 1 or type 2 diabetes who wish to fast, remains a challenge. The ideal glucose-lowering therapy for Ramadan should be such that it prevents both hyper- and hypoglycaemia, while minimizing glycaemic variability.3 Recent advances in pharmacotherapeutics have allowed the availability of such drugs, and made such treatment possible. Various randomized controlled trials (RCTs), observational trials, guidelines and case reports have documented the use of modern drugs in Ramadan. The quality of such trials, however, is not uniform.

Review of Published Trials
A recent article by Sifri and Rizvi reviews the quality of 30 trials of non-insulin drugs on glycaemic management during Ramadan.4 The review provides a comprehensive overview of 20 RCTs and 10 observational trials using sulfonylureas, dipeptidyl peptidase 4 inhibitors and glucagon-like peptide 1 receptor agonists, with or without metformin, detailing strengths, omissions and flows in their methodology and reporting.

Such trials are limited in their ambit to efficacy and safety of glucose control, and are unable to quantify the entire biopsychosocial experience of fasting. They focus purely on biomedical markers such as glucose control, hypoglycaemia and weight, without taking spiritual and emotional health into account. While fasting is said to provide spiritual upliftment and emotional wellbeing to the devout,5 this must be weighed against possible medical harm. Keeping this in mind, a person-centered approach to Ramadan fasting is suggested in persons with diabetes.6 Decisions regarding whether to fast or not, and what medication to take, must be made through a process of informed, and shared, decision making.7 No data exists, however, to help predict and quantify the potential spiritual benefits of fasting and weigh them against possible biomedical risks.

Islamic Religiosity
Islam is a well-structured religion with five central pillars or tenets of faith. El Menovar has studied and listed five dimensions of Muslim religiosity, which include basic religiosity, central duties, religious experience, religious knowledge and orthopraxis.8 Basic religiosity, or spirituality, refers to the importance of religiosity in one's life. This is usually a stable variable for an individual, and is a resource for coping with stress. Such stress may include the physical discomfort imposed by prolonged fasting.

Fasting is a great opportunity for a spiritual uplift as well as cleansing of mind and body.5,6 Ramadan fasting provides spiritual benefits for persons with higher innate religiosity or spirituality, a highly spiritual orientation, or greater spiritual experiences. Such persons take better care of themselves and demonstrate better adherence and persistence to
prescribed anti-diabetic therapy, during as well as after Ramadan. The astute and empathic health care professional should take this into account while counselling for Ramadan observance. We discuss some possible ways of measuring this in an objective manner.

**Objective Measurement**

The Centrality of Religiosity Scale (CRS)\(^9\) is a well validated measure of the centrality, importance or salience of religious meanings in personality. It assess five dimensions, including an intellectual dimension, ideology, public practice, private practice and religious experience. This scale has been customized and validated for use in Muslim populations as well. Such scales may assist in pre-Ramadan assessment risk stratification. While there are some absolute contraindications to fasting, other risk strata may be relative. It is plausible that persons with high CRS valued may benefit from fasting, and may actually experience emotional ill health if not allowed to fast.

The Intrinsic Spirituality Scale (ISS) is a well-researched, extensively utilized instrument,\(^10\) which has been validated in a Muslim population.\(^11\) The ISS provides a simple, yet accurate, construct of the inner spirituality of a person, and has the potential to be used as a pre-Ramadan screening tool. Persons with diabetes, with high scores on the ISS, should be assisted by providing pre-Ramadan counseling, making apposite adjustment to therapeutic regimes and doses, and ensuring regular follow up during Ramadan.

The Muslim Experiential Religiousness Scale, validated in Iran as well as Pakistan, is another way of measuring the spiritual benefits of fasting and assess the transcendental experience. These include the Spiritual Well Being Scale (SWBS), Spiritual Well Being Questionnaire (SWBQ), and Daily Spiritual Experience Scale (DSES).\(^14, 16\) While these have been validated in multi-religious and multi-denominational cohorts, they have not been used specifically to monitor the “intangible” benefits perceived during and after Ramadan.

**Conclusion: Holistic Trial Design**

Along with bio medical markers such as blood pressure, weight, blood glucose and lipids, holistic studies on diabetes management during Ramadan should take spiritual health into account. Validated instruments should be researched as possible tools to aid in pre-Ramadan counseling, risk stratification and decision making. They should also be studied as means of quantifying and monitoring spiritual bliss before, during and after Ramadan. The results thus obtained should be correlated with biomedical markers, to assess if spiritual well being, biomedical (physical) health, and laboratory values go hand in hand. Such holistic research will reinforce the complementary nature of science and religion, and help clinicians in their pursuit to achieve holistic health for persons living with diabetes who wish to observe Ramadan in their guidance.

**References**