

The effects of Ramadan fasting on patients with prosthetic heart valve taking warfarin for anticoagulation

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Introduction: Oral anticoagulation with warfarin is indicated for patients with prosthetic heart valves. The effects of religious fasting during Ramadan month (in the Islamic calendar) on anticoagulation aren't clear.

Objectives: To study the impact of Ramadan fasting on international normalized ratio (INR), quality of anticoagulation, dose of warfarin used and blood osmolarity.

Methods: 18 patients were followed-up prospectively for 3 months (pre-Ramadan, Ramadan and post-Ramadan months). Patients presented for weekly visits in which blood samples were obtained.

Results: No significant difference in INR and warfarin dose was found between Ramadan month, and months before and after it. The post-Ramadan INR was significantly larger than pre-Ramadan ($p = 0.004$). Blood osmolarity was significantly lower during Ramadan compared to pre- and post-Ramadan months. A significantly better quality of anticoagulation was noticed during Ramadan ($p < 0.001$). A significantly larger ratio of supratherapeutic INR values occurred in the post-Ramadan month ($p < 0.05$). A significantly larger ratio of infra-therapeutic INR values was noticed in the pre-Ramadan month ($p < 0.05$).

Conclusion: No significant difference in mean INR or warfarin dose was found and a better quality of anticoagulation was achieved during Ramadan. A tendency toward supra-therapeutic anticoagulation occurred after Ramadan, thus a closer follow up during this period may be reasonable.

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Keywords: Prothrombin time, International normalized ratio, Coumadin, Antithrombotic therapy, Muslim

Introduction

Patients with prosthetic heart valves (PHVs) require chronic oral anticoagulation. Although newer oral antithrombotic agents

(rivaroxaban, apixaban, dabigatran, etc.) are now available, current guidelines do not recommend their use for antithrombotic therapy in patients with PHVs [1–3]. Vitamin K antagonists (mainly warfarin) remain the most widely used agents for this purpose.

Disclosure: Authors have nothing to disclose with regard to commercial support.

Received 9 May 2016; revised 18 May 2016; accepted 8 June 2016.

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Peer review under responsibility of King Saud University.

URL: www.ksu.edu.sa

<http://dx.doi.org/10.1016/j.jsha.2016.06.004>



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During the 9th month of the Islamic calendar, the month of Ramadan, Muslims fast from sunrise to sunset. Since it is emphasized that patients' diet may affect the efficacy of anticoagulation, clinicians are frequently faced with the question whether a patient taking warfarin can fast or not.

Materials and methods

The study was conducted between May 22, 2015 and August 14, 2015. The study was approved by the Ethics Committee of the Dr Siyami Ersek Cardiovascular and Thoracic Surgery Educational and Research Hospital, Istanbul, Turkey.

The hospital records were screened for adult patients living in Istanbul and taking warfarin who underwent mitral, aortic, or tricuspid valve replacement surgery between April 2014 and March 2015. 243 patients were contacted by phone and given brief information about the study. The patients were invited for an initial assessment visit in which they were provided with further details of the study, their demographic information was recorded and they underwent a medical assessment to ensure they were fit to fast.

A schedule of 12 weekly follow-up visits was prepared. Four visits were in the pre-Ramadan month, four during Ramadan, and four in the post-Ramadan month. In each visit, blood samples were obtained to measure international normalized ratio (INR) and the total amount of warfarin used in the previous week was recorded. Biochemical markers for hepatic dysfunction (alkaline phosphatase, alanine aminotransferase, aspartate aminotransferase, γ -glutamyl transferase, total protein, and albumin) were also obtained. Sodium, potassium, blood urea nitrogen (BUN), and glucose levels were obtained and used to calculate blood osmolarity using the equation:

$$2 \times (\text{Na} + \text{K}) + (\text{Glucose}/18) + (\text{BUN}/2.8). \quad (1)$$

Signs and symptoms of major bleeding and thrombotic events were questioned in each visit.

The therapeutic INR range used in our study was 2.0–3.50. The warfarin dose was adjusted when the INR values were out of this range. Patients were asked to take warfarin when they woke up for the meal of suhur (the meal just before sunrise). No adjustment of the other medications was made and no specific instructions about when to take them was made. Patients continued to take diuretics during Ramadan in their usual doses. Enoxaparin was prescribed for 5 days when subtherapeutic INR values were obtained.

The primary outcome of this study is the mean INR value before, during, and after Ramadan.

Abbreviations

PHV	prosthetic heart valve
INR	international normalized ratio
AST	aspartate aminotransferase
ALT	alanine aminotransferase
GGT	gamma-glutamyl transferase
ALP	alkaline phosphatase
BUN	blood urea nitrogen
AVR	aortic valve replacement
MVR	mitral valve replacement
BMI	body mass index

Secondary outcomes are the dose of warfarin used, quality of anticoagulation, blood osmolarity, and any biochemical evidence of hepatic dysfunction that may cause variation in the INR before, during, and after Ramadan. Clinical endpoints for termination of the study included any major hemorrhagic or thrombotic events.

Descriptive statistics were used to report patients' demographic data. Data are expressed as mean \pm standard deviation for continuous variables and percentages for categorical variables. Paired sample *t* test was used to compare the variables in the three study periods (pre-Ramadan, Ramadan, and post-Ramadan). A *p* value <0.05 was considered statistically significant. All statistical analyses were performed using SPSS version 22.0 (IBM-SPSS Inc., Armonk, NY, USA).

Results

Thirty-six patients presented for the initial visit. Two patients were considered medically unfit to fast and they were excluded from the study (these patients were both frail, elderly, diabetic, and on multiple medications). Nine patients did not consent to the study protocol. Three patients could not tolerate fasting this year so they were excluded on the first follow-up visit in Ramadan. Four patients were lost to follow up (these 4 patients went to their hometowns to celebrate the feast after Ramadan and they then spent the summer vacation there). Eighteen patients met the minimum criteria for inclusion in the study, which were as follows: patients who presented for follow up at least twice before and during Ramadan and at least once after Ramadan. Details of our patient recruitment process are illustrated in Fig. 1.

The study cohort included 12 (66.7%) men and six women. The mean age was 52.7 ± 13.2 years. Twelve participants had mitral valve replacement and six participants had aortic valve replacement;

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