Attitudinal Determinants of Fasting in Type 2 Diabetes Mellitus Patients During Ramadan

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Abstract

Objective: Fasting during Ramadan has been dissuaded by the physicians for patients of Diabetes, yet fasting being a religious issue cannot be made a contraindication for those who are determined. The aim of the present study was to find out whether counseling prior to Ramadan can result in successful fasting with lesser adverse events. We have also studied clinical, social and demographic factors causing attitudinal difference in patients and its effect on fasting and diabetes control.

Research Design and Methods: We recruited 96 (males 54, Females 42) Muslim patients of Type 2 Diabetes, 2-3 weeks prior to Ramadan. Patients were educated about lifestyle, diet and medications. Awareness regarding diabetes management during fasting was assessed by a scored questionnaire prior to and after Ramadan. Last year Ramadan’s experiences were recorded for comparison, on a recall basis.

Result: There was an increase in post Ramadan awareness score. Average increase in awareness score was more in rural patients (1.23 ±3.76; n=52) than in urban (1.09 ±2.01; n=44). Average number of fasts had positive correlation with duration of Diabetes. There was significant increase (p<0.05) in the number of fasts kept this year. Maximum increase was in the age group 40-60 year (25.74%). Fifteen days fast was completed by all patients on diet control, 81.3% patients on OHA and 35.7% on insulin. Hypertensive patients had more hypoglycemic episodes. Lesser number of tobacco addicts could fast for >15 days. No patient needed hospitalization or emergency care.

Conclusion: Fasting in Type2 Diabetes patients during Ramadan can be facilitated with safer outcomes and lesser adverse events. Individual attitude is important as increases in awareness and education are not linked to specific improved end-points.

Introduction

Large number of Muslim type 2 Diabetes patients fast globally every year for one lunar month during Ramadan as an obligatory religious duty.¹² Although Islam exempts the sick from fasting, yet many patients of Diabetes insist on fasting against the advice of their physicians. It is a religious issue and hence cannot be made a contraindication for those who are determined to do so. An international consensus meeting to establish guidelines on fasting during Ramadan suggested that patients with stable type 2 diabetes without progressive co-morbid pathology, under treatment with oral hypoglycemic agents could safely undertake the fast.²

An Indian study done on 13 subjects has evaluated dietary pattern and metabolic alterations in patients of type 2 diabetes and demonstrated the safety of fasting.³ Studies from many other countries also concluded that stable Type 2 Diabetes patients can fast if properly educated and carefully managed.³ These recommendations may be useful when the patients are being actually educated and they remain compliant to the advice of doctors. Earlier studies depict difficulty in achieving compliance regarding dietary advice and caloric control.⁴ Certain dietary practices have been evolved over centuries and are thought to be helpful in fasting in ways which have yet not been scientifically evaluated. These specific socio-cultural based dietetic behaviors may prevent compliance to physician’s advice. Blood sugar measurements always become difficult during Ramadan as most patients show a denial for giving venous blood samples during fast due to religious constraints. A large epidemiological survey in 13 countries with a sizeable Muslim population including India, reported that among Type 2 Diabetes patients 25% changed their oral drug dose while fasting.⁵

All these changes have been made by the patients on their own, without the advice of the physician.

These reports show that achieving compliance in these patients may be difficult, for this a total change in the attitude of the patients is needed. The need for explaining the risk of fasting and benefits of good control of diabetes can not be overemphasized. For a health care provider, education of patients is identified as the cornerstone of safe fasting which is needed both on community and individual basis.⁶⁷ A study showed that only 33% of our diabetic patients received general advice on fasting during Ramadan.⁸ We have taken up the aspect of counseling, practical application of recommendations regarding diet and drug modifications during Ramadan and patient attitudes towards fasting and Diabetes. Research in this area is lacking in India as well as abroad. We organize regular pre-Ramadan counseling clinics every year and felt that apart from clinical and biochemical markers, successful and safe fasting in patients who intend to fast may depend on some other factors as well.

Aims and Objectives

This study had been done with a primary objective to facilitate fasting by applying standard recommendations in Type 2 Diabetes patients (who insist on fasting), by increasing their awareness through pre Ramadan counseling and to provide them help in emergency. We also tried to recognize

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Received: 04.08.2010; Revised: 11.11.2010; Accepted: 07.12.2010

630 © JAPI • OCTOBER 2011 • VOL. 59
attitudinal factors involved in successful fasting like individual
determination, family motivation and previous experiences of
fasting.

Methods

This was a hospital based study conducted on the outpatients
in our diabetes clinic before Ramadan of 2009. Ninety six patients
(54 males, 42 females) were selected by purposive sampling
method, as study subjects.

The eligibility criteria of inclusion were all patients with a
diagnosis of type 2 diabetes mellitus for more than one year
who had decided to fast in Ramadan.

Whole study was planned in three visits. A ‘pre-Ramadan
visit’ (2-4 weeks before) a ‘during Ramadan’, (third week of
Ramadan) and a ‘post-Ramadan’ visit (2-4 weeks post-Ramadan).

In the first visit clinical and routine biochemical assessment
of patients was done. A structured questionnaire consisting of 10
simple questions, was given enquiring about diabetes, possible
adverse events, any adverse events during previous Ramadan,
whether dietary restrictions and drugs should continue or dose
may change during fast and the permission given by religion
to sick or pregnant. They had to put a tick mark on the ‘yes’ or
‘no’ boxes. Every correct response was given 1 mark, the sum
of which made “awareness score.” Seriously sick, pregnant
and those having serious clinical/biochemical abnormalities
indicating renal, cardiac or neurological involvement and who
could not complete the questionnaire were excluded. In the
pre-Ramadan visit a detailed history which included assessment
of education level and socioeconomic status, previous
hospitalizations, concomitant diseases, their determination
to fast, family history including number of family members
who would fast, current treatment, (whether on insulin) their
frequency of medical follow-up and whether they were doing
self monitoring of blood glucose, was recorded. Level of physical
activity and usual dietary practices during Ramadan was
noted. Complete general and systemic examination of patients
including weight was done.

Patients were educated about taking medications and
meals regularly. We gave standard suggestions about drug
modifications.11 Diet measurements were told by household
items like glass and bowl. Patients were reminded to abstain
from high calorie and highly refined food prepared for fast.11
Light to moderate exercise was permitted. Symptoms of
hypoglycemia and instructions to break fast on its appearance
were emphasized. Biochemical and other tests were done
including Hb, FBS, PPBS, S. creatinine, lipid profile, routine urine
examination, HbAlc, ECG and pregnancy test if needed. Muslims
who fast usually take 2 or 3 meals in 24 hours. A breakfast like
meal just before dawn (Sehar), an after-sunset meal (Iftar) and
another meal taken 2-3 hours after Iftar as dinner. We had
not given glibenpiride at sehar (predawn meal) due to risk of
hypoglycemia during daytime.

Drugs given were as follows

- Glitazones and sulphonylureas like Glimepiride, Gliclazide
  modified release, and Glipizide were given only at Iftar
  (sunset meal).
- α-glucosidase inhibitors, and metformin were given twice
  or thrice.
- Morning dose of insulin (premix 30/70 preparation) was
given at Iftar and half of evening dose at sehar (pre-dawn
  meal).

Patients on insulin were taking premix 30/70 preparation.

Their dose of Insulin was modified according to standard
recommendations and they were strictly instructed to break
their fast on appearance of hypoglycemic symptoms.

They were given morning dose at Iftar and half of evening
dose at sehar. Patients were told and were given a list of
symptoms of hypoglycemia and what measures to be taken
when they appear. They were also asked to maintain a diary of
hypoglycemic episodes and were educated about breaking fast
as soon as any warning symptom appears. Four patients
were having their own glucometers and therefore self monitoring
of blood glucose was possible in them. In the ‘during-Ramadan’
visit their clinical assessment was done and verbal and written
feedback of hypoglycemic episodes was taken, need for dose
readjustment was judged and necessary changes were done.

Patients were called again in the month following Ramadan
and they were re-assessed. Follow up feedback of events during
Ramadan was noted and hypoglycemia diary was checked. The
same questionnaire was provided to patients for re-assessing
their level of awareness in post-Ramadan visit. Their clinical
examination and biochemical investigations were repeated.
The therapeutic regimens were changed back to its previous
schedules.

Statistical Methods

The data was tabulated on Microsoft excel. Values were
expressed mainly as median, mean + standard error (or SD) or
as percentages. Comparison between pre Ramadan and Post
Ramadan values were done using students paired t test or chi
square test wherever appropriate. Two tailed tests were used. P
value <0.05 was considered statistically significant. Correlation
was tested by Karl-Pearson’s correlation coefficient. Statistical
analysis was done using windows SPSS 17 software.

Results

Median age of the patients was 46 years (range 32-71 years),
Forty two patients (43.75%) were females and 54 patients
(56.25%) were males. No significant change in weight was
observed. Baseline patient characteristics are described in
Table 1. In paired sample analysis there was a general increase
in awareness of patients after Ramadan from pre-Ramadan
level (Pre Ramadan awareness score 6.81±1.63; Post Ramadan
awareness score 9.15±3.76) and it was significant at p<0.05 level.
A low degree of negative correlation (-0.218) was found between
increase in awareness and the level of education. Increase in
awareness scores showed an increasing trend up to middle
education group and then decreased with higher education.
Awareness scores both before and after Ramadan were compared
with the duration of diabetes using Pearson’s correlation and it
was found significant at <0.01 level. Increase in awareness over
basal awareness score was more in rural population (1.23 ±3.76;
n=52) than urban population (1.09 ± 2.01; n=44) after Ramadan.
An overall significant increase (p<0.05) was seen in the number
of fasts kept this year when compared with the number of
fasts last year. Maximum increase was observed in 40-60 years
age group that is 25.74%, while it was 20.46% in <40 years age
and 2.64% in >60 years age group. 74 (77.08%) patients
could complete the target of more than half of fasting days. All
patients who were on diet control could complete ≥15 days fast
whereas patients on oral hypoglycemic agents, 81.6% and those
on insulin only 35.7% could keep >15 days fast. Lesser percentage
(70.45%) of tobacco users could complete >15 days fast than
non users (82.6%). Hypoglycemic episodes showed negative
correlation with level of education of patients. Three patients
Table 1: Demographic and clinical characteristics of the study population

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value: number (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Patients</td>
<td>96</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td>54 (56.3%)</td>
</tr>
<tr>
<td>Women</td>
<td>42 (43.7%)</td>
</tr>
<tr>
<td>Age group</td>
<td></td>
</tr>
<tr>
<td>&lt; 40 years</td>
<td>14 (14.6%)</td>
</tr>
<tr>
<td>41-59 years</td>
<td>72 (75.0%)</td>
</tr>
<tr>
<td>&gt; 60 years</td>
<td>10 (10.4%)</td>
</tr>
<tr>
<td>Education level</td>
<td></td>
</tr>
<tr>
<td>Illiterate</td>
<td>32 (33.3%)</td>
</tr>
<tr>
<td>Primary education</td>
<td>10 (10.4%)</td>
</tr>
<tr>
<td>Secondary education</td>
<td>24 (25%)</td>
</tr>
<tr>
<td>Middle education</td>
<td>10 (10.4%)</td>
</tr>
<tr>
<td>Graduate</td>
<td>18 (18.8%)</td>
</tr>
<tr>
<td>Post graduate</td>
<td>2 (2.1%)</td>
</tr>
<tr>
<td>Residential location</td>
<td></td>
</tr>
<tr>
<td>Urban</td>
<td>52 (54.2%)</td>
</tr>
<tr>
<td>Rural</td>
<td>44 (45.8%)</td>
</tr>
<tr>
<td>Duration of diabetes</td>
<td></td>
</tr>
<tr>
<td>&lt; Years</td>
<td>32 (33.3%)</td>
</tr>
<tr>
<td>5-10 years</td>
<td>53 (55.2%)</td>
</tr>
<tr>
<td>&gt; 10 Years</td>
<td>11 (11.4%)</td>
</tr>
<tr>
<td>Hypertension</td>
<td></td>
</tr>
<tr>
<td>Absent</td>
<td>40 (41.6%)</td>
</tr>
<tr>
<td>Controlled on drugs</td>
<td>28 (29.2%)</td>
</tr>
<tr>
<td>Inadequately controlled</td>
<td>28 (29.2%)</td>
</tr>
<tr>
<td>Treatment for Diabetes</td>
<td></td>
</tr>
<tr>
<td>Diet control</td>
<td>11 (11.5%)</td>
</tr>
<tr>
<td>Oral hypoglycemic</td>
<td>71 (73.9%)</td>
</tr>
<tr>
<td>Insulin</td>
<td>14 (14.6%)</td>
</tr>
</tbody>
</table>

on insulin had significant fall in HbA1c. These patients reported higher number of hypoglycemic symptoms. In rest 11, HbA1c was not significantly altered. Many patients on insulin and/or oral hypoglycemic therapy have broken fasts on occurrence of Hypoglycemia. Some of them skipped fasting for subsequent 2-3 days. No patient needed acute medical care or emergency hospitalization.

**Discussion**

To our knowledge only few Indian studies are there on the subject of diabetes and Ramadan. Two studies addressed the use of drugs eg. gliclazide modified release14 and pioglitazone15 while one of these have been done on metabolic alterations during Ramadan fasting. These studies are done on small number of patients and do not report any significant change in metabolic and glycemic parameters after Ramadan. Previous Indian studies have shown the safety of long acting gliclazide modified release tablets given at Iftar14 and safety and efficacy of pioglitazone.15 The ADA recommendations for management of patients of Diabetes during Ramadan are based on consensus rather than clinical trials. There is no such study considering comprehensive pre-Ramadan patient education and counseling and applying the recommendations on the patient population desirous of fasting and assessing the effects prospectively. We included those diabetes patients who decided to fast despite being told the risk of adverse events. The bulk of literature indicates that fasting in Ramadan is safe for the majority of type 2 Diabetes Mellitus patients with proper education and counseling.13-18 EPIDARI study has concluded that these patients represent a challenge to their physicians and more intensive education before fasting is needed.11 Whether counseling and educational programs will lead to successful fasting with minimum adverse events, is yet to be scientifically evaluated.

Our study aimed at applying the same recommendations on our patients to facilitate fasting and to identify some intervening and confounding attitudinal or clinical variables. Success of our counseling programs was assessed by surrogate markers and hard end points. Surrogate markers were, increase in awareness and change in attitude in patient groups after Ramadan and their decision to break their fast on the occasions of hypoglycemic episodes. We had also assessed some hard end points like number of fasts kept successfully this year as compared to previous year, the lesser number of adverse events this year and the immediate and medium duration effects of fasting which were hypoglycemia, ketoacidosis or dehydration during fasting period, re-assessment of glycemic control and effect on their few biochemical parameters after Ramadan.

Awareness scores were increased in all patient groups after Ramadan (Fig. 1). This showed the success of educational counseling. Awareness scores both before and after Ramadan were more in those who had diabetes for a longer duration (>5 years) because they had ample experience of fasting with Diabetes. Increase in awareness score after Ramadan was more in rural patients, because they had a lower initial level of awareness and were more receptive to such program based on religion. The fact that in all age groups, the number of fasts kept this year was more than the previous year showed that they have faced less adverse events this year (this was a verbal comment made by patients) (Fig. 2). Maximum increase was seen in 40-60 years age group probably because in this age there is maximum inclination towards religion and spirituality with high level of determination and fitness to fast. Younger age group may be less inclined towards religious issues many of them are involved in jobs concerning frequent travel and other highly demanding activity where drug dose and diet management becomes difficult. Tobacco users could complete fasting for lesser number of days as compared to non tobacco users. The reason may be the inability to resist the urge for tobacco as this is also prohibited during fast. An interesting finding was a significantly higher percentage of hypoglycemic episodes in hypertensives. A possible explanation may be that during hypoglycemia the blood pressure rises and may give rise to increased intensity of symptoms. In addition to that, symptoms of uncontrolled hypertension like headache and palpitations may be mistaken as hypoglycemia. Most patients were happy if they could keep more than 50% of fasts. This capability to fast ≥ 15 days was seen to be significantly affected by type of treatment taken for Diabetes. All patients on diet control were able to complete ≥ 15 days fast and it showed decreasing trend in patients on oral hypoglycemic drug and on Insulin respectively. Hypoglycemic episodes were more in higher education groups because of a better awareness and more cautious approach towards disease management. Glycemic control which was assessed by fasting and post prandial blood glucose was better after Ramadan in most patient groups. Two Indian studies have used fructosamine16 and glycosylated hemoglobin17 respectively for assessing glycemic control. We had got HbA1c done only in those 14 patients who were on insulin.
Three patients showed a significant fall and rest others had only a non significant change. Serum lipid profile showed no significant change after Ramadan. On several occasions, on experiencing hypoglycemic symptoms, patients had wisely decided to break their fast and did not fast for 2-3 days subsequently. No patient needed acute medical care or emergency hospitalization.

**Conclusion**

We conclude that physician facilitated fasting during Ramadan should be ensured and awareness of risks can be increased by counseling. Attitude of patients is very important determinant as it helps patients making their own decisions to break or skip fasting. Increased awareness is not the only marker on which safe and successful fasting depends. Many other factors like level of education of patients, previous experience of fasting, age and habits (tobacco use) of patient as an indicator of personal determination, have their effect on the success of these counseling programs on real grounds. Co-morbid conditions like hypertension may have profound effect on outcomes and careful approach must be made in dealing with these patients.

The decision to fast in a diabetic must be an individual’s own but it is the physicians duty to help such patients by increasing their knowledge and telling about precautions needed and crisis management if so occurs. Dosage adjustments have to be made in majority of patients on oral drugs and all patients on insulin. For Insulin requiring patients larger studies are needed before definite recommendations can be made. Safer immediate outcomes may be predicted in Type 2 Diabetes patients especially those on oral hypoglycemic agents or diet control. The long term possible effects of symptomatic hypoglycemia need to be studied.

**Acknowledgements**

We acknowledge the valuable efforts of Dr. Arshad Mehdi Rizvi, MD., in data collection and Dr. Athar Rizvi PhD, Shia PG College Lucknow, for statistical inputs, without whom this project could not have reached completion. We have no relevant conflict of interest to disclose.

**Questionnaire**

Ques.1. Should patients of diabetes take special care of themselves during Ramadan ? (Yes/No)

Ques.2. Whether it may be needed to change the drug or its dosages? (Yes/No)

Ques.3. Should a Diabetes patient stop the drugs during Ramadan at all? (Yes/No)

Ques.4. Should general dietary restrictions for diabetes be followed during Ramadan fasting? (Yes/No)

Ques.5. Those who are on insulin may suffer from low blood sugar during fast? (Yes/No)

Ques.6. On feeling low blood sugar symptoms one must break the fast? (Yes/No)

Ques.7. Pregnant ladies are permitted, not to keep fast? (Yes/No)

Ques.8. During the month of Ramadan if a Diabetes patient suffers from low blood sugar or develops high blood sugar or uncontrolled diabetes, does it have ill effect on the body? (Yes/No)

Ques.9. Does religion give the permission to skip or quit fasting, to those who are sick or Pregnant? (Yes/No)

Ques.10. Is it necessary for the diabetes patients to take medical advice before undertaking the fast? (Yes/No)

**References**

(Abstract) in 187th American Endocrine Society Annual meeting, San Diego, California, 4-7 June 2005. Chevy Chase, MD. The Endocrine society.


