Information about the Critically Appraised Topic (CAT) Series

The objective of the Doctor of Nursing Practice (DNP) program at George Mason University is to prepare graduates for the highest level of nursing practice. Emphasis is placed on evaluating and applying the evidence that supports practice, understanding and creating practice delivery systems based on patient outcomes, and assuming leadership roles in practice settings. Graduates of the program will be able to assume many roles in the health care system, including direct patient care, clinical nursing faculty, practice management, and policy development.

All DNP students take an evidence-based practice course titled Evidence Based Practice in Nursing and Healthcare (NURS 883). This hallmark course for the DNP program builds on knowledge of research methodologies to analyze the selection and evaluation of research underlying evidence based practice. Emphasis is placed on the translation of research in practice, the evaluation of practice and the improvement of the reliability of health care practice and outcomes.

The first assignment students complete is a Critically Appraised Topic (CAT). CATs are mini-systematic reviews and considered a snapshot of the literature on a topic of interest. Students critically appraise literature related to a focused clinical question and summarize the best available research evidence on the topic of interest. CATs conclude with clinical bottom lines for practitioners to quickly take away for consideration in practice.

The CATS published in MARS (Mason Archival Repository Service; mars.gmu.edu) are submitted by students after they have been reviewed, revised, and approved by their instructor. All CATs are current at the time of original publication but will not be updated over time.

Contact Information:
Dr. Lora Peppard, DNP, PMHNP-BC
DNP Program Coordinator
lpeppard@gmu.edu

GEORGE MASON UNIVERSITY

Are hemoglobin A1c levels affected if a type II diabetic fasts for religious observance?

Purpose: To explore if hemoglobin A1c values in type II diabetics increase, decrease or remain the same after fasting for Ramadan.

Appraised by: Ruhi Lakhani

Date of Completion: June 28th, 2013.

Date of Review: June 10th, 2013.

Question: Are hemoglobin A1c levels affected if a type II diabetic fasts for religious observance?

Search Strategies and Results: EBSCO HOST search engine was used to search: a) CINAHL, b) MEDLINE and c) PubMed databases. MESH TERMS used included "Islam and Ramadan and Diabetes: which resulted in 63 articles from CINAHL, 116 from MEDLINE and 115 from PubMed, with no time frame specified. Two of the articles were quasi-experimental studies and the other article was an observational study, which discussed fasting during Ramadan and effects on hemoglobin A1c levels. These articles were selected because they provided higher level of evidence (level 1b and 1c) on the specified topic with the MESH TERMS searched, in comparison to the other articles that were retrieved in the search.

Selected Articles:

1) Norouzy, A., Mohajeri, S.M.R., Shakeri, S., Yari, F., Sabery, M., Philippou, E., Varasteh, A.R., & Nematy. (2012). Effect of Ramadan fasting on glycemic control in patients with Type 2 diabetes. *Journal of Endocrinology Investigation, 35*, 776-771. doi: 10.3275/8015

2) M'Guil, M., Ragala, M.A., El Guessabi, L., Fellat, S., Chraibi, A., Chebraoui, L., Israili, A.H., Lyoussi, B. (2008). Is Ramadan Fasting Safe in Type 2 Diabetic Patients in View of the Lack of Significant Effect of Fasting on Clinical and Biochemical Parameters, Blood Pressure, and Glycemic Control? *Clinical and Experimental Hypertension, 30,* 339-357. doi: 10.1080/10641960802272442

3) Cesur, M., Corapcioglu, D., Gursoy, A., Gonen, S., Ozduman, M., Emral, R., Uysal, A.R., Tonyukuk, V., Yilmex, A.E., Bayram, F., & Kamel, N. (2007). A comparison of glycemic effects on glimepride, repaglinide, and insulin glargine in type 2 diabetes mellitus during Ramadan fasting. *Diabetes Research and Clinical Practice, 75*, 141-147. doi: 10.1016/j.diabres.2006.05.012

Evidence Retrieved:

Norouzy et al: Type 2 diabetics were recruited from Khorasan Diabetes Society and Ghaem

teaching hospital in Mashad, Iran. The sample size included 88 patients (45 male, 43 female, age 51 +/- 10 yrs). Patients had lab samples of fasting (FBG), insulin, glycated hemoglobin (HbA1c) total cholesterol, LDL, HDL, VLDL-cholesterol, triglycerides (TG) and CBC, 1 week prior to Ramadan (Period 1), day after the end of Ramadan (Period 2), and 1 month after the end of Ramadan (Period 3). Of the 88 patients who completed period 1 and 2 assessments (before and after Ramadan), 61 patients were on OHD (17 metformin, 10 on sulphonylurea, 34 on combination of the two), and 27 patients were diet controlled. FBG and HbA1c significantly increased (p=0.002 and <0.001, respectively), while insulin concentration showed significant reduction (p=0.017) during Ramadan. Values of HbA1c were 8.2 +/-1.6% (66+/-18 mmol-mol), 9.4+/-2% (79+/-22 mmol-mol), and 8.4+/-205% (69+/-27mmol-mol), in the three periods (p<0.001). Although HbA1c increased slightly during Ramadan, it did not show any significant change between the 1st and 3rd period i.e. when comparing values before Ramadan and 1 month after the end of Ramadan. According to the glycemic control values, significant increase in HbA1c between beginning and end of Ramadan in poorly controlled patients (p=0.016) and well-controlled patients (p<0.001). However, only poorly controlled patients had a significant reduction in HbA1c 1 month following Ramadan compared to the end of Ramadan (p=0.016). This study showed that Ramadan fasting had a negative effect on HbA1c and FBG. The increase in FBG and HbA1c maybe due to food intake and lifestyle changes during Ramadan.

Appraisals:

Strengths: This was a prospective cohort clinical trial, quasi-experimental study. Participants were part of 3 periods that measured glycemic control, prior to Ramadan, before and after Ramadan, and 1 month after Ramadan, which gave a solid comparison analysis. Subjects were assessed 3 times, which made it possible to follow and evaluate their progression in free-living conditions.

Weaknesses: In this study, there was no control group, and the sample size was small. Also, dietary intake of the patient during Ramadan was not recorded. HbA1c was used as a marker of long-term glycemic control; it would have been useful to utilize a short-term marker lab study such as fructosamine levels.

M'Guil et al: This study was conducted in 120 Moroccan patients with non-insulin type 2 diabetes (62 women aged 49.8+/- 1.5 yrs and 58 men aged 55.1 +/- 1.4 yrs) with duration of diabetes 4.4 to 5.5 years, that attended the Endocrinology, Dialectology and Nutrition Services of Hospital Ibn Sina, Rabat, in an outpatient setting. Study subjects were on oral hypoglycemic drug (OHD), and fasted for a 30-day period. The time frame of the study was conducted during December 2001 to January 2002, with the average duration of the fast being 13 hours long. HbA1c was measured at the beginning of Ramadan and 2 weeks after fasting was completed. Plasma fructosamine levels decreased with fasting, more in males than in females, but levels of HbA1c and C-peptide did not change. Plasma insulin levels increased with fasting and returned to baseline values two weeks after Ramadan. HbA1c levels for females prior to Ramadan were 6.70+/-0.65, the results on the 15th day of Ramadan were 6.65+/-0.62, and for males prior to Ramadan the results were 6.59+/-0.97, and the

results on the 15th day of Ramadan were 6.61+/-0.71. Statistical significance between the value on day 0 and day 15 $p<0.05$, the statistical significance between values on day 0 and day 29, $p<0.05$, $p<0.01$, and the statistical significance between values on day 29 and day 45 $p<0.05$, $p<0.01$, which demonstrated that fasting had no effect on HbA1c. There was no change in the level of HbA1c after two weeks of fasting. A decrease in plasma fructosamine levels indicated that glycemic control was not adversely affected.

Appraisals:

Strengths: This was a quasi-experimental study. Participants took part in 4 different laboratory measurements, 1) prior to Ramadan, 2) day 15 of Ramadan, 3) day 29 of Ramadan, and 4) day 45, (15 days after Ramadan). Patients received appropriate dietary and physical activity education and their OHDs were rescheduled according to their fasting and eating periods.

Weaknesses: There was no control group present, and convenience sampling was used. The study took place in an outpatient setting, which made compliance an issue with participants in regard to recommendations for nutrition and exercise. OHD dosing could not be assessed, and the study had no control over the lifestyle of the patients, i.e. exercise, daily activities.

Cesur et al: This was an open-label, multicenter, prospective, observational study that was carried out in three University hospitals and one private hospital in Turkey. This study took place during October 15th to November 13th, 2004, with the average fasting period being 12.5 hours. This study included type 2 diabetics; age 33-67 years on oral hypoglycemic drugs, fasting throughout the month of Ramadan. 49 type 2 diabetic patients were in a fasting group, then divided into 3 smaller groups organized by the type of hypoglycemic drug the patient was taking. The control group consisted of 16 type 2 diabetics (non fasting group). Blood samples were obtained from all subjects 1 to 2 days prior to Ramadan, 4 days after the fasting period finished, and 1 month after Ramadan to test HbA1c and fructosamine levels. In the fasting group, both FBG and PBG levels showed no significant changes during the post-Ramadan and 1-month post Ramadan period in comparison to the pre Ramadan period. In the non-fasting group, FBG levels did not change significantly, whereas PBG levels increased at the post Ramadan and 1 month post Ramadan period in comparison to the pre Ramadan period ($p<0.05$ and $p<0.001$). At post Ramadan and 1 month Post Ramadan, changes of PBG values of fasting group were lower than PBG values of non fasting group ($p<0.01$ for both time). Although HbA1c levels increased somewhat in NFG, there was not a statistically significant increase, and showed no significant changes in the fasting group. HbA1c fasting group pre-Ramadan levels were 7.0+/-1.1, post-Ramadan levels were 6.9+/-1.1, and one-month post Ramadan levels were 6.9+/-1.1. Non-fasting pre-Ramadan levels were 7.8+/-1.1; post-Ramadan levels were 7.9+/-1.2, and one-month post-Ramadan levels were 8.0+/-1.1.

Appraisals:

Strengths: The patients were randomized into one of three treatment groups for the study (randomized control). Type 2 diabetic control groups were present within the study, which provided a good comparison between fasting and non-fasting diabetics.

Weaknesses: This study had a small sample size; there were 49 type 2 diabetic participants. It would have been appropriate to use fructosamine lab values (which is a accurate lab value to use for a short time frame measurement to detect change in glucose level) instead of HbA1c, because measuring HbA1c at 1-month interval may not have been an ideal lab indicator to evaluate glycemic control.

Conclusions/Clinical Bottom Line: These studies have shown with the evidence of statistical measurement, that little or no impact is made on a type 2 diabetic's HbA1c level if they fast for religious purposes, with proper diabetic diet and activity level guidance prior to starting the fasting regimen. However, further evidence may be needed to determine if fasting has an impact on a type 2 diabetic's HbA1c levels in a long-term time frame. HbA1c is a reliable index of long-term control of glucose in diabetic patients, while measurement of fructosamine provides an index of glycemic status over preceding 1-2 weeks. Future studies may take into consideration of the parameters and possible use fructosamine as a baseline measurement after Ramadan then followed by an HbA1c measurement 2 months (60 days) during the post Ramadan period.