DO "FAR-INFRARED" SAUNAS HAVE CARDIOVASCULAR BENEFITS IN PEOPLE WITH TYPE II DIABETES MELLITIS? A SEQUENTIAL LONGITUDINAL INTERRUPTED TIME SERIES DESIGN STUDY

Dr. Richard Beever BSc, MD, CCFP

Acknowledgments

We thank the UBC Clinical Investigator R3 program, and Dr. Harvey Thommasen, for their guidance and input. We also thank Dr. Michael Klein, Dr. S Douglas, Dr. J Pawlovich and Dr. S. Pawlovich for peer-viewing this article.

Contributors

Dr. Richard Beever was involved in all aspects of this original study. Mrs. Evanson participated in designing the study and gathering the data. All authors reviewed and approved the final version of the manuscript.

Competing interests

None.

Corresponding author

Dr. Richard Beever, Box 98, Fraser Lake, BC, V0J-1S0. Fax 250-699-6510; email Richard.beever@northernhealth.ca

Word count: Text-Abstract-

Two tables. One figure.

DO FAR-INFRARED SAUNAS HAVE CARDIOVASCULAR BENEFITS IN PEOPLE WITH TYPE II DIABETES MELLITIS?

ABSTRACT:

OBJECTIVES:

To determine if far-infrared saunas have a beneficial effect on cardiovascular health in those with type II Diabetes.

DESIGN:

Sequential, longitudinal interrupted time series design study.

SETTING:

Fraser Lake BC. A rural community located 165 KM west of Prince George. **PARTICIPANTS:**

Type II Diabetes from the Fraser Lake Community Health Center. 165 people were invited, 22 people signed up and 15 people completed the study.

INTERVENTIONS:

20 minute, thrice-weekly infrared sauna sessions, over a period of three months.

MAIN OUTCOME MEASURES:

Weight, height, waist circumference, blood pressure (BPtru), HbgA1c, fasting blood glucose and cholesterol profile. Baseline study parameters were measured within one week prior to commencing sauna sessions. Post intervention measurements were collected between 1 and 3 days after the last sauna session.

RESULTS:

Mean systolic blood pressure decreased by 6.4 mmHg (124.3+-12.4 vs 117.9+-14.9, p=0.05, CI 0.01 to12.71 mmHg). There was a trend towards decreased waist circumference (115.0+-13.4 vs 112.7+-11.9, p=0.09, CI - 0.4 to 5.1 cm). There was also a trend towards a worsened cholesterol ratio (4.2+-0.9 vs 4.4+-0.9, p=0.054, CI 0.411 to 0.004). All other measurements did not change.

CONCLUSION:

We conclude that infrared sauna use maybe beneficial for lowering blood pressure and decreasing waist circumference but is not effective for lowering fasting blood sugar, HgA1c, cholesterol or triglyceride levels. Uptake of infrared saunas use is greater than the uptake of other lifestyle interventions.

Keywords: infrared sauna, hypertension, weight loss, cholesterol.

Diabetes Care Journal of Alternative&Complamentary Medicine

"The health consequences of obesity, diabetes and cardiovascular disease will overwhelm and cripple our health care system unless the current trend is stopped"(1). As the risk of coronary heart disease increases with multiple risk factors, reducing multiple risk factors may have a synergistic effect in the prevention or treatment of cardiovascular disease (2). Manufactures of far-infrared saunas (FIRS) claim numerous health benefits including: "weight loss, improving cardiovascular health, normalizing blood pressure, removing cholesterol and reducing pain, stress and fatigue" (3). If FIRS improve multiple risk factors, then their benefit in reducing cardiovascular disease could be significant. Although FIRS are advertised in publications targeting Canadian Physicians (3) the evidence to support such claims is limited (4,5,6,7,8,9,10,11,12,13).

Diabetes is a major risk factor for cardiovascular disease (14,15). However there is no published research examining the effects of infrared sauna use in diabetics. The proposed study will address this question and overcomes the pitfalls of the prior studies by having a larger sample size, longer study duration and using validated measurement tools.

As such, this study is of importance to those currently suffering from diabetes or cardiovascular disease. The implications will be of significant interest to health care providers, patients, manufactures, regulatory agencies and consumers.

The purpose of this study is To determine if far-infrared saunas have a beneficial effect on cardiovascular health in those with Type II Diabetes.

METHODS:

DESIGN: We employed a sequential, longitudinal interrupted time series cohort study.

INTERVENTON: We studied a CSA approved Sunlight Armana 3 person infrared sauna, in accordance with the manufactures instructions. Subjects were asked to attend 20-minute sauna sessions, three times a week over a 3month period. MEASUREMENTS: To determine if far-infrared saunas have beneficial effects on cardiovascular health, we measured: height, weight, waist and hip circumference, blood pressure, HbgA1c, fasting glucose and fasting lipid profile. Blood pressure was measured using the BPTru – 5 measurements taken 2 minutes apart. This has been shown to have similar accuracy as a 24-hour ambulatory blood pressure (16,17,18).

Baseline measurements were taken with-in one week prior to starting sauna sessions and post-intervention measurements were taken between 1 and 3 days after the last sauna session.

The study period ran over the winter of 2007-2008.

Subjects were asked to refrain from modifying their current exercise routine, to refrain from starting any new 'diets' or herbal medications and to review any new prescription meds with the Principle Investigator. An exercise routine and medication review was conducted during the baseline and follow-up interviews.

INCLUSION CRITERIA: Type II diabetic patients from the Fraser Lake Community Health Centre were invited to participate in this study.

EXCLUSION CRITERIA: See table 1.

STATISTICAL ANALYSIS: The UBC Statistical Department conducted the statistical analysis. A value of p<0.05 was considered statistically significant. Due to the smaller sample size our statistician advised to include finds with a p<0.10 as possibly significant.

ETHICS: Both the University of British Columbia and the Northern Health Authority Ethics Review Boards have approved this study.

FINDINGS:

The results are summarized in Table 2.

Blood pressure decreased by 6.4 mmHg (124.3+-12.4 vs 117.9+-14.9, p=0.05, CI 0.01 to12.71 mmHg). There was a trend towards decreased waist circumference by 2.33 cm (115.0+-13.4 vs 112.7+-11.9, p=0.09, CI -0.4 to 5.1 cm). There was also a trend towards a worsened cholesterol ratio by 0.2 mM (4.2+-0.9 vs 4.4+-0.9, p=0.054, CI 0.411 to 0.004). Weight, fasting blood glucose, cholesterol and triglyceride levels did not change.

Quality Assurance: Baseline screening revealed one person with a BP >160/90, HgbA1c >9.0 or a Cholesterol/HDL ratio >7.0. She was referred to

her Family Physician and removed from the formal study, as initiation of pharmacological treatment would invalidate our findings. Those who made changes to their physical activity, diet, OTC/herbal supplements or medication prescriptions throughout the 3-month study period were excluded from the analysis. Accordingly, improvements among study subjects in blood pressure, and possibly weight and waist circumference, cannot be attributed to changes in exercise, food, OTC/herbal supplements or medications.

Adverse Events: There were no adverse events. Specifically there were no reported symptoms suggestive of pre-syncope, heat rash, heat exhaustion or heat stroke.

Participant attenuation: see table 3. Letters of invitation were sent out to our diabetic population (167 people). 38 subjects expressed interest in participating. 22 subjects signed up and completed the baseline measurements. 2 were excluded, leaving 20 to participate in the formal study. All 20 began the study, 15 (75%) completed the study. Of the 5 who did not complete the study, one was lost to follow-up, two cited time commitment factors, and the other two were a husband/wife who cited transportation and mobility problems.

DISCUSSION:

The purpose of this study was to measure the effects of infrared saunas on cardiovascular health and quality of life. This study represents an improvement from previously published studies in that it has a larger sample size (4,7,8,13) and substantially longer duration (4,5,6,8,9,10,11,12,13). Post intervention measurements were taken at least 24 hours after the last session, allowing sufficient time for re-hydration.

Another important difference is that our study did not rely on inpatients as subjects. While this was associated with a lower completion rate, it was more discerning of the real-world uptake of sauna use as a therapeutic lifestyle intervention. As such, this study has the advantage of examining generalizable compliance/adherence rates of infrared sauna use. The completion rate of 75% is significantly better than one would expect to see regarding the successful uptake of lifestyle change in diabetics (19). Effective lifestyle modifications that have high patient uptake are key to preventing and treating the current epidemic of lifestyle induced chronic disease (20,21). Infrared sauna may be a novel therapeutic intervention in this regard.

Blood pressure control is the single most important risk reduction strategy for patients with type II diabetes (22,23,24). Infrared sauna use is beneficial for lowering blood pressure. The clinical relevance of lowering systolic blood pressure by 6.4 mmHg is clinically significant and well documented (22,23,24,25,26,27,28,29). As such, regular use of an infrared sauna may serve as a useful non-pharmacological adjunct in treating hypertension.

Up to 90% of type II diabetics are overweight (30). Obesity is a national and global epidemic and is a leading cause of morbidity and mortality (31,32,33,34). Infrared sauna use may reduce waist circumference. The clinical relevance of lowering waist circumference imparts significant benefits to those with obesity, diabetes, hypertension, coronary artery disease, hyperlipidema, obstructive sleep apnea, arthritis, metabolic syndrome and polycystic ovarian syndrome (25,31,33,35,36,37,38,39,40).

Our results suggest that, in our study population, infrared sauna treatment is not effective for lowering weight, HbgA1c, fasting blood glucose, cholesterol or triglyceride levels. This strengthens the conclusions of previous studies which have also have found no effect on cholesterol or triglyceride levels and clarifies_those which have given conflicting results regarding changes in weight, blood pressure and fasting glucose (8,9,10,11,12). It should be noted that all our subjects were on a statin during the study. As such their cholesterol levels were already lowered pharmaceutically. As such the results of this study regarding cholesterol reduction cannot be extended to those not on a statin.

Limitations:

This study is not a randomized, blinded, placebo controlled trial. In studies examining sauna therapy it would not be possible to have a blinded placebo control group. Randomization was not a possibility given our sample size. We therefore chose the sequential, longitudinal interrupted time series cohort design as it has the unique advantage of allowing subjects to serve as their own controls, thereby ensuring perfectly matched groups and allowing all subjects to participate in the intervention. This design is well suited to small and remote centers, where subject recruitment is a significant barrier to research.

A potential disadvantage of sequential, longitudinal interrupted time series design studies is the presence of confounding variables that may affect the study population. For example, weight and blood pressure have a tendency to increase over the winter months (41,42). This would have a negative confounding impact on our data, leaving the impression that sauna therapy was less effective than it truly was. Likewise, it strengthens the validity of our positive findings.

This study is limited by a small sample size and relatively short duration. Nevertheless, our study represents an improvement over the majority of previously published studies. Our study had the advantage of having a larger sample size (4,7,8,13) and/or a substantially longer duration (4,5,6,8,9,10,11,12,13). In fact this study is the largest/longest study to date.

CONCLUSION:

Our results suggest that infrared sauna use lowers blood pressure and waist circumference. It does not seem to lower weight, fasting blood sugar, cholesterol, or triglycerides. For these outcomes, larger studies are needed. Such studies may want to focus on subjects with cardiovascular risk factors such as hypertension, dyslipidemia, diabetes or obesity.

This study is the first to examine compliance/adherence rates of infrared sauna use in an ambulatory population. We found that the uptake of infrared saunas use is greater than the uptake of the standard lifestyle interventions. The combination of favorable compliance/adherence as well as effectiveness in improving blood pressure and waist circumference makes infrared sauna therapy an attractive lifestyle option.

This study is an improvement from previously published studies in that: it has the largest sample size and/or longest duration than any study to date; post intervention measurements were taken at least 24 hours after the last session, allowing sufficient time for re-hydration and; the use of validated, internationally recognized measurement tools.

This study is of importance to those currently suffering from diabetes, hypertension, obesity, high cholesterol or cardiovascular disease. The implications may be of significant interest to health care providers, patients, manufactures, regulatory agencies and consumers. **Table 1**: Contraindications.

ABSOLULTE CONTRAINDICATIONS:

a) Anhydrosis.

b) Inability to fit into sauna: although this is a three-person sauna, the door is relatively small (63.5 cm, 25") so some of our more obese patients may not be able to enter.

c) Communicable skin disease.

d) Pregnancy. Although far-infrared treatment is not harmful to the pregnancy (16,17,18), the weight gain and blood pressure changes experienced during pregnancy would invalidate the results of the study.e) Unstable angina, recent myocardial infarction (30 days) and severe aortic

stenosis.

f) Medications via a patch delivery system (such as nicotine, fentanyl, nitroglycerine or contraceptive patches) – the increased temperature may cause an increased rate of delivery from the patch, leading to unwanted side effects.

g) Any illness causing a fever.

h) Newly discovered or currently uncontrolled diabetes, hypertension or hypercholesterolemia necessitating medical treatment.

i) If baseline screening finds anyone with a BP >160/90, A1c>9.0 or a Cholesterol/HDL ratio >7.0, they will be referred to their Family Physician and removed from the study as initiation of pharmacological treatment may invalidate our findings. (They will have the option of continuing to use the sauna for the duration of the study if they so choose – however we would not collect further data from them as it may invalidate our results.)

RELATIVE CONTRAINDICATIONS:

a) Medications that may impair sweating (such as B-blockers and anticholinergics).

b) Medical conditions that may impair sweating (such as Parkinson's

Disease, Multiple Sclerosis, CNS tumors, or Autonomic Neuropathies). c) Claustrophobia – although one is never fully covered by the sauna: the subjects' head can remain out of the sauna for the duration of treatment.

9 of 15

Measurement		Mean	Standard Deviation	Mean Improvement	p-value	95% Confidance Interval
Systolic Blood Pressure	-pre	124	12.4	6.4	0.050*	0.01 to 12.7
(mmHg)	-post	117	14.9			
Diastolic Blood Pressure-pre		74	8.9	2.6	0.32	-2.8 to 7.9
(mmHg))	-post	71	9.9			
Pulse	-pre	71	13.2	3.0	0.49	-6.3 to 12.3
	-post	68	8.0			
Fasting Blood Glucose	-pre	7.4	1.9	-0.2	0.63	-0.94 to 0.59
(mmol/l)	-post	7.5	1.7			
HgbA1c	-pre	6.7	0.7	0.0	0.92	-0.32 to 0.30
	-post	6.7	0.8			
Fasting Cholesterol Rati	io-pre	4.18	0.9	-0.2	0.054*	-0.41 to 0.00
	-post	4.38	0.9			
Fasting Triglycerides	-pre	2.05	0.8	0.04	0.82	-0.31 to 0.38
(mmol/l)	-post	2.02	0.8			
Waist Circumference	-pre	115	13.4	2.3	0.095*	0.4 to 5.1
(cm)	-post	113	11.9			
Weight	-pre	98.7	18.0	-0.8	0.26	-2.3 to 0.7
(Kg)	-post	99.5	17.9			
Body Mass Index (BMI) -pre		35.1	7.2	-0.3	0.27	-1.0 to 0.3
	-post	35.5	7.5			

Figure 1: Participant Attenuation.

167 letters of invitation.
38 people expressed interest.
/ \
16 22 people signed up.
/ \
2 20 people started using the sauna
/ \
5 15 people completed

References:

 Emili A, Abushomar H, Kalpana N. *Treating metabolic syndrome*. *Lifestyle change or medication*.Canadian Family Physician vol 53:July 2007, 1203-1205.
 Hoeg JM. *Evaluating coronary heart disease risk: titles in the mosaic*.

JAMA 277:1387-1390, 1997.

3. Just for Canadian Doctors: Lifestyle, Leisure, Recreation. Winter 2006, Page 2. Advertisement.

4. Masuda A. Kihara T. FukudomeT. Shinsato T. Minagoe S. Tei C. *The effects of repeated thermal therapy for two patients with chronic fatigue syndrome*. J of Psychosomatic Research. 58(4):383-7, 2005, Apr.

5. Masuda A. Koga Y. Hattanmura M. Minagoe S. Tei C. *The effects of repeated thermal therapy for patients with chronic pain*. Psychotherapy&Psychosomatics. 74(5):288-94, 2005.

6. Kihara T. Biro S. Ikeda Y. Fukudone T. Shinsato T. Masuda A et al. Effects of repeated sauna treatment on ventricular arrhythmias in patents with chronic heart failure. Circulation Journal. 68(12):1146-51, 2004, Dec. 7. Sugahara Y. Ishii M. Muta H. Egami K. Akagi T. Matsuishi T.. Efficacy and safety of thermal vasodilation therapy by sauna in infants with severe congestive heart failure secondary to ventricular septal defect. The American J of Cardiology Vol 92. July 1, 2003.

8. Miyamoto H. Kai H.Nakaura H. Osada K. Mizuta Y. Matsumoto A et al. *Safety and efficacy of repeated sauna bathing inpatients with chronic systolic heart failure: a preliminary report.* Journal of Cardiac Failure. 11(6):432-6, 2005, Aug.

9. Nguyen Y. Naseer N. Frishman W. Sauna as a therapeutic option for cardiovascular disease. Cardiology in Review. 12 (6):321-4, 2004 Nov-Dec.

10.Kihara T. Biro S. Imamura M. Yoshifuku S. Takasaki K. Ikeda Y et al. *Repeated sauna treatment improves vascular endothelial and cardiac function in patients with chronic heart failure*. Journal of the American College of Cardiology. 39(5):754-9, 202 Mar 6.

11.Masuda A. Miyata M. Kihara T. Minagoe S. Tei C.. *Repeated sauna therapy reduces urinary 8-epi-prostaglandin F2alpha*. Japanese Heart Journal. 45(2):297-303, 2004, Mar.

12. Imarmura M. Biro S. Kihara T. Yoshifuku S. Takasaki K. Otsuji Y et al. *Repeated thermal therapy improves impaired vascular endothelial function in patients with coronary risk factors.* Journal of the American College of Cardiology. 38(4):1083-8, 2001 Oct.

13. Biro S. Masuda A. Kihara T. Tei C.. *Clinical implications of thermal therapy in lifestyle-related disease*. Experimental Biology & Medicine. 228(10):1245—9, 2003 Nov.

14. Gerstein H, Meltzer. *Preventive medicine in people at high risk for chronic disease: the value of identifying and treating diabetes.* Can Med Assoc J. 1999:160(11):1593-5.

15. Kaur J, Singh P and Sowers J. *Diabetes and cardiovascular disease*. Am J Theher 2002;9(6):510-5.)

16. Mattu GS, Heran BS, Wright JM. *Overall accuracy of the BpTRU-an automated electronic blood pressure device*. Blood Pressure Monitoring. 9(1):47-52, 2004, Feb.

17. Beckett L and Godwin M. *The BpTRU automatic blood pressure monitor compared to 24 hour ambulatory blood pressure monitoring in the assessment of blood pressure in patients with hypertension*. BioMed Central Cardiovascular Disorders.2005, 5:18-23.

18. Greiver M. *improving diabetes care in my practice*. Canadian Family Physician – Practice Tips. Vol 53, nov 2007. pg 1897.

19. Jones H. Ruggiero L. Edwards L. *Diabetes Stages of Change*. *Methodology and study design*. Can J Diabetes Care. 2001;25:97-107.

20. Gaede P, Videl P, Larsen N et al. *Multifactorial intervention and cardiovascular disease in patents with type 2 diabetes.* N Engl J Med. 2003:348:383-393.

21. Harris SB, Petrella RJ, Lambert_Lanning A et al. *Lifestyle management for type 2 diabetes. Are family physicians ready and willing?* Can Fam Physician. 2004;50:1235-43.

22. Snow V, Weiss KB, Mottur-Pilson C et al. *The evidence base for tight blood pressure control in the management of type 2 diabetes mellitus*. Ann Intern Med 2003:138:587-92

23. Vajan S, Hayward RA. Treatment of hypertension in type 2 diabetes mellitus: blood pressure goals, choice of agents and setting priorities in diabetes care. Ann Intern Med 2003;138:593-602

24. UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). Lancet 1998;352:837-853

25. Padwal R. Campbell N. Touyz RM.. Applying the 2005 Canadian Hypertension Education Program recommendations: 3. Lifestyle modifications to prevent and treat hypertension. CMAJ 2005;173: 749-51.

26. Quan A. Kerlikowske K. Gueyffier F. Boissel JP. *Efficacy of treating hypertension in women*. J Gen Intern Med 1999;14:718-729.

27. Bhavnani S. Nicholls S. Shi H. Thakker K. Tuzuc EM. Thompson P et al. Clinical Benefit of Intensive Blood Pressure Lowering in Obese Patients with Coronary Artery Disease. A Camelot sub-study. The Journal of Clinical Hypertension 2007:supplament A volume 9 no 5, P-66. 28. Lackland DT. Gilbert G. Carter R. Mountford W. Woolson R. Egan B. *Long-term Survival by Hypertension Status for White and Black Men and Women*. The Journal of Clinical Hypertension 2007:supplament A volume 9 no 5, P-137.

29. Staessen JA, Wang JG, Thijs L. What can be expected from optimal blood pressure control? J Hypertens Suppl. 2003 May;21(2):S3-9.
30. Sigal RJ, Kenny G. Physical Activity – 2003 Clinical Practice Guidelines Hightlights. Canadian Diabetes. Vol 18 No.1. Spring 2005 Pg 2,3 and 7.

31. Kopelman PG. Obesity as a medical problem. Nature 404:635-643,2000.
32. World Health Organization. Obesity and overweight. Global strategy on diet, physical activity and health. Geneva, Switz: World Health Organization; 2005.

33. Lau D, Douketis J, Morrision K et al. 2006 Canadian clinical practice guidelines on the management and prevention of obesity in adults and children [summary]. CMAJ 2007;176 (8 SUPPL): S1-13.

34. Tjepkema M. *Adult obesity in Canada: measured height and weight.* Ottawa, Ont: Statistics Canada: 2005.

35. Kato J. Eto T. Kitamura K.. Importance of Body Weight Control and Commitment by Physicians in Controlling Blood Pressure: A Community-Based Observational Study. . The Journal of Clinical Hypertension 2007:supplament A volume 9 no 5, P-134.

36. Foreyt JP. *The Role of Lifestyle Modification in Dysmetobolic Syndrome Management [Review]*. Nestle Nutrition Workshop Series Clinical & Performance Program. 11:197-205; discussion 205-6, 2006.

37. Douketis JD. Feightner JW. Attia J. Feldman WF. *Periodic health examination, 199 update: 1. Detection, prevention and treatment of obesity.* CMAJ Feb.23 1999;160 (4):512-25.

38. Marshall, Ken. *Mosby's Family Practice Sourcebook – Evidence Based Emphasis*. 2001, Mosby, Inc. ISBN: 1-55664-469-8

39. Canadian Diabetes Association Website, Diabetes Facts: The prevalence and costs of diabetes. <u>www.diabetes.ca/Section_About/prevalence.asp</u>, (accessed on October 1, 2007.)

40. Knowler WC, Barrett-Connor E, Fowler SE et al. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin *Diabetes prevention program research group*. New Engl J Med 346:393-403,2002

41. Argani H. Javanshir, MR. Seasonal variations of blood pressure in hemodialysis and renal transplant recipients. Transplantation Proceeding, 36, 148-149 (2004).

42. Woodhouse, PR. Khaw KT. Plummer M. Seasonal variation of blood pressure and its relationship to ambient temperature in an elderly population. Journal of Hypertension. Nov;11(11):1267-1274.