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## Naturopathic Medicine and Type 2 Diabetes: A Retrospective Analysis from an Academic Clinic

**Ryan Bradley, ND [Research Fellow]** and

Bastyr University, Kenmore, WA; Supervises the Diabetes and Cardiovascular Wellness Program, Bastyr Center for Natural Health

**Erica B. Oberg, ND [Associate Physician]**

Institute for Complementary Medicine, Seattle, WA. Research affiliations, Bastyr University and the University of Washington School of Public Health

Erica B. Oberg: eoberg@u.washington.edu

### Abstract

**INTRODUCTION**—Accurate descriptions of naturopathic medicine as a whole system of medical practice are rare in the literature and nonexistent for type 2 diabetes.

**METHODS**—Using retrospective analysis of medical records at an academic naturopathic outpatient clinic, data was abstracted to investigate patterns of patient status, details of treatment recommendations, and levels of evidence.

**RESULTS**—Most naturopathic medical care for type 2 diabetes is adjunctive, although naturopathic physicians are qualified to fill the role of primary care providers. Glycemic control and other vital statistics in patients receiving naturopathic care are comparable to published national averages. Naturopathic physicians prescribe comprehensive therapeutic lifestyle change recommendations supported by a high level of evidence – 100 percent received dietary counseling, 69 percent were taught stress reduction techniques, and 94 percent were prescribed exercise. Patients additionally received prescriptions for botanical and nutritional supplementation, often in combination with conventional medication. Analysis of individual supplement effects was not performed due to inadequate records. Components of treatment recommendations are often evidence-based, with varying evidence quality.

**CONCLUSION**—Naturopathic medicine as a whole medical system supplies evidence-based lifestyle recommendations as suggested in management guidelines for diabetes, hypertension, and hyperlipidemia set forth by the respective national organizations – the American Diabetes Association (ADA), the Joint National Committee on Hypertension (JNC-7), and the National Cholesterol Education Program results of the third Adult Treatment Panel (NCEP ATP-III). Increased research effort to determine the safety and efficacy of combinations of supplements or medications and supplements is warranted. Education of other health care providers, patients, and health policy makers regarding the value of the naturopathic approach in the treatment and prevention of type 2 diabetes is warranted, yet prospective data on efficacy must be collected.

### Background

Naturopathic medicine is a unique, whole medical system emphasizing disease prevention and patient empowerment. Chart review of current and past patients with type 2 diabetes was conducted to extract data on characteristics of care of diabetic patients at the Bastyr Center for Natural Health (BCNH). BCNH is the principal teaching clinic for Bastyr University, a naturopathic medical school in Kenmore, WA. The BCNH facility provides science-based natural medicine care to more than 38,000 patients a year. The data extracted from the charts

of these patients was analyzed for: (1) role of BCNH providers in diabetic patient's health care, (i.e., primary care or adjunctive care), (2) status of patient's glycemic control, blood pressure, and lipid measures, (3) characteristics of conventional and naturopathic treatment approaches, (4) level of evidence supporting current naturopathic practices, and (5) potentially efficacious treatment protocols for further study.

Type 2 diabetes mellitus is a major cause of morbidity and mortality in the United States and incidence is rising. There are over 16 million people in the United States with type 2 diabetes and 800,000 new cases are diagnosed annually.<sup>1,2</sup> It is estimated one in three Americans will have diabetes by 2025. The estimated annual cost of diabetes-related medical expenses was \$132 billion in 2002, accounting for more than 12 percent of the U.S. health care budget.<sup>3</sup> Despite this expenditure, national statistics show that only 37 percent of diabetics are in good glycemic control, as defined by a glycosylated hemoglobin (HbA1c) <7 percent, the standard set by the American Diabetes Association (ADA).<sup>1</sup>

In 2002–2004, the National Center for Complementary and Alternative Medicine (NCCAM) funded a two-year study for the naturopathic medical community to define research priorities for the next 5–10 years. The resulting research agenda identified two foci of priority for the naturopathic community – type 2 diabetes and geriatric care. As descriptions of naturopathic medical care are just emerging in the medical literature, the investigators first sought to characterize the current care delivered for the purposes of future rigorous evaluation.<sup>4</sup> The identification of unique, efficacious prevention and treatment strategies used by naturopathic physicians would serve individual diabetes patients in their overall health and increase understanding of the role of naturopathic treatment within the medical community at large.

## Specific Aims

- Assess the role of BCNH in providing care for patients with type 2 diabetes, i.e., primary care or adjunctive care.
- Assess the percentage of patients meeting ADA recommendations for glycemic control, lipid management, and blood pressure control at BCNH compared to national averages.
- Assess the content of treatment recommendations, i.e., nutritional supplementation, dietary recommendations, exercise prescription, etc.
- Assess the level of evidence supporting naturopathic treatment approaches used at BCNH based on United States Preventive Services Task Force (USPSTF) and ADA classification methods.
- Identify potentially efficacious treatment protocols for further prospective study.

## Level of Evidence

Many health delivery organizations have developed evidence-based guidelines to assist physicians in translating the growing body of scientific research into clinical practices. Two relevant agencies, the ADA and the USPSTF, have published analyses of the level of evidence for diet/lifestyle/complementary alternative medicine (CAM) care in diabetes. These agencies provide definitions used for the “level of evidence” analysis.<sup>5,6</sup>

## ADA Level of Evidence Definitions

Level A:

- Clear evidence from well-conducted, generalized, randomized, controlled trials (RCTs) that are adequately powered, e.g., multicenter trial, meta-analysis incorporating quality ratings

Level B:

- Supportive evidence from well-conducted cohort studies or supportive evidence from case-control study
- Well-conducted prospective cohort study or registry
- Well-conducted meta-analysis of cohort studies

Level C:

- Supportive evidence from poorly controlled or uncontrolled studies
- RCTs with one or more major, or three or more minor, methodological flaws that could invalidate
- Observational study with high potential for bias
- Case series or case reports
- Conflicting evidence with the weight of the evidence supporting the recommendation

Level E:

- Expert consensus or clinical experience. Expert opinion (E) is a separate category for recommendations in which there is as yet no evidence from clinical trials, in which clinical trials may be impractical, or in which there is conflicting evidence.

### USPSTF Definitions

- I: One or more RCTs
- II-1: Evidence from controlled trials; norandomization
- II-2: Evidence from cohort or case-controlled studies
- II-3: Evidence from multiple time or historic controls
- III: Expert opinion based on clinical experience

### Preventive Guidelines

As prevention is critical to naturopathic medical philosophy, the investigators feel it is appropriate to highlight current preventive guidelines. The ADA guidelines include recommendations for glycemic control, lipids, and blood pressure, based on large, well-designed clinical trials.<sup>7</sup>

Level A evidence exists for lowering HbA1c to prevent and reduce microvascular and neurological complications of type 2 diabetes; approximately 10.5-percent risk reduction occurs per 0.5-percent reduction in HbA1c.<sup>8</sup> Level B evidence supports achievement of a HbA1c <7 percent.<sup>7</sup>

Level A evidence supports therapeutic lifestyle changes (TLC) to reduce LDL cholesterol.<sup>5</sup> Level B evidence supports reducing LDL cholesterol to less than 100 mg/dL to reduce cardiovascular complications.<sup>7</sup> Additionally, Level A evidence suggests first coronary events can be prevented with a 30-percent reduction in LDL (22% reduction in five years; Heart Protection Study).<sup>12</sup>

ADA guidelines for prevention of complications due to elevated blood pressure (BP) are based on Level A evidence from the U.K. Prospective Diabetes Study (UKPDS).<sup>7,8</sup> This study found that for each 10-mmHg decrease in mean systolic BP, a 12-percent risk reduction for any complication related to type 2 diabetes, 15-percent reduction in deaths related to type 2 diabetes, an 11-percent reduction in myocardial infarction, and 13-percent reduction in microvascular complications was achieved. Thus, the ADA recommendation (Level B evidence) supports a target systolic BP <130 and diastolic BP <80.

#### **Summary: ADA Guidelines for Prevention**

- HbA1c <7 percent
- HDL >40 mg/dL
- LDL <100 mg/dL or 30-percent reduction if >40 years of age and total cholesterol >135 mg/dL
- Triglycerides <150 mg/dL
- Blood pressure <130/80

## **Methods**

### **Subjects/Inclusion Criteria**

The investigators performed a retrospective chart review of patients receiving care at the Bastyr Center for Natural Health diagnosed with type 2 diabetes (ICD-9 250.00) or related complications between April 2002 and October 2003. This study was reviewed and a Health Insurance Portability and Accountability Act (HIPPA) authorization waiver was granted by the Bastyr University Institutional Review Board (IRB) (approval number 03A-1139) prior to obtaining patient records. Three student reviewers were included in this study; student chart reviews were assessed for consistency by having each student review three identical charts and make comparisons. Charts were identified by doing an ICD-9 search in the patient electronic record management software used at BCNH.

Five inclusion criteria were used during the chart review:

- Patient had an ICD-9 diagnosis of type 2 diabetes and related complications at the time of the office visits.
- Patient received care specifically for type 2 diabetes or complaints of diabetic complications.
- Duration of care was greater than six months.
- Medical records were required to contain at least two objective findings at least three months apart.
- Only visits since 1998 were included in order to capture treatment advances and reduce potential educational disparities between current and past faculty.

### **Evaluation of Level of Evidence**

Level of evidence analysis for dietary recommendations was based on available reviews by the ADA.<sup>5</sup> The systematic review of the level of evidence for the use of nutritional and botanical supplements in diabetes performed by Yeh et al was also used for this study.<sup>6</sup>

## Results

### Specific Aim #1: Characteristics of Care – Primary or Adjunctive Care

Eighty-one percent of diabetes patients were receiving adjunctive care for their diabetes and related complications at the BCNH. Results were dichotomized to adjunctive or primary care; thus, a smaller percentage (19%) of diabetic patients at BCNH see a naturopathic physician for the primary management of their diabetes.

### Specific Aim #2: Assess Percentage of Patients Meeting ADA Guidelines for Glycemic Control, Lipid Management, and Blood Pressure

Table 1 illustrates the percentage of diabetic patients receiving care at BCNH meeting current guidelines for HbA1c, lipid measures, and blood pressure. The final column includes national averages to serve as a point of comparison. Patients received treatment for at least six months.

Table 2 illustrates the percentage of diabetic subjects making improvement during the course of treatment. For purposes of this analysis, “good control” is defined by the ADA or USPSTF guidelines set forth previously. “Making Improvement” is a non-quantitative analysis of patients trending in direction of better control. It is encouraging to see, although not quantitatively, that diabetic patients show improvement in vital measures once beginning naturopathic medical care. However, changes to medication and conventional management are not captured by this analysis and cannot be ruled out as alternative explanations for improvement.

### Specific Aim #3: Assess Characteristics of Treatment Recommendations

Table 3 characterizes the general treatment approach at BCNH and describes the content of office visits. The results demonstrate a clear emphasis on TLC with 100 percent of patients receiving a dietary prescription, 94 percent receiving an exercise prescription, and 64 percent receiving advice on stress reducing activities, as well as an additional supplement prescription. Table 4 provides details on the characteristics of dietary recommendations provided by naturopathic physicians at BCNH, including “level of evidence.” Table 5 details the characteristics of supplement prescribing, including “level of evidence.” Results of this study show concurrent use of supplements and medication is extremely common, as illustrated in Table 6. While there is little research substantiating the potential risks or benefits of interactions, patients continue to use conventional medication and nutritional supplements, and may not fully disclose their use of supplements to their conventional physicians. Naturopathic physicians may be in a unique position to obtain detailed information on both medication and supplement use.

### Specific Aim #4: Assess Level of Evidence Supporting Treatment Recommendations

Level of evidence for dietary and nutritional supplement/botanical medicine prescriptions is included in Tables 4 and 5, respectively. High protein and low simple carbohydrate diet recommendations were most frequently made, while other dietary elements, such as reducing total caloric intake or modifying specific amounts and types of fats were never recommended. Supplement prescriptions most commonly included chromium and omega-3 fatty acids. Chromium has a high level of research supporting its efficacy, and omega-3 fatty acids have level B support for diabetes specifically, while omega-3s have level A support for the treatment of other cardiovascular conditions that may be concurrent in the diabetic patient.

### **Specific Aim #5: Identify Potentially Useful Treatment Approaches for Prospective Study**

The investigators were unable to address this specific aim due to limits on the data available in patient records. Well-designed, prospective data collection is better suited to identify promising treatment strategies.

## **Discussion**

### **Study Strengths and Limitations**

Qualitative descriptions of a naturopathic approach to diabetes have been unavailable in the literature to date. This study provided a method to generate an accurate descriptive review of care provided to diabetic patients at BCNH. By reviewing the actual care, this study generated qualitative, as well as some quantitative, data.

The final analysis was based on a small data set (n=16; 29% of 55 total candidate patients); most candidate patients were excluded from analysis due to incompleteness of patient records. Another limitation was that data abstraction was performed by student research assistants. While training was provided, and consistency control was attempted, some variability in interpretation among assistants is still likely.

### **Adjunctive versus Primary Care**

The percentage of patients receiving adjunctive naturopathic care for diabetes (81%) versus primary care raises interesting questions around the responsibilities of an “adjunctive care provider” and also identifies an area for increased transition into primary care delivery. As identified by this study, naturopathic medical treatment regularly includes the diet and lifestyle guideline components identified by national organizations defining medical standards, such as the ADA, the Joint National Committee on Hypertension (JNC-7), and the National Cholesterol Education Program results of the third Adult Treatment Panel (NCEP ATP-III).<sup>7,13,14</sup>

In Washington, naturopathic physicians administer therapeutic lifestyle change and are licensed to diagnose and order all laboratory testing. This skill set adequately prepares naturopathic physicians as primary care providers in the diabetes population and offers patients the advantage of appropriate intensive lifestyle therapy. As identified by Watts et al, barriers in insurance coverage for naturopathic care and limited public education on the scope of naturopathic care may account for limited naturopathic primary care.<sup>15</sup>

As the efficacy and cost effectiveness of life -style modification for prevention of diabetes accumulates, the authors encourage the unique character of naturopathic care to be recognized by health policy makers.<sup>16,17</sup> A recent review from Germany of diet/lifestyle modification in diabetes states, “A nationwide improvement in lifestyle could result in a significant decrease in health care expenditures....” The authors suggest primary care is the ideal forum for this improvement to occur.<sup>17</sup>

### **Patient Health Status in the Context of Medical Guidelines**

Controversy exists surrounding the creation of medical guidelines in the naturopathic medical community. The preventive nature of medical guidelines in diabetes care is congruent with naturopathic philosophy and require consideration.

Naturopathic physicians at BCNH see a lower percentage of patients with HbA1c >10 percent, compared to the national average. While it is tempting to cite this as evidence of efficacy of naturopathic treatment, caution is warranted. Although naturopathic clinical care may offer improvement to patients in poor control, such a conclusion can only be made following future prospective clinical trials. The authors speculate the lower percentage of patients at BCNH

compared to national averages with HbA1c >10 percent may represent patient self-selection, as these patients are poorly controlled and may not be appropriate candidates for outpatient naturopathic care. Similarly, patients in the “moderately” controlled range of 7–10 percent may be more likely to seek additional therapies, while those in “good” control are likely satisfied with their current treatment approach. Also, patients who achieved “good” control following treatment at BCNH, but who are no longer receiving care, would have been omitted from this study due to the exclusion criteria. This could potentially bias the results toward a higher percentage in poorer control. This discussion is speculative and these conclusions cannot be confirmed from this analysis.

### Characteristics of Medical Care

**Therapeutic Lifestyle Change**—TLC is comprised of dietary counseling, exercise, and stress reduction; these components are included in conventional treatment guidelines for type 2 diabetes and associated conditions – primary diabetes (ADA),<sup>7</sup> hypertension (JNC-7),<sup>13</sup> and dyslipidemia (NCEP ATP-III).<sup>14</sup>

Naturopathic physicians receive extensive training in applying these elements of treatment to patients, and often consider themselves expert in therapeutic lifestyle protocols. This analysis demonstrates that naturopathic physicians frequently prescribe TLC and, likely more importantly, continue guidance and recommendations during multiple patient visits. Although dietary recommendations are frequently evidence-based, this analysis identifies additional recommendations that can aid in delivery of more precise and effective dietary recommendations for diabetes self-management, e.g., total caloric reduction and recommendations for <10-percent saturated fat calories.

**Nutritional/Botanical Supplementation**—This study describes the prevalence of nutritional/botanical supplementation in naturopathic clinical care for diabetes. While evidence is beginning to accumulate supporting the value of adjunctive supplementation, there are many unanswered questions regarding their use that demand research attention. In the investigators’ opinion, the largest unanswered question concerns the use of many nutritional/botanical supplements in combinations that lack research support.

**Adjunctive Medication Use**—The data in this study suggests naturopathic care is commonly combined with conventional care and conventional medications. Because the data suggest nutritional/botanical supplements do share mechanisms of action with conventional medications, questions regarding complementary versus competing action arise.<sup>6</sup> These issues demand systematic research since, according to one survey, 35 percent of individuals with diabetes use some form of CAM therapy specifically for diabetes treatment.<sup>2</sup> Some medications used commonly in the diabetic population are known to cause nutritional deficiencies<sup>19,20</sup> and nutrients may prolong the benefit of other medications.<sup>21</sup> For example, metformin can deplete vitamin B12, and niacinamide can prolong the activity of sulfonylureas. Therefore, universal statements about the use of nutritional supplements in combination with medications should be avoided until more data is compiled.

Aspirin provides another interesting interface of naturopathic medicine with conventional medicine. Twenty-five percent of BCNH patients receiving care for type 2 diabetes are receiving aspirin as part of their treatment; this finding is comparable (25% versus 26.6%) to published findings in conventional primary care clinics.<sup>22</sup> The under-utilization of aspirin is a primary point of medical education efforts among conventional preventive medicine experts. The authors recommend alternative providers educate themselves as well on the role of aspirin in the prevention of cardiovascular disease and events in the diabetic population.<sup>7,23</sup> Considering 70 percent of diabetic patients die of premature heart disease, the authors believe

naturopathic provider education on the value of aspirin in prevention will increase the incidence of this recommendation and improve patient outcomes.<sup>25</sup>

### Level of Evidence

Although the “level of evidence” supporting dietary recommendations by naturopathic physicians in this sample is quite good overall, this analysis does identify some areas for increased precision.

Similarly, although nutritional and botanical supplements are widely criticized for lack of supportive research, this analysis illustrates that data does exist on many treatments recommended by naturopathic physicians. Important questions exist about the transferability of one profession’s guidelines to another, yet the authors believe this system represents a clear method that all providers can use to assist them in translating scientific research to clinical practice. Similarly, the question, “How much evidence is enough to recommend a treatment?” is complex and involves analysis of patient choice as well as risk/benefit ratio. An excellent discussion and approach to answering this question is available in a recent Institute of Medicine publication on CAM.<sup>21</sup>

### Summary

Naturopathic medicine is a philosophy-based, whole medical system. This description of naturopathic care can serve other health professionals in their referral recommendations. Naturopathic care for diabetes at this representative academic facility remains mostly adjunctive, although physicians possess the training and skills necessary to participate as primary care providers. The naturopathic treatment approach frequently includes important dietary and lifestyle recommendations included in current medical treatment guidelines for diabetes, hypertension, and hyperlipidemia, although improvements can be made on the precision of recommendations. Nutritional and botanical supplements are frequently prescribed, and evidence is growing for their value in treatment. Because of the potential public health benefit, the use of supplements as adjuncts to conventional medications deserves research attention and funding. Prospective data collection and analysis on the naturopathic medical approach to diabetes care is vital in order to determine the impact of this novel approach on the personal and economic burden of type 2 diabetes.

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**Table 1**

Distribution of Glycemic Control: BCNH versus National Averages (NHANES 2001)

HbA1c Range	BCNH	National Average
<7%	31%	37%
7-10%	61%	50.6%
>10%	8%	12.4%

**Table 2**

BCNH: Percent of Patients in “Good Control” and Percent of Patients “Making Improvement”

Measurement	Percent Current “Good Control”	Percent Making Improvement
HbA1c	31%	60%
LDL Cholesterol	13%	63%
HDL Cholesterol	80%	63%
Triglycerides	43%	57%
Blood Pressure	44%	60%

**Table 3**

Percentage of Patients Receiving TLC/Supplement Prescription

Specific Prescription	Percent of Patients Receiving the Prescription	Percentage of Office Visits Including the Prescription
Dietary modification	100%	46%
Stress reduction	69%	13%
Exercise prescription	94%	38%
Supplement prescription	100%	100%

**Table 4**

## Characteristics of Dietary Recommendations

Dietary Recommendation	Percent of Patients Receiving	Level of Evidence
High Protein	87.5%	B
Low Simple Carbohydrate	81.25%	B
High Fiber	75%	B
Low Glycemic Index	50%	B
Whole Foods Diet*	43.75%	A
Low Fat	37.50%	B
Increase Essential Fatty Acids	43.75%	B
Paleolithic Diet	18%	N/A
Atkins Diet	6.25%	N/A
ADA Diet	6.25%	A
Bernstein Diet	0%	N/A
Reduce Total Calories	0%	A
<10% Saturated Fat	0%	A
<300 mg Cholesterol	0%	A
No "trans" Fats	0%	B
<10% Polyunsaturated Fats	0%	C

\* A "whole foods" diet includes beans, whole grains, and lean proteins, and emphasizes liberal consumption of organic (when possible) fruits and vegetables.

**Table 5**

## Description of Supplements Prescribed and Level of Evidence

<b>Nutrient/Botanical</b>	<b>% of Patients Receiving</b>	<b>Level of Evidence</b>
Chromium	69%	I/C
Magnesium	25%	I/C
Vanadium	0% (44% received combination product w/vanadium)	II-1/C
Carnitine	19%	I/A
Vitamin E	50%	I/C
Alpha-lipoic Acid	56%	II-3/C
Omega-3 Fatty Acids	94%	B
Gymnema sp.	25% (56% received combination product w/Gymnema sp.)	II-1/C
Trigonella sp.	19% (56% received combination product w/Trigonella sp.)	II-2/C
Momordica sp.	12% (56% received combination product w/Momordica sp.)	III/C
Cinnamon	25%	RCT evidence exists; <sup>9</sup> not reviewed
Coenzyme Q10	44%	RCT evidence exists; <sup>10,11</sup> not reviewed

**Table 6**

## Adjunctive Medication Use

Medication Class	Percent Concurrent Use
Oral Anti-diabetic	44%
Insulin	40%
Lipid-lowering	13%
Anti-hypertensive	44%
Aspirin	25%