

## Development of an Evidence-Based Practice Protocol to Support the Use of Olive Oil for Managing Type 2 Diabetes

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### Abstract

**Background:** Type 2 diabetes (T2D) is a worldwide issue, and the complications are life-threatening. The main T2D-related causes of early death are cardiovascular risk factors. Although the association between olive oil consumption and T2D has been examined, guidelines for its use in patients with T2D have not been established.

**Objectives:** The aim of this review was to develop a protocol and provide recommendations for managing T2D in adults, focusing on daily olive oil consumption to control blood glucose level and prevent T2D complications. As a result, evidence-based practice (EBP) guidelines were developed.

**Design:** This review relied on the Stevens ACE STAR Model of Knowledge Transformation©, which aids in understanding the knowledge phases and features that are used in several aspects of EBP.

**Data sources:** Scoping searches using the keywords “olive oil” and “type 2 diabetes” were undertaken using different websites and six databases including the Cochrane Database, PubMed, Google Scholar, Research Gate and EBSCO.

**Review methods:** Studies that compared the effects of olive oil consumption and the effects of the Mediterranean diet between patients with and those without diabetes mellitus were selected based on both the level of evidence and quality. Articles that described studies comparing olive oil consumption with consumption of other ingredients or another type of oil were excluded. Studies were restricted to those with adults (aged ≥18 years) with T2D; adults with type 1 diabetes and children were excluded. The association between olive oil consumption and T2D was examined.

**Results:** Olive oil improves numerous cardiovascular risk factors, while controlling blood glucose levels and preventing T2D complications. The new EBP guidelines include an assessment of diet consumption, plan of implementation, and patient education. This policy applies to adults (aged ≥18 years) with type 2 diabetes.

**Conclusion:** The suggested guidelines will decrease blood glucose levels and body weight, prevent T2D complications, improve lipid profiles, and lower healthcare costs.

**Keywords:** Blood glucose level, Evidence-Based practice, Nurse, Olive oil, Type 2 Diabetes.

approximately \$245 billion, and the cost is expected to increase with time [3-6].

### Introduction

Type 2 diabetes (T2D) is a worldwide issue. The International Diabetes Federation reported, “415 million adults have diabetes and this will rise to 642 million by 2040 [1].” According to the Centers for Disease Control, nearly 29 million people in the United States have diabetes, and the World Health Organization reported that majority of those with diabetes worldwide have T2D [2,3]. Considering that the main causes of early death are T2D-associated cardiovascular risk factors, T2D is life threatening. Furthermore, the estimated cost of diabetes in the US in 2012 was

T2D is related with many metabolic syndrome components such as hyperlipidemia, which is the strongest risk factor for coronary artery disease, and central obesity, which contributes to the high rate of cardiovascular diseases [5]. According to the American Diabetes Association (2016), chronic un-controlled high blood glucose levels can lead to eye, kidney, foot, nerve, and heart problems. Therefore, controlling T2D is very important for both the individual and community. Several studies have reported that controlling blood glucose levels through a healthy diet and regular physical activity, as key interventions, is both feasible and cost

saving [3,5]. A program consisting of long-term modification (a healthy diet, maintenance of normal body weight, and physical activity) is effective for controlling T2D [3,7,8].

Regarding a healthy diet, olive oil improves numerous cardiovascular risk factors [4,8-10]. Moreover, patients were more satisfied with their dietary therapy that consisted of changing from a high carbohydrate diet to a diet containing olive oil [4]. Therefore, olive oil should not be ignored as a component of T2D prevention and management.

However, the effects of olive oil consumption on blood glucose levels require further consideration. Although many studies have examined the association between T2D and olive oil, to my knowledge, a specific protocol regarding the use of olive oil for T2D management has not been developed. Therefore, the aim of this study was to determine the association between olive oil consumption and T2D and to develop an evidence-based practice (EBP) protocol for the use of olive oil to manage T2D.

### Research Terms

“Type 2 diabetes” is non-insulin dependent diabetes mellitus where the body does not properly use insulin (insulin resistance) [7].

“Mediterranean diet” is characterized by consumption of vegetables and fruit, nuts, low amounts of fat, extra virgin olive oil (EVOO) as the main source of fat, foods high in monounsaturated fatty acids (MUFAs) and fiber, foods low in saturated fat, and limited amounts of alcohol [11].

“Lipid profile” includes total cholesterol (Ch), low-density lipoprotein (LDL), and high-density lipoprotein (HDL) levels [4]. “Dipeptidyl-peptidase-4 (DPP-4) inhibitor” is an oral hypoglycemic medication for treating T2D that helps to down-regulate insulin secretion [12].

### Methods

This review relied on the ACE STAR Model of Knowledge Transformation©, which aids in understanding the knowledge phases and features that are used in several aspects of EBP [13]. The STAR Model consists of five stages that help to organize the EBP process: discover research, summarizing of the evidence, translating the evidence into guidelines, integrating into practice, and evaluation (Figure 1) [13]. In this review, the last two steps were not conducted.



**Figure 1:** Stevens Star Model of Knowledge Transformation© (Stevens, 2012).

The review was conducted between June 2016 through September 2016. Scoping searches were undertaken using “olive oil” and “type 2 diabetes” as keywords in websites and databases including the Cochrane Database, PubMed, Google Scholar and EBSCO. The literature search was performed in June 2016, with two updated on September, 2016. The chosen articles were only in English and between 2011 and 2016. Studies that compared the effects of olive oil consumption and the effects of the Mediterranean diet between patients with or without diabetes mellitus were selected based on both the level of evidence and quality. Articles that described studies comparing olive oil consumption with consumption of other ingredients or another type of oil were excluded. Most of the reviewed studies were randomized controlled trials (RCTs); after reading these articles, a rapid critical appraisal was performed. The articles were synthesized in a table format, and the evidence was summarized and translated into guidelines. Owing to the nature of the study, approval by an institutional review board (IRB) was not required.

### Literature Review Results

Several studies examined the association between olive oil consumption and T2D [4,8,10,11]. In an RCT that examined the effects of olive oil consumption on blood glucose levels in 45 healthy subjects and patients with T2D aged  $\geq 40$  years in Jordan, olive oil had a positive effect by decreasing blood glucose levels among both the healthy controls and patients with T2D; these findings support those of other studies [4,8,10,11]. Al Jamal and Ibrahim (2011) also concluded that after 4 weeks of consuming olive oil, fasting blood glucose levels were significantly lower among the patients with T2D, by 16%, compared with the healthy controls. Moreover, Guasch-Ferré et al. (2015) found that participants who consumed  $>8\text{g/d}$  of olive oil had a 6% lower risk of T2D than those who had never consumed or had lower consumption of olive oil. Interestingly, olive oil consumption significantly decreased LDL levels and increased HDL levels in several studies [4,8-11].

Surprisingly, the change in these parameters was more profound among patients with T2D than among the healthy controls [4]. Many studies reported that the intense effect of olive oil, especially the extra virgin types, for the prevention of T2D and improvement in glycemic control parameters is attributed to the contents of olive oil. Olive oil is high in MUFAs, polyphenol, antioxidants, and anti-inflammatory parameters [4,8,10,11].

The association between the Mediterranean diet and T2D has also been tested [10,11]. Violi et al., utilizing a cross-over design, demonstrated an association between the Mediterranean diet with consumption of EVOO and post-prandial blood glucose and LDL levels in healthy participants. In a comparison between EVOO and non-EVOO consumption among healthy subjects, the consumption of 10 mL EVOO 3 times/d after meals was beneficial [10]. There is a significant decrease in blood glucose levels and an increase in insulin levels when the meal contains EVOO; however, when

the meal did not include EVOO, blood glucose levels significantly increased. The study also compared the consumption of olive oil with that of corn oil, and the participants who consumed olive oil had better control of their blood glucose levels than those who consumed corn oil [4,10]. The authors suggested that olive oil behaves as a DPP-4 inhibitor; however, further investigation is needed to determine the exact mechanism of olive oil in the down-regulation of DPP-4.

In a longitudinal study, more than 60,000 US women aged 26–65 years of varying ethnicities and without diabetes mellitus, cardiovascular, and cancer were followed for 22 years. The consumption of olive oil resulted in greater benefits among participants originally from the Mediterranean/Southern European region than among people of Caucasian and other ancestries, potentially because olive oil is a large part of the traditional diet for the former groups. In addition, older people consumed olive oil. Although consumption of olive oil, whether as a salad dressing or with foods or as total olive oil intake, was associated with a lower risk of T2D, the effect of olive oil consumption as a dressing on salads was weaker than adding olive oil to foods. Additionally, substituting olive oil for mayonnaise, butter, or stick margarine was associated with a lower risk of T2D. This study and other studies concluded that a higher intake of olive oil resulted in a lower risk of T2D. Furthermore, higher intake of olive oil within a healthier diet is more beneficial than within an unhealthy diet [8,10,11].

Olive oil not only has considerable effects on blood glucose but could also affect body weight. In the PRIDMED study, a multicentric parallel trial was conducted with 191 participants to compare the effects of two Mediterranean diets (one supplemented with EVOO and one supplemented with mixed nuts) and a low-fat meal on glycemic control in patients with T2D; the effects of both Mediterranean diets on both body weight and glycemic control were similar to those of the low-fat diet [11]. Although the energy intake, measured as caloric intake, was higher with the EVOO-supplemented Mediterranean diet, the parameters of glycemic control and insulin sensitivity were improved, owing to the high levels of phenols and MUFA in EVOO [11].

Santangelo et al. studied the effect of high polyphenol (HP)-EVOO on metabolic control in overweight patients with T2D. Participants were asked to consume EVOO daily for 8 weeks and practice a healthy lifestyle, such as walking 30 min/day and control alcohol consumption; fasting blood glucose levels and HbA1c were significantly decreased after consumption of HP-EVOO. Supplementing a diet with EVOO reduced both body weight and body mass index (BMI) [9,11]. Additionally, there was a significant reduction in visfatin after HP-EVOO consumption. At the same time, liver enzymes improved.

Collectively, these findings indicate the need to develop a protocol for the use of olive oil that could improve the health of patients with T2D, prevent complications, and control blood glucose levels.

## EBP Guidelines for Implementing the Use of Olive Oil for T2D Management

**Guideline Objective:** To provide recommendations for managing T2D in adults with a concentration on dietary advice, specifically the daily consumption of olive oil to control blood glucose levels and prevent T2D complications.

**Target Population:** This policy applies to all adults (aged  $\geq 18$  years) with T2D; it does not apply to adults with type 1 diabetes or children.

### Assessment

- Review the patient's medical history for any metabolic abnormalities and other complications and the current use of diabetic or blood pressure medications, to help determine the appropriate dose of olive oil.
- Assess blood glucose levels at each visit, to enable comparisons of levels before and after baseline.

### Dietary Olive Oil Consumption

- Supplement  $>8$  g olive oil (1 tbsp. olive oil = 8–10 g) DAILY (2–3 tbsp. with breakfast, lunch, and dinner). The literature review indicated that participants who consume  $>8$  g per day are at a lower risk of developing T2D complications and have better blood glucose control [8,9].
- Use EVOO, which is the first pressure of olives, because it is more beneficial for diabetes management and is the best type of olive oil. EVOO is more effective for weight loss and blood glucose control than other types such as refined olive oil [9].
- Instruct patients to consume olive oil with meals, by preferably adding it to food. Guasch-Ferré et al. (2015) concluded that supplementing food with olive oil has stronger effects than using it as a salad dressing.
- Discuss the patient's detailed plan with doctors and dietitians, who act within the protocol to determine the appropriate dose and mealtime plan.
- Instruct patients to substitute a carbohydrate-based diet with a Mediterranean diet. For patients with T2D, the Mediterranean diet decreases LDL levels and increases HDL levels. The Mediterranean diet also significantly decreases body weight [4,11].
- Incorporate this dietary advice with other lifestyle modification advice for patients with T2D such as controlling weight, regularly exercising, and avoiding smoking. The main program, which includes long-term modification, a healthy diet, maintaining a healthy body weight, and being physically active, is effective for T2D control [3,5,6,8].
- Instruct the patient not to substitute diabetic medication with olive oil. Although olive oil might have similar effects on blood glucose levels as some diabetic medications such as PPD-4s, evidence to substitute olive oil for diabetic medication is lacking [10].
- Do not stop supplementing with olive oil. Consistent, daily consumption of olive oil has demonstrated benefits on blood glucose levels, LDL levels, and body weight.
- Consider the patient's preference when providing dietary

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advice for using olive oil.

- Ask patients about any side effects of olive oil consumption such as hypoglycemia. Although allergenic or side effects of olive oil consumption have not been reported, the combination of olive oil consumption and diabetic medication might impact the patient's health.
- If an adult with T2D consistently achieves adequate blood glucose control and does not experience hypoglycemic or major side effects, advise the patient to maintain olive oil consumption for the rest of their lifetime.
- Patient Education
- Provide an explanation of the benefits of olive oil, including the ability to lower the risk of heart diseases and other diabetes-related conditions.
- Provide instruction for when to use olive oil, the amount of olive oil to use, and general healthy eating.
- Instruct patients to monitor their blood glucose levels and call a physician or their diabetes educator if they experience any signs of hypoglycemia, such as headache, confusion, sweating, irritation, or weakness [14].
- Instruct patients not to stop taking their diabetic medication while supplementing with olive oil.
- Instruct family members who are at risk to also consistently supplement with olive oil.

### Side Effects

Overconsumption of olive oil may act as a natural laxative. Using olive oil in addition to diabetes medication may significantly decrease blood glucose levels. Because olive oil also reduces blood pressure, consumption of olive oil in addition to blood pressure medication may lead to hypotension [15]. Consult with the patient's doctor about decreasing the dose of diabetes medication prior to implementation of the olive oil program. Nurses or diabetic educators should regularly monitor and document blood pressure and blood glucose levels. Although reliable evidence about the safety of olive oil supplementation is not yet available, no major side effects or participant harm associated with olive oil consumption were identified from the review of literature.

### Implementation Plan

A diabetes center or outpatient clinic is an appropriate place for implementation of the protocol. Prior to implementation of the protocol, official permission should be obtained from the supervisor of the selected center. Doctors, nurses, dietitians, patients, and family are all included in the protocol. Initially, the new practice recommendations should be discussed with doctors and nutritionists to ensure safety. The nurses and diabetes educators will provide a 1-week educational program during follow-up care consisting of lectures, scientific articles, and an explanation of the association between olive oil consumption and T2D, specifically how the use of olive oil is related with blood glucose control. The use of TV screens within the clinic and labels on patient records for the new protocol would help remind nurses to provide education. In addition, a daily email reminder before implementation will be sent to nurses and diabetes educators. Nurse adherence to the protocol will be ensured by reviewing patient records for updated

documentation and a signature.

There are some driving and restraining factors when implementing a new protocol. Providing positive support from supervisors, such as explanations of the protocol process, description of the expected outcomes, and open communication with stakeholders, could facilitate protocol implementation. Nevertheless, some patients may resist using olive oil because of taste or absence of it in their diet. To manage this barrier, patients could be provided with an explanation during their educational session of the great benefits of olive oil and alternative methods of consumption such as a salad dressing or in supplemental pills.

### Cost-Effectiveness

Although olive oil is relatively expensive, it would be very cost effective for the purpose of T2D management. Olive oil helps to prevent T2D complications and improves health. Health expenditure is lower for patients with controlled T2D than for those without controlled T2D. Furthermore, medical costs are approximately 2.3 times higher for people with diabetes than for people without have diabetes, and the cost of prescriptions to manage the complications of diabetes is 18% of total medical expenditure [5,6].

### Timeline

After the week of educational sessions, the following timeline for data collection will be used:

- 4 weeks – After 4 weeks, measurement of all variables will be repeated for comparisons with baseline values. A consistent decrease in blood glucose levels is expected.
- 2 months (8–10 weeks) – After 2 months of consistent olive oil consumption, blood glucose level and lipid profiles are expected to change.
- 3 months (12–16 weeks) – Change in weight will be assessed.

### Outcome Assessment Plan

The need for olive oil should not be viewed as a personal choice but rather as a certain component of T2D management. The expected outcome indicators for following the guidelines are blood glucose control, changes in lipid profile, cost savings, and weight loss.

Controlling Blood Glucose Levels and Delaying T2D Progression Studies have shown the effectiveness of blood glucose control for preventing diabetes complications [5,6]. Blood glucose will be routinely monitored using a glucometer at each visit. Measurements will also be based on the stability of the patient's condition. Nurses or diabetes educators will be asked to enter the measurements in a timely manner. Annual eye exams and frequent monitoring of the feet, vital signs, blood pressure, and pulse pressure will be considered to prevent complications. Electronic patient records will be reviewed for data collection. Results will be documented if patients are hospitalized. Upon discharge, the patients will be asked to call the diabetes educator or nurse if their blood glucose level increases. Comparisons between pre-intervention and post-intervention blood glucose levels will be conducted. As long as patients consume at least 3 tbsp./d olive oil, blood glucose control,

increased insulin levels, and prevention of complications are expected.

### Weight Loss

Olive oil is more effective when consumed within a healthy diet. Lasa et al. (2014) concluded that people who consumed a Mediterranean diet experienced significant weight loss.

A body weight scale should be used to measure weight, without shoes and in light clothes; the scale should be calibrated prior to each measurement. Nurses should measure patient weight at each visit, and the measurement should be documented electronically. BMI should be calculated. To ensure weight is measured, the electronic chart should be tracked for updated date and weight. Comparisons between pre-intervention and post-intervention weight should be conducted.

### Changes in Lipid Profiles

Olive oil significantly reduces LDL levels and increases HDL levels [4,8,10,11]. Changes in lipid profile based on the patient laboratory test chart should be reviewed by nurses. LDL and HDL levels should be regularly measured and documented. Increased HDL levels and decreased LDL levels are expected.

### Cost Savings

To measure cost effectiveness, the cost effectiveness ratio (C/E) is suggested. The C/E is determined as the cost of the current intervention divided by the number of health outcomes: “the sum of all benefits divided by the sum of all costs”. The lower the C/E, the greater the cost savings because of the intervention [16]. The result will be considered for the purpose of changes and improvements.

### Future Research

A review of literature indicated that olive oil lowers blood glucose levels; however, none of the studies examined whether insulin administration could be replaced by long-term olive oil consumption. Moreover, the studies did not examine whether consumption of olive oil on an empty stomach is better than adding it to food. It is possible that consumption of olive oil on an empty stomach is more efficient than the consumption with food; however, further studies are needed to confirm this. In addition, owing to inadequate sample sizes, more studies are needed to explain the effects of olive oil on T2D [4,10,11]. Future research should also evaluate substituting diabetic medication with olive oil.

### Conclusion

This protocol is designed to provide recommendations about the effectiveness of olive oil consumption for managing T2D and preventing complications. Implementation of the olive oil protocol should significantly decrease blood glucose levels, LDL levels, and weight as well as decrease the cost of health care.

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