



ISSN NO. 2320-5407

Journal Homepage: - www.journalijar.com

INTERNATIONAL JOURNAL OF ADVANCED RESEARCH (IJAR)

Article DOI:10.21474/IJAR01/2740
DOI URL: <http://dx.doi.org/10.21474/IJAR01/2740>



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ADVANCED RESEARCH (IJAR)
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Journal Homepage: <http://www.journalijar.com>
Journal DOI:10.21474/IJAR01

RESEARCH ARTICLE

IMPACT OF OLIVE LEAVES CONSUMPTION ON BLOOD SUGAR LEVEL IN ADULTS WITH TYPE-2 DIABETES.A CLINICAL TRIAL:ALMADINAH ALMUNAWARAH, KSA.

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Manuscript Info

Manuscript History

Received: 15 November 2016
Final Accepted: 17 December 2016
Published: January 2017

Abstract

Aim of the Research:- The purpose of this research was to study the effect of drinking boiled olive leaves extracts on blood sugar level among adults with type-2 diabetes (both males and females) in Al-Madinah Al-munawarah, KSA. The following research questions guided the study:

- Is there a relationship between olives leaves consumption and blood sugar level?
- Can olive leaves reduce high blood glucose level?

Materials and Methods:- Seventy-three participants (29 males & 44 females) were chosen from 120 applicants according to the inclusion and exclusion criteria. Each patient was given a box that contains (3 disposable cups, 3 packs containing 5 gram grounded olive leaves, 18 lancets & strips for measuring blood glucose, follow-up card & instruction card and diabetes education book). Participants were asked to measure blood glucose level for 6 days (Before the main meal, after 1 hour of eating and after 3 hours of eating). The last three days they added drinking boiled olive leaves powder immediately after the main meal. Comparison of blood glucose levels in the three reading times before and after olive leave powder consumption.

Results:- Reduction in mean blood glucose level after drinking boiled olive leave extracts was found in all measurements during the 3 days of consumption but the only significant reduction in blood glucose was found on the third day one hour after meal.

Conclusion:- Hypoglycemic effect of olive leaves was found in the study with minor side effects. Further studies are recommended to identify the ideal dose, duration, preparation and timing of consumption to produce the maximum impact on blood glucose.

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Introduction:-

Diabetes mellitus (DM) is one of the major ailments globally.¹ “DM is a chronic metabolic disease that occurs when the pancreas is not able to produce enough of the hormone insulin or when the body cannot effectively use the

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insulin it produces.”²

Globally Saudi Arabia has the seventh highest rate of DM and the second highest rate in the Middle East according to the World Health Organization (WHO).³

Diabetes has become an epidemic health problem in several economically developing countries.⁴ By 2015 it was estimated that 3.4 million people in Saudi Arabia were diagnosed with DM.⁵ This prevalence of diabetes in Saudi Arabia might be due to various influences but most researches speculate that obesity and lack of exercise are very prominent factors.¹ Proportion of people diagnosed with type 2 diabetes accounts for 90% of all the diagnosed cases of DM.⁶

The number of people diagnosed with diabetes around the world is 336 million, which is expected to reach 550 million people by the year 2030. Almost five million people die of diabetes each year corresponding to one victim every 7 seconds. Diabetes is one of the major 10 causes of disability.²

For countless years, human beings have used the curative power of nature to live healthier lives. Conventional medicines and herbal remedies are woven through every nation and society. In specific Olive plant leaves have been used for eras all over the world. Several researchers have been investigating for the subproducts of olive leaves that might have positive outcome on human health.

Complementary and alternative medicine (CAM) refers to a wide range of clinical therapies outside of conventional medicine, the term “complementary” refers to therapies that are used in conjunction with conventional medicine, whereas “alternative” medicine includes therapies that are used in place of conventional medicine.⁷

One of the commonly used CAM herbs in Saudi Arabia is olive leaf. However, until recent time, the use of olive leaf as a potential diabetes treatment had not been appropriately examined.

Olive leaf plus olive leaf extracts (OLE), are currently promoted as anti-aging, immunostimulator, antioxidant, anti-inflammatory and antibiotic agents.⁸

The antioxidants oleuropein and hydroxytyrosol are assumed to be the main functional composites in unprocessed olive leaf, along with a number of other polyphenols and flavonoids, including oleocanthal.⁹ Oleuropein the primarily active component is highly bioavailable, comprising nearby 60-90mg/g (6-9%) of the leaf dry weight.¹⁰

“Studies on olive leaf extract have failed to notice any significant side-effects when doses up to 1000mg daily for 8 weeks¹¹ or lower doses.¹² Overall, olive leaf extracts in supplemental dosages are not associated with any major side effects.¹³

The purpose of this research was to study the effect of olives leaves on blood sugar level among type-2 diabetic adults (both male and female) in Al-Madinah Al-munawarah. The following research questions guided the study:

1. Is there a relationship between olives leaves consumption and blood sugar level?
2. Can olive leaves drink reduce high blood glucose level?

The general objective is to examine the short-term safety and efficacy of drinking boiled olive leaves on glycemic control among adults with type-2 diabetes living in Al-Madinah Al-munawarah. Furthermore the specific objectives were to assess blood glucose level before and after consumption of olive leaves among diabetic adults and to determine acceptability and immediate side effects of consumption of olive leaves (diarrhea, hyperacidity ...etc.).

The hypothesis was that the Consumption of olive leaves drink can reduce elevated BG level (to a normal range).

Methodology:-

The study Design was a clinical trial conducted to achieve the research objectives; furthermore the setting was in Taibah University and community in Almadinah Almunawarah.

This study was conducted on 73 diabetic adults (29 males & 44 females) with type 2 diabetes who were enrolled according to the inclusion and exclusion criteria

Inclusion Criteria:-

- Agree to participate.
- Having type 2 diabetes.
- Able to measure BG using home device and accurately record results.
- Living in Al-Madinah Al-Munawarah

Exclusion Criteria:-

- Pregnancy and lactation.
- Blood glucose ≤ 70
- Using Insulin treatment.
- Presence of diabetic complication or poor metabolic compensation.
- Following a diet to change weight or lifestyle during the trial days.
- Changing medical therapy during the trial days.

Subjects were recruited by advertisements at the University female section, flyers, Internet survey and face-to-face promotion of the study. Signing written consent was a pre-requisite to enrollment.

The active preparation was a commercial olive leaves powder; they were packed in empty bags for tea.

An Internet questionnaire was distributed, One hundred and twenty diabetic patients responded but upon phone calling them, we found that only 80 fulfill the inclusion criteria and were enrolled in the study. Another 7 subjects did not complete all the required measurements and were excluded from the study. 73 participants were enrolled according to the inclusion and exclusion criteria.

Each patient was given a box that contains (3 cups, 3 olive leaves bags, 18 lancets & strips for measuring BG, follow-up card, instruction card and Diabetes education book from the ministry of health).

Instructions to the patients were given to drink olive leaves immediately after the main meals. Measuring blood glucose level was done according to the following schedule:

1. Immediately before the main meal and drinking the olive leaves powder.
2. After 1 hour of eating.
3. After 3 hours of eating.

The patients were asked to complete a symptom questionnaire including any possible unexpected side effects e.g. GIT troubles.

In this study, the control group was of utmost importance. Due to the great variability of glycemic control among patients, patients were used as their own control so every patient repeated the test for 3 days under the same conditions but without using olive leave drink. Patients started with the 3 days with no olive leave drink and after that they added the drink for 3 more days.

The techniques, tools and equipment's were forms designed to record participants' information such as; personal data of the patient, medical history, treatment history and usual BG level, to ensure that the participants were suitable for the study, home monitoring BG measuring devices (freestyle optimum), follow up cards used to assess participants' BG level throughout the trial and finally questionnaires used to review the participants' side effects, tolerability and acceptance.

Pre-testing was done before the start of the study on 20 participants and the following problems were encountered:

1. Long fasting period
2. No compliance with the exact described methodology due to patients having to eat CHO (20 gram CHO biscuit).

So methodology was changed from:-

Measuring blood glucose level after at least 2 hours fasting according to the following schedule:-

- Before the study
- 1/2 hr after eating a biscuit containing 20g carbohydrates and drinking the olive leaves powder.
- Two hours after eating a biscuit containing 20g carbohydrates and drinking the olive leaves powder.

If blood glucose level is >140 the participant will drink olive leaves powder alone:-

If blood glucose level is <140 the participant will eat 20g biscuits then drink olive leaves powder.

To the current described method.

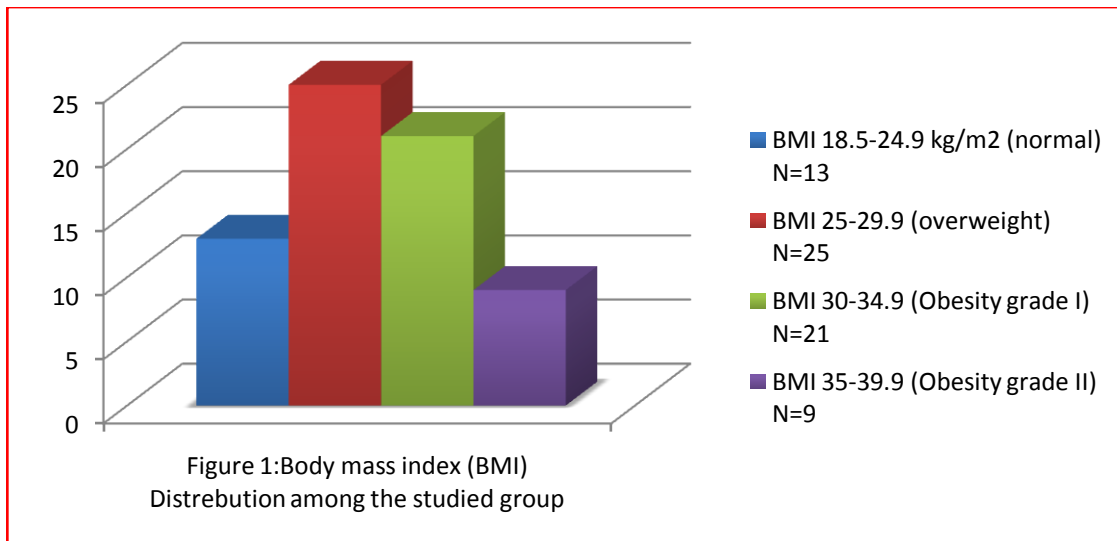
Ethical permission to conduct the current study was obtained from the Vice-Dean at the faculty of Applied Medical Sciences. Also permission was sought from The Medical directory of Taibah University (female section). Consent was obtained from all participants prior to the start of the study. The research explained to the participants in simple language, all data was kept confidential and patients were free to withdraw from the study.

Statistical Analysis was done by entering the encoded answers into Microsoft Excel and coping it to SPSS program. Descriptive analysis was done using statistical package for social sciences (SPSS17) and the comparative outcomes of results were analyzed by using T-test for paired samples for continuous data. The minimal level of significance was set at $P < 0.05$.

Results:-

The study included 73 subjects suffering from type 2 diabetes, the majority were females (60.3%, n=44), males represented 39.7% of the subjects (n=29), and Mean age was 49 years with range from 19-65.

Mean level of BMI was 30.46 ± 5.548 . Distribution of BMI category among the studied group is presented in figure 1.



Blood glucose level was compared time by time (before meal, 1 & 3 hours after meals) between the control days (no intake of boiled olive leaves) and after the intake of olive leaves. Results showed that there is reduction in mean level of blood sugar three hours after consumption of boiled olive leaves. The third day showed borderline significance. However, the only significant reduction in BG was found on the third day of consuming olive leaves 1 hour after meal. Results are shown in table 1.

Table 1:- Statistical comparisons in mean blood sugar level (mg/dl) between patients before and after olive leave intake (n=73):

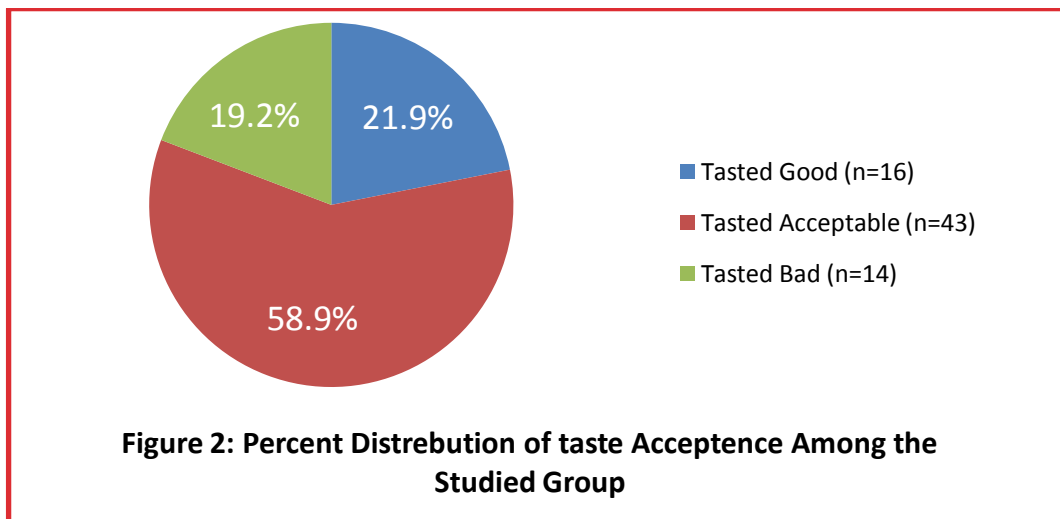
Measurements	Timing	Mean blood sugar level (mg/dl) \pm SD		P value
		Before olive leave intake (Control days)	After olive leave intake (Therapy days)	
First day	Before meal	180.52 \pm 70.44	189.67 \pm 75.48	.450
	1 hour after meal	238.63 \pm 77.165	239.25 \pm 85.448	.964
	3 hours after meal	207.84 \pm 71.518	193.96 \pm 66.588	.227
Second day	Before meal	186.44 \pm 67.044	191.6 \pm 70.816	.649
	1 hour after meal	236.88 \pm 74.857	231.45 \pm 70.858	.654
	3 hours after meal	206.90 \pm 73.660	199.41 \pm 74.417	.542
Third day	Before meal	189.97 \pm 74.119	177.60 \pm 72.205	.309
	1 hour after meal	242.16 \pm 79.757	216.00 \pm 68.302	.035*
	3 hours after meal	210.74 \pm 79.617	188.99 \pm 59.739	.064

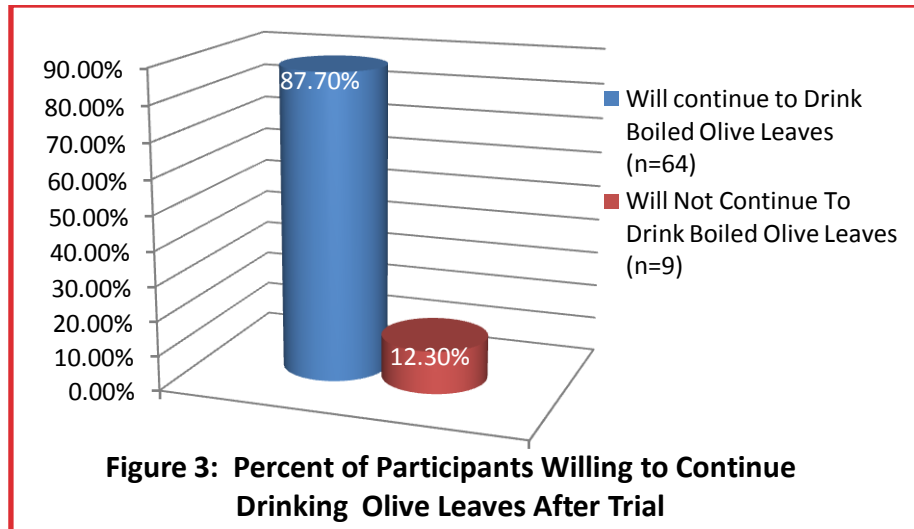
*Significant difference

The side effects experienced by the studied group during trial were: Hyperacidity and GIT disturbances reported by only 19 subjects (26%) and diarrhea among 13 subjects (17.8%). Diarrhea was reported by 13 subjects (17%) and constipation was reported by only 2 subjects (2.7%) of the studied group.

Although olive leaves drink has a very bitter taste, yet the majority of participants 58.9% (n=43) reported that they could accept its taste, 21.9% (n=16) of participants reported that the taste was good and bad taste was reported by only 14 subjects (19.2%), Figure 2.

However, only 9 subjects (12.3%) stated that they would not continue to use it after the end of the trial, figure 3.





Discussion:-

Up until today there's no known cure for DM. ¹⁴Management concentrates on keeping blood sugar levels as close to normal as possible, which can be achieved through eating a healthy diet, being physically active, having a normal BMI and using diabetic medications.

One of the commonly used complementary and alternative medicine herbs in Saudi Arabia is olive leaves, few human studies were available about the hypoglycemic effect of drinking boiled olive leaf therefore, this study was aimed to examine its effect.

In our study and with using 5 gram OLE dose once per day for three days which were preceded with three control days, the blood glucose level started to show significant reduction at the third day and that effect was significant one hour after the meal. We believe that drinking olive leaf extracts was responsible for reduction of blood glucose from mean level of 242.16 ± 79.757 mg/dl to 216.00 ± 68.302 mg/dl one hour after meal ($P=0.035$), and from 210.74 ± 79.617 mg/dl to 188.99 ± 59.739 , three hours after meal ($P=0.064$).

Pre-testing was done before the start of the study on 20 participants and the following problems were encountered:-

1. Long fasting period
2. No compliance with the exact described methodology due to patients having to eat CHO (21gram CHO biscuit)

So methodology was changed from:-

Measuring blood glucose level after at least 2 hours fasting according to the following schedule:-

- Before the study
- 1/2 hr after eating a biscuit containing 20 g carbohydrates and drinking the olive leaves powder.
- Two hours after eating a biscuit containing 20 g carbohydrates and drinking the olive leaves powder.

If blood glucose level is >140 the participant will drink olive leaves powder alone.

If blood glucose level is <140 the participant will eat 20 gm biscuits then drink olive leaves powder.

To the current method.

The results from this study were supported by the results from previous studies. Results of improved blood glucose level of (79 middle aged, overweight men with type 2 diabetes) were shown after conducting human studies on hypoglycemic effect of consumption of olive leaf and during a longer period with higher concentrations ¹⁵

A controlled clinical trial was conducted in New Zealand, 46 participants were given olive leaf polyphenols supplements for 12 weeks results revealed significant enhancement in insulin sensitivity by 15% ($p=0.02$) in comparison to placebo furthermore pancreatic β -cell secretory capacity improved by 28% ($p=0.01$) in overweight

middle-aged men who were at risk of developing the metabolic syndrome.¹²

An experimental study in Al-Mustansiriyah University, Baghdad where oleuropein was given to diabetic rabbits for a period of 16 weeks with a dose of 20 mg/kg body weight found that it inhibits hyperglycemia and oxidative stress induced by diabetes and proposes that oleuropein might be useful in the prevention of diabetic complications associated with oxidative stress.¹⁶

The University of Grenada researchers conducted a study in rats with alloxan-induced diabetes, doses of 16 and 32 mg/kg had a significant hypoglycemic effect and an increased peripheral glucose uptake depending on the dose given.¹⁷

The majority of the participants in our study were females 60.3% (n=44), males represented 39.7% of the subjects (n=29). Mean age was 49 years with a range from 19-65. Mean level of BMI was 30.46 ± 5.548 .

Descriptive analysis was done using statistical package for social sciences (SPSS17), mean and standard deviation of BG levels among studied group of each measurement each day before and after consuming olive leaves were determined, statistical significant difference between BG level before and after olive leaves intake was found on the third day of consuming olive leaves 1 hour after the meal (216.00 ± 68.302) (where P value =0.035) where in the control days Mean blood sugar level (mg/dl) in the third day 1 hour after meal was 242.16 ± 79.757 . And the measurement in the third day 3 hours after the meal were 210.74 ± 79.617 for the control day and Mean blood sugar level (mg/dl) after olive leaf intake 188.99 ± 59.739 (where P value =0.064).

Previous literature suggests that blood glucose may be lowered by two mechanisms: (1) enhanced insulin release, and (2) amplified glucose uptake.¹⁸, and some animal studies showed that reducing starch digestion and absorption might facilitate the hypoglycemic effect of olive leaf extract.¹⁵

The potential health promoting effect of Olive leaf appears to be related to its antioxidant activity, which was found in previous literature to be beneficial in the prevention of diabetic complications associated with oxidative stress.

Our result was independent of lifestyle factors (such as dietary intakes and physical activity levels). Hence, the result of our study may have been stronger if we have instructed the participants to engage in regular physical activity and to consume a healthy diet.

At the end of the study the participants were asked to complete a symptom questionnaire regarding any unexpected side effects, the amount of olive leaves taken and if they were going to continue taking olive leaf.

There was no significant side effect to taking olive leaf; with only minority reporting hyperacidity 26% (n=19), diarrhea 14% (n=12), constipation 2.7% (n=2).

Other studies conducted even at higher concentration and when taken for longer periods showed also no side effects.¹⁵

Only 5% (n=4) of the participants didn't drink the whole cup with olive leaf while others took the whole 100ml amount with a 5 mg of olive leaf.

Despite these reported side effects and even though olive leaf had a very bitter taste yet the majority of participants (87.7%) reported that they would continue to drink olive leaves.

Conclusion and Recommendations:-

Olive leaf extract may represent an effective therapy that normalizes glucose homeostasis in individuals with diabetes. Hypoglycemic effect of olive leaves was approved in the third day of use and minor side effects were reported, and the majority accepts this therapy.

Pharmaceuticals and drug companies should separate and investigate the impact of individual ingredients of olive leaves on blood glucose level with the objective of finding a safe, effective and cheap cure for diabetes. This could be a milestone in modern medicine.

However, more research into the possible hypoglycemic effects of olive leaf extract is needed before it can be recommended for use as a natural safe treatment. This could be a millstone in modern medicine.

Dedication and Acknowledgment:-

To our caring, loving, and supporting Dr. Sahar Ali, our deepest and sincerest gratitude for her continuous support, for her patience, motivations, and immense knowledge. Without her guidance and consistent help, this research would not have been completed, our heartfelt thanks.

Our genuine gratefulness and warmest regard to our families, and our friends we would not be who we are today without your constant love and support. We are sincerely thankful for the encouragement and help you have given us throughout our life to succeed and make our dreams come true. We have been blessed to have you.

Finally, a special feeling of gratitude to our study participants whose words of encouragement and prayers for us has pushed us to do our best.

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