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Evaluation of the Clinical Effect of Zallouh Extract (Ferula Hermonis) on Diabetic Patients with Erectile Dysfunction

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Abstract

Ferula hermonis has been widely used as a sexual tonic in the Middle East. It is reputed to enhance erectile function especially in diabetic patients, although no scientific verification was found. This study aimed to investigate the clinical and biochemical effects of *Ferula hermonis* on diabetic patients with erectile dysfunction.

Materials and Methods: Capsules containing the dried alcoholic extract of *Ferula hermonis* were administered to sixty diabetic patients divided into three groups; group one (control group) consisted of twenty patients received placebo capsules, group two consisted of twenty patients received capsules containing 500 mg of the dried alcohol extract of *Ferula hermonis* and group three consisted of twenty patients received capsules containing 1000 mg of the dried alcohol extract of *Ferula hermonis*. Patients were examined both before and after eight weeks of dried extract intake for these biochemical tests; total testosterone, estrogen, total cholesterol, triglycerides, LDL-C, HDL-C, blood glucose, body weight, ALT, and AST and

for erectile function tests; international index of erectile function (IIEF-5), Rigiscan, and duplex ultrasound.

Results: In comparison to control group, the treated groups showed a statistically significant increase in total testosterone (47%, and 145.66% increase for group two and group three respectively, $P < 0.05$), a statistically significant increase in estrogen (52.2%, and 125.66% increase for group two and group three respectively, $P < 0.05$), a statistically significant increase in IIEF-5 (21.48%, and 48.4% increase for group two and group three respectively, $P < 0.05$), and a statistically significant increase in Rigiscan parameters ($P < 0.05$). Lipid profile showed a statistically significant decrease only at high dose (group three) in total cholesterol, triglycerides, and LDL (23.3%, 22.69%, and 26.52% respectively, $P < 0.05$) but no statistically significant difference was found in HDL ($P > 0.05$). Other biochemical parameters and duplex ultrasound showed no statistically significant difference ($P > 0.05$).

Conclusions: *Ferula hermonis* has shown to be of a beneficial effect on diabetic men with erec-

tile dysfunction through increasing serum testosterone and through improving lipoproteins abnormalities associated with Diabetes mellitus. The current study concluded the beneficial effects of *Ferula hermonis* in diabetic patients with erectile dysfunction. *Ferula hermonis* could be used as a natural alternative remedy. However, further studies of longer duration and larger numbers of patients are required. In addition, active ingredients should be separated and tested for their specific activities and toxicities.

Introduction

After the launching of sildenafil citrate in treating erectile dysfunction, the interest in *Ferula hermonis* in folk medicine has been increased. Zallouh "*Ferula hermonis*" is one of the most frequently used plants as sexual tonic. *Ferula hermonis* is a small shrub, with pale pink flowers. *Ferula* species have been approved by FDA as one of the substances generally recognized as safe for human consumption. This plant has been reputed to enhance erectile function especially in diabetic patients, although no scientific clinical study was found. The aim of this work was to evaluate the biochemical and clinical effects of *Ferula hermonis* on diabetic patients with erectile dysfunction.

Materials and Methods

The dried roots of *Ferula hermonis* were purchased from Haraz herbal drug store in Cairo, Egypt. The roots were kindly identified by Dr. Salwa Kosha (Plant Taxonomy and Egyptian Flora Department, National Research Center, Giza, Egypt). The powder of *Ferula hermonis* (100gm) was extracted by maceration with 95% hot ethanol (El-Gomhoria, Egypt) until completely exhausted. The collected alcohol extracts were then distilled at not more than 45°C to leave a dried gummy residue (25 gm) which was kept in tightly sealed glass vial and stored in a refrigerator until its use. The gummy residue was dissolved in the least amount of ethanol then we added 75 gm starch (Adsorbent) in a stepwise manner to the gummy residue of *Ferula hermonis* in a ratio of 3:1. Aerosil (1.0 gm) 1%

of total weight was then added to the mixture. This was followed by removing the remaining ethanol by blowing compressed air to obtain dried fluffy powder. Then, a quantity equal to 1 gm of the obtained powder (equivalent to 0.25 gm of *Ferula hermonis* dried extract) was accurately weighed and packed manually in hard gelatin capsules. The study involved sixty patients recruited from the outpatient clinic of the urology department, Tanta University, Tanta, Egypt. Their ages ranged from 40-55 years. All patients complained of type 2 diabetes mellitus for 5-7 years and are using oral hypoglycemic treatments. All patients were married with erectile dysfunction for about 1 year. Patients abstained taking any medication (except for oral hypoglycemic drugs) for at least one month before starting treatment course. Patients were excluded if they had cardiovascular disorders (unstable angina pectoris, uncontrolled atrial tachy-arrhythmia, or myocardial infarction), hypertension, hepatic disorder including a history of hepatitis B, hepatitis C, bilharziasis, severe chronic liver disease or abnormal laboratory values in ALT (Alanine transaminase) and AST (Asparatate transaminase), a history of malignancy within the previous 5 years, any pituitary disorder, heavy alcohol ingestion, or radiotherapy. After signing a consent form, accepted patients were interviewed for complete history and clinical examinations which were done by qualified physicians from the Department of Urology, Tanta University Hospital. Tanta. Capsules containing the dried alcoholic extract of *Ferula hermonis* were administered to sixty diabetic patients divided into three groups; group one (control group) consisted of twenty patients received placebo capsules, group two consisted of twenty patients received capsules containing 500 mg of the dried alcohol extract of *Ferula hermonis* (equivalent to 2 gm of *Ferula hermonis* powder), and group three consisted of twenty patients received capsules containing 1000 mg of the dried alcohol extract of *Ferula hermonis* (equivalent to 4 gm of *Ferula hermonis* powder). Patients were examined both before and after eight weeks of dried extract intake for these biochemical tests; total testosterone, estrogen, total cholesterol, triglycerides, LDL-C, HDL-C, blood glucose, body

weight, ALT, and AST and for erectile function tests; IIEF(international index of erectile function), Rigiscan, and duplex ultrasound. IIEF is a subjective method to assess erectile function where all patients were asked to answer a questionnaire composed of five main questions. Rigiscan is a device allows measuring the duration, frequency, degree of rigidity, and tumescence of the penis. The device provides a graphical and tubular display of base and tip penile rigidity and tumescence data for interpretation by physician. Duplex ultrasound gives hemodynamic data of the same quality of normal erection. Duplex ultrasound is performed by first obtaining a baseline study of the flaccid penis. A pharmacologic erection is then induced by the intracavernous injection of papaverine (15 mg) moreover audio-visual stimulation was added to initiate erection. Then, Duplex ultrasound started immediately following injection. To assess arterial response, PSV (peak systolic velocity) was calculated. PSV should be measured 5-10 minutes after injection. To assess veno-occlusive response, RI (resistive index) was calculated 15-20 minutes after injection. Resistive index calculations 15-20 minutes after injection correlated well with maintenance flow rate and hence veno-occlusion.

Results

Following eight weeks of *Ferula hermonis* extract administration, the mean changes in biochemical findings were presented in Table (1). There was a statistically significant increase in total testosterone levels by 47%, and 145.66% for groups 2 and 3 respectively, and a statistically significant increase in estrogen levels by 52.2%, and 125.66% for groups 2, and 3 respectively (paired t-test, $P<0.05$) Increasing the dose of *Ferula hermonis* showed a statistically significant increase in both total testosterone and estrogen suggesting a dose dependant effect on total testosterone level (two sample t-test, $P<0.05$).

Lipid profile showed a statistically significant decrease only in group three in total cholesterol, triglycerides, and LDL (23.3%, 22.69%, and 26.52% respectively, $P<0.05$) but no statistically significant difference was found in HDL ($P>0.05$). This might suggest a possible role of *Ferula hermonis* as antihyperlipidemic agent at high dose. Other biochemical parameters showed no statistically significant difference ($P>0.05$).

Regarding erectile function tests, following eight weeks of *Ferula hermonis* extract administration, there was a statistically significant increase in IIEF scores by 21.48%, and 48.4% for groups 2 and 3 respectively (paired t-test, $P<0.05$). Increasing the dose of *Ferula hermonis* showed a statistically significant increase in IIEF scores suggesting a possible dose dependant effect on IIEF scores (two sample t-test, $P<0.05$). Regarding Rigiscan parameters, there was a statistically significant increase in event duration by 6.26%, and 11.39% for groups 2 and 3 respectively (paired t-test, $P<0.05$). In addition, there was a statistically significant increase in average event rigidity by 12.7%, and 18.72% for groups 2 and 3 respectively (paired t-test, $P<0.05$) with respect to the tip. Regarding the base, there was a statistically significant increase in average event rigidity by 13.76%, and 18.8% for groups 2 and 3 respectively (paired t-test, $P<0.05$). Furthermore, there was a statistically significant increase in event tumescence more than the base tumescence by 9.00%, and 23.34% for groups 2 and 3 respectively (paired t-test, $P<0.05$) with respect to the tip (paired t-test, $P>0.05$). Regarding the base, there was a statistically significant increase by 9.01%, and 19.4% for groups 2 and 3 respectively (paired t-test, $P<0.05$). Regarding duplex ultrasound, PSV and RI showed no statistically significant difference in the three groups (paired t-test, $P>0.05$).

Table 1. Mean changes in biochemical tests following eight weeks of *Ferula hermonis* extract administration in group 1 (control group), group 2 and group 3.

	Group 1		Group 2		Group 3	
	Before mean ± SD	After mean ± SD	Before mean ± SD	After mean ± SD	Before mean ± SD	After mean ± SD
T. Test.	1.962 ± 0.849	2.313 ± 1.099	2.743 ± 1.048	4.037* ± 1.095	2.293 ± 0.875	5.632* ± 1.52
Estrogen	20.26 ± 8.55	18.40 ± 5.06	17.14 ± 7.41	26.1* ± 7.72	15.90 ± 7.29	35.88* ± 6.35
ALT	24.60 ± 9.91	27.6 ± 9.69	20.90 ± 8.3	23.55 ± 8.04	22.85 ± 9.69	25.40 ± 8.70
AST	23.70 ± 8.6	25.25 ± 8.04	21.05 ± 9.3	24.35 ± 8.83	26.30 ± 10.02	22.70 ± 7.9
T. Chol.	190.54 ± 24.4	188.5* ± 25.4	205.8 ± 32.58	203.4 ± 33.24	208.55 ± 39.7	159.95 ± 28.3
TGs	151.6 ± 43.34	156.7* ± 41.6	148.1 ± 47.04	150.3 ± 47.2	154.2 ± 52.6	119.2 ± 49.2
LDL	123.5 ± 34.44	117.9* ± 28.05	117.3 ± 31.65	115.8 ± 33.87	131.0 ± 24.59	96.25 ± 18.34
HDL	51.3 ± 13.7	52.1 ± 9.93	46.10 ± 10.51	47.35 ± 9.34	49.65 ± 9.50	50.90 ± 12.30

* Significant difference after *Ferula hermonis* extract administration compared with their respective values before extract administration (paired t-test, P < 0.05)

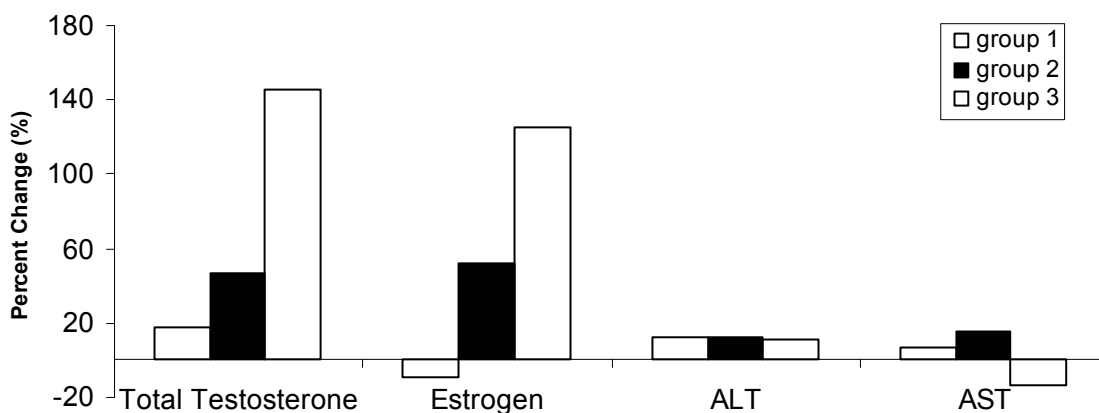


Fig. 1. The percent change in total testosterone, estrogen, ALT, and AST both before and after eight weeks of *Ferula hermonis* extract administration in the three groups

Table 2. Mean changes in erectile function tests Following Eight Weeks of *Ferula hermonis* Extract Administration in Group 1 (Control Group), Group2, and Group 3

		Group 1		Group 2		Group 3	
		Before mean ± SD	After mean ± SD	Before mean ± SD	After mean ± SD	Before mean ± SD	After mean ± SD
IIEF	Ques 1	2.90±0.85	3.10±0.64	2.50 ±0.94	3.45*±0.94	2.25± 0.71	4.05*±0.5
	Ques 2	3.05±0.82	3.1± 0.78	3.35 ± 0.87	3.50±0.761	3.40±0.50	3.90*±0.64
	Ques 3	2.75±0.639	2.85 ± 0.7	2.80 ± 0.83	2.85 ±0.846	2.85± 0.81	4.10*±0.44
	Ques 4	2.40±1.05	2.30±0.97	2.000 ± 0.85	2.35*±0.876	2.60±0.59	3.55*±0.75
	Ques 5	2.20±0.875	2.35±0.76	2.05 ± 0.78	3.55*±0.53	2.00±0.649	4.00*±0.56
	Total score	13.25±1.55	13.65 ±1.4	12.8 ± 2.30	15.6*±2.32	13.0± 2.34	19.3*± 1.3
Rigis- can	Duration (min)	21.1±5.42	19.9±4.99	20.90 ±4.22	22.2*±5.12	22.70±5.94	24.35*±6.19
	Tip avg rig	55.50±7.93	58.4±6.75	57.25 ±7.83	64.5*±4.78	60.20±7.06	69.1*±3.61
	Tip event tum>B line	24.8±3.427	24.4±2.90	24.50 ±3.60	26.7*±2.40	22.5±2.283	27.7*±2.751
	Base avg rig	50.75±7.15	53.15±5.2	54.30 ±7.74	59.5*±4.17	52.15±6.87	62.0* ±3.2
	Base event tum>B line	25±2.176	25.3±2.63	24.95 ±3.23	27.9*±2.42	23.56±3.18	28.2*±1.293
Duplex	PSV	28.95±3.81	29.6±5.57	30.55 ±3.86	32.1±3.93	31.9±4.567	33.15 ±3.96
US	RI	1.051±0.18	1.123±0.2 1	0.995 ±0.20	1.07±0.148	1.135 ±0.24	1.208 ±0.15

*-Significant difference after *Ferula hermonis* extract administration compared with their respective values before extract administration (paired t-test, P < 0.05)

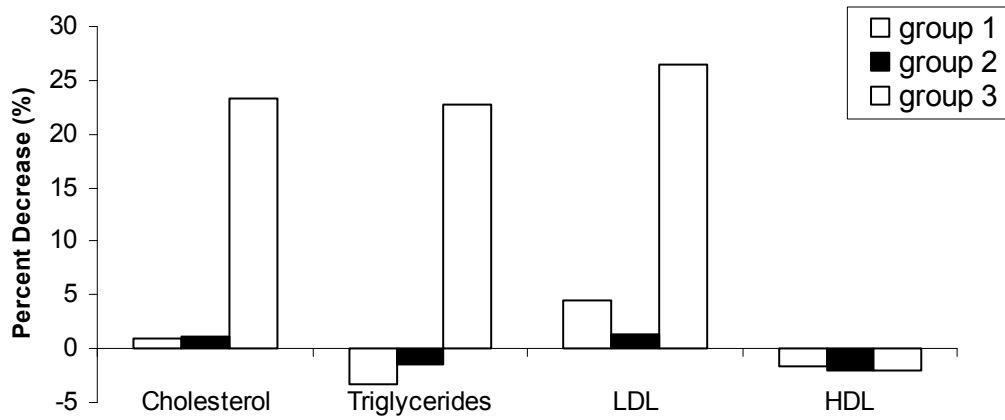


Fig. 2. The Percent Change in lipid profile both before and after eight weeks of *Ferula hermonis* extract administration in the three groups

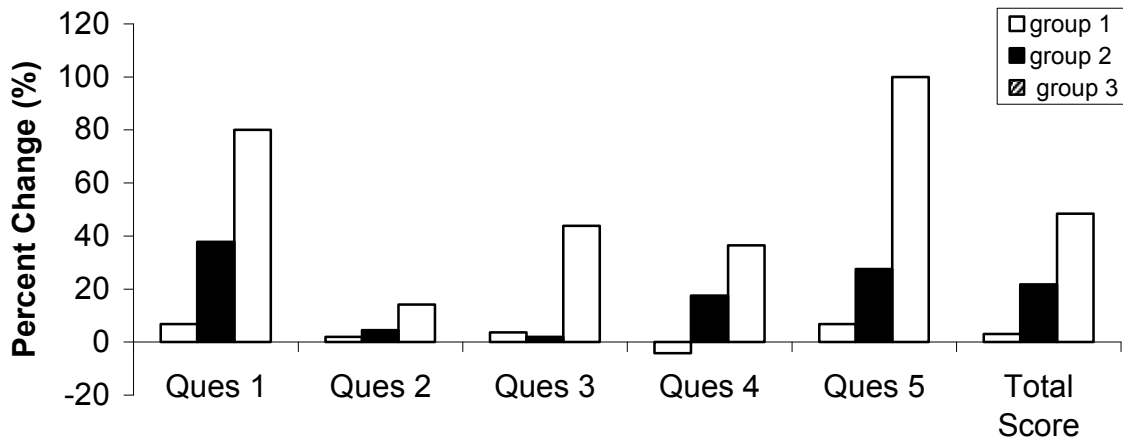


Fig. 3. The Percent Change in IIEF both before and after eight weeks of *Ferula hermonis* extract administration in the three groups

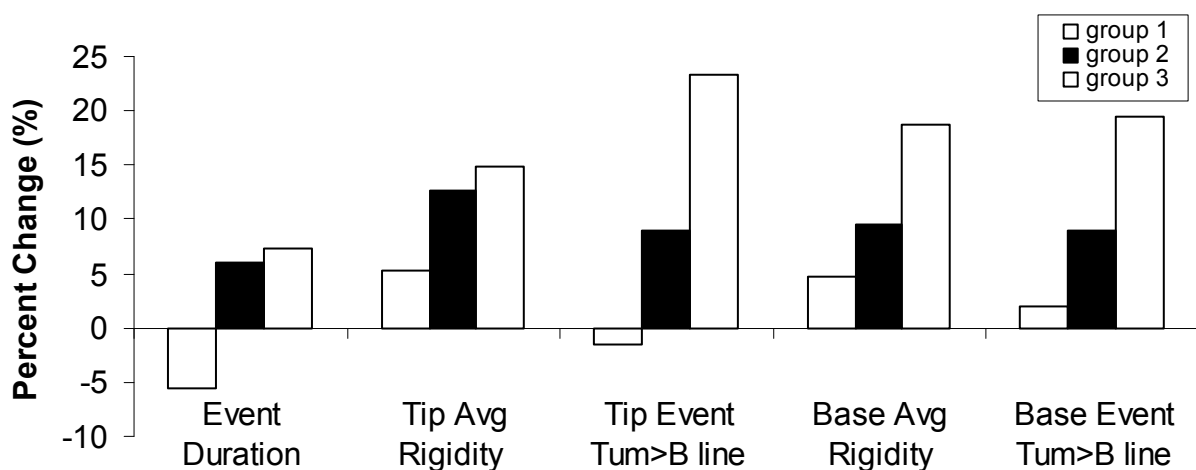


Fig. 4. The Percent Change in Rigiscan parameters both before and after eight weeks of *Ferula hermonis* extract administration in the three groups.

Discussion

Ferula hermonis showed a significant increase in total testosterone level in a possible dose dependant manner. This was expected as it was found earlier that *Ferula hermonis* contains compounds such as ferutinine, feroline, and tenuferidine. these compounds have shown to have an estrogenic activity and structures resemble diethylstilbesterol, a synthetic estrogen, which have the ability to increase synthesis and release of testosterone through the pituitary – luteinizing hormone – testicles axis⁽⁷⁾. Ferutinine, the main active constituent of *Ferula hermonis*, is described as being a half agonist of estradiol receptors⁽¹⁰⁾. In presence of estradiol, Ferutinine is considered as a weak estrogen that is capable of blocking the effects of more potent estrogens (estradiol) thus producing a mixed agonist/antagonist. Ferutinine showed a binding affinity for both estrogen receptors (ER α and ER β) with about one-tenth of the binding affinity of estradiol. In male, Ferutinine appears to exert its major effects by binding to estradiol receptors in the hypothalamus area. So, estradiol is incapable of exerting its negative feedback on gonadotropin releasing hormone (GnRH). This causes the hypo-

thalamus to release a leutenising hormone (LH) and GnRH. This circulates through the body to the testicles where it causes the production and release of testosterone into the blood stream⁽⁹⁾. Recently, it has been shown that Ferutinine increases nitric oxide synthase activity (49%) in the median eminence (ME) of the rat brain (Median eminence is one important region in the hypothalamus essential for neuroendocrine control), suggesting that ferutinine affecting nitric oxide production⁽⁶⁾. This effect is attributed to the estrogenic activity of ferutinine on the ME which able to increase gonadotropin hormone and then increase NO production.

Ferula hermonis showed a significant increase in estrogen level in a dose dependant manner. This may be explained by the catabolism of testosterone to 17- β estradiol. In males, testosterone is the major source of plasma estradiol, the main biologically active estrogen⁽¹⁶⁾. This occurs through 19- hydroxyl testosterone intermediate formation by enzyme complex known as aromatase system, which is associated with the endoplasmic reticulum inside cells⁽¹¹⁾. The production of estrogens may play a role in male protection against atherosclerosis.

In the current study, *Ferula hermonis* had no significant reductive effect on body weight during

the eight weeks period, as well as it non-significant change on fasting blood glucose concentration.

Earlier studies gave a controversial results regarding *Ferula hermonis* effect on liver. In the current study, *Ferula hermonis* caused non-significant difference in ALT, and AST serum levels. This might suggest minimal if any risk of hepatotoxicity. Although, further studies of long term duration, larger numbers of patients, and higher doses are required to investigate the possible effect of *Ferula hermonis* on liver function.

Ferula hermonis showed a significant reduction in LDL-C, total cholesterol, and triglycerides only at high dose of *Ferula hermonis* extract (1 gm daily) and non-significant effect on HDL serum level. These plasma lipoproteins variations can be explained as a consequence of both testosterone and estrogen concentration changes.

The reduction in the LDL serum level following *Ferula hermonis* administration might be attributed to the increase in estradiol concentration, which enhances hepatic expression of LDL receptors increasing LDL clearance. Estradiol increases hepatic mRNA for the LDL receptor and increases the synthesis of LDL receptor protein out of proportion to the increase in hepatic LDL receptor mRNA, indicating both transcriptional and posttranscriptional regulation of the LDL receptor by estradiol⁽⁴⁾. In addition to estrogen, the decrease in LDL might be attributed to the rise in plasma testosterone⁽³⁾.

The reduction in triglycerides serum level following *Ferula hermonis* administration may be attributed to the increase in testosterone concentration which in turn increases lipase enzyme activity and decreases triglycerides⁽³⁾. The obtained results might suggest that testosterone effect predominated on the opposing effect of estrogen which known to increase triglycerides serum level through increasing production of VLDL which is the main carrier of triglycerides⁽¹²⁾.

The non-significant effects of *Ferula hermonis* on HDL might be attributed to that the increase in HDL concentration by estradiol is opposed by the reductive effect of testosterone on HDL and the net

outcome was non significant difference. Estrogen can increase HDL concentration through increasing HDL2, Apo A1, and Apo A11⁽¹⁴⁾. On the other hand, testosterone might decrease HDL concentration through affecting the large HDL subclass (HDL2) and Apo A1 rather than affecting HDL3 or Apo A11 production⁽¹⁵⁾.

Various methods have been considered in the evaluation of erectile function with only the subjective method IIEF-5 remained the corner stone in evaluating treatments for erectile dysfunction. The mean scores of IIEF-5 showed a significant increase following *Ferula hermonis* administration in a dose dependant manner. The significant increase in IIEF-5 scores and favorable responses to questions 1 and 5 has been suggested to represent a clinically relevant success. Although, the number of patients examined was small and it was not likely that all patients were accurate and uniform when recording IIEF scores, this study allowed a preliminary conclusions to be considered. The significant increase in the scores of question 1 and question 5 confirmed the significant increase in the IIEF-5 scores and suggested a specific positive action of *Ferula hermonis* extract on improving the confidence to keep and get erection (question 1) & improving sexual intercourse satisfaction (question 5).

Mean Rigiscan parameters after *Ferula hermonis* administration revealed a significant increase in duration, rigidity, tumescence. Although, the Rigiscan was not considered to be good predictors of therapeutic response⁽¹³⁾. This uniform increase in Rigiscan parameters (correlated with IIEF-5 improvements) should be considered as a definite improvement triggered by *Ferula hermonis* administration.

The significant increase in IIEF scores and Rigiscan parameters was suggested to be due to the following reasons. First, improvement in lipid profile associated with *Ferula hermonis* reduces the risk of atherosclerosis enhancing vascular blood flow and improves endothelium dependent relaxation of the cavernosal smooth muscle⁽¹⁾. Second, improvement in sexual desire and libido associated with testosterone increase⁽²⁾. Third, possible endo-

thelial improvement by induction of NO secretion induced by Testosterone rise⁽⁵⁾.

We noticed no significant difference in penile hemodynamic on duplex ultrasonography following *Ferula hermonis* administration. Although improvement in lipid profile was suggested to have antiatherosclerotic activity and to enhance vascular blood flow thus improving hemodynamic parameters on Duplex ultrasonography. These unexpected results might be rationalized as following: First, duplex ultrasound test is not a physiologic test. In some patients, anxiety and fear of injection could lead to a sympathetic response that will hinder erection and mask the improvements in hemodynamic parameters measured by duplex⁽¹³⁾. Second, limitations of study conditions regarding the small number of patients, duration of the study, and the dose of *Ferula hermonis* administered.

The current study concluded the beneficial effects of *Ferula hermonis* on diabetic patients with erectile dysfunction and the obtained results suggest that *Ferula hermonis* could be used as natural alternative remedy. However further studies of longer duration, larger numbers of patients are required. In addition, active ingredients should be separated and tested for their specific activities and toxicities.

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تقييم التأثير الاكلينيكي لمستخلص الزلوع (فيريو لا هرمونيس) على ضعف الانتصاب المصاحب لمرضى السكري

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تهدف هذه الدراسة إلى التحقق من التأثيرات الإكلينيكية و الكيميائية الحيوية لنبات الفريولا هرمونيس على عدم القدرة على الانتصاب المصاحب لمرضى السكري.

وقد أشتملت الدراسة على ستين مريضاً مقسمين الى ثلاث مجموعات: المجموعة الاولى (المجموعة الضابطة) وشملت عشرين مريضاً وقد تم إعطاؤها كبسولات فارغة من مستخلص النبات، المجموعة الثانية وشملت عشرين مريضاً وقد تم إعطاؤها كبسولات تحوى ٠,٥ جم من المستخلص الكحولي لنبات الفريولا هرمونيس ، المجموعة الثالثة وشملت عشرين مريضاً وقد تم إعطاؤها كبسولات تحوى ١ جم من المستخلص الكحولي لنبات الفريولا هرمونيس وقد تم فحص هؤلاء بأخذ التاريخ المرضى لكل منهم و عمل الاختبارات الكيميائية الحيوية التالية: إجمالي هرمون الذكورة، هرمون الأنوثة، إجمالي الكوليسترول، ثلاثية الدهون، الدهون منخفضة الكثافة، الدهون عالية الكثافة، سكر الدم، وزن الجسم، إنزيمات الكبد، بالإضافة إلى إختبارات قدرة الانتصاب وشملت المؤشر الدولي لقدرة الإنتصاب، معايير الريجيسكان، الموجات فوق الصوتية وقد تم إعادة عمل الإختبارات السابق ذكرها بعد تناول المرضى المستخلص الكحولي لنبات الفريولا هرمونيس لمدة ثمانية أسابيع متتالية.

وقد أظهرت نتائج الدراسة زيادة احصائية ملحوظة في المجموعة الثانية و الثالثة مقارنة بالمجموعة الضابطة في كل من إجمالي هرمون الذكورة الثانية، زيادة إحصائية ملحوظة في هرمون الأنوثة، زيادة إحصائية ملحوظة في المؤشر الدولي لقدرة الانتصاب، وكذلك زيادة إحصائية ملحوظة في معايير الريجيسكان و قد أظهرت الدهون انخفاضاً احصائياً ملحوظاً في المجموعة الثالثة فقط في كل من إجمالي الكوليسترول ، ثلاثية الدهون ، الدهون منخفضة الكثافة (دون تغير إحصائى ملحوظ في الدهون عالية الكثافة) في حين أن باقي الإختبارات الكيميائية الحيوية و الموجات فوق الصوتية لم تظهر أى تغيرات إحصائية ملحوظة.

أظهرت النتائج أن تناول نبات الفريولا هرمونيس لمدة ثمانية أسابيع متتالية أدى الى حدوث تأثيرات فعالة على عدم القدرة على الانتصاب المصاحب لمرضى السكري ، مما يشير الى أهمية استخدامه كبديل طبيعى لعلاج عدم القدرة على الانتصاب.