Effect of Electrolipolysis versus Metformin in the Treatment of Polycystic Ovarian Syndrome

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ABSTRACT:

This study was conducted to determine which is more effective, electrolipolysis or metformin in the treatment of obese polycystic ovarian syndrome (PCOS). Thirty obese patients diagnosed with PCOS were selected from Kasr El Aini university Hospital to participate in this study. Their ages ranged from 20 to 30 years, their BMI> 32 kg/m2 and waist/hip ratio >0.8. Patients assigned randomly into two equal groups. Group (A) received electrolipolysis at abdomen, thigh and gluteal regions (3sessions/week) and group (B) received metformin 850 mg twice/day). Both groups received treatment for four months and followed the same hypo caloric diet 1200 kcal/day. Evaluations of all patients were done before and after 4 months of treatment through measuring weight, BMI, waist/hip ratio, LH, FSH, LH/FSH ratio, fasting blood insulin fasting blood glucose , fasting glucose / insulin ratio, regularity of the menstruations and follicle size for both groups (A&B). The result of this study showed that there was statistically non-significant difference between both groups before treatment and after treatment there was statistically significant decrease ($p< 0.05$) in weight, waist and hip circumference, waist/hip ratio, LH, LH/FSH ratio, fasting blood glucose and fasting blood insulin between both groups in favor to group (A). While, in fasting glucose/insulin ratio and follicle size there were statistically significant increase in favor to group (A), and FSH showed a statistically non significant difference between both groups (A & B). Also, there was improvement in the menstrual regularity in group (A) than group (B) and only one case get pregnant in group (A). It could be concluded that electrolipolysis is more effective than metformin in treating obese PCOS patients.

Key words: Obesity, Polycystic ovarian syndrome, Electrolipolysis, Insulin resistance, Female sex hormones, Metformin

Introduction

Introduction

Polycystic ovarian syndrome (PCOS) is a common endocrinological disturbance that 6 to 10% of females in their reproductive period suffered(1).Chronic anovulation and hyperandrogenism are the most two classic criteria used in the diagnosis of PCOS as its specific diagnosis is still controversy. Considerably 60% of women with PCOS have hyperinsulinemia (2). This increase in insulin level adds to hyerandrogenism via two ways; the first is by stimulating androgen production from ovaries, the second through inhibiting sex hormone binding globulin (SHBG) causing eventually increase in the levels of free testosterone (3). PCOS pathogenesis could be contributed mainly to three factors; hyperinsulinemia, insulin resistance and abdominal obesity (4,5). These three factors also predispose women to cardiovascular problems and diabetes mellitus type 2 (6,7).

PCOS therapeutic approaches are focused on inhibiting androgen production from ovaries. Understanding this relationship between hyperandrogenism and hyerinsulinism explain the recent widely usage of insulinsensitizating drugs likethiazolidinediones and biguanidein PCOS. There is a biguanide medication taken orally named as metformin used in diabetes mellitus type 2 which has been found its effectiveness in enhancing insulin sensitivity , pattern of menstural cycle and hence pregnancy consequences (8-12).

Obesity is observed in 30-70% of women with PCOS, and it greatly affects both laboratory and clinical syndrome expression.there is no clear or exact cause could clarify the pathogenesis of PCOS ; But no way that insulin resistance, hyperandrogenism and abdominal obesity are the main factors that affecting each other in a vicious pattern.

So, the first recommendation for treatment of PCOS is Weight losswhich was found to improve the clinical concomitant manifestations of the disease such as the disturbances in the mensturalcycle, hirsutism and even infertility.Nevertheless, the best approach for treating obese PCOS females remains to be clarified (13).

Electrolipolysis is an electrical current passed beneath the skin, this breaks down fat into fatty acid and water (14). Electrolipolysis is not onlyleading to weight loss butalso affecting the process of fat remobilizing and causing its relocating. It actsby reactivation of inactive cells and hence the liberated fatty acid will be deposited in active cells, if the body didn't use them on its physical efforts to produce heat (15).

Our present study aims to compare the efficacy of four months electrolipolysis course versus metformin therapy as a first-line treatment of diet controlled anovulatory PCOS patients.

Subject, materials and methods

Subjects:

This prospective randomized study involved 30 obese females (BMI > 32 kg/m2) their ages ranged from 20 to 30 years and waist /hip ratio>0.80 from attendants of the gynecology outpatient clinic of Kasr-El-Aini hospital. They were diagnosed by appling the revised criteria of2003 Rotterdam used in diagnosing PCOS (16), i.e. 2 fro the following 3 criteria are diagnostic ; polycystic ovaries ,anovulation and/or oligoovvulation and biochemical and/or clinical hyperandrogenism signs. All patients were not previously treated for ovarian stimulation. The

study was approved by Faculty Council at Faculty of Physical Therapy, Cairo University, and it started from November 2007 to September 2008.

All patients were free from any medical or endocrinological disorders as well as skin diseases in the abdominal, gluteal region and any other conditions that may prevent the usage of electrical stimulation. Ahead of enrollment, a full explanation of the treatment protocol was given to each participant to obtain their confidence and informed consent.

All patients were prescribed a low caloric diet along the treatment period lasting for four months. They were randomly allocated into two treatment groups; ELip group (n = 15) undergoes electrolipolysis treatment and Met group (n = 15) treated by metformin 850 mg twice/day. Electrolypolysis was applied to abdomen, thigh and gluteal regions, 3 sessions/week, 60 minutes/session; 30 minutes on the abdomen and thigh and 30 minutes on gluteal region. The diet program was 1200 kcal/day as described by Cairo Nutrient Institute (17).

Assessment:

Assessment included detailed medical and gynecological history, height,weight,hip and waist circumferences measurement calculating the waist to hip ratio and the body mass index (BMI). A venous blood sample was drawn after 12-hour fasting on the third day of the menstrual cycle to determine LH, FSH, blood glucose and fasting blood insulin.

Electrolipolysis Procedure:

Electrolipolysis was applied using Body Program Slimmy (Model IGC 601-1). Bladder was evacuated before session. Body Program Slimmy electrodes were covered with wetted pads before strapping to the site of electrolipolysis. The patient lied supine in a relaxed comfortable position. At abdominal region, the electrodes of 1st and 2nd channels were placed just above and below umbilicus by 5 cm and 10 cm in between electrodes on the right and left side. At thigh region the electrodes of 3rd and 4th channels were placed just below inguinal ligament and on the most raised area of the quadriceps muscle on both body sides, the electrodes of the 5th channels were placed on the greater trochanter and on the mid point of the thigh at the right side of the body and the electrodes of the 6th channel on the same place at the left side of the body. The electrodes were wrapped in their positions with Velcro straps. The device was adjusted to a frequency of 20 pulses/min. to induce contraction for 4 seconds and a relaxation for 4 seconds in a pulse width of 400 microseconds for duration of 30 min. and then switched on.

The patient was instructed to lie in a relaxed prone position resting the chin on the hands with eyes and face facing forward. The electrodes of 1st channel were placed on the side of sacrum and on the most raised area of buttocks on the right side of the body and the electrodes of the 2nd channel on the same place at the left side of the body. The electrodes were wrapped in their position with Velcro straps and the device was adjusted as before and switched on and the intensity increased gradually until a good contraction was seen and felt comfortably. After the end of electrolipolysis, the device was automatically switched off and electrodes removed.

As indicated in table (1), no statistical significant difference in age, height, weight and BMI between both groups.

Concerning waist circumference, hip circumference,no statistical significant difference between the two studied groups (Table 2) at pre treatment.

After treatment significant reduction of BMI, weight, hip and waist circumference and waist/hip ratio was perceived in the two studied groups ($p < 0.001$ for all comparisons) (Table 2). Treatment resulted in significantly more reduction of body measurements in the ELip group compared to Met group.

There was no statistical significant difference between bothtwo groups regarding LH level, FSH level and the ratio of LH /FSH before treatment; ($p = 0.900$, 0.995, and 0.583, respectively). After treatment, significant reduction of LH levels and LH/FSH ratio occurred in both groups. The post-treatment LH/FSH ratio was significantly lower in ELip group ($p = 0.001$) compared to MET group. Treatment resulted in significant reduction of blood glucose and insulin levels. After treatment, blood glucose and insulin levels were significantly lower in ELip group ($p < 0.001$).The ratio of Glucose/insulin was significantly lower before treatment in the ELip group ($p = 0.017$). After treatment, there was nostatisistical significant difference in glucose/insulin ratio between the two studied groups ($p = 0.884$) (Table 3).

Table 1. Baseline physical characteristics of the two studied groups

Variables	**ELip Group (n = 15)**	**Met Group (n = 15)**	**p value**
Age (yrs)	26.40±3.97	27.87±2.23	0.082
Height (cm)	165.07±5.97	164.20±6.02	0.576
Weight (kg)	95.53±7.60	98.33±7.20	0.148
BMI (kg/m^2)	35.19±1.11	36.14±3.31	0.146

Table 2. Change of body measurements of the two studied groups after treatment

Variables	**ELip Group (n = 15)**		**Met Group (n = 15)**		**p value**	
	Before ttt	After ttt	Before ttt	After ttt	Before ttt	After ttt
Weight (kg)	95.53±7.60	77.33±7.00	98.33±7.20	86.50±5.63	0.148	0.001
BMI (kg/m^2)	35.19±1.11	28.47±1.12	36.14±3.31	31.79±2.78	0.146	0.001
Waist circumference (cm)	107.77±3.46	88.67±5.49	109.50±4.82	99.93±3.88	0.115	0.001
Hip circumference (cm)	115.70±2.23	106.60±4.84	117.27±4.10	110.80±2.11	0.073	0.001
Waist/Hip ratio	0.92±0.04	0.83±0.05	0.93±0.03	0.90±0.03	0.095	0.001

Table 3: Change of laboratory parameters of the two studied groups after treatment

Variables	ELip Group (n = 15)		Met Group (n = 15)		**p value**	
	Before ttt	After ttt	Before ttt	After ttt	Before ttt	After ttt
LH	11.09±3.30	7.84±2.44	11.00±2.66	8.97±2.03	0.900	0.001
FSH	4.46±1.24	4.63±1.20	4.47±1.02	4.47±0.96	0.995	0.001
LH/FSH Ratio	2.53±0.57	1.71±0.44	2.47±0.27	2.11±0.43	0.583	0.001
Glucose	85.80±3.91	70.83±1.95	87.33±4.06	81.83±3.83	>0.05	<0.001
Insulin	18.73±1.60	11.93±0.83	18.13±2.75	13.90±2.02	>0.05	<0.001
Glucose/Insulin Ratio	4.60±0.30	5.96±0.43	4.90±0.59	5.99±0.73	>0.05	0.884

Discussion

This study compared the effect of metformin, an insulin sensitizer versus electrolipolsis, a method of weight reduction and remobilization of fat to combat abdominal obesity in women with PCOS. Both treatment modalities were accompanied by a low caloric dietary regimen for 4 months. The two methods proved to be effective in reconfiguration of anthropometric measurements as well as rebalancing the hormonal defects observed in PCOS cases. Electrolipolysis was more effective in weight reduction and readjustment of local obesity of the abdomen, thigh and gluteal regions.

Using of metformin has been shown to have extensive usage in improvingbothhormonal and metabolic PCOS disturbances (8,18,19). However, to the best of our knowledge, this is the first article comparing electrolipolysis with other treatment modalities of PCOS.

Obesity is well known to be concomitant with,late pregnancy complications (20),pregnancy loss (21) andanovulation (20). Obesity is encountered commonly in PCOS women and it has a link withthedelayed response or failure of response to many treatments modalities including clomiphene citrate (23,24), gonadotrophins (25,26)andlaparoscopic ovarian diathermy (27).

PCOS Consensus Workshop Group (2008) recommended weight reduction to be the first-line management in obese PCOS women seeking pregnancy, on the base of extrapolating the weight loss benefits in other circumstances as cardiovascular and diabetes mellitus diseases, in addition to appreciationof the association between obesity and miserable reproductive outcome **(**28).

Many researches have been clarified that BMI reduction caloric restriction has great benefitsin PCOS women benefit from.Weight loss also can result in ovulation restoration and acanthosisnigricansregression. Possible mechanisms of these benefits may be reduce in insulin-induced gonadotropin release, decrease of the direct influence on the ovary,insulin-like growth factor-binding protein 1 (IGF-BP1) and normalization of serum SHBG levels, and possibly also decrease of leptin concentration. Lower activity of hypothalamus-pituitary-ovary axis may be resulted from he latter effect (29,30).

The treatment of obesity involves diet and exercise therapy in addition to pharmacological treatment and bariatric surgery (31,32).

However, there are no properly designed studies to guide the choice of such interventions in overcoming infertility in women with PCOS. Literature supports the adjuvant use of bariatricsurgery and pharmacological weight loss for the treatment ofobesity in PCOS[28]. Morbidly obese women with PCOS have been found to improve markedly after sustainedweight loss following bariatric surgery (32).

In the current study, we tested the effect of low caloric diet on body mass disturbed hormonal milieu characteristic of PCOS. Electrolipolysis, a method for remobilizing and relocating body fat, with reactivation of inactive cells, was compared with metformin that reduces insulin resistance, diminishes hyperandrogenism and restores the normal secretion of LH and FSH (33-35).

So, the improvements which occur after the application of electrolipolysis could be explained by Stephen, (2004) who found that electrolipolysis current cause splitting of triglycerides into free fatty acids. Triglycerides cannot be excreted through the cell membrane, but free fatty acids can freely pass through the cell wall and out into tissue fluid, to be further transported by lymph vessels.

In addition, Joseph, 1987 reported that when muscle contracts as a result of electrical stimulation, the chemical changes taking place within the muscles are similar to those associated with voluntary contractions in normal exercising muscles utilize glycogen, fat and other nutrients stored in the muscle (36). Also, it enhances energy consumption, carbohydrate oxidation and whole body glucose uptake (37).

Electrolipolysis was proved to be as effective as metformin for weight reduction and restoration of hormonal imbalance. It induced significant reduction of LH levels and, consequently, LH/FSH, the same way as in metformin group. Even, the post-treatment LH/FSH ratio was significantly lower in Electrolipolysis group ($p = 0.001$). It was also effective in reducing insulin resistance.

Hence, electrolipolysis may be an effective adjuvant in managing obese women with PCOS. In addition to improving hormonal imbalance and insulin resistance, electrolipolysis offers the advantage of combating disfigurement commonly encountered in these women due to obesity localized to abdominal and gluteal regions. This may have an enhancing psychological impact in addition.

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تاثير اذابة الدهون كهربيا مقابل الميتفورمين في علاج متلازمة تكيسات المبايض

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المستخلص

لقد اجريت هذه الدراسة لتحديد ايهما أكثر تاثيرا، اذابة الدهون كهربيا ام الميتفورمين في علاج السيدات البدينات اللاتي تعانين من متلازمة تكيسات المبايض. لقدشاركت في هذه الدراسة ثلاثون سيدة بدينة ممن تعانين من متلازمة تكيسات المبايض، تم اختيارهن من مستشفي قصر العيني الجامعي وقد تراوحت اعمارهن بين عشرين وثلاثين عاما، كتلة الجسك الي مربع الطول اكبر من 32 كجم/م2 ، ونسبة دوران الوسط الي محيط الأرداف اكثر من 0.8. وقد تم تقسيم العينه عشوائيا الي مجموعتين متساويتين. تم علاج المريضات في المجموعة (أ) باذابة الدهون كهربيا علي منطقة البطن، الفخذ والاليتين (ثلات جلسات في الاسبوع). أما مريضات المجموعة (ب) فقد تم علاجهن بالميتفورمين (850 مجم مرتين يوميا). استمرت فترة العلاج للمجموعتين لمدة أربعة شهور مع اتباع نظام غذائي 1200 ك كالوري يوميا. وقد تم التقييم لجميع الحالات قبل وبعد أربعة أشهر من العلاج عن طريق قياس الوزن، كتلة الجسم الي مربع الطول، نسبة دوران الوسط الي محيط الأرداف، نسبة الهرمون المحفز للتبويض الي الهرمون المحفز لنمو حويصلة جراف، نسبة السكر الي الانسولين وكذلك حجم البويضة وذلك للمجموعتين (أ و ب). وقد أظهرت نتائج هذه الدراسة عدم وجود فرق ذو دلالة احصائية فيما بين المجموعتين قبل بدء العلاج، بينما أظهرت النتائج نقص ذو دلالة احصائية $p<0.05$) فى الوزن ،كتلة الجسم الي مربع الطول، نسبة دوران الوسط الي محيط الارداف، نسبة الهرمون المحفز للتبويض الي الهرمون المحفز لنمو حويصلة جراف، مستوي السكر و الانسولين في الدم فيما بين المجموعتين، ولكن كان اكثر تأثيرا في المجموعة (أ) ، بينما كان هناك زيادة ذو دلالة احصائية في نسبة السكر والانسولين وكذلك حجم البويضة بالنسبه للمجموعة (أ)، كما اظهرت النتائج عدم وجود فروق ذات دلالة احصائية بالنسبه للهرمون المحفز لنمو حويصلة جراف بين المجموعتين (أ و ب). ايضا كان هناك تحسن في انتظام الدورة الشهرية في المجموعة (أ) اكثر من المجموعة (ب)، وكان هناك حالة واحدة اصبحت حاملا فى المجموعة (أ). ونستخلص من هذه الدراسة أن اذابة الدهون كهربيا أكثر فاعلية عن الميتفورمين في علاج السيدات البدينات اللاتي تعانين من متلازمة تكيسات المبايض.

الكلمات الدالة: السمنة، متلازمة تكيسات المبايض، اذابة الدهون كهربيا، مقاومة الانسولين، الهرمونات الأنثوية لدى السيدات، الميتفورمين.