

## EFFICACY OF MEDICAL TREATMENT IN VARICOCELE PATIENTS PRESENTING WITH OLIGOASTHENOTERATOZOOSPERMIA

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### ABSTRACT

**Background:** Varicocele is the most common cause of male infertility. It affects spermatogenesis by multiple theories; the most recent is by increasing the levels of reactive oxygen species. Medical treatment in the form of tamoxifen, anti-oxidant (Zinc) and MPFF (Micronised purified flavonoid fractions), may improve spermatogenesis and semen parameters in patients with varicocele. **Aim:** show the efficacy of medical treatment on semen parameters and varicocele degree in varicocele patients with oligoasthenoteratozoospermia (OAT). **Patients and methods:** This study included 60 male patients with varicocele and OAT. Clinical and radiological assessment of varicocele and WHO semen analysis have been performed before and 3 months after medical treatment. Patients were treated with Tamoxifen 20 mg / day, Oral Zinc and (Diosmin 450 mg and Hesperidin 50 mg) 3 time / day for 3 months. **Results:** There was a statistically significant increase in sperm concentration, progressive sperm motility, total sperm motility and sperm morphology ( $p = .009, .005, .020, 0.001$ ) after 3 months of treatment. No significant changes in varicocele degree and veins diameter after treatment. **Conclusion:** Medical treatment has a significant beneficial effect on sperm concentration, progressive motility, morphology and total motility. It has no significant effect on decreasing vein diameter of varicocele or presence of reflux.

**Keywords:** Infertility, Oxidative stress, Semen analysis, Varicocele

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### INTRODUCTION

Infertility is a real problem for 10–15% of reproductive age couples (*Gnoth et al., 2005*). It can be caused by female factor, male factors or both. Male factor infertility is responsible for about 50% of infertility cases (*Brugh et al., 2004; Witt et al., 1993*). Causes of male infertility are multiple; the most common of which are varicocele, hormonal, genetic and environmental factors (*Abdel-Raheem et al., 2012*).

Varicocele is defined as dilatation of the pampiniform plexus of veins. About 10–15% of normal males have varicocele. This increases to 30–40% in men with primary infertility, and the percentage increases further to reach up to 80% in patients with secondary infertility (*Witt et al., 1993; Kamal et al., 2001*).

Varicocele is classified into three grades: grade I, palpable only during a valsalva maneuver; grade II, palpable distension with the

patient standing upright; and grade III, visible distension (*Jarow, 2001*). Clinically undetectable varicocele are diagnosed only by investigations such as color doppler ultrasonography, venography or plethysmography (*French et al., 2008; Gat et al., 2004*).

The mechanism by which varicocele affects spermatogenesis and sperm parameters is still not completely understood. Many theories have been proposed to explain this effect. One theory stated that varicocele increases the scrotal temperature, which negatively affects spermatogenesis. It was found that the decrease in scrotal temperature following varicocele ligation supports this theory (*Sofikitis and Miyagawa, 1994; Sofikitis et al., 1992*). Another theory suggested that varicocele causes testicular hypoxia, which may cause impairment in spermatogenesis in patients with varicocele (*Gat et al., 2005*). The most theory, which is

widely accepted, hypothesizes that varicocele increases the level of reactive oxygen species (ROS). This increase may reach critical levels that cause oxidative stress (OS). Previous studies have shown that infertile men with varicocele have markedly elevated levels of seminal ROS (*Hendin et al., 1999; Pasqualotto et al., 2008*).

There is growing interest in OS as one of the underlying causes for deterioration of semen parameters in infertile men with varicocele, especially sperm DNA damage. OS was found to have many pathological effects on spermatozoa; the most important are DNA fragmentation, sperm lipid peroxidation, mitochondrial anomalies and apoptosis (*El Taieb et al., 2013*).

There is evidence that clinical varicocele has variable negative effects on semen parameters including decreased sperm concentration, sperm motility and normal sperm morphology. These findings may present single or all together, which is known as oligoasthenoteratozoospermia (OAT) or stress pattern (*Gat et al., 2004; Sofikitis and Miyagawa, 1994; Gat et al., 2003*).

Varicocele treatment is mainly surgical. There are many surgical maneuvers, The three most common approaches are inguinal (groin), retroperitoneal (abdominal), and infra-inguinal/sub-inguinal (below the groin). Gat-Goren nonsurgical method for treating varicoceles is performed under local anaesthesia (*Hsu et al., 2005*).

Empirical medical treatment including hormonal therapy and antioxidant drugs is known to improve semen parameters in OAT patients. Oral administration of the antioxidant vitamins C, D, Zinc and E reduces the sperm DNA damage attributable to ROS and has improved sperm function and conception rates in vivo in men with varicoceles (*Agarwal et al., 2009*).

Micronised purified flavonoid fractions (MPFF), which consists of 90% micronised diosmin (a flavone derivatives) and 10% flavonoids expressed as hespreidin (a flavone derivatives), is an oral phlebotropic drug which improves venous tone and elasticity and decrease venous distensibility and venous emptying times in patient with venous insufficiency (*Struckmann, 1999*).

The present study aims to show the efficacy of medical treatment for OAT in patients with varicocele as regard to semen parameters and vein diameters and varicocele

reflux.

## PATIENTS AND METHODS

### Patients:

This is a cross-sectional study performed on patients with varicocele attending the Department of Dermatology, Venereology, and Andrology, South Valley University Hospital, Egypt, in the period from July 2014 to May 2015. The study included 60 male patients with ages ranging from 19 to 40 years. All patients had clinically palpable and ultrasound proved varicocele and semen analysis had shown OAT.

### Methods:

Complete history taking and general examination of each patient has been performed to exclude other causes of male infertility. A genital examination has been performed to exclude genital anomalies and to detect varicocele. Examination of the scrotal neck for varicocele was done in supine and upright positions using valsalva's maneuver. According to **Dubin and Amelar** classification (*Jarow, 2001*), varicocele classified clinically into three grades; Grade I: Varicocele felt only with Valsalva's maneuver, Grade II: Varicocele felt without Valsalva's maneuver, Grade III: Varicocele felt and seen through the scrotum. Semen analysis was performed according to WHO guidelines (*WHO, 2010*) before and three months after treatment. Scrotal color duplex ultrasonography was done before and three months after treatment to evaluate diameter of the right and left internal spermatic veins, right and left refluxes (if present) and to detect subclinical varicocele. the diagnosis of a varicocele with scrotal sonography include standard measurement of venous diameter and color flow Doppler study which allows determining the direction and magnitude of venous blood flow.

### Treatment:

All patients had to be treated by Tamoxifen 20 mg / day, Oral Zinc and (Diosmin 450 mg and Hesperidin 50 mg ) 3 time / day for 3 months.

### Follow up:

All patients had followed up 3 months after treatment by scrotal doppler ultrasonography and semen analysis.

### Ethical considerations:

This study received approval from the Medical School Ethics Committee of the Faculty of Medicine, South Valley University. A signed written consent was obtained from each participant before obtaining the sample.

Confidentiality was assured for all participants.

### Statistical Methodology:

Analysis of data was done by using SPSS (statistical program for social science version 20) as follows; Description of quantitative variables as mean, SD and range, Description of qualitative variables as number and percentage, Chi- square test was used to compare qualitative

variables between groups, Fisher exact test was used instead of chi-square test when one expected cell less than or equal 5 and Unpaired t-test was used to compare quantitative variables, in parametric data ( $SD < 50\%$  mean). Significance was considered with a P value  $< 0.05$ .

## RESULTS

This study was performed on 60 infertile patients to evaluate the efficacy of medical treatment for Oligoasthenoteratozoospermia in patients with varicocele. The mean ages for all patients were  $(31.00 \pm 6.180)$  ranged between 22 and 43 years (table 1). All patients had clinically palpable and ultrasound proved varicocele and semen analysis had shown OAT.

Mean values of left and right vein diameter before treatment were  $(3.013 \pm 0.8050)$ ,  $(2.507 \pm 0.5356)$  respectively. After treatment these parameters altered to  $(2.940 \pm 0.7650)$ ,  $(2.443 \pm 0.5117)$  for left and right vein diameter respectively. There was no a statistically significant decrease in left and right vein diameter after treatment ( $p = .771, 0.641$ ) (table 2).

The presence of reflux before and after treatment was  $(1.23 \pm 0.430)$  and  $(1.23 \pm 0.430)$  respectively. There was no statistically significant association between treatment and Presence of reflux ( $p = 1.000$ ) (table 2).

The mean value of sperm concentration before treatment was  $(10.27 \pm 6.214)$  and after

treatment increased to  $(36.0 \pm 33.574)$ . There was a statistically significant positive association between treatment and sperm concentration ( $p = .009$ ) (table 2).

The mean value of progressive sperm motility before and after treatment was  $(20.63 \pm 14.580)$  and  $(41.10 \pm 8.872)$  respectively. There was a statistically significant improvement of progressive sperm motility after treatment ( $p = 0.005$ ) (table 2).

The mean value of sperm morphology before and after treatment was  $(3.40 \pm 3.7)$  and  $(8.04 \pm 4.3)$  respectively. There was a statistically significant association between treatment and improvement in sperm morphology ( $p = 0.001$ ) (table 2).

There was a significant association between presence of reflux, sperm concentration ( $p$  value = 0.05) and progressive motility ( $p$  value = 0.04) (Table 3).

There was a high significant association between left vein diameter, sperm concentration per ml (in millions) ( $p = 0.001$ ) and progressive motility percentage ( $p = 0.001$ ) (table 4).

**Table (1): Descriptive statistics of the patient's age:**

Age	Statistic
Mean	31.87
Median	31.00
Minimum	22
Maximum	43
Range	21
Std. Deviation	6.180

**Table (2): Diameter of right and left vein, presence of reflux, sperm concentration, progressive motility, total motility and sperm morphology before and after treatment:**

	Before treatment	After treatment	P value
	Mean± SD	Mean± SD	
Right vein diameter (in millimeter)	2.507±.5356	2.443±.5117	.641 NS
Left vein diameter (in millimeter)	3.013±.8050	2.940±.7650	.771 NS
Presence of reflux	1.23±.430	1.23±.430	1.000 NS
Concentration per ml	10.27±6.214	36.20±33.574	.009 HS
Progressive motility (percentage)	20.63±14.580	41.10±8.872	.005 HS
Total motility (percentage)	35.70±14.704	57.13±10.013	.020 S
Sperm Morphology (percentage)	3.40±3.7	8.04±4.3	0.001 HS

*HS: Highly Significant, S: Significant, NS: NonSignificant*

**Table (3) Presence of reflux, sperm concentration per ml (in millions) and progressive motility.**

	Presence of reflux	Mean	Std. Deviation	P value
Concentration per ml	non refluxing	23.39	28.789±4.2	0.05 S
	Refluxing	22.71	22.523±6.02	
Progressive motility	non refluxing	28.89	16.631 ±2.4	0.04 S
	Refluxing	37.36	10.796±2.8	

*S: Significant*

**Table (4) Left Vein Diameter, sperm concentration per ml (in millions) & progressive motility (percentage):**

	Mean	Std. Deviation	T value	P value
lt vein diameter - Concentration per ml	-20.2567	27.3194±3.5	-5.743-	.0001 HS
lt vein diameter - Progressive motility	-27.8900	15.6736±2.02	-13.783-	.0001 HS

*HS: Highly Significant*

## DISCUSSION

Varicocele is one of the most common causes of male infertility and it is well established that it has negative effects on spermatogenesis and sperm parameters in infertile patients (*Shiraishi et al., 2012*). The most acceptable theory explains these negative effects is OS resulting from excessive accumulation of ROS (*El Taieb et al., 2013*). Excessive ROS concentrations have been detected in about 25-40% of semen samples of infertile patients (*Walczak et al., 2013*).

Oxidative stress increases with the increase in varicocele grade and the resulting DNA sperm damage (*Shiraishi et al., 2012; Venkatesh et al., 2009; Cocuzza et al., 2008*).

In many cases of iOAT, high level of ROS may be produced and negatively affect sperm functions in the absence of detectable causes. Increased ROS levels to the limit that exceed the antioxidant mechanisms will produce OS (*Agarwal et al., 2012; Rowe et al., 2000*).

This study evaluated the efficacy of medical treatment on OAT and vein diameter and reflux in patients with varicocele. It was done on 60 infertile males with clinically and ultrasound proved varicocele associated with infertility and semen analysis had shown OAT. All patients had been treated by Tamoxifen 20 mg / day, Oral Zinc and (Diosmin 450 mg and Hesperidin 50 mg) 3 time / day for 3 months.

Our results showed that there is a statistically significant increase concentration, progressive motility, normal morphology and total motility after treatment for 3 months. Otherwise, our results showed no statistically significant decrease in right and left vein diameters by mm and presence of reflux after treatment for 3 months.

Tamoxifen citrate was proposed by WHO working committee as the first line of treatment for idiopathic oligozoospermia (*Rowe et al., 2000*). *Chua et al., 2013* reported that estrogen antagonists as empirical medical therapy for idiopathic male infertility may increase spontaneous pregnancy rate, improve sperm concentration and % sperm motility. While a significant increase in serum FSH and testosterone is associated with the treatment (*Chua et al., 2013*).

There is now a little doubt regarding the efficacy of antioxidants on sperm quality and function which represent a promising treatment approach that should be attempted together with the identification and treatment of the

underlying Causes (*Walczak et al., 2013; Turner and Lysiak, 2008*). Seminal plasma normally contains many antioxidants such as superoxide dismutase, catalase, and glutathione peroxidase, glutathione reductase in addition to non-enzymatic antioxidants such as ascorbate, urate, vitamin E, Zinc, pyruvate, glutathione, albumin, vitamin A, ubiquinol, taurine, and hypotaurine. These antioxidants protect healthy spermatozoa from ROS produced by abnormal spermatozoa, scavenge ROS produced by leukocytes, prevent DNA fragmentation, and improve semen quality in smokers and varicocele patients. They also reduce cryodamage to spermatozoa, block premature sperm maturation and stimulate spermatozoa and improve ART outcome (*Walczak et al., 2013; Twigg et al., 2000*).

Many studies have demonstrated that MPFF has antioxidant activities in many tissues and suppresses tissue MDA levels to their normal baseline values (*Tirkey et al., 2005; Hwang and Yen, 2008*).

Good tolerance and the efficacy of MPFF in the treatment of CVI encouraged researchers to try it in the management of varicocele (*Kilic et al., 2005*). MPFF is effective in reducing edema, pain, and heaviness especially in mild and moderate cases of CVI (*Dogan et al., 2014*).

The first study on the MPFF with painful varicocele was done by *Kilic et al.*, in 2005, but it was pilot non-controlled study. The result of this study showed that MPFF is a safe and effective drug for treating varicocele-associated pain medically, at least within treatment period, and in improving semen analysis and color Doppler parameters (*Kilic et al., 2005*).

Favorable effects of MPFF on the regression of testicular damage secondary to varicocele have been observed by Armagan et al., by histopathological examination of testes of rats with induced varicocele (*Armagan et al., 2012*). Dogan et al., found that diosmin decreased levels of OS and increased levels of matrix metallo-proteinase-2 (MMP-2), matrix metalloproteinase-9 (MMP-9) and matrix metalloproteinase inhibitor-1 (TIMP-1) in the testis of rats with induced varicocele (*Dogan et al., 2014*).

Conceding with the previous studies, we found improvement in spermatogenesis and sperm parameters and non-significant changes in varicocele diameter and reflux. This could be explained by the efficacy of both MPFF and

tamoxifen on seminal levels of ROS produced by varicocele. Further studies needed to evaluate the efficacy of MPFF on varicocele parameters.

### CONCLUSION

Our study concluded that MPFF in combination with zinc and tamoxifen can be used in the treatment of varicocele patients with OAT. Further studies with a larger sample number and controls are needed to support our results.

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فعالية العلاج الطبي لمرضى دوالي الخصية الذين يعانون من نقص وضعف حركة وتشوه الحيوانات المنوية  
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#### المقدمة :

الدوالي مرض يصيب أوردة الخصية يؤدي هذا المرض إلى اتساع الأوردة و ركود الدم بها، محملاً بالمخلفات و النفايات التي تضر الخصية. من هذه النفايات ثاني أكسيد الكربون، الحرارة، و غيرهما. و في الدرجات الأعلى من الدوالي، يرتجع الدم في اتجاه عكسي من أعلي إلى أسفل، محملاً بهرمون الأدرينالين لقابض للشرابين، مما يؤدي إلى انخفاض تدفق الدم المحمل بالأكسجين و الغذاء إلى الخصية. تلك هي الكيفية التي تؤدي الدوالي بها إلى العقم.

في حال الإصابة بدوالي الخصية، يبدأ الضرر بتهيج الخصية، فتنتج عدداً من الحيوانات المنوية أعلى بكثير من المعتاد، ثم يبدأ عدد الحيوانات المنوية و حركتها في الانخفاض إلى ما تحت المستوي الطبيعي، و تكثر التشوهات و يقل حجم الخصية و تقل صلابتها، انتهاءً بضمور الخصية (التلف الكامل). و ليس من الضروري أن يكون هذا الأمر مصحوباً بالألم أو أعراض معينة، بل يمكن أن تضر الدوالي بالخصية في الخفاء.

تتكون الدوالي على الناحية اليسرى غالباً، و في بعض الأحيان على الناحيتين اليمنى و اليسرى، و نادراً ما تكون دوالي الخصية على الناحية اليمنى فحسب. زيادة حدوث دوالي الخصية على الناحية اليسرى يعود إلى أسباب عدة، منها كون الوريد الأيسر رأسي، مما يجعل محتواه من الدم المساعد إلى أعلى أثقل و حركته أبطأ بفعل الجاذبية الأرضية إذا كان الشخص واقفاً. الدم بطئ الحركة يتراكم و يساعد على اتساع الوريد و تكون الدوالي. أسباب تكون دوالي الخصية أياً كانت الناحية: السبب غير معروف، لكن توجد نظريات مختلفة حول السبب، منها العامل الوراثي المؤدي إلى ضعف جدران الأوعية الدموية المكونة من مادة الكولاجين. و يكون الخلل في هذه المادة: ضعف الجدار يؤدي إلى اتساع الوريد بفعل محتواه من الدم. يستثنى من ذلك الدوالي التي تحدث على الناحية اليمنى دون اليسرى، و تكون غالباً نتيجة جسم ضاغط في البطن، يضغط على الأوردة و يمنع صعود الدم فيها. أعراض دوالي الخصية :-

كثيراً ما تكون الدوالي بلا أعراض، و تُكتشف بعد حدوث الضرر و تأثر الخصية، و تكون الشكوى في هذه الحالة هي العقم. في بعض حالات الدوالي كبيرة الحجم، يشتكي المريض من ألم في الخصية، و بخاصة مع الوقوف المستمر و المشي لمسافات طويلة. إلا أن حدوث الألم ه و الاستثناء، و ليس القاعدة. و هنا تكمن أهمية فحوصات ما قبل الزواج، التي تكشف وجود المرض حتي إن كان بلا أعراض

تهدف هذه الدراسة إلى إظهار فعالية العلاج الطبي التحفظي لعلاج مريض دوالي الخصية وتقييمها بواسطة:-

- دلالات السائل المنوي (عدد الحيوانات المنوية، الحركة والنسبة المئوية للأشكال الحيوانات المنوية غير الطبيعية ) .

- الاشعة التلفزيونية فوق الصوتية على الخصية .

#### المرضى وطرق البحث :

سوف يتم إجراء البحث على مرضى دوالي الخصية الذين يعانون من نقص وضعف حركة وتشوه الحيوانات المنوية بعد الحصول على موافقة مكتوبة مبنية على المعرفة من هؤلاء المرضى المترددين على عيادات التناسلية بقسم الجلدية والتناسلية وطب الذكورة بمستشفى قنا الجامعي سيتم اخذ التاريخ المرضي ، اي أمراض مصاحبة ، اي أدوية أخرى، والتاريخ الجنسي من كل الحالات بالإضافة إلى إجراء تحليل سائل منوي واشعة تلفزيونية فوق صوتية على الخصية في كل المرضى. سوف يتم تقييم المرضى قبل بدأ العلاج وبعد ثلاثة اشهر من بداية العلاج ومتابعتها بتحليل السائل المنوي والاشعة التلفزيونية فوق الصوتية على الخصية.

#### نتائج البحث:

١ - يوجد اختلاف ذو دلالة إحصائية في عدد وحركة وشكل الحيوانات المنوية بعد العلاج لمدة ثلاثة اشهر.

٢- وأيضاً لوحظ عدم تغير في حجم أوردة الخصية وارتجاع الدم الوريدي في أوردة الخصية وذلك بعد مرور ثلاثة اشهر من العلاج