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DIOSMIN VERSUS CABERGOLINE FOR PREVENTION OF OVARIAN HYPERESTIMULATION IN ICSI

By

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ABSTRACT

Background: Ovarian hyperstimulation syndrome is the most serious iatrogenic complication of ovarian stimulation, usually self-limited, but occasionally life threatening. Although the pathophysiology of this syndrome has not been completely elucidated, the underlying mechanism responsible for the clinical manifestations of OHSS appears to be an increase in capillary permeability of mesothelial surfaces. Many preventive strategies have been tried but there is as yet no means of completely preventing it.

Objective: To prevent ovarian hyperstimulation syndrome (OHSS) in high risk patients undergoing intracytoplasmic sperm injection (ICSI) cycles by using diosmin and cabergoline.

Patients and Methods: This study was conducted on 100 infertile female patients of high risk for developing OHSS undergoing intra-cytoplasmic sperm injection (ICSI) cycle.The cases were then be divided into2 groups:(Group A will be given 2 tab (500mg)/8hs diosmin orally, for two weeks starting at the day of HCG injections and group B will recieve 1 tab. (0.5 mg)/day cabergoline orally for 14 days starting at day of HCG injection). All patients accepted and consented to the IVF/ICSI program Group.

Results: Our results revealed that: there were no statistical significant differences between the two studied groups regarding BMI, patients' age, infertility duration, type and cause of infertility. Estradiol levels on day of HCG showed no statistical significant difference between the 2 groups with a mean of 4343.5 ± 628.53 and 4390.6 ± 724.9 for diosmin and cabergoline groups respectively. Among the two studied groups, there was no statistical significant difference between the mean of the number of oocytes retrieved and injected. Also there was no statistical significance as regards total number of embryos or embryos transferred between the two groups. In our study, hospitalisation rate showed no significant difference in diosmin and cabergoline-treated groups (6%, 12% respectively).

Conclusion: The primary approach in the prevention of OHSS involved individualized ovarian stimulation protocols, judicious administration of gonadotropins, and careful monitoring of follicular development and serum E2 level. Using dopamine agonists of the strategies discussed, the incidence of OHSS can be significantly reduced. However, none of the strategies is universally successful.

Keywords: Diosmin, Cabergoline, Ovarian Hyperestimulation and ICSI.

INTRODUCTION

Ovarian hyperstimulation syndrome (OHSS) is the most serious iatrogenic complication of controlled ovarian stimulation (COS), which can vary from mild illness to severe, potentially life-threatening disease. The syndrome almost always occurs a few days after receiving human chorionic gonadotropin (HCG)

(early OHSS), or later (late OHSS) in case of pregnancy *(Orvieto, 2013)*.

Although OHSS may occasionally occur spontaneously between eight and twelve weeks of pregnancy or with a follicle-stimulating hormone (FSH) producing pituitary adenoma, the great majority of cases are iatrogenic due to ovulation induction in women undergoing assisted reproductive techniques (ART) *(Dey et al., 2015)*.

OHSS is a potentially fatal systemic disorder, characterized by ovarian enlargement due to multiple follicular, theca lutein ovarian cysts and an acute fluid shift into the extravascular space due to increased capillary permeability, complicated with ascites, pleural effusion, hemoconcentration, hypovolemia, electrolyte imbalance, and thrombo-embolic manifestations *(Lainas et al., 2019)*.

OHSS has a broad spectrum of clinical manifestations, most cases are mild but a small proportion is severe. OHSS is a self-limiting disorder that usually resolves spontaneously within several days, but may persist for longer duration, particularly in conception cycles. However, the duration does not exceed the first trimester *(Chin et al., 2019)*.

The present work aimed to determine the efficacy of Diosmin in comparison to Cabergoline in preventing OHSS in high-risk women undergoing IVF.

PATIENTS AND METHODS

One hundred high risk patients after meeting these inclusion criteria, attending Ahmed Maher Teaching Hospital Infertility Clinic, were recruited for this study during the period from May 2019 to November 2020.

A sample size of 100 cases was randomly divided into 2 equal groups: Group A was given 2 tablets (500mg)/8hs of Diosmin orally for two weeks starting at the day of HCG injections, and group B received one tablet (0.5 mg)/day of Cabergoline orally for 14 days starting at day of HCG injection.

All patients accepted and consented to the IVF/ICSI program and signed informed consents to be enrolled in the study.

Randomization was done on the day HCG administration using computer generated method.

Inclusion criteria: AGE less than 35 years old, previous episodes of OHSS, polycystic ovaries, high AMH (more than 3.0 ng/ml), large number of small follicles (8-12mm) seen on ultrasound during ovarian stimulation, high serum estrogen 2 at hcg trigger (E2 more than 3000pg/ml), presence of more than 20 follicles by ultrasound on day of retrieval or large number of oocytes retrieved.

Exclusion criteria: Low antimullarian hormone level and low number of follicles on day of retrieval.

The cases were subjected to the following: Detailed history taking, clinical examination including general and gynecological examination to confirm the criteria of selection into the study.

Laboratory investigations: Estradiol (E2), prolactin (PRL), Thyroid Stimulating Hormone (TSH), Antimullerian Hormone (AMH).

Pelvic ultrasound using transvaginal probe was made to assess uterine size, shape and endometrial thickness is screening had been initiated at any time point during the COH cycle, but the last checks for eligibility were made on the day of HCG administration (day of randomization), Treatment consisted of Diosmin 2 tab (500 mg) for first group and Cabergoline (0.5 mg tablets) for second group were taken orally once daily for 14 days. Evaluation of early OHSS signs/symptoms was performed on the day of OR, Day 2, Day 5, Day 7 and Day 10. Transvaginal ultrasound was applied to measure pelvic fluid pockets, body measurements, and blood samples were taken at each visit. All individual signs/symptoms of OHSS were assessed, and OHSS was classified as mild or severe using Golan's classification system with certain modifications and specifications.

The primary end-point was the percentage of subjects with a mild /severe early OHSS (onset 9 days or less after HCG administration). In addition to the primary end-point, treatment comparisons were also made for secondary trial end-points which included clinical pregnancy rate. Clinical pregnancy was defined as at least one intrauterine gestational sac with fetal heart beat documented by transvaginal ultrasound about 5 weeks after embryo transfer.

Statistical analysis: Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. Significance of the obtained results was judged at the 5% level.

Chi-square test was for categorical variables, to compare between different groups. Fisher's Exact or Monte Carlo correction and Chi-square when more than 20% of the cells have expected count less than 5. Student t-test was for distributed quantitative variables to compare between two studied groups, and Mann Whitney test was for abnormally distributed quantitative variables to compare between two studied groups.

RESULTS

There was no statically significant difference between the two groups (Table 1).

Table (1): The socio-demographic parameters of the entire study population

Groups / Patients	Group I (n = 50)	Group II (n = 50)	p
Patient age (years)			
Min. – Max.	20.0 – 36.0	18.0 – 36.0	0.751
Mean ± SD.	28.70 ± 4.69	28.40 ± 4.74	
Median	29.50	29.0	
Husband age (years)			
Min. – Max.	24.0 – 50.0	23.0 – 65.0	0.846
Mean ± SD.	35.86 ± 6.01	35.60 ± 7.28	
Median	34.50	34.50	
BMI (kg/m^2)			
Min. – Max.	18.0 – 29.0	19.0 – 28.0	0.821
Mean ± SD.	23.36 ± 2.57	23.48 ± 2.73	
Median	23.0	23.0	

Group I: diosmin 500 mg daily from day of HCG for 14 days, Group II: Cabergoline 0.5 mg daily from day of HCG for 14 days.

There was no statistical significant difference between the study groups according to E2 on HCG day **(Table 2)**.

Table (2): Comparison between the two studied groups according to estradiol (E2) on HCG day

Groups / Estradiol on HCG (day)	Group I (n = 50)	Group II (n = 50)	P
Min. – Max.	3581.0 - 6120.0	3300.0 - 6100.0	0.719
Mean ± SD.	4343.5 ± 628.53	4390.6 ± 724.9	
Median	4164.0	4243.5	

Group I: Diosmin 500 mg daily from day of HCG for 14 days, Group II: Cabergoline 0.5 mg daily from day of HCG for 14 days.

There was no statistical significant difference between the mean of the number of oocytes retrieved between the two groups, also the difference between the mean of the number of oocytes injected was not statically significant **(Table 3)**.

Table (3): Number of oocytes (Retrieved and Injected) among the two studied groups

Groups / No. of oocytes	Group I (n = 50)	Group II (n = 50)	P
Retrieved	**952**	**920**	
Min. – Max.	11.0 – 28.0	10.0 – 39.0	0.280
Mean ± SD.	19.04 ± 4.49	18.40 ± 5.19	
Median	18.0	17.50	
Injected	**662**	**716**	
Min. – Max.	9.0 – 21.0	8.0 – 34.0	0.737
Mean ± SD.	13.24 ± 2.89	14.20 ± 5.36	
Median	13.0	13.0	

Group I: diosmin 500 mg daily from day of HCG for 14 days, Group II:Cabergoline 0.5 mg daily from day of HCG for 14 days.

In both groups, the total number of embryos and number of embryos transferred were not statistically significant **(Table 4)**.

Table (4): Total number of embryos and transferred embryos

Groups / Patients	Group I	Group II	P
Total no. of embryos	**348**	**388**	
Min. – Max.	1.0 – 11.0	1.0 – 22.0	0.833
Mean ± SD.	6.99 ± 2.56	7.76 ± 4.65	
Median	7.0	7.0	
No. of embryos transferred	**143/348 (41.1%)**	**144/388 (37.1%)**	0.269
Min. – Max.	1.0 - 4.0	1.0 – 4.0	0.841
Mean ± SD.	2.86 ± 0.88	2.88 ± 0.85	
Median	3.0	3.0	

Group I: diosmin 500 mg daily from day of HCG for 14 days, Group II: Cabergoline 0.5 mg daily from day of HCG for 14 days.

There was no statically significant difference between the two groups. In group I, 11 cases suffered from OHSS (22% of case) mild 10%, moderate 8%, severe 4% of these cases 3 cases were hospitalized. In group II, 17 cases suffered from OHSS (34% of cases) distributed as follows: mild 18%, moderate 12%, severe 2% critical 2%, of these cases 6 cases were hospitalized **(Table 5)**.

Table (5): Ovarian Hyperstimulation Syndrome (OHSS)

Groups / Patients	Group I (n = 50)		Group II (n = 50)		P
	No.	%	No.	%	
Early OHSS					
No	39	78.0	33	66.0	$MC_{p=}$ 0.528
Total OHSS	11	22.0	17	34.0	
Mild	5	10.0	9	18.0	
Moderate	4	8.0	6	12.0	
Severe	2	4.0	1	2.0	
Critical	0	0.0	1	2.0	
Hospitalization					
No	47	94.0	44	88.0	$FE_{p=}$ 0.487
Yes	3	6.0	6	12.0	

Group I: diosmin 500 mg daily from day of HCG for 14 days, Group II:Cabergoline 0.5 mg daily from day of HCG for 14 days.

In group I, clinical pregnancy occurred in (46%) of the cases (n= 23), while in group II clinical pregnancy occurred in (40%) of cases (n= 20). This means that clinical pregnancy rate of both groups showed no statically significance **(Table 6)**.

Table (6): Clinical Pregnancy Rate

Groups / Patients	Group I		Group II		P
	No.	%	No.	%	
Clinical pregnancy	23	46.0	20	40.0	0.545

Group I: diosmin 500 mg daily from day of HCG for 14 d ays, Group II:Cabergoline 0.5 mg daily from day of HCG for 14 days

There was no statistically significant difference between the two groups regarding the other side effects. None of the patients in either group dropped out of the study or discontinued medication among who reported side effects **(Table 7)**.

Table (7): Comparison between the two studied groups according to side effects

Groups / Patients	Group I (n = 50)		Group II (n = 50)		P
	No.	%	No.	%	
Side Effects					
Negative	21	42.0	24	48.0	0.546
Positive	**29**	**58.0**	**26**	**52.0**	
Nausea	24	82.8	13	50.0	0.023
Vomiting	22	75.9	11	42.3	0.19
Diarrhea	6	20.7	8	30.8	0.564
Abdominal Pain	11	37.9	10	38.5	0.806
Headache	3	10.3	4	15.4	0.436
Syncope	2	6.9	2	7.7	$^{FE}p=1.000$

Group I: diosmin 500 mg daily from day of HCG for 14 days, Group II:Cabergoline 0.5 mg daily from day of HCG for 14 day.

DISCUSSION

OHSS is a life-threatening complication induced by ART which is more frequently observed when a strong ovarian response occurs.This strong ovarian response is characterized by development of several ovarian follicles and high levels of serum estradiol *(Busso et al., 2010).*

OHSS is regarded as an iatrogenic complication which should be avoided, and in case of occurrence its severity must be reduced. Considering the physical and psychological consequences along with medical costs like hospitalization, every intervention to decrease OHSS would be valuable *(Mourad et al., 2017).*

In this prospective randomized study, 100 patients undergoing IVF/ICSI treatment considered to be at risk of OHSS were randomized to receive either 0.5mg Cabergoline (50 patients) or Diosmin 2 tab 5oo mg/8 hrs (50 patients) daily for 14 days starting on the day of hCG injection in an attempt to prevent the development of this potentially life-threatening condition.

Dose of Cabergoline, used in our study was based on a previously published study by *Baumgarten et al. (2013)* who found that 0.5mg cabergoline daily for 8 days could help reduce the incidence and severity of OHSS, whereas *Zhu et al. (2017)* found that Diosmin (1000mg) was prescribed twice a day for a period of 10 days orally can effectively prevent OHSS and reduce the incidence and severity of moderate to severe OHSS.

In contrast to our study, *Saad and Mohamed (2017)* found that prophylactic administration of Cabergoline and Diosmin, is associated with a significant decrease in incidence of signs and symptoms related to moderate or severe OHSS but Diosmin was more effective in preventing severe OHSS and decreasing OHSS occurrence rates than Cabergoline when used in high-risk patients.

The present study showed that BMI, patients' age, infertility duration, type and cause of infertility, PCOS, estradiol level, number of oocytes retrieved and injected were similar between the two groups. In spite of the small sample size, the present study has the advantages similarity of basal or background characteristics, cycle stimulation characteristics and minimal selection bias all of which make the study reliable for future practical and clinical purposes.

The main driving force for our search was for a better agent for a higher level of prevention to reach an OHSS-free ICSI/IVF cycles. *Saad and Mohamed (2017)* found that Diosmin was used for the treatment of varicose veins extensively and in our field were used in mastodynia, PMS, preterm labour management, pelvic pain in pelvic congestion syndrome and internal hemorrhoids of pregnancy.

Neither embryo toxicity, nor any significant effects on reproductive function were reported on the use of Diosmin in pregnancy and the transplacental migration and passage into breast milk are minimal *(Shelygin et al., 2016).* So, we used it with an accepted safety profile.

Concerning the pathogenesis and pathophysiology of OHSS, *Bush et al. (2017)* demonstrated a significant decrease in plasma VEGF (the main player in the development of OHSS) in

patients with chronic venous disease treated with oral diosmin for 60 days.

Urios et al. (2014) demonstrated correction of hypoalbuminemia and decrease of urinary albumin clearance in diabetic rats which is one of the most important cascades of events causing the wide morbidity in OHSS. *Tanrikulu et al. (2013)* proved the protective effect of diosmin on hepatic ischemia reperfusion injury. So, both studies are proving a role of diosmin in preventing the complications of OHSS.

Youssef et al. (2010) conducted a meta-analysis to answer the question about the success of dopamine agonist in the treatment of OHSS, and a statistically significant reduction in the incidence of OHSS in the Cabergoline group (with an absolute risk reduction of 12%, but there was no statistically significant evidence of a reduction in severe OHSS.

There was no evidence for a difference in clinical pregnancy rate and miscarriage rate. They concluded that although Cabergoline block the onset of early stage OHSS in 50% of women, it was not effective in preventing the late onset form *(Youssef et al., 2010)*. This was comparable to our results, but all the studies involved were versus no treatment or placebo.

The last Cochrane review by *Tang et al. (2012)* evaluated three types of dopamine agonists: Cabergoline, Quinagolide and Bromocriptine. When compared with placebo or no intervention, dopamine agonists seemed effective in the prevention of moderateor severe OHSS (moderate quality evidence). The use of dopamine agonists lowered the incidence of OHSS to 7–14% of women. When they compared dopamine agonist plusco-intervention (hydroxyethyl starch or albumin), there was no evidence of a difference in outcomes of moderate or severe OHSS, live birth rate, clinical pregnancy rate, miscarriage rate or adverse events between dopamine agonist alone or with the cointervention.

There was no evidence of a difference in OHSS rates between Cabergoline and other lines (e.g. hydroxyethyl starch, prednisolone or coasting) with holding anymore ovarian stimulation for a few days. But coasting had a lower pregnancy rate than Cabergoline.

There was a substantial body of literature systematic review *(Youssef et al., 2010)*, and a Cochrane Systematic review *(Tang et al., 2012)* that support the role of prophylactic cabergoline in the prevention of OHSS; thus, we used the Cabergoline group as the reference by which to compare the efficacy of Diosmin. Besides, we also didn't include placebo group for ethical issues for not leaving high risk patients without prevention against OHSS.

CONCLUSION

Diosmin seemed to be just as effective as Cabergoline in the prevention of OHSS with the advantage of being substantially cheaper in the Egyptian market, not carrying a risk of cardiac valve fibrosis and having a shorter half-life, thus avoiding any potential risk on organogenesis.

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مقارنة بين عقار الديوسمين والكابرجولين في منع حدوث متلازمة التحفيز الزائد للمبايض في حالات الحقن المجهري

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خلفيـــة البحـــث: تعـــد متلازمـــة فـــرط تنبيـــه المبـــيض أخطـــر مضـــاعفات علاجيـــة المنشـــأ لتحفيـــز المبـــيض، وعـــادة مـــا تكـــون محـــدودة ذاتيًـــا، ولكنهـــا تهـــدد الحيـــاة أحيانًـــا. علـــى الـــرغم مـــن أن الفيزيولوجيـــا المرضـــية لهـــذه المتلازمـــة لـــم يـــتم توضـــيحها بالكامـــل، يبـــدو أن الآليـــة الأساســـية المســـؤولة عـــن المظـــاهر الســـريرية لـــمتلازمة التحفيـــز الزائـــد للمبـــيض هـــي زيـــادة فـــي نفاذيـــة الشـــعيرات الدمويـــة للأســـطح الظهاريـــة. تمـــت تجربـــة العديـــد مـــن الاســـتراتيجيات الوقائيـــة ولكـــن لا توجـــد حتـــى الآن وسيلة لمنعها تمامًا.

الهـــدف مـــن البحـــث: للوقايـــة مـــن متلازمـــة فـــرط تنبيـــه المبـــيض (OHSS) فـــي المرضـــى المعرضـــين للخطـــر والـــذين يخضـــعون لاخصاب المساعد باستخدام ديوسمين وكابيرجولين.

المريضـــات وطـــرق البحـــث: أجريـــت هـــذه الدراســـة علـــى 100 مريضـــة مصـــابات بـــالعقم معرضـــة لخطـــر الإصـــابة بمتلازمـــة التحفيـــز الذائـــد للمبـــيض خـــلال دورة الاخصـــاب المســـاعد. وقـــد تـــم تقســـيم الحـــالات إلـــى مجمـــوعتين: المجموعـــة أ أعطيـــت 2 قـــرص (500 مجـــم)/ 8 ســـاعات ديوســـمين عـــن طريـــق الفـــم لمـــدة أســـبوعين ابتـــداء مـــن يـــوم حقـــن HCG

والمجموعة ب حصلت على علامة تبويب واحدة (0.5 مجم)/ يوم كابيرجولين عن طريق الفم لمدة 14 يومًا بدءا من يوم حقن HCG.

وقد قبلت جميع المريضات ووافقن على مجموعة برامج أطفال الأنابيب / الحقن المجهري.

نتائج البحث: الديوسمين لديه نفس تاثير الكبريجولين فى منع متلازمة التحفيز الزائد للمبيض، إضافة لكونه أرخص ومتوفر في السوق المصري.

الاستنتاج: الديوسمين لديه نفس تاثير الكبريجولين فى منع متلازمة التحفيز الزائد للمبيض.

الكلمات الدالة: الديوسمسن، الكبريجولين، متلازمة التحفيز الزائد للمبيض.