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Efficacy and safety of outpatient management of moderate to severe ovarian hyperstimulation syndrome

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ORIGINAL ARTICLE

Efficacy and safety of outpatient management of moderate to severe ovarian hyperstimulation syndrome

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Abstract

Background: ***One potentially dangerous side effect of assisted reproductive therapy is ovarian hyperstimulation syndrome. Hospitalization has long been a standard part of care for women with moderate to severe ovarian hyperstimulation syndrome, providing them with supportive care and careful observation.***

Aim and Objectives: ***To assess the safety and effectiveness of managing moderate to severe ovarian hyperstimulation syndrome as an outpatient.***

Patients and Methods: ***140 women who met the inclusion and exclusion criteria for our observational cohort research received in vitro fertilization and had moderate to severe ovarian hyperstimulation syndrome. Intravenous hydration, paracentesis of the ascetic fluid, and anti-thrombo-embolic measures were the main lines of treatment.***

Results: ***Merely 5. instances (3.6%) of the patients included were admitted to the hospital, while 135 cases (96.5%) were effectively handled as outpatients without needing a follow-up hospital stay.***

Conclusion: ***This study suggests that When patients are properly chosen, outpatient therapy of moderate to severe ovarian hyperstimulation syndrome is a safe approach with no documented increase in morbidity or death.***

Keywords: Outpatient; Ovarian hyperstimulation; Paracentesis; Hospitalization

1. Introduction

Ovarian hyperstimulation syndrome (OHSS) is a dangerous side effect of ovulation induction that affects 1–10% of individuals undergoing in vitro fertilization,. [1,2]

There is a wide range of clinical and biochemical signs of this iatrogenic illness, from moderate to severe, even potentially fatal disorders. [3]

This syndrome is defined by a prolonged and persistent increase in ovarian size brought on by an overreaction to controlled ovarian stimulation. It is also accompanied by a build-up of fluid in the third space due to increased capillary permeability caused by the ovaries' release of vascular endothelial growth factor. [4]

After OHSS has been diagnosed, the illness's severity must be ascertained.[5] Several systems have been put out to categorize OHSS severity. The Royal College of Obstetricians and Gynecologists recognizes the Mathur, Evbuomwan, and Jenkins classification in the United Kingdom. [6,7]

All systems identify a group of women with considerable fluid shift, observable as clinically apparent ascites and hemoconcentration, equating to Grade IV[8] or severe OHSS, despite the lack of an internationally accepted categorization. [7]

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Furthermore, women classed as serious OHSS have the most severe type of OHSS along with problems related to renal, pulmonary, or thromboembolism. For women with mild to moderate OHSS and, in some situations, severe OHSS, outpatient therapy is suitable; hospital admission should be considered for patients who are worsening or have critical OHSS. [6]

Individuals who have a partial remission of their symptoms, have significant hyperproteinuria or have an electrolyte imbalance should not be treated as outpatients for OHSS. [9]

Patients with significant OHSS, such as those with severe pleural effusion, decreased urine output, severe hemoconcentration, and elevated risk of thromboembolism, should not be treated as outpatients. [10]

Observational studies have shown that outpatient care is safer and less expensive than inpatient care. [6,11,12,13]

It was unusual for these individuals to need further hospitalization, and no problems were seen. The outpatient treatment of OHSS will increase the women's psychological anguish and lower the frequency of the most severe forms, hence reducing the need for hospital admission and saving money on care and beds. [14]

Thus, the goal of this thesis is to review the literature and evaluate the viability and cost-effectiveness of treating women with severe OHSS as outpatients.

2. Patients and methods

This was an observational cohort study that included 140 women who underwent in vitro fertilization, selected from the outpatient clinic in the ART Unit of the International Islamic Center for Population Studies and Research, Al Azhar University, between July 2019 and October 2022, and developed moderate to severe OHSS by the Royal Colleague of Obstetricians and Gynecologists 2016 classification 6.

Inclusion criteria: Moderate OHSS and severe OHSS

According to severity, OHSS is classified into (RCOG 2016): Mild OHSS (Abdominal bloating, mild abdominal pain, and ovarian size usually < 8 cm), moderate OHSS (Moderate abdominal pain, nausea ±vomiting, ultrasound evidence of ascites and ovarian size usually 8–12 cm), severe OHSS (Clinical ascites ± hydrothorax, oliguria < 300 ml/day or < 30 ml/hour, hematocrit > 0.45, hyponatremia in which sodium < 135 mmol/l, hypo-osmolality in which osmolality < 282 mOsm/kg, hyperkalemia in which potassium > 5 mmol/l, hypoproteinaemia in which serum albumin < 35 g/l and ovarian size usually > 12 cm) and critical OHSS (Tense ascites/large hydrothorax, hematocrit > 0.55, white cell count > 25000/ml, oliguria/anuria, thromboembolism, and acute respiratory distress syndrome).

Exclusion criteria: cases with critical OHSS according to the severity requirements by RCOG 2016. patients with difficult communication with us and individuals who live in distant places or cannot attend routine outpatient follow-up appointments.

After approval from the local ethical committee, before study enrollment, each woman who consented to participate in the experiment gave verbal and written informed consent.

Sample size:

Calculate the sample size for a study using the LarryConnors method.

DATA ON WHICH THE CALCULATION WILL BE BASED:

STUDY CHARACTERISTIC	ASSUMPTIONS MADE BY INVESTIGATOR
TYPE OF STUDY	EFFICACY AND SAFETY OF OUTPATIENT MANAGEMENT OF MODERATE TO SEVERE OVARIAN HYPERSTIMULATION SYNDROME
DATA SETS	STUDY OBSERVATIONS IN COHORT AND OBSERVATIONAL
VARIABLE	EFFICACY AND SAFETY OF OUTPATIENTS
DESIGN OF SAMPLE SIZE	THE SAMPLE SIZE OF PATIENTS REQUIRED CAN BE CALCULATED ACCORDING TO THE FOLLOWING FORMULA.
FORMULA	$N = \frac{T^2 \times P(1-P)}{M^2}$
DESCRIPTION:	N = REQUIRED SAMPLE SIZE T = CONFIDENCE LEVEL AT 95% (STANDARD VALUE OF 1.96) P = ESTIMATED MEASUREMENTS M = MARGIN OF ERROR AT 5% (STANDARD VALUE OF 0.05)

CALCULATION OF SAMPLE SIZE (N):

$$N = \frac{1.96^2 \times 0.099(1-0.099)}{0.05^2}$$

$$N = \frac{3.8416 \times 0.0892}{0.0025}$$

$$N = \frac{0.3427}{0.0025}$$

$$N = 140$$

Sample size: The sample size must be at least 140patients

Methods

Written and spoken information regarding their disease was given to women with moderate-to-severe OHSS.

Every patient chosen to participate in this research was subjected to the following: complete history taking, which includes menstruation history, age, and the history of any medical conditions or surgeries. The assessment of the patient comprised a general examination to check for edema and dehydration; measure body weight, blood pressure, and heart rate; an examination of the abdomen to measure the circumference, peritonism, and palpable mass; a respiratory examination to measure breathing rate and check for lung edema, pneumonia, and pleural effusion; Comprehensive examinations include hematocrit, liver function tests, coagulation profile, B-hCG, complete blood count, and ultrasound scans for ovarian size, pelvic and abdominal free fluid are among the procedures that are performed.

The ability of patients to keep fluid input-output charts benefited from outpatient treatment. Women were given access to paracetamol for pain treatment.[6] Because nonsteroidal anti-inflammatory medicines (NSAIDs) may impair renal function in women with OHSS, they were avoided. 15. IV fluid hydration was performed thrice daily using 500 mL of normal saline 0.9% to ensure sufficient urine production and reverse hemoconcentration.[6] When necessary, abdominal paracentesis was performed on patients with lower abdominal discomfort, nausea, vomiting, substantial abdominal distension, and shortness of breath.[9] Ascitic fluid removal improves renal function, raises urine production, enhances renal blood flow, and decreases intra-abdominal pressure.[13]

Thromboprophylaxis

Our trial used low-molecular-weight heparin (LMWH) to lower the risk of thrombotic problems [e.g., 40 mg Enoxaparin or ClexaneTM daily]. [16]

When OHSS resolved, ClexaneTM 40 mg was stopped in women who were unable to conceive. ClexaneTM was administered to women who became pregnant for the first trimester, or longer if necessary, based on the OHSS's progression and the existence of extra risk factors. We called and assessed women daily if needed, but they only had outpatient appointments once every three days. Women who displayed signs of worsening OHSS despite outpatient intervention (tachycardia, hypotension, dyspnea, intractable pain & vomiting, hematocrit > 0.45, weight gain, reduced urine output [less than 1000 ml/24 hours], and raising abdominal distension and girth) or who were unable to achieve satisfactory pain control were evaluated for hospital admission. [6]

Statistical analysis: Version 24.0 of the IBM SPSS software program was utilized to feed data into the computer. Numbers and percentages were utilized to describe the qualitative data. The Chi-square test was utilized to compare the category variables between the groups. For regularly distributed data, the mean and standard deviation were utilized to characterize quantitative data. The results of significance tests are expressed as a two-tailed probability. The findings' significance was assessed at the 5% level.

3. Results

Table 1. General examination among the studied patients.

	NUMBER "N=140"	PERCENT
CHEST		
NORMAL	140	100.0
ABNORMAL	0	0.0
HEART		
NORMAL	140	100.0
ABNORMAL	0	0.0
DEHYDRATION		
YES	0	0.0
NO	140	100.0
EDEMA		
YES	72	51.43
NO	68	48.57

This table showed that 100% was normal in chest and heart examination results, and 100% had no Dehydration, and showed that 51.43 of patients that had odema while 48.57% not.

Table 2. Abdominal examination among the studied patients.

	NUMBER "N=140"	PERCENT
ABDOMINAL ENLARGEMENT	117	83.6
ABDOMINAL TENDERNESS	140	100
ASCITES	140	100

This table showed that 83.6% of patient had Abdominal enlargement and 100% had

abdominal tenderness while 100% had Ascites.

Table 3. Abdominal and Transvaginal U/S among the studied patients.

ABDOMINAL AND TRANSVAGINAL U/S	NUMBER "N=140"	PERCENT
UTERUS	98	66.3
NORMAL	42	33.7
BIGGER THAN USUAL		
UTERINE CAVITY	140	100.0
NORMAL		
OVARIES	0	0
NORMAL	140	100
MULTICYSTIC		
LIVER	140	100.0
NORMAL		
KIDNEYS	140	100.0
NORMAL		
FREE FLUIDS	0	0
NORMAL	68	48
MILD ASCITES	72	52
MODERATE ASCITES		

This table showed that 66.3% had normal uterus while 33.7% had bigger uterus than usual, 100% had normal Uterine cavity, 100% had Multicystic ovaries, 100% had normal liver and kidneys, and 48% had Mild ascites while 52% had Moderate ascites.

Table 4. Laboratory investigations among the studied patients.

	NUMBER	PERCENT
UREA AND ELCTROLYTES		51.43
(SODIUM AND POTASSIUM)		48.57
NORMAL	72	
ABNORMAL	68	
LIVER ENZYMES		96.43
NORMAL	135	3.57
ELEVATED	5	
LIVER ALBUMIN		96.43
NORMAL	135	3.57
DECREASED	5	
FIBRINOGEN	137	97.86
NORMAL	3	2.14
ABNORMAL		
ANTI-THROMBIN	137	97.86
NORMAL	3	2.14
ABNORMAL		
B-HCG		68.57
NEGATIVE	96	31.43
POSITIVE	44	

B-hCG; Beta human chorionic gonadotropin

This table showed that 51.43% had normal sodium and potassium while 48.57% had decreased sodium and potassium, 96.43% had normal Liver enzymes while 3.57% had elevated Liver enzymes, 96.43% had normal Liver albumin while 3.57% had Decreased Liver albumin, 97.86 % had normal Fibrinogen and Anti-thrombin while 2.14% had Abnormal Fibrinogen and Anti-thrombin, and 68.57% was negative B-hCG

While 31.43% was positive.

Table 5. Laboratory findings of the studied patients.

	NUMBER "N=140"	PERCENT
HEMOGLOBIN		5.00
LEVEL	7	90.71
ANEMIC	127	4.29
NORMAL	6	
HIGH		
RANGE		10.0-16.0
MEAN		13.12
S.D.		2.85
HEMATOCRIT		48
NORMAL	68	52
ELEVATED	72	
RANGE		38.0-59.2
MEAN		43.22
S.D.		5.65
WBCS		45.2
NORMAL	64	54.8
ELEVATED	76	
RANGE		6000-28000
MEAN		16200
S.D.		5236.1

This table showed that the mean Hemoglobin level was 13.12±2.85, and 5% of patient was Anemic, 90.71% was Normal while 4.29 %was high, and the mean Hematocrit was 43.22±5.65, and 48% of patient was normal, while 52% was Elevated, and the mean WBCs was 16200±5236.1, and 45.2% of patient was Normal while 54.8% was Elevated.

Table 6. Outcome of the studied patients.

OUT COME	NUMBER	PERCENT
RESOLUTION	135	96.4
HOSPITAL ADMISSION	5	3.6
PERCENT OF IMPROVEMENT AND RESOLUTION		96.4%

This table showed that 96.4% was resolution while 3.6% was Hospital admission, and 96.4% was the Percent of improvement and resolution.

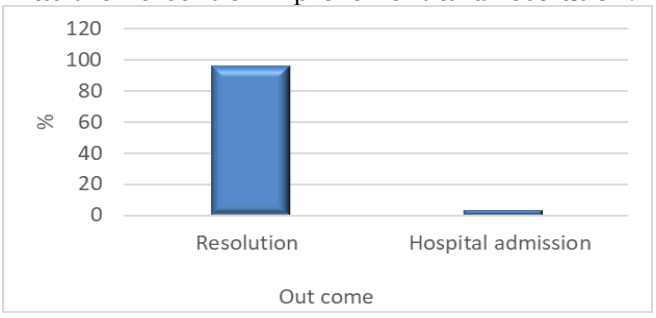

Figure 1. Outcome of the studied patients.

Table 7. Cause of hospital admission of the studied patients (morbidity and mortality).

CAUSE OF ADMISSION	NUMBER	PERCENT
THROMBOSIS	0	0.0
DYSPNEA OR TACHYPNEA	5	3.6
SEVERE SYMPTOMS OR DISCOMFORT IN THE ABDOMEN	5	3.6
INTRACTABLE NAUSEA AND VOMITING	5	3.6
EXTREME ANURIA OR OLIGURIA	1	0.7
TENSE ASCITES	5	3.6
ABNORMAL LIVER FUNCTION TESTS	5	3.6
DEATH	0	0.0

This table showed that Thrombosis was present in 0% of the patients, dyspnea or tachypnea in 3.6%, severe abdominal pain or peritoneal symptoms in 3.6%, intractable nausea and vomiting in 3.6%, severe oliguria or anuria in 0.7%, tense ascites in 3.6%, abnormal liver function tests in 3.6%, and no patient was fatal.

4. Discussion

A life-threatening side effect of ART known as OHSS is more often seen when there is a substantial ovarian response. [17]

High blood estradiol levels and the formation of many ovarian follicles indicate this robust ovarian response. [18]

OHSS is considered an iatrogenic consequence that has to be prevented, and if it does occur, its severity needs to be minimized. Given the psychological and physical effects and care expenditures, such as hospital stays, any effort to reduce OHSS would be beneficial. [19]

The current recommended practice gold standard and the growing body of research proving the efficacy and safety of outpatient care were compared with the advisory body standards. Since 1994, the literature has made reference to OHSS's outpatient care. [11]

In UK practice, however, hospitalization is almost always provided for severe cases since most current advisory body recommendations advise inpatient care. Personalized care for each patient and an eye toward outpatient options might lessen the financial burden of one of the most dangerous side effects of assisted reproductive technology (ART). To properly identify patients suited for outpatient care, a comprehensive evaluation of the severity of the illness and patient selection is necessary. [9,13]

Patients chosen for outpatient care should be well-behaved, have access to urgent care when required, be able to follow up regularly, tolerate oral fluid intake, and have excellent compliance. [9]

Fertility facilities that want to provide OHSS outpatient care must possess enough knowledge of the conventional inpatient treatment of severe OHSS. Furthermore, these facilities must have access to interventional radiology treatments and inpatient care if needed. Therefore, fertility units that provide outpatient care for severe OHSS should create their protocols for outpatient care, specifying when a patient should be admitted to the hospital, the best course of action for paracentesis, how often and for how long to follow up, and whether to follow up over the phone or in person. A total of 140 patients with mild to severe OHSS were treated as outpatients in this research. Five patients (3.5%) needed hospital hospitalization. The development of significant OHSS, such as pleural effusion, vomiting, and an inability to maintain enough oral hydration, were the reasons for the hospital admission. 96.5% of the patients were effectively treated as outpatients and did not need a second hospital stay. The primary treatment plan was ascitic fluid paracentesis with rehydration and thromboprophylaxis.

In our study, only 5 cases (3.6%) were admitted to the hospital. Univariant analysis showed that young age, low BMI, previous OHSS, and high levels of hemoglobin, hematocrit, and WBC were indications of hospital admission.

The first retrospective case series describing the safe outpatient treatment of severe OHSS was reported by Shrivastav et al. [11].

Smith et al. reported a larger-scale retrospective case study of 183 OHSS patients handled as outpatients over an eight-year period (1999–2007); the results demonstrated a considerable decrease in the requirement for hospitalization with early and frequent paracentesis. [20]

The research evaluating the financial cost of managing OHSS needs more data. However, hospitalization is the primary cause of the economic burden of care in the conventional approach to treating severe OHSS, and paracentesis as an outpatient active therapy has been proposed as a more economical course of action. [21]

Amr Gebril et al. revealed that the evaluated result was the effectiveness of outpatient care in managing patients with serious OHSS without the requirement for hospitalization or the emergence of life-threatening complications. [22]

In 2016, the American Society of Reproductive Medicine (ASRM) practice committee released guidelines for treating OHSS. According to the recommendation, "There is fair data to recommend paracenteses or culdocenteses for the treatment of

OHSS in an outpatient setting." .[23]

In 2013, the British Fertility Society released a guidebook on the handling of OHSS. The recommendation underlined how crucial it is to evaluate the severity of the sickness to prepare the best course of action. For patients with moderate OHSS, the guideline suggested outpatient care with routine follow-up, while for patients with severe OHSS, inpatient care was advised. [24]

A collaborative guideline on diagnosing and treating severe OHSS was released in 2012 by the Health Service Executive's Directorate of Strategy and Clinical Programs, the Royal College of Physicians of Ireland, and the Institute of Obstetricians and Gynecologists. For patients with severe OHSS, the guidelines advised inpatient treatment that included rehydration, fluid balance monitoring, analgesia, anti-emetics, and thromboprophylaxis. Ascitic fluid drainage was only recommended in cases of significant abdominal distention, dyspnea, or persistent oliguria that did not improve with fluid replacement. [25]

Notwithstanding the results of our investigation, it is crucial to stress that OHSS is still a dangerous condition that may worsen quickly, necessitating hospitalization and special care for a patient who is sick. The life-threatening side effects of OHSS are secondary to multi-organ failure, impaired pulmonary or cardiovascular function, or thrombosis. [6]

There are several advantages to the current review. These include: We were able to speak with a wide variety of patients from various regions of Egypt, patients with OHSS varying in severity and degree, and patients with both moderate and severe OHSS. In addition, a thorough literature search was conducted to identify certain possible treatments that may influence OHSS. Each intervention was then carefully evaluated for quality using techniques chosen specifically for the research design. There were some restrictions: Due to the COVID-19 epidemic, which forced the International Islamic Center for Population Studies and Research at Al-Azhar University to close its ART Unit for part of the research, and the discovery of fewer OHSS patients than anticipated, the study took longer than expected to complete; The dataset was rich in pertinent insights, so we had enough information power to explore this topic even though the sample size was smaller than it would have been. We excluded patients who couldn't attend for routine outpatient follow-up, such as those who lived in remote areas. This investigation is observational rather than a randomized controlled study without a control group. Information, communication, and decision-making problems are probably more difficult in this demographic than in this one. We did not investigate the effects of OHSS on spouses and other family members since we limited our questioning to women who have experienced OHSS. This research did not calculate the cost savings in Egyptian Pounds for each patient treated as an outpatient instead of being admitted to the hospital for mild to severe OHSS.

5. *Conclusion*

In conclusion, this study suggested that When patients are carefully chosen, outpatient therapy of moderate-to-severe OHSS is a safe alternative with no known rise in morbidity or death. A tiny number of individuals with severe OHSS will still need to be admitted to the hospital and receive inpatient care, nevertheless. Although the relatively low incidence of severe OHSS and the different severity classifications present potential challenges for future researchers, more research was also required to assess further the safety, efficacy, and cost-effectiveness of moderate/severe OHSS outpatient management.

Disclosure

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Authorship

All authors have a substantial contribution to the article

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