

Ozone Therapy and its Efficacy on Fetoplacental Circulation in Hypertensive Patients

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ABSTRACT

This study was conducted to determine the efficacy of ozone therapy on fetoplacental circulation in hypertensive patients. Forty volunteer hypertensive pregnant women at 24 weeks gestation were participated in this study. They were recruited from the outpatient clinic of the Obstetric and Gynaecologic Department of Kasr El-Aini University Hospital. They were divided randomly into two groups (Study and control) equal in number. Group (A) study group: consisted of 20 patients received ozone therapy, 3 sessions per week for 7 weeks and continued their drug (Methyldopa), and Group (B) control group, consisted of 20 patients had been treated with (Methyldopa) only. Evaluation of all patients were done before starting the study and after 7 weeks through measuring of maximum systolic and end diastolic velocities of the umbilical artery, systolic diastolic (S/D) ratio, resistance index (RI), pulsatility index (PI) before and after the study. The results of this study showed a highly significant ($P < 0.001$) decrease of the maximum systolic velocity, (S/D) ratio, (RI) and (PI) while there was a highly significant ($P < 0.001$) increase in end diastolic velocity in group (A). And in group (B) there was a non significant decrease in maximum systolic velocity and (PI), ($P > 0.05$) while there was a significant ($P < 0.05$) increase of the end diastolic velocity, and a statistically significant ($P < 0.05$) decrease of (S/D) ratio as well as (RI). Comparison between both groups (A and B) at the end of the study there was statistically significant difference in the maximum systolic velocity, while there was a highly statistically significant ($P < 0.001$) decrease in the (S/D) ratio, (RI) and (PI) in the study group. Accordingly, it could be concluded that ozone therapy was effective in improving fetoplacental circulation for hypertensive pregnant women, and it is a safe modality and has no harmful effects either on the mother or her fetus.

Key words: Ozone therapy, Placental circulation, Hypertension, pregnancy.

INTRODUCTION

The placenta is the primary site of exchange between the mother and her fetus. Its major function is to provide diffusion of food stuffs and oxygen from the mother's blood into the fetus blood and diffusion of excretory products from the fetus back into the mother¹¹.

Consequently, placental blood flow and vascular development are essential components of normal placental function and are critical to fetal growth and development¹¹.

Severely reduced blood flow to the fetus associated with growth restriction, which is followed by long-term impairment of intellectual development and partial neurodevelopment delay⁶.

Hypertensive disorders are the most common medical complications of pregnancy. Hypertension during pregnancy can cause serious complications for the mother and her fetus. All forms of hypertension can constrict the blood vessels in the uterus that supply the fetus with oxygen and nutrients. When this occurs before term, it can slow the fetus's

growth, sometimes resulting in low birth weight¹⁷.

Hypertension also, increases the risk of preterm delivery, premature fetus and low-birth weight newborn¹⁷.

Nearly all drugs that are administered during pregnancy will enter to some degree the circulation of the fetus via passive diffusion. In addition, some drugs are pumped across the placenta by various active transporters located on both the fetal and maternal side of the trophoblast layer¹⁹.

Antihypertensive drugs were found to increase uterine muscle tone causing IUGR, which result in neonatal respiratory depression, bradycardia and hypoglycemia¹⁸.

Therefore, treatment guidelines have recommended the use of non-pharmacological approaches for hypertension during pregnancy, with or without antihypertensive drugs, particularly for mildly increased blood pressure¹⁶.

The use of ozone therapy has been known for its ability to stimulate the circulation and to stabilize the state of the cell membranes⁵.

It has been found to be an extremely safe modality, free from the dangerous side effects associated with the usage of drugs in the treatment of many diseases¹⁵.

Ozone therapy has been usefully used in the treatment of different obstetrical and gynaecological conditions as spontaneous abortion, early toxicosis, fetoplacental insufficiency; inflammatory diseases of genitals¹³.

Further fundamental investigations have fully confirmed the applicability of ozone therapy in the treatment of gestational complications, since it has been reliably established that the use of ozone leads to the correction of basic links of pathogenesis and the most important clinical appearances of

diseases as improvement of macro and microcirculation that results in the normalization of placental hormonogenic function¹³.

So the purpose of the present study was to determine the efficacy of ozone therapy on fetoplacental circulation in hypertensive patients.

SUBJECTS, MATERIAL AND METHODS

Subjects

Forty volunteer primigravidae and multipara (1-3 times) hypertensive pregnant women at 24 weeks gestation, were participated in this study. They were recruited from the outpatient clinic of the Obstetrics and Gynaecologic Department of Kasr El-Aini University Hospital. Their age ranged from 20-30 years old. Patients were classified into two groups (study and control) equal in number.

Blood pressure of the participated women in this study was 140/90 mmHg and not exceeded 160/100 mmHg. Twins, hydramnios, placenta previa, cardiorespiratory diseases, IUGR and diabetes mellitus were excluded from this study.

Informed consent form had been signed from each patient before starting the study indicating her voluntary participation in this study.

Croup A (study group)

Composed of 20 patients. They received ozone therapy, 3 sessions per week (duration of each session was about 30 minutes), for 7 weeks, with the continuation of their regular antihypertensive drug (Methyldopa) three times per day.

Group B (control group)

Composed of 20 patients. They were only subjected to the same regular

antihypertensive drug (Methyldopa) as in group A. Three times per day.

Summary of patients physical characteristic summarized in table (1).

Table (1): Physical characteristics of both groups (study and control).

	Group	Range		Mean	SD	P. value	Significance
		Min	Max				
Age (yrs)	Study	20.00	30.00	24.73	±3.22	> 0.05	NS
	Control	20.00	30.00	24.87	±3.04		
Weight (Kgs)	Study	67.00	90.00	78.53	±6.38	> 0.05	NS
	Control	69.00	88.00	79.13	±5.33		
Height (cms)	Study	156.00	170.00	163.00	±3.00	> 0.05	NS
	Control	157.00	170.00	63.00	±4.00		
BMI (Kg/m ²)	Study	26.80	31.60	29.49	±1.28	> 0.05	NS
	Control	26.00	31.60	29.86	±1.76		
Parity	Study	0.00	3.00	0.93	±1.10	> 0.05	NS
	Control	0.00	3.00	1.13	±1.12		

Instrumentations**1- Ozone Generator**

The Ozone LabTM OL80 Desktop line (45° panel series) of Ozone generator, was used to deliver the ozone gas, which was used in the treatment of all patients in group (A).

2- Doppler Ultrasound Machine

Sony, Au530 ESAOTE EIOMECIA Geno. It was used before starting the study to estimate and calculate the gestational age, and to measure the umbilical artery blood flow for each patient in both groups (A and B).

3- Catheter

Disposable Nelaton catheter gage 16 was introduced into the patient's rectum through her anus for administration of ozone therapy for all patients in group (A).

4- Ky gel

To lubricate the catheter.

5- Clamp

To close the catheter before changing the syringes.

6- Syringes

50 ml disposable syringe was used to collect the ozone dose from the generator and introduce it into the catheter.

7- Mercury Sphygmomanometer and Stethoscope. They were used to measure the arterial blood pressure for all patients in both groups (A&B), before beginning of treatment.

8- Weight – Height scale

Was used to measure weight and height to calculate the BMI for each patient in both groups (A&B) before starting the study.

Procedures**A) Evaluative procedures**

1- Personal data: Data and information of each participant in this study were recorded in a recording sheet.

2- History taking: A detailed medical, obstetrical as well as gynaecological history were taken from each participant.

B) Measurement Procedures

1- Ultrasonographic examination: was done for each patient in both groups, (A&B) before starting the study.

2- Blood pressure measurement: was done while the patient was relaxed in half lying position for at least 5 minutes from the left arm.

Umbilical artery Doppler Measurement

Systolic and end diastolic velocities of the umbilical artery were measured and calculated⁷.

S/D Ratio= maximum systolic velocity/ end diastolic velocity.

RI= (maximum systolic velocity-end diastolic velocity)/ maximum systolic velocity.

PI= (maximum systolic velocity-end diastolic velocity)/ mean velocity.

C) Treatment procedure

1- Group (A): Each patient in group (A), received Ozone therapy in the form of rectal insufflation with Ozone concentration of 20 µg/ml, increased gradually up to 40 µg/ml and the volume was ranged from 150-300 ml, 3 sessions per week for 7 weeks (21 sessions), and the duration of each treatment session, was 30 minutes.

- Three syringes of 50 ml were filled with Ozone from the generator (total ozone dose of 150ml), with the appropriate concentration was used to deliver the ozone into the rectum via the catheter in the first session, then the dose and concentration of ozone was increased gradually in the subsequent sessions to reach the maximum range (ozone dose of 300 ml & concentration of 40 µg/ml by using 6 syringes).
- In addition, all patients received their regular antihypertensive drug (Methyldopa) 750-2000 mg per day for 7 weeks.
- Before starting the first treatment session each patient in group (A) was instructed carefully about the ozone therapy procedure, its safety, values, to gain her

confidence and co- operation during the treatment session.

- Also, each patient was advised and instructed to evacuate her bladder and rectum before starting each ozone therapy session.
 - Each patient was assuming a relaxed modified side lying position, then the catheter was held and lubricated with a (KY gel) and closed by the clamp before inserting it into the rectum through the anus. After that, syringes were introduced in the free end of the catheter then the clamp was removed, and the ozone was injected into the catheter after that, the catheter was closed with the clamp again, to change the syringes. This procedure was repeated from 3 to 6 times according to the ozone dose which was used. Finally, the catheter was removed from the patient's rectum, when all the syringes were used. Then the patient clean her anus by using sterile dressing.
 - In addition, all patients received their regular antihypertensive drug (Methyldopa) 750-2000 mg per day for 7 weeks.
- 2- Group (B): Each patient received the regular antihypertensive drug (methyldopa) 750-2000 mg per day for 7 weeks.

Data analysis and statistical design

- Descriptive statistics was used for the collected data to calculate the mean and the standard deviation. Inferential statistical analysis was used in the form of independent t-test for comparing between the study and control groups.
- Significance level of 0.05 was used throughout all the statistical tests within this study, P-value < 0.05 indicated a significant result⁸.

RESULTS

In the present study, the maximum systolic velocity, end diastolic velocity, systolic – diastolic ratio, pulsatility index and resistance index in both groups (study and control) were investigated.

As shown in table (2) the mean values of maximum systolic velocity of the umbilical artery for the study group before treatment with ozone was (0.42 ± 0.08 m/sec). While after the end of the treatment it was (0.39 ± 0.07 m/sec) with a decrease in the mean difference of 0.03 m/sec and a percentage of difference of 7.1%. This difference was found to be statistically highly significant ($P < 0.001$) decrease.

And, the mean values of the maximum systolic velocity of the umbilical artery for the control group before starting the medical treatment was (0.42 ± 0.09 m/sec). While, after the end of the treatment it was (0.41 ± 0.07 m/sec), with a decrease in the mean difference of 0.01 m/sec and a percentage of difference of 2.4%. This difference was found to be statistically non significant ($P > 0.05$) decrease.

Comparing between the mean values of both groups (A and B) as observed in table (3) and fig. (1), there was statistically significant ($P < 0.05$) after the end of treatment.

As shown in table (2) the mean values of end diastolic velocity of the umbilical artery for the study group before starting the treatment with ozone was (0.13 ± 0.03 m/sec), while after the end of the treatment, it was (0.15 ± 0.02) with an increase in the mean difference of -0.02 m/sec and a percentage of 15.4%. This difference was found to be statistically highly significant ($P < 0.001$) increase.

And the mean value of the end diastolic velocity of the umbilical artery for the control group before starting the medical treatment

was (0.13 ± 0.01 m/sec), while after the end of treatment it was (0.14 ± 0.03 m/sec) with an increase in the mean difference of -0.01 m/sec and a percentage of difference of 7.7%. This difference was found to be statistically significant ($P < 0.05$) increase.

Comparing between the mean values of both groups (A and B) as observed in table (3), after the end of treatment, the difference between them was statistically highly significant ($P < 0.001$).

Also as shown in table (2) the mean value of the S/D ratio of the umbilical artery for the study group before starting the treatment was (3.21 ± 0.12 m/sec). While after the end of treatment it was (2.62 ± 0.34 m/sec) with a decrease in the mean difference of 0.58 and a percentage of difference of 18.4%. This difference was found to be statistically highly significant ($P < 0.001$) decrease.

And, the mean value of the S/D ratio of the umbilical artery for the control group before starting the medical treatment was (3.22 ± 0.10 m/sec). While after the end of treatment it was (3.04 ± 0.26 m/sec), with a decrease in the mean difference of 0.18 and a percentage of difference of 5.6%. This difference was found to be statistically significant ($P < 0.05$) decrease. Comparing between the mean values of both groups (A and B) after the end of treatment, the difference between them showed that there was statistically highly significant ($P < 0.001$) decrease in the study group.

Also as shown in table (2), the mean values of PI of the umbilical artery for the study group before starting the treatment with ozone was (1.08 ± 0.19). While after the end of treatment, it was (0.90 ± 0.14), with a decrease in the mean difference of 0.18 and a percentage of difference of 10.6%.

This difference was found to be statistically highly significant ($P < 0.001$)

decrease. And, the mean value of the PI of the umbilical artery for the control group before starting the medical treatment was (1.13 \pm 0.14) while, after the end of treatment it was (1.08 \pm 0.11) with a decrease in the mean difference of 0.04 and a percentage of difference of 4.4%. This difference was found to be statistically non significant ($P > 0.05$).

Comparing between the mean values of both groups (A and B) as observed in table (3) and fig. (1) after the end of treatment, the difference between them showed that there was statistically highly significant ($P < 0.001$) decrease in the study group.

As shown in table (2) the mean values of the RI of the umbilical artery for the study group before starting the treatment with ozone was (0.69 \pm 0.01), while after the end of the treatment it was (0.61 \pm 0.05) with a decrease

in the mean difference of 0.08 and a percentage of difference of 11.6%. This difference was found to be statistically highly significant ($P < 0.001$) decrease. And, the mean values of the RI of the umbilical artery for the control group before starting medical treatment was (0.69 \pm 0.03). While, after the end of the treatment it was (0.67 \pm 0.03) with a decrease in the mean difference of 0.02 and a percentage of difference of 2.9%. This difference was found to be statistically significant ($P < 0.05$) decrease.

Comparing between the mean values of both groups (A and B) as observed in table (3) after the end of treatment, the difference between them was found to be statistically highly significant ($P < 0.001$) in the study group.

Table (2): Mean values of maximum systolic velocity, end diastolic velocity, S/D ratio, PI and RI for patients in both groups (A and B).

Variable	Maximum systolic velocity			
	Study group		Control group	
Group	Before treatment	After treatment	Before treatment	After treatment
Mean	0.42	0.39	0.42	0.41
SD	± 0.08	± 0.07	± 0.09	± 0.07
MD	0.03		0.01	
Percent of difference %	7.1%		2.4%	
P. value	< 0.001		> 0.05	
Variable	End diastolic velocity			
	Study group		Control group	
Group	Before treatment	After treatment	Before treatment	After treatment
Mean	0.13	0.15	0.13	0.14
SD	± 0.03	± 0.02	± 0.01	± 0.03
MD	-0.02		-0.01	
Percent of difference %	15.4%		7.7%	
P. value	< 0.001		< 0.05	
Variable	Systolic – Diastolic ratio			
	Study group		Control group	
Group	Before treatment	After treatment	Before treatment	After treatment
Mean	3.21	2.62	3.22	3.04
SD	± 0.12	± 0.34	± 0.10	± 0.26
MD	0.58		0.18	
Percent of difference %	18.4%		5.6%	
P. value	< 0.001		< 0.05	
Variable	Pulsatility index			
	Study group		Control group	
Group	Before treatment	After treatment	Before treatment	After treatment
Mean	1.08	0.90	1.13	1.08
SD	± 0.19	± 0.14	± 0.14	± 0.11
MD	0.18		0.04	
Percent of difference %	10.6%		4.4%	
P. value	< 0.001		> 0.05	
Variable	Resistance – Index (RI)			
	Study group		Control group	
Group	Before treatment	After treatment	Before treatment	After treatment
Mean	0.69	0.61	0.69	0.67
SD	± 0.01	± 0.05	± 0.03	± 0.03
MD	0.08		0.02	
Percent of difference %	11.6%		2.9%	
P. value	< 0.001		< 0.05	

Table (3): Mean values of maximum systolic velocity, end diastolic velocity, S/D ratio, PI between both groups (A and B) after the end of treatment.

Variable	Maximum systolic velocity	
Group	Group (A)	Group (B)
Mean	0.39	0.41
SD	±0.06	±0.07
MD	-0.02	
P. value	<0.05	
Variable	End diastolic velocity	
Group	Group (A)	Group (B)
Mean	0.15	0.14
SD	±0.02	±0.03
MD	0.01	
P. value	<0.001	
Variable	Systolic – Diastolic ratio	
Group	Group (A)	Group (B)
Mean	2.62	3.04
SD	±0.34	±0.26
MD	-0.42	
P. value	<0.001	
Variable	Pulsatility Index	
Group	Group (A)	Group (B)
Mean	0.90	1.08
SD	±0.14	±0.11
MD	-0.18	
P. value	<0.001	
Variable	Resistance – Index (RI)	
Group	Group (A)	Group (B)
Mean	0.61	0.67
SD	±0.05	±0.03
MD	-0.06	
P. value	<0.001	

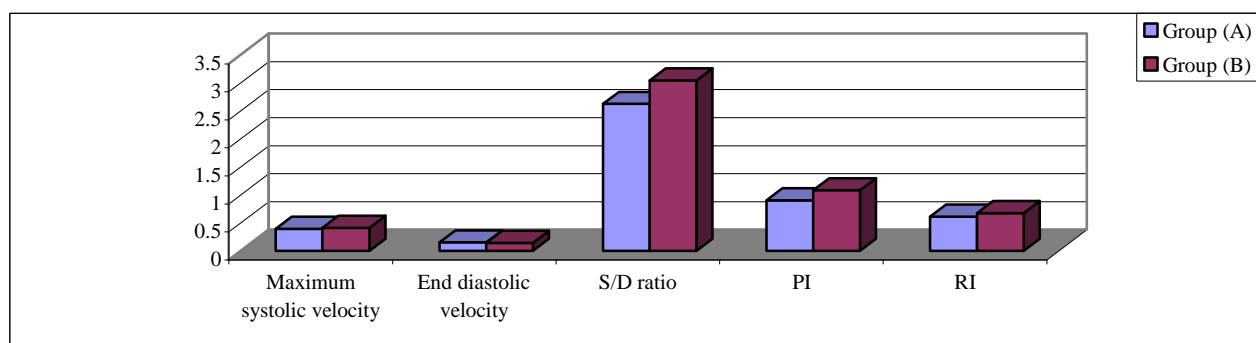


Fig. (1): Mean values of maximum systolic velocity, end diastolic velocity, S/D ratio, PI and RI between both groups (A and B) after the end of treatment.

DISCUSSION

Hypertension during pregnancy can be the cause of placental insufficiency which may be contributed to: reduced production of

vasodilatory prostacyclin, nitric oxide and increased level of plasma endothelin (Witlin et al., 2000)²⁰; Diffuse placental micro thrombosis, and inflammatory placental

decidual vasulopathy and abnormal trophoblastic invasion of the endometrium¹⁰.

Ozone therapy is considered as a biological response modifier leading to increase erythrocyte filterability and a decrease of blood viscosity, and stimulate the growth and differentiation of terminal villi¹, and also increase tissue oxygenation and enhance endogenous angiogenic procedure². Medical ozone increase cardiac output, and decrease the total peripheral vascular resistance¹⁴ synthesizing and realizing several vasodilator factors, including prostacyclin, and endothelium-derived hyperpolarizing factor (EDHF)¹².

The results of the current study showed a highly significant ($P < 0.001$) decrease in the maximum systolic velocity, (S/D) ratio, RI, and PI, while there was a highly significant ($P < 0.001$) increase in the end diastolic velocity in group (A). while in group (B), there was a non-significant difference in the maximum systolic velocity and PI, while there was a statistically significant ($P < 0.05$) increase in the end diastolic velocity, and a statistically significant ($P < 0.05$) decrease of S/D ratio as well as, RI.

The results of this study was in agreement with the study of Clemente et al., (2005)⁴ who concluded that there was a significant improvement of the fetoplacental blood flow after using ozone therapy, and this was attributed to the reduction of blood flow resistance, impedance and normal vascular reactivity.

Makarov et al., (2002)⁹ concluded that medical ozone exposure in high-risk pregnancy, decreased the incidence of pregnancy complications, and they recommended the use of ozone therapy as a treatment and prevention of fetoplacental insufficiency in high-risk pregnancy.

Also, the results of this study were supported by that of Belyaev et al., (2001)³ who reported that there was significant increase of blood flow rate in arterioles and venules after Ozone therapy. They explained the significant increase in the blood flow rate to the great reduction in erythrocyte aggregation, especially in the venular compartment of the microcirculatory channel in addition to a marked spasmolytic effect and reduction of micro vessels permeability produced by ozone therapy.

Mukhina et al., 2005¹² stated that reinfusion of ozonated blood by using low ozone concentration induce vasodilatation in ischemic areas and reduce hypoxia through stimulating the endothelium which plays an important role in maintaining vascular haemostasis by synthesizing several vasodilating factors, and induce small oxidant stress and some activation of enzyme system of antioxidant protection as a result of release of ozonolysis products.

So it could be concluded that ozone therapy is an effective method improving fetoplacental circulation in hypertensive patients.

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الملخص العربي

تأثير العلاج بالأوزون على الدورة الدموية المشيمية لدى السيدات المصابات بارتفاع ضغط الدم

لقد أجريت هذه الدراسة لمعرفة مدى تأثير العلاج بالأوزون على الدورة الدموية المشيمية لدى السيدات المصابات بارتفاع ضغط الدم ، حيث شاركت في هذه الدراسة أربعون سيدة متطوعة ، في الأسبوع 24 من الحمل من المترددات علي العيادة الخارجية بقسم أمراض النساء والتوليد بمستشفى قصر العيني الجامعي . وقد تم تقسيمهن عشوائياً إلى مجموعتين متساويتين في العدد : مجموعة (أ) مجموعة الدراسة وتضمنت 20 سيدة تم علاجهن بالأوزون بواقع ثلاث جلسات أسبوعياً لمدة سبعة أسابيع مع استمرار العلاج الدوائي (مينثيل دوبا) ومجموعة (ب) المجموعة الضابطة وتضمنت 20 سيدة تلقين العلاج الدوائي (مينثيل دوبا) فقط . وتم القيام لجميع الحالات بواسطة قياس أقصى سرعة انقباض وادني سرعة انبساط للشريان السري ثم حساب معدل سريان الدم ونسبة المقاومة ونسبة النبض في الشريان السري للجنين قبل بداية الدراسة وبعد سبوع أسابيع من العلاج وقد أظهرت النتائج وجود نقص ذو دلالة معنوية عالية في أقصى سرعة انقباض ومعدل سريان الدم ونسبة المقاومة ونسبة النبض للشريان السري ، وكذلك زيادة ذو دلالة معنوية عالية في ادني سرعة انبساط للشريان السري في المجموعة (أ) بينما في المجموعة (ب) كان هناك نقص ذو دلالة غير معنوية في أقصى سرعة انقباض ونسبة النبض للشريان السري ، بينما كان هناك زيادة ذو دلالة معنوية في ادني سرعة انبساط للشريان السري ، ونقص ذو دلالة معنوية في معدل سريان الدم ونسبة المقاومة للشريان السري . وبالمقارنة بين المجموعتين (أ ، ب) نجد فرق ذو دلالة معنوية في أقصى سرعة انقباض ووجود فرق ذو دلالة معنوية عالية في أدنى سرعة انبساط للشريان السري وفي معدل سريان الدم ونسبة المقاومة ونسبة النبض في المجموعة (أ) عنه في المجموعة (ب) بعد الانتهاء من الدراسة وهكذا يمكن أن نستخلص من هذه الدراسة أن الأوزون يمكن تحسين الدورة الدموية المشيمية لدى السيدات المصابات بارتفاع ضغط الدم ، كما انه يعتبر علاج آمن وليس له أي ضرر علي الأم أو جنينها .

الكلمات الدالة : العلاج بالأوزون – الدورة الدموية المشيمية – ارتفاع ضغط الدم – الحمل .