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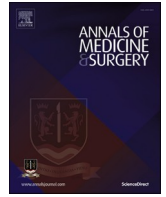


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# The outcome of hyperbaric oxygen therapy versus core decompression in the non-traumatic avascular necrosis of the femoral head: Retrospective Cohort Study<sup>☆</sup>

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## ABSTRACT

**Background:** Core decompression (CD) has been used in the treatment of pre-collapse stages avascular necrosis (AVN) with good results. Hyperbaric oxygen therapy (HBO) was used as a non-invasive treatment for pre-collapse stages osteonecrosis with favorable results. This study aimed to compare the outcomes of HBO versus CD in stage II of non-traumatic AVN of the femoral head.

**Methods:** Data were collected retrospectively for patients with non-traumatic AVN of the femoral head that was confirmed by MRI and underwent HBO or CD between January 2010 and December 2018, with a minimum follow-up of 12 months. Oxford Hip Score (OHS), radiographic progression, and Short-Form 12(SF12) were used to assess the outcomes.

**Results:** Nineteen patients with 23 stage II AVN of the femoral head were included, 12 (52.2%) in CD, and 11 (47.8%) in the HBO group with an average follow-up of  $34.2 \pm 18.4$  months.

66.7% of patients in CD and 81.8% in the HBO group achieved satisfactory hip function outcome with statistically significant mean Oxford Hip Score ( $35.8 \pm 6.7$  and  $35.5 \pm 5.1$ ) ( $P 0.009$  &  $.003$ ) respectively.

No statistical difference of OHS and SF12 (PCS & MCS) was found between the two groups ( $P 0.202$ ,  $0.128$  &  $.670$  respectively).

Eight (34.7%) cases progressed to a higher radiological stage at one year follow-up. The rate of progression was not statistically significant between both groups ( $P 0.469$ ) with no statistical difference of OHS and SF12 (PCS & MCS) in the progressed group ( $P 0.747$ ,  $0.648$  &  $0.416$ ) respectively.

**Conclusion:** This study showed that the HBO is promising and as effective as CD in the treatment of non-traumatic pre-collapsed AVN of the femoral head. Hence, HBO could be used as an alternative non-invasive treatment option.

## 1. Introduction

Osteonecrosis of the femoral head is a potentially disabling disorder, which mainly affects young adults. Different causes and risk factors have been described in the literature, e.g. corticosteroids, irradiation, coagulopathy, smoking, alcohol, etc. [1–4]. Osteonecrosis of femoral head is one of the risk factors for progressive degenerative disease of the hip joint [2,3,5]. The stage of the disease at the time of treatment is a major factor for the success of hip preservation [6–8].

Core decompression of the femoral head has been performed since 1971 and recommended as a successful form of hip preserving procedure for pre-collapsed stages AVN with good results. It reduces the intraosseous pressure, promotes bone healing, and prevents head collapse [9–13].

Recently, Hyperbaric Oxygen (HBO) therapy was used as a non-invasive joint preserving treatment for symptomatic pre-collapsed stages of AVN with a promising result, it reduces the intraosseous hypertension and bone edema, restores the venous drainage and induces

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angiogenesis, and prevent the collapse of the head and hence improve the pain symptoms [14].

To the best of our knowledge, no previous studies have compared the outcomes between the two methods.

This study aimed to compare the functional and radiological outcomes of the Hyperbaric Oxygen therapy (HBO) versus Core Decompression (CD) in pre-collapsed stage II of non-traumatic AVN of the femoral head.

## 2. Material and methods

### 2.1. Patient selection

This study was approved by the Institutional Review Board at our institution with IRB number MRC/1402/2017). The work is compliant with the STROCSS criteria [15]. The study was registered with Clinical Trial.gov and the unique identifying number is NCT04657653. The data were retrospectively collected from the medical records of patients between January 2010 and December 2018. The patient's demographics (age, gender, BMI) comorbidities, risk factors for AVN, (DM, HTN, alcoholic, smoking, steroid used, sickle cell disease, chemo or radiation therapy), pre-and post-treatment radiological stage (Steinberg's classification) [16], functional outcome (Oxford Hip Score and SF 12), complications and need for further surgical intervention or Total Hip Arthroplasty (THA) were collected.

The inclusion criteria for participation in the study were 18 years old patients and more, with non-traumatic AVN stages II (Steinberg) [16] that was confirmed by MRI and underwent either Hyperbaric Oxygen therapy or Core Decompression with bone substitute augmentation with a minimum follow up of one year were included.

Patients with traumatic AVN, other stages of AVN (stages I, III, IV, V and VI), core decompression without bone graft, combined therapy, other hip procedures and less than one year follow-up were excluded from the study.

Written informed consent was obtained from all patients and they were interviewed through their regular clinical follow-up with a minimum of 1-year after the treatment.

The work has been reported in line with the STROCSS criteria: Strengthening the Reporting of Cohort Studies in Surgery [17].

### 2.2. Clinical and radiological evaluation

The clinical outcome was measured using Oxford hip score and SF12 for both groups, the forms were used in two languages Arabic and English, the Arabic form was translated through the institutional medical research center by a certified translator.

The radiological progression of the AVN stage was assessed by comparing radiographs before and after treatment. All radiographs and MRI images were reviewed and staged by a musculoskeletal radiologist.

Satisfactory clinical outcome was defined as an OHS score of over 30 and no further surgical interventions. Radiological progression was identified with more advanced stages in post-treatment radiographs.

### 2.3. Core Decompression surgical technique

After preoperative optimization of the patient. The procedure was performed under general anesthesia by an orthopedic hip specialist with the aid of an image intensifier. All patients were positioned in a supine position on a fracture table. The core decompression was performed using the direct lateral approach with a 2 cm skin incision. A fluoroscopic guided large single drill with 8 mm diameter over a guidewire was used to remove the necrotic tissues from the femur head through the lateral cortex distal to the trochanteric tubercle. After the removal of the core necrotic bone, the track was filled with a 5 ml synthetic bone paste substitute (tricalcium phosphate) and intraoperative fluoroscopy was used to confirm the adequacy of the decompression and grafting.

### 2.4. Post-operative management

All patients received cefazoline for 24 hours. Active movement of the knee and hip were encouraged, and patients were allowed a protected weight-bearing for at least 6 weeks, followed by partial weight-bearing for 6 weeks then full weight-bearing after 12 weeks from the surgery. Clinical follow-up was scheduled at 2 weeks, 6 weeks 3 months, 6 months, and 12 months then annually.

### 2.5. Hyperbaric Oxygen Therapy

After optimization of patients, each patient had received between 25 and 40 sessions of HBO therapy, with 3–4 sessions per week to avoid any possibility of oxygen toxicity. The treatment protocol was delivered by a HBO therapy specialist and involved breathing 100% oxygen at 22.5 pounds per square inch (2.2 atm) in a hyperbaric oxygen pressure chamber for 90 min. With additional 15 min for decompression till reaching 22.5 pounds per square inch, two air breaks of 5 min and 15 min for recompression back to surface. Each patient was provided with a well-sealed breathing mask from which he or she received the oxygen treatment.

### 2.6. Data analysis

Descriptive statistics were used to summarize the patients' demographics, comorbidities, and radiological measurements. Chi-square test and Fisher Exact test were used to express the associations between two or more qualitative variables, whereas unpaired Student *t*-test was used to compare the quantitative data (Oxford Hip Score & SF12) between the two groups. Frequency (percentage) and mean  $\pm$  SD or median and range were used as appropriate for categorical and continuous values. The result was considered statistically significant if the *P* value  $\leq$  0.05. All statistical analyzes were done using statistical packages SPSS 23.0 (SPSS Inc. Chicago, IL) and Epi InfoTM 2000 (Centers for Disease Control and Prevention, Atlanta, GA).

No sample size calculations were performed before conducting this study, because all patients who met the inclusion criteria were included.

## 3. Results

### 3.1. Demographic data

Nineteen patients with 23 pre-collapsed stage II non-traumatic AVN of the femoral head were included, 12 (52.2%) in the CD and 11 (47.8%) in the HBO group with an average of  $39.5 \pm 13$  sessions.

9 (47.3%) males, 10 (52.7%) females, the average age was  $35.2 \pm 9.8$  years with an average BMI  $27.3 \pm 4.3$  and follow-up was  $34.2 \pm 18.4$  months.

Risk factors were observed in 6 cases on steroids, 4 smokers, 1 DM, 3 sickle cell disease, 2 alcoholics, and 7 cases with no risk factors. Table 1 summarizes the patients' demographics.

### 3.2. Functional outcomes

66.7% of patients in the CD group at one year follow-up have a satisfactory hip function with statistically significant mean Oxford Hip Score of  $35.8 \pm 6.7$  (Pp value = 0.009), the mean SF 12 PCS of  $43 \pm 10.1$ , and SF 12 of MCS  $39 \pm 12.2$  with no statistical significance (P value 0.0797 & 0.975) respectively (Table 2).

81.8% of patient in the HBO group at one year follow up have satisfactory hip function with a statistically significant mean Oxford Hip Score of  $35.5 \pm 5.1$  (P value 0.003), the mean SF 12 PCS of  $45.3 \pm 9.8$ , and SF 12 MCS of  $45.1 \pm 15.2$  with no statistical significance (P value 0.128 & 0.670) respectively (Table 2).

However, there is no statistical difference of Oxford Hip Score and SF12 (PCS and MCS) between the CD and HBO groups. (P value 0.202,

**Table 1**  
Patients' Demographics.

Total AVN* Number	Total 19 patients/23 hips	CD** 12 (52.2%)	HBO*** 11 (47.8%)	P value
<b>Lateralilty</b>	Unilateral	15 (78.9%)	–	–
	Bilateral	4 (21.1%)	–	–
<b>Side</b>	Right	12 (52.1%)	8	0.146
	Left	11 (47.9%)	4	0.146
<b>Age (years)</b>	35.2 ± 9.8	35.4 ± 10.5	35.1 ± 9.5	0.951
<b>BMI #</b>	27.3 ± 4.3	29.1 ± 3.3	25.2 ± 4.5	0.43
<b>Gender</b>	Male	9 (47.3%)	5	0.809
	Female	10 (52.7%)	5	0.809
<b>Risk Factors</b>	Alcohol	1 (5.3%)	2	0.660
	DM ##	1 (5.3%)	1	0.330
	Smoking	4 (21.1%)	2	0.906
	SCD ###	3 (15.8%)	1	0.466
	Steroid	6 (31.6%)	3	0.876
	No risk factor	7 (5.3%)	3	0.466
<b>Follow up (Months)</b>	34.2 ± 18.4	48.7 ± 13.3	18.2 ± 4.2	<0.001

\* = AVN: Avascular Necrosis, \*\* = CD: Core Decompression, \*\*\* = HBO: Hyperbaric Oxygen Therapy.  
# = BMI: Body Mass Index, ## = DM: Diabetes Mellitus, ### = SCD: Sickle Cell Disease.

0.128 & 0.670) respectively (Table 2).

### 3.3. Radiological outcome

Eight cases (34.7%) (5 in CD and 3 in HBO) progressed to a higher stage, whereas 15 (65.3%) (7 in CD and 8 in HBO) did not progress at one-year follow-up radiographs. The rate of progression was not statistically significant between both groups (P value 0.469) (Table 3).

The mean OHS was 31.3 ± 9.5 and 32.6 ± 8 in the progressed and non-progressed groups with no statistical difference (P value 0.747) (Table 3).

The mean of SF12 PCS and MCS was (40.1 ± 11 and 42.2 ± 9.8) and (44.8 ± 9.6 and 40.5 ± 12.9) in the progressed and non-progressed groups with no statistically significant (P value 0.648 & 0.416) respectively.

No further surgical interventions or Total Hip Arthroplasty were undertaken, and no complications were reported throughout the follow-up in both groups.

### 4. Discussion

The primary goal of treatment for early stages of femoral head AVN was to control pain, preserve the femoral head, delay progression, and

**Table 2**  
Clinical Functional Outcomes.

Outcomes	CD*			HBO**			P value
	Satisfactory	Non-Satisfactory	P	Satisfactory	Non-Satisfactory	P	
Number	8 (66.7%)	4 (33.3%)	<b>0.001</b>	9 (81.8%)	2 (18.2%)	<b>0.001</b>	0.408
OHS***	35.8 ± 6.7	21.7 ± 8	<b>0.009</b>	35.5 ± 5.1	23 ± 5.6	<b>0.003</b>	0.202
SF12 PCS#	43 ± 10.1	31.8 ± 7	0.079	45.3 ± 9.8	36.9 ± 5.3	0.063	0.128
SF12 MCS##	39 ± 12.2	38.8 ± 4.6	0.975	45.1 ± 15.2	46.4 ± 5.2	0.887	0.670

\* = CD: Core Decompression, \*\* = HBO: Hyperbaric Oxygen Therapy, \*\*\* = OHS: Oxford Hip Score, # = SF12 PCS: Short Form 12 Physical Component Summary Scale, ## = SF12 MCS: Short Form 12 Mental Component Summary Scale.

the need for total hip replacement [18].

This study demonstrated satisfactory functional outcome at short-term follow-up in patients who underwent either core decompression or HBO, however, no statistical difference was found between both groups. Additionally, the radiological progression of the disease was noticed in almost one-third of the patients, however, it was not statistically significant (P 0.469) and it did not affect the clinical outcomes in both groups.

Core decompression with or without bone graft augmentation is a simple, safe, and established procedure for the treatment of patients with early stages of AVN femur head [16,19].

Several authors have investigated the core decompression with variable results. The augmentation of CD can be achieved with the addition of several adjuncts such as vascularized bone graft, tantalum rods, bone morphogenic proteins, electromagnetic stimulation, or demineralized bone matrix and bone marrow aspirate [19–25].

Yoon et al. in a retrospective study of 31 patients with 39 hips followed for 61 months have reported success rates of 70% with core decompression alone in Ficat stage I [26]. Also, Ficat et al. in a review article reported a more favorable result of core decompression in stages I and II with a failure rate of 33% [9]. Aigner et al. in a prospective study of 39 patients with 49 hips followed for an average of 68 months have reported a success rate of 66% in stage II treated with core decompression [27].

Scully et al. in a prospective cohort study, with a large sample of 784 patients with a minimum follow up of 21 months, reported that the core decompression with vascularized fibular graft augmentation had superior results than core decompression alone for the prevention of head collapse [28]. Also, Ali et al. in a systematic review of 1252 patients with an average of 61 months, suggested that the vascularized fibular grafting with core decompression is a better treatment option than

**Table 3**  
Radiological Progression and Outcome.

AVN radiological stages *		N(%)	CD **	HBO ***	P value
Pre treatment	Stage 2	23	12 (52.1%)	11 (47.9%)	–
Stage	Progression	8 (34.7%)	5 (62.5%)	3 (37.5%)	0.469
Post treatment	No progression	15 (65.3%)	7 (46.6%)	8 (53.4%)	–
stage					
Outcome		Progression	No progression	P value	
	OHS #	31.3 ± 9.5	32.6 ± 8	0.747	
	SF12 PCS ##	40.1 ± 11	42.2 ± 9.8	0.648	
	SF12 MCS ###	44.8 ± 9.6	40.5 ± 12.9	0.416	

\* = AVN: Avascular Necrosis, \*\* = CD: Core Decompression, \*\*\* = HBO: Hyperbaric Oxygen Therapy.

# = OHS: Oxford Hip Score, ## = SF12 PCS: Short Form 12 Physical Component Summary Scale, ### = SF12 MCS: Short Form 12 Mental Component Summary Scale.

non-vascularized fibular grafting [29].

Hua et al. in a meta-analysis of 1865 patients followed for an average of 54 months, reported that core decompression is an effective and safe method for treating early stages of femoral head AVN and the combined use of autologous bone or bone marrow can increase the success rate [23].

Hyperbaric oxygen therapy was introduced recently as the treatment method for the early stages of femoral head AVN. It acts by targeting the underlying pathophysiology and facilitates oxygenation of hypoxic tissue, reducing edema through creating a high concentration of dissolved oxygen and hence promotes and speeds up healing prior to the collapse of the head [24,30].

Several studies have investigated the role of hyperbaric oxygen therapy in the treatment of femoral head AVN and reported favorable outcome results [18,30,31].

Li et al. studied 623 patients in a meta-analysis, showed that HBO therapy could significantly improve the clinical outcome in patients with femoral head necrosis [32]. While Resi et al. in a retrospective cohort study of 12 patients with a minimum follow-up of 24 months, reported 81% of patients treated with HBO therapy have restored the normal MRI findings in stage I Steinberg [18]. Furthermore, Koren et al. in a retrospective study of 58 hips with a mean follow-up of 11 years, concluded that hyperbaric oxygen therapy is effective in preserving the hip joint when used in stage I and II osteonecrosis of the femur head [30].

#### 4.1. Strength and limitation

There was no previous study that compared the short-term outcome results between these two methods of treatment for AVN.

Limitation of this study includes the small sample size, retrospective design, lack of long-term outcomes and possibility of other confounding factors. The high cost of treatment, duration, and frequency of treatment sessions pose concerns on patient compliance. This could be overcome by conducting a large randomized controlled clinical trial to compare the short- and long-term outcomes.

## 5. Conclusions

This study showed that the Hyperbaric Oxygen Therapy is promising and as effective as the core decompression in the treatment of non-traumatic pre-collapsed AVN of the femoral head. Hence, hyperbaric oxygen therapy could be used as an alternative non-invasive treatment option.

### Disclosures

All authors declared that they have no conflict of interest.

### Ethical approval

Ethical Approval for the study was given by our Institutional IRB, and all subjects provided informed consent to take part in the study.

### Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

### Prior presentation

The study was presented as a podium presentation in SICOT Congress in December 2019.

### Provenance and peer review

Not commissioned, externally peer-reviewed.

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### Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.amsu.2021.01.084>.

### Ethical Approval

Ethical Approval for the study was given by our Institutional IRB with reference number MRC/1401/2017.

### Sources of funding

There are no sources of funding for conducting this study.

### Author contribution

Isam Magamis: Data collection, manuscript writing.  
Abduljabbar Alhammoud: data analysis and manuscript review.  
Osama Kokash: Data collection, manuscript review.  
Ghalib Alhaneedi: First proposal, study design, data analysis, manuscript writing and editing.

### Conflicts of interest

All authors declared that they have no conflict of interest.

### Registration of research studies

1 Name of the registry: Clinical Trial.gov.  
2 Unique Identifying number or registration ID: NCT04657653.  
3 Hyperlink to your specific registration (must be publicly accessible and will be checked): <https://clinicaltrials.gov/ct2/show/NCT04657653>.

### Guarantor

Ghalib Alhaneedi.

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