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ORIGINAL ARTICLE
VENOUS DISEASE

EDITOR'S CHOICE

Effect of stent shape in areas of high compression on patency rates after venous recanalization in patients with chronic venous obstruction

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ABSTRACT

Background: Venous stenting of the obstructed iliofemoral veins has gained significant popularity over recent years due to its efficacy in restoring venous flow and alleviating symptoms associated with chronic venous obstruction (CVO). The success of venous stenting has been demonstrated through high patency rates, even in cases where stents are implanted in areas of high compression. These stents have been observed to adopt an elliptical shape at areas of high compression, deviating from the expected circular morphology that stents are designed to maintain. This phenomenon raises important questions about its potential impact on stent function and long-term patency rates. The objective of this study was to investigate, through a retrospective analysis, the presence and clinical impact of non-circular-shaped venous stents on patency rates.

Methods: From December 2015 to December 2020, a cohort of 115 patients (127 limbs) diagnosed with chronic obstruction of the iliofemoral veins underwent venous angioplasty with stent implantation. Throughout follow-up visits, detailed data were collected, including patient demographics, characteristics, stent types, and ultrasound findings, while especially focusing on the shape and diameter of stents at areas of known external compression, such as the May-Thurner point and under the inguinal ligament.

Results: The average follow-up duration was 21.9±8.7 months. The primary patency rate was 79.5%, with an assisted primary patency rate of 92.1% and a secondary patency rate of 96.7%. All the stents implanted were dedicated venous stents, which demonstrated favorable outcomes overall. However, during the follow-up period, 76.56% of the stents were found to have adopted an elliptical shape at areas of high external compression, regardless of the type or structure of the stent. Interestingly, neither the change in stent shape nor a reduction in stent area of less than 25% showed any statistically significant impact on the overall patency rates.

Conclusions: This study demonstrates that changes in stent shape are to be expected at points of high external pressure. However, as long as these changes do not lead to a severe reduction in stent lumen (<25% of stent area), they do not negatively impact patency rates.

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Key words: Vascular patency; Angioplasty; Stents; Postthrombotic syndrome; May-Thurner Syndrome.

Venous hypertension is the hallmark of chronic venous obstruction (CVO), which typically arises from either thrombotic or non-thrombotic obstructions of the deep venous system. This impairment of venous outflow can result in a broad spectrum of clinical manifestations collectively termed post-thrombotic syndrome. These manifestations range from mild, intermittent leg swelling to severe complications such as persistent pain, leg heaviness, and non-healing venous ulcers. Additional symptoms, including venous claudication and a sensation of leg heaviness, are frequently reported and can significantly impact the quality of life.[1, 2]

Over the past decade, the treatment strategy for iliofemoral or caval CVO has shifted markedly, with open venous reconstruction largely being replaced by minimally invasive endovascular techniques. This transition has been driven by advancements in endovascular materials and procedural approaches, which have improved the safety, efficacy, and durability of these interventions.[3, 4] Dedicated venous stents, in particular, have become an essential adjunct to conservative management for patients with moderate to severe CVO, offering high success and long-term patency rates. Their use is now widely accepted, especially in cases where traditional medical therapies alone fail to adequately address the severity of the clinical symptoms.[1, 3, 5, 6]

Despite the advances in endovascular therapy, a notable challenge has emerged: a significant proportion of implanted stents fail to retain their ideal (in vitro) circular geometry. This change proves particularly significant in areas subject to high external compression, such as the May-Thurner point or beneath the inguinal ligament. While venous stents are engineered with superior radial force to withstand such pressures, they are not immune to external compressive forces that can alter their shape and potentially compromise their patency. By observing the impact of stent geometry alterations in these critical areas, we aim to shed light on potential factors influencing stent performance and ultimately refine the efficacy of endovascular venous interventions.

Materials and methods

A total of 105 patients (127 limbs) with chronic venous obstruction (CVO) who underwent venous angioplasty and stenting between December 2015 and December 2020 at a single center were included in this retrospective analysis. Due to the observational and retrospective nature of this study, it was exempt from an ethics committee approval by adhering to standard regulatory guidelines for retrospective analyses. Data was gathered through reviewing medical records ensuring the inclusion of a broad range of variables. These were patient demographics such as age, sex, and BMI; clinical risk factors such as prior history of thrombosis; coexisting conditions including diabetes, hypertension, and renal impairment; and documented prothrombotic states. Procedural data, such as the type and size of stents used, the precise anatomical location of the obstruction, and details of pre- and post-procedural management, were also recorded. This provided a dataset for subsequent analysis and outcome evaluation.

The intervention process began with venography to visualize venous anatomy and identify the obstructed segments requiring treatment. Navigation through the obstructed segments of the vein was achieved using specialized wires and support catheters, facilitating access across the site of obstruction. Once passed, high-pressure balloons were employed to dilate the obstructed segments, restoring patency and preparing the vessel for stenting. Intravascular ultrasound (IVUS) played a pivotal role in the procedure, allowing for detailed imaging of the vessel lumen and accurate identification of proximal and distal stent landing zones. Post-dilation was performed after stent placement, using a balloon size tailored to the nominal stent diameter, to achieve optimal stent expansion and alignment with the venous wall. Detailed descriptions of these technical aspects, including variations based on individual patient anatomy, have been extensively covered in prior publications.[7]

Post-procedure, conservative treatments were implemented minimize the risk of complications, such as the use of thigh-high compression stockings to support venous

return and minimize edema. An individualized anticoagulation regimen was also a key component of postoperative care. The regimen typically involved the use of new-generation anticoagulants (NOACs), administered for a minimum duration of six months. Adjustments to the anticoagulation protocol were made during follow-up visits based on patient response, coagulation profiles, and any new clinical developments. Early mobilization was strongly encouraged, as it has been shown to reduce venous stasis, improve circulation, and support stent patency.

Follow-up care with DUS were conducted at multiple intervals – 2 weeks, 3 months, and 6 months post-procedure. Patients demonstrating adherence to follow-up protocols were transitioned to annual visits for long-term monitoring. These appointments aimed to assess stent performance, ensure sustained symptom relief, and evaluate the efficacy of ongoing management strategies. During each follow-up, data were collected on subjective changes in symptoms, such as pain, swelling, or heaviness, as well as objective measures, including stent patency, change in circular stent geometry, lumen diameter, and area. Anticoagulation regimens were reviewed and adjusted as necessary to reflect the patient's evolving clinical status.

Duplex ultrasound (DUS) was the primary imaging modality used during follow-up evaluations, providing a non-invasive means of assessing stent geometry, morphology, and patency. The Philips iU22 ultrasound system (Philips Healthcare, Best, the Netherlands) equipped with a 5-10 MHz curved transducer optimized for venous imaging was utilized for all DUS evaluations. Measurements were taken at multiple stent levels, including proximal, distal, mid-segment, and at points of known external compression, such as the May-Thurner point or beneath the inguinal ligament. These detailed measurements ensured proper evaluation of stent performance and identification of areas at risk of restenosis or occlusion. Stent area was calculated using the formula: Pi* x (major axis÷2) x (minor axis÷2), enabling quantification of the degree of compression at various points in patent and occluded stents.

A patent stent was characterized by adequate radial expansion and unobstructed venous flow, ensuring the alleviation of initial obstruction or narrowing, as well as the symptoms associated with venous hypertension. Primary patency was defined as uninterrupted patency without any need for reintervention following the initial procedure. Assisted primary patency referred to instances where prophylactic measures, such as balloon angioplasty, were employed to maintain patency in the absence of occlusion. Secondary patency was defined as restoration of patency following occlusion, achieved through additional interventions. These definitions allowed for standardized evaluation of outcomes and facilitated comparisons with other studies in the field.

Statistical analysis

Statistical analysis was performed using the IBM SPSS software package version 20.0 (Armonk, NY: IBM Corp). Kurtosis and skewness were employed to assess the normality of distribution of variables. The Kolmogorov-Smirnov was used to verify the normality of distribution of variables; Comparisons between groups for categorical variables were assessed using Chi-square Test (Fisher or Monte Carlo). Student's *t*-test was used to compare two groups for normally distributed quantitative variables. Mann Whitney test was used to compare between two groups for not normally distributed quantitative variables. Binary Logistic regression analysis was used to detect the most affecting factor for occlusion. Kaplan-Meier survival curve was used for the relation with overall patency. Significance of the obtained results was judged at the 5% level.

Results

This study included a cohort of 105 patients, of whom 22 individuals (20.9%) underwent bilateral treatment of the iliofemoral venous segment, resulting in a total of 127 treated limbs. Among the study population, 48 patients were men, and 57 were women, with a mean age of 41.5 years (aged 16-70). Of the total cohort, 80 patients retained stent patency up to the last recorded follow-up. Notably, left-sided chronic venous obstruction (CVO) was more common, observed in 65.7% of cases. Additionally, 43 patients (40.9%) were diagnosed with May-Thurner Syndrome, reflecting the substantial prevalence of this condition among individuals with iliofemoral venous disease.

Analysis of patient demographic and clinical characteristics revealed no significant correlation to stent patency (Table I). During follow-up visits, data collection was undertaken to assess changes in stent characteristics and patient outcomes. Information on anticoagulation regimens, stent measurements, stent area, and shape was gathered and evaluated. Despite this detailed assessment, also no direct correlation was identified between these variables and overall stent patency (Table II). The data did however show that 84% of stents placed at the May-Thurner point, as well as 66% of stents located under the inguinal ligament, underwent a noticeable shape change. Further investigation showed that a reduction in stent area by less than 25%, did not impact stent patency.

Table I.—*Patient characteristics according to number of limbs.*

Characteristics	Open (N.=100)	Occluded (N.=27)	Missing data	P value
Gender			0%	
Male	49 (49.0%)	13 (48.1%)		0.937
Female	51 (51.0%)	14 (51.9%)		
Age at the time of operation				
Mean±SD	44.69±13.86	38.33±15.55		0.041
Median (range)	47 (20-69)	39 (16-70)		
BMI (kg/m^2)				
Mean±SD	26.95±5.7	25.44±4.6		0.207
Median (range)	26.27 (13.96-45.64)	24.57 (18.6-36.2)		
History of DVT	78 (78%)	23 (85.2%)		0.412
Thrombophilia	15 (15%)	6 (22.2%)		0.388
Side				
Right	27 (27.0%)	6 (22.2%)		0.615
Left	73 (73.0%)	21 (77.8%)		

BMI: Body Mass Index; DVT: deep vein thrombosis.

Table II.—*Data collected during follow-up according to number of limbs.*

Parameters	Open (N.=80)	Occluded (N.=25)	Missing data	P value
Anticoagulation	80/80 (100.0%)	25/25 (100.0%)		–
Duration (months)	(N.=68)	(N.=24)	12.3%	
Mean±SD	20.5±16.9	23.3±17.6		0.463
Median (range)	14 (1-67)	17 (1-58)		
Shape of stent at MTP	(N.=58)	(N.=17)	28.5%	
Round	8 (14%)	4 (23%)		0.451
Elliptical	50 (86%)	13 (77%)		
Shape of stent at groin	(N.=39)	(N.=14)	49.5%	
Round	11 (28%)	7 (50%)		0.191
Elliptical	28 (72%)	7 (50%)		
Decrease in the maximum stent diameter from nominal to last FU (MTP)	(N.=50)	(N.=16)	37.1%	
Mean±SD	0.05±3.24	0.24±2.67		0.799
Median (range)	0.60 (-6.90 – 4.80)	0.10 (-3.40 – 5.70)		
Decrease in the minimum stent diameter from nominal to last FU (MTP)	(N.=48)	(N.=16)	39%	
Mean±SD	4.48±3.19	3.80±3.12		0.490
Median (range)	4.30 (-6.60 – 12.10)	3.85 (-3.10 – 8.40)		
Decrease in the maximum stent diameter measurement from nominal to last FU (groin)	(N.=31)	(N.=13)	58.1%	
Mean±SD	1.85±1.16	2.32±3.33		0.241
Median (range)	1.90 (-1.0-4.40)	1.10 (0.0-12.43)		
Decrease in the minimal stent diameter measurement from nominal to last FU (groin)	(N.=31)	(N.=13)	58.1%	
Mean±SD	2.78±1.48	3.26±3.53		0.681
Median (range)	2.80 (-0.20 – 6.0)	2.20 (0.0-12.43)		

MTP: May-Thurner point; FU: follow-up.

Due to the lack of sufficient number of patients with stenosis higher than 25% in this study's population, no further relevant results could be drawn regarding the effect of higher degree of stenosis on stent occlusion. As such, the relationship between higher degrees of stenosis and stent occlusion remains an area requiring further investigation with larger patient cohorts and more extensive datasets (Table III).

Similarly, data regarding procedural variables, such as intervention duration, the number of stents deployed, and stent types used, showed no statistically relevant association with long-term stent patency (Table IV). These find-

Table III.—*Comparison between open and occluded stents according to decrease area in first control from last control during the follow-up controls according to number of limbs.*

Decrease area in first control from last control	Open	Occluded	χ^2	MCp
MTP	(N.=45)	(N.=16)		
<25	36 (80.0%)	14 (87.5%)	0.944	1.000
25- <50	5 (11.1%)	2 (12.5%)		
50- <75	2 (4.4%)	0 (0%)		
≥75	2 (4.4%)	0 (0%)		
Groin	(N.=30)	(N.=13)		
<25	27 (90.0%)	10 (76.9%)	2.680	0.297
25- <50	2 (6.7%)	3 (23.1%)		
50- <75	0 (0%)	0 (0%)		
≥75	1 (3.3%)	0 (0%)		

χ^2: chi square test; MC: Monte Carlo.
MCp: P value for comparing between open and occluded.

Table IV.—*Intervention details according to number of limbs.*

Parameters	Open (N.=100)	Occluded (N.=27)	Missing data	P value
Duration of intervention (min)				
Mean±SD	199.3±116.1	239.8±147.1		0.248
Median (range)	170 (44-655)	203 (29-519)		
Total number of stents				
Mean±SD	3.14±1.84	3.44±2.49		0.904
Median (range)	2.5 (1-8)	2.0 (1-8)		
Type of stent used in groin	(N.=50)	(N.=15)	38.1%	
Sinus venous	26 (52.0%)	10 (66.7%)		0.493
Venovo	18 (36.0%)	3 (20.0%)		
Abre	6 (12.0%)	2 (13.3%)		
Type of Stent used in MTP	(N.=68)	(N.=20)	16.1%	
Sinus Venous®	25 (36.8%)	12 (60.0%)		0.064
Venovo®	30 (44.1%)	4 (20.0%)		0.052
Abre®	7 (10.3%)	1 (5.0%)		0.676
Sinus Obliquus®	4 (5.9%)	1 (5.0%)		1.000
Veniti-vici®	2 (2.9%)	2 (10.0%)		0.221

min: minutes; MTP: May-Thurner point.

ings suggest that other factors may play a role in determining the outcomes of venous stenting.

Out of the 127 treated limbs, stent occlusion was observed in 28 limbs, corresponding to an overall occlusion rate of approximately 22%. The median time to stent occlusion was 9.9 months following the procedure. During the mean follow-up period of 21.9±8.7 months, primary patency, assisted primary patency, and secondary patency rates were documented as 79.5%, 92.1%, and 96.7%, respectively (Figure 1, 2).

Analysis of follow-up data also revealed that all implanted stents exhibited a reduction in area compared to their nominal dimensions. This reduction was accompanied by changes in stent shape, with the majority (76.56%) transitioning from their typical round, *in-vitro* configuration to an elliptical shape when observed *in vivo*. However, despite this notable alteration in geometry, no statistically significant correlation between the modified stent shape and stent patency could be established. This suggests that stents may retain functional effectiveness despite changes in their morphology.

Discussion

The first significant observation was that 84% of stents placed at the May-Thurner point, as well as 66% of stents located under the inguinal ligament, underwent a noticeable shape change. Specifically, these stents no longer maintained their circular form but instead became elliptical-shaped. The second major finding was that this shape change was consistent across all types of dedicated venous stents, irrespective of their structural design. Stent materials and mechanical properties appeared to have little effect

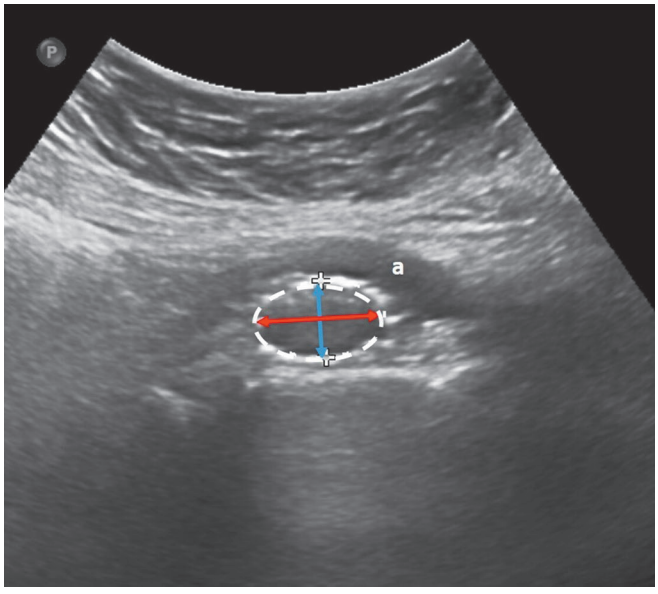

Figure 1.—Ultrasound images in a patient with May-Thurner Syndrome treated using a stent with a diameter of 16 mm. External compression due to overriding right common iliac artery (A) results in an elliptical shape (dotted line) and decrease in intraluminal area (measured: 1.57 cm^2, expected: 2.01 cm^2). Short axis (vertical arrow): 1.12 cm, long axis (horizontal arrow): 1.79 cm.

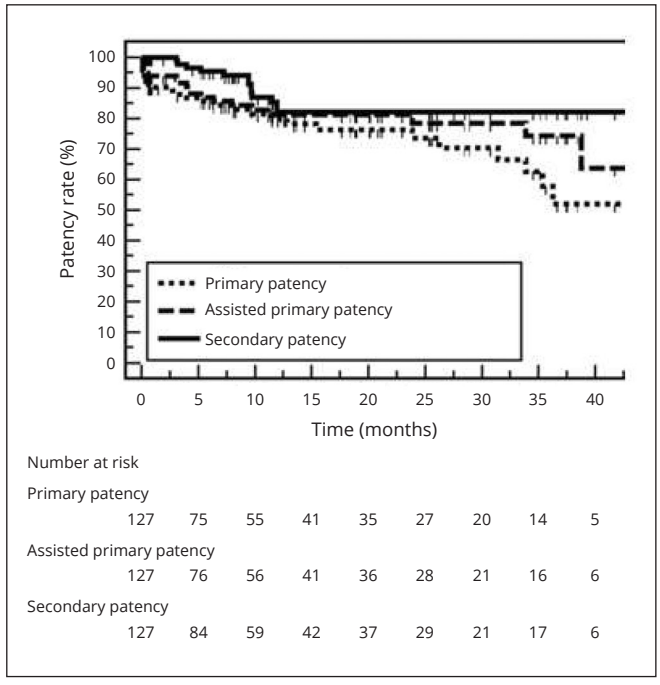

Figure 2.—Cumulative primary assisted primary and secondary patency rates after iliofemoral stenting (all standard errors of the mean <10%).

on preventing the occurrence of this alteration. The third result was that stents that had developed an elliptical shape at regions of maximal external compression did not exhibit any increased tendency to occlude. Finally, the study found that even a reduction of stent area by as much as 25% had no negative impact on patency rates, challenging assumptions that narrowing the lumen necessarily leads to increased occlusion risk.

Current literature revealed that the use of dedicated venous stents in the treatment of obstructive venous pathologies is an excellent choice and contributes to a favorable effect on patency rates.[7, 8] In the current study sample, different dedicated venous stents were used to yield better results owing to their high flexibility and radial force.[9] Despite differences in the mechanical properties of these stents,[10] a decrease in diameter was constantly observed when compared to the nominal measurements after implantation.[11] This decrease was also evident in all types of venous stents, even those with high radial force.[12] This has been previously reported in different studies. Data from our study shows that changes of aspect ratio in segments with high external compression are to be expected, especially at areas of pre-existing anatomical external compression.

Prior theoretical studies, including an *in-vitro* analysis by Raju *et al.*, suggested that a reduction in caliber or aspect ratio in cases of iliac vein stenosis might lead to peripheral venous hypertension, which in turn could contribute to re-occlusion or the recurrence of symptoms. They emphasized that interventions should aim to not only recanalize but also to restore the vessel's aspect ratio to as close to 1 as possible, which would reflect a circular shape.[10] However, it is important to note that the observed transition from a round to an elliptical shape in stents did not necessarily result in a significant reduction in the luminal area. Consequently, despite changes in stent shape, the clinical impact on blood flow may be minimal, especially if the reduction in area is not significant. The findings from our study support this idea, as changes in stent shape, particularly in the presence of external compression, did not seem to correlate with adverse clinical outcomes. In fact, the data indicated that even a reduction of up to 25% in the stent's cross-sectional area did not influence patency, suggesting that such changes in shape do not lead to loss of patency. Evaluation of the effect of a reduction beyond 25% was not possible as the sampled population with a higher degree of stenosis was not large enough to allow for an adequate conclusion on stent patency to be drawn.

Recurrence of symptoms in patients with venous stents is often associated with disruptions in hemodynamic flow, typically caused by a reduction in the vessel's intralumi-

nal area.[13] Initially, this reduction is compensated for by an increase in blood pressure at the point of stenosis, which helps maintain adequate blood flow. Symptoms usually arise when the degree of stenosis becomes severe enough that these compensatory mechanisms are no longer able to maintain proper circulation. The exact point at which lumen reduction necessitates re-intervention is still debated in the literature, as there is no consensus on the precise degree of narrowing that justifies further treatment. A study by Neglén *et al.* recommended that re-intervention should be considered when the lumen is reduced by more than 50%, regardless of whether the patient exhibits symptoms, in order to prevent impending occlusion.[14] However, other research, such as that by Jayaraj *et al.*, has suggested that re-intervention may be warranted even for stenosis levels below 50%, provided that the patient is symptomatic.[15] Another group of researchers has argued that once in-stent stenosis occurs, it is typically a progressive condition that requires close follow-up and early intervention to prevent further complications.[16] A study by Butts *et al.* stated that that native vein aspect ratio does not determine the initial clinical presentation or Quality of life (QoL) or impact the clinical or QoL outcomes after stenting for Chronic iliofemoral venous obstruction (CIVO). Also that IVUS-determined minimal cross-sectional luminal area and not the aspect ratios should be used for confirmation of the diagnosis of CIVO and to assess the adequacy of stenting.[17]

These divergent views highlight the complexity of decision-making when it comes to managing venous stent patency, and suggest that the need for re-intervention should be based on changes in patients symptoms than solely on imaging findings.

Despite these complexities, the findings of the current study emphasize the importance of considering a variety of factors when evaluating stent patency and making decisions about re-intervention. Changes in stent shape, particularly at sites of external compression, are common and, on their own, do not necessarily correlate with adverse clinical outcomes, such as an increased risk of occlusion. However, when these shape changes are accompanied by the reappearance of symptoms, they are strongly indicative of the need for re-intervention.

Limitations of the study

This study was not without limitations. One major limitation was the use of Doppler ultrasound (DUS) for data collection, which is operator-dependent and subject to limitations related to patient body habitus and artifacts that could interfere with accurate visualization and measurement of the stents. Additionally, the retrospective design of the study meant that certain confounding factors could not be fully controlled, such as non-standardized perioperative documentation and loss of follow-up data due to patient non-compliance. An additional limitation appeared when we were unable to assess the effects of a greater than 25% reduction in stent area due to the relatively small number of patients with higher degrees of stenosis. As the population with severe stenosis was underrepresented, it was not possible to draw conclusions regarding the long-term effects of more pronounced narrowing. This may be due in part to the relatively short median follow-up period of the study. Additional data from longer follow-up periods or larger patient populations could help clarify the effects of severe stenosis and provide more information on the thresholds at which significant lumen reductions might impact stent patency.

Conclusions

In conclusion, change in stent shape is to be expected at points of high external pressure. However, changes without severe reduction of stent lumen (<25% of stent area), have no effect on patency rates.

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Conflicts of interest

Houman Jalaie reports grants and personal fees from Medtronic, BO BARD, Cook, and Boston Scientific, as well as personal fees from Bentley, all outside of the submitted work. Mohammad E. Barbati reports personal fees from Optimed GmbH and BO Bard, outside of the submitted work. All other authors have no conflicts of interest to declare.

Authors' contributions

Sharif Elshafei and Mohamed E. Barbati have given substantial contributions to the conception and design of the manuscript. Sharif Elshafei to acquisition, analysis and interpretation of the data and drafted the manuscript. All authors revised it critically. All authors read and approved the final version of the manuscript.

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