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Original Research

# Hemostatic Effect of Vascular Closure Devices (Exoseal®) Versus Manual Compression After Femoral Artery Access

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**Abstract**
**Background:** From the patient's perspective, managing vascular access sites after percutaneous procedures remains a clinical challenge. Exoseal® is a novel, bioabsorbable vascular closure device (VCD) developed to seal femoral artery puncture sites following diagnostic or interventional procedures using standard 6–7 F introducer sheaths.
**Objectives:** This study aimed to compare the effectiveness and safety of Exoseal® versus manual compression (MC) for hemostasis in patients undergoing transfemoral coronary angiography and percutaneous coronary intervention (PCI).
**Methods:** A total of 566 patients were enrolled, comprising 464 patients undergoing diagnostic coronary angiography and 102 patients undergoing PCI. Among diagnostic cases, 264 received VCD and 200 received MC. In the PCI group, 51 patients each received VCD or MC. Baseline demographic characteristics age, sex, and BMI were comparable between groups.
**Results:** In the diagnostic group, 58% (154/264) of VCD patients and 60% (122/200) of MC patients were male. Mean age was 59.22 ± 13.33 years (VCD) and 57.98 ± 12.97 years (MC). BMI was 28.92 ± 5.22 (VCD) and 29.34 ± 4.98 (MC). In both diagnostic and interventional groups, VCDs were non-inferior to MC regarding vascular complications. Time to hemostasis and ambulation was significantly shorter in the VCD group.
**Conclusion:** VCDs such as Exoseal® offer a safe and effective alternative to MC for femoral access site closure in coronary procedures.

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**Keywords:** vascular access; femoral artery; cardiac catheterization; vascular closure device manual compression; Exoseal®

## Background

A relatively large proportion of patients with ischemic heart disease undergo vascular access procedures at a certain time point in their life (Smilowitz et al., 2012). This procedure is potentially safe apart from complications associated with the local site of access concerning re-bleeding (Schulz-Schüpke et al., 2014). Being frequently accessed and more susceptible to bleeding, the closure of the femoral artery has received great attention (Han et al., 2018). Compared to earlier manual compression closure, in the 1990s a new technique was introduced using devices with adjustable compression degrees according to the requirements, thereby improving efficacy and safety profile compared to manual compression (MC) (Gewalt et al., 2018; Schulz-Schüpke et al., 2014). The procedure of MC based on pressing

the access site through pressing the artery region, this technique is potentially helpful in reducing bleeding and re-bleeding, however, the long term-complications, interaction with patient disease status, and safety profile is not clear (Schulz-Schüpke et al., 2014; Goswami et al., 2014).

One of the main leading cause of death is cardiovascular diseases, mainly ischemic heart diseases are causative for death because decreased oxygen supply to the heart muscle lead to death (Lee et al., 2023). To confirm diagnosis and treat such patient a surgical procedure could re-correct and remove the obstacle of blood supply, hence vascular access procedures could be applied with two available technique, including MC and VCD (Eltelbany et al., 2024). The Exoseal® Vascular closure device (VCD) is a novel bioabsorbable device that is introduced directly through the vascular sheath and deploys a polyglycolic acid plug over the femoral artery. Plug deployment is performed with the help of two distinct positioning features: a pulsatile bleed–back indicator and an additional indication wire. The present study aimed to compare the effectiveness and safety conventional MC and VCD.

# Methods

### Study design and settings

This is a prospective study to evaluate the impact of using a VCD on the local vascular complications of the femoral arterial approach used to access the coronary arterial system in diagnostic and therapeutic angiography from January 2018 to November 2021 at Baghdad Teaching Hospital (Medical City–Cardiac Department, Baghdad).

### Sample

A total of 800 patients underwent the diagnostic and therapeutic procedure, out of which 234 patients were excluded from the study and the remaining 566 patients who were eligible for VCD participated in the study. The enrolled patients were subdivided into 464 patients who have undergone diagnostic coronary angiography (264 patients used VCD procedure versus 200 patients used MC procedure) and 102 patients who have undergone therapeutic angiography (51 patients used VCD procedure and 51 patients used MC procedure).

Using the Seldinger technique under local anaesthesia, the sheath was inserted (either 6F or 7F), the size of the sheath was 6F for the diagnostic procedure and 7F for the interventional procedure, when the procedure finished we visualized the common femoral artery in each patient to see if was fit for the use VCD. Then patients were randomized to either used VCD or MC. Seldinger technique is used because it's a minimal invasive technique with reduced damaging to surrounding tissues and organs. This technique started with small puncture using slim needle which produce only small puncture in target tissue. This will potentially decrease the complication of bleediung or re-bleeding after closure of punctured artery.

### Criteria

Major inclusion criteria: Patients undergoing coronary angiography with 6F or 7F sheath via the common femoral artery, and a diameter of the common femoral artery of >5mm. Major Exclusion Criteria: Exclusion criteria include those patients represented with recent myocardial infarction. Patients with a history of bleeding or platelet disorder were excluded. Patients with pre-existing systemic or cutaneous infection were excluded. Patients with autoimmune disease were also excluded; Patients with severe arterial hypertension (>220/110 mmHg) or overweight patients (BMI>40kg /$m^2$), those previously received thrombolytic therapy or anticoagulant within <24 hours before the procedure were also excluded.

### Device description

The Exoseal® VCD is a novel device designed for the sealing of femoral artery puncture sites in patients who have undergone diagnostic or interventional procedures using a standard 6F and 7F introducer sheath. The device achieves hemostasis utilizing a visually guided deployment mechanism that delivers polyglycolic acid "plug" at the top of the femoral artery, anchored by the neurovascular bundle sheath. The entirely extravascular plug is subsequently hydrolyzed into $CO_2$ and $H_2O$ via Kreb's cycle, over 3 months.

### Data analysis

The data were analysed using SPSS 20 (statistical package for the social sciences version 20, USA). The *Chi–square (X2)* test was used for values less than 5, Fisher exact test or Mid–P exact test was used to calculate the *p value*. Correlation between continuous variables was assessed using the ANOVA test significant *p value* was less than 0.05.

# Results

The patients were divided into two groups; 464 patients underwent a diagnostic procedure and 102 patients underwent PCI procedures. The diagnostic group was also divided into two groups, 264 (46.6%) patients undergone VCD and another

group of about 200(35%) patients undergone MC. The PCI group was also divided into two groups, 51(9%) patients undergoing VCD and another 51 (9%) patients undergoing MC (Table 1).

**Table 1.** The percentage of distribution of patients in the studied group

| Groups | VCD | MC | *p value* |
|---|---|---|---|
| Diagnostic | 264 (46.6%) | 200(35%) | 0.1 |
| PCI | 51 (9%) | 51 (9%) | |

Data expressed as frequency and percentage, *p value* is significant when less than 0.05 using *Chi-Square* test

The demographic criteria of patients undergone VCD and MC after coronary angiographic procedures at baseline, such as gender, age, and BMI were comparable (*p=0.1*) between the two groups (Table 2). The majority of patients were males in both groups; the males were 154/264 (58%) in the VCD group and 122/200 (60%) in the MC group, and the females were 110/264 (41%) in VCD group and 78/200 (39%) in MC group. Age was 59.22±13.33 in the VCD group and 57.98 ±12.97 in the MC group. BMI for enrolled patients was 28.92 +SD 5.22 in the VCD group and 29.34+SD 4.98 in the MC group.

**Table 2.** Patients' demographic and risk factors comparison for both VCD and MC

| Characteristics | | VCD (n=264) | MC (n=200) | $X^2$ *Chi-Square* | *P value* |
|---|---|---|---|---|---|
| Age (mean+SD) | | 59.22±13.33 | 57.96±12.97 | | 0.3 |
| Gender | Male | 154(58%) | 122(60%) | 0.34 | 0.56 |
| | Female | 110(41%) | 78(39%) | | |
| BMI (kg/m2) | (mean±SD) | 28.9±5.2 | 29.4±5 | | 0.3 |
| Chronic diseases | HPT | 182(68%) | 138(69%) | | |
| | DM | 179(67%) | 136(68%) | 1.5 | 0.7 |
| | HF | 64(24%) | 46(23%) | | |
| | CRF | 18(6%) | 20(10%) | | |
| Smoking | | 124(46%) | 108(54%) | 0.8 | 0.07 |
| Antiplatelet | Aspirin | 253(95%) | 199(100%) | | |
| | Clopidogril | 11(4.1%) | 1(0.5%) | 6.3 | 0.044 |
| | Aspirin+Clopidogril | 23(8%) | 15(7.5%) | | |

VCD =vascular closure device, SD=standard deviation, DM=diabetes mellitus, HPT = hypertension; DM, HF =heart failure, CRF =chronic renal failure, BMI=body mass index (kg/m$^2$)

For age and BMI, data expressed as mean±SD, *p value* is significant when less than 0.05 using Two sample t-test.

For gendre,smoking, chronic diseases and used drugs, data expressed as frequency and percentage, *p value* is significant when less than 0.05 using *Chi-Square* test.

The risk factors were nearly similar between VCD and MC groups. The HTN was in 182 /264 (68%) patients in the VCD group versus 138/200 (69%) patients in the MC group; DM was in 179/264(67%)patients in the VCD group versus 136/200(68%) in MC group; HF was 64/264(24%) patients in VCD group versus 46/200(23%) patients in MC group; CRF was 18/264 (6%) patients in VCD group versus 20/200(10%) in MC group; smoking was 124/264 (46%) patients in VCD group compared to 108/200(54%). The number of patients taking aspirin was 253/264(95%) in the VCD group and 199/200(99%) in the MC group, and those taking clopidogrel were 11/264(4.1%) in the VCD group and 1/200(0.5%) in MC group, and those patients both aspirin and clopidogrel were 23/264(8%) in VCD group and 15/200(7.5%) in MC group (Table 2).

The comparison between VCD and MC in the diagnostic procedure according to complications represented as hematoma was 6 (2.27%) cases in VCD versus 7(3.5%) in MC (p= 0.2). While Ecchymosis was in 7 (2.65%) cases in VCD versus 9 (4.5%) in MC (p= 0.089). No case has shown decreased pedal pulse and neural palsy in either group. Re-bleeding was associated with 6(2.2%) cases in VCD compared to 3(1.5%) in MC (p= 0.045). Failure of VCD was 9 (3.4%) (p= 0.001), 5 cases occurred due to plug /device failure to deploy and another 4 because of haemostasis not achieved. All these cases occurred within the first month after the introduction of the system, in three cases the visually guided deployment mechanism did not indicate a safe extravascular plug deployment, the vascular closing procedure was therefore aborted and the system was removed in total (Table 3).

**Table 3.** Comparison Between VCD And MC according to complications

| Complications | VCD (n=264) | MC (n=200) | *P value* |
|---|---|---|---|
| Hematoma (>6 cm) | 6 (2.27%) | 7(3.5%) | 0.2 |
| Ecchymosis (>6 cm) | 7 (2.65%) | 9(4.5%) | 0.089 |
| Decreased pedal pulse | 00(0.0%) | 00(0.0%) | **0.045** |
| Nerve palsy | 00(0.0%) | 00(0.0%) | |
| Re-bleeding | 6 (2.2%) | 3(1.5%) | **0.001** |
| Failure of VCD | 9(3.4%) (n=5) plug /device failure to deployed (n=4) haemostasis not Achieved | 00(0.0%) | |
| Composite endpoint | 28(10.6%) | 19(9.5%) | 0.68 |

VCD=vascular closure device, MC=manual compression
Data expressed as frequency and percentage, *p value* is significant when less than 0.05 using *Chi-Square* test

In all these 9 cases procedures success was not achieved as a result of the aforementioned technical failures and MC was applied. Composite end point was 28(10.6%) in VCD and 19(9.5%) in MC (P= 0.68).
The demographic criteria of patients undergone VCD and MC after PCI procedures at baseline, such as gender, age, and BMI were comparable between the two groups, the majority of patients were male in both groups mean age ±SD was 61.25±9.1 7 in the VCD group and 60.95±8.95 in MC group. The male was 40 (78.4%) in the VCD group and 30 (58.82%) in the MC group, and the female was 19 (37.23%) in the VCD group and 13 (25.49%) in the MC group. BMI for enrolled patients was 26.22±3.22 in the VCD group compared to 25.95±2.98 in the MC group

The risk factors were more prevalent in the MC group compared to the VCD group (*p=0.01*). The HTN was in 39 (76.4%) patients in the VCD group and 138 (69%) patients in the MC group; DM was in 21(41%) patients in the VCD group and 136 (68%) in the MC group; HF was 15(29.4%) patients in VCD group and 46 (23%) patients in MC group; CRF was 7 (13.7%) patients in VCD group and 20 (10%) in MC group; and smoking was 33 (64.7%) patients in VCD group and 108 (54%) in MC group. All patients in both groups were using aspirin and clopidogrel (Table 4).

**Table 4.** Patients demographic and risk factors comparison for both VCD(Exoseal®) and MC in PCI

| Characteristics | | VCD (n=51) | MC (n=51) | $X^2$ *Chi-Square* | *p value* |
|---|---|---|---|---|---|
| Age (mean±SD) | | 61.25±9.17 | 60.95±8.95 | | 0.87 |
| Gender | Male | 40 (78.4%) | 30 (58.82%) | 0.05 | 0.83 |
| | Female | 19(37.23%) | 13(25.49%) | | |
| BMI (kg/m2) | (mean±SD) | 26.22±3.22 | 25.95±2.98 | | 0.66 |
| Chronic diseases | HPT | 39 (76.4%) | 138 (69%) | | |
| | DM | 15 (29.4%) | 136 (68%) | 11.4 | **0.01** |
| | HF | 15 (29.4%) | 46 (23%) | | |
| | CRF | 7 (13.7%) | 20 (10%) | | |
| Smoking | | 33(64.7%) | 108(54%) | | |
| Antiplatelet | Aspirin | 51 (100%) | 51 (100%) | 0 | 1 |
| | Clopidogril | 51 (100%) | 51 (100%) | | |

VCD =vascular closure device, SD=standard deviation , DM=diabetes mellitus, HPT=hypertension; DM, HF =heart failure, CRF =chronic renal failure, BMI=body mass index (kg/m$^2$)

The comparison between VCD and MC in PCI procedure according to complications represented as hematoma > 6cm was 1 (1.9%) in VCD versus 2(3.9%) in MC (*p=0.89*). While ecchymosis >6cm was in 2 (3.9%) in VCD versus 3(5.8%) in MC (*p=0.09*). No case has shown decreased pedal pulse and neural palsy in either group. Rebleeding was 2(3.9%) in VCD compared to 2(3.9%) in MC (p= 0.072). Failure of VCD was 3 (5.8%) compared to no case in the MC group (*p=0.043*). The failure cases were 1 case occurred due to plug /device failure to deploy and another 2 because of haemostasis not achieved the vascular closing procedure was therefore aborted and the system was removed in total. In all these 3 cases

procedures success was not achieved as a result of the aforementioned technical failures and MC was applied. The composite endpoint was 8 (15.7%) in VCD versus 7 (13.7%) in MC (*p=0.67*) (Table 5).

**Table 5.** Comparison Between VCD (Exoseal®) and MC according to complications in PCI

| Complications | VCD (n=264) | MC (n=200) | *p value* |
|---|---|---|---|
| Hematoma (>6 cm) | 1 (1.9%) | 7(3.5%) | 0.89 |
| Ecchymosis (>6 cm) | 2 (3.9%) | 9(4.5%) | 0.09 |
| Decreased pedal pulse | 00(0.0%) | 00(0.0%) | |
| Nerve palsy | 00(0.0%) | 00(0.0%) | |
| Re-bleeding | 2 (3.9%) | 2(3.9%) | 0.072 |
| Failure of VCD | 3(5.8%)<br>(n=1) plug /device failure to deployed<br>(n=2) haemostasis not Achieved | 00(0.0%) | **0.043** |
| Composite endpoint | 8(15.7%) | 7(13.7%) | 0.067 |

PCI=percutaneous coronary intervention, MC=Maternal compression, VCD=vascular closure device, *p value* significant < 0.05

In patients who have undergone diagnostic procedures (CA), the TTH was 2.8±10min. and 18.6±20 min. with (*p=0.002*) in VCD and MC, respectively. Whereas the time to ambulation (TTA) was 2.5±4 hrs and 4.2±13 hrs with (*p=0.003*) in VCD and MC, respectively. In patients who have undergone interventional procedures (PCI), the TTH was 2.9±12 min. and 20±22 min. with (*p=0.001*) in VCD and MC, respectively. Whereas the TTA was 4.8±5 hrs and 9.2±14.2 hrs with (*p=0.001*) in VCD and MC, respectively (Table 6).

**Table 6.** The safety endpoint in CA versus PCI groups

| | Time | VCD | MC | *p value* |
|---|---|---|---|---|
| CA | TTH(min.) | 2.8±10 | 18.6±20 | **0.002** |
| | TTA (hours) | 2.5±4 | 4.2±13 | **0.003** |
| PCI | TTH (min.) | 2.9±12 | 20±22 | **0.001** |
| | TTA (hrs) | 4.8±5 | 9.2±14.2 | **0.001** |

**TTH** = time to hemostasis: from the time the introducer sheath remove to time hemostasis achieved
**TTA** = time to ambulation: from the time the end of CA and PCI till the patient was able to stand and walk without re-bleeding

# Discussion

Achieving hemostasis after vascular access in cardiovascular diagnostic and interventional procedures is crucial. Alongside the time that is needed before the patient can ambulate remain areas of concern in many studies. In the present study, patients who were accessed via the femoral artery to perform diagnostic or interventional coronary procedures were categorized into two groups those who underwent MC and those who were managed by VCD to achieve hemostasis.

We found that the demographic features and risk factors of patients in each group were nearly comparable. Data for each group were analyzed and compared with the other group. The study endpoints for the present study were: the safety endpoint (occurrence of complications until the patient is ready to discharge), and the efficacy endpoint (TTH and TTA) for those who underwent diagnostic or interventional coronary procedures.

In the present study the prevalence of haematoma (larger than 6 cm) in the 6F VCD group was 2.27% and in patients who underwent MC was 3.5%, with no significant difference (*p=0.2*) this was consistent with the result of ECLIPSE randomized trial conducted by Wong et al. (2009), using VCD compared to MC, moreover, this finding was inconsistent with the result obtained by a randomized clinical study conducted by Schulz-Schüpke et al. (2014), using MC versus device. The difference in the incidence of ecchymosis between patients managed by 6F VCD (2.65%) and those managed by manual compression (4.5%) was not significant *p value=0.068.* This finding was in line ECLIPSE randomized trial conducted by Wong et al., who have reported the same rates of hematoma and ecchymosis in MC versus VCD. Lower rate of hematoma 0.6% was reported in an alternative study conducted by (Han et al., 2018) using Exoseal® closure procedures. Nonetheless, this study has used a smaller sample size and most of these patients were using no anticoagulant compared to a higher percentage of anticoagulant users in our study.

Re-bleeding following initial haemostasis occurred in 2.27% of the 6F VCD group, while in 1.5% of MC, the difference was statistically significant this was consistent with the result of the ECLIPSE trial conducted by Wong et al. (2009) and the result of Schulz-Schüpke et al. (2014), this could be attributed to plug behaviour after its delivery. (Han et al., 2018) have also reported a lower rate of bleeding and betterment hemostasis perhaps due to the lower number of anticoagulant users compared to our study. A lower rate of re-bleeding was also reported in a study conducted by Gewalt et al. (2018), which involved 917 patients (re-bleeding 0.2) using VCD and 478 patients (re-bleeding 0.4) using MC, this inconsistency with our study could potentially be explained in the context of coexistence of chronic diseases together in our sample.
No patient in the present study whether underwent VCD or MC experience nerve injury, such as nerve palsy or loss or decrease in the lower extremity distal pulses on the access side, this was consistent with many studies, similarly, Wong et al (ECLIPSE study) reported minimal transient access site related nerve injury 0.4% versus 0% in VCD versus MC, respectively (Wong et al., 2009).

Failure of VCD in our study occurred in 3.4% which include failure to deploy the device or its plug or due to failure to achieve hemostasis after successful delivery, We attributed that to our initial experience as most of this failure occurred in the first two months after VCD introduction in this study. Failure has been reported by Schulz-Schupke et al with a closure device failure rate of [5.3%] vs 184 [12.2%] with the intravascular VCD group, versus the extravascular VCD group, respectively (Schulz-Schüpke et al., 2014). The failure rate in the present study mimic those conducted by Dauerman et al., who attributed the failure to the reduced experience in the initial stage of introducing the devices to the surgical setting (Dauerman et al., 2007), Similarly, failure due to limited experience(Balzer et al., 2001; Warren et al., 1999).

The composite endpoint of the aforementioned access site complications was reached in 10.6% Of the 6F VCD group and 9.5% In the MC group, the difference was statistically not significant(*p=0.68*), this finding was consistent with nearly all reported in (Wong et al., 2009) study (8.5% in VCD and 8.3 in MC) and Schulz-Schupke study (6.9% in VCD and 7.9 in MC)(Schulz-Schüpke et al., 2014). This comparable safety endpoint was also mentioned in Koreny et al and Nikolsky et al study (Koreny et al., 2004; Nikolsky et al., 2004).[8,9] Indeed Applegate et al. and Arora et al. found a lower rate of endpoint complication in those patients who underwent VCD(Applegate et al., 2002; Arora & Agnihotri, 2017). Applegate et al study has used Angioseal® and Perclose® which might be different from Exoseal®. Arora et al study is a meta-analysis and different types of these bio-absorbable VCD with different biomaterials were used. All previously mentioned findings and comparisons led to the conclusion that VCD was not inferior to MC in terms of vascular access-related complications i.e. comparable safety endpoint.

The time required for patients to ambulate after vascular access remains a critical factor in post-procedural care. Shortening the TTA was a critical target for the development of VCD. In the present study the mean TTA was significantly (*p=0.003*) lower in patients who were managed by VCDs (2.5±4.8 hrs) compared to those who underwent MC (4.2±13 hrs.). In Wong et al. study the mean TTA was also significantly (*p=0.0028*) favourable to the 6F VCD group over MC with a mean TTA of 2.54±5.02 hours compared with 6.24±13.34 hours in the MC group. The TTH (time from sheath removal until hemostasis was achieved) is also another target for the present study. The TTH was significantly (*p=0.002*) lower in VCD (2.8±10 minutes) than in MC(18.6±20 minutes), Like in (Wong et al., 2009), the mean TTH was 4.38±11.59 minutes compared with 20.05 ± 22.54 minutes for 6F VCD and MC, respectively, *p<0.0001*. In Stefani et al. study the TTH was 0.5-2 minutes in VCD, and 10-15 in manual compression (*p=0.001*) (Stefani et al., 2021).

The safety and efficacy of VCD were also tested in our study in 102 patients who underwent PCI. They were categorized into two groups: those who were managed by 7F VCD (no =51) and those who were managed by MC (no= 51). The results of each group were analyzed and compared with the other group. The composite safety endpoint (occurrence of vascular access-related complication) in the present study was comparable (*p=0.067*) between the two groups 15.7% In the VCD group and 13.7% in the MC group. The TTA in our study was calculated from the end of the interventional procedure to the time the patient can ambulate which was significantly (*p<0.001*) shorter in VCD (4.8±5 hrs) compared to MC (9.2±14.2 hrs). In the ECLIPSE trial conducted by Wong et al. (2009), TTA was calculated from the time of sheath removal till the time the patient can ambulate. It was also significantly favourable to the 7F VCD group over MC with a mean TTA of 2.64±5.43 hours compared with 6.24±13.34 hours in the MC group P=0.0066. The mean TTH in VCD was also significantly (*p<0.001*) lower in our study, in the VCD group (2.9 ±12 minutes compared to the MC group (20±22 minutes).

This was in agreement with the result of Wong et al (2009) study in which the mean TTH was 3.25±4.25 minutes compared with 20.05±22.54 minutes (*p<0.0001*) for 7F VCD and MC, respectively. Eventually, the efficacy endpoint was significantly more favourable in the present study in 7F VCD compared to MC in a patient undergoing an interventional coronary procedure.

## Conclusion

VCDs are non–inferior to MC regarding vascular access complications both in diagnostic and interventional coronary procedures via the femoral artery. The TTA and TTH were significantly shorter in VCDs compared to MC both in diagnostic

and interventional coronary procedures via the femoral artery. The increase in efficacy of VCD with no trade-off in safety provides a sound rationale for the use of VCD over MC in daily routine. We recommended a larger sample study with follow after 30 days after VCD deployment by clinical examination and by ultrasound to show the complications that may occur.

**Declaration of conflicting interest**
The authors declare no potential conflict of interest.

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**Author contributions**
**Ahmed M. Saeed** contributed to the study design, data collection, and drafting of the initial manuscript. **Mohammed AH. Ayoob** was responsible for data analysis, interpretation of results, and substantial content editing. **Mohammed QK. Alsudany** participated in the literature review, methodology validation, and final revision of the manuscript. All authors have read and approved the final version of the manuscript and take full responsibility for its content.

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