A Simple Scale for Screening Lower-Extremity Arterial Disease as a Possible Cause of Low Back Pain: a Cross-sectional Study Among 542 Subjects



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BACKGROUND: Epidemiological, imaging, and anatomical studies suggest an association between proximal arterial atherosclerosis and development of low back pain (LBP).

OBJECTIVES: We aimed to define (1) the frequency and (2) factors associated with exercise-induced proximal ischemia (EIPI) in individuals with LBP and (3) develop a clinical screening scale.

DESIGN: Monocentric cross-sectional study.

PARTICIPANTS: All patients with history of ongoing LBP referred to our exercise investigation laboratory for exercise transcutaneous oximetry (ex-tcPO₂) between January 2011 and December 2017 (n = 542; mean age, 65.4 ± 10.9 ; 83.9% men).

MAIN MEASURES: EIPI was defined as a decrease from rest of oxygen pressure (DROP) below – 15 mmHg on the lumbar and/or buttock probes. Ex-tcPO₂ is a reliable validated tool for diagnosing EIPI in comparison with arteriography and computed tomography angiography. ExtcPO₂ was performed on a treadmill until symptom manifestation or exhaustion. Clinical data were collected using interview questionnaires, medical file review, and clinical examination.

Highlights

• To date arteriography is recommended as a first approach to proximal ischemia.

 \bullet An arterial contribution to low back pain (LBP) is rare and difficult to diagnose.

• Proximal ischemia at exercise (EIPI) is detectable with transcutaneous oximetry.

Five clinical factors available to the general practitioner can predict EIPI.
These factors could be used to screen for patients to be referred for angiography.

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Received September 12, 2019 Accepted January 13, 2020 Published online May 4, 2020 **KEY RESULTS:** EIPI was diagnosed in 282 patients (52%). Age \leq 70 years (OR, 2.22; 95% CI, 1.35–3.57; p= 0.002), a history of proximal revascularization (OR, 2.64; 95% CI, 1.50–4.65; p= 0.001), use of antiplatelet medication (OR, 1.71; 95% CI, 0.96–3.06; p= 0.069), a relationship between exercise and LBP (OR, 2.61; 95% CI, 1.49–4.57; p= 0.001), and an abnormal ankle to brachial index (OR, 2.87; 95% CI, 1.77–4.66; p< 0.0001) were identified as EIPI predictors. Using these items, we developed a screening scale that showed an area under the receiver operating characteristics curve of .756. At a score of \geq 3, the sensitivity, specificity, and accuracy for EIPI were 84%, 55%, and 71%, respectively.

CONCLUSIONS: EIPI was common among our patients with LBP undergoing ex-TcPO₂. Our screening scale could help better select the patients who require angiography.

KEY WORDS: peripheral arterial disease; low back pain; cardiovascular disease; mass screening.

Abbreviations

ABI	Ankle to brachial index
AHA	American Heart Association
CI	Confidence interval
CVRFs	Cardiovascular risk factors
EIPI	Exercise-induced proximal ischemia
ESC	European Society of Cardiology
Ex-tcPO ₂	Exercise transcutaneous oximetry
LBP	Low back pain
NLR	Negative likelihood ratio
No-EIPI	Absence of exercise-induced proximal ischemia
NPV	Negative predictive value
ORs	Odds ratios
PAOD	Peripheral artery occlusive disease
PLR	Positive likelihood ratio
PPV	Predictive positive value
ROC	Receiver operating characteristics

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INTRODUCTION

Low back pain (LBP) affects 39.9% of the population¹ and includes pain in the lumbar and gluteal regions.² Recurrence or

chronic evolution of LBP occurs in 24 to 50% of individuals.³ Most studies define chronic LBP as LBP lasting for at least 3 months,^{4, 5} which is observed in 15 to 45% of the population.³, ⁶ LBP results in disability and work incapacity, and negatively affects quality of life.⁷ The burden imposed by LBP on the economy of the USA reportedly reaches billions of dollars^{3, 7} and deeply impacts the individual's financial state.⁷ The rising prevalence of LBP and aging of the population underline the importance of optimizing its management.^{3, 4} Approximately 90% of LBP cases are described as non-specific after exclusion of classical causes.⁷ Peripheral artery occlusive disease (PAOD) affects approximately 13% of individuals over the age of 50 years.⁸ It is mainly caused by atherosclerosis that results in arterial stenosis and thereafter a reduction in blood flow in the affected area. Initially asymptomatic at rest, patients may experience intermittent claudication owing to the inability of the vascular system to meet the increased local vascular demand during exercise.⁸ Prevalence of PAOD in patients with LBP is unknown but the association with other cardiovascular disease has been well established.9-11 PAOD in proximal (aorto-iliac) arteries can induce LBP or buttock pain during exercise.¹² Proximal ischemia may be difficult to diagnose^{13, 14} and frequent misdiagnoses occur.¹⁴

Routine ultrasonography lacks sensitivity to proximal claudication¹³ and the ankle to brachial index (ABI) is inadequate for diagnosing internal iliac artery lesions.¹⁵ Consequently, the European Society of Cardiology (ESC) has proposed angiography as the primary approach for the diagnosis of internal iliac artery disease.¹⁶ Physicians need to be able to appropriately identify patients with LBP in whom invasive vascular imaging would be beneficial. Exercise transcutaneous oximetry (ex-tcPO₂) is a reliable validated tool for diagnosing EIPI in comparison with arteriography and computed tomography angiography.^{17–20}

As a result, the aim of this study was to develop a simple, easyto-use scale for screening patients with history of ongoing LBP who have a high probability of having exercise-induced arterial proximal ischemia (EIPI) as a possible cause of their LBP, and as such that should be referred for vascular investigations. To achieve this, we first determined the frequency of EIPI among patients with history of ongoing LBP referred to us for treadmill testing. Second, we identified factors associated with positive ex-TCP02 (a measure of EIPI) among these patients. Third, we tested our screening tool in a second "validation" group.

MATERIALS AND METHODS

Subjects

This cross-sectional study was conducted between January 2011 and December 2017 at the exercise investigation laboratory of our University Hospital and included individuals referred for extcPO₂. The inclusion criteria were exercise-related symptoms of potentially vascular origin and presence of a history of ongoing LBP, at referral for ex-tcPO₂. If more than one test had been performed, we only considered the first test for the present study (results for eventual retests are reported in the Supplemental Information). Non-French speaking persons, adults protected by law, or individuals with a contraindication to exercise testing were excluded (e.g., unstable heart disease, inability to walk on a treadmill). As per routine practice, all participants were systematically informed that they had the option to deny the use of their medical file for research purposes. The study was approved by the Local Ethics Committee of our University Hospital (ref no. 2016-108).

Clinical Data Collection

Clinical data were collected using an interview questionnaire, medical record review, and clinical examination. LBP was defined as the presence of pain in the lumbar or para-lumbar region. Pain was considered exercise-related if self-reported absent at rest and present during exercise. Exercise-related pain was considered of a "typical vascular type" if relieved within 10 min of the end of exercise.¹² We recorded morphological data (height, body weight); age; sex; history of proximal (aorta or iliac arteries) and/or distal arterial revascularization; ongoing treatments; symptoms according to the Edinburgh claudication questionnaire, which includes eventual proximal locations (buttocks and/or back)¹²; and cardiovascular risk factors (CVRFs) according to the American and European Guidelines (dyslipidemia, diabetes mellitus, hypertension, active smoking).^{21, 22} If the patient was an active smoker or had stopped smoking less than 3 years ago, smoking status was also considered as a separate item. The ABI of each limb was defined as the ratio of the highest systolic blood pressure at the ankle to the highest systolic blood pressure at the brachial artery and the lower result was included in the analysis.^{23, 24} The ABI was measured as recommended by the American Heart Association (AHA) guidelines, using Doppler examination of the posterior tibial and dorsalis pedis arteries.^{23, 24} ABI values under 0.90 were considered abnormal.^{23, 24}

Exercise-tcPO₂

Ex-TcPO₂ has been developed in our laboratory for EIPI investigations where arterial lesions are less accessible to ultrasound owing to obesity or gaseous interpositions.¹³ Measurements were performed using a tcPO₂ device with 6 probes (TCM 400 Radiometer; Copenhagen, Denmark; or PF6000; Perimed, Järfälla, Sweden). A reference probe was placed on the chest to measure eventual systemic PO₂ changes. Limb probes were positioned as follows: one on each buttock, 4–5 cm behind the bony prominence of the trochanter; one on each calf, 2–4 cm above the ankle; and one in the lumbar region, as close as possible to the location of pain.

Once all probes were positioned, a pre-test heating period of approximately 10 min in the standing position was required to allow stable resting values to be reached. The treadmill test was performed using a 10% slope at a speed of 3.2 km/h. For the few patients who walked 10 m in more than 15 s at a normal pace, the increase in treadmill speed was limited to 2 km/h. Subjects were encouraged to walk at their highest possible speed for the longest time possible. Exercise was discontinued at the subject's request for maximal pain or until exhaustion. A 12-lead electrocardiogram was used to monitor heart during exercise.

TcPO₂ values were recorded for 2 min in the standing position before the treadmill was started, during the walking period, and for 10 min in the standing position after the end of the exercise test. For each sample, the tcPO₂ change from rest in the peripheral location was corrected with the corresponding absolute value of the chest electrode's tcPO2 change to calculate the decrease from rest of oxygen pressure (DROP) index (limb changes minus chest changes from rest). For the analysis, the lowest negative value resulting from this calculation during or within 10 min of the exercise was used. A cutoff point under - 15 mmHg has been validated in previous studies for diagnosing exercise-induced ischemia.^{17, 25, 26} The complete procedure for ex-tcPO₂ measurement has been extensively described elsewhere.¹⁸ Thereafter, subjects were classified according to the presence (EIPI) or absence (No-EIPI) of ischemia involving at least one of the following locations: lumbar and left or right buttock(s).

Statistical Analysis

Categorical data are presented as percentages and were compared using Fisher's exact test. Continuous data are presented as means with standard deviations or medians [25th/75th percentiles] and were compared using the Mann-Whitney test. Missing or unmeasurable data were encoded as noncontributive for the diagnosis ("normal").

The studied sample was randomly divided into a learning group (361 subjects) and a validation group (181 subjects). A screening score for EIPI was developed based on the learning group using multivariate logistic regression from all clinical variables. Odds ratios (ORs) are presented with their confidence intervals (CIs). An initial version of the diagnosis score was based on the linear predictors of the multivariate logistic model. Subsequently, the score was simplified by making all coefficients equal to one to facilitate easy use of the scale. The characteristics of this final score were then studied using the validation group by estimating the area under the receiver operating characteristics (ROC) curve (AUC) and its 95% CI, and the sensitivity, specificity, PPV, NPV, accuracy, and positive and negative likelihood ratio of the score cutoff. All statistical analyses were performed using Stata 13.1 software (StataCorp, College Station, TX).

RESULTS

A flowchart of the studied sample is shown in Figure 1. Only 542 of the 2705 patients, referred to our laboratory during the study period, reported a history of ongoing LBP at time they were referred for ex-TcPO₂ (20%).



Fig. 1 Study flow chart.

As shown in Table 1, subjects were mostly men (83%) with a mean age of 65.4 years. The proportion of CVRFs was high, especially hypertension, dyslipidemia, and tobacco stopped for less than 3 years. Subjects exhibited exercise-related LBP, for a median duration of 2 [1/5] years. A history of previous cardio-/cerebrovascular disease or lower-limb revascularization was found in 71% and 33% of the patients, respectively. Based on the history of revascularization or lower-limb vascular imaging, at referral, only 292 (53.9%) patients had known lower-limb PAOD, and 160 (29.5%) were investigated or treated for suspected osteo-articular disease or sciatica. The mean ABI value was 0.86 and 55% of patients had abnormal results suggestive of PAOD.

EIPI was found in 282 (52%) patients, mostly in the buttocks region with or without associated lumbar ischemia. A typical example is presented in Figure 2. Isolated lumbar EIPI was relatively rare (4% of patients with EIPI). Among the

Table 1 Characteristics of the sample

	MD	No-EIPI	EIPI	р
N	-	260	282	
Age (years)	_	$66.0 \pm$	$64.8 \pm$	0.032
		12.2	9.6	0.002
Height(cm)	-	$79.0 \pm$	$81.4 \pm$	0.025
8 ()		15.7	14.4	
Body weight (kg)	-	$167.6 \pm$	$170.1 \pm$	<
5 6 6		8.3	7.4	0.001
Body mass index (kg/m^2)	-	$28.1 \pm$	$28.1 \pm$	0.732
		5.1	4.5	
Male gender	-	195	258	<
8		(75.3%)	(91.8%)	0.0001
Active smokers		39	59	0.075
		(15.0%)	(20.9%)	
Active smoker or stopped		121	185	<
for less than 3 years		(46.5%)	(65.6%)	0.0001
Diabetes mellitus		67	77	0.698
		(25.8%)	(27.3%)	
hypertension		189	223	0.088
		(72.7%)	(79.1%)	
Dyslipidemia		168	238	<
v 1		(64.6%)	(84.4%)	0.0001
History of lower-limb arterial	revasc	ularization		
Any level		53	126	<
		(20.4%)	(44.7%)	0.0001
Proximal only		33	97	<
		(12.7%)	(34.4%)	0.0001
Known cardio or		175	212	0.46
cerebrovascular disease		(67.3%)	(75.2%)	
Duration of symptoms	34	4.3 ± 5.3	4.3 ± 4.4	0.297
(years)				
Chronic evolution (>		233	255	1
3 months)		(95.9%)	(96.2%)	
Pain description				
Exercise-related pain	3	164	233	<
		(63.6%)	(82.9%)	0.0001
Typical vascular pain	6	20	11	0.065
		(7.8%)	(3.9%)	
Ongoing antiplatelet		167	246	<
treatment		(64.2%)	(87.2%)	0.0001
ABI result				
Mean value	11	$0.94 \pm$	$0.79 \pm$	<
		0.28	0.25	0.0001
Proportion of ABI under		103	191	<
0.9		(40.2%)	(69.5%)	0.0001
Associated distal ischemia		33	270	<
on ex-tcPO ₂		(12.7%)	(95.7%)	0.0001

ABI, ankle-brachial index; EIPI, exercise-induced proximal ischemia; MD, missing or unmeasurable value patients with EIPI, bilateral buttock ischemia was found in 71% of patients with lumbar ischemia and in only 39% of patients without lumbar ischemia (p < .0001).

The step-by-step linear regression analysis of the learning group identified the following 4 factors: an age \leq 70 years old (OR, 2.22; 95% CI, 1.35–3.57; p = .002), a history of proximal revascularization (OR, 2.64; 95% CI, 1.50–4.65; p = .001), relationship between exercise and LBP (OR, 2.61; 95% CI, 1.49–4.57; p = .001), and an abnormal ABI (OR, 2.87; 95% CI, 1.77–4.66; p < .0001). The use of antiplatelet medication was not a significant factor (OR, 1.71; 95% CI, 0.96–3.06; p = .069) but a high degree of association was observed, and it improved the questionnaire's performance. Therefore, this fifth item was maintained in the final scale (Fig. 3).

The developed scale was then applied to the validation group. The results are presented in Figure 4 and Table 2. No differences between the learning and validation groups were observed, except for active tobacco use or discontinuation for less than 3 years more frequent in the validation with No-EIPI group. The use of the exact coefficients for each factor instead of the equivalent 1-point per item did not lead to a significantly better AUC than the simplified tool (Fig. 4). The AUC for the 5-item scale was .756 (95% CI, .687–.825), which was significantly different from random choice (p < .01), confirming the performance of the proposed scale in our population.

DISCUSSION

Three important observations were made during the present study. First, LBP was associated with EIPI in more than half of the patients in our specific series. Second, four items (age, history of proximal revascularization, relationship between exercise and LBP, and abnormal ABI) were associated with the presence of EIPI. Third, from these four items and an additional question concerning antiplatelet treatment, a clinical and easy-to-use scale (0 to 5 points) was developed to screen for patients having a high probability of EIPI and as such should be referred for angiography.

The proportion of EIPI was high in patients referred for LBP, compared with the 10 to 20% prevalence found in our usual exercise-related lower-limb pain population.¹⁸ Vascularization of the lumbar region originates from the lumbar arteries arising from the abdominal aorta, while the lower lumbar area (from the fifth lumbar vertebra to the sacrum) depends on the medial sacral or ilio-lumbar arteries.^{5, 26–28} Buttock circulation is mainly attributed to the ipsilateral hypogastric and lumbar pathways, which share de facto common arteries with the lumbar region.³¹ This last point justifies an approach based on assessment of EIPI in both the buttocks and lumbar regions.^{2, 5, 28–32} The presence of lumbar ischemia during ex-tcPO₂ seems a sign of aorto-iliac rather than hypogastric lesions, as shown by the significant association with bilateral buttock ischemia.



Fig. 2 Subject 122, a 39-year-old woman with no vascular history who was assessed for exercise-related buttock and low back pain. Bilateral proximal ischemia was shown on exercise transcutaneous oximetry (ex-tcPO₂). Computed tomography angiography showed atheromatous

rig. 2 Subject 122, a 39-year-old woman with no vascmar instory who was assessed for exercise-related buttock and low back pain. Bhateran proximal ischemia was shown on exercise transcutaneous oximetry (ex-tcPO₂). Computed tomography angiography showed atheromatous stenosis (red arrow) from the distal abdominal aorta (orange star) to the common iliac arteries (double orange stars) on 3D reconstruction and axial section (from left to right: L3 level, L3-L4 intervertebral disk level, and L4 level). Then, the subject underwent implantation of "kissingstents" in the distal abdominal aorta and the pain was subsequently relieved. No further tests were performed postoperatively. DROP decrease from rest of oxygen pressure.

Previous studies on the associations between cardiovascular diseases and LBP were only concerned with epidemiological,^{10, 32–34} anatomical,^{5, 28} or imaging factors^{27, 32, 35–40} rather than objective measurement of EIPI. The prevalence of impaired lumbar arteries was 57 to 58% in a non-selected population³² and ranged from 19 to 78% in the LBP population in a postmortem angiographic study involving 140 subjects.²⁸ In 228 non-selected male subjects, a significant association was found between arterial stenosis of at least two arteries and duration of sciatica (OR 2.70), intensity of LBP (OR 1.38), and leg pain (OR 1.32).³⁵ Furthermore, a positive

correlation was found between both lumbar and aortic atherosclerosis and degenerative spinal disease, especially lumbar intervertebral disk (LID) degeneration.⁴⁰ The LID is an avascular tissue that relies on the diffusion of nutrients from surrounding structures, making it particularly sensitive to ischemia.³⁹ The proportion of EIPI in the studied sample was high, in accordance with the rate of lumbar arterial stenoses or occlusions found in previous anatomic and radiological studies^{27, 28, 35, 37, 40} whereas LBP does not appear to be more prevalent in our laboratory recruitment than in the global population.^{3, 6}



Fig. 3 Screening scale for proximal ischemia among subjects with low back pain. Please note that the questionnaire is to be used by the treating physician, not the subject.



Fig. 4 Receiving operating characteristic curves for the screening questionnaire with or without the coefficients and the item, "antiplatelet medication."

PAOD and LBP share common risk factors.^{3, 41–45} LBP is associated with aortic calcification.^{32, 33} cardiovascular disease, and cerebrovascular disease in women¹⁰ and appears to be a significant risk factor for death due to ischemic heart disease.³⁴ Contrary to previous results,³² younger age appeared to be a pejorative factor in our cohort. The mean age of our sample was older and this should be associated with more comorbidities (such as spine osteoarthritis) that may contribute to LBP. Dyslipidemia was more prevalent in the EIPI group, which is consistent with previous results.^{27, 45} The ABI is recommended for diagnosing PAOD but can give results within normal limits, especially in cases involving proximal lesions.¹⁵ It cannot be used alone to screen for EIPI but may be useful when combined with another modality, as shown in our study. Ultrasound imaging was not included among studied items, because on the one hand our aim was to use only items readily available to the general practitioner, and on the other hand as previously suggested ultrasound imaging was shown of poor performance in proximal claudication diagnosis.¹³

For screening, a high sensitivity is required; thereafter, a cutoff point of 3 points or more seems to be a good compromise

to screen for EIPI. The AUC of our scale (.756) is similar to those for the revised and simplified Geneva score (.75 and .74) for screening pulmonary embolism⁴⁶ or the Framingham Heart Study's risk scoring system for coronary heart disease (.74 for men, .78 for women).⁴⁷

Study Limitations

One limitation of our study is that the cutoff for DROP in the lumbar position in comparison with the calf and buttock positions was not validated.^{17, 25, 26} Nevertheless, isolated lumbar ischemia was noted in only 14 subjects (5% of those with EIPI). Second, we did not use post-exercise ABI or penile-pressure to detect PAOD, or blood samples to objectively detect diabetes mellitus or dyslipidemia. Our approach was to use routine clinical parameters that are immediately available at the bedside for the general practitioners. Third, spinal clinical investigation findings (e.g., flexibility extensibility, pain measurement) were not available since the exercise investigations were mainly performed by sports or vascular physicians. Nevertheless, our purpose was not to disregard an osteo-articular origin but rather to detect vascular disease as a potential cause of

Table 2	Interpretation	of	screening	questionnai	re
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Score	Sensibility	Specificity	Accuracy	PPV	NPV	PLR	NLR
>0	100%	0%	57%	57%	100%	1.0	
>1	100%	4%	58%	58%	100%	1.0	0.0
$\frac{-}{2}$	96%	29%	67%	64%	84%	1.3	0.1
$\frac{-}{3}$	84%	55%	71%	71%	72%	1.8	0.3
≥ 4	44%	88%	63%	83%	54%	3.8	0.6
5	14%	96%	50%	83%	46%	3.6	0.9

PPV, positive predictive value; NPV, negative predictive value; PLR, positive likelihood ratio; NLR, negative likelihood ratio

or contributor to LBP.28, 32, 36, 40, 48 Our study did not include follow-up assessments and could not draw conclusions on treatment efficacy. However, our own experience (as well as previous studies) suggests that arterial surgery (when possible) is effective for LBP symptoms in patients with high aortic occlusion and abdominal aortic aneurvsms.⁴⁹ We have also estimated the consequences of the detection of EIPI in our sample (reported in the appendices section). Lastly, the subjects investigated in our laboratory are mainly but non-exclusively recruited by vascular specialists.¹⁸ It could contribute to the high proportion of subjects with EIPI found in our sample, and result in a selection bias. However, previous studies have underlined that around one-third of patients with chronic LBP reported a history of cardiovascular disease.^{9, 10} Also, LBP or radicular pain have been previously associated with high prevalence of cardiovascular risk factor such as smoking,⁴³ dyslipidemia,⁴⁵ diabetes mellitus,⁵⁰ hypertension, and family cardiovascular disease.⁵¹ Beyond its implication for LBP, detecting EIPI has direct clinical implications for the risk and prevention of cardiovascular sequelae.^{8, 23,} ^{24, 52} PAOD has been found to be associated with a higher risk of developing ischemic heart and cerebrovascular disease, carotid and renal artery stenosis, cardiac conditions, and death from cardiovascular disease.^{8, 23, 24, 52} Both American (American College of Cardiology (ACC) and AHA) and European (ESC) societies have agreed on key aspects of management, namely, reduction of CVRFs, physical activity, diet optimization, statin use, antiplatelet therapy if PAOD is symptomatic (ESC) or not (AHA/ AAC), and screening for aortic aneurysms (AHA/ACC) or heart failure (ESC).^{23, 24} Vascular surgery can be proposed depending on the functional consequences, location, and extent of the lesion.^{23, 24} Roughly, assuming a 5% prevalence of EIPI among 1000 patients with chronic unexplained LBP (one tenth of the one found in our group), screening with our scale rather than referring systematically to injected angiography would save more than 400 useless injected radiological investigations while missing only 8 patients (<1%).

CONCLUSION

The pathogenesis of LBP is multifactorial. Physicians should keep in mind a possible arterial origin in patients with unexplained LBP that—when possible—may benefit from specific arterial revascularization. The proposed 5-item quick and simple clinical scale to select subjects to be referred for arterial angiography remains to be externally validated on a nonselected LBP population. **Corresponding Author:** M. Gahier, MD; Sports Medicine and Exercise Investigations University Hospital, Angers, France (e-mail: matthieu.gahier@hotmail.fr).

Author's Contribution SH and PA did the conception or design of the work; MG, JH, YS, JFH, and AB participated to the acquisition, analysis, or interpretation of data. MG, SH, and PA drafted the work, JH, YS, SFH, and AB revised it critically for important intellectual content; All authors approved the final version to be published and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Compliance with Ethical Standards:

The study was approved by the Local Ethics Committee of our University Hospital (ref no. 2016-108).

Conflict of Interest: None declared.

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