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● *Original Contribution*

OPTIMAL ULTRASOUND CRITERIA FOR GRADING STENOSIS OF THE SUPERFICIAL FEMORAL ARTERY

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Abstract—This retrospective study determined the duplex ultrasound scanning criteria for detecting 50%–69% and 70%–99% stenosis of the superficial femoral artery (SFA). Examinations of 278 limbs in 185 patients with peripheral arterial disease were performed. Duplex ultrasound scanning was used to measure the diameter of the vascular lumen, the peak systolic velocity (PSV) at the stenotic segment of the SFA (PSV_{st}), the segment proximal to the stenosis (PSV_{pro}) and the popliteal artery (PSV_{pop}, distal to the stenosis). The ratios PSV_{st}/PSV_{pro} and PSV_{st}/PSV_{pop} were calculated. Receiver operator characteristic curves were plotted, with digital subtraction angiography as the reference. PSV_{st} and PSV_{st}/PSV_{pop} had the highest diagnostic value for stenosis. Cut-off thresholds were: for 50%–69% stenosis, $PSV_{st} \geq 210$ cm/s, $PSV_{st}/PSV_{pop} \geq 2.5$, with PSV_{st} the better parameter; for 70%–99% stenosis, $PSV_{st} \geq 275$ cm/s, $PSV_{st}/PSV_{pop} \geq 4.0$, with PSV_{st}/PSV_{pop} superior. PSV_{st}/PSV_{pop} may be a better parameter than PSV_{st}/PSV_{pro} for diagnosing SFA stenosis. (E-mail:)

Key Words: **Duplex ultrasound, Superficial femoral artery, Stenosis, Diagnostic criteria, Grade, Atherosclerosis.**

INTRODUCTION

Peripheral artery disease can lead to critical limb ischemia, intermittent claudication, gangrene or even necessitate amputation (Conte et al. 2015). In the lower extremities, the superficial femoral artery (SFA) is the most common artery to undergo arteriosclerotic stenosis or occlusion, which will affect blood perfusion of the entire limb (Kasapis and Gurm 2009). Therefore, accurate assessment of the severity of the lesion in the SFA is essential to formulate a therapeutic strategy.

Duplex ultrasound scanning (DUS) is a non-invasive technique for the clinical screening of peripheral artery disease (Rooke et al. 2013). Cossman et al. (1989) established ultrasound criteria for the diagnosis of lower limb arterial disease based on changes in peak systolic velocity (PSV) at the stenotic segment of the SFA (PSV_{st}) and the ratio of PSV_{st} to the PSV of the segment proximal to the stenosis (PSV_{pro}), that is, PSV_{st}/PSV_{pro}. However, their cut-off value for PSV_{st}, at 400 cm/s, was high for detecting severe stenosis and lowered diagnostic sensitivity. Since then, a series of studies have reported various optimal PSV_{st} and PSV_{st}/PSV_{pro} cut-off values for differentiating moderate and severe stenosis (Favaretto et al. 2007; Khan et al. 2011; Ramaswami et al. 1999; Ranke et al. 1992).

Regarding ultrasonic diagnosis of SFA stenosis, those studies mainly focused on the ratio PSV_{st}/PSV_{pro}, but not on the ratio of PSV_{st} to the PSV distal to the stenotic segment. After placement of the SFA stent, the PSV of the popliteal artery (PSV_{pop}) effectively indicated the blood supply to the distal limb (Gao et al. 2016). Thus, the ratio PSV_{st}/PSV_{pop} may be superior to PSV_{st}/PSV_{pro} for grading the extent of stenosis, because PSV_{pop} reflects more directly the change in blood perfusion after SFA stenosis.

To date, criteria are lacking in China and abroad for hemodynamic parameters of PSV_{st}/PSV_{pop} to evaluate SFA stenosis. Moreover, the optimal cut-off values for DUS-derived PSV_{st} for grading SFA stenosis are still debated.

Through receiver operating characteristic (ROC) curve analysis, the present study determined the optimal cut-off values of PSV_{st} and PSV_{st}/PSV_{pop} for detecting 50%–69% and 70%–99% stenosis of the SFA, using digital subtraction angiography (DSA) as the reference standard. This study may help ultrasonic professionals improve the diagnostic accuracy of SFA stenosis when using DUS.

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Conflicts of Interest: The authors declare no conflict of interest associated with this study.

METHODS

Study population

The Ethics Committee of Xuanwu Hospital, Capital Medical University, Beijing, China, approved the retrospective study protocol. The study population comprised 185 patients (125 men and 60 women; 278 limbs) with a mean age of 70.8 ± 9.5 y (range 47–91 y). These patients were selected from 465 consecutive patients, who presented with symptoms of intermittent claudication, rest pain, foot ulcers or gangrene, underwent peripheral artery DUS examinations at our institution January 2015–December 2016. We further checked the electronic medical record to judge whether the patient was eligible.

The inclusion criteria were as follows: available DUS and DSA data pairs <30 d apart and one or both limbs with SFA stenosis ≥50% as confirmed by DSA. Patients with any of the following were excluded: severe stenosis; occlusion of the aortoiliac artery; femoropopliteal occlusion; or three-bifurcation occlusion of the anterior tibial artery, posterior tibial artery and peroneal artery. In addition, the result of DSA was judged by two independent vascular surgeons. Patients were excluded from this study if the two vascular surgeons had any disagreement concerning the extent of SFA stenosis. Patients were also excluded if the image quality of their ultrasound (*e.g.,* location or angle of sample volume) did not meet the protocol.

The sample size was planned and calculated according to Cossman's study (Cossman et al. 1989). The sensitivity and specificity of the DUS for detecting ≥50% stenosis of the SFA was 72%–97% and 83%–92%, respectively. In our study, the following essential parameters were used for sample size calculation: acceptable error 9%; sensitivity 72%; specificity 83%; α value 0.05; and $Z\alpha$ value 1.96. Thus, ≥96 limbs were necessary for the lesion group and ≥67 limbs were needed for the control group. Finally, we included a total of 278 limbs. These 278 limbs were grouped as ≥50% stenotic (lesion group, 205 limbs), <50% stenotic or normal (control group, 73 limbs). Subject demographic characteristics and lesion characteristics were acquired.

DUS examination

DUS examinations were performed by a team of four physicians who had ≥5 y of vascular ultrasound experience. Each patient was evaluated by two ultrasonic physicians who were blinded to the DSA results. One physician scanned the patient, obtained the data and stored the acquired images in digital format in Picture Archiving and Communication Systems (DJ Health Union Systems, Shang Hai, China). The other physician checked the image quality based on the vascular ultrasound protocol (Zwiebel and Pellerito 2012). A Philips ultrasound system (IU-22, Philips, Bothell, WA, USA) with a 3.0–9.0 MHz linear array probe and a 2.0–5.0 MHz convex array probe (for relatively obese patients) was used to examine the lower limb arteries. All ultrasound equipment was subjected to rigorous annual inspection for quality control. A Doppler flow phantom (ATS Laboratories, Bridgeport, CT, USA) was used to assess the accuracy of the frequency shift information of the DUS machine.

During the examination, each patient was positioned supine with the hips rotated externally. For evaluating a complete lower extremity artery, the evaluation of each lower extremity began with the common femoral artery, the proximal deep femoral artery and then the entire SFA course. During scanning of the popliteal artery, each patient was supine with the leg externally rotated and flexed at the knee and then the anterior tibial artery, posterior tibial artery and peroneal (fibular) artery below the knee joint were examined.

With the use of appropriate compression, the structure of the lower limb arteries was visualized. The residual diameter of the stenotic segment and the diameter of the original lumen were detected in B-mode. When the residual diameter was not revealed clearly in B-mode, we measured it under the color mode guide. In this study, we measured the vessel diameter for morphologic observation, as routine, but did not analyze this parameter. Under the color mode, the location of aliasing because the arterial stenosis was determined, which facilitated precise placement of the sample volume for spectral waveform analysis.

To assess the flow velocity using DUS with spectral analysis, at the stenotic segment of the SFA, we measured the PSV and diastolic reverse velocity or end diastolic velocity (EDV). In addition, the PSV of the segments proximal and distal to the stenosis were measured (PSV_{pro} and PSV_{pop}, respectively; Figs. 1–3). Specifically, the PSV_{pro} was measured in the normal lumen just proximal to the stenosis and the PSV_{pop} was determined in the normal lumen of the popliteal artery. The ratios PSV_{st}/PSV_{pro} and PSV_{st}/PSV_{pop} were calculated. When measuring velocity, the angle between the ultrasound beam and blood flow was set at ≤60°. The gate on the active scan line was carefully adjusted so that spurious movement could not contaminate the frequency shift data. By manual movement of the angle-corrected scan line, the maximum velocity in the stenotic area could be determined. The velocity was automatically measured by the instrument's spectral envelope. If the curve could not completely envelope the spectra because of narrow turbulence or other factors, we measured the velocity manually.

DSA examination

DSA was used as the reference for defining and grading stenosis of the SFA. Within 30 d of the DUS examination, all patients underwent DSA for the evaluation