ORIGINAL RESEARCH

Predictive Value of Quantitative Duplex Ultrasound Analysis for In-stent Carotid Artery Restenosis

Zhen Liu, MM; Yan Pan, MM; Qingdong Zhang, MM; Xiaofei Wang, MM

ABSTRACT

Context • In-stent restenosis (ISR) is a common clinical complication after carotid artery stenting (CAS) and a major risk for a stent's fatigue life. Duplex ultrasound (DUS) is widely used for the preliminary evaluation and follow-up of extracranial carotid artery disease, but DUS stenosis grading is mainly based on the original or nonsurgical carotid artery. That grading may not be applicable to carotid artery stenosis after CAS.

Objective • The study intended to investigate the predictive value of quantitative analysis of results from the DUS examination in the evaluation of ISR following CAS.

Design • The research team designed a control analysis of result samples.

Setting • The study took place in the Ultrasound Department at the Affiliated Yantai Yuhuangding Hospital of Qingdao University in Yantai, Shandong, China.

Participants • Participants were 103 patients who underwent carotid artery stenting (CAS) between March 2017 and April 2018 at the hospital.

Outcome Measures • The study used Doppler DUS and digital subtraction angiography (DSA) of the carotid artery at 12 months postoperatively to analyze the consistency of DUS and DSA in the evaluation of ISR. Taking the results of the DSA examination as the standard, the research team analyzed the differences between those results and the indicators from the DUS examination for participants with different severities of stenosis. The research team plotted the receiver operating characteristic curve (ROC) and evaluated the diagnostic efficiency of DUS indicators in the determination of restenosis, including diagnostic accuracy, sensitivity, specificity, positive predictive value, and negative predictive value.

Results • The DSA examination showed that stenosis severity was 0%-30% for 51 participants, 31%-50% for 27 participants, 51%-80% for 16 participants, and >80% for 9 participants. The DUS showed that stenosis severity was 0%-30% for 35 participants, 31%-50% for 38 participants, 51%-80% for 22 participants, and >80% for 8 participants. The consistency was found to be Kappa (κ) = 0.74. Taking the DSA as the standard, the peak systolic velocity (PSV), end diastolic velocity (EDV), peak systolic velocity of the internal carotid artery/peak systolic velocity of the common carotid artery (PSVICA/PSVCCA) significantly increased in participants with a stenosis severity of 51-80% and >80%, compared with those with a stenosis severity of <50%, and the difference was statistically significant ($P < .05$). The ROC curve showed that the area under curve (AUC) of the PSV predicting restenosis at a >50% severity was significantly higher than those of the EDV and PSVICA/PSVCCA ($P < .05$). Where the optimal cut-off-off point for the PSV was 195 cm/s, the ROC curve showed that the AUC of the PSV predicting restenosis at an >80% severity was significantly higher than that of the EDV and PSVICA/PSVCCA ($P < .05$). Where the optimal cut-off point for the PSV was 280 cm/s, the PSV had significantly higher diagnostic accuracy, sensitivity, and positive predictive value than the EDV and PSVICA/PSVCCA in evaluating the restenosis at a severity of >50% and >80%.

Conclusions • Doppler DUS can effectively evaluate restenosis after carotid artery stenting (CAS), where a PSV ≥195 cm/s and 280 cm/s can be used as the reference indicators for >50% and >80% restenosis. (*Altern Ther Health Med.* 2023;29(1):52-57).

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Stroke is one of the major causes of disability and death in middle-aged and older people, and carotid atherosclerosis is the leading cause of carotid artery stenosis. Treatment regimens such as carotid artery stenting (CAS) can serve as both a primary or a secondary prophylaxis of stroke.[1,2] CAS can be an effective treatment for severe carotid artery stenosis and prevention of stroke, but in-stent restenosis (ISR) is a common clinical complication and a major risk for a stent's fatigue life.

Chen's study in China found that unilateral carotid stenosis before admission in patients with carotid stenosis had >50% restenosis and carotid stent implantation patients had >80% stenosis after stenting.[3] Dynamic monitoring of the severity of carotid artery stenosis following CAS is conducive to early intervention and prevention of stroke.

Digital subtraction angiography (DSA) is the gold standard for diagnosing the severity of carotid artery stenosis, and CT angiography (CTA) is also efficacious, but economic factors and radiation emissions can limit their use in postoperative follow-up.[4,5]

As a noninvasive examination, duplex ultrasound (DUS) can provide good diagnostic value for different severities of stenosis after adequate diagnostic tests. An advantage of DUS examination over DSA is the ability to repeat the measurements several times at a lower cost than for DSA and with no risk of contrast-media toxicity, which can provide great convenience for clinical applications.

DUS is widely used for the preliminary evaluation and follow-up of extracranial carotid artery disease, and the severity of carotid artery stenosis is mainly analyzed based on the peak systolic velocity (PSV), end diastolic velocity (EDV), and/or the PSV ratio of the internal carotid artery (ICA) / common carotid artery (CCA), the PSVICA/PSVCCA.

However, as the DUS stenosis grading is mainly based on the original or nonsurgical carotid artery, several studies have found that these evaluation criteria for stenosis aren't applicable to carotid artery stenosis after angioplasty such as CEA and CAS.[6,7] However, no clear clinical definition exists of cut-off criteria for the measurement of ISR severity. Postoperative restenosis at a severity of >50% is generally defined as clinically significant restenosis.[8]

In 2016, Zhou et al found that the main cause of restenosis after CAS is abnormal proliferation of vascular endothelial cells after injury.[9] In addition, stimulation of endothelial cells by operative procedures and implanted stents, as well as activation of platelets and the coagulation system, all have a large impact on the process, and this process develops rapidly in the first 6 months after surgery and maintains stable restenosis at 12-18 months after surgery.[10]

In 2017, Zhou et al found that in ISR the stenotic segment in the arterial lumen blood flow rate changes, changes in blood flow velocity in the stenotic segment in the arterial lumen in ISR and the peak systolic velocity (PSV) threshold is one of the main criteria for grading stenosis of the internal carotid artery, which is the mechanism of DUS for assessing the severity of stenosis.[11]

Wu found that the PSV cut-off value was 90 cm/s for >50% stenosis.[12] In terms of the cut-off value for >80% stenosis, Wo et al and Yang et al found that the PSV value was 210 cm/s according to the ROC curve.[13,14]

Some studies have demonstrated that severe stenosis, for patients with a tendency to restenosis, is generally absent within 6 months postoperatively due to the use of high-dose anticoagulant drugs and that restenosis occurs mostly at 6-12 months.[15,16]

To the knowledge of the current research team, the existing studies on quantitative analysis of use of ultrasound for evaluation of restenosis after carotid artery stenting have mostly been retrospective, with few prospective studies, which may have minimized the possibility of bias affecting the results.

The current study intended to investigate the predictive value of quantitative analysis of results from DUS in the evaluation of ISR following CAS.

METHODS

Participants

The research team designed a controlled study. The study took place in the Ultrasound Department at the Affiliated Yantai Yuhuangding Hospital of Qingdao University in Yantai, Shandong, China. Participants were patients who underwent CAS between March 2017 and April 2018 at the hospital.

Potential participants were included in the study if they: (1) had obvious carotid artery stenosis after DSA examination and underwent CAS, (2) took anticoagulant drugs regularly and received other related treatments after surgery, and (3) showed good revascularization and unobstructed blood flow at the postoperative examination.

Potential participants were excluded from the study if they: (1) had serious complications, such as intimal tear and stent dislodgement, after stenting; (2) were allergic to the contrast media; or (3) couldn't complete the follow-up visits,meets exclusion criteria.

Although there are many cases, some data are insufficient or no further examinations have been carried out, and the screening of cases is nearly 3-5 years, so many patients are not included.

Patients signed informed consent, and the study also met the standards of the ethics committee. It is not yet registered because it is only a sample analysis for imaging assessments, but it complies with the Declaration of Helsinki.

Procedures

The research team performed Doppler DUS and DSA on all participants at 12 months postoperatively to analyze the consistency of the result from the DUS and DSA in the evaluation of ISR.

Ultrasound examination. The examination used a color duplex ultrasound (model LOGIQ E9,General Electric (GE) Company,Boston,United States) with a probe frequency of 6.0-15 MHz. An experienced vascular ultrasonographer independently operated it.

First, the ultrasonographer used the two-dimensional gray-scale imaging mode for continuous scanning of the bilateral carotid arteries, to detect the presence of thrombus and plaque in the surgical vessels. Subsequently, the ultrasonographer switched the device to Doppler mode, with a sampling volume of 1.0 mm and an angular correction of ≤60°, for the measurement of the in-stent flow width and the normal inner diameter at the distal end of the ICA stent.

The research team calculated the stenosis severity using the following formula: stenosis severity = (1 - flow width at the narrowest site of the internal carotid artery (ICA) stent / normal inner diameter at the distal end of the ICA stent) × 100%. After calculating the ICA, the team measured the hemodynamic parameters of the ICA and CCA, including the PSV and EDV, and the PSVICA/PSVCCA at the stenotic segment.[17]

DSA examination. The examination used a 64-row computed tomography (CT) scanner (SOMATOM DefinitionAS64, Siemens, Amberg, Bavaria, Germany) to perform the scan in both the sagittal and the coronal views, which an experienced radiologist evaluated under single-blind conditions, to detect the presence of in-stent stenosis in both the sagittal and the coronal reconstructions.

Using the methods of the North American Symptomatic Carotid Endarterectomy Trial (NASCET),[18] the research team also performed measurements to assess the stenosis severity at the location where the most severe in-stent lumen reduction was present in the sagittal or the coronal reconstructions.

The research team drew lines for wall-to-wall diameter measurements perpendicular to both container walls. The team then calculated the distal reference diameters in the ICA that were distal to the stent, where the lumen diameter of the carotid artery was constant. The research team used these two measured values to calculate the severity of stenosis.

Outcome Measures

The research team analyzed the consistency between the DUS examination's results and those of the DSA examination in the ISR assessment. Taking the stenosis severity found in the DSA examination as the standard, the research team defined three categories of stenosis severity: 0-50% mild stenosis, 51%-80% moderate stenosis, and >80% severe stenosis.

The team compared the PSVs and EDVs of participants fitting into the three categories of stenosis severity as well as their PSVICA/PSVCCA ratios at the stenotic segment after calculation of the ICA. Taking the stenosis severity in the DSA examination as the standard, the research team evaluated the diagnostic efficiency of the DUS indicators in the determination of stenosis, including diagnostic accuracy, sensitivity, specificity, positive predictive value and negative predictive value.

Statistical Analysis

SPSS 22.0 (IBM, Almonk, New York, United States) was used for data analysis. Measurement data were expressed as means ± standard deviations (SDs), and an analysis of variance (ANOVA) was used for comparisons among the three categories of stenosis severity. The Student-Newman-Keuls test was used for paired comparisons, and count data were expressed as number of participants, constituent ratios, n (%). The χ^2 test was used to compare the differences between groups.

The receiver operating characteristic (ROC) curve was plotted to evaluate the efficacy of a separate and combined evaluation of the three categories. The area under the curve (AUC) and its 95% confidence interval, standard error, and *P* value were calculated, and the optimal cut-off point was calculated using the Youden index. The De long method was used for the AUC comparison among the three categories. All tests were two-sided hypothesis tests with a test level of $\alpha = 0.05$. A $P < .05$ level indicated that the difference was statistically significant.

RESULTS

The study included and analyzed the data of 103 participants, involving 103 surgical vessels. Of the 103 participants, 81 were males and 22 were females, aged 47-79 years.

DSA and DUS Results

The DSA examination showed that the stenosis severity was 0%-30% for 51 participants (49.52%), 31%-50% for 27 participants (26.21%), 51%-80% for 16 participants (15.53%), and >80% for 9 participants (8.74%).

The DUS examination showed that the stenosis severity was 0%-30% for 35 participants (33.98%), 31%-50% for 38 participants (36.89%), 51%-80% for 22 participants (21.36%), and >80% for 8 participants (7.77%).

The research team found the consistency between the two examinations to be Kappa (κ) = 0.74, as Table 1 shows.

DUS Indicators and Stenosis Severity

The values for the PSV, EDV, and PSVICA/PSVCCA of the carotid artery gradually increased as participants' stenosis severity increased from 0-50% to 51-80% to >80%, with the values for participants at 0-50% severity being significantly lower than those for participants at >80% severity, with *P* = .000 for all three variables. The evaluation criteria or grading criteria for the carotid artery stenosis rate are different, and this is the grading criteria in this study.

ROC Curve at >50% Severity After CAS

As Figure 1 and Table 3 show, the ROC curve showed that the AUC of the DUS indicators predicting restenosis at

Table 1. Comparison of the Diagnosis Consistency Between DUS and DSA (N = 103)

DUS	DSA 0%-30% n (%)	DSA 31%-50% n (%)	DSA 51%-80% n (%)	DSA >80% n (%)	Total
0%-30%	35 (33.98)	0 (0.00)	0 (0.00)	0 (0.00)	35 (33.98)
31%-50%	10 (9.71)	27 (26.21)	0 (0.00)	1 (0.97)	38 (36.89)
51%-80%	6 (5.83)	0 (0.00)	16 (15.53)	0 (0.00)	22 (21.36)
>80%	0 (0.00)	0 (0.00)	0 0.00 ()	8 (7.77)	8 (7.77)
Total	51 (49.52)	27 (26.21)	16 (15.53)	9 (8.74)	103 (100.00)

Kappa (κ) = 0.74, indicating the consistency between the results of the DSA examination and those of the DUs examination.

Abbreviations: DSA, digital subtraction angiography; DUS, duplex ultrasound.

Table 2. Comparison of DUS Indicators in Participants with Different Severities of Stenosis

Stenosis Severity	Number of Blood Vessels (Vessel)	PSV cm/s	EDV cm/s	PSVICA/ PSVCCA
0-50%	78	162.33 ± 31.42	42.72 ± 11.63	1.42 ± 0.65
51-80%	16	247.38 ± 30.65	56.14 ± 18.75	2.34 ± 0.81
>80%	9	403.04 ± 72.61	76.82 ± 14.44	2.96 ± 1.08
F		194.785	109.775	48.732
P value		.000[a]	.000[a]	.000[a]

[a]$P = .000$, indicating that the values for the three variables for participants at 0-50% severity were significantly lower from those for participants at >80% severity

Abbreviations: EDV, end diastolic velocity; PSV, peak systolic velocity; PSVCCA, peak systolic velocity of the common carotid artery; PSVICA, peak systolic velocity of the internal carotid artery.

Table 3. AUC of the DUS Indicators for Evaluating Restenosis at >50% Severity After CAS

DUS Indicator	Optimal Cut-off Value	AUC	Standard Error	*P* value	95% CI Lower Limit	95% CI Upper Limit
PSV	195	0.967	0.017	.000	0.933	1.000
EDV	53	0.783	0.061	.000	0.663	0.903
PSVICA/ PSVCCA	1.89	0.739	0.066	.000	0.610	0.868

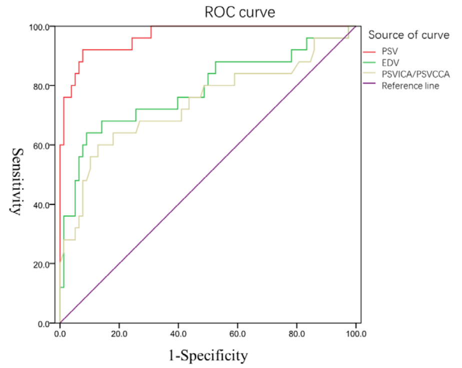
Abbreviations: AUC, area under curve; CAS, carotid artery stenting; EDV, end diastolic velocity; PSV, peak systolic velocity; PSVCCA, peak systolic velocity of the common carotid artery; PSVICA, peak systolic velocity of the internal carotid artery.

Table 4. AUC of DUS Indicators for Evaluating the Restenosis at >80% Severity After CAS

DUS Indicator	Optimal Cut-off Value	AUC	Standard Error	*P* value	95% CI Lower Limit	95% CI Upper Limit
PSV	280	0.993	0.008	.000	0.978	1.000
EDV	78	0.701	0.091	.047	0.522	0.879
PSVICA/ PSVCCA	2.55	0.716	0.101	.033	0.518	0.913

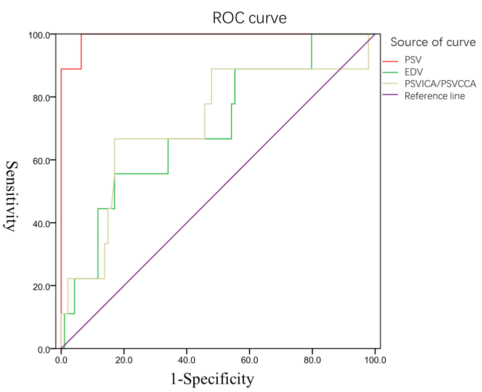
Abbreviations: AUC, area under curve; CAS, carotid artery stenting; EDV, end diastolic velocity; PSV, peak systolic velocity; PSVCCA, peak systolic velocity of the common carotid artery; PSVICA, peak systolic velocity of the internal carotid artery.

Figure 1. ROC Curve of Each DUS Indicator for Evaluating Restenosis at >50% Severity After CAS



Abbreviations: CAS, carotid artery stenting; DUS, duplex ultrasound; EDV, end diastolic velocity; PSV, peak systolic velocity; PSVCCA, peak systolic velocity of the common carotid artery; PSVICA, peak systolic velocity of the internal carotid artery; ROC, receiver operating characteristic.

Figure 2. ROC Curve of Each DUS Indicator for Evaluating Restenosis at >80% Severity After CAS



Abbreviations: CAS, carotid artery stenting; DUS, duplex ultrasound; EDV, end diastolic velocity; PSV, peak systolic velocity; PSVCCA, peak systolic velocity of the common carotid artery; PSVICA, peak systolic velocity of the internal carotid artery; ROC, receiver operating characteristic

>50% severity after CAS was significantly higher for the PSV indicator, at 0.967, than those for the EDV and PSVICA/ PSVCCA indicators, at 0.783 and 0.739, respectively, with the differences in the AUC. Comparison of different blood flow velocities in predicting restenosis >50% severity]

ROC Curve at >80% Severity After CAS

As Figure 2 and Table 4 show, the ROC curve showed that the AUC of the DUS indicators predicting restenosis at >80% severity after CAS was significantly higher for the PSV indicator, at 0.993, than those for the EDV and PSVICA/ PSVCCA indicators, at 0.701 and 0.716, respectively, with the differences in the AUC, at $P = .047$ for the comparison and at $P = .033$ for the comparison of different blood flow velocities in predicting restenosis >80% severity.

Table 5. Diagnostic Efficiency of DUS Indicators in the Determination of ISR

Stenosis Severity	Diagnosis Mode	Accuracy	Sensitivity	Specificity	Positive Predictive Value	Negative Predictive Value
>50%	PSV	96.88%	91.67%	98.61%	95.65%	98.61%
	EDV	90.63%[a]	79.17%[a]	94.44%	82.61%[a]	93.15%
	PSVICA/PSVCCA	89.58%[a]	83.33%[a]	91.67%	76.92%[a]	94.29%
>80%	PSV	94.79%	100.00%	94.19%	66.67%	100.00%
	EDV	84.38%[a]	70.00%[a]	86.05%	36.84%[a]	96.10%
	PSVICA/PSVCCA	86.46%[a]	70.00%[a]	88.37%	41.18%[a]	96.20%

[a]$P < .05$, indicating that the PSV indicator had significantly greater accuracy, sensitivity, and positive predictive value than did the EDV and the PSVICA/PSVCCA indicators at both levels of stenosis severity.

Abbreviations: EDV, end diastolic velocity; ISR, in-stent restenosis; PSV, peak systolic velocity; PSVCCA, peak systolic velocity of the common carotid artery; PSVICA, peak systolic velocity of the internal carotid artery

Diagnostic Efficiency of DUS Indicators

Table 5 shows the results. Based on the ROC curve, the PSV at a stenosis severity of >50% had an optimal cut-off point of 195 cm/s, a diagnostic accuracy was 96.88%, diagnostic sensitivity was 91.67%, and positive predictive value of 95.65%.

Based on the ROC curve, the PSV at a stenosis severity of >80% had an optimal cut-off point of 280 cm/s, a diagnostic accuracy of 94.79%, a diagnostic sensitivity of 100.00%, and a positive predictive value of 66.67%.

The values for the PSV were significantly higher than those for the EDV and PSVICA/PSVCCA in evaluating restenosis ($P < .05$).

DISCUSSION

Restenosis after stenting has been an intractable issue in clinical treatment, and in the current study, 25 participants (24.27%) had >50% restenosis, and 9 participants (8.74%) had >80% stenosis, which is slightly lower than that the findings reported in the past in China,[3] probably due to small sample size.

The low consistency test between DUS and DSA in the current study confirms indirectly the findings from several prior studies that showed that the evaluation criteria for stenosis used for a nonsurgically altered carotid artery aren't applicable to carotid artery stenosis after angioplasty.[6,7]

In the present study, according to the criteria for determining the DSA stenosis severity, the PSV, EDV, and PSVICA/PSVCCA of the carotid artery gradually increased in as participants' stenosis severity increased from 0-50% to 51-80% to >80%, with the values for participants at 0-50% severity being significantly lower than those for participants at >80% severity.

In addition, the ROC curve in the current study showed that when PSV predicts restenosis >50%, the best cutoff point for PSV is 195cm/s; when PSV predicts restenosis >80%, the best cutoff point for PSV is 280cm/s. which is slightly higher than the reported overseas value (125 cm/s).[12]

The current research team proposes that this difference may be caused by the removal of data bias in the current study. The team also demonstrated that that the sensitivity of PSV may increase if the PSV cut-off value is further reduced, but its specificity decreases sharply. This evidence means that patients with <50% stenosis may be considered to have clinically significant stenosis. The research team therefore used an optimal cut-off value based on the position closest to the upper left corner in the ROC curve.

Because DSA technology continuously develops, the image quality may have become clearer, providing the possibility that the technology allowed the current research team to make a more accurate measurement of stenosis severity. If so, it may have shown the association of higher stenosis severity with a higher PSV, providing a higher cut-off value. In terms of the cut-off value for >80% stenosis, the PSV cut-off value in the current study was 280 cm/s according to the ROC curve, which is consistent with the reported value in China and abroad.[12,13] The fact that no significant difference existed in the number of participants with >80% stenosis, as measured by DUS and DSA, compared with participants at >50% stenosis, indicates that DUS alone can detect severe restenosis.

For diagnostic efficiency, based on the cut-off values obtained by ROC in the current study, the DUS PSV indicator had a significantly higher diagnostic accuracy, sensitivity, and positive predictive value than the EDV and ICA/CCA indicators in evaluating the restenosis at a severity of >50% and >80%. This evidence further supports the application of ultrasound measurements of PSV in predicting the severity of postoperative restenosis.

Due to hospital's size and other factors in the current study, the research team analyzed the data of only those patients who had undergone stenting.

In the current study, the follow-up time point was defined at 12 months after surgery, as previous studies have done,[19] and for patients with a tendency to restenosis, severe stenosis is generally absent within the postoperative 6 months due to the use of high-dose anticoagulant drugs, while restenosis occurs mostly between 6 and 12 months.

One issue that the authors would like to discuss with peers is that the variability of events that have occurred in proximal ICA..For example, intimal hyperplasia caused by different factors, in addition to carotid artery stenosis caused by arteriosclerosis, there are also carotid artery stenosis caused by other factors. Carotid artery stenosis, etc. After stenting is rarely investigated, and some stents may produce different PSVs for the ICA when they unfold incompletely, which may affect the bias of final results. For example, among the surgical factors, incomplete stent expansion, long stents (caused by most diseases), non-ionic contrast agents, and insufficient anticoagulation therapy.

Based on the cut-off values obtained in the current study and the chain velocity criterion widely used in ultrasound laboratories, the authors have concluded that the operational procedures for stents can be ignored when PSV is used to determine the severity of arterial stenosis.

CONCLUSIONS

Doppler DUS can effectively evaluate restenosis after CAS, where PSV ≥195 cm/s and 280 cm/s can be used as the reference indicators for >50% and >80% restenosis.

AUTHOR CONTRIBUTIONS

Zhen Liu and Yan Pan both are Co-first authors, contributed equally. Zhen Liu, Methodology, Designing and conducting experiments, Writing-original draft; Yan Pan, Investigation, Data analysis, Writing-original draft. Qingdong Zhang is Co-corresponding author , Writing review & editing, Supervision. Xiaofei Wang is Corresponding author, Project administration, Supervision.

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