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A Study of Sensitivity and Specificity of Color Duplex Ultrasound for the Evaluation of Carotid Artery Stenosis

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Original Research Article

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Abstract: Diagnosis of the carotid artery stenosis is an important tool for reducing the incidence of strokes in patients with comorbidities. Colour duplex ultrasonography is widely used for diagnosing Internal Carotid Artery (ICA) stenosis. Management decision of carotid stenosis is many times based on this technique alone. Therefore we in the present study tried to evaluate the sensitivity, specificity, and accuracy of color duplex ultrasonography compared with a standard for the diagnosis of ICA. Methods: The present study was carried out in the Department of Radiology, Prathima Institute of Medical Sciences, Naganoor, Karimnagar. Routine patients who were referred to the radiology department with comorbidities for evaluation of ICA were included in the study. Results: A total number of 94 patients were included in the study Internal Carotid Artery velocities were recorded and a comparative study was done. Peak Systolic Velocities [PSV] and End Diastolic Velocities [EDV] and percentage of stenosis were calculated. Stenosis based on arteriographic modalities ranged from 0 – 99% (complete occlusion was excluded). The mean stenosis was 74.6% (SD 22.5%). The PSV ranged from 48 – 410 cms/sec and the mean value was 298 cms/sec. The EDV was from 0 to 250 cm/sec (130.2 cm/sec) with a mean value of 82.5 cm/sec. The sensitivity, specificity, and accuracy were then calculated for > 50% stenosis the overall sensitivity was 96.15%, accuracy was 94.95% the specificity was 90.48%, the PPV was 97.40% and NPV was calculated to be 86.36%. The sensitivity, specificity, and accuracy were then calculated for > 70% stenosis the overall sensitivity was 96.43%, accuracy was 93.75% the specificity was 90.00%, the PPV was 93.10% and NPV was calculated to be 94.74%. Conclusion: Within the limitations of the present study it has been concluded that Doppler ultrasonography has acceptable accuracy, sensitivity, and specificity for evaluating the Internal Carotid Artery Stenosis. However, it must be validated from time to time with standards like DSA and CTA.
Keywords: sensitivity, specificity, color duplex ultrasound, carotid artery stenosis.

INTRODUCTION

Atherosclerosis of arteries supplying the brain are the main reasons for the ischemic stroke [1]. Pathophysiologically there are two main mechanisms involved in the development of stroke. An arterio-arterial embolism is the most common cause of stroke. Hemodynamic flow along with perfusion reduction is the cause in the minority of cases [2]. Repair of carotid artery stenosis has been shown to be effective in reducing the chances of embolic strokes from the carotid plaque rupture and embolization to the brain [3]. Clinical trials of carotid artery revascularization methods such as carotid endarterectomy and carotid artery stenting are providing guidance for clinicians regarding the choice of therapy. Conventional arteriography is considered the Gold standard for determining which patient would benefit from the operative interventions. However, risks of angiography include strokes and death [4]. Consequently, some clinicians have advocated endarterectomy on the basis of DUS findings alone, or in combination with magnetic resonance angiography (MRA) or computed tomographic angiography (CTA) [5-8]. Thus lesser invasive techniques with good sensitivity and specificity are solicited as the first step towards diagnosis. Duplex ultrasonography (DUS) is the primary noninvasive screening procedure for evaluation of ICA stenosis and is widely used in clinical practice to select patients for angiography. Several studies have demonstrated the accuracy of ultrasonographic duplex imaging for both moderate and high-grade ICA stenosis using angiography as a reference [9-15] The sensitivity of duplex ultrasonography ranges from 65 to 87% and specificity from 71 – 91% as compared to conventional radiography [16, 17] The sensitivity and specificity of the DUS is also operator dependent and is limited by anatomic variations and plaque morphology. Several studies have demonstrated the accuracy of B-mode

imaging in predicting grade of stenosis [18-20] However, in severe disease, adequate B-mode images may be difficult to obtain, as more complex and heavily calcified plaques create shadowing and other artifacts that impair correct plaque measurements. Therefore the severe stenosis hemodynamic criteria are used. The correlation between the degree of stenosis and velocity is demonstrated by the "Spencer's [21]. This has proven to be a reliable criterion for grading stenosis [21, 22]. Therefore we in the present study tried to evaluate the ICA using the color Doppler ultrasonography compared it with conventional standards of CTA and standard angiography to calculate the sensitivity, specificity, and accuracy of DUS for diagnosis internal carotid artery stenosis.

MATERIALS AND METHODS

This study was conducted in the Department of Radiology, Prathima Institute of Medical Sciences, Naganoor, Karimnagar. This was a prospective cross-sectional study. Institutional Ethical Committee permission was obtained for the study. Written consent was obtained from all the patients involved in the study after explaining the procedure of the study and possible outcomes in their local language. The patients were selected from those undergoing routine examinations in the Department of General Medicine suspected of having high risks of developing carotid artery stenosis. Excluded patients were those detected with stroke, cerebral hemorrhage found using CT scans, severe heart disease, and other vascular diseases. A total of 94 patients were included in this study during the two year study period from March 2016 to Feb 2018. The patients underwent examination with Color Doppler Ultrasound Machine give a visual representation of the movement of blood through veins, blood vessels, and arteries. The Examination was performed using several scanners. A standard 7.5 MHz linear array transducer was used with 5 Mhz Doppler frequency both longitudinal and transverse views of Internal Carotid Artery and Common Carotid Artery were examined bilaterally. Peak ICA, Peak Systolic Velocity [PSV], End Diastolic Velocity [EDV] and ICA/CCA ratios were recorded. The results obtained were correlated with Standard measurements of *Digital subtraction angiography* [DSA] and Computed Tomographic Arteriography [CTA] considered as gold standards. The measurements obtained were in accordance with NASCET criteria [23]. The obtained data was put is MS Excel and analyzed using SPSS software.

RESULTS

A total number of 94 patients were included in the study Internal Carotid Artery velocities were recorded and a comparative study was done. Peak Systolic Velocities [PSV] and End Diastolic Velocities [EDV] and percentage of stenosis were calculated. Stenosis based on arteriographic modalities ranged from 0 – 99% (complete occlusion was excluded). The mean stenosis was 74.6% (SD 22.5%). The PSV ranged from 48 – 410 cms/sec and the median was 298 cms/sec. The EDV was from 0 to 250 cm/sec (130.2 cm/sec) with a median of 82.5 cm/sec.

Table 1 shows the duplex ultrasound criteria for internal carotid artery stenosis they were categorized based on the Peak Systolic Velocity [PSV] and End Diastolic Velocity in centimeters per second. Those with peak systolic velocities of less than 135 cm/sec and EDV with < 40 cm/sec were classified with < 50% stenosis. Those with PSV of 136 – 151cm/sec and EDV of 41 – 50 cm/sec were having 50 – 59% stenosis similarly those with PSV of 152 – 182 and EDV of 51 – 60 cm/sec were having 60 – 69% and those with > 251 cm/sec and > 81 cm/sec were having 80 -90% stenosis.

Table-1: Duplex ultrasound criteria for internal carotid artery stenosis.

Range of Stenosis	PSV cm/sec	EDV cm/sec
< 50%	<135	< 40
50 – 59%	136 - 151	41 - 50
60 – 69%	152 - 182	51 – 60
70 – 79%	182 – 251	61 – 81
80 – 99%	> 251	> 81

When the carotid duplex was compared with standard comparison using NASCET criteria it was established by angiographic calculation of ICA stenosis percentage using the following formula: % ICA stenosis = (1 - [narrowest ICA diameter/diameter normal distal cervical ICA]) x 100. True positive were 75 and false positive were 2 true negatives were 19 and false negative were 3 given in table 2.

Table 2: Color duplex findings in the standard comparison

Carotid duplex findings	Standard comparison	
	> 50%	< 50 %
> 50 %	75	2
< 50%	3	19

The sensitivity, specificity, and accuracy were then calculated for > 50% stenosis the overall sensitivity was 96.15%, accuracy was 94.95% the specificity was 90.48%, the PPV was 97.40% and NPV was calculated to be 86.36% shown in table 3.

Table-3: Sensitivity, Specificity and accuracy

Statistic	Average Percentage	95% Confidence Interval
Sensitivity	96.15 %	89.17 – 99.20 %
Specificity	90.48 %	69.62 – 98.83 %
PPV	97.40 %	90.93 - 99.29 %
NPV	86.36 %	67.43 – 95.09 %
Accuracy	94.95 %	88.61 – 98.34 %

The carotid duplex ultrasonography of > 70% as compared to the standard measurements the true positive was 54 and false positive was 4 the true negative were 36 and false negative was 2 shown in table 4.

Table-4: Color duplex findings in the standard comparison

Carotid duplex findings	Standard comparison	
	> 70%	< 70%
> 70%	54	4
< 70%	2	36

The sensitivity, specificity, and accuracy were then calculated for > 70% stenosis the overall sensitivity was 96.43%, accuracy was 93.75% the specificity was 90.00%, the PPV was 93.10% and NPV was calculated to be 94.74% shown in table 5.

Table-5: Sensitivity, Specificity and accuracy

Statistic	Average Percentage	95% Confidence Interval
Sensitivity	96.43 %	87.69 – 99.56 %
Specificity	90.00 %	79.34 – 97.21 %
PPV	93.10 %	84.18 - 97.16 %
NPV	94.74 %	82.13 – 98.60%
Accuracy	93.75 %	86.89 – 97.67 %

DISCUSSION

The measurements with color Doppler sonography are now becoming a standard procedure in the diagnosis of carotid diameter stenosis before suing angiographic examination. The CD is considered to be the least invasive and most commonly used imaging technique. However, the results of CD obtaining PSV and EDV must be continuously validated using gold standards like DSA and CTA. In the present study, we tried to evaluate the sensitivity, specificity, and accuracy of Internal Carotid Artery stenosis versus DSA and CTA examinations. Carotid endarterectomy (CEA) guidelines in symptomatic carotid artery stenosis are based on ECST and NASCET (North American Symptomatic Carotid Endarterectomy Trial) criteria of ≥70% carotid stenosis as estimated from angiography [24]. A NASCET 50% to 69% stenosis is equivalent to an ECST ≥70%, while a NASCET 70% to 99% stenosis equates to an ECST ≥ 80% [25]. Symptomatic patients with 70% or more of stenosis of carotid artery have a lower risk of developing subsequent cerebral infraction if treated with endarterectomy [26, 27]. The PSV in the ICA appears to be the single best criteria for detecting and quantifying stenosis [28]. It is also the earliest value to be obtained. Some studies have determined optimal sonographic criteria for identifying ICA Stenosis of 70% or more, the threshold PSV has raged from 130 to 325 cm/sec. The PSV of most studies has averaged at 200 cm/sec. In the present study, we found the average velocities of about 298 cm/sec. In a similar study done by Jon CH *et al;* [29] found the PSV values ranged from 23 to 638 cm/s and had a median of 315 cm/s our values were close to these values. The relationship between Doppler velocity and angiographic stenosis within the significant stenosis range of interventional trials is poor. The sensitivity and specificity of the test only improve when a large number of cases with minimal or no stenosis are included. In this study the sensitivity, specificity, and accuracy were then calculated for > 50% stenosis the overall sensitivity was 96.15%, accuracy was 94.95% the specificity was 90.48%, the PPV was 97.40% and NPV was calculated to be 86.36%. The sensitivity, specificity, and accuracy were then calculated for > 70% stenosis the overall sensitivity was 96.43%, accuracy was 93.75% the specificity was 90.00%, the PPV was 93.10% and NPV was calculated to be 94.74%. Jon CH *et al;* [29] found Overall accuracy for detecting >50% stenosis by CD neared 95% whereas overall accuracy for detecting >70% stenosis was over 92%. AbuRahma *et al.* tested

the SRU criteria in comparing the CD and angiographic findings. [14] They concluded that the criteria for diagnosing a > 70% stenosis were appropriate using SRU criteria and there was a scope of improvement in 50-69% category. Raising the threshold of PSV from 125cm/sec to 140cm/sec improved the overall accuracy from 85% to 92% and sensitivity from 93% to 94% and specificity from 68% to 92% they also did not find EDV to add further value in diagnostic accuracy. In this study, the PSV was used as a primary parameter in assessing the percentage of carotid stenosis. The results of this study we in agreement with other similar studies with regard to sensitivity, specificity, accuracy and positive predictive value [30 -32].

CONCLUSION

Within the limitations of the present study, it has been concluded that Doppler ultrasonography has acceptable accuracy, sensitivity, and specificity for evaluating the Internal Carotid Artery Stenosis. However, it must be validated from time to time with standards like DSA and CTA.

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