Feasibility and Clinical Impact of Point-of-Care Carotid Artery Examinations by Experts using Hand-Held Ultrasound Devices in Patients with Ischemic Stroke or Transitory Ischemic Attack

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Background and purpose: To evaluate the feasibility and clinical influence of carotid artery examinations in patients admitted with stroke or TIA with hand-held ultrasound by experts, to identify individuals not in need of further carotid artery diagnostics. *Materials and methods:* Cardiologists experienced in carotid ultrasound examined 80 patients admitted to a stroke unit with suspected stroke or TIA with hand-held ultrasound devices (HUD). Grey scale and color Doppler images were stored using a GE Vscan with dual probe (phased array and linear transducer). High-end triplex ultrasound performed by a cardiologist, blinded to the details of the HUD study, was performed in all patients and used as reference. Computer tomography angiography was performed when clinically indicated. *Results:* Stroke or TIA was diagnosed in 62 (78%) patients. Age was median (range) 72 (23−93) years. A significant stenosis (> 50% diameter reduction) was ruled out in 61 (76%) of patients by the HUD examinations. Sensitivity and specificity for diagnosing a significant stenosis was 92% and 93%, respectively. One of 12 significant stenoses was missed by HUD. All four patients in need of surgery were identified by the HUD examination. Sensitivity and specificity to identify a significant stenosis by HUD was 87% and 83%, respectively, compared to CT angiography. *Conclusion:* HUD examinations of the carotid arteries by experts, using hand-held ultrasound devices, were feasible and may reduce the need for high-end diagnostic imaging of the carotid vessels in patients with stroke and TIA. Thus, HUD may improve diagnostic workflow in stroke units in the future.

Key Words: Stroke—Transitory ischemic attack—Carotid stenosis—Hand-held ultrasound—Vascular ultrasound

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Non-standard Abbreviations and Acronyms

HUD	hand-held ultrasound device
HIGH	high-end ultrasound
CTA	computed tomography angiography
ICA	internal carotid artery
CCA	common carotid artery
ECA	external carotid artery
TIA	transitory ischemic attack

Introduction

Stroke represents the 2nd leading cause of mortality and is a leading cause of acquired disability worldwide.[1] Approximately 15% of ischemic strokes are due to occlusive carotid artery disease.[2] Carotid endarterectomy is effective for the prevention of stroke in individuals with transient ischemic attack (TIA) or minor stroke caused by carotid stenosis,[3] but the clinical benefit decreases rapidly from 2 weeks after a TIA.[4,5] Physical examination, and specifically auscultation for carotid bruit, is insufficient to exclude carotid stenosis and select patients for further evaluation.[6] Thus, there is a need for all stroke patients to receive diagnostic imaging. After a minor ischemic event with ipsilateral carotid stenosis, there is a 32% risk of a large ischemic event without surgical intervention,[7] with the majority of events during the first two weeks. Carotid endarterectomy in patients with symptomatic stenosis with at least 70% diameter reduction confers a 16% absolute reduction in stroke or death, but this effect is only significant in the first two weeks after the index event.[8] Thus, a rapid evaluation of the carotid arteries in patients with stroke or TIA is needed,[9] and beyond patient delay, hospital logistics are the major sources of delay in appropriate treatment.[10]

Carotid duplex ultrasound is recommended as the primary examination, while computed tomography angiography (CTA) or magnetic resonance angiography is regarded as confirmatory and discretionary tests.[6] Diagnostic ultrasound has, compared to CTA, the advantage of no ionised radiation or use of contrast agent, and to magnetic resonance angiography, of being more available, less time consuming and feasible regardless of implanted devices and metallic objects. Still, carotid ultrasound examinations are traditionally performed with expensive equipment and specially trained personnel in dedicated laboratories, contributing to a bottleneck in the workflow of stroke departments. Subsequently, there is a risk for delayed treatment.[11]

Advances in microprocessor and ultrasound technology has led to the development of affordable hand-held ultrasound devices (HUD). These diagnostic imaging devices have entered routine clinical use as a tool for focused cardiac and abdominal ultrasound.[12–15] Feasibility and accuracy of HUD as a screening tool for gross cardiac function and abnormalities has been demonstrated in experts[16] and non-expert users.[17,18]

The use of HUDs in detection of atherosclerosis in the carotid arteries for risk stratification in primary prevention of atherosclerotic disease has been presented.[19,20] One study has demonstrated the accuracy of HUDs in examination of carotid arteries prior to coronary artery bypass grafting.[21] Another study investigated the role of mobile ultrasound equipment without color flow Doppler in screening for carotid stenosis in patients with stroke and TIA.[22] The use of HUDs in diagnostic workup of patients with stroke or TIA is not established. We aimed to investigate the feasibility and potential clinical impact of HUDs to detect or exclude significant carotid disease in patients admitted with stroke or TIA when operated by an experienced operator.

Materials and methods

Study population

Patients admitted with stroke or TIA to the non-university stroke unit at Levanger Hospital, Norway were included. Inclusion was limited to days where at least two out of four cardiologists were available (for performing both the HUD and the reference examinations). Exclusion criteria were lack of informed consent or diagnostic imaging of extracranial neck arteries within the last year. Examinations were performed by four cardiologists experienced in carotid ultrasound, whereof all had performed a minimum of 200 (range 200 to approximately 2000) carotid ultrasound examinations prior to inclusion. All operators were also experienced in echocardiography with a minimum of 2000 examinations each.

Written informed consent was obtained from all participants. The study was approved by the Regional Committee for Medical and Health Research Ethics (REK 2013/648) and conducted according to the second Declaration of Helsinki. The study was registered in the ClinicalTrial.gov database (unique ID: NCT0214193).

Examinations of the carotid arteries by hand-held ultrasound devices

A standardised protocol was used. Vascular territories examined were the common carotid artery (CCA), the extracranial internal carotid artery (ICA) and the external carotid artery (ECA). The operator graded the carotid artery disease per territory based on visual assessment of the carotid walls in grayscale recordings and blood flow patterns in color Doppler mode. The atherosclerosis of the arterial territories was graded from 1 through 6 (1; normal, 2; increased intima media thickness, 3; less than 50% stenosis, 4; 50−69% stenosis, 5; 70−99% stenosis, 6; near-occlusion and 7; occluded).

The carotid HUD examinations were performed at the patients' bedside (point-of-care) in the stroke unit using a

Vscan with Dual Probe® (version 1.4; release 1 and 2, GE Ultrasound AS, Horten, Norway). The device was equipped with both a phased array cardiac probe with bandwidth of 1.7−3.8 MHz and a field-of-view of 70° and a linear vascular probe with bandwidth 3.3−8.0 Mhz, an aperture of 2.9 cm and a maximum scanning depth of 8 cm. The device was capable of recording, displaying and storing twodimensional grayscale and color Doppler images and cine-loops. The device had no spectral Doppler capabilities.

Reference imaging by high-end ultrasound

Reference carotid ultrasound was performed by one of the study cardiologists using a high-end scanner (Vivid E9, GE Ultrasound AS with phased array cardiac (M5S) and linear vascular (9L) transducer) in a dedicated clinical ultrasound laboratory. In each case, one cardiologist performed the HUD examination at the patient's bedside while another cardiologist performed the reference carotid ultrasound examinations and echocardiography in the echocardiographic laboratory. Reference imaging was performed with minimal time delay in all patients regardless of the results from the HUD examination. The order of the cardiologists who performed the HUD examination and the reference imaging was random. The cardiologist performing the reference examination was blinded to the results of the HUD examination.

Image quality of the recordings obtained by the hand-held ultrasound was categorised semi-quantitatively as good, moderate or poor by an experienced cardiologist blinded to the clinical data and the results of the carotid examination. If the operator judged the image quality as too poor for diagnostics the instruction was not to use the HUD examination for clinical decisions. Clinical decision making was based on the reference examinations only.

The reference recordings included grayscale, color Doppler and pulsed wave Doppler recordings from CCA, ICA, ECA as well as baseline echocardiographic characteristics and evaluation of cardiac sources of emboli. The carotid artery pathology was graded using the same numerical scale as described for HUD from 1 through 6. Grading of stenoses below 50% was based on visual assessment of color Doppler and grayscale images alone, while distinction between 50−69% stenosis, 70−99% stenosis, near occluded- and occluded vessels was made following the criteria recommended by the American Society of Radiologists in Ultrasound which incorporates Doppler measurements of peak systolic velocities in both the stenosis and the proximal CCA, their ratio and the end-diastolic velocity measured in the ICA.[23]

CTA was performed upon clinical indication and was interpreted by a radiologist blinded to the results from the ultrasound examinations. The degree of the carotid disease was classified according to the European Carotid Surgery Trial method,[24] which measures diameter stenosis as residual lumen diameter divided by estimated original diameter of lumen. Subsequently, the grade of the stenosis was classified semi-quantitatively as for HUD and reference carotid ultrasound.

Statistical analysis

As some of the data were not normally distributed baseline characteristics were described as percentages or mean ± SD or median (range) depending on the distribution of the data. Feasibility data are presented descriptively. Sensitivity and specificity were calculated according to reference imaging by ultrasound and CTA, and by image quality group. All statistical analyses and plots were performed using R version 3.6.2 (Vienna, Austria). Confidence intervals were computed as exact binomial confidence interval. Leaf probability plot was based on script by Zampieri.[25] Sample size was based on power calculation of the ability to detect patients with significant stenosis (SamplePower; SPSS, Inc., Chicago, IL, USA) estimating a prevalence of 7% (power 0.8 at the 0.05 significance level). For the other aims of the study this sample size provided power ≥ 0.9 at the 0.05 significance level. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Results

Study population

Baseline characteristics of the 80 subjects (38 women and 42 men) are shown in Table 1. Mean age and body mass index were 71.5 years and 28 kg/m^2, respectively. Moderate hypertension was common with mean systolic blood pressure 159 mmHg. Previous cardiovascular disease defined as stroke, TIA or myocardial infarction was present in 22 (27.5%). Final diagnosis at discharge was stroke or TIA in 62 (78%) subjects. The distribution of carotid artery disease is shown in Table 2 and Fig. 1. In sum 9 (11%) of the participants had at least 50% ICA stenosis.

Table 1. *Basic characteristics of the 80 study participants.*

Variable	
Women, *n* (%)	38 (47.5%)
Age, median (range)	71.5 (23-93)
Body mass index, kg/m^2	27.9 ± 4
Systolic blood pressure, mm Hg	159 ± 24
Diastolic blood pressure, mm Hg	84 ± 16
Prior transitory ischemic attack, *n* (%)	12 (15%)
Diabetes, *n* (%)	11 (14%)
Hypercholesterolemia, *n* (%)	15 (19%)
Prior Ischemic Stroke, *n* (%)	6 (7.5%)
Prior Hemorrhagic stroke *n* (%)	2 (2.5%)
Cardiac source of emboli *n* (%)	10 (12.5%)

*Values are mean ± SD unless otherwise stated.

Table 2. *Distribution of internal carotid artery pathology in the population.*

Ultrasound findings	Number of patients (%)	Number of vessels (%)
Normal	9 (11%)	22 (14%)
Increased intima media thickness	8 (10%)	29 (18%)
≤50% occlusion	54 (68%)	97 (61%)
50−69% occlusion	3 (4%)	5 (3%)
70−99% occlusion	3 (4%)	4 (3%)
Near-occlusion	2 (3%)	2 (1%)
Occluded	1 (1%)	1 (1%)

The distribution of internal carotid artery (ICA) pathology revealed by high-end carotid ultrasound is shown by worst ICA stenosis degree per subject and as individual ICA, counting left and right separately.

Feasibility of carotid ultrasound by hand-held devices

The average time used for the HUD examinations was 5 min and 36 s (range 3−10 min). Each cardiologist performed 15−25 HUD examinations. Most of the reference examinations were performed directly after the HUD examination, and with only one exception, the reference examinations were performed on the same day as the HUD examination.

The feasibility for satisfactory assessment of extracranial carotid territories was excellent, where assessment of ICA and CCA was feasible in all and ECA in 96%.

The image quality was categorised as good in 60 patients, moderate in 19 and poor in 1. Amongst those with good, moderate and poor image quality there were 4, 4 and 1 with at least 50% ICA stenosis, respectively.

Clinical impact of carotid ultrasound by hand-held devices

In 61 (76%) patients, the HUD examinations were judged as negative (defined by no ICA stenosis ≥ 50%) and no further evaluation of the extracranial carotid arteries was deemed necessary by the cardiologist, while 14 (17.5%) were judged to have no ICA plaques. In comparison, 71 (89%) were found to have less than 50% ICA stenosis by reference ultrasound, while 14 had no ICA plaques. Carotid endarterectomy was performed due to significant (≥ 70%) ICA stenosis in four (5%) patients and all of these were identified as significant stenosis by the HUD examination. Table 3 shows the characteristics and carotid ultrasound findings (by HUD and reference) for the nine (9) individuals with at least 50% ICA stenosis (totally 12 ICA stenoses by reference examinations). Overall, the ability to identify ICA stenosis by HUD was very good (Fig. 2A and Table 4). Of 12 ICA stenoses identified by reference ultrasound, 11 (92%) were identified by HUD, but in one patient a 50-69% stenosis was not identified by the HUD examination. The cardiologist who performed the examination with the missed 50−69% stenosis annotated the image quality as poor but judged it good enough for clinical decision making. The high sensitivity and specificity for detecting at least 50% stenosis by HUD compared to reference ultrasound and CTA is presented in Table 4, and according to image quality in Fig. 2B.

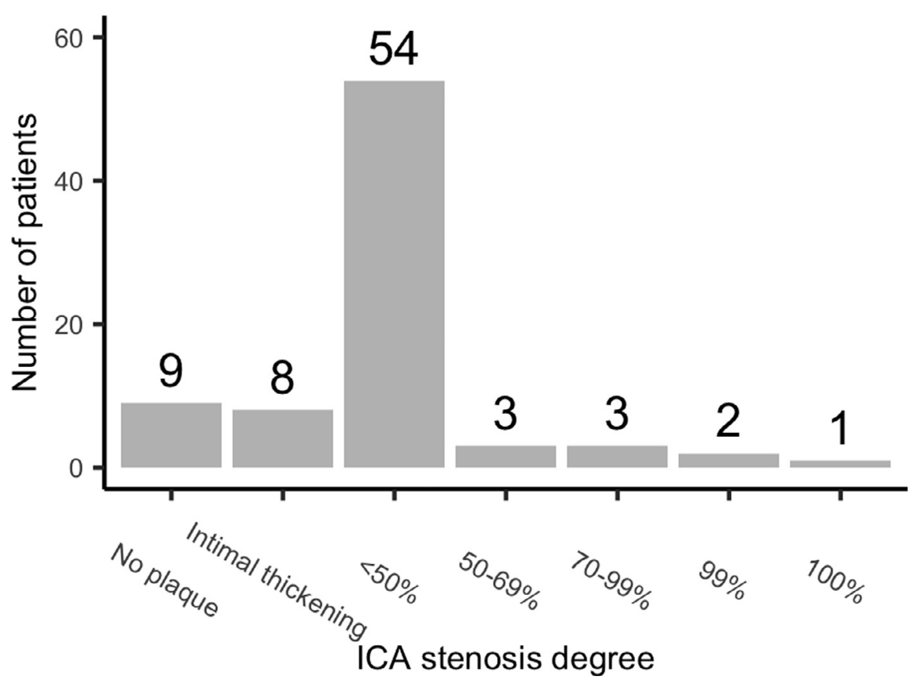

Fig. 1. *Distribution of internal carotid stenoses in the study population. Fig. 1. The number of patients with the specified maximal degree of ICA pathology is shown for all sub-classifications of ICA stenosis or pathology by reference imaging. Abbreviation: ICA, internal carotid artery. Size: 15 cm by 9 cm, 300 dpi.*

Table 3. *Characteristics and ultrasound findings by bedside hand-held ultrasound and reference imaging in individuals with internal carotid artery stenosis of at least 50%.*

Age (years)	Sex	Smoker	Diabetes	Hyper-cholesterolemia	Hyper-tension	Former TIA	Side	Reference-degree of stenosis	HUD-Degree of stenosis
>80	Male	Never	Yes	Yes	No	No	Left	50–69%	50–69%
							Right	50–69%	50–69%
60–80	Male	Present	Yes	Yes	Yes	No	Left	100%	100%
							Right	<50%	50–69%
60–80	Female	Former	Yes	Yes	No	No	Left	<50%	<50%
							Right	70–99%	<50%
60–80	Male	Former	Yes	No	No	No	Left	50–69%	50–69%
							Right	99%	50–69%
60–80	Female	Never	Yes	Yes	No	Yes	Left	50–69%	100%
							Right	<50%	<50%
60–80	Male	Former	Yes	Yes	Yes	No	Left	<50%	<50%
							Right	50–69%	50–69%
60–80	Female	Present	Yes	Yes	Yes	No	Left	<50%	50–69%
							Right	99%	70–99%
60–80	Female	Present	No	No	No	Yes	Left	<50%	70–99%
							Right	70–99%	99%
>80	Female	Present	No	Yes	No	No	Left	70–99%	70–99%
							Right	70–99%	70–99%

Abbreviation: HUD, hand-held ultrasound device.

Discussion

The presented study of 80 patients admitted with suspected ischemic stroke or TIA shows that bedside diagnostic ultrasound by hand-held devices in the hands of expert users can be used as a quick initial examination to both exclude carotid stenosis and select patients in need of further carotid diagnostic imaging.

The population was an unselected group of patients with suspected stroke or TIA referred for carotid ultrasound and 78% of the patients were diagnosed as stroke or TIA at discharge. The prevalence of carotid stenosis was comparable to previous studies[26] and the results may be generalised to other users with similar experience.

HUD in cardiovascular disease has primarily been investigated as a tool to improve the physical examination.[17] Our results are comparable to previously published results on the use of mobile ultrasound equipment in screening for carotid stenosis in stroke/TIA where it had a sensitivity of 100% and specificity of 64% for at least 60% stenosis.[22] Another study in patients scheduled for cardiac surgery showed a sensitivity of 100% for HUD examinations to detect significant ICA stenosis.[21] In the presented study, one significant carotid stenosis (70–99%) was missed. Image quality was perceived as the limiting factor in inconclusive studies. Heavy calcification, adipose tissue and anatomical features such as tortuous arteries are the major impediments to the image quality in ultrasound recordings. As the image quality of HUDs, particularly the spatial resolution and contrast, is lower than for high-end vascular ultrasound, the HUD examination may be challenging in some patients. Similarly, soft plaques may be missed unless care is taken to align color Doppler angle.[27] Thus, it is important that image quality is included in the evaluation before ruling out carotid stenosis by HUDs and omit of further diagnostic evaluation must be restricted to cases with sufficient image quality. Furthermore, as for focused cardiac ultrasound, it is important that the operators are well-trained and familiar with the limitations and potential pitfalls of the equipment to gain the best possible yield of the method.[15]

According to guidelines, less than 50% ICA stenosis can be quantified visually by measuring diameter.[23] As such, we selected 50% stenosis as the limit of what should be characterised as significant stenosis and further evaluated by high-end carotid ultrasound or CTA. By this cut-off we could avoid further carotid diagnostics in 3 out of 4 patients. Choosing a stricter criterion of no plaque in the internal carotid artery, only 14 (17.5%) of the patients would have been judged as no need of further evaluation after examination with HUD.

The hand-held devices are simple in use, with adequate image quality in most patients and they are capable of color Doppler imaging. However, as spectral Doppler is not available, quantification of the degree of stenosis must be based on visual assessment and simple linear measurements. Thus, we do not recommend the application of HUD for classification of stenosis around or above the limit of 50%. As shown by this study HUD examinations can be used to select stroke and TIA patients that benefit from further diagnostic testing with respect to carotid artery pathology.

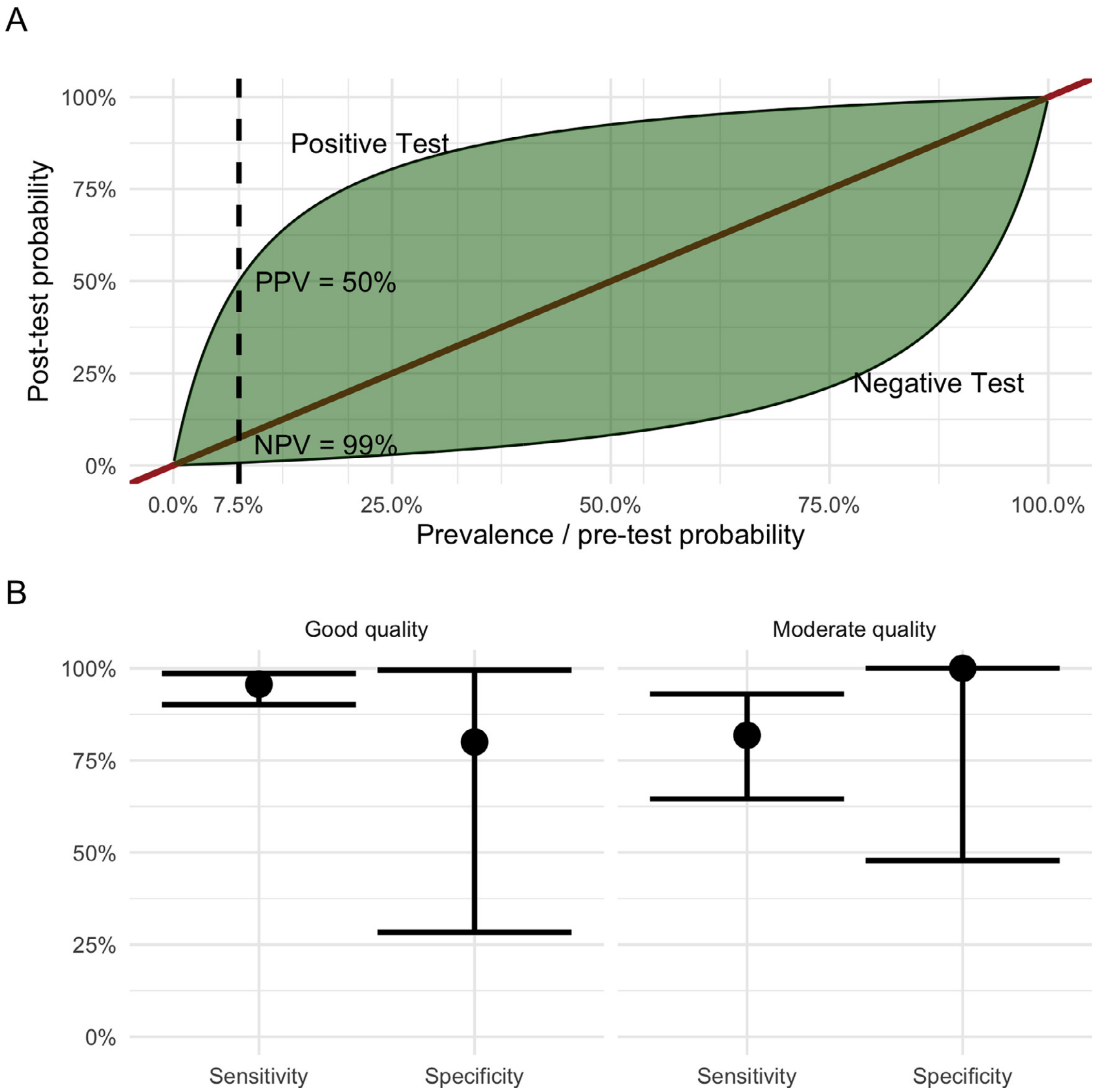

Fig. 2. *Leaf plot for posterior probability of over 50% carotid stenosis, and sensitivity and specificity of hand-held ultrasound compared to high-end ultrasound stratified by image quality. Fig. 2. A Leaf probability plot for the detection of at least 50% internal carotid stenosis by hand-held ultrasound compared to high-end ultrasound. Upper and lower curve depicting post-test probability given positive and negative test result respectively. The dashed line marks the prevalence found in this study, and the corresponding predictive values. B Sensitivity and specificity to detect at least 50% ICA stenosis with 95% confidence intervals (shown as error bars), according to image quality. Good image quality was rated in 60 (75%) and moderate image quality was rated in 19 (24%). As only one exam was rated as poor quality this is not shown. Abbreviation: ICA; internal carotid artery.*

Table 4. *Sensitivity and specificity of examinations by hand-held ultrasound devices to detect at least 50% stenosis in the internal carotid arteries in the study population.*

	Number of patients	Sensitivity (95% CI)	Specificity (95% CI)
HUD vs high-end ultrasound	80	91.7% (59.8−99.6%)	92.6% (86.8−96.1%)
HUD vs CTA	19	85.7% (56.2−97.5%)	79.2% (57.3−92.1%)

Limitations

As the examinations, both with hand-held devices and reference scanners were performed by experts, the results are not directly applicable to less trained operators. In this study, the judgements based on the examinations by HUDs were used solely for the purpose of the study and did not influence the clinical care of the included patients.

We did not compare to an absolute gold standard such digital subtraction angiography, as this is an invasive test which carries potential risks. We performed CT angiography when it was clinically indicated according to local practice, in total

19 (24%) of patients, thus it was not used as the reference imaging for the whole patient population. While conventional duplex ultrasound has lower specificity for greater than 70% stenosis compared to CTA (duplex ultrasound; 86%, CTA; 98%), sensitivity is comparable (duplex ultrasound; 99%, CTA; 95%).[28] In rare cases, carotid stenoses < 50% may cause ischemia and even undergo surgery. However, the usefulness of carotid surgery in symptomatic patients with carotid artery stenosis < 70% has not been unequivocally recommended, and thus this remain only a minor limitation to this study. Even though the sample size was adequate for the main aims of the study, we still present a limited number of patients in general and patients with carotid stenosis in specific. This may reduce the generalizability of the study.

Conclusion

Carotid ultrasound examinations by experienced ultrasonographers using hand-held devices at the patients' point-of-care could rule out significant carotid stenosis in patients with stroke and TIA with a high specificity. In the future this may improve in-hospital logistics and diagnostic workflow. For evaluation of the true clinical effect, larger clinical studies are warranted.

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