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Is 3D ultrasound reliable for the evaluation of carotid disease? A systematic review and meta-analysis

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Abstract

Aim: Studies assessing the use of 3D ultrasound (3DUS) for the evaluation of carotid disease reported varying views among observers about its reliability vis-à-vis 2DUS or angiography; ratings provided ranged from poor to excellent. This study aims to systematically review and analyze the reliability of 3DUS for the evaluation of carotid disease. **Materials and methods:** The PubMed database was searched for studies that evaluated carotid disease (i.e. plaque measurements and characteristics and degree of stenosis) using 3DUS. **Results:** Sixteen studies comprising a total of 918 stenosed carotids were reviewed and meta-analyzed. Data on intra- and inter-observer reproducibility and inter-method agreement (i.e. 3DUS vs 2D and 3DUS vs angiography) were analyzed. Overall analysis showed excellent intra- and inter-observer reproducibility (intra-observer: correlation coefficient *r*=0.88, 95% confidence intervals (CI) 0.84-0.92; intra-observer: *r*=0.91, 95% CI 0.87-0.95). The analysis also showed excellent agreement between 3DUS and 2DUS (*r*=0.89, 95% CI 0.83-0.95) and between 3DUS and angiography (*r*=0.73, 95% CI 0.44-0.1). **Conclusion:** 3DUS has excellent intra- and inter-observer reproducibility and excellent agreement with 2DUS and angiography for the evaluation of carotid disease. Further studies assessing the reliability of carotid plaque characteristics using 3DUS in symptomatic and asymptomatic patients are required.

Keywords: ultrasound; 3DUS; carotid stenosis; atherosclerosis; stroke

Introduction

Stroke is a known leading cause of death and disability worldwide [1] and carotid atherosclerosis accounts for approximately up to 30% of ischemic stroke [2]. The development of atherosclerotic plaque involves attaching monocytes to an injured or irritated endothelium and crossing into the smooth muscle layer of the arterial wall. They gradually grow and mature into macrophages [3]. These macrophages absorb fat from the circulating blood and form foam cells leading to the build-up of fatty plaque [4]. Continuing growth of the atherosclerotic plaque in carotid arteries can lead to lumen narrowing and restricting blood flow to the brain [5,6].

Bidimensional ultrasound (2DUS) is routinely used in clinical practice for the diagnosis of carotid disease [7]. However, the use of 2DUS may limit the ability of quantification of carotid disease [8]. US is safe, portable, and cost-effective compared to computed tomography and magnetic resonance imaging and the trend is to shift toward using tridimensional (3D) US for the evaluation of carotid disease to provide more information on plaque morphology, degree of stenosis, and haemodynamics in real-time [9]. 3DUS has been shown to improve visualization of plaques and provide volume measurements that could be used as an additional diagnostic tool of carotid diseases [8,10,11]. 3DUS images for clinical diagnosis can be obtained through mechanical-swept and free-hand scanning systems [12]. Mechanical-swept imaging can be achieved by placing the 3D transducer on the region of interest and performed by either a mechanical arm

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attached to the transducer or via a motor-driven crystal within the transducer [11,12]. Free-hand 3DUS imaging is achieved by moving the transducer over the region of interest [11,13].

It has been reported that 3D duplex US can be as accurate as angiography for the quantification of arterial stenosis [14]. However, studies assessing the use of 3DUS for the evaluation of carotid stenosis reported different levels of agreement among observers about its reliability compared to 2DUS or angiography; levels of agreement ranging from poor to excellent [14–20]. Therefore, the aim of the present study was to systematically review and analyze the reproducibility and reliability of 3DUS for the evaluation of carotid stenosis.

Material and methods

This study was conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline. Ethics approval was not required for this systematic review and meta-analysis.

Search strategy and study selection

PubMed database was searched for all studies potentially evaluating carotid plaque using 3D ultrasound from 2015 to 2020. Keywords used for searching titles and abstracts included the following: Three-dimensional *OR* 3-dimensional *OR* 3D ultrasound *OR* sonography *OR* ultrasonography *AND* carotid disease *OR* carotid artery *OR* carotid plaque *OR* carotid plaque volume. The search was restricted to "humans" and "adults +19" and "English." References from included studies were also hand searched. Pre-specified inclusion criteria were used to prevent bias. Included in the study were original, peer-reviewed published papers that involved measurements of carotid stenosis and/or carotid plaque using 3DUS. They had to have used correlation tests to evaluate 3DUS intra-observer and/or inter-observer reproducibility and/or inter-method agreement with 2DUS or angiography. Phantom studies, studies assessing vessel wall volume of non-stenosed carotid artery, review studies, letters to editor, unpublished materials, case studies, and abstracts were excluded.

Data acquisition

Correlation coefficient from intra and inter-observer and inter-method analysis were extracted from included publications. Intra-observer reproducibility was defined as the variation between measurements obtained by the same observers on different visits on the same carotid artery using the same 3DUS imaging technique. Inter-observer reproducibility was considered to be the variation between results obtained by two observers on the same carotid artery using the same 3DUS imaging technique. Inter-method agreement was defined as the variation between results obtained by a repeated measure on the same carotid artery using different imaging methods (i.e. 3DUS vs 2DUS and 3DUS vs angiography). The mean correlation coefficient was calculated and used for analysis if the following existed: 1) a correlation value of each carotid artery (i.e. common, internal and external carotid arteries) on the same subject was provided, 2) correlation values of manual and automated assessment on the same outcome (i.e. intra, inter-observer reproducibility or inter-method agreement) were provided, 3) more than one observer obtained data on the same carotid artery using the exact same imaging techniques in a study, 4) carotid stenosis was assessed using two imaging mode (i.e. B-mode and Doppler), 5) the mean correlation coefficient of plaque volume, length and area was used for plaque measurements, 6) the mean correlation coefficient of diameter reduction and area reduction was used for residual lumen analysis, 7) and the mean correlation coefficient for plaque with and without ulcer was used for plaque characteristics analysis. If the correlation coefficient was stated in the paper with (>) or (<), the stated value was used for analysis (e.g. if correlation coefficient of >0.8 was stated in the paper, the correlation coefficient of 0.8 was used for analysis). The number of carotid arteries with stenosis assessed with 3DUS was considered as the sample size. If the number of carotid arteries with stenosis was not provided, the number of patients assessed with 3DUS was used.

Quality

Criteria from the Quality Assessment of Diagnostic Accuracy Studies (QUADAS) [21] were used for quality assessment of the included studies. Each of the following criteria was equal to one point: selection criteria of patients was clearly described; patients recruited were with carotid disease; clinical information of patients were provided; a reference diagnostic test was used and the reference test was independent of 3DUS and was used for all patients; the degree of carotid stenosis from 3DUS was verified using the reference test and the period between the carotid evaluation using 3DUS and the reference test was reported. The methods of performing the reference test were described as was the 3DUS imaging method. The blinding of personnel and the blinded analysis was performed and finally complete data, and subject withdrawals if present were clarified.

Statistical analysis

A correlation coefficient with 95% confidence intervals (95% CIs) was used as the estimates of statistics for the following outcomes: intra and inter-observer reproducibility and inter-method agreement (i.e. 3DUS vs 2D and 3DUS vs angiography). Each outcome was analyzed

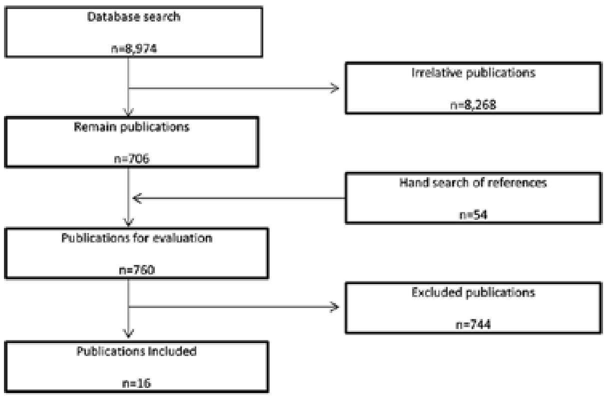

Fig 1. Flow chart for study retrieval and selection. Phantom studies, studies assessed vessel wall volume of non-stenosed carotid artery, review studies, letter to editor, unpublished material, case study, and abstract were excluded.

on a separate forest plot. Data of each outcome was subgrouped into plaque measurements (i.e. plaque volume, plaque area and plaque length), plaque characteristics (i.e. echotexture and surface morphology), and residual lumen (i.e. stenosis percentage, measured through diameter reduction and/or area reduction methods). The forest plot analysis was performed and produced using the Stata/SE Statistical Software version 16.1 (StataCorp., College Station, TX) random-effect models, due to the different scale of measurement methods used in assessing carotid stenosis across included studies. Correlation coefficient (*r*) was interpreted as following: r <0.40, weak correlation; r = 0.40-0.70, moderate correlation; r >0.70, strong correlation [22]. I^2 statistics was used to test for heterogeneity between studies. Egger's test and funnel plots were used to assess possibility of publication bias [23]. Spearman's rank correlation coefficient was used to determine the relationship between quality score and outcomes. Statistical significance was set at the conventional p level of <0.05.

Results

From the initial 8,974 publications found in the PubMed database, 16 relevant publications comprising a total of 918 diseased carotid arteries were identified and evaluated (fig 1) [15-20,24–33]. A summary of the included studies is shown in Table I.

Intra and inter-observer reproducibility

Nine [15,18,19,25–27,29,32,33] and eleven [15,17–20,24–27,29,30] publications assessed intra- and inter-observer reproducibility of 3DUS for the evaluation of carotid disease, respectively. Overall analysis showed excellent intra and inter-observer reproducibility (intra-observer: correlation coefficient r=0.88, 95% CI 0.84-0.92, number of carotid arteries (n)=501; intra-observer: r=0.91, 95% CI 0.87-0.95, n=698). Sub-group analysis also showed excellent intra and inter-observer reproducibility of 3DUS for carotid plaque measurements (intra-observer: r=0.91; inter-observer: r=0.93), assessment of plaque characteristics (intra-observer: r=0.80; inter-observer: r=0.89) and measurements of residual lumen (intra-observer: r=0.81; inter-observer: r=0.83). There was no statistically significant heterogeneity across the studies (intra-observer: I^2=4.30%, p=0.59; inter-observer: I^2=46.89%, p=0.06) (fig 2, fig 3).

Inter-method agreement

Nine publications [15,17,18,20,24–26,30,31] assessed the inter-method agreement between 3DUS and 2DUS, and three publications [20,28,31] assessed the inter-method agreement between 3DUS and angiography for the assessment of carotid disease. Overall analysis showed excellent agreement between 3DUS and 2DUS (r=0.89, 95% CI 0.83-0.95, n=586). Subgroup inter-method analysis between 3DUS and 2DUS also evidenced excellent agreement for carotid plaque measurements (r=0.96), assessment of plaque characteristics (r=0.81) and measurements of residual lumen (r=0.84). The inter-method agreement between 3DUS and angiography for the measurements of residual lumen was excellent (r=0.73, 95% CI 0.44-0.1, n=98). Hetero-

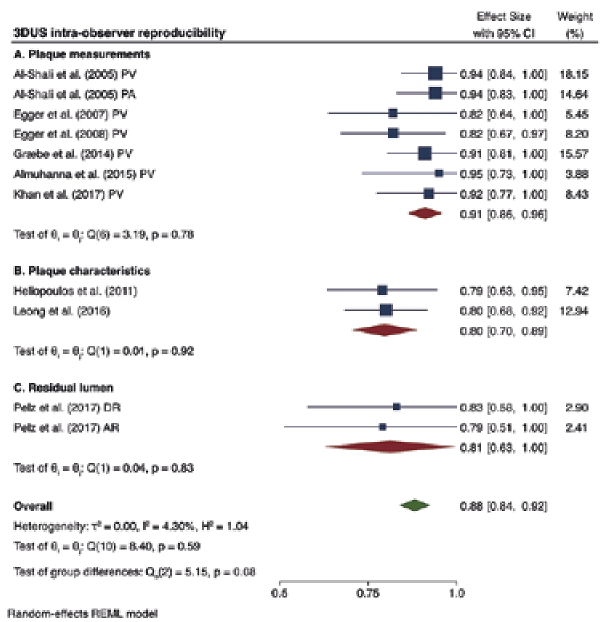

Fig 2. Intra-observer reproducibility of 3D ultrasound for the assessment of carotid stenosis. Intra-observer reproducibility for the assessment of carotid stenosis (number (n)=501) is excellent (correlation coefficient (r) = 0.88, 95% confidence interval (CI) 0.84-0.92). AR: area reduction; DR: diameter reduction; PA: plaque area; PV: plaque volume.

Table I. Summary of included studies in chronological order.

Reference	Aim	Sample size	Subject pathology	US machine	3DUS imaging technique	Findings
Keberle 2000 [30]	To evaluate 3DUS for screening carotid atherosclerosis	139	CAS	3-Scape Siemens	Freehand	3DUS is an accurate method for screening carotid atherosclerotic
Keberle 2001 [31]	To examine whether 3DUS is superior to 2DUS when compared to angiography in the assessment of carotid stenosis	19	CAS	Sonoline Elegra	NA	3DUS shows excellent correlation to angiography, with no superiority over 2DUS assessment of carotid stenosis
Bucek 2003 [20]	To assess the accuracy of 3DUS for the evaluation of carotid stenosis	32	CAS	GE Logiq 700	Freehand	3D CDUS excellent inter-observer reproducibility and good correlation with 2D CDUS and angiography for the detection of high-grade ICAS
Wessels 2004 [28]	To assess the agreement between 3DUS and angiography for the evaluation of internal carotid stenosis	62	CAS	Agilent HP Sonos 5500	Freehand	3D CDUS demonstrates good agreement with DSA yielding higher accuracy than 2D CDUS
Al-Shali 2005 [29]	To assess the association between 3DUS measure of carotid morphology and different biological determinants	90	CVR	HDI-5000 US	Mechanical	3DUS measure of carotid TPA and TPV is surrogate marker of risk factors including smoking, plasma cholesterol and diabetes.
Egger 2007 [32]	To validate a 3DUS measurement of carotid atherosclerosis	40	CAS	ATL HDI 5000 Philips	Freehand	3DUS shows excellent intra-observer agreement for the measurements of carotid PV
Egger 2008 [33]	To assess 3DUS intra-observer variability of carotid atherosclerosis	60	CAS	HDI 5000 Philips	Mechanical	3DUS shows excellent intra-observer agreement for the measurements of carotid TPV
Ludwig 2008 [24]	To investigate the variability of assessing carotid plaque volume measured with 3DUS	105	CAS	GE Ultraschall	Mechanical	3DUS is a reliable method for the assessment of carotid PV
Heliopoulos 2011 [25]	To evaluate the ability of the 3DUS to characterise carotid plaque ulceration	62	CAS	ATL HDI 1500	Freehand	3DUS reliably characterized the surface morphology of atherosclerotic carotid plaques. A trend of superiority of 3DUS over 2DUS was found in detecting ulcers of carotid plaque
Græbe 2014 [26]	To compare 3DUS with 2DUS for quantification carotid atherosclerosis	62	PAD	Philips VL13-5	Mechanical	3DUS and 2DUS exhibit high reproducibility with 3DUS being superior to the 2DUS for quantification carotid atherosclerosis
Almuhanna 2015 [27]	To test the reliability of 3DUS for imaging carotid plaque	10	CAS	Sonix MDP	Mechanical	3DUS measurement of carotid plaque is reliable with low variability and can be accomplished in clinical vascular laboratory
Pelz 2015 [17]	To evaluate 3DUS quantification of internal carotid stenosis	21	CAS	Toshiba Aplio500	Freehand	3DUS of CAS shows moderate inter-method agreement with 2DUS and good inter-observer reproducibility for the quantification of CAS
Leong 2016 [15]	To determine the reproducibility of 3DUS in characterizing carotid plaque	105	CAS	Philips IU-22	Mechanical	High reproducibility in carotid plaque characterization was obtained using 3DUS compared to 2DUS
Pelz 2017 [18]	To evaluate 3DUS quantification of internal carotid stenosis	43	CAS	Toshiba Aplio500	Freehand	3D PUS showed superiority in visualisation and quantification of ICAS compared to 3D BUS
Khan 2017 [19]	To estimate carotid plaque volume obtained from 3DUS manual and semi-automated software plaque segmentation	30	CAS	SonixTouch	Freehand	The estimation of carotid PV obtain by semi-automated software is accurate, repeatable, implementable in a clinical environment and quicker than manual 3DUS imaging
Sandholt 2018 [16]	To assess reproducibility of carotid plaque measurements using 3DUS	38	CAS	Philips Epiq7	Mechanical	3DUS of carotid plaque showed high reproducibility in assessing PT and PV

2DUS: two-dimension ultrasound; 3DUS: three-dimension ultrasound; BUS: B-mode ultrasound; CVR: cardiovascular risk factors; CAS: carotid artery stenosis; CDUS: color-Doppler ultrasound; DSA: digital-subtraction angiography; NA: not available; PAD: peripheral arterial disease; PDUS: power-Doppler ultrasound; PT: plaque thickness; PV: Plaque volume; TPA: total plaque area; TPV: total plaque volume

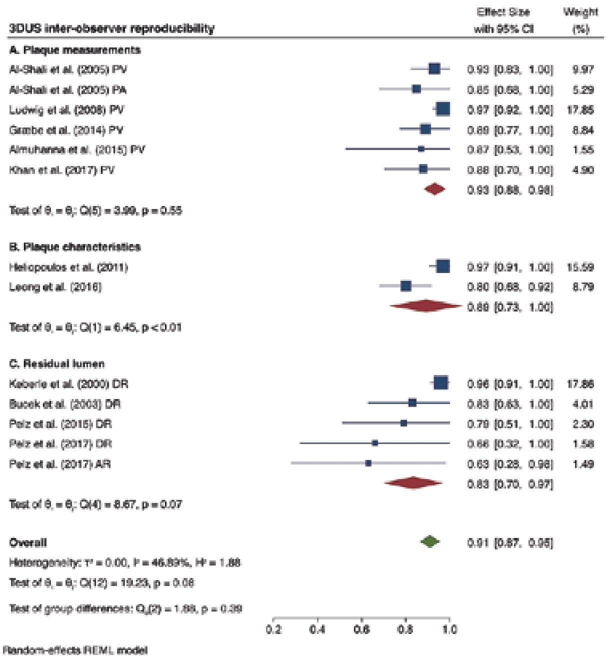

Fig 3. Inter-observer reproducibility of 3D ultrasound for the assessment of carotid stenosis. Inter-observer reproducibility for the assessment of carotid stenosis (number (n)=698) is excellent (r = 0.91, 95% confidence interval (CI) 0.87-0.95). AR: area reduction; DR: diameter reduction; PA: plaque area; PV: plaque volume.

geneity was statistically significant in studies assessing inter-method agreement between 3DUS and 2DUS (I^2=76.66%, p<0.01), and between 3DUS and angiography (I^2=82.59%, p<0.01) (fig 4, fig 5).

Quality

All 16 included publications clearly described selection criteria of patients and recruited patients with carotid disease, nine [16,19,26,27,29–33] provided clinical information of patients included in the study, nine [15,17,18,20,25,26,28,30,31] used reference diagnostic test, six [15,20,26,28,30,31] used reference

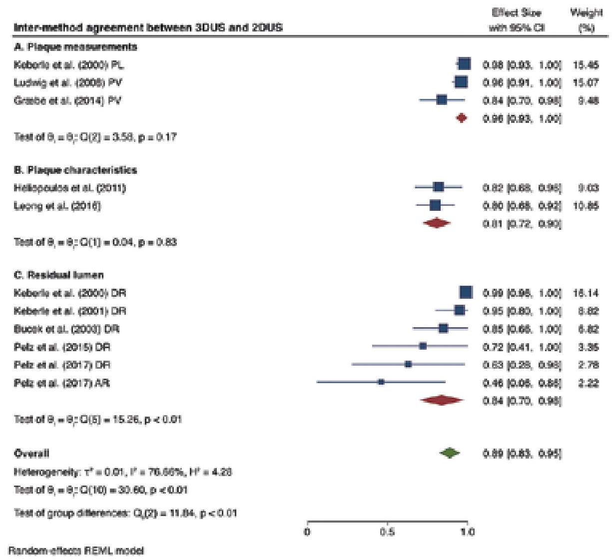

Fig 4. Inter-method agreement between of 3D ultrasound and 2D ultrasound for the assessment of carotid stenosis. Inter-method agreement between 3D ultrasound and 2D ultrasound for the assessment of carotid stenosis (number (n)=586) is excellent (correlation coefficient (r) = 0.89, 95% confidence interval (CI) 0.83-0.95). AR: area reduction; DR: diameter reduction; PL: plaque length; PV: plaque volume.

test that was independent of 3DUS, nine [15,17,18,20, 25,26,28,30,31] used the same reference test for all patients and described methods of performing reference test, nine [15,17–20,25,28,30,31] verified the degree of carotid stenosis from 3DUS using the reference test, seven [15,17,18,25,26,28,33] reported the period between the carotid evaluation using 3DUS and the reference test, 15 [15–20,24–27,28,30–33] described 3DUS imaging method, 14 [15–20,24–29,32,33] reported blinding of personnel and analysis, 10 [15,18–20,24,27,29,31–33] provided complete data, and six reported subject withdrawals [16,17,25,26,28,30]. There was significant relationship between quality score and intra-observer cor-

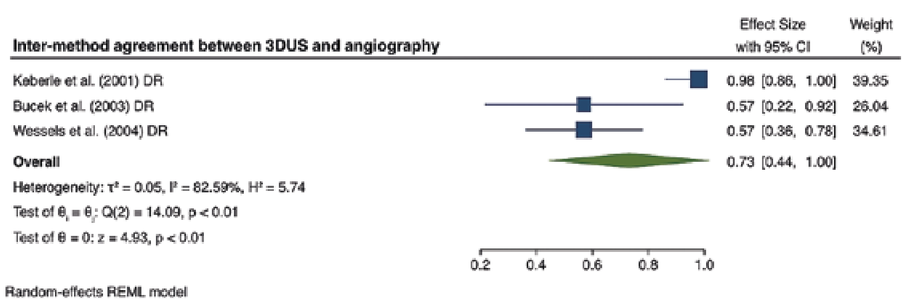

Fig 5. Inter-method agreement between of 3D ultrasound and angiography for the assessment of carotid stenosis. Inter-method agreement between 3D ultrasound and angiography for the assessment of carotid stenosis (number (n)=98) is excellent (correlation coefficient (r) = 0.73, 95% confidence interval (CI) 0.44-0.1). DR: diameter reduction.

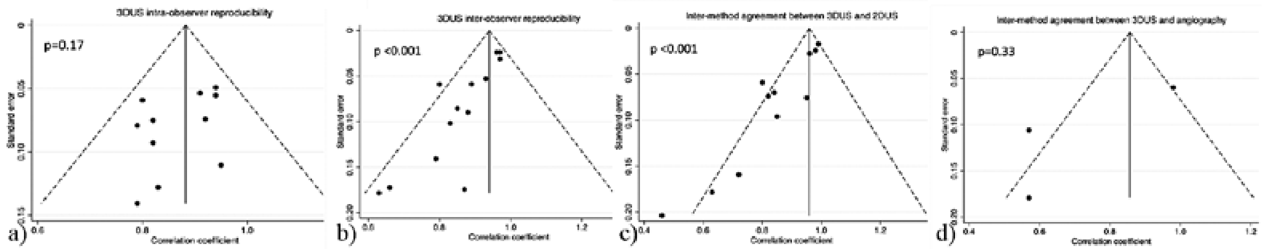

Fig 6. Funnel plots for each outcome evaluating publication bias. Standard error (SE, vertical axes) of each outcome (i.e. intra-observer reproducibility (A), inter-observer reproducibility (B), inter-method agreement between three dimension ultrasound (3DUS) and 2DUS (C), inter-method agreement between 3DUS and angiography (D) is plotted against the correlation coefficient (horizontal axes). There was significant bias in studies assessing inter-observer reproducibility and inter-method agreement between 3DUS and 2DUS (p <0.001).

relation (Spearman's rho coefficient, −0.6, p=0.02), and inter-method correlation (Spearman's rho coefficient, −0.6, p=0.03). No significant relationship was found between quality score and intra-observer correlation (Spearman's rho coefficient, −0.4, p 0.1).

Publication bias

Egger's test showed significant bias in studies assessing inter-observer reproducibility and inter-method agreement between 3DUS and 2DUS (p<0.001), but not in studies assessing intra-observer reproducibility (p=0.17) and inter-method agreement between 3DUS and angiography (p=0.33) (fig 6).

Discussion

In this study, we aimed to systematically review and meta-analyze the reproducibility and reliability of 3DUS for the evaluation of carotid disease. This included carotid plaque volume and length measurements, plaque characteristics, and degree of stenosis. Our analysis showed that 3DUS has excellent intra- and inter-observer reproducibility and excellent agreement with 2DUS and angiography for the evaluation of carotid disease. This indicates that 3DUS is a reliable imaging method for the evaluation of carotid disease.

Our study showed excellent intra and inter-observer reproducibility of 3DUS for the evaluation of carotid disease. Similar findings with high levels of reproducibility were reported by a number of studies in which the mechanical-swept 3DUS technique was used for the evaluation of carotid stenosis [14,15,24–26]. The mechanical-swept technique can create volume data sets producing 3DUS images in real-time, instead of reconstructing 3D images from 2D cross-sectional images [12,27]. Studies evaluating carotid stenosis using the freehand 3DUS imaging technique reported good to excellent reproducibility [16,19,28]. Although the freehand method is less expensive and capable of scanning a larger region of interest compared to mechanical-swept method [11,25,28], the range of reproducibility level seen with the use of the freehand scanning technique could be accused of being more operator-dependent. Therefore, low calibration accuracy, localization errors, and image reconstruction errors are more common in the free-hand technique compared to the mechanical scanning technique [12,25,29].

In addition, US modes used in scanning (i.e. B-mode and Doppler-mode) may affect the accuracy of the assessment of carotid plaques and the measurement of stenosis degree. A study done by Plez et al to evaluate 3DUS in grading and quantifying the internal carotid arteries stenosis showed that 3DUS with Doppler-mode has a higher reproducibility and is superior to the B-mode [18]. Although B-mode US allows the assessment of carotid vessels with high resolution, echolucent plaques restrict the visualization of carotid stenosis [17]. On the other hand, Doppler-mode can depict blood flow in the vessel which helps to discriminate between plaque surface and lumen, allowing for plaque measurement and grading of stenosis [16,17]. It is important to keep in mind that plaque with calcification is still considered as a limitation for the assessment of carotid disease with US.

Furthermore, it has been reported that 3DUS has a high reproducibility in characterizing atherosclerotic carotid echotexture, echogenicity, and surface characteristics [15]. Our sub-group analysis also showed excellent reliability of 3DUS in assessing plaque characteristics. However, a study done by Heliopoulos et al showed that non-ulcerated plaque had a higher reproducibility compared to ulcerated plaque [25]. This indicates that plaque morphological characteristics may affect reproducibility level for the evaluation of carotid plaque using 3DUS. The assessment of carotid plaque characteristics, including presence of fibrous cap, lipid-rich core, intraplaque hemorrhage, and neovascularization, in addition to the measurement of residual luminal, is important as it may provide stroke risk information [30,31]. Further studies assessing the reliability of carotid plaque characteristics using 3DUS in symptomatic and asymptomatic patients are required.

Our analysis also showed excellent inter-method agreement in the evaluation of carotid disease. Findings in which good and excellent agreement of 3DUS with 2DUS and angiography have been reported [19,20,32], with a superiority of 3DUS over 2DUS in the evaluation of carotid plaque and carotid stenosis when compared to angiography as a gold standard [24,32,33]. Together, these suggest that 3DUS is a reliable and reproducible imaging method for the evaluation of carotid diseases and can be implemented in clinical practice with appropriate training. Factors that may limit the accuracy of 3DUS should be considered in future studies.

Limitations in this study include the following: 1) heterogeneity between studies in terms of scanning techniques and imaging mode was observed; 2) publication bias in studies assessing inter-observer reproducibility and inter-method agreement between 3DUS and 2DUS was present; 3) there was a significant relationship between quality score and studies assessing intra-observer reproducibility, and inter-method agreement. Further high-quality research assessing the reliability and reproducibility of 3DUS for the evaluation of carotid disease is required.

In **conclusion**, this systematic review and meta-analysis highlighted the reliability of 3DUS in the evaluation of carotid disease. 3DUS has excellent intra- and inter-observer reproducibility and excellent agreement with 2DUS and angiography for the evaluation of carotid disease. Further high-quality studies assessing the reliability of carotid plaque characteristics using 3DUS in symptomatic and asymptomatic patients are required.

Conflict of interest: none

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