

ORIGINAL RESEARCH

Validity of Ultrasound for the Diagnosis of Arterial Thoracic Outlet Syndrome

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WHAT THIS PAPER ADDS

In a prospective study of 51 consecutive patients with suspected thoracic outlet syndrome (TOS) the agreement between individual ultrasound and digital subtraction angiography (DSA) raters with the gold standard DSA reference by a multifunctional specialist group was poor. Inter-rater agreement for the detection of arterial (a) TOS was excellent for ultrasound, moderate for DSA assessed by vascular surgeons, and poor for DSA assessed by radiologists. Latent class analysis showed discrepant findings between ultrasound and DSA in about 25% of cases. In these cases, ultrasound tended to be more conservative in the classification of aTOS without missing any relevant haemodynamic impairment.

Objective: Thoracic outlet syndrome (TOS) is a rare disorder mostly seen in younger individuals. Although patient wellbeing is relevantly impaired, it often takes a long time before the diagnosis is made. Digital subtraction angiography (DSA) is routinely used despite its radiation exposure, which is a major concern in this young patient population. Moreover, DSA offers limited opportunities for functional assessment. By contrast, ultrasonography is widely accessible without causing radiation exposure and allows for flexible functional assessment. The main goal of the study was to investigate whether ultrasound (US) was a viable alternative to DSA in diagnosing arterial TOS (aTOS).

Methods: Patients, referred to a tertiary centre for evaluation of suspected TOS, were recruited into the study. DSA was routinely performed with the patient's arms both in the raised (abducted) and neutral (adducted) position. Two vascular surgeons and two radiologists assessed the resulting images for the presence of aTOS. Additionally, two examiners performed US according to a standardised protocol. The reference for presence of aTOS was the DSA based interdisciplinary vascular conference consensus. Inter-rater agreement and latent class analysis (LCA) were performed between assessors and diagnostic methods.

Results: Fifty one consecutive patients (two thirds female) aged 39.3 ± 13.0 years were included within 11 months. US agreement was excellent at 0.94 (0.841–0.980), DSA agreement for vascular surgeons was good at 0.779 (0.479–1.000), whereas it was moderate at 0.546 (0.046–1.000) for radiologists. Results suggest that DSA is untenable as the gold standard for aTOS diagnosis. In LCA, US was shown to be a reliable diagnostic tool for the detection of aTOS.

Conclusion: US examination is a valid test for the detection of haemodynamically relevant compression of arteries in the diagnostic work up of aTOS using a standardised protocol. The role of DSA as the gold standard should be reviewed and needs to be reconsidered.

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INTRODUCTION

The term thoracic outlet syndrome (TOS) describes a heterogeneous disease pattern resulting from compression of nerves (brachial plexus) and vessels (subclavian artery and subclavian vein) in the space of the upper aperture of the thorax.¹ TOS affects younger people with congenital abnormalities of the first rib, either in the presence of cervical ribs, following severe symptomatic acceleration trauma, or among overhead throwing athletes.^{2–4} Prevalence of TOS does not seem to be influenced by sex.^{5,6} TOS is an infrequent and heterogeneous disease, which may be the reason why diagnostic studies including a larger number of patients are lacking. Diagnostic pathways are therefore generally based on expert opinion.^{7,8} A diagnosis of TOS requires an extensive clinical workup including examination of the vascular structures of the extremity affected.^{9–11} TOS usually affects younger patients and complications can lead to severe consequences if left untreated. On the other hand, consensus exists that rash decisions must be avoided and the indications to operate on TOS should be well founded. Imaging is complementary in establishing the diagnosis of TOS,³ but it is indispensable for confirming the diagnosis and especially for necessary surgical planning.^{6–8,12}

Arterial TOS (aTOS) is the least frequent of the thoracic outlet compression disorders but may result in peripheral embolism due to post-stenotic dilatation of the subclavian artery.^{1,13} Traditionally, contrast enhanced procedures such as angiography, computed tomography, and magnetic resonance imaging have been considered the gold standard.^{3–5,12,14,15} There is limited evidence supporting the use of ultrasound (US) in the diagnosis of aTOS. US is considered a useful additional diagnostic tool when compared with digital subtraction angiography (DSA) but is generally not acknowledged as an adequate and independent imaging tool.¹² One advantage of ultrasonography is the ability to perform targeted and flexible provocation manoeuvres while simultaneously recording the haemodynamic response of compression. The used set of manoeuvres is based on personal experience as they have never been truly validated.^{10,11,13} Radiation exposure by DSA is substantial, representing a relevant risk in this predominantly young population. As the authors' vascular centre specialises in the diagnosis and treatment of TOS and functions as a tertiary centre, US was explored to see whether it is a valid and robust tool in the diagnostic work up of aTOS. The objective was to determine the validity of US in the diagnosis of aTOS in terms of non-inferiority compared with DSA. The purpose of this study was to determine whether US could function as a viable alternative to DSA for diagnosing aTOS.

MATERIALS AND METHODS

Study design

In this prospective study all consecutive patients with suspected TOS were included for one year (November 2019 until October 2020). All patients gave written informed

consent prior to inclusion in the study. The study protocol was approved by the institutional review board of Philipps University Marburg (144/19). All patients independently underwent two US examinations of the upper thorax and limb by two sonographers (SON) in addition to the routinely performed digital subtraction angiography.

Clinical assessment

A comprehensive clinical examination was performed, which included anamnesis, presence of cardiovascular risk factors, history of previous trauma, physical examination, and plain neck and or chest radiographs. Routinely, motor conduction velocity of the ulnar and median nerves was measured in a side by side comparison. Additionally, fingertip plethysmography was performed at rest and during provocation tests.

Ultrasound examination protocol

Prior to starting the study, a standardised US examination protocol (Table 1) was developed. The protocol was crafted by an experienced sonographer with the highest DEGUM (German Society of Ultrasound in Medicine) certification for vascular US based on his clinical expertise. The protocol was designed to identify haemodynamically relevant changes in blood flow both at rest and during provocation manoeuvres, and to detect peripheral embolisation. Flow at pre-specified locations was assessed as normal, reduced flow (monophasic), or no flow. Furthermore, presence of thrombotic material or pathological changes in vessel diameter or vessel wall morphology of the subclavian artery were noted. Both sonographers were trained on the protocol prior to the start of the study.

In the clinic, DSA was performed in an upright seated position, offering the advantage that provocative manoeuvres could be executed. To ensure consistency with DSA, the US evaluation, incorporating the provocative manoeuvres, was also conducted in an upright seated position.

Provocation manoeuvres

DSA image acquisition for TOS is recommended at rest, in the abduction elevation rotation position, and with maximum elevation or maximum pain. In the study, these provocation manoeuvres were not only applied as part of DSA image acquisition but also as part of the US protocol.

Endpoints

The primary endpoint of the study was presence of aTOS, while the secondary endpoint was presence of aneurysm or thrombus formations. DSA images were evaluated independently by two radiologists and two vascular surgeons. US examinations were performed and evaluated independently by two ultrasonographers.

Furthermore, a reference assessment of the primary and secondary endpoint was performed by a multidisciplinary committee composed of specialists in vascular surgery, radiology, and angiology based on DSA images. The reference assessment served as the gold standard for evidence of

Table 1. Summary of the structured ultrasound protocol.

Location	Examination
Proximal subclavian artery	B image, CCDS, pw Doppler
Mid subclavian artery	B image, CCDS, pw Doppler
Distal subclavian artery	B image, CCDS, pw Doppler
Axillary artery, resting position	B image, CCDS, pw Doppler
Axillary artery, AER position	CCDS, pw Doppler
Axillary artery, max elevation	CCDS, pw Doppler
Distal brachial artery	B image, CCDS, pw Doppler
Distal radial artery	B image, CCDS, pw Doppler
Distal ulnar artery	B image, CCDS, pw Doppler
Digital arteries D2 to D5	High resolution CCDS

AER = abduction elevation rotation; CCDS = colour coded duplex sonography; D2 to D5 = digital arteries 2 to 5; pw Doppler = pulsed wave Doppler.

relevant arterial compression, and presence of aneurysm or thrombus formation. The committee's decision was made by majority vote. Endpoints were evaluated blindly, without knowledge of the patient's history.

Study data collection and processing

All clinical data and endpoints from all raters were collected on paper case report forms and entered into a validated research database (RedCap, Vanderbilt, USA). Data were checked for completeness and correctness prior to export for analysis; missing or inconsistent data were queried.

Statistical methods

Statistical analysis was performed using R (R version 4.1.2, Vienna, Austria) and RStudio (Posit, Boston, USA). Two by two contingency tables were created to assess the association between categorical variables between two raters. Contingency tables and associated statistics were calculated using the R Conf function from DescTool (version 0.99.43) package.

Fleiss' kappa was calculated to assess the inter-rater agreement among a set of multiple raters using the concordance function from the Rater (version 2.0.1) package.

Latent class analysis (LCA) was used to explain the classification outcome from all raters by a minimal set of classes using the randomLCA (version 1.1–1) package. In LCA only classes with a class prevalence greater than 5% were kept in the final model.

Continuous variables were expressed as mean \pm standard deviation or median and interquartile range, depending on

Table 2. Patient baseline characteristics.

Age – y	39.3 \pm 13.0
Sex	
Female	34 (66.7)
Male	17 (33.3)
Height – cm	173.9 \pm 9.3
Weight – kg	73.4 \pm 13.4
Body mass index – kg/m ²	24.3 \pm 3.9

Data are presented as mean \pm standard deviation or *n* (%).

normality of data. Categorical variables were expressed as counts and percentage. Statistical tests were performed as two sided tests. Significance was defined as a probability value of $p \leq 0.050$.

RESULTS

Fifty one consecutive patients were enrolled, 34 (67%) of them female. Baseline characteristics are listed in Table 2. The US examination protocol could be successfully performed in all participants; there were no dropouts due to adverse events during US. One mild allergic reaction was observed during DSA, which was managed conservatively without permanent consequences.

Prevalence

Overall aTOS prevalence was high. The prevalence as reported by each rater for all aTOS endpoints is summarised in Table 3. The overall prevalence for the main endpoints was as follows: aTOS, 0.876 \pm 0.068; aneurysm, 0.203 \pm 0.044; thrombus, 0.016 \pm 0.014. Prevalence for the main aTOS endpoint was lower for US than for DSA (aTOS, 0.794 \pm 0.013 vs. 0.917 \pm 0.033; $p = 0.003$). For the main aTOS endpoint the pre-defined reference gold standard (REF) was not statistically different for DSA ($p = 0.13$) and US ($p = 0.071$). There was no significant difference in prevalence for the other endpoints (aneurysm, 0.167 \pm 0.013 vs. 0.221 \pm 0.043 [$p = 0.089$]; thrombus, 0.029 \pm 0.014 vs. 0.010 \pm 0.011; $p = 0.25$).

Accuracy

Accuracy for all endpoints compared with the pre-defined reference was moderate to high (Table 4). Overall accuracy for aTOS was 0.830 \pm 0.052 ($p = 0.83$); for aneurysm 0.931 \pm 0.027 ($p = 0.53$); and for thrombus 0.962 \pm 0.007 ($p = 0.78$). However, accuracy did not exceed the no information rate for any rater or any endpoint, thus was not beyond chance.

Concordance with reference

Prevalence for aneurysm and thrombus was low, so that concordance analysis for aneurysm and thrombus did not provide any meaningful results. For aTOS, the concordance among individual raters and the pre-defined reference gold standard was poor (Fig. 1). Concordance with the reference was poor for both DSA (0.219 \pm 0.157) and US (0.191 \pm 0.123). Concordance with the reference did not exceed the pre-defined threshold of 0.8. The concordance between raters and the pre-defined reference gold standard was variable and inconsistent.

Concordance between raters

For aTOS, there was no significant concordance between US and DSA raters (Fig. 1). Concordance was very good between US raters (0.822), good between vascular surgeon raters (0.799), and moderate between radiologist raters (0.613). Concordance was significantly higher for US raters compared with DSA raters ($p < 0.001$).

Table 3. Prevalence of main arterial thoracic outlet syndrome (aTOS) endpoints for all different raters.

	VAS1 DSA	VAS2	RAD1	RAD2	SON1 US	SON2	REF DSA
aTOS	0.921	0.882	0.960	0.901	0.784	0.803	0.882
Aneurysm	0.235	0.156	0.235	0.255	0.176	0.157	0.137
Thrombus	0.020	0.020	0.000	0.000	0.039	0.020	0.059

aTOS = arterial thoracic outlet syndrome; US = raters using ultrasound; DSA = raters using digital subtraction angiography, VAS = vascular surgeon, RAD = radiologist, SON = sonographer, REF = reference.

Agreement between ultrasound and digital subtraction angiography reference: (pre-defined endpoint)

There was no agreement between the pre-defined reference gold standard (REF) and US with $\kappa = 0.098$ (−0.325, 0.521). The test accuracy was 0.745 (0.611, 0.824), not exceeding the no information rate ($p = 1.0$), so that accuracy can be explained by chance alone.

Summary

Poor concordance was found between individual raters and the reference. Similarly, poor concordance was found between any rater group and the reference. Very good concordance was found within the US group, good concordance within the vascular surgeon group, and moderate concordance within the radiologist group. Similarly, concordance between vascular surgeon and radiologist raters was only moderate. However, only poor concordance was found between the US and the DSA group.

Results of latent class analysis

The pre-defined reference gold standard did not perform well. In the absence of a valid reference, LCA was used to better understand the performance of US and DSA in the diagnosis of aTOS.

Using LCA, the observed classification results between DSA and US were best described by the following three classes: Both diagnostic imaging methods rated aTOS as present in 76.5 % of cases (LCA class I) (DSA 0.981; 0.947, 1.000 vs. US 0.961; 0.898, 1.000). There was a clear statistically significant discrepancy between the diagnostic imaging methods in 15.6% of cases for the presence of aTOS (LCA class II) (DSA 0.969; 0.893, 1.000 vs. US 0.002; 0.000, 0.364). In this class DSA tended to diagnose aTOS, while US rejected aTOS in most cases. Finally, the third class showed an opposite but non-significant difference between diagnostic imaging methods in the remaining 7.8 % of cases (LCA class III) (DSA 0.188;

0.000, 0.525 vs. US 0.750; 0.002, 1.000). In this class US tended to diagnose aTOS, while DSA frequently rejected aTOS.

In the group with discordant results, the US examination was more conservative and showed a tendency to underdiagnose aTOS (Fig. 2). However, in no case was aTOS requiring surgery overlooked. On the other hand, two patients without pathological DSA and or plethysmography findings needed immediate surgery. In one patient US detected pectoralis minor syndrome and in another peripheral embolism was found by US but not by DSA and plethysmography because of good compensation.

DISCUSSION

In a pre-selected cohort with highly suspected thoracic outlet syndrome, vascular US was performed in addition to the routinely performed DSA using a standardised examination protocol. The US method used in this study served the sole purpose of evaluating its potential as a replacement for the functional angiography of the thoracic outlet. DSA is generally used as the gold standard in the diagnostic work up of arterial TOS. In the study it was found that DSA did not perform well. There was an overall poor concordance with the pre-defined DSA reference gold standard. Within groups, concordance was moderate between DSA raters while being very good between US raters. In addition, overall concordance was higher for US compared with DSA.

In the absence of a valid gold standard, LCA demonstrated that US performed well in diagnosing aTOS. Diagnostic discrepancies between US and DSA as described by LCA, safely identified patients with aTOS without missing relevant diagnoses.

Vascular ultrasound as a diagnostic tool in arterial thoracic outlet syndrome

Vascular US can detect relevant flow limitations and vessel wall changes and provides information about perivascular structures.¹⁶ In aTOS, there is a lack of robust data regarding the use of US as the diagnostic tool,³ which contrasts with other vascular regions where US provides excellent service and makes other imaging modalities obsolete. In contrast to other imaging modalities, US is non-invasive and can be used dynamically; positional changes and various stress tests can be performed without much effort. Standardised US protocols result in excellent inter-rater agreement.¹⁷ Therefore, a standard US protocol was developed for the diagnosis of aTOS based on practical expertise, experience, and expert opinion. Comparable studies were not available. aTOS was the focus: It is easier to diagnose than venous or

Table 4. Accuracy of main arterial thoracic outlet syndrome (aTOS) endpoints for all different raters compared with the pre-defined reference.

	VAS1 DSA	VAS2	RAD1	RAD2	SON1 US	SON2
aTOS	0.843	0.882	0.882	0.823	0.745	0.803
Aneurysm	0.950	0.931	0.951	0.882	0.922	0.951
Thrombus	0.961	0.961	0.971	0.971	0.951	0.961

aTOS = arterial thoracic outlet syndrome; US = raters using ultrasound; DSA = raters using digital subtraction angiography; VAS = vascular surgeon; RAD = radiologist; SON = sonographer.

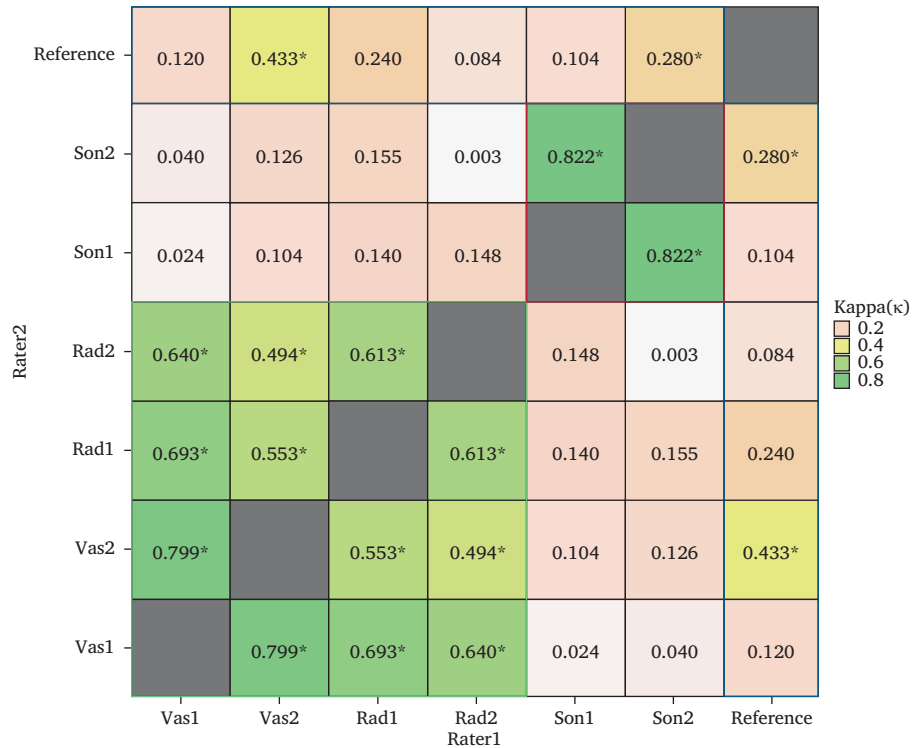


Figure 1. Concordance for arterial thoracic outlet syndrome between all raters. Blue box: rater concordance against reference. Red box: concordance between ultrasound raters. Green box: concordance among digital subtraction angiography) raters. *Values of concordance that are significantly different from $\kappa = 0$. Vas = vascular surgeon; Rad = radiologist; Son = sonographer.

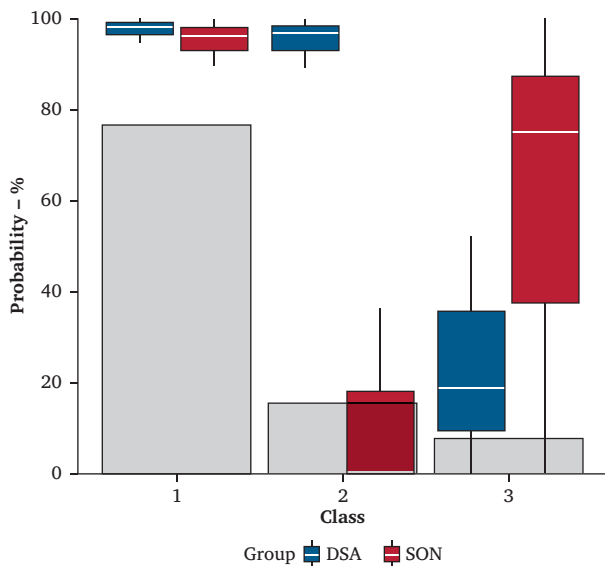


Figure 2. Probabilities for detection of arterial thoracic outlet syndrome by digital subtraction angiography raters (DSA) and sonography raters (SON) for the three classes found in latent class analysis (LCA). Grey shaded bars show the prevalence of the three classes found. LCA class 1 shows high concordance for 76% of cases. Class 2 and 3 describe discrepant cases. Class 2 shows that in 16% of cases DSA leads to arterial thoracic outlet syndrome diagnosis in contrast to ultrasound. The final 8% of class 3 shows the opposing pattern.

neurogenic TOS. Besides vessel wall changes such as dilatation or intravascular thrombi, haemodynamic patterns were included downstream from suspected compressed artery segments using spectral Doppler analysis deliberately excluding screening for local compression of the artery. Digital arteries, including the radial and ulnar arteries, were examined to exclude digital embolism. It is important to mention that this is not a comprehensive examination of the entire flow path; rather, it is a focused evaluation specifically aimed at confirming or ruling out aTOS.

Can digital subtraction angiography serve as a gold standard?

Aware of the difficulties and potential discrepancies in interpreting DSA, an *a priori* interdisciplinary gold standard was established. All DSA studies were submitted to an interdisciplinary vascular committee composed of radiologists, vascular surgeons, and angiologists. The outcome of this conference served as the gold standard.

What was surprising was the extremely low agreement between this interdisciplinary gold standard and the US and DSA investigations performed. The overall agreement was not better than chance. At the same time, there was very good to moderate agreement within the US, vascular surgeon, and radiologist groups. This indicates that US and DSA are reliable. The pre-defined gold standard was therefore questioned.

Latent class analysis

In such cases where a valid gold standard is lacking, LCA can be useful.^{18,19} LCA applied to the study cohort identified three distinct classes. The predominant class demonstrated consistent findings between DSA and US. This class most closely corresponds to extreme findings of, for example, complete compression of the artery with resulting no flow in the distal vessel. In this group, there were no discrepancies between the two imaging tools. Thus, US reliably diagnosed definitive aTOS. The second and third class comprised patients where discrepancies were found between DSA and US. Specifically, in the second class, pathological findings suggestive of aTOS were found by DSA but not by US. Notably, not one single patient in this group was advised surgical intervention based on any of the examinations performed. In this class, DSA showed only mild compression, contrast was not optimal, clavicle overlays hindered assessment, or compression was labelled probable.

To obtain better images with better assessment ability by DSA, a second image sequence would have been necessary. To avoid higher contrast and radiation exposure in these young patients, radiologists decided against it, mainly because of the lack of consequences when, at best, only minor compression was present. It is in these cases that the different approach of the methods plays a major role.

US as a dynamic method combines vessel wall and colour changes with haemodynamic parameters. The US information content is substantial and reveals much more than just information about intraluminal contrast.¹⁰ According to the standardised US protocol, compression was diagnosed only when relevant changes in pulsed wave Doppler could be registered downstream from the compressed arterial segment. Mild compression of the subclavian artery without haemodynamic consequences is thus overlooked. However, mild compression has no pathological significance, and in the absence of additional vessel wall damage or evidence of peripheral embolism, there is no reason to intervene. Mild compression detected by DSA has always been classified as being relevant, probably to avoid accusations of ignoring facts. Clearly, DSA cannot distinguish between compression with haemodynamic relevance and compression without such relevance. This may also be explained by the fact that angiography was performed using one projection only at rest and for each of the provocation manoeuvres. Thus, DSA overestimates aTOS and cannot discriminate well between haemodynamically relevant and irrelevant aTOS. Interestingly, US was able to diagnose peripheral embolism and pectoralis minor syndrome in two patients. Both were not detected by the other diagnostic tools because distal vessel obliteration was excellently compensated for by collaterals.

CONCLUSION

In summary, US has been shown to be highly reliable in the diagnosis of aTOS, even more so than DSA. The method demonstrates high US inter-rater agreement when carried out according to a standardised protocol. By applying LCA, US was shown to be the best test available to diagnose

aTOS and should therefore be considered as the gold standard for the detection of haemodynamically relevant compression of arteries in the diagnosis of aTOS.

The study suggests that US using a standardised protocol is a valid tool to diagnose aTOS.

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CONFLICT OF INTEREST

None.

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