Decision making in the treatment of peripheral arterial disease - A single-institution comparative study using information from color Doppler and digital subtraction angiogram studies

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Abstract

Background: Numerous studies have compared the accuracy of color Doppler (CD) with that of digital subtraction angiography (DSA) in the diagnosis of peripheral arterial disease (PAD). However, only a few have looked at the influence of these diagnostic tests on the treatment decision in PAD. **Aim:** This study evaluated the differences in treatment decisions that were based on CD and with those based on DSA findings. **Methods and Materials:** Findings from CD and DSA studies obtained in 40 patients were entered on line diagrams by two radiologists working separately. These were randomized and sent to three experienced clinicians – two vascular surgeons and one interventional radiologist. The treatment decisions of the clinicians based on each proforma were collected and analyzed to look for the degree of agreement between Doppler-based and DSA-based decisions. **Results:** There was fair to moderate agreement between CD-based and DSA-based decisions for all three clinicians, with some improvement in agreement with the addition of clinical data. The vascular surgeons showed better agreement with each other on treatment decisions compared to the interventional radiologist who showed a fair-to-moderate level of agreement with the vascular surgeons, which did not significantly change with the addition of clinical data. **Conclusion:** There is a fair to moderate agreement between treatment decisions based on CD findings and those based on DSA findings. We conclude that CD along with clinical data is sufficient to make decisions in the treatment of PAD..

Key words: Color Doppler; decision making; digital subtraction angiography; peripheral arterial disease; treatment

Introduction

Color Doppler (CD) and digital subtraction angiography (DSA) are diagnostic tests used in the evaluation of peripheral arterial disease (PAD). CD gives information about the blood flow within the vessel as well as the condition of the vessel wall. DSA, which is considered to be the gold standard, gives information regarding the luminal patency and the presence of collaterals. Many studies have compared the two tests and have found CD to have a reasonably good sensitivity and specificity in the evaluation of PAD.[1–4] Since clinicians prefer to base their decisions on the disease patterns as seen on DSA studies and the clinical status, we felt that it would be clinically relevant to evaluate the effect of CD on treatment decisions.

The primary objective of this study was to determine whether the clinicians involved in treating PAD of the lower limbs would choose a different treatment plan if

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provided with information from a CD study as compared to information from a DSA study. A secondary objective was to determine whether the addition of relevant clinical information would result in any change in the treatment decision.

Materials and Methods

This prospective study involved 40 consecutive patients with PAD who were scheduled to have DSA studies of the lower limbs. Approval for the study was obtained from the institutional ethics committee. All the patients underwent CD evaluation by the same radiologist a day prior to the DSA. The DSA studies were performed and interpreted by another radiologist who was blinded to the findings of the CD study. The information from the CD and DSA studies was entered on separate data sheets containing line diagrams of the lower limbs [Figure 1]. Disease was indicated by shading the affected segments and mentioning the length of the stenosis or occlusion, the presence of collaterals, and distal reformation. For CD studies, the peak systolic velocity and pattern of blood flow in each segment were also mentioned.

The data sheets containing the line diagrams (80 in all) were randomized using a computer-generated code and emailed to two vascular surgeons (A and B) and an interventional radiologist working in the same institution, all having many years of experience in the treatment of PAD. They examined each proforma independently and noted down their treatment decision, i.e., angioplasty, surgery, both, or neither. Later, the patient's clinical data (i.e., age, sex, general health status, and the presenting symptoms, including which was the more affected limb) were entered on each data sheet, and these sheets were then sent back to the three clinicians after randomization once again, thus ensuring that the clinicians were unaware of their previous decisions. The treatment decisions were noted down separately and the data of both sessions were collected and analyzed.

Statistical analysis

The kappa statistic was used to measure the degree of intraobserver and interobserver agreement after correcting for any agreement that may have occurred by chance. The kappa statistic has a maximum value of one, indicating perfect agreement, and a minimum value of zero, indicating no agreement better than that which may have occurred by chance. Kappa values were interpreted using the guidelines provided by Landis and Koch,[5] according to which values of kappa in the range of 0–0.25 indicate poor agreement, 0.25–0.5 indicate moderate agreement, 0.50–0.75 indicate good agreement, and 0.75–1 indicates excellent agreement.

For assessing intraobserver agreement we compared the CD-based and DSA-based treatment decisions of each physician. For assessing interobserver agreement we compared the decisions taken by different clinicians based on the findings of the same diagnostic modality. The decisions taken without and with clinical data were also compared. All data analysis was done using Stata® 10.0 (StataCorp, College Station, TX, USA).

Results

Treatment decisions were made by the clinicians on all 80

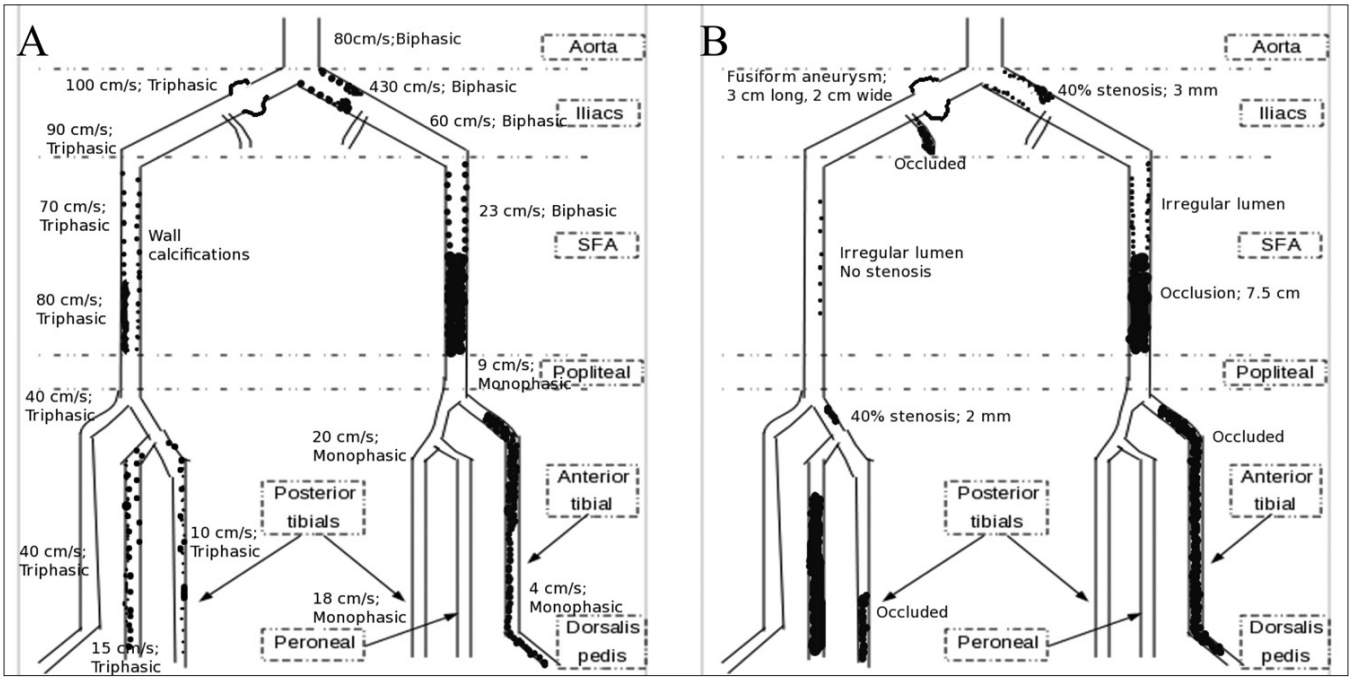

Figure 1 (A,B): Proforma containing line diagrams showing the Doppler (A) and DSA (B) findings of a sample patient

data sheets. The values of intraobserver and interobserver agreements are given in Tables 1 and 2, respectively. Table 3 describes the region-wise distribution of cases where the treatment strategy was changed after DSA results were provided.

Intraobserver agreement

For vascular surgeon A there was a marked improvement in agreement between CD-based and DSA-based decisions when clinical data was provided, the agreement improving from poor (kappa value 0.22) to moderate (kappa value 0.52).

Vascular surgeon B showed moderate agreement between CD-based and DSA-based decisions, with a minimal change of kappa value from 0.5 to 0.48 with the availability of clinical data.

The interventional radiologist showed fair to moderate agreement between CD-based and DSA-based decisions, with a small change of kappa value from 0.52 to 0.46 with the availability of clinical data.

Table 1: Intraobserver agreement between color Doppler-based and DSA-based decisions

Decision maker	Without clinical data	With clinical data
Surgeon 1	0.22	0.52
Surgeon 2	0.5	0.48
Radiologist	0.52	0.46

Table 2: Interobserver agreement between color Doppler-based and DSA-based decisions

Decision makers	Color Doppler–based		DSA-based	
	Without clinical data	With clinical data	Without clinical data	With clinical data
Surgeon 1 *vs* Surgeon 2	0.47	0.74	0.49	0.58
Surgeon 1 *vs* Radiologist	0.48	0.45	0.41	0.43
Surgeon 2 *vs* Radiologist	0.56	0.51	0.50	0.37

DSA: Digital subtraction angiography

Table 3: Region-wise distribution of cases describing the change in treatment strategy after DSA results were provided

Region involved by peripheral arterial disease	Treatment strategy after DSA results were provided		Number of decision making events (Number of cases X 3 investigators)
	Changed (%)	Unchanged (%)	
Aorto-iliac	4 (16.7)	20 (83.3)	24
Femoro-popliteal	4 (33.3)	8 (66.7)	12
Infrapopliteal	0	3 (100)	3
Aorto-iliac and femoro-popliteal	3 (25)	9 (75)	12
Femoro-popliteal and infrapopliteal	19 (42.2)	26 (57.8)	45
Aortoiliac, femoropopliteal and infrapopliteal	11 (45.8)	13 (54.2)	24
Total	41 (34.2)	79 (65.8)	120

Interobserver agreement

The two vascular surgeons showed moderate agreement with each other in the absence of clinical data. The agreement between them was similar for CD-based (kappa 0.47) and for DSA-based (kappa 0.49) decisions. With availability of clinical data, the agreement improved for both CD-based (kappa 0.74) and for DSA-based decisions (kappa 0.54).

Vascular surgeon A and the interventional radiologist showed moderate agreement in the absence of clinical data for both CD-based (kappa 0.48) and for DSA-based (kappa 0.41) decisions. With the addition of clinical data, moderate agreement was seen for both CD-based (kappa 0.45) and for DSA-based (kappa 0.43) decisions.

Vascular surgeon B and the interventional radiologist showed fair agreement in the absence of clinical data for both CD-based (kappa 0.56) and for DSA-based (kappa 0.50) decisions. With the addition of clinical data, moderate level of agreement was seen for both CD-based (kappa 0.51) and DSA-based (kappa 0.37) decisions.

Discussion

Clinical decision making in the treatment of PAD is based on detailed history, physical examination, noninvasive tests like ankle-brachial pressure index or CD and selective angiography. The decision whether or not to intervene is based on the patient's age, health, clinical symptoms, and the presence of disabling claudication or rest pain or ulceration. The factors that influence the treatment plan are the disease pattern and severity, the clinical status of the patient, the experience of the decision maker, and the cost of the treatment. The cost of the treatment plays an important role, especially if the patient has to pay for it, as is often the case in developing countries. The cost-effectiveness of the treatment plan is also an important issue for the healthcare economy. There are various guidelines to help standardize the decision-making process and make it more objective.[6] While many studies have compared the diagnostic accuracy of CD with that of DSA in the evaluation of PAD,[1–4] only a few have studied the influence of these modalities on the planning of the patient's treatment.[7–9]

The improvement of the agreement between the CD-based and DSA-based decisions of vascular surgeon A when clinical data was provided suggests that appropriate decisions could be made based on CD findings if clinical information was also provided.

The moderate agreement between CD-based and DSA-based decisions for vascular surgeon B suggests that CD is almost as good as DSA for deciding the treatment plan. Similarly, the fair agreement between CD-based and DSA-based decisions for the interventional radiologist also suggests that CD is almost as good as DSA for treatment planning.

The moderate agreement between the two vascular surgeons suggests that they followed a similar approach when treating patients with PAD; this was probably because both were working in the same institution and followed similar treatment protocols. The improvement in agreement with the addition of clinical information is expected. The surgeons and the interventional radiologist showed moderate to fair degree of agreement, which improved with the addition of clinical data, suggesting that similar decisions could be made based on CD findings which could be improved with clinical data.

It has been observed in other studies that DSA-based interobserver agreement was sometimes lower than CD-based agreement. This has been attributed to the fact that DSA probably gives more information in the same clinical situation and thus probably provides more treatment options.[6]

As described in Table 3, the treatment strategy did not change at all when infrapopliteal regions were involved. The treatment strategy remained unchanged in a majority of the cases when aortoiliac and femoropopliteal regions were involved together or separately.. There was some change in treatment strategy in 42% to 45% of cases where multiple regions (femoro-popliteal and infrapopliteal with or without the aortoiliac regions) were involved.

Presently, the only time most centers perform DSA is prior to a planned endovascular treatment for PAD. For diagnostic purposes, other non-invasive modalities such as CT angiography and MRI angiography are preferred since all the findings can be visualized on a single image. The findings of color Doppler, if provided on a single sheet containing a line diagram of the lower limb arteries, would have the same visual effect and potentially increase the acceptance of color Doppler as a diagnostic tool in PAD.

CT and MRI angiography have certain disadvantages that include the higher procedure cost, increased resources required and potential for contrast induced nephropathy. On the other hand, the reliability of color Doppler depends on the expertise of the person performing the scan and the amount of time taken. This is relevant especially in the infrapopliteal vessels where scanning is difficult but very important.

This study reveals that there would be no change in the treatment strategy in PAD if the findings of color Doppler are considered along with the clinical data. There is no need for a DSA study purely for diagnostic purposes. If more resources could be devoted to upgrading the quality of color Doppler scans by improving training and experience, it would improve the cost-effectiveness of the treatment, reduce the radiation dose and inconvenience to the patient and would make a difference in the management of PAD especially in scenarios where resources are limited.

Involving more clinicians from different institutions might have improved this study by including more decision makers and allowing evaluation of different treatment approaches in the same patient. We have therefore planned a larger study involving multiple vascular surgeons and interventional radiologists from different institutions.

Conclusion

There is a fair to moderate level of agreement between treatment decisions based on CD and DSA. This suggests that CD along with clinical data is sufficient to make appropriate treatment decisions. This approach can limit the need for diagnostic angiography in the evaluation of PAD.

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