

# Reproducibility of Carotid Duplex Scanning for a Quality Assurance Program

Trina Thompson, BSN, RVT,<sup>1</sup> Kim Sutton-Tyrrell, DrPH,<sup>2</sup>  
Dawn Johnson, BSS,<sup>1</sup> Sidney K. Wolfson, Jr, MD<sup>1</sup>

**ABSTRACT** Quality assurance (QA) in a vascular laboratory is essential to provide accurate and consistent test results. Whatever accreditation process is ultimately required will surely involve ongoing documentation of the quality of test data. Thus, it is prudent for all vascular laboratories to begin to develop mechanisms for ongoing QA. Part of our QA program monitors carotid duplex examinations by duplicating the scan on one carotid system on random patients. The first sonographer is unaware of the duplicate test, since scheduling of the repeat scan is the responsibility of the second observer. Each examination includes B-mode images and spectral analyses in the common carotid artery and the proximal and distal internal carotid artery. Immediately after the examination, the sonographers review and discuss the results. This program has been a valuable tool for the identification of problems in scanning technique, in testing protocol, and also problems due to equipment. The program also serves to document accuracy and consistency in test results by monitoring technologist variability.

## Introduction

The importance of quality assurance (QA) for calibrating ultrasound equipment has been well documented,<sup>1-4</sup> indicating that both pulsed Doppler and B-mode instrument settings must remain fairly well standardized to provide accurate noninvasive testing. Sonographer performance also affects quality of examinations, therefore a means to monitor variability between sonographers is of equal importance. However, few published reports exist to define how to initiate such a program and guidelines for evaluating results.<sup>5,6</sup>

A formal QA program provides monitoring of data accuracy, provides a measure of variation between sonographers, and fosters consistency in vascular testing. In addition, QA provides a basis for raising equipment and personnel to a desired standard and maintaining that standard.

## Materials and Methods

One goal of our quality assurance effort is to evaluate the accuracy of carotid duplex imaging in clinical patients by assessing intersonographer variability. This was relatively easy to implement because all laboratory operations were already overseen by a

comprehensive computer program. History and test data are entered directly into the computer, and a preliminary report is generated before the patient leaves. While the computer system was helpful, it was not essential for the success of the program.

Sonographers are required to perform QA examinations twice monthly. Each sonographer selects a patient that is going to be scanned by another sonographer and makes sure that there is time for a 15-30-min re-scan of one side. This intent is entered into the computer by the secretary. The first sonographer performs the study, unaware that a repeat examination is planned until the initial scan and data entry are complete. The examination consists of gray scale B-mode imaging with color Doppler of the entire common carotid artery (CCA) and the primary branch vessels. Sample volumes for spectral analyses are obtained in the mid-CCA, proximal internal carotid artery (ICA) (at 1 cm), or highest velocity and distal ICA (most distal). All data are entered directly into the computerized medical data base. Immediately following the initial scan, the repeat examination is explained to the patient, permission is obtained, and the second scan is performed by the second sonographer using the same scanner. At the completion of the repeat scan, the two sonographers compare results before the patient leaves the laboratory. Any major discrepancies are investigated and the reasons are recorded for reference during statistical analysis and problem solving. When a discrepancy is of clinical significance, the two sonographers and the supervisor participate in a reevaluation of the patient. The reports are reviewed on a daily basis by the supervisor and videotapes are reviewed when necessary. The results are analyzed and documented every 6 months.

From the <sup>1</sup>Noninvasive Vascular Laboratory, University of Pittsburgh Medical Center; Department of Surgery, School of Medicine, and <sup>2</sup>Department of Epidemiology, Graduate School of Public Health, University of Pittsburgh, Pittsburgh, PA 15213.

Address correspondence to: Trina Thompson, BSN, RVT, Jefferson Vascular Laboratory, Coal Valley Road, Pittsburgh, PA 15025.

DISTRIBUTION OF DIFFERENCE IN PEAK VELOCITY READINGS BETWEEN 1ST & 2ND OBSERVERS

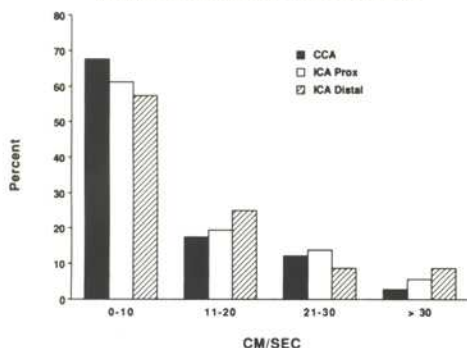


Figure 1

A total of 74 QA examinations were performed. This graph illustrates the variability of measurements between different sonographers in the CCA and the proximal and distal ICA segments during QA scans.

## Results

The program included four full-time sonographers. There were 74 QA scans performed over a 15 month period. Initially, one QA examination was done each month by the supervisor, but eventually all four sonographers performed two scans a month.

Between first and second sonographers, the difference in peak systolic velocity measurements were compared in the CCA and proximal and distal ICA (Figure 1). In the CCA, paired readings were within 10 cm/sec of each other 68% of the time and within 11–20 cm/sec 18% of the time (86% were within 20 cm/sec). The distal ICA readings were slightly less reproducible with 57% within 10 cm/sec and 25% within 11–20 cm/sec (82% within 20 cm/sec). The ICA proximal readings were within 20 cm/sec 83% of the time.

Next, the data were analyzed by sonographer to determine whether any one sonographer consistently performed better or worse than the others (Figure 2). Replicate measures in the CCA were within 0–10 cm/sec in 64%, 74%, and 60% of cases for sonographers A, B, and C, respectively. Readings were within 20 cm/sec in 92%, 86%, and 82% of cases for each sonog-

Table 1

Percent Differences in Peak Velocity Readings over Time

| Time           | CCA (0–20 cm/sec) | ICA proximal (0–20 cm/sec) | ICA distal (0–20 cm/sec) |
|----------------|-------------------|----------------------------|--------------------------|
| ≤3/28/91       | 90                | 83                         | 81                       |
| 4/5/91–8/30/91 | 80                | 60                         | 75                       |
| ≥9/4/91        | 86                | 91                         | 88                       |
| Total          | 85                | 81                         | 82                       |

DIFFERENCE IN PEAK VELOCITY READINGS BETWEEN SONOGRAPHERS FOR THE CCA

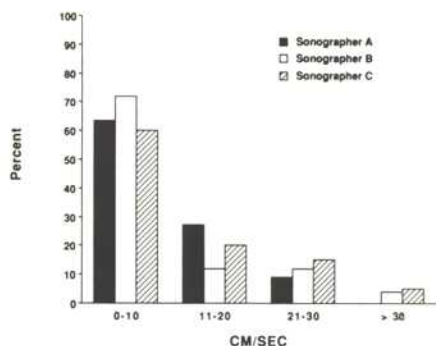


Figure 2

This graph illustrates the differences in peak velocities of the CCA when the sonographers were checked by any one of three other sonographers in the laboratory.

rapher, respectively. Based on these observations, we arbitrarily defined replicate measures within 20 cm/sec as acceptable.

Velocity measures were compared over time for the three locations (Table 1). The time frames were the first 6 months; the next 5 months and the last 4 months. This division provided approximately the same number of examinations per period. For the CCA, there was little variation in reproducibility over time, with acceptable results obtained in 90%, 80%, and 86% of the cases for the three time frames, respectively. For the distal ICA, acceptable replicate measures were obtained in 81%, 75%, and 88% of cases for the three time frames respectively. In general, rates of accept-

Table 2

Agreement within 20 cm/sec for Different Peak Velocity Ranges

|                 | Average peak velocity (cm/sec) | Number of measurements | ICA number within 20 cm/sec | % Within 20 cm/sec |
|-----------------|--------------------------------|------------------------|-----------------------------|--------------------|
| A. Proximal ICA | <50                            | 25                     | 16                          | 64.0               |
|                 | 50–99                          | 35                     | 23                          | 65.7               |
|                 | 100–149                        | 5                      | 1                           | 20.0               |
|                 | 150–199                        | 4                      | 1                           | 25.0               |
|                 | 200+                           | 5                      | 1                           | 20.0               |
|                 | Totals                         | 74                     | 42                          | 56.8               |
| B. Distal ICA   | <50                            | 13                     | 12                          | 92.3               |
|                 | 50–99                          | 54                     | 28                          | 51.9               |
|                 | 100–149                        | 6                      | 2                           | 33.3               |
|                 | 150–199                        | 1                      | 0                           | 0.0                |
|                 | 200+                           | 0                      | 0                           | 0.0                |
|                 | Totals                         | 74                     | 42                          | 56.8               |

Table III

Comparison of ICA/CCA Peak Velocity Ratios

| Clinical sonographer ratio | QA sonographer |      | Totals |
|----------------------------|----------------|------|--------|
|                            | <1.8           | ≥1.8 |        |
| <1.8                       | 59             | 2    | 61     |
| ≥1.8                       | 1              | 10   | 11     |
| Totals                     | 60             | 12   | 72     |

able results were lower during the 04/05/91 to 08/30/91 time period (Table I).

Because of the altered hemodynamics associated with higher blood flow velocities, we suspected that reproducibility would differ in patients with low versus high disease states. We therefore averaged the two replicate readings as a measure of the patients' disease state, then analyzed reproducibility across these levels. For both the proximal and distal ICA, reproducibility became progressively worse as the mean velocity increased (Tables IIa, IIb). The distal site had slightly better agreement overall.

Most importantly, we wanted to determine if the technologists' results were the same from a clinical perspective. In our clinical laboratory, an ICA/CCA ratio of 1.8 or greater is clinically important. Overall, there was substantial agreement in the determination of whether or not the lesion was stenotic (Table III). When the ratios resulting from replicate readings were compared, results were clinically different in only three cases.

### Discussion

To pilot the program, two replicate scans were performed by the supervisor monthly. Later, each sonographer was asked to perform two QA scans per month. When two scans per month were started, the sonographers found it difficult to get both scans accomplished because the daily schedule often did not allow time for the replicate scans. In addition, because the first sonographers were unaware of the QA examination to follow, they often finished their test and sent the patient away before the second sonographer could do the repeat scan. This problem was solved by creating an alert on the last data entry screen of the original scan. The intent to perform a QA scan was entered by the secretary into the data base. The alert served to notify the initial sonographer at the conclusion of the examination that a QA examination was to follow. If the patient refused the repeat scan, the response would reflect the refusal. To date, no patient has refused the second examination. After 2-3 months, this procedure became routine and the examinations were planned and performed with less time and effort.

We stressed peak velocity measurements for the QA scans as these were most easily quantified in the clinical setting. Other data such as cross-sectional area measurements, end-diastolic velocities, spectral broadening, etc. are obtained and utilized for clinical

diagnosis on all clinical scans in our laboratory. However, peak systolic velocities (PSV's) are the most reliable index of clinically significant stenoses and certainly of critical stenoses. Therefore, we chose to use PSV for our QA scans for comparing reproducibility and diagnosing a critical stenosis. It is advisable that each laboratory define their own set of protocols and establish a quality assurance program to affirm the validity of results.

When this project was first begun, we were unsure as to how much variability in paired measurements would be acceptable in a clinical laboratory. Research protocols require stringent reproducibility,<sup>6</sup> and no standards were available for clinical settings. The initial goal was for velocities to remain within 10 cm/sec. As results were reviewed, it became apparent that with linear array probes, small angle changes caused enough of a difference in velocity that the 10-cm/sec standards that were initially set seemed too stringent.<sup>2</sup> More importantly, we realized that 10 cm/sec usually was not clinically significant. Therefore, we decided that velocity differences within 20 cm/sec of each other were acceptable. Over 80% of all replicate readings were within this range.

When reviewing early results, replicate readings done by sonographer C were acceptable less than 80% of the time, clearly more unfavorable than the other two. The supervisor reviewed the videotapes and reports, and found that Doppler angles were routinely greater than 60° for sonographer C. Techniques for obtaining optimal Doppler angles were reviewed with the staff. Subsequent scans involving sonographer C showed improved agreement.

Stability of results was the best for the CCA over time, while the proximal ICA velocities varied most. The inferior performance in the second time period occurred during a hospital merger that combined two vascular laboratories. This was a time of major change, considerable stress, and increased patient load. It is possible that this had an adverse effect on the quality of the sonographers' work. By the third time period, disruptions due to the merger were resolved and improvement in reproducibility was seen. More specific reasons for variability with the ICA velocities may have been twofold. Since the ICA proximal is often tortuous or curved, setting the angle was frequently a problem. Secondly, the exact location of sampling varied from sonographer to sonographer, often due to flow separation from the bulb. These findings elicited a closer look at the protocol thus defining the landmarks for sampling more carefully. This program encouraged sonographers to be more attentive in adhering to the protocol, and to sharpen their imaging techniques.

As expected, increased variability was found in patients with stenotic lesions and associated higher velocities. This may be due to several factors. First, small differences in angle placement result in larger variations when velocities are high. Secondly, when aliasing occurs with high velocities, sonographers are required to assess the spectral waveform visually and estimate wrap around due to limitations of the equip-

ment used. The precision of this observation frequently creates variances of more than 20 cm/sec in peak systolic readings. Thirdly, when a spectral analysis is obtained in a tight stenosis, slight differences in sample volume placement can result in differences of greater than 20 cm/sec.

The three discrepancies in the ICA/CCA ratios provoked a close inspection of the QA reports. It was determined that both sonographers had detected the stenosis, but that each reported it at a different segment (proximal vs. distal). These discrepancies called attention to the need for more consistent guidelines for site selection. Even so, by requiring velocities at two ICA sites in the protocol, the existence of significant stenosis was not missed in any patient.

In conclusion, a formal program evaluating reproducibility for QA has been found feasible for carotid studies in the clinical peripheral vascular laboratory setting. Accuracy and consistency of test results can be improved while making technical and mechanical problems easily detectable and quickly solved. As a result of this QA program, we were able to identify and solve difficulties in techniques, recognize the

possible ramifications of stress and increased patient load on staff, and improve our scanning protocol. While the protocol was defined to examine the easily quantified velocity measurements, the increased effort and attention that it engendered also resulted in a subjective increase in the quality of the B-scan.

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