

COOPERATIVE STUDIES

Sensitivity and Specificity of Assessing Coronary Bypass Graft Patency With Ultrafast Computed Tomography: Results of a Multicenter Study

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Because a significant number of all patients seen by cardiologists have had coronary bypass surgery, a relatively noninvasive method of assessing coronary bypass graft patency would be very helpful. Ultrafast computed tomography, by virtue of its rapid data acquisition time and reasonable spatial resolution, may be useful in this regard. To determine the sensitivity, specificity and predictive accuracy of this imaging modality as compared with cardiac catheterization, a multicenter study was undertaken.

There were two parts to the study. Part I involved the evaluation of 179 grafts in 74 patients studied in the five participating centers between March 1985 and August 1986. Twenty-nine percent of these graft studies were found to be technically inadequate and were excluded before patency determinations began. The remaining group of 127 bypass grafts in 62 patients had studies adequate for interpretation. Fifty-one grafts were to the left anterior descending coronary artery or a diagonal branch, 37 to branches of the left

circumflex artery and 28 to the right coronary artery or a posterior descending vessel; in addition, there were 11 internal mammary artery bypass grafts primarily into the left anterior descending or diagonal artery distribution. The sensitivity of detecting angiographically open grafts was 93.4%, the specificity of detecting angiographically closed grafts 88.9% and the predictive accuracy was 92.1%. A subsequent study (Part 2) was performed 9 months later to assess the ability to carry out technically adequate examinations. Of the 138 consecutive graft examinations (50 patients) included in this part of the study, 94.2% of the examinations were found to be technically adequate.

From these data it is concluded that 1) ultrafast computed tomography is a very useful, minimally invasive technique for evaluating coronary artery bypass graft patency, and 2) technically adequate studies can be effectively performed in the majority of patients with bypass grafts.

(*J Am Coll Cardiol* 1988;12:1-7)

In patients who have had coronary bypass surgery, the symptoms and clinical course are largely dependent on the status of the bypass grafts (that is, whether they remain

patent or become occluded) (1-3). Although bypass graft patency is affected by many factors, it is generally held that 10 to 30% of grafts are occluded 1 to 2 years after surgery and 45 to 55% are occluded by 10 to 12 years (4-6). Because >165,000 coronary bypass operations are performed each year (7), bypass graft occlusions pose a significant problem in clinical cardiology.

Graft patency can be accurately assessed by cardiac catheterization with angiography. Because this invasive technique is expensive and associated with some risk, both indirect and direct minimally invasive approaches to assessing graft patency have been attempted. Indirect approaches (stress electrocardiography [8], stress thallium-201 imaging [9], stress radionuclide ventriculography [10]) attempt to detect regional myocardial ischemia and then equate the presence of regional ischemia with probable graft closure.

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Manuscript received July 24, 1987; revised manuscript received February 18, 1988, accepted March 4, 1988.

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Other minimally invasive approaches attempt to visualize or detect flow in bypass grafts directly. Such approaches include transcutaneous Doppler echocardiography (11), digital subtraction angiography (12), nuclear magnetic resonance imaging (13) and conventional computed tomography (14,15). However, none of these approaches has resulted in a highly accurate diagnostic procedure that is widely accepted.

Ultrafast computed tomography is a promising new approach for accurately detecting coronary bypass graft patency. The ultrafast computed tomographic scanner has reasonably high temporal and spatial resolution that permits one to obtain rapid sequential images during bolus injections of contrast medium from a peripheral vein, and several small preliminary studies (16-18) with this technique have shown promising results. The purpose of this investigation was to assess the sensitivity, specificity and predictive accuracy of the evaluation of coronary bypass grafts with ultrafast computed tomography in a large, carefully controlled multicenter trial. The results suggest that ultrafast computed tomography is a highly accurate, relatively noninvasive approach to assessing bypass graft patency.

Methods

Study patients. Two groups of patients were studied. In Group I, all patients underwent both an ultrafast computed tomographic examination and coronary angiography. This enabled us to assess the sensitivity, specificity and accuracy of the determination of graft patency in patients who had technically adequate studies. The examinations were performed between March 1985 and August 1986. All of the patients in this group had a clinical syndrome that required coronary angiography.

Group I consisted of 74 patients with 179 coronary bypass grafts. The examinations were done in the five centers participating in the study: Deborah Heart and Lung Center (Browns Mill, NJ), University of Illinois (Chicago, IL), Cedars-Sinai Medical Center (Los Angeles, CA), University of California (San Francisco, CA) and the University of Iowa (Iowa City, IA). In 12 patients (30 grafts), the entire computed tomographic study was considered technically inadequate and was excluded before data analysis began. The reasons for exclusion were poor bolus administration in one case, poor image resolution in five, excessive respiratory motion in two, defective recording tape in one and failure to acquire an adequate number of scan levels in three. An additional 16 grafts in 15 patients with otherwise satisfactory studies were also excluded because a portion of the examination was technically inadequate. The technical problems include poor bolus administration in 2 cases, patient motion in 1, interference artifact in 1 and failure to acquire an adequate number of scan levels in 12. Seven of these latter study failures were in right coronary artery grafts, one was in

a left anterior descending graft and four were in internal mammary artery grafts. Six grafts in five patients were also excluded because the cardiac catheterization studies failed to include an aortic root injection in cases where the stump of a presumably occluded graft could not be visualized. These technically inadequate studies were also excluded before data analysis began.

This left a study group of 62 patients with 127 grafts. There were 52 men and 10 women aged 32 to 83 years (mean \pm SD 57.5 ± 9.8). Their weight ranged from 59 to 121 kg (mean 83.1 ± 13.5) and body surface area varied from 1.6 to 2.4 m² (mean 1.96 ± 0.15). In the group, there were 51 saphenous vein grafts to the left anterior descending/diagonal distribution, 37 to the left circumflex artery distribution and 28 to the right coronary artery distribution. In addition, there were 11 internal mammary artery bypass grafts (9 to the left anterior coronary artery and 2 to left circumflex vessels). Several of the saphenous vein bypass grafts continued in a sequential manner to additional vessels; however, we only assessed the patency of the proximal segment of the graft. The average interval between cardiac catheterization for determination of graft patency and the ultrafast computed tomographic study was 8.9 ± 8.8 days (range 0 to 86).

Group II consisted of 50 consecutive patients with 138 bypass grafts studied in the five participating centers. These patients were included because they represented a series of consecutive ultrafast computed tomographic studies for graft patency performed after August 1986 in each of the five participating centers. There were 45 grafts to the left anterior descending coronary artery diagonal branch, 34 to the left circumflex coronary artery, 41 to the right coronary artery and 18 internal mammary artery grafts. These studies were evaluated using the same criteria as used initially (that is, to be included as an adequate study, there had to be adequate bolus administration, adequate image resolution, lack of motion, lack of interference artifact and an adequate number of levels scanned). These patients did not undergo cardiac catheterization.

Ultrafast computed tomographic protocol. Initially the patients' history was reviewed to determine the location, number and type of grafts and to exclude patients with contrast medium allergies or renal disease as manifested by elevated urea nitrogen and creatinine blood levels. After fasting for a minimum of 4 h, the patient was brought to the scanner and placed in a supine position perpendicular to the scanner gantry (neutral position). Electrocardiographic (ECG) leads were attached to the skin in the right and left infraclavicular areas and left lower thorax, and a no. 16, 18 or 20 gauge 1.5 to 3.5 inch (3.8 to 8.9 cm) plastic catheter was placed into a right or left antecubital vein. A localization scan was then done to assure that the uppermost image would be taken at the undersurface of the aortic arch or at the uppermost metallic clip if markers were placed at oper-

ation. In patients with an internal mammary artery graft, the uppermost image was at the thoracic inlet.

The scanner was programmed to obtain four, six, or eight mm axial slice thicknesses of the chest in 108, 166 and 224 ms, respectively. The triggered acquisition sequence was initiated on the R wave of either every first (heart rate < 78 beats/min) or every second (heart rate > 78 beats/min) heartbeat. In some instances, a more complex imaging sequence encompassing images obtained during the arrival and clearance of a test injection of contrast medium was used. The slices from the same ring were contiguous; however, there was a 4 mm interslice separation between images from different rings (19). For left-sided grafts, imaging extended to a point 2 cm below the origin of the left main coronary artery; in right-sided vein grafts, the imaging levels extended to a point 2 cm below the origin of the native right coronary artery.

The contrast agents used were Renografin-76, MD-76, Conray-400 and Iohexol-350, with a total patient dose of 24 to 120 ml being administered by means of a flow-controlled power injector at 5 to 12 ml/s. In 58 (93.5%) of the 62 patients in Group I, more than one injection of contrast medium was required. Similar volumes of contrast medium were employed in the 50 Group II patients.

Once the levels were selected, an arm to tongue circulation time was determined by an intravenous injection of 1 ml of 50% magnesium sulfate diluted in 9 ml of saline solution. On a few occasions, a circulation time was not determined before the study, and in other instances, the circulation time was estimated using an ear densitometer and an antecubital vein injection of indocyanine green (20).

Imaging was begun at 50 to 75% of the circulation time and continued for 10, 13 or 20 consecutive images. This sequence of images encompassed contrast wash-in, peak concentration and, usually, complete washout and allowed for graft visualization as well as facilitation of time-density analysis curves of the grafts and aorta. Images were played back in a closed loop movie mode. In most instances where more than one injection of contrast medium was employed, the table was repositioned between injections so that the lowermost scan of the upper set of images overlapped one level with the uppermost scan of the lower set of images.

Some of the patients had examinations requested by the referring physicians for clinical purposes and in these instances informed consent for the ultrafast computed tomographic study was not obtained. In all other patients, informed written consent for the study was obtained. The protocol of the study was approved by the Human Use Committees in all five study centers.

Cardiac catheterization protocol. The cardiac catheterization protocol was performed using the Judkins technique. Renografin-76 or other comparable agents were used for selective graft injections. If a patent graft or closed stump

could not be visualized, an aortic root power injection in one or more projections was carried out.

Angiographic criteria for graft patency. Cardiac catheterization studies were read by three experienced cardiologists with knowledge of where bypass grafts had been placed. Grafts were considered open when a patent graft lying in the distribution of the bypassed coronary vessel was present. Differences in interpretation were settled by consensus. Grafts were additionally assessed for adequacy of flow and for the location and severity of stenoses if present. Graft closure at cardiac catheterization was assumed if the stump of the graft was visualized but there was no flow or, in the absence of a visualized stump, if an aortic root power injection failed to opacify a patent graft. In two instances, a long saphenous vein bypass graft stump was placed as it exited the aorta but was found to have a high grade occlusion distally. In these instances, the graft was classified as open but identified as having a near total distal obstruction.

Ultrafast computed tomographic criteria for graft patency. A graft was considered patent if a majority of four or five experienced readers with prior knowledge of the operative report visualized the graft at two or more levels in the distribution of the vessel bypassed. The observers were unaware of the cardiac catheterization findings. In equivocal cases, time-density curves were used to confirm that the structure in question opacified concomitantly with or immediately after the aortic root opacification.

Data analysis. The sensitivity [true positive/(true positive + false negative)], specificity [true negative/(true negative + false positive)] and predictive accuracy [(true positive + true negative)/total group] were determined and expressed as a percent. When appropriate, differences between groups were assessed using Fisher's exact test, with the null hypothesis being rejected when the *p* value was <0.05. Whenever possible, data are presented as the mean \pm SD. All data were reviewed retrospectively. Additionally, at a different sitting, two of the original readers independently reread the scans in 20 Group I cases. These cases were randomly selected from scans performed at two different institutions.

Results

Figure 1 shows representative images of saphenous vein grafts in the distribution of the left anterior descending and left circumflex coronary arteries.

Overall sensitivity, specificity and accuracy. The sensitivity of detecting angiographically open grafts by ultrafast computed tomography was 93.4% (85 of 91 grafts), the specificity of detecting angiographically closed grafts was 88.9% (32 of 36 grafts) and the predictive accuracy was 92.1% (117 of 127 grafts) (Fig. 2). In 52 (83.9%) of 62 patients, all grafts were identified correctly.

Grafts in selected perfusion fields (Table 1A). No significant differences in sensitivity, specificity and accuracy were

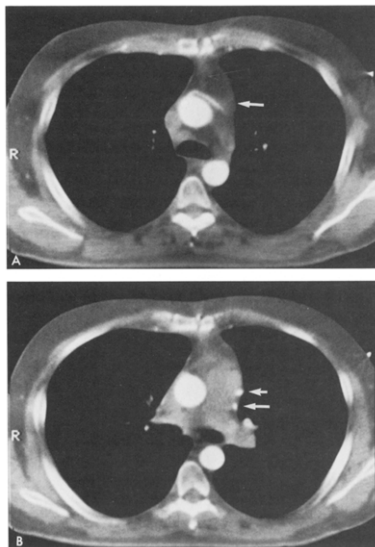


Figure 1. Representative tomographic scans. A, A patent left anterior descending coronary artery graft is seen tangentially as it exits the aorta (arrow). B, Grafts in the left anterior descending coronary artery distribution (short arrow) and left circumflex artery distribution (long arrow) are seen in cross section. R = right.

noted among grafts to specific perfusion fields. However, interpretive accuracy was slightly better with the left anterior descending/diagonal branch grafts ($p = NS$).

Reading accuracy per number grafts per patient (Table 1B). The number of grafts originating from the aorta varied from one to five per patient. The number of grafts placed, however, did not influence reading accuracy ($p = NS$).

Internal mammary artery versus vein bypass grafts (Table 1C). The number of correct interpretations in the internal mammary artery group as compared with the saphenous vein group was not significantly different ($p = NS$).

Results in severely stenotic grafts (Table 1D). There were 11 grafts with $>50\%$ luminal obstruction as determined from cardiac catheterization. Of these, nine were saphenous vein grafts and two were internal mammary artery grafts. The accuracy of correctly classifying stenotic grafts was not significantly different from that of classifying the unobstructed group ($p = NS$).

Days between scan and catheterization. There was no significant difference between the error rate in patients undergoing cardiac catheterization ≤ 10 days or >10 days after the scan (accuracy 94.9% and 82.1%, respectively) ($p = NS$).

Body size. Body surface area in patients with interpretive errors on ultrafast computed tomography was 1.93 ± 0.10 versus 1.96 ± 0.15 m^2 for the group without errors in classification ($p = NS$).

Evaluation of errors (Group I). In the 62 Group I patients, 10 of the 127 grafts were incorrectly classified as open or closed. Two of the three false positive interpretations occurred because a radiodense structure (coronary calcification or left atrial appendage) moved in and out of the scanning plane during the contrast bolus injection and thereby simulated opacification of an open graft. Four of the seven false negative interpretations occurred because a metal surgical clip produced sufficient scan artifact to obscure an adjacent open graft. Among the four other misinterpretations, in one, the graft was in an unusual location, two of the grafts were seen at only one level and in one no reason for the misinterpretation was evident.

Evaluation of study adequacy (Group II). All of the 45 left anterior descending/diagonal and 34 left circumflex artery graft examinations were technically adequate. Inadequate studies were performed in 3 of 41 right coronary artery grafts and 4 of 18 internal mammary artery grafts; in all 7 technically inadequate studies the cause of the inadequacy was an insufficient number of scan levels obtained. These studies were evaluated using the same criteria used initially (that is, to be included as an adequate study, there had to be adequate bolus administration, adequate image resolution, lack of motion, lack of interference artifact and an adequate number of levels scanned).

Evaluation of interobserver/intraobserver variability in Group I. There were three interobserver interpretive differences among the 52 grafts reevaluated (5.8%). The intraobserver variability was 9.6% for reader 1 and 7.7% for reader 2.

Figure 2. Sensitivity, specificity and predictive accuracy of evaluating bypass grafts with ultrafast computed tomography in Group I.

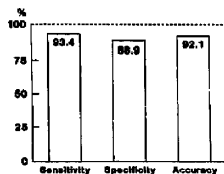


Table 1. Interpretation Sensitivity, Specificity and Accuracy of Ultrafast Computed Tomography in 62 Group I Patients

Graft	Sensitivity	Specificity	Predictive Accuracy
A. Graft Distribution Sensitivity, Specificity and Accuracy			
LAD/diagonal	100% (38/38)	84.6% (11/13)	96.1% (49/51)
LCx	91.7% (22/24)	92.3% (12/13)	91.9% (34/37)
RCA	85.7% (18/21)	85.7% (6/7)	85.7% (24/28)
IMA	87.5% (7/8)	100% (3/3)	90.9% (10/11)
B. Reading Accuracy per Number of Grafts Placed			
Grafts/Patient	No. of Grafts	No. of Errors	Reading Accuracy
1	13	2	84.6%
2	29	3	89.7%
3	58	4	93.1%
4	26	1	96.2%
5	1	0	100%
C. Reading Accuracy per Graft for IMA versus SV Grafts			
SV	116	9	92.2%
IMA	11	1	90.9%
D. Reading Accuracy for Stenotic Versus Nonstenotic Open Grafts			
Saphenous vein grafts			
Obstructed grafts	9	2	77.8%
Nonobstructed grafts	74	3	95.9%
Internal mammary artery bypass			
Obstructed grafts	2	0	100%
Nonobstructed grafts	6	1	83.3%

IMA = internal mammary artery; LAD = left anterior descending coronary artery; LCx = left circumflex coronary artery; RCA = right coronary artery; SV = saphenous vein.

Discussion

The most important observations in this study were that, with ultrafast computed tomography, bypass graft patency can be defined with 92.1% predictive accuracy and, at present, 94.2% of studies performed are technically adequate. Furthermore, the location, type and number of grafts did not influence this predictive accuracy.

Alternative approaches to assessing coronary bypass graft patency. Approaches to evaluating bypass graft patency can be broadly classified as indirect and direct. The indirect techniques (stress ECG [8], stress thallium-201 scintigraphy [9], exercise radionuclide ventriculography [10]) are used to attempt to detect myocardial ischemia and it is assumed that, if evidence of ischemia is demonstrated in a zone perfused by a graft, the graft supplying that area is likely to be closed or stenotic. Such an approach is not without error because an open graft perfusing an area of hypertrophied or infarcted myocardium may be thought to be closed because of electrical, mechanical or perfusion abnormalities associated with the hypertrophy or infarction. In addition, the indirect approaches such as stress thallium-201 scintigraphy and exercise radionuclide ventriculography are not sufficiently

sensitive to predict multiple separate ischemic zones. Hence, the status of an individual graft in a patient with multiple grafts cannot be predicted with precision.

Transcutaneous Doppler echocardiographic examination of the coronary arteries is a direct technique that is still considered an experimental procedure. Reports [11] have shown a 10% false positive rate in the determinations of flow in left circumflex and lateral ventricular vessels because of the juxtaposition of the aorta and pulmonary arteries.

Digital subtraction angiography has also been used to evaluate bypass grafts. In this method, a contrast agent needs to be introduced into the ascending aorta at an injection rate of 20 ml/s or greater and multiple injections are required. Using these techniques, Guthaner et al. [12] reported visualization of 101 (98.0%) of 103 grafts and were able to see both patent grafts and occluded stumps. However, if the contrast medium was given intravenously, only 13 (40.6%) of 32 grafts could be visualized.

Nuclear magnetic resonance imaging can also identify patent grafts. In 20 patients, Gomes et al. [13] were able to visualize right-sided grafts in 83% of patients, left-sided grafts in 89% and internal mammary grafts in 45%. The

advantages of this technique are the absence of radiation and contrast exposures; at present, although it is a promising approach, significant improvements are needed.

Previous studies (14,15) from two centers employing conventional computed tomography have predicted graft patency with a sensitivity of 91 to 93% and a specificity of 68 to 99%; however, poor graft opacification, 2 to 5 s scan times, motion artifacts and difficulties in the timing of the bolus arrival have detracted from the usefulness of conventional computed tomography and this approach is not in widespread use.

Advantages and disadvantages of ultrafast computed tomography. The principal advantage of this technique for detecting graft patency is that it is relatively noninvasive, reasonably accurate, readily performed in outpatients and requires only that the patient be fasting for 4 h and tolerant of angiographic contrast medium. The examination requires about 30 min to complete and results are usually reported within 1 to 2 h. In this study, 46 (26.6%) of 173 grafts had technically inadequate scans for reasons previously stated. Most of these difficulties, however, could be attributed to inexperience with a new technology rather than to problems that are not amenable to resolution. Currently, centers with substantial experience with ultrafast computed tomography can obtain technically adequate studies in >90% of grafts examined.

There are several disadvantages of ultrafast computed tomography. The test requires intravenous injection of 24 to 120 ml of contrast medium and skin exposure to approximately 4 to 8 rads, and it costs slightly more than conventional computed tomography. Nonetheless, the current alternative procedure, namely cardiac catheterization, requires a similar amount of contrast medium, about two to three times more radiation exposure, does not produce axial tomographic images, costs substantially more and is associated with a small risk of a serious complication.

Ultrafast computed tomography has four other disadvantages: partially obstructed versus nonobstructed grafts cannot be differentiated, the status of sequential distal anastomoses cannot be determined, the status of the native coronary vessels remains unknown and a mechanical intervention on an obstructed graft cannot be done in association with the study. Recent animal studies (21), however, have suggested that flow reserve in bypass grafts can be accurately assessed with ultrafast computed tomography and this approach may well be applicable in humans. If so, it should help to differentiate stenotic grafts from nonobstructed grafts.

Interpretive accuracy. The substantial increase in the number of technically adequate computed tomographic studies in Group II can be attributed to greater expertise on the part of the physicians performing the procedure and several improvements in equipment. Because the technically inadequate studies in these patients were all operator related, it is

likely that with further experience, the percent of technically adequate studies will continue to increase. Few complex diagnostic procedures in cardiology produce technically adequate studies in >95% of examinations performed.

In summary, although assessment of bypass graft patency with ultrafast computed tomography is imperfect, it represents a substantial improvement over the indirect approaches that have been widely employed during the past decade to predict graft patency. In addition, it is safer and more convenient than conventional angiography.

We extend our appreciation to Mark Acker for technical assistance, Tudy Burns, PhD for statistical consultation and Janice Widmer for secretarial assistance.

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