S T A R T L I N G  F A C T S about the incidence of complications of coronary arteriography in the U. S. during the years 1970 and 1971 emerge from the study reported by Adams et al. in the September 1973 issue of Circulation. The following findings seen nationally are most significant. (1) Death or the serious nonfatal complications of myocardial infarction and/or cerebral embolus occur in an unacceptable 1.5% of all patients examined; the occurrence is ten times higher in institutions performing fewer than 100 examinations/year than in those doing more than 400/year. Reported death rates vary more than one hundred fold, from 0.05% to 8%.1,2 (2) The serious complications, primarily thrombotic, occur eight times more frequently when the percutaneous transfemoral approach is used. (3) Fifty-five percent of laboratories using a femoral method do fewer than 50 cases/year. As volume increases, the complication disparity between the brachial and the femoral approach dramatically narrows to near equality.

The reported complication rates are unacceptably high. Two clearly evident factors emerge: (1) the competence of the operator (training and maintenance of skill) and (2) the time-thrombogenicity relationship of the tools with which he works. The lack of the former predisposes to increased problem with the latter.

To inflict serious injury or death as the result of an important but diagnostic examination is very distressing, but for either of these to occur for the lack of competence is tragic. Absolute honesty, ego control, and courage to say "No!" are demanded if the required commitment in training, staff, and equipment is not available. To undertake coronary arteriography unprepared courts excessive complications and renders questionable service.

An unheralded complication of coronary arteriography that is frequently overlooked but equal in importance to the most severe surveyed by Adams, Fraser, and Abrams is the incomplete or nondiagnostic study. The patient risks his life and for what?--erroneous diagnosis and misdirected therapy. This is double jeopardy; it approaches 100% in many laboratories. This jeopardy, frequently unrecognized or denied by its perpetrator, is usually highest in laboratories that have the highest risk of death or major complications. In discussing complications, one must evaluate both the examination's risk and its information retrieval. We frequently hear reports of this or that noninvasive diagnostic study, with the implication of its being angelic when compared with the big, bad invasive angiogram. The issue is not invasive vs noninvasive; it is information vs risk. Likewise in cardiac angiography, we must weigh the quality of examination vs risk. In both situations, unreliable,

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Circulation, Volume XLIX, April 1974
inaccurate, or absent information can clearly be both risk and complication. For example, we have re-examined a dozen patients who have had prior revascularization surgery only to find normal coronary arteries. Are these examples of faith healing or suboptimal initial study? The incomplete or nondiagnostic study must be considered equal to a complication. I cannot overemphasize the seriousness of this complication because it can alter patient management.

What is an acceptable complication rate? Over-all complication rates are difficult to assess because of variable recognition and soft end-points. Comparative laboratory safety is probably best measured by the death rate, defined as all deaths occurring within 24 hours after the procedure, unless the procedure can be completely exonerated, and any late deaths known or suspected to be procedure-related. Laboratories with a death rate of over 0.1% should give serious thought and study to methods of reducing their total serious complication rate. Laboratories with death rates over 0.3% should terminate coronary arteriography and then reassess their goals and total commitment to the program. They should then either abandon the program or remedy the deficiencies prior to reactivation.

A society in which men recognize no check on their freedom soon becomes a society in which freedom is a possession of only a savage few.

Justice Learned Hand

Whenever relative laboratory deficiencies are compared and discussed, the cry is always, "Laboratory A does only easy, good risk patients without a teaching commitment." This is not true; it is the risk-prone laboratory's rationalization for poor results; it is easy to blame trainees and high risk patients. It is true that trainees do increase the risks, but if they are carefully supervised, the risk factor need not double. The prime reasons for laboratory differences are (1) variations in the experience of the operator, (2) realistic selection of patients for study, and (3) the length and complexity of the examination.

Laboratories reporting the lowest complication rates do not combine coronary arteriography with extensive physiological study. One invites complications when he subjects a patient exhausted from more than an hour of physiological study to an appended coronary study. By dividing these studies, patient and myocardial exhaustion are avoided and optimal data retrieval can be achieved with lower total risk.1-4

What can be done? Training and maintenance of skills is the fundamental answer to the reduction of complications associated with coronary arteriography. For various reasons, those who have developed techniques for transfemoral coronary arteriography using pre-shaped catheters have not trained significant numbers of cardiac angiographers. A spot check of laboratories performing coronary arteriography from the femoral approach shows that the vast majority of coronary arteriograms performed from the femoral approach are being done by cookbook, self taught angiographers. The majority have not performed percutaneous femoral techniques before beginning coronary arteriography. Few have had any experience in the use of any type of preformed catheters. A similar survey of institutions reporting high complication rates from the femoral approach fails to find a coronary angiographer taught by the originator of a femoral technique or anyone trained by him to the third generation. There is no question that the femoral technique's ease of performance and quality of examination induces many to undertake it with scarcely any grounding, most with no apparent sense of their inadequacies. Such misadventure can be expected to generate a high percentage of complications.

It is alarming to note that two-thirds of the institutions reporting state that they use both the brachial and the femoral approach. These two techniques are as different as day and night; the finger calisthenics required for their performance are entirely different. The finger motions used for the brachial technique are extremely hazardous when transferred to the femoral approach. It is true that the novice with a minimum of training can, using the femoral approach, catheterize the coronary arteries over 90% of the time. But he cannot do it 99% of the time and with consistent safety. For the proper performance of the transfemoral technique, the angiographer should have basic training in the fundamentals of the use of preshaped catheters. Both approaches are excellent; select one technique and become proficient.

Over the past ten years, the nation has been training virtually every new cardiologist in the techniques of cardiac physiology and arteriography, most with a somewhat limited experience in coronary arteriography. It is well known that not every physician has the hands or conceptual skills to do good arteriography even though he may be an excellent clinician. Yet each enters the field with the inalienable right to perform such unforgiving techniques. It is our belief that each physician planning

Circulation, Volume XLIX, April 1974
to do laboratory cardiology and cardiac angiography should have at least one year laboratory training in addition to his basic preparation in cardiology and cardiac physiology. This must include sophisticated training in radiographic imaging. It is only with adequate training (whatever adequate may be) that we are going to see nationwide, really safe coronary arteriography.

The Adams survey\(^1\) shows that complication rates relate directly to the volume of cases performed in any one laboratory. The Inter-Society Commission for Heart Disease Resources (ICHD), in its recommendation on coronary arteriography manpower, suggests 500 cases per year are necessary to provide laboratory competence.\(^4\) This figure appears to be reasonable in view of the Adams report. The question arises—"How does a new laboratory begin?" It is difficult to start up at a rate of 400-500 examinations per year.

Laboratories can start with experience and safety. New laboratories should be developed in an area of real need, rather than a "me too" prestige service; need will assure volume. The forming laboratory should bring together cardiac angiographers—cardiologist and radiologist—and a technical team, all with current, adequate training at an active, safe, established laboratory. Team effort is essential to safety and quality of examination. There is no place for the prima donna or cocky angiographer.

What is an acceptable level of training for a cardiac angiographer? This, too, is difficult to define. The ICHD defines optimal training as two years of training in (1) cardiology with emphasis on clinical and laboratory cardiology and basic electrocardiography; (2) cardiac physiology, cardiac pathology, and cardiac embryology; (3) radiology, with emphasis on the fundamentals of radiographic interpretation, imaging techniques, equipment design, and radiography; and (4) catheter technology—all based on an initial two years of training in internal medicine or radiology.\(^4\) This is optimal—what is adequate? There is no doubt that a few hours or weeks of observation does not adequately prepare one for coronary arteriography.

We have an urgent need of highest priority for a stepped-up program of basic cardiac angiography training because of recent advances in the field of both definitive medical and definitive surgical therapy for coronary artery disease, this at a time of disastrous cutbacks in federal support.

What can be done? Time-thrombogenicity of the tools. All commonly-used catheterization tools are THROMBOGENIC. Significant amounts of clot can form on catheter surfaces in 10-15 minutes. Commonly used thermoplastic catheter materials can be shown experimentally to have some difference in thrombogenicity; however, none of these time-thrombogenicity differences are procedurally significant. Antithrombogenic material can be used to coat guides and catheters with some success. Guides used expeditiously for catheter introduction are rarely in the vascular system for more than 30-90 seconds—hardly time enough for significant thrombogenesis. It seems futile to attack the thrombogenicity problem at this location. The same cannot be said of catheters or the sites of vascular injury.

Most of the major complications of coronary arteriography are thromboembolic. The two prime sites of thrombogenicity are the catheter surface (thrombogenicity of the tools) and the entrance site (thrombogenicity of injury); they are of about equal importance. In either case, a doughnut or Cheerio-like clot is formed by stripping thrombotic elements from the catheter at the puncture site (G. Tornell, personal communication) and/or there is thrombus formation at the entrance site.\(^5\) The thrombus thus formed may then be carried from the entrance site to the ascending aorta on the catheter tip, only to embolize as soon as flow reversal permits (fig. 1).

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**Figure 1**

Mechanism of clot embolism with catheter exchange. Typical clot forms at the puncture site as a result of the injury of entry. This clot or platelet aggregate adherent to the catheter surface is wiped off the catheter at the entrance site during catheter withdrawal. The exchange (2nd) catheter carries the ring of compacted blood elements to the ascending aorta where embolism to coronary or cerebral circulation can occur. Expedition of procedure, meticulous technique, and heparinization will minimize this complication.
The attack on thrombosis and thromboembolism will be most effective if the following points are observed. (1) *Expeditious Procedures*. Procedures must be carried out expeditiously and with purpose. The factors are simple—increase in catheter time equals increase in the likelihood of thrombus formation (time-thrombogenicity of the tools). There is no time for extensive physiological evaluation or standing around sucking one’s thumb. (2) *Meticulous technique*. It is the fine points of technique that make the big difference in the serious complication rate (the thrombogenicity of injury). (3) *Heparinization*. Single-dose total-body heparinization (30-60 mgm) is an effective method of reducing the thrombogenicity of the tools and of injury. It is probably more effective than coating of the tools at this time because it is effective in thrombogenicity of injury and at sites where coatings may fail. Heparin is probably the best anticoagulant because it is safe, easily administered, and has a rapid onset. Its effect postprocedure can be quickly and effectively reversed with Protamine.

The users of the brachial approach have classically, however inadvertently, used single-dose total-body heparinization, ostensibly to prevent brachial and radial artery thrombosis. The systemic effect has been instrumental in the prevention of thrombotic complications. Forty or fifty mgm of heparin injected into the brachial artery produce a therapeutic increase in the Lee-White cloting time. In our laboratory we have not, until recently, used heparin because our complication rate has been very low and comparable in all respects to that of the Sones’ laboratory. We have accomplished this despite heavy trainee involvement; our antithrombogenic weapons have been careful attention to detail, meticulous technique, and expeditious procedures. Since we began using heparin, our thrombotic complications, however few, are fewer—0% myocardial infarct and cerebral vascular accident (700 patients); 0.3% femoral thrombosis. (The former down from 0.12%; the latter unchanged from pre-heparin control).

It is evident that single-dose total-body heparinization should be used routinely, when not specifically contraindicated, regardless of the approach. We have but one fear or reservation: heparin provides a cover-up for sloppy technique. On average, a technically-deficient laboratory will continue to have needless complications not completely covered by heparin and unnecessary complications unrelated to thromboembolism. However, for the patient’s sake, we would not for an instant suggest that heparin be withheld while the laboratory technique reaches a satisfactory stage of development. Coronary arteriography is unforgiving. If near perfection is to be achieved, more than heparinization is needed. It is the little things that count.

We are confident that if this survey had been taken two years later, after a good number of labs began using heparin, the result would have been different. We would encourage Adams et al. to expand their study and repeat it at frequent intervals. Such national self-assessment will in the end improve patient care and technique.

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