
Complication Rate of Coronary Arteriography
A Review of 5250 Cases Studied by a Percutaneous Femoral Technique
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SUMMARY Distressing rates of embolic complications from coronary arteriography performed by the percutaneous femoral approach have been reported since 1972. From 1970–1974, 5250 patients underwent coronary arteriography in our laboratory by the same percutaneous femoral technique with preformed polyethylene catheters and no systemic heparinization. Data were recorded during and for 24 hours postcatheterization. The annual mortality rate averaged 0.23% and remained relatively stable. Our incidence of embolic complications was very low. In patients with normal coronary arteries, no fatal or serious nonfatal complications occurred. Left main coronary artery disease was present in all cases of mortality and ≥ 60% stenosis was shown in nine of 12 instances. Thus major risk was proportional to the severity of disease in the left coronary system. The use of more aggressive supportive measures in these high-risk cases appears essential to reduce the total complication rate from coronary arteriography significantly.

Recently, a distressing incidence of thromboembolic complications from coronary arteriography performed by the percutaneous femoral technique has been reported in many institutions.1–10 This has raised the important question: What is an acceptable rate of mortality and serious complications from the procedure? In 1972, the ad hoc Committee on Coronary Artery Surgery of the Inter-Society Commission for Heart Disease Resources11 recommended that deaths associated with coronary arteriography should not exceed 0.3% and that mortality rates above this level should be considered unacceptable. More recently, Judkins and Gander12 have suggested that laboratories with a death rate of over 0.1% should give serious thought and study to methods of reducing their total serious complication rate. The present review was undertaken with this objective in mind and demonstrates that even in institutions that experience few technical problems, this projection is presently unrealistic. Whereas mortality and a high rate of serious nonfatal complications are unacceptable in subjects with normal coronary arteries, more adequate preventive measures applied prior to coronary arteriography must be instituted before the mortality rate of patients with severe coronary artery disease can be reduced significantly below 0.3%.

Material
Between January 1, 1970, and December 31, 1974, 5250 patients underwent at least one percutaneous transfemoral coronary arteriogram at the Montreal Heart Institute. This material forms the basis of the present review. A small number of cases with a Leriche syndrome who were investigated through a percutaneous axillary approach (also using preformed polyethylene catheters) were excluded. In most instances, coronary artery disease was strongly suspected or was documented clinically and the patients were studied primarily to determine their appropriate therapeutic management. The severity, extent, and localization of coronary artery disease and quality of the distal vascular bed were evaluated at coronary arteriography and left ventricular function was estimated from cineventriculography. Clinical diagnoses included stable, usually severe angina, crescendo angina, acute coronary insufficiency, and previous myocardial infarction. Patients with recent or acute myo-
cardiac infarction, left ventricular failure and cardiogenic shock were rarely studied. A limited number of patients underwent a diagnostic investigation for atypical chest pain, unexplained arrhythmias, and ventricular conduction disturbances, valvular heart disease, and cardiomyopathies. Finally, several hundred patients were studied after aortocoronary bypass surgery. Graft patency, changes in the coronary circulation, and modifications of left ventricular function were assessed in these patients.

To evaluate the relative safety of multiple coronary angiographic studies, 57 patients who underwent four to six successive coronary arteriograms during this five-year period were studied as a separate group. Severe angina, class III or IV of the New York Heart Association, and severe coronary artery disease were documented preoperatively. One to several aortocoronary saphenous vein bypass procedures were performed in these patients between September 1969 and September 1970. Four successive coronary arteriograms were carried out in 46 patients, five in ten patients and six in one patient, for a total of 242 examinations.

Methods

Following an extensive experience with retrograde left heart and selective arterial catheterization using preformed polyethylene catheters, a percutaneous femoral technique of coronary arteriography was developed at this center in 1966 and has been used routinely since 1967.\textsuperscript{15, 16} The preshaped catheters\textsuperscript{*} are made of a special blend of polyethylene material (RPX, B-D and Co., Rutherford, N.J.). The excellent plastic memory of the catheters allows selective coronary artery catheterization with very little manipulation.

Patients were fasting and premedicated with meperidine 50 mg and phenergan 25 mg, or with diazepam 10 mg intramuscularly, approximately 30 min before the study. No antibiotics were administered prior to catheterization. Left heart catheterization including pressure measurements using standard methods and left cineventriculography in a 30° right anterior oblique plane were first obtained. Then multiple consecutive injections of the coronary arteries were carried out. In 1970, 1971, and 1972, both coronary arteries were selectively opacified in four, standard transverse planes: a 30° right anterior oblique (RAO), an anteroposterior, a 45° left anterior oblique (LAO), and a true lateral plane. Since 1973, additional sagittal projections were used.\textsuperscript{16} They included for the left coronary artery: a 35° caudo-cranial angulation in a 15° RAO position and a 25° crano-caudal angulation in a 40° LAO position and for the right coronary artery: a 15° crano-caudal angulation in a 30° LAO position. These sagittal views were done routinely and were often essential for complete visualization of the proximal left and distal right coronary arteries.

All patients were admitted to the hospital for a period of at least 48 hours. In the first 24 hours, any clinical information not already available was recorded, the procedure was explained to the patient and his informed consent was obtained. Patients were observed for a minimum of 24 hours after the study. All complications were recorded in a consecutive manner immediately after as well as 24 hours after coronary arteriography. Any procedure-related complications reported to us thereafter were also included.

Since 1970, six to eight residents and fellows were trained continuously during periods of six to 12 months in our laboratory. They were briefly initiated to the principles and technique of coronary arteriography and were subsequently assigned regular cases under the alternate supervision of four to five experienced cardiologists. These trainees have performed, with or without any direct assistance, over 60% of the procedures reported in this study. All angiographic documents were read by three experienced radiologists.

Results

Incidence and Nature of Complications/Cardiac

Deaths

Twelve deaths were recorded during this five-year period, a mortality rate of 0.23%. A fairly comparable number of cases was studied annually. The mortality rate was almost identical in 1970, 1972, and 1974 (0.24%, 0.21%, and 0.24% respectively). It was 0.09% in 1971 and 0.34% in 1973 (table 1).

Eleven patients had angina pectoris (table 2). Angina was severe, class III or IV in all cases. The total duration of angina was five years or greater in eight patients. Unstable crescendo angina of one to three months duration was observed in six patients. On the resting electrocardiogram, six patients showed deep T wave inversion consistent with myocardial ischemia and two additional patients had ST-segment depression in the precordial leads. Only four patients had a previous myocardial infarction. Cineventriculography performed in 11 patients showed severe left ventricular dysfunction in five patients, inferior wall akinesis in one patient, and a normal cineventriculogram in five patients (table 3).

A striking observation in this series was the presence of left main coronary artery disease in all 12 patients (table 3). In eight of the 11 patients with coronary atherosclerosis, the left main coronary artery stenosis was equal to or greater than 60% and was located at or near the ostium of the artery in four patients. In two patients, the left main coronary artery was diffusely narrowed. In the other patient (patient #12), no stenosis was demonstrated at coronary arteriography (table 3). However, at postmortem examination, severe atherosclerotic narrowing was present at the trifurcation of the left coronary artery. All but one of these 11 patients also had double or triple coronary vessel disease. Finally, one patient with valvular heart disease and nonatherosclerotic coronary vessels had congenital atresia of the left main coronary artery (patient #1).

The course of the complication was consistent with an acute complicated myocardial infarction in all 11 patients with coronary atherosclerosis (table 2). Severe chest pain rapidly followed by ST-T segment elevation and/or recurrent ventricular arrhythmias occurred unexpectedly during or immediately after the study in nine patients and three and 18 hours later, respectively, in two patients. This led to electromechanical dissociation and irreversible cardiogenic shock in all patients. Emergency aortocoronary bypass to the anterior descending and/or circumflex arteries was attempted unsuccessfully in four patients (table 2).

An unfortunate accident occurred in a 31-year-old female

\*Bourassa catheters, USCI, Billerica, Mass.
(patient #1) with severe aortic and mitral valvular disease and congenital atresia of the left coronary ostium. A large right coronary artery was dissected proximally during coronary arteriography. The dissection was followed by substernal chest pain of 5 min duration without subsequent electrocardiographic or serum enzyme changes. The patient died suddenly 48 hours later while awaiting cardiac surgery. At postmortem examination, a dissecting hematoma occluded the lumen of the middle segment of the right coronary artery. There was no histologic evidence of recent myocardial infarction (table 3).

An autopsy was performed in nine of the 11 patients with coronary atherosclerosis. A thrombus was found in the coronary arteries of only two patients, in the anterior descending and left main coronary artery respectively. Only three patients had microscopic evidence of a fresh myocardial infarction (table 3).

**Myocardial Infarction (table 1)**

An acute nonfatal transmural myocardial infarction was observed in five patients or 0.09% of the cases. All had severe coronary artery disease. However, none had a left main coronary artery stenosis.

**Coronary Dissection (table 2)**

Coronary artery dissection (0.07% of all cases) involved the right coronary artery primarily. In two instances, this was followed by a brief episode of retrosternal chest pain without myocardial necrosis or any subsequent deleterious effect. In a third case, it led to transient cardiac arrest without further incident. Finally, as previously mentioned, right coronary artery dissection was responsible for sudden death in a young female with atresia of the left main coronary ostium.

**Coronary Embolism (table 1)**

This complication was strongly suspected in three instances (0.07%). In two patients, one to several intracoronary filling defects were seen to progress downward toward the distal coronary tree during coronary opacification. Both patients had transient anginal attacks with simultaneous hypotension but no subsequent evidence of myocardial infarction. A distal right coronary segment became occluded during angiography in the third patient. The study was discontinued after the patient developed an inferior wall myocardial infarction. Almost complete recanalization of the right coronary artery was demonstrated on a subsequent coronary arteriogram six months later.

**Arrhythmias and Conduction Disturbances (table 1)**

Ventricular fibrillation occurred during coronary arteriography in 0.4% of all cases. It was immediately converted to sinus rhythm by electrical countershock without further consequences. Persistent episodes of ventricular tachycardia required specific therapy in 0.15% of cases, also with uneven recovery. Transient episodes of asystole occurred in 0.25% of cases and responded rapidly to external cardiac massage, sometimes followed by temporary demand cardiac pacing. These potentially serious ventricular arrhythmias were observed then in 0.8% of cases. In approximately half of these instances, they occurred in subjects with normal coronary arteries. All were without sequelae and coronary arteriography was continued after termination of the arrhythmia, whenever necessary, to obtain a satisfactory diagnostic examination.

Conduction disturbances and atrial arrhythmias were less frequent. Atrial fibrillation occurred in 0.07% of cases, paroxysmal atrial tachycardia in 0.12% of cases, complete atrioventricular block in 0.07% of cases and transient left bundle branch block in 0.17% of cases. These rhythm and conduction disturbances either subsided spontaneously or responded rapidly to appropriate drug therapy.

**Impending Pulmonary Edema (table 1)**

At the termination of coronary arteriography, four patients (0.1%) experienced sudden dyspnea requiring intravenous injection of furosemide. This clinical situation was rapidly controlled following subsequent medical treatment.
### Table 2. Deaths Following Selective Coronary Arteriography: Clinical Features

<table>
<thead>
<tr>
<th>Pt/Age/sex</th>
<th>NYHA Class*</th>
<th>Total duration (yr)</th>
<th>Status or instability</th>
<th>Number of MI</th>
<th>Previous MI</th>
<th>ST-T changes</th>
<th>Course and complications</th>
<th>Delay between study and complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1/CB /31F</td>
<td>None†</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>None</td>
<td>None</td>
<td>RCA dissection</td>
<td>48 hours</td>
</tr>
<tr>
<td>2/TB /55F</td>
<td>None</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>None</td>
<td>None</td>
<td>Sudden death</td>
<td></td>
</tr>
<tr>
<td>3/RB /50M</td>
<td>III</td>
<td>5</td>
<td>Stable</td>
<td>—</td>
<td>None</td>
<td>V₁ - V₆</td>
<td>Acute MI - CS</td>
<td>18 hours</td>
</tr>
<tr>
<td>4/HG /49M</td>
<td>III</td>
<td>8</td>
<td>Unstable</td>
<td>2 mo</td>
<td>Inferior</td>
<td>ST depression</td>
<td>Acute MI - CS</td>
<td>During study</td>
</tr>
<tr>
<td>5/BL /49M</td>
<td>III</td>
<td>2</td>
<td>Unstable</td>
<td>1 mo</td>
<td>Anterolateral</td>
<td>Ischemic</td>
<td>Acute MI - CS</td>
<td>3 hours</td>
</tr>
<tr>
<td>6/PM /44F</td>
<td>III</td>
<td>1</td>
<td>Stable</td>
<td>—</td>
<td>None</td>
<td>V₁ - V₆</td>
<td>Emerg AC Bypass</td>
<td>5 min</td>
</tr>
<tr>
<td>7/IP /65F</td>
<td>IV</td>
<td>8</td>
<td>Unstable</td>
<td>3 mo</td>
<td>None</td>
<td>Ischemic</td>
<td>Acute MI - CS</td>
<td>During study</td>
</tr>
<tr>
<td>8/CG /43M</td>
<td>III</td>
<td>1</td>
<td>Stable</td>
<td>—</td>
<td>Anterolateral</td>
<td>Ischemic</td>
<td>Acute MI - VF</td>
<td>During study</td>
</tr>
<tr>
<td>9/RF /50M</td>
<td>III</td>
<td>6</td>
<td>Unstable</td>
<td>1 mo</td>
<td>None</td>
<td>V₁ - V₆</td>
<td>A-V block</td>
<td>During study</td>
</tr>
<tr>
<td>10/VB /52M</td>
<td>III</td>
<td>10</td>
<td>Unstable</td>
<td>1 mo</td>
<td>None</td>
<td>None</td>
<td>Acute MI - CS</td>
<td>During study</td>
</tr>
<tr>
<td>11/PM /49M</td>
<td>III</td>
<td>5</td>
<td>Stable</td>
<td>—</td>
<td>None</td>
<td>ST depression</td>
<td>Emerg AC Bypass</td>
<td>5 min</td>
</tr>
<tr>
<td>12/LA /60M</td>
<td>III</td>
<td>6</td>
<td>Stable</td>
<td>—</td>
<td>Inferior</td>
<td>None</td>
<td>A-V block</td>
<td>20 min</td>
</tr>
</tbody>
</table>

*New York Heart Association functional classification.
†This patient had symptomatic mitral and aortic valvular disease.

Abbreviations: MI = myocardial infarction; RCA = right coronary artery; VF = ventricular fibrillation; CS = cardiogenic shock; Emerg AC Bypass = emergency aortocoronary bypass; A-V block = atrioventricular block.

### Table 3. Deaths Following Selective Coronary Arteriography: Angiographic and Postmortem Findings

<table>
<thead>
<tr>
<th>Patient</th>
<th>Number of LMCA injections</th>
<th>LMCA</th>
<th>LAD</th>
<th>1st Diag.</th>
<th>Lcx</th>
<th>Right</th>
<th>Coronary dominance</th>
<th>Left cine ventriculogram</th>
<th>Postmortem findings</th>
<th>Thrombus in coronary artery</th>
<th>Histologic examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 CB</td>
<td>—</td>
<td>Atresia of ostium</td>
<td>—</td>
<td>—</td>
<td>—</td>
<td>Right</td>
<td>Normal</td>
<td>Dissecting hematoma of RCA</td>
<td>No infarct</td>
<td>None</td>
<td>Fresh and old infarct</td>
</tr>
<tr>
<td>2 TL</td>
<td>2+++</td>
<td>75%</td>
<td>50%</td>
<td>—</td>
<td>90%</td>
<td>100%</td>
<td>Right</td>
<td>Diffuse hypokinesis</td>
<td>None</td>
<td>Interstitial fibrosis, no fresh infarct</td>
<td>Fresh and old infarct</td>
</tr>
<tr>
<td>3 RB</td>
<td>6</td>
<td>50%</td>
<td>Diffuse AS</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>Right</td>
<td>AL and apical akinesis</td>
<td>At origin of LAD</td>
<td>Interstitial fibrosis, no fresh infarct</td>
<td>Fresh and old infarct</td>
</tr>
<tr>
<td>4 MG</td>
<td>6</td>
<td>75%</td>
<td>80%</td>
<td>100%</td>
<td>75%</td>
<td>100%</td>
<td>Balanced Left</td>
<td>Inferior akinesis</td>
<td>None</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>5 BL</td>
<td>6</td>
<td>85%</td>
<td>75%</td>
<td>100%</td>
<td>80%</td>
<td>80%</td>
<td>Right</td>
<td>AL and apical akinesis</td>
<td>None</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>6 PM</td>
<td>3+++</td>
<td>85%</td>
<td>At ostium</td>
<td>85%</td>
<td>—</td>
<td>90%</td>
<td>Not done Left</td>
<td>Not done</td>
<td>None</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>7 IP</td>
<td>2+++</td>
<td>95%</td>
<td>—</td>
<td>100%</td>
<td>—</td>
<td>—</td>
<td>Right</td>
<td>Al and apical akinesis</td>
<td>Not done</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>8 CG</td>
<td>6</td>
<td>80%</td>
<td>50%</td>
<td>50%</td>
<td>—</td>
<td>50%</td>
<td>Not done Right</td>
<td>Al and apical akinesis</td>
<td>Not done</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>9 RF</td>
<td>6</td>
<td>100%</td>
<td>50%</td>
<td>50%</td>
<td>—</td>
<td>—</td>
<td>Right</td>
<td>Normal</td>
<td>None</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>10 VA</td>
<td>6</td>
<td>65%</td>
<td>100%</td>
<td>80%</td>
<td>90%</td>
<td>90%</td>
<td>Right</td>
<td>Normal</td>
<td>None</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>11 PM</td>
<td>6</td>
<td>100%</td>
<td>70%</td>
<td>80%</td>
<td>90%</td>
<td>—</td>
<td>Right</td>
<td>Normal</td>
<td>None</td>
<td>Fresh and old infarct</td>
<td>Fresh infarct</td>
</tr>
<tr>
<td>12 LA</td>
<td>6</td>
<td>100%</td>
<td>70%</td>
<td>70%</td>
<td>—</td>
<td>50%</td>
<td>Right</td>
<td>Apical aneurysm Inferior akinesis</td>
<td>At origin of LMCA</td>
<td>No infarct</td>
<td>Fresh and old infarct</td>
</tr>
</tbody>
</table>

Abbreviations: + = Complication leading to death. AS = atherosclerosis; AL = anterolateral; LMCA = left main coronary artery; LAD = left anterior descending artery; DIAG = diagonal branch; Lcx = left circumflex artery; RCA = right coronary artery.
Incidence and Nature of Complications/Local

One of the most frequent complications in this series was femoral artery thrombosis (0.7% of cases) (table 1). Surgical thrombectomy was always required within a period of two to 12 hours after the study. As previously noted, a strong female predominance was observed. Whereas females constituted less than one-third of our cases, 65% of all femoral artery thromboses were seen in women. The majority of these female patients had normal coronary arteries.

In 1973, scanning electron microscopic studies of extruded RPX polyethylene catheters and Ducor polyurethane catheters were performed in our laboratory.* These studies demonstrated that polyurethane has rough and irregular external and internal surfaces (fig. 1). These surface irregularities have previously been described. The external surface of polyethylene was also rough and irregular (fig. 2a). However, polyethylene had a rather homogeneous and smooth internal surface (fig. 2b). The difference in smoothness between the inner linings of polyethylene and polyurethane catheters are illustrated in figures 1b and 2b.

Previous studies have shown that these surface defects are important factors in the initiation of thrombogenesis on vascular catheter surfaces. After January 1974, we have, following the suggestion of Amplatz, covered the external surface of all our catheters with a benzalkonium-heparin complex. A comparison of 1149 patients studied in 1973

*These studies and photographs have been provided through the courtesy of Drs. E. Sanborn and M. Cantin, University of Montreal.

with non-heparin-coated catheters with 1255 patients studied in 1974 with heparin-coated catheters has shown only a slight decrease in the total incidence of femoral artery thrombosis from 0.78% to 0.56% (table 1).

A false aneurysm of the femoral artery occurred much less frequently (0.17% of cases) and always required surgical correction (table 1).

Incidence and Nature of Complications/Systemic

Five patients presented definite signs of transient cerebral ischemia (table 1). Localized sensory and/or motor impairment evolved toward complete recovery within one to 24 hours in all cases. Two patients had episodes of temporal-spatial disorientation without local manifestations and recuperated completely within one hour. In three patients, a sensation of blurred vision persisted for several minutes during or immediately after coronary arteriography.

The exact etiology of these manifestations could not be determined. Several possibilities were considered including microembolization, in situ thrombosis, and reaction to contrast material or to premedication.

Finally, severe allergic accidents or systemic infections were not encountered in this study.

Incidence of Complications Following Repeated Coronary Arteriograms

In 57 patients, a total of 242 coronary arteriograms were not associated with any fatality, acute myocardial infarction or neurological accident (table 4). Cardiac complications

![Figure 1 Scanning electron photomicrographs of Ducor polyurethane catheters. A) External surface (X300). B) Internal surface (X300). Both the internal and external surfaces of polyurethane catheters are rough and show marked irregularities.](image-url)
FIGURE 2 Scanning electron photomicrographs of RPX polyethylene catheters. A) External surface (×300). The external surface of the catheter is rough and irregular. B) Internal surface (×300). The internal surface of RPX polyethylene catheters is smooth and regular.

were characterized by arrhythmias in two patients: ventricular fibrillation in one case (0.41%) and asystole of 6 sec duration in the other (0.41%).

Local complications, the incidence of which was comparable to the whole series, included two femoral artery thromboses (0.82%) treated surgically. An arteriovenous femoral fistula was discovered one year after coronary arteriography in an asymptomatic patient with excellent distal pulses and did not require surgical correction. A transient neurological incident consisted of a temporal disorientation lasting approximately one hour and was followed by complete recovery. Periarterial fibrosis sometimes led to difficulties in cannulation of one or the other femoral artery but this was successful in all instances (table 4).

Discussion

The number of cases submitted annually to coronary arteriography in our institution increased progressively between 1965 and 1970.14, 31, 32 One hundred and forty-two patients were studied during the years 1965 and 1966, 247 in 1967, 415 in 1968, and 543 in 1969. Sones' technique was used exclusively in the first 250 cases and was progressively replaced during the year 1967 by a percutaneous femoral approach using preformed polyethylene catheters. This shift was motivated by three major factors. First, the remarkable safety of retrograde left heart catheterization and transfemoral selective arterial catheterization using polyethylene catheters (RPX, B-D) had been well established in over 8,000 procedures since 1959. Secondly, it soon became apparent that this technique of selective coronary catheterization possessed great simplicity and rapidity of execution. Thirdly, it led to substantial improvement in the quality of the angiographic documents through highly selective coronary artery injections. During this initial five-year period, the procedure was carried out for diagnostic as well as prognostic purposes in most instances. Unstable angina or myocardial infarction during the preceding three months were considered a contraindication to the study. Our in-

| Type and Incidence of Complications Associated With Multiple Coronary Angiographic Studies |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|-----------------|
| Number of patients: 57          | Number of studies: 242 |
| Deaths                         | Number of Studies | Total |
| Cardiac complications          | 1                | 0.41 |
| Myocardial infarction          | 1                | 0.41 |
| Coronary dissection            | 2                | 0.82 |
| Coronary embolism              | 2                | 0.82 |
| Pulmonary edema                | 2                | 0.82 |
| Ventric. fibrillation          | 1                | 0.41 |
| Ventric. asystole              | 1                | 0.41 |
| Other arrhythmias              | 2                | 0.82 |
| Local complications            | 2                | 0.82 |
| Femoral thrombosis             | 1                | 0.41 |
| False aneurysm                 | 1                | 0.41 |
| Arteriovenous fistula          | 1                | 0.41 |
| Systemic complications         | 1                | 0.41 |
| Cerebral ischemia              | 1                | 0.41 |
| Contrast reaction              | 1                | 0.41 |
| N                              | %                | %    |
| Total                          | 2                | 0.82 |

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cidence of serious complications with the percutaneous femoral approach before 1970 was low. No death was encountered in the first 515 patients. One death was observed in 1337 patients (0.07%) and the incidence of cardiac complications including arrhythmias was 1.2%. It was generally agreed from the data published in the literature before 1970 that the mortality rate and incidence of major complications from selective coronary arteriography were low. In 1968, a cooperative study on coronary arteriography recorded a lethal complication rate of 0.1% and a nonlethal complication rate of 1.9% in 3264 patients. In 1969, it was estimated that the potential mortality from coronary arteriography was 0.3% and that the incidence of significant nonlethal complications was 2.2%.

Widespread acceptance of coronary artery bypass surgery since 1970 has had major consequences on the practice of coronary arteriography. Surgical bypass procedures were introduced at our institution in September 1969. As shown in the present review, this has led to a marked increase in the number of cases studied annually (approximately 1000) and to rapid stabilization at this level thereafter. A second major effect of the enthusiasm for direct myocardial revascularization was a drastic shift from previous diagnostic investigations toward the study of surgical candidates having severe documented or strongly suspected coronary artery disease. This has included a significant number of patients with unstable crescendo angina or acute coronary insufficiency. The optimal management of these patients remains controversial. However, when angina persists after a brief period of in-hospital medical treatment, they are frequently submitted to an early angiographic study to evaluate the possibility of surgical treatment. Aortocoronary bypass surgery is not infrequently performed shortly after angiography. Mechanical supportive measures, such as intra-aortic balloon counterpulsation, are still rarely used in this situation.

Early in our experience, we anticipated that such a change in the indications would significantly increase the risk of coronary arteriography. This is confirmed in the present review. The mortality rate from the procedure in 5250 patients over a five-year period averaged 0.23% annually. This incidence has remained relatively stable since 1970. In addition, mortality was closely related to the severity of coronary artery disease, and was particularly associated with left main coronary artery disease in all instances. In nine of the 12 deaths, the left main coronary artery stenosis was equal to or greater than 60% and was at or very near the ostium in five patients. Eleven patients had anginal symptoms. The presence of class III or IV angina in all instances, the long duration of symptoms, equal to or greater than five years in eight patients, instability during the preceding three months in six patients and electrocardiographic evidence of anterior or anterolateral wall ischemia in eight patients indicated severe coronary artery disease before angiography. The circumstances surrounding the complication and death were stereotyped and were characterized by sudden, unexpected irreversible mechanical failure. As previously described in patients experiencing sudden death, the pathological findings were sparse. A fresh thrombus was found in the coronary arteries of only two patients. None of these two thrombi had the characteristic cord-like aspect of the coronary emboli described by Price and coworkers. Only three patients had microscopic evidence of a recent myocardial infarction.

In this study, acute nonfatal myocardial infarction was seen in 0.09% of patients. All had severe coronary artery disease. However, none had a left main coronary stenosis. In retrospect, following close inspection of the coronary arteriograms, coronary embolism was diagnosed in three patients (0.07%). This was responsible for myocardial infarction in one patient and had no measurable residual consequences in the other two cases. Localized subintimal dissection of the right coronary artery occurred in three cases (0.07%) and was also without long-term consequences. However, one of our deaths was the consequence of a right coronary dissection in a very unusual case involving a young female patient having severe valvular heart disease and complete, presumably congenital atresia of the left main coronary ostium.

Cerebral embolism resulting in residual damage or hemiplegia was never documented in this study. Five patients had transient signs of cerebral ischemia, the etiology of which could not be precisely determined and could include microembolization, in situ thrombosis, and reaction to contrast material or to premedication.

Serious nonfatal complications leading to sequelae were almost invariably seen in patients with severe coronary artery disease. No death, myocardial infarction, or neurological accident was encountered in subjects with strictly normal coronary arteries. However, arrhythmias such as ventricular fibrillation or asystole were frequently seen in subjects with normal coronary arteries, usually during right coronary injection.

Femoral artery thrombosis remains the major local complication of percutaneous coronary arteriography and was observed in 0.7% of our cases. Two-thirds of these patients were females, most of whom had normal coronary arteries. When this complication occurs, prompt surgical intervention under local anesthesia is mandatory. In 36 patients in this series, thrombectomy within 12 hours was never followed by sequelae. In our experience, coating the external surface of the catheters with a benzalkonium-heparin complex before sterilization, as suggested by Amplatz, did not significantly reduce the incidence of this complication. On the other hand, recent reports have demonstrated that systemic heparinization decreases the incidence of femoral artery thrombosis.

One advantage of the percutaneous femoral approach is to facilitate repetition of the examinations. The present review demonstrates that multiple repeated studies in the same individual do not entail an additive risk of death or of serious nonfatal complications. This observation is obviously important. Follow-up coronary arteriograms are often essential in patients with progressive symptoms or after aortocoronary bypass surgery.

That the incidence of mortality and serious nonfatal complications is proportional to the severity and duration of coronary artery disease has been stressed in a few recent reports. This was rarely related, as in the present review, to the total experience of a given institution. However, specific groups of high-risk cases have been described and, in most reports, have consisted of patients with severe triple coronary vessel disease almost invariably.
associated with left main coronary artery stenosis. In a previous study from this institution, mortality related to coronary arteriography in 147 patients with \( \geq 50\% \) stenosis of the left main coronary artery was approximately 6%.\textsuperscript{21} In the more detailed studies on patients with left main coronary lesions, the mortality related to coronary arteriography was 6.1%,\textsuperscript{5} 10%\textsuperscript{7} and 15%.\textsuperscript{28} Such a high risk in this category of patients stresses the need for preventive supportive measures.

Rather unexpectedly, since the technical aspects of coronary arteriography were well described before 1970, most complications reported recently have been technical or thromboembolic.\textsuperscript{1-11} A distressing incidence of coronary and cerebral embolic accidents has been described. They have resulted in sudden unexpected deaths, acute myocardial infarctions, and strokes in an unacceptable percentage of cases submitted to transfemoral percutaneous coronary arteriography. The embolic nature of these accidents was usually recognized by the sudden catastrophic clinical picture and was frequently documented during coronary arteriography\textsuperscript{2, 5} or at postmortem examination.\textsuperscript{2, 8, 8} In a recent survey by Adams and coworkers\textsuperscript{10} of 45,903 patients studied in 1970 and 1971 in 173 institutions, the combined incidence of death, myocardial infarction and stroke was 2.22% (deaths: 0.78%) for the femoral approach compared to 0.38% (deaths: 0.13%) for the brachial approach. The authors emphasize the limits of their survey and stress the fact that their data represent minimum figures. A more limited but more complete survey of 17 institutions by Takaro and coworkers\textsuperscript{8} has also shown a mortality incidence of 2.2% in 2300 transfemoral approaches and of 0.3% in 750 transbrachial approaches. Several institutions have independently reported a similar experience and have attributed most of their fatalities or serious nonfatal complications to coronary or cerebral embolization. Many of these have been reported in subjects with normal coronary arteries or during reevaluation of aortocoronary bypass surgery, making the incidents totally unacceptable.

Polyurethane catheters cling tenaciously to conventional steel wires and require the use of teflon-coated wires for percutaneous introduction into the systemic circulation. McCarty and Glasser\textsuperscript{29} have shown that clot formation occurs much more rapidly on these teflon-coated wires than on stainless steel wires. Since wires are used repeatedly for short periods during percutaneous femoral catheterization, this difference in thrombogenicity may be very important.

The internal surface of polyurethane catheters is highly irregular (fig. 1b) and it has been demonstrated that these surface irregularities play a major role in platelet aggregation, fibrin deposition, and red blood cell thrombus formation.\textsuperscript{17, 18} Rapid thrombus formation from the inner lining of these catheters has been demonstrated.\textsuperscript{17, 18} On the other hand, studies done in our laboratory recently demonstrate that the lumen of extruded RPX polyethylene catheters is smooth and regular (fig. 2b).

Although different mechanisms have been proposed to explain these accidents, it seems that thrombus formation occurs rapidly at the interface of teflon-coated wires and inner lining of polyurethane catheters. These thrombi are transferred by the teflon-coated wires to a second catheter, usually the left coronary catheter, and dislodged into the coronary or cerebral circulation during contrast injection.

It is generally agreed that the combination of teflon-coated wires and polyurethane catheters makes the use of systemic heparinization mandatory.\textsuperscript{8, 9, 12} It must be realized, however, that routine systemic heparinization decreases but does not eliminate the incidence of embolic complications. Recently, a relatively high rate of embolic complications has been described despite the routine use of systemic heparinization.\textsuperscript{22}

Sones' technique has repeatedly been shown to be relatively free of embolic complications. Other techniques such as ours\textsuperscript{13, 14} and the techniques described by Amplatz et al.\textsuperscript{20} and Schoonmaker et al.\textsuperscript{23} have also been demonstrated to be safe and offer alternatives.

Once these technical complications have been eliminated, as in our experience, what can one expect as an acceptable rate of fatalities and other serious complications from selective coronary arteriography? This depends to a large extent on appropriate management of high-risk patients. Our study as well as previous reports demonstrate that the majority of this high-risk population is composed of patients with main left coronary artery obstruction associated with severe double or triple coronary vessel disease. This group can frequently be identified before coronary arteriography. They are characterized by severe long-standing (> five years) angina despite intense medical therapy and recent instability or marked ischemic changes in the precordial leads on the resting electrocardiogram. Other features frequently described in these patients are dyspnea during the angina attacks and marked (\( \geq 2 \) mm) ST segment depression on the exercise electrocardiogram.\textsuperscript{27, 28}

Left main coronary artery stenosis can be readily recognized at coronary angiography by careful injection of a small amount of contrast material at or near the left coronary ostium in a 10° to 15° right and left anterior oblique plane. Once the presence of left main coronary artery stenosis has been established, the number of selective injections in both left and right coronary arteries should be limited to the minimum essential to assess the degree of stenosis and adequacy of distal run off. However, even such a restrictive attitude, although always essential, is probably not sufficient to prevent a high incidence of mortality in these cases.

A promising approach has recently been reported by Gold et al.\textsuperscript{30} and Weintraub et al.\textsuperscript{31} In selected cases with severe recurrent angina unresponsive to medical therapy, the use of intra-aortic balloon counterpulsation resulted in relief of myocardial ischemia and allowed coronary arteriography and saphenous vein aortocoronary bypass grafting to be performed safely. Their results strongly suggest that, whenever pharmacological measures are ineffective, sustained relief of severe myocardial ischemia could be obtained by mechanical assistance administered before, during, and after coronary arteriography.

Ideally, as suggested by Judkins and Gander,\textsuperscript{12} selective coronary arteriography should carry a very low risk of mortality (0.1% or less) and of major complications. However, our experience during the past five years demonstrates that such a low complication rate will not be generally possible until more adequate preventive measures are available and used before coronary arteriography. As subgroups of
patients at high risk for coronary arteriography and bypass surgery continue to be better defined, these measures will undoubtedly improve. At the present time, these preventive measures should include selection of a catheter technique with a demonstrated low incidence of embolic complications, frequent or routine use of systemic heparinization and, possibly, more liberal use of external mechanical assistance in selected cases with severe persistent myocardial ischemia despite adequate pharmacological therapy.

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