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WHAT ARE THE CURRENT RISKS OF CARDIAC CATHETERIZATION?

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Introduction

Since the first heart catheterization performed by Werner Forssmann on himself in 1929, this technique has undergone an extraordinary expansion and widespread application. Today, several million heart catheterizations are performed throughout the world each year. Heart catheterization is not only a fantastic investigative tool that provides precise information regarding anatomy and physiology, but it also offers a number of important and very effective interventions. Forssmann imagined heart catheterization as a delivery mechanism for drugs to enhance their efficacy, and heart catheterization has indeed become, in a large number of cases, a therapeutic tool.

Cardiac catheterizations are performed in a large number of centers worldwide, and the complication rate is low. Nevertheless, zero risk does not exist in medicine. This analysis focuses on the procedural risks of cardiac catheterization and coronary angiography but does not discuss the risks related to specific interventions (e.g., the risks of stent implantation, atherectomy, or systemic anaphylactoid reactions to iodinated contrast media). Actually, vital risks of heart catheterization are very rare, and most complications are related to the access site.

Recent Data Concerning the Risks of Procedure-Related Complications

Many publications and books about complications during and after cardiac catheterization refer to the publication of a 1991 report prepared by Noto for the Society for Cardiac Angiography and Interventions.[1] Ten years later, a single-center report, summarized in Table 1, was published by the Montreal Heart Institute.[2] The report is a prospective analysis collected over a 2-year period (April 1996 to March 1998) of 11,821 procedures and includes in-hospital and one-month follow-up of 7,953 diagnostic and 3,868 therapeutic procedures.

More recent data can be obtained from the ALKK registry (Arbeitsgemeinshaft Leitende Kardiologische Krakenhausärzte) initiated in 1992 in Germany. The last report, published in 2005,[3] covers the year 2003 and 89,064 procedures performed in 75 German centers, including 58,935 invasive procedures, 23,867 invasive

Complication	Diagnostic	Therapeutic	Total
	n=7,953	**n=3,868**	**n=11,821**
Death	34 (0.4%)	42 (1.1%)	76 (0.6%)
Procedure-related death	8 (0.1%)	21 (0.5%)	29 (0.2%)
Q-wave MI	3 (0.04%)	24 (0.6%)	27 (0.2%)
Non-Q-wave MI	5 (0.06%)	133 (3.4%)	138 (1.2%)
Emergency CABG	4 (0.05%)	13 (0.3%)	17 (0.1%)
Pulmonary edema	11 (0.1%)	21 (0.5%)	32 (0.3%)

Table 1. Incidence of cardiac complications from a single center reporting 11,821 procedures (April 1996-March 1998).[2]

Complications	Total	Stable angina	Unstable angina	NSTEMI	STEMI
In-hospital death	0.45%	0.21%	0.48%	1.74%	2.84%
In cath-lab death	0.02%	0.01%	0%	0.03%	0.30%
Myocardial infarction	0.10%	0.08%	0.26%	0.25%	0.34%
TIA/stroke	0.11%	0.01%	0.17%	0.25%	0.05%
CPR	0.16%	0.10%	0.30%	0.43%	0.87%
Pulmonary embolism	0.01%	0%	0.10%	0%	0%

Table 2. Mortality and procedure-related complications in a cohort of 57,581 patients with coronary artery disease and lone diagnostic procedures (ALKK registry).[3]

procedures followed by PCI, and 6,802 lone PCIs. A summary of this registry is presented in Table 2.

Two years ago, Mehta et al. published the rate of complications occurring in 11,703 pediatric cardiac catheterization: the rate was 7.3% of cases with a mortality risk of 0.23%.[4]

Major Vital Complications

The overall risk of death from heart catheterization is less than 0.5%, and only 0.02% occur in the catheterization laboratory. Death may be caused by perforation of the heart (extremely rare) or great vessels, cardiac arrhythmias, myocardial infarction, or systemic anaphylactic reactions to iodinated contrast media (1 death per 55,000). The risk of in-hospital death is significantly higher when catheterization is performed in the presence of acute coronary syndrome (2.84% in patients with ST elevation myocardial infarction) than when it is performed in stable patients (0.21%).

The risk of myocardial infarction (MI) is 1 per 1,000 patients (0.1%). However, these figures are certainly higher after coronary interventions, especially with the new definitions based upon elevation of troponin levels. Several studies have investigated the relationship between a rise in periprocedural levels, indicating myonecrosis, and the clinical outcome; an increase of more than three times the upper limit of normal for creatine kinase-MB has a significant clinical impact, and this cut-off is routinely used in many clinical trials concerning percutaneous coronary interventions.

Large MI are caused by catheter-induced coronary injury or embolization from the catheter or left ventricular (LV) thrombus. The most common site of catheter-induced injury is the ostium of the coronary vessel with occlusive dissection. Coronary embolization usually occurs when catheters are insufficiently rinsed, allowing a thrombus to be pushed into the vessel and leading to infarction and, even more likely, to cardiac arrest when the thrombus is expelled into the left main. Small air emboli are usually benign but may create ischemia for 5-10 minutes.

The rate of cerebrovascular accidents ranges from 0.11 to 0.4%.[5-7] Major cerebrovascular accidents with permanent disabling disorders have been noted but with a very low incidence. In most cases, these cerebral ischemic events are transient and without sequel. Several reports[8,9] have mentioned the high incidence of microemboli during left heart catheterization, the majority of which are probably of gaseous origin since they occurred predominantly during contrast media injection in this study. With the advent of diffusion-weighted MRI (DW-MRI), which is particularly sensitive in detecting acute ischemic lesion,[10] it has been shown that the rate of asymptomatic cerebral emboli might be much more frequent. Omran[11] observed that silent cerebral embolism after retrograde catheterization of the aortic valve in valvular aortic stenosis was present in 22% of cases, and Lund[12] and Busing[13] found an incidence of 13.5% and 15%, respectively. More recently, Hamon et al.,[10] using DW-MRI, found an incidence of only 2.2% in patients with severe aortic valve stenosis.

Serious, life-threatening arrhythmias are observed mainly during coronary angiography (0.5%). They were noted in the past when the large coronary catheters (>8F) were used, particularly during intubation of the right coronary artery. They generally occurred when the anatomical configuration of the first segment of the right coronary artery allowed untimely deep intubation and suppression of the flow by the wedged catheter. The resulting arrhythmia was most often a ventricular fibrillation, easily reducible by electrical defibrillation. In some other cases, it was an A-V block, which sometimes required a temporary pacing. These complications have become less frequent with the use of smaller catheters (5–6F).

Ventricular tachycardia is most likely to occur when introducing a catheter (most often a pigtail catheter) in the left ventricle and mainly in patients with LV dysfunction or LV aneurysm. Atrial fibrillation and supraventricular tachycardia might be observed when the catheter is introduced in the left atrium through an atrial septal defect or patent foramen ovale.

Vascular Access Complications

A number of local vascular complications have been described and are observed in 0.5 to 1.5% of patients, although these complications are probably underreported. They occur after left heart catheterization and arterial access.

Perforation of peripheral arteries by a guide wire or a catheter is uncommon but may occur in cases of very tortuous vessels and when stiff wires and catheters are used. A retroperitoneal hemorrhage can occur with or without hemodynamic compromise. The use of a J-type tip prevents this rare complication.

Artery dissection is more frequent with stiff guide wires, but fortunately the flap is created against the flow of blood (from distal to proximal), and in most the cases the flap is sealed. However, dissection may promote local thrombosis and artery occlusion.

Arterial occlusion is rare. It can be observed when the femoral artery puncture is done exactly at the site of an atherosclerotic plaque. This "iatrogenic" plaque rupture may lead to thrombosis in situ and occurrence of acute leg ischemia. In most cases, this peripheral acute leg ischemia is related to a distal embolism of a plaque or a fragment of plaque dislodged during the passage of the catheter in an atherosclerotic iliac artery. This complication requires rapid embolectomy with the Fogarty's catheter.

Pseudoaneurysm is an intraparietal artery hematoma[14] characterized by swelling at the puncture site and a murmur at auscultation. Initially, surgical repair was recommended, but ultrasound-guided compression therapy (UGCT) is currently the nonsurgical recommended treatment.[15] Routine color duplex control of the puncture site the day following the removal of the sheath after percutaneous catheterization and UGCT increases the success rate of UGCT and minimizes the need for surgical repair.[14] Infection may occur at the site of pseudoaneurysm.[16]

Arteriovenous (AV) fistula occurred at a rate ranging from 0.017% in 1989 to 0.86% in 2002.[17, 18] In most cases, the fistulas are located below the bifurcation of the common femoral artery. Actually, the common femoral artery and the common femoral vein are located side by side, but after the bifurcation, the proximal femoral vein crosses the proximal superficial femoral artery laterally and lies posterior to the artery. Thus, a puncture at that site might interest both vessels, and this facilitates the connection. Between 30-38% of iatrogenic AV fistulas close spontaneously within one year. Cardiac volume overload leading to heart failure and limb damage is highly unlikely, so, in general, conservative management for at least one year is justified.

Numerous closure devices have been developed in recent years to obtain an efficient arteriotomy closure immediately at the end of the procedure. For the moment, evidence-based data are disappointing, and all randomized studies included in a recently published meta-analysis[8] confirmed that, compared to manual management of the puncture site, these devices are unable to reduce complications; moreover, they sometimes induce additional complications such as infection or ischemia.

Retroperitoneal hemorrhage requires a specific mention because it can affect the vital prognosis of the patient, and early recognition is especially critical. The clinical signs derived from the retrospective study of Farouque et al. are listed in Table 3.[19]

Symptoms	
Abdominal pain	42%
Groin pain	46%
Back pain	23%
Diaphoresis	58%
Physical signs	
Abdominal tenderness	69%
External groin hematoma	31%
Bradycardia	31%
Hypotension	92%

Table 3. Summary of clinical signs for retroperitoneal hemorrhage diagnosis (n=26 patients; incidence of 0.74%, adapted from Farouque et al.[19]).

Different mechanisms can lead to major bleeds, which represent an important complication after left heart catheterization. Within the last 10 years, diagnostic or therapeutic cardiac catheterizations have been performed in patients who received a combination of very powerful antithrombotic drugs. Large groin hematomas and retroperitoneal hemorrhage, which occur with the femoral approach, are associated with important blood loss that requires blood transfusion. These complications and related transfusions have been identified as a predictor of poor outcome. The transradial approach is associated with fewer bleeding events and transfusions than is the femoral approach. A meta-analysis of 15 randomized clinical trials (including 3,662 patients)[20] showed that in terms of major adverse cardiovascular events (death, MI, stroke, emergency PCI or CABG), both the radial and femoral approach yielded similar results, with 2.3% and 2.6% of events respectively. The radial approach was significantly superior in the risk of entry site complications (0.3% versus 2.8%; odds ratio: 2.2, 95% confidence interval, 0.11–0.44) but at the price of a higher rate of procedural failure (odds ratio 3.45, 95% confidence interval, 1.63–6.71; $p<0.001$). Nevertheless, patient comfort is increased and nursing staff workload is reduced with the radial approach.

Complications Related to Specific Types of Catheterization

The radial approach[21] is used more and more often, especially in Europe, because of the low rate of vascular-access complications and major bleedings and because the procedure results in a shorter hospital stay. The most frequent complication is radial spasm, which might be prevented by injection of a spasmolytic cocktail (nitrates or calcium antagonists). It is rare that a refractory spasm requires switching to the femoral access. Wire perforation of small branches of the radial artery has been described, and radial artery occlusion is rare and asymptomatic, occurring in only 3–5% of patients.

The transseptal approach, performed for the first time in 1959 by John Ross,[22] was almost completely abandoned until the description of percutaneous mitral valvuloplasty and the development of electrophysiological studies. Now this approach is widely used in cardiac catheterization centers and electrophysiology laboratories. The major risk is the perforation of the left atrium with or without occurrence of heart tamponade. An Italian survey[23] conducted in 33 electrophysiology centers collected 5,520 procedures performed since 1992. The rate of complications was low (0.76%), with 11 cardiac perforations (0.2%), of which 5 were accompanied by tamponade. The risk of death was 0.02%.

Right heart catheterization at the CCU bedside was performed for the first time with the Swan-Ganz Pulmonary Artery Flow-directed Balloon Catheter (PAC) in 1970.[24] Since the first case, millions of procedures have been performed with this device in CCUs and surgical units, and this technique is known to be very safe. However, one very rare complication may be underreported: the rupture of a branch of the pulmonary artery,[25] which occurs when the tip of the catheter is already wedged into the distal part of a branch of the pulmonary artery when the investigator inflates the balloon. This can induce a rupture of the vessel, which is expressed by the sudden occurrence of a hemoptysis and rapidly followed by a drop in blood pressure. This response requires deflating the balloon in order to withdraw the catheter two or three centimeters proximally, followed by gently re-inflating the balloon to block the pulmonary arterial flow. In a second step, distal injection of glue — or, even better, an embolization with a coil — must be performed to prevent hemodynamic compromise and even death. More recently, it has been proposed to implant a stent graft in the pulmonary branch.[26]

Conclusions

Over the last 20 years, and despite the development of noninvasive diagnostic procedures, cardiac catheterization remains the gold standard for assessing cardiovascular disease. The risks associated with heart catheterization have markedly decreased over time despite its widespread use. Overall, the major complications — death, Q-wave MI, and disabling stroke — are very rare. It appears that one of the most important risks is related to the vascular access site and involves the risk of bleeding, which may compromise the vital prognosis. Clearly, heart catheterization must be performed by skilled, properly trained operators, but recognizing the predictive factors of risk is also important. Age > 75 years, female gender or obesity, and renal insufficiency or a prior history of bleeding represent the major predictive factors of complications.

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