Diagnostic and Therapeutic Percutaneous Cardiac Interventions Without On-Site Surgical Backup – Review of 11 Years Experience

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Abstract

Background: Current clinical guidelines restrict catheterization laboratory activity without on-site surgical backup. Recent improvements in technical equipment and pharmacologic adjunctive therapy increase the safety margins of diagnostic and therapeutic cardiac catheterization.

Objective: To analyze the reasons for urgent cardiac surgery and mortality in the different phases of our laboratory's activity in the last 11 years, and examine the impact of the new interventional and therapeutic modalities on the current need for on-site cardiac surgical backup.

Methods: We retrospectively reviewed the mortality and need for urgent cardiac surgery (up to 12 hours post-catheterization) through five phases of our laboratory's activity: a) diagnostic (years 1989–2000), b) valvuloplasties and other non-coronary interventions (1990–2000), c) percutaneous-only balloon angioplasty (1992–1994), d) coronary stenting (1994–2000), and e) use of IIb/IIIa antagonists and thienopiridine drugs (1996–2000).

Results: Forty-eight patients (0.45%) required urgent cardiac surgery during phase 1, of whom 40 (83%) had acute coronary syndromes with left main coronary artery stenosis or the equivalent, and 8 (17%) had mechanical complications of acute myocardial infarction. Two patients died (0.02%) during diagnostic procedures. In phase 2, eight patients (2.9%) were referred for urgent cardiac surgery due to either cardiac tamponade or severe mitral regurgitation, and two patients (0.7%) died. The combined need for urgent surgery and mortality was significantly lower in phase 4 plus 5 as compared to phase 3 (3% vs. 0.85%, $P = 0.006$).

Conclusion: In the current era using coronary stents and potent antithrombotic drugs, after gaining experience and crossing the learning curve limits, complex cardiac therapeutic interventions can safely be performed without on-site surgical backup.

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During the last two decades there has been a shift in cardiac catheterization laboratory activity worldwide – from diagnosis of cardiac and coronary pathologies to treatment [1,2]. Recent improvements in technical equipment and pharmacotherapy enable the safe performance of a wide range of interventional procedures in both acute and chronic cardiac diseases [3,4]. Yet, recently published clinical guidelines and expert consensus documents still restrict diagnostic and therapeutic cardiac catheterization laboratory activity only to hospitals with on-site surgical backup due to the potential need for immediate surgical intervention [5,6].

In the late 1980s, in accordance with several pre-termed conditions raised by the Israel Ministry of Health, our cardiac catheterization laboratory was authorized to perform *diagnostic* procedures *without* an on-site cardiac surgical backup. The conditions were: a) competence of the medical and nursing staff in performing invasive cardiac procedures, b) on-site vascular surgery unit capable of treating immediate vascular complications, c) an agreement with a tertiary center for cardiac surgical backup capable of accepting patients in the event of "crisis" within 60 minutes, and d) competence in operating a transportable intra-aortic balloon pump. After performing more than 400 diagnostic procedures without major complications, we were further authorized to perform *therapeutic* interventions in selected cases. Excluded were patients in whom the culprit vessel supplied more than 40% of left ventricular mass, patients with type C lesions, patients with multivessel coronary disease, and patients with acute coronary syndromes [7]. Subsequently, after gaining experience with advanced technologies and new pharmacologic therapies, we gradually started performing more complex and demanding therapeutic procedures in patients with stable angina pectoris and acute coronary syndromes, or in patients with high risk coronary artery disease.

In this paper we retrospectively review our diagnostic and therapeutic experience from 1989 to 2000. We analyze the reasons for urgent cardiac surgery and mortality in the different phases of our laboratory's activity in the last 11 years, and examine the impact of the new interventional and therapeutic modalities on the current need for on-site cardiac surgical backup.

Methods

We retrospectively reviewed data from June 1989 to December 2000. The data were collected from several sources: the catheterization laboratory's activity logbook, catheterization reports and films, and patients' records. The data were analyzed for the following parameters, defined as follows:

Severity of CAD

Severity was based on the Coronary Artery Surgery Study (CASS) definitions [8].

Complexity of coronary lesions by angiography [7]

These included: type A lesion – a lesion with a high likelihood of success (>85%) in percutaneous coronary intervention and a low likelihood for complications; type B lesion – a lesion with an intermediate likelihood of success in PCI; and type C lesion – a

PCI = percutaneous coronary intervention

complex coronary lesion with low likelihood (<65%) of success in PCI and a high likelihood of complications.

Major complications

These included any of the following:

- Death within 12 hours of cardiac catheterization or intervention.
- Myocardial infarction, as defined by the World Health Organization [9]. Post-procedural creatine kinase and CK-MB levels were measured only in patients with recurrent chest pain or electrocardiographic changes.
- Mechanical complications of percutaneous balloon valvuloplasty – acute severe mitral insufficiency, cardiac rupture and cardiac tamponade.
- Perforation of a coronary artery.
- Cardiogenic shock secondary to massive cardiac ischemia caused by PCI or diagnostic catheterization.

Other complications

These included any vascular or neurologic complications, acute renal failure, infections, or hypersensitivity reactions due to cardiac catheterization.

Urgent cardiac surgery

This category includes cardiac surgery performed within 12 hours of cardiac catheterization in a cardiothoracic department located 50 kilometers from our hospital. We have divided the catheterization laboratory's activity into five phases:

- The diagnostic era – starting in June 1989.
- The non-coronary interventions era (mainly valvuloplasties) – starting in 1990.
- The percutaneous-only balloon angioplasty era – starting in 1992.
- The coronary stenting era – starting in 1994.
- The antiplatelet/pharmacologic era – starting with the use of IIb/IIIa receptor antagonists and thienopiridine drugs (ticlopidine and clopidogrel) in 1996.

Statistical analysis

Data are presented as absolute numbers or percentage. Continuous variables are presented as mean ± standard deviation. Statistical significance analysis for categorical values was performed with the Chi-square test. A P value < 0.05 was considered as statistically significant.

Results

In phase 1, from June 1989 to December 2000, we performed 10,320 diagnostic cardiac procedures. The indications for the procedures are presented in Figure 1. The most common indication (82%) was evaluation of known CAD. Most of the procedures (10,272 cases, 99.5%) were performed through the femoral approach.

CK = creatine kinase

CAD = coronary artery disease

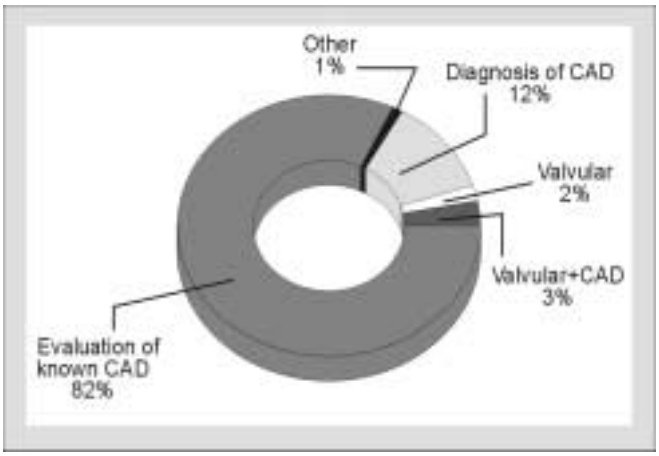

Figure 1. Indications for cardiac catheterization

In phase 2 we performed 271 percutaneous balloon mitral valvuloplasties, 8 balloon pulmonic valvuloplasties, and 3 balloon aortic valvuloplasties. Three patients underwent balloon dilatation of the aorta due to aortic recoarctation.

In phase 3, June 1992 to December 1994, we performed 235 percutaneous-only balloon angioplasties, 148 (63%) in patients with single vessel CAD, and 87 (37%) in patients with double vessel CAD as a two-staged procedure. We excluded from treatment patients with three-vessel CAD. In this phase, abrupt vessel closure and coronary dissections were treated with either prolonged low pressure balloon inflation or with perfusion balloons.

In phase 4, December 1994 to December 2000, 1,016 patients underwent coronary stent implantation, with an average of 1.1 stents per patient. The use of coronary stents increased dramatically from 1995, when we used stents in 30% of the PCIs, to 70% of all PCIs in the year 2000. Most of the stents (955 stents, 94%) were implanted in coronary arteries ⩾ 3 mm in diameter. A comparison of PCI characteristics in the years 1995 and 2000 is presented in Table 1.

In phase 5, starting in October 1996, we used IIb/IIIa receptor antagonists (abciximab, eptifibatide or tirofiban) in 160 patients (9% of all PCIs); most of them (139 patients, 87%) had either acute coronary syndromes or complex coronary lesions.

Table 1. A comparison of PCI characteristics in 1995 and 2000

	1995 (n=1,175)	2000 (n=1,325)	*P* value
No. of PCIs	198 (17%)	452 (34%)	<0.001
Single vessel disease	145 (73%)	249 (55%)	<0.001
Multi-vessel disease	53 (27%)	203 (45%)	<0.001
Primary PCI	–	22 (5%)	–
Type B+C lesions	38 (19%)	181 (40%)	<0.001
Stents	38 (19%)	316 (70%)	<0.001
Intra-aortic balloon pump	12 (6%)	32 (7%)	NS
Perfusion balloon	6 (3%)	–	–
IIb/IIIa antagonists	–	45 (10%)	–

NS = non-significant, PCI = percutaneous coronary intervention.

Complications of cardiac catheterization

As shown in Table 2, there were 113 (0.9%) major complications in 12,002 patients who underwent diagnostic and/or therapeutic cardiac catheterization during the years 1989–2000 in all five phases of our activity. In phase 1, two patients died during diagnostic catheterization: one had acute coronary syndrome and severe left main coronary disease (year 1991), and the other patient had severe aortic valve stenosis and died during a left and right cardiac catheterization (year 1992). Six patients (0.05%) had major complications: one had a Q wave MI, three had non-Q wave MI, one had cardiac tamponade (treated conservatively), and one had cardiogenic shock stabilized with an intra-aortic balloon pump. Thirty-five patients (0.3%) had other complications as defined in the Methods section.

In phase 2, two patients (0.7%) died during PBMV. One patient died as a result of pulmonary artery perforation in a trans-septal puncture attempt, and the other patient with severe mitral stenosis and pulmonary hypertension developed severe mitral insufficiency during PBMV and died shortly after urgent mitral valve replacement. Seven patients (2.6%) had major non-fatal complications during PBMV: five developed severe mitral insufficiency and two had cardiac tamponade.

In phase 3, prior to the stenting era, four patients (1.7%) died during PCI, three of them due to coronary dissection leading to cardiogenic shock, with no response to perfusion balloon insertion. As presented in Table 3, there was a significant difference in death rates between phase 3 and phases 4 plus 5 (1.7 vs. 0.25%, respectively, $P < 0.001$). In phase 4, three patients died during PCI, all from suboptimal stent insertion leading to coronary occlusion and cardiogenic shock. These cases occurred in the years 1994–1996. In the last 4 years none of our patients died during PCI.

Referral to urgent cardiac surgery

As shown in Table 3, in phase 1, 48 patients (0.45%) required urgent cardiac surgery: 40 had acute coronary syndrome associated with significant left main coronary artery stenosis or left main equivalent, 8 patients had mechanical complications of myocardial infarction. Intra-aortic balloon pump was used in most of the patients (46/48, 96%). Mean transport time to the surgical backup center was 47 $\pm$ 7 minutes, and no patient died during transfer.

In Phase 2, eight patients (2.9%) undergoing PBMV needed urgent cardiac surgery, five of them in the years 1990–93. Only one patient in phase 5 needed urgent surgery due to left main dissection. The need for urgent surgery was significantly lower in phases 4 and 5 compared to phase 3 (0.6 vs. 1.3%, respectively, $P < 0.001$).

Discussion

The main results of our analysis show that in the last decade there was a gradual and significant reduction in both the need for urgent cardiac surgery and in immediate mortality related to diagnostic and therapeutic cardiac catheterization. Our results need to be examined and compared to data from the late 1980s and early 1990s, i.e., the pre-stenting era, as well as to data from single and multicenter studies.

MI = myocardial infarction

PBMV = percutaneous balloon mitral valvuloplasties

Table 2. Complications in all phases of the catheterization laboratory activity

	Major complication	Other complications	Death
Diagnostic (n=10,320)	6 (0.05%)	35 (0.3%)	2 (0.02%)
Therapeutic (n=1,682)	29 (1.7%)	32 (1.9%)	9 (0.5%)
Total (n=12,002)	35 (0.3%)	67 (0.56%)	11 (0.09%)

Table 3. Death and referral to urgent cardiac surgery in all phases of the catheterization laboratory activity

Phase	No. of patients	Urgent cardiac surgery	Death
1	10,320	48 (0.45%)	2 (0.02%)
2	271	8 (2.9%)	2 (0.7%)
3	235	3 (1.3%)*	4 (1.7%)*
4	1016	6 (0.6%)*	3 (0.3%)*
5	160	1 (0.6%)*	–

*$P = 0.006$ for the combined urgent surgery and death in phase 3 versus the combined urgent surgery and death in phases 4+5.

Diagnostic procedures

The Collaborative Studies in Coronary Artery Surgery (CASS) registry, which analyzed 7,553 consecutive patients undergoing coronary angiography, reported a mortality rate in 1979 of 0.2% [10]. In 1982 the Society for Cardiac Angiography reported a mortality rate of 0.14% among 53,581 patients (aged <1 year to >60 years) who underwent diagnostic coronary angiography [11]. In 1990 the same society reported a mortality rate of 0.11% during diagnostic procedures [12]. A recent study of 2,804 patients undergoing diagnostic procedures in a single center without surgical facilities, but which excluded critically ill patients, reported a mortality rate of 0.07% [13]. Only two fatal events in diagnostic procedures occurred in 11 years of our activity (a mortality rate of 0.02%), and both occurred in the first 3 years of our experience.

Therapeutic procedures

The mortality rate in our laboratory during 10 years of therapeutic interventional experience was 0.5% and the need for urgent cardiac surgery 1%. This includes both coronary and non-coronary interventions. Most of the mortality cases and the need for urgent cardiac surgery occurred in the early days of PBMV when we used stiff over-the-wire balloon systems. These systems have a higher potential for causing pericardial tamponade than the Inoue balloon system currently in use. In the last 5 years, after crossing the learning curve limits [15], using the Inoue balloon system and improving patient selection, the complication rate of PBMV in our institute is low and comparable to other reports [16].

As for coronary interventions, a multicenter study in the pre-stenting era comparing complications of PCI in the years 1986–87

and 1991 documented a decreased incidence of emergency coronary artery bypass graft surgery from 5.5% to 1% with no change in mortality (1% and 1% respectively) [14]. These results were attributed mainly to two factors: a) operator's skill with a high individual volume of procedures, and b) changing characteristics of diagnostic and therapeutic equipment. In our laboratory the most experienced operators performed nearly 60% of the diagnostic and 80% of the therapeutic procedures. These operators had previous experience in therapeutic procedures prior to starting our invasive program, thus the learning curve limitation was eliminated. The learning process should therefore be completed in a hospital with cardiac surgery. Downsizing of the diagnostic catheter diameter from 7 and 8 French to 5 and 6 French, shifting from hard to soft-tip diagnostic catheters, and gradual decrease in the use of high osmolar contrast agents improved the safety of the procedures. It is only reasonable to assume that a combination of all the above-mentioned factors contributed to the low rate of complications in our diagnostic and therapeutic procedures.

Treatment of abrupt vessel closure and coronary dissections in phase 3, i.e., our initial experience with balloon angioplasty, was limited to either repeated low pressure balloon inflation or perfusion balloons. The introduction of coronary stents to the interventional armamentarium has undoubtedly revolutionized coronary therapeutic interventions, mainly affecting the management of acute vessel closure and reducing the need for urgent coronary artery bypass graft [17,18]. The use of coronary stents is one of the main reasons for the rapid universal increase in diagnostic and therapeutic cardiac procedures [19]. A recent report analyzing the outcome of PCI from 1990 to 1997 noted a dramatic decline in the need for urgent CABG from 2.3% to 1.3% and attributed it to the availability of stents [20]. The use of glycoprotein IIb/IIIa inhibitors has also been reported to be effective in reducing the incidence of acute ischemic complications during and after PCI [21,22]. Our data comparing PCIs in 1995 and in 2000, as presented in Table 1, confirm and strengthen these observations. In the last 5 years, none of our patients died during PCI in our catheterization laboratory using both stents and aggressive antiplatelet agents.

The declining rates of the need for urgent cardiac surgery and the decrease in major complications and mortality occur despite a significant change in the characteristics of treated patients. Whereas most of our patients in phase 3 had stable angina pectoris [Table 1], we currently treat higher risk patients with acute coronary syndromes, multivessel CAD, severely reduced left ventricular function, saphenous vein graft stenoses, as well as an increasing numbers of elderly patients and octogenarians. This is in accordance with a universal trend and common practice of treating higher risk patients without having an on-site surgical backup and with a low complication rate [2,23,24]. Yet, the recently published American guidelines and expert consensus documents for the operation of cardiac catheterization laboratories without an on-site surgical backup still suggest excluding intermediate and high risk patients from any diagnostic or invasive procedures [5,6]. Some of their suggested exclusion criteria include age >75, intermediate or high risk acute coronary syndrome patients, recent MI with post-MI angina, ischemic pulmonary edema, class III or IV heart failure, severe valvular dysfunction, especially with reduced left ventricular function, all valvuloplasty procedures, and any elective coronary intervention.

Our hospital is located 50 km from a cardiothoracic surgical department, and the mean transfer time is 47 minutes. Even when transferring a patient from the catheterization laboratory to surgery in the same hospital there is some delay. If procedures performed routinely in the hospital depended on surgical backup, it would be impossible to keep the operating room and surgical team on standby all the time while therapeutic procedures are being performed. Usually, during the working hours of the catheterization laboratory, the operating room is busy and a patient who needs surgery waits while the operating room is being prepared. Therefore, if there is only a small time difference between transferring a patient from one hospital to another or between departments within the same hospital, a discussion regarding the need for on-site surgical backup has no clinical relevance. It would probably be relevant for peripheral hospitals, where the transfer time is significantly longer than within the same hospital that has a cardiac surgery department.

A potential limitation of our study was the small number of patients undergoing primary PCI as an initial treatment for acute myocardial infarction. More data, preferably from multicenter randomized studies, are still needed to reach any conclusions regarding the routine use of primary PCI in hospitals without surgical backup. Recent data, however, suggest that this approach is safe without an increase in mortality or need for urgent cardiac surgery [23,24].

We conclude that in the current era, the use of coronary stents and potent antithrombotic drugs has significantly increased the safety margins of activities of the catheterization laboratory. After gaining experience and crossing the learning curve limits, complex and high risk cardiac therapeutic interventions can safely be performed in centers without on-site surgical backup where the transfer time to cardiac surgery is not significantly longer than within a hospital that performs cardiac surgery.

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What the detective story is about is not murder but the restoration of order

P.D. James (1920-), British author often described as the "Queen of crime." Her experience as a nurse and as a civil servant in the police and Home Office provided useful background for her chilling detective novels.

Capsule

Music in the brain

Is there a correlation between the formal geometric representation of tonal music and the brain activity in a listener trying to detect a wrong note in a melody? In a functional magnetic resonance imaging study, Janata et al. found consistent activity within the rostromedial area of prefrontal cortex across different listening sessions. Representations of tonality were structured within sessions with different subregions representing different parts of the tonality surface, but this structure varied across sessions and subjects. This dynamic organization might reflect the relative nature of musical structure, and its representation in the rostromedial prefrontal cortex in a given session may be influenced by interactions between short- as well as long-term memory.

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