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## Percutaneous Transluminal Coronary Angioplasty: 13.5 Years of Follow-up

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PTCA was introduced into Queen Alia Heart Institute (QAHI), Jordan, in April 1985. The objective of the study is to report the Jordanian experience with the procedure as regards success rates, clinical outcomes, and factors associated with survival following the procedure.

All Jordanian patients who underwent PTCA at QAHI during the period April 1985 through December 1993, a total of 752 subjects, were followed-up to November 1<sup>st</sup>, 1998. Baseline demographic, angiographic, and clinical data were obtained from the medical records. Follow-up data were obtained from medical records as well as by telephone interviews. The Statistical Package for Social Sciences (SPSS) was used for data analysis. The Cox proportional hazard model was used to identify factors independently related to survival.

Angiographic and clinical success rates were 91.5 % and 86.5 % respectively. Procedural complications occurred in 18.5 % of the subjects. There were 7 in-hospital deaths, emergency coronary artery bypass grafting (CABG) was performed for 23 patients and non-fatal myocardial infarction (MI) occurred in 53 patients before discharge from the hospital. Overall, cardiac, and event-free survival probabilities 13.5 years after PTCA were 73.6 %, 77.0 % and zero respectively. Age < 45 years and left ventricular ejection fraction (LEVF)  $\geq$  40 % were predictive of a better overall and cardiac survival. Female gender was associated with a better cardiac but not overall survival.

About three fourths of PTCA-treated patients survived 13.5 years after the procedure. However, none survived event-free beyond 13.5 years. *J Clin Basic Cardiol* 2001; 4: 285–8.

**Key words:** angioplasty, Jordan, PTCA, restenosis, survival

Cardiovascular diseases are the leading cause of death in developed as well as in many developing countries including Jordan [1]. Coronary artery disease (CAD) accounts for one third of all cardiovascular diseases in developing countries [2]. In 1977, PTCA was introduced by Gruentzig as a non-surgical method of coronary revascularization [3]. Shortly thereafter, PTCA rapidly became an established therapeutic option for selected patients with coronary artery disease. In Jordan, the procedure has been practiced since 1985 in QAHI at King Hussain Medical Center. In the present study, we report our experience with PTCA focusing on prognosis during a 13.5-year follow-up period.

### Methodology

#### Study population

All Jordanians who underwent PTCA at QAHI during the period April 1985 through December 1993, a total of 752 patients, were included in the study.

#### Baseline data

For each patient, the medical record was carefully scrutinized and abstracted on a special form specifically designed for the purpose of this study. Data obtained included age, sex, CAD risk factors, duration of symptoms prior to PTCA, functional class of angina, history of MI, presence of congestive heart failure, extent of CAD, degree of stenosis, LVEF, procedural outcome, and complications.

#### Follow-up data

Patients were followed up to November 1<sup>st</sup>, 1998. Information was obtained from medical records as well as by telephone interviews with the patients. Complete follow-up in-

formation up to November 1<sup>st</sup>, 1998 was possible on 669 patients. For the remainder (83 patients) follow-up information were available for differing time periods after which they were considered as lost to follow-up. Comparison of those losses to follow-up with the patients who remained under observation showed no differences in baseline demographic and clinical characteristics.

#### Operational definitions

*Angiographically successful PTCA:* Reduction of stenosis by at least 20 % with residual narrowing < 50 % [4].

*Clinically successful PTCA:* Angiographic success with no death, MI, or CABG.

*Restenosis:* Loss of > 50 % of the previous gain in the luminal diameter with a final stenosis > 50 % [5].

*Overall survival:* Not dying from any cause during the follow-up period.

*Cardiac survival:* Not dying from cardiac causes during the follow-up period.

*Event free survival:* Survival with no angina, MI, CABG, or re-PTCA.

#### Data analysis

Data analysis was carried out using the Statistical Package for Social Sciences (SPSS-PC) software. Descriptive statistics were obtained for relevant study variables. The actuarial life table method was performed for three long-term outcomes, namely, overall, cardiac, and event-free survival probabilities. The method was performed for all PTCA-treated patients (whether PTCA was successful or not) and also for patients with successful PTCA only. The Cox proportional hazard model was used to assess the association between a variable and an outcome after adjustment for confounders.

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## Results

A total of 752 patients underwent PTCA during the period April 1985 through December 1993. The follow-up period ranged from 0–14 years with a mean of 7.3 years. Table 1 shows selected demographic and clinical characteristics of these patients. The mean age was 52 years with approximately 73 % of the patients 45–64 years of age. Over 88 % were males. The majority were current smokers (63.8 %). The prevalence of hypertension and diabetes mellitus were 28.1 % and 28.3 % respectively. Over half of the patients gave history of MI while 13.3 % had congestive heart failure.

The total number of stenosed vessels was 1105. The left anterior descending artery was most commonly involved (53.3 %) followed by the right coronary (23.5 %).

### PTCA success rate

The overall angiographic success rate was 91.5 % and the overall clinical success rate was 86.5 %. Angiographic success varied from 90.4 % for the right coronary to 100 % for the diagonal arteries and from 72.5 % for patients with multiple vessel disease to 92.9 % for patients with single vessel disease ( $P < 0.0001$ ) (Table 2).

### Procedural complications

Complications during the procedure occurred in 139 patients (18.5 %) with some patients developing more than one complication (a total of 184 complications). The types and frequency of these complications are shown in Table 3. The most common complication was coronary dissection followed by coronary spasm.

**Table 1.** Baseline characteristics of Jordanian patients who underwent PTCA at Queen Alia Heart Institute, 1985–1993

Characteristic	n	%
<b>Total</b>	<b>752</b>	<b>100</b>
<b>Age (Y)</b>		
< 45	142	18.9
45–64	548	72.9
> 65	62	8.2
<b>Gender</b>		
Men	667	88.7
Women	85	11.3
<b>Smoking</b>		
Current	480	63.8
Ex-smokers	110	14.6
Never	162	21.5
<b>Family history of CAD</b>	307	40.8
<b>Hypertension</b>	211	28.1
<b>Diabetes mellitus</b>	213	28.3
<b>Previous MI</b>	385	51.2
<b>Congestive heart failure</b>	100	13.3
<b>Obesity (BMI &gt; 30 kg/m<sup>2</sup>)</b>	59	7.8
<b>Duration of symptoms before PTCA (months)</b>		
< 1	342	45.5
1–6	242	32.1
7–12	37	4.9
> 12	117	15.6
Asymptomatic	14	1.9
<b>Type of chest pain</b>		
Stable angina	381	50.7
Unstable angina	298	39.6
Atypical chest pain	59	7.8
Asymptomatic	14	1.9
<b>Left ventricular ejection fraction</b>		
> 40 %	645	85.8
≤ 40 %	107	14.2
<b>Timing of PTCA</b>		
Elective	639	85.0
Immediate	113	15.0

### Immediate outcomes

Immediate outcomes refer to events occurring during or after the PTCA procedure but before discharge from hospital. There were 7 in-hospital deaths (0.9 %). Emergency CABG was performed for 23 patients (3.1 %) and non-fatal MI occurred in 53 patients (7 %).

### Long-term prognosis

In addition to the 7 immediate in-hospital deaths, a total of 105 patients died during the follow-up period (13.9 %), of whom 21 died of non-cardiac causes. More than half of the patients reported recurrence of angina – 144 within 6 months after PTCA. Re-stenosis was diagnosed in 60 % of the 510 patients who received a follow-up angiography, 120 within 6 months after the procedure. Late MI occurred in 12.6 % of the patients most of them within 6 months of the procedure. Over 13 % of the subjects underwent elective CABG, most of them within 6 months after PTCA. Re-PTCA was performed in 12.9 % of the patients (Table 4).

### Survival analysis

The cumulative probability of overall survival 13.5 years after PTCA was 73.6 %, and the cumulative probability of cardiac survival was 77.0 %. Event-free survival 13.5 years after PTCA was zero with a median of 9.4 years (Figure 1).

### Factors related to overall and cardiac survival

Of the different demographic, clinical and angiographic characteristics assessed, age and left ventricular ejection fraction were independently and significantly related both to overall and cardiac survival after PTCA (Tables 5 and 6). Patients aged ≥ 65 years and those with LVEF < 40 % were respectively 5.7 and 2.9 times more likely to die after PTCA compared to patients aged < 45 years and those with LVEF > 40 % (Table 5). As regards death from cardiac causes, the corresponding relative risks were 7.2 and 2.2 (Table 6). Females were less likely to die from cardiac causes (RR = 0.51,  $P < 0.05$ ) but were similar to males in overall survival.

### Note

The above reported analyses were based on all patients who underwent PTCA whether successful or not. The same analyses were repeated for patients who underwent a suc-

**Table 2.** Angiographic success among patients with single and multiple vessel disease

Type of disease	n	Angiographic success (%)
<b>Single vessel</b>	701	92.9
<b>Multiple vessel</b>	51	72.5
<b>Total</b>	752	91.5

$p < 0.0001$

**Table 3.** Procedural complications among the study population

Complication	n	% of all patients
Coronary dissection	47	6.3
Coronary spasm	32	4.3
Arrhythmias	28	3.7
Coronary thrombus	26	3.5
Bleeding	15	2.0
Coronary aneurysm	10	1.3
Shock	8	1.1
Cardiac tamponade	4	0.5
Others	14	1.9

Note: Some patients developed more than one complication.

cessful PTCA. Results were very close. For example, the 13.5 year cumulative overall, cardiac, and event-free survival probabilities were 73.6 %, 77.1 %, and 0 respectively.

### Discussion

The present report is an attempt to summarize the Jordanian experience with PTCA with emphasis on prognosis starting from the procedure and up to 13.5 years of follow-up.

The outcomes of PTCA depend on many factors including patient selection, the time period in which the procedure was carried out, and the technical skills. The selection criteria used in Jordan are not different from others and the procedure was carried out in a well-equipped center (QAHI) by western-trained physicians. The study included all Jordanian patients who underwent PTCA during the period 1985 through 1993. Those patients were followed up to November 1st, 1998. Results of the study are generally consistent with most of the published literature as regards the short- and long-term outcomes. Reported angiographic success rates ranged from as low as 59 % [6] in the early days the procedure was practiced during the late 1970s to as high as 100 % [7] during the 1990s with most of the studies reporting success rates between 85 % and 95 % [8–15]. Considering the time period in which the procedure was performed, our figure (91.5 %) compares favorably with many of these studies. Similar to previous reports [16, 17], angiographic success in this study was better among patients with single vessel than among patients with multivessel disease ( $p < 0.05$ ).

Complications during the procedure necessitating urgent CABG occurred in 3.1 % of the subjects. Nonfatal MI and death occurred in 7 % and 0.9 % respectively. These results are consistent with a number of previous studies [18–20].

Restenosis after PTCA remains a major common problem. It has been reported that restenosis occurs within 6 months of the procedure in the majority of the patients [21].

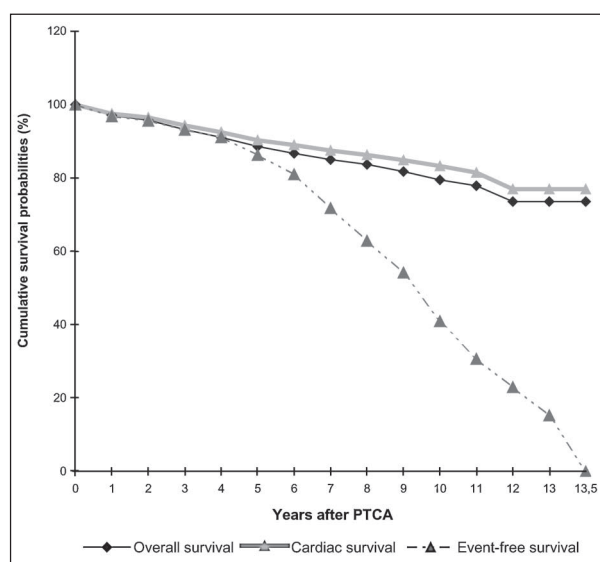
**Table 4.** Long-term outcomes after PTCA

Outcome	n	%
<b>Late deaths</b>		
Cardiac	84	11.1
Non-cardiac	21	2.8
<b>Total</b>	<b>105</b>	<b>13.9</b>
<b>Recurrence of angina</b>		
Within 6 months	144	19.1
After 6 months	239	31.8
<b>Total</b>	<b>383</b>	<b>50.9</b>
<b>Restenosis*</b>		
Within 6 months	120	23.5
After 6 months	186	36.5
<b>Total</b>	<b>306</b>	<b>60.0</b>
<b>Late myocardial infarction</b>		
Within 6 months	17	2.3
After 6 months	78	10.3
<b>Total</b>	<b>95</b>	<b>12.6</b>
<b>Elective CABG</b>		
Within 6 months	17	2.3
After 6 months	85	11.3
<b>Total</b>	<b>102</b>	<b>13.6</b>
<b>Re-PTCA</b>		
Within 6 months	43	5.7
After 6 months	54	7.2
<b>Total</b>	<b>97</b>	<b>12.9</b>

\*: Restenosis among 510 patients who received a follow-up angiography

In the present study, about 61 % (186/306) of the patients developing restenosis did so 6 months after the procedure. This may be explained by the prolonged period of follow-up for our patients (13.5 years). Intracoronary stents may reduce the risk of restenosis although long-term follow-up is currently unavailable.

The present study provides a relatively very long period of follow-up and thus contributes to the understanding of the long-term clinical outcomes of PTCA. About three fourths of our patients were still alive 13.5 years after the procedure. A number of studies have reported survival probabilities at 5 and 10 years of follow-up [17, 18, 22–26]. The 5-year survival was generally 90–98 % and the 10-year survival was around 80 %. Our data showed 88.6 % and 79.5 % survival at 5 and 10 years respectively. Survival of our patients, however, showed a steeper decline thereafter to reach 73.6 % after 13.5 years of follow-up which may reflect an aging effect. As re-



**Figure 1.** Overall, cardiac, and event-free survival following PTCA

**Table 5.** Factors related to overall survival following PTCA using Cox proportional hazard regression.

Factor	Adjusted relative risk	P-value
<b>Age (years)</b>		
< 45	1.0	
45–64	1.1	
≥ 65	5.7	< 0.0001
<b>Left ventricular ejection fraction</b>		
≥ 40 %	1.0	
< 40 %	2.9	< 0.0001

**Table 6.** Factors related to cardiac survival following PTCA using Cox proportional hazard regression.

Factor	Adjusted relative risk	P-value
<b>Age (years)</b>		
< 45	1.0	
45–64	1.4	
≥ 65	7.2	< 0.0001
<b>Left ventricular ejection fraction</b>		
≥ 40 %	1.0	
< 40 %	2.2	< 0.0001
<b>Sex</b>		
Males	1.0	
Females	0.51	< 0.05

gards cardiac survival, our data are consistent with previous reports [19, 27].

The event-free survival observed in this study at 5 and 10 years following PTCA was 86.3 and 41.0 % respectively, which is generally lower than reported by others [22, 28]. Event-free survival declined rapidly thereafter to reach the zero point at 13.5 years of follow-up.

The present study identified age < 45 years, and LVEF  $\geq$  40 % as factors predicting better overall and cardiac survival while female gender was associated with a better cardiac survival. These findings are consistent with previous reports [20, 29–30].

An important assumption for actuarial life table analysis is that those lost to follow have the same fate as those remaining under observation. In the present study, 83 patients were lost to follow-up after being under observation for different time periods after PTCA. Comparison of those patients with those who remained under observation showed no difference in baseline demographic, angiographic and clinical profile. The likely reasons for loss to follow-up are change in address and change in the center from which they receive follow-up care. QAHI was the only center providing PTCA services in Jordan till the mid 1990s and it is currently overloaded. Therefore, some patients may have shifted to the several newly established centers for follow-up care.

In conclusion, findings of the present study support previous reports of a good survival after PTCA although all patients are likely to have had an event (death, CABG, MI, or re-PTCA) within 14 years after the procedure.

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