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Outcome of percutaneous coronary intervention in hospitals with and without on-site cardiac surgery standby

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Objective: To compare characteristics and outcome of patients undergoing percutaneous coronary intervention (PCI) in clinics with (WSB) or without (NOSB) on-site cardiac surgery backup.

Design: Analysis according to hospital, type of prospectively collected data of all patients who underwent PCI during 2000–3.

Setting: The Swedish Coronary Angiography and Angioplasty Registry covers all PCI procedures performed in Sweden.

Patients: 34 363 patients underwent PCI between January 2000 and December 2003. 8838 procedures were performed in NOSB (mean age of patients was 64.5 years) hospitals and 25 525 in WSB (mean age of patients was 64.1 years) hospitals ($p=0.002$).

Results: More patients in NOSB hospitals had diabetes (17.8% vs 16.8%; $p=0.03$). Other clinical characteristics (previous infarct, previous coronary artery bypass graft (CABG)) also showed a tendency towards worse patients being treated in NOSB hospitals. However, there was a higher percentage of patients with ST-segment elevation myocardial infarction (18% vs 9.7%; $p<0.01$) in WSB hospitals. After adjusting for differences in baseline risk no significant differences regarding outcome (30-day mortality, 1-year mortality, stroke and emergency CABG) were observable between WSB and NOSB hospitals. This applied to elective and non-elective procedures.

Conclusions: On the basis of these data it does not seem warranted to recommend against percutaneous transluminal coronary angioplasty in NOSB hospitals.

Since its introduction in 1977 by Grüntzig,¹ percutaneous transluminal coronary angioplasty (PTCA) has become a mainstay in the treatment of coronary artery disease. Around 2 000 000 percutaneous coronary interventions (PCI) are being performed every year worldwide with a steady increase.² The most serious risks of PTCA are death, myocardial infarction and emergency coronary artery bypass graft (CABG) surgery. All risks including that of emergency CABG have been dramatically reduced since the early years of PTCA through the introduction of stents and development of pharmacotherapy—namely, the introduction of glycoprotein inhibitors.^{3–7} To assure a high standard and maximum safety of the procedure, guidelines for PTCA have been published, including the US,² UK⁷ and Europe.⁸ Among the most debated issues in this context is the question of on-site surgical standby or backup.^{7–19} The latest American College of Cardiology/American Heart Association/Society of Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) guidelines² recommend that elective PTCA should not be performed in facilities without on-site cardiac surgery backup (NOSB). On the other hand, the European guidelines do not even mention the issue.⁸ The most sophisticated discussion can be found in the British guidelines that require an “adequate provision for cardiac surgery” whether that is on-site or off-site.⁷

The database for clear “Yes” or “No” recommendations is more than sparse. There are, of course, no randomised trials investigating the need of an on-site surgery facility. The necessity of surgical backup is based on published numbers of acute CABG after failed PTCA³ and observational data and single centre experiences of varying quality.^{20–24} Primary PCI in patients with ST-segment elevation myocardial infarction (STEMI) is a different topic and is considered acceptable by some NOSB hospitals if certain standards are met,^{20–25} and the updated ACC/AHA/SCAI practice guidelines qualify primary PCI

for STEMI without on-site cardiac surgery facility to be a class IIb indication.²

The following data comparing the outcome of PTCA with (WSB) and without on-site cardiac surgery backup (NOSB) stem from the Swedish Coronary Angiography and Angioplasty Registry (SCAAR) that registers all invasive cardiology procedures in Sweden.

METHODS

The SCAAR consists of patients from all centres performing PCIs and/or coronary angiography in Sweden. During the existence of the registry there has been an ongoing process with improvement of the database with a successive modification of used variables and in the numbers of participating hospitals. Since 2001, SCAAR has been based on the internet and the recording of data was performed online via a web interface in the catheterisation laboratory, with the exception of data regarding late-occurring complications. These data were collected later during the hospitalisation, for input into the database via the web interface from the coronary care ward or from the catheterisation laboratory. For security reasons, all patient data that were sent over the internet were prepared with a 124 bits crypto. Definitions and specifications of the used parameters were provided by the website.

Vital status of the patients could be followed up to 31 December 2004 by combining SCAAR and the Swedish National Population Register. The combination of the two registers was done in cooperation with the Swedish National

Abbreviations: ACC, American College of Cardiology; AHA, American Heart Association; CABG, coronary artery bypass graft; NOSB, without on-site cardiac surgery backup; PCI, percutaneous coronary intervention; PTCA, percutaneous transluminal coronary angioplasty; SCAAR, Swedish Coronary Angiography and Angioplasty Registry; STEMI, ST-segment elevation myocardial infarction; WSB, with on-site cardiac surgery backup

Table 1 Baseline characteristics of patients

On-site surgical backup	Yes	No	p Value
n	25 525	8838	–
Mean procedure volume/year	812	307	<0.001
Age (years)	64.1	64.5	0.002
Female (%)	28.8	29.3	NS
History of MI (%)	37.7	39.7	<0.001
Current smoker (%)	20.6	18.7	<0.001
History of CABG (%)	9.2	9.5	<0.001
Diabetes mellitus (%)	16.8	17.8	<0.03
Hypertension (%)	38.0	41.4	<0.001
Hyperlipoproteinaemia (%)	41.5	48.9	<0.001
Extent of CAD (%)			
1 vessel	47.5	48.0	NS
2 vessel	31.1	29.5	NS
3 vessel	16.9	17.0	NS
Left main stem	3.3	3.0	NS

CABG, coronary artery bypass graft; CAD, coronary artery disease; MI, myocardial infarction; NS, not significant.

Board of Health and Welfare and approved by the local ethics committee at the University of Uppsala. The study complied with the Declaration of Helsinki.

An unpaired *t* test was used for continuous variables and the Pearson χ^2 test for categorical data to test the difference between patient groups. Multivariable logistic regression analyses were performed to evaluate the effect of hospital type (WSB vs NOSB) on the complication rate during the coronary procedures. In the model the following clinical background variables were entered: age, sex, previous CABG, diabetes, previous myocardial infarction, extent of coronary artery disease and indication for the procedure. A logistic regression model was used, with the same covariates, to analyse the effect of the hospital type on mortality. In addition, the volume of PCI procedures per centre was entered into the model. In patients with multiple PCIs during the studied time period, only the first one was included in the analysis. $p < 0.05$ was considered significant in all tests. The data processing and statistical analyses were performed by using the SPSS V.11.5.1 statistical program for personal computers.

RESULTS

Between January 2000 and December 2003, a total of 34 363 procedures were registered on an intention-to-treat basis; 10 WSB hospitals performed 25 525 procedures and 14 NOSB hospitals performed 8838 procedures. The 10 WSB hospitals had 300–2000 (mean 812) procedures per year and the 14 NOSB hospitals had 100–800 (mean 307) procedures per year. Information about operator caseload is not provided.

Table 1 gives the baseline features of the patients.

Compared with WSB hospitals, the patients in NOSB clinics were older, and more often had a history of myocardial

infarction and CABG. Diabetes, hypertension and hyperlipoproteinaemia were also considerably more prevalent in the group of patients treated in NOSB hospitals compared with WSB clinics.

However, PTCA was more often performed on patients for acute myocardial infarction (STEMI) in WSB hospitals compared with NOSB clinics (table 2).

The angiographic extent of coronary artery disease was comparable in the two types of clinics when looking at the percentages of 1-vessel, 2-vessel and 3-vessel diseases. Stent implantation was used in 86.4% (WSB) and 85.4% (NOSB) of procedures ($p = 0.017$).

The total unadjusted 30-day mortality after PTCA of all types was 2.2% in WSB hospitals and 1.4% in NOSB hospitals ($p < 0.001$). Table 3 gives the other unadjusted complication rates; with the exception of acute CABG no significant differences were found.

A multivariate analysis showed that neither hospital type (NOSB vs WSB) nor centre volume was a predictor of 30-day mortality ($p = 0.18$) in contrast to age, diabetes, acute coronary syndrome and a history of myocardial infarction (all $p < 0.001$; fig 1).

The unadjusted long-term mortality is illustrated in fig 2.

The 44 patients with an emergency CABG (table 3) in connection with the angioplasty had a high mortality, nine died within 30 days (20.5%), compared with 1.9% in those without emergency CABG. One of the four NOSB patients (25%) died after emergency CABG compared with eight of 40 WSB patients (20%; $p = ns$).

DISCUSSION

The debate whether or not on-site cardiac surgery backup is necessary for PTCA is as old as the procedure itself.^{7–9,19} The most recent addition to this discussion was provided by the New Jersey Health Commissioner's decision to permit nine NOSB hospitals to perform elective PTCA, a decision that led to a heated debate in the US.²⁶ The present study should be viewed in this context and can hopefully be seen as an increase in clinical data as requested in the ACC/AHA/SCAI 2005 guideline update for PCI.²

The presented data of contemporary practice could not show significant differences with respect to adjusted outcome variables between WSB and NOSB hospitals. This was true for both elective and emergency PTCA. Together with this set of data, there are only four large direct investigations into the issue of surgical backup using comparison of hospitals with current medical practice,^{13–15,16} two of which are published so far only in abstract form.^{15,16} Other evidence comes from single hospital reports with the general message that it is feasible to perform PTCA without backup under certain clinical circumstances.^{20–24} Another approach in the discussion is to look at the incidences of emergency CABG after failed PTCA.^{3,7}

Emergency bypass surgery after failed PTCA was not uncommon with rates of 10–25% in the early 1980s, decreasing to 2–5% in the late 1980s and decreasing further to <1% in the late 1990s.¹² Complications of PTCA like coronary dissection, acute recoil, coronary perforation and coronary thrombosis could often only be managed by acute CABG. Since the early 1990s, with improvements in procedural success due to stents and newer pharmacological strategies, there has been a reduction in complications and the need for emergency CABG became a rare event, with current rates as low as 0.1–0.2% in this study to 0.3%³ or 0.7%⁷ in other investigations. However, emergency CABG for failed PTCA comes with a high mortality rate of up to 14%^{3,16} in the literature and 20.5% in our material. This is true for both on-site and off-site surgery without well-documented difference between the two. Theoretically, and

Table 2 Lesion and procedure details

On-site backup	Yes	No	p Value
Number of dilated vessels (%)			
Two or more	16.3	14.4	<0.001
Dilatation of venous graft (%)	2.9	2.9	NS
Indication (%)			
Elective, stable angina	29.2	38.4	<0.001
Unstable angina/NSTEMI	47.3	47.2	NS
Elective, other	5.5	4.7	NS
STEMI	18.0	9.7	<0.001
Stent implantation (%)	86.4	85.4	0.017

NS, not significant; NSTEMI, non-ST-segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction.

Table 3 Outcome and complications (non-adjusted)

On-site backup	Yes	No	p Value
30-day mortality, all patients (%)	2.2	1.4	<0.001
30-day mortality, STEMI (%)	6.7	7.0	NS
30-day mortality, UA/NSTEMI (%)	1.0	1.2	NS
30-day mortality, stable patients (%)	0.2	0.4	NS
TIA/stroke (%)	0.3	0.4	0.09
Emergency CABG (%)	0.2	0.1	0.025

CABG, coronary artery bypass graft; NS, not significant; NSTEMI, non-ST-segment elevation myocardial infarction; STEMI, ST-segment elevation myocardial infarction; TIA, transient ischaemic attack; UA, unstable angina.

with the assumption that the mortality of off-site CABG is 100% higher than for on-site CABG, the excess rate of death would be 1.5/10 000 procedures. This number would then to be counterbalanced with the number of deaths due to longer waiting times and transportation for PTCA if this procedure would be limited to facilities with on-site surgery. However, Kutcher *et al*¹⁶ reported a mortality rate of 9% in emergency CABG in on-site surgery compared with 0% in off-site surgery. In the presented data no significant difference was found in mortality rates of emergency CABG between WSB and NOSB hospitals. Although this discussion is theoretical, is based on very low frequencies and numbers, and data are insufficient to come to conclusions, the direct comparison of clinics promises to provide more accurate and relevant information. Moreover, as the UK guidelines point out, there is no clear evidence that WSB centres will necessarily have the patient on bypass any quicker than the NOSB centres.⁷ The UK guidelines therefore recommend that such an emergency patient should be on cardiopulmonary bypass within 90 min of referral whether or not the backup is on-site.⁷

To our knowledge, there are only three previous reports that directly compare outcomes in WSB and NOSB clinics.^{13–16} Two have the disadvantage of being published so far only as abstracts,^{15–16} the published third one comes with the limitation that the clinics compared were essentially uncomparable because of the large volume differences.¹³ The third study looked at Medicare patients who underwent PCI during 1999–2001 in WSB and NOSB hospitals. The authors found that the overall odds ratio of death for patients in NOSB hospitals was 29% higher than for patients having PCI in WSB hospitals. After adjusting for different risk factors, this difference was not significant for primary/rescue PCI, but was highly significant for the non-primary/rescue population.¹³ The most serious problem with that study was the large differences in PCI volume between the two hospital types. Although 178 NOSB hospitals performed 8168 procedures, 943 WSB clinics performed 617 686 PCI; >50% of the NOSB hospitals had a volume of <11 Medicare PCI per year and only 19.4% of patients had been treated at hospitals with a volume of >102 Medicare procedures per year.¹³

From that publication it is impossible to differentiate the issue of volume^{27–28} from the question of backup. The increase in mortality was therefore also primarily confined to hospitals performing ≤50 Medicare PCI per year.¹³

After adjusting for underlying risk, neither the present study nor the other two pertinent studies^{15–16} could find a difference in outcome between procedures performed in WSB hospitals compared with NOSB hospitals. This study, although smaller than that of Wennberg *et al*,¹³ has none of the disadvantages of that study. It is not limited to patients who were aged ≥65 years, and the differences in PCI volumes between WSB hospitals and NOSB hospitals are smaller; with a current rate of 0.1% versus 0.2%, respectively, emergency CABG after PCI it also is highly unlikely that centres with a high volume and

30 day mortality

Patient group	Odds ratio and 95% CI	p Value
NOSB vs WSB	0.682 to 1.073	0.18
Age	1.045 to 1.064	<0.001
No diabetes vs diabetes	0.386 to 0.877	<0.001
Stable angina vs ACS	0.396 to 0.696	<0.001
Previous infarct vs no infarct	1.073 to 1.463	<0.001

Figure 1 In-hospital mortality and non-deadly complications (myocardial infarction, stroke/transient ischaemic attack) after percutaneous transluminal coronary angioplasty (PTCA) in hospitals with versus without on-site cardiac surgery backup. ORs (95% CIs) are adjusted for age, sex, diabetes, kidney failure and previous myocardial infarction. A-PTCA, acute PTCA in cases of non-ST-segment elevation myocardial infarction (STEMI) and STEMI; E-PTCA, elective PTCA in stable patients. ACS, acute coronary syndrome; NOSB, without on-site cardiac surgery backup; WSB, with on-site cardiac surgery backup.

grade of proficiency should show mortality differences just on the basis of having or not having on-site surgery backup. If it is indeed so that the literature and guidelines have used “on-site cardiac surgical capabilities as a surrogate for angioplasty centers where large volumes of procedures are performed by experienced operators ...”,¹⁴ then one should stop talking about backup and concentrate on volume issues. However, newer data²⁸ even cast doubt on the operator volume–outcome relationship that might no longer be as important as in the earlier days²⁷ of the PTCA procedure. Although it remains as a trend, efforts should be made to enforce the volume requirements of the guidelines^{2–7–8} and not the backup issue that has a questionable contemporary data basis. With the relatively small volume differences between Swedish PCI centres compared with US practice, it was not possible to show PCI centre volume as a predictor of outcome.

Limitations

Several limitations of this study need to be mentioned. All adjustment for different baseline risks is not as good as a randomised study. An underlying bias in the way patients or doctors chose a clinic with or without on-site surgical backup could not totally be excluded. However, the geographical particularities and the very low population density make it unlikely for a patient to travel hundreds of miles for PCI at a different centre than the nearest one. Moreover, the structure

Figure 2 Kaplan–Meier curve illustrating long-term mortality after percutaneous coronary intervention with on-site cardiac surgery backup (dotted line; n=8835) and without on-site cardiac surgery backup (full line; n=25 519).

of the Swedish health system essentially does not permit patients to choose a hospital. The gold standard would be a randomised study with the question of backup. Such a study has not been performed yet, and it is questionable whether it will ever be performed. In this light, the available database is as good as it gets.

Another possible shortcoming is the question of applicability of the Swedish data to other countries. The existence of very-low-volume centres in the US (<30 procedures/year) in contrast to Sweden, the UK, Germany and other European countries poses a problem in the discussion. However, one should not confuse the issue of volume with that of backup although it seems, at least in the US, to be indirectly related.¹⁴

CONCLUSIONS

On the basis of the presented data it does not seem warranted to recommend against PTCA in NOSB hospitals. Further research should try to differentiate the issue of volume and backup and should focus on risk characteristics of those patients who end up needing emergency CABG after PTCA.^{29 30}

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