Neth Heart J (2013) 21:446–448
DOI 10.1007/s12471-013-0464-1

EDITORIAL COMMENT

Percutaneous coronary intervention without surgery on-site is here to stay

R. J. de Winter

Published online: 8 August 2013

The need for emergency cardiac bypass surgery due to a complication occurring during a PCI procedure has gone down from an initial 6–10 % in the early 1980s to less than 0.5 % in the present era [1]. Technological advances have made the procedure very safe in the hands of experienced operators working in dedicated centres. In Europe in the last decade, many PCI programs without surgery on-site have been started as a consequence of this rare need for actual surgical back-up. In addition, these PCI programs were started in (mostly rural) regions where travel distances to PCI centres with surgery on-site resulted in long delays for STEMI patients undergoing primary PCI. The safety and long-term efficacy outcome of PCI programs in centres without surgery on-site have been shown in registries and large randomised studies. Just recently, the MASS COMM investigators demonstrated in a large randomised trial including 3691 patients that there was no difference in the incidence of MACE at 30 days (9.5 % vs 9.4 %; RR 1.00; $P<0.001$ for non-inferiority) and at 12 months (17.3 % vs 17.8 %; RR 0.98; $P<0.001$ for non-inferiority) [2]. These data confirm and extend the results from the CPORT study published in 2012, which randomised 18,867 patients and showed no difference in 6-week mortality and no difference in MACE at 9 months (12.1 % vs 11.2 %; $P=0.05$) [3]. Both these studies excluded patients undergoing urgent PCI procedures for STEMI and NSTEMI. Reports using non-randomised data from the NRMI database by Pride et al., which included 58,821 STEMI patients and more than 100,000 NSTEMI patients treated either in centres with or without surgery on-site confirmed that the safety (e.g., as assessed on the basis of short-term mortality and need for emergency surgery) and efficacy (e.g., procedural success and longer-term rate of survival) of such PCI procedures was similar [4, 5].

Following these developments, the Dutch Guidelines for Interventional Cardiology 2004 included recommendations for centres and operators that provide PCI without surgery on-site regarding facilities, staffing, training requirements etc [6]. The minimum number of procedures per centre and per operator are required in order to ensure proficiency, experience and continued quality of care. Moreover, structural relations with a surgical centre and protocols for emergency transfer should be present. In order to provide primary PCI for patients with STEMI, a 24–7 service is required and finally, centres are obliged to prospectively register procedures and outcomes and submit these data to the Dutch Society of Cardiology.

In this issue of the Netherlands Heart Journal, the experience of the first year of PCI procedures of the Venlo Percutaneous Coronary Intervention Program at VieCurie Medical Centre Venlo and the six-month clinical outcome is reported by Mol et al [7]. A total of 333 patients were included and, as expected, the incidence of procedural complications and MACE at 6 months was low, 5.7 % and 13.1 % respectively. The results at 30 days were comparable to the earlier report by Mol et al [7] from the Medical Center Alkmaar. The authors are to be commended that they report their results, illustrating efficacy and safety of a PCI program without surgery on-site. Together with the data from the literature, we can conclude that PCI without surgery on-site is safe for selected patients when performed in experienced hands in dedicated centres. It is convenient for patients to be treated in a hospital nearby, and for ACS patients it is probably cost-saving as it avoids ambulance transfers.

R. J. de Winter (✉)
Department of Cardiology, B2-137, Academic Medical Center, Meibergdreef 9, 1105AZ Amsterdam, the Netherlands
e-mail: r.j.dewinter@amc.uva.nl

Several questions regarding the future quality of care in PCI programs remain:

Has the outcome of STEMI patients undergoing primary PCI improved with more hospitals offering this service at shorter transfer distances? We live in a small country. Some remote regions may have been underserved 10 years ago, but transfer distances in the Netherlands are not very long, and adding 20–30 min of transfer time is unlikely to have a major impact on outcome. Outside office hours, cathlab staff travel to the hospital while the patient is being transferred. Although availability of primary PCI has been an important argument for starting new PCI programs, unfortunately systematic data are not collected in order to demonstrate that the larger number of hospitals providing this service results in a better outcome for STEMI patients.

How do we select patients who should not undergo a PCI procedure in a centre without on-site surgical back-up and what do we tell patients? The European Guidelines on Myocardial Revascularisation 2010 are quite clear on this issue: [8] 'There is growing public demand for transparency regarding site and operator results. Anonymous treatment should be avoided. It is the patient's right to know who is about to treat him or her and to obtain information on the level of expertise of the operator and the volume load of the centre. In addition, the patient should be informed whether all treatment options are available at the site and whether surgery is offered on-site or not. Non-emergent high-risk PCI procedures, including those performed for distal left main disease, complex bifurcation stenosis involving large side branches, single remaining coronary artery, and complex chronic total occlusion recanalisation, should be performed by adequately experienced operators at centres that have access to circulatory support and intensive care treatment, and have cardiovascular surgery on-site.'

How do we ensure that new technologies and best practices that are developed together with the cardiac surgeons will find their way to non-surgical sites? The Dutch guidelines stated that: 'Close cooperation with cardiac surgeons is essential for a balanced assessment of the patient's options. Elective or acute interventional procedures should continuously be compared with standards of cardiac surgery. Appropriate use of new technology is recommended to keep up to date with more difficult procedures.' Appropriate decisions must be reached together with a cardiac surgeon regarding concomitant (trans-catheter) valve replacement, staged and hybrid procedures, circulatory back-up, simultaneous treatment for (surgical) atrial fibrillation, coronary revascularisation together with indications for ICD placement, resynchronisation therapy, etc.

What is the optimal number of PCIs and how many PCI centres are needed in the Netherlands? Table 1 shows the number of sites performing PCIs and the total number of PCIs each year. Total PCI volume has increased from 17,000 in 2000 to 35,000 in 2007 and to 42,000 in 2011. At the same time, the number of PCI centres went from 13 in 2000 to 30 in 2011. At first glance, the growth in volume is paired by the growth in number of centres, suggesting cathlab availability drives volume. However, the increase in volume is (at least in part) explained by the availability of centres for primary PCI in regional systems, the general adoption of FFR measurements for the assessment of coronary lesions and the recommendation in the European Guidelines for non-STE-ACS patients to adopt an early invasive strategy. In 2007, the Netherlands ranked number seven in Europe in PCI/millions inhabitants, behind countries such as Germany, Switzerland, Norway and Latvia [9]. Is 42,000 PCIs the optimal number of procedures? Importantly, there are no incentives within the system to stabilise or reduce the number of procedures. With the start of new PCI programs, investments have been made and regional collaborations started. A volume of 600 procedures with four operators may not be viable in the long run and for centres to strive for a larger PCI volume, providing a return on investment and the means to hire more operators, is the obvious solution. Regional collaboration may encounter tensions, however, when centres try to increase their catchment area and compete for referrals. Depending on regional developments, if the optimal volume per centre is somewhere between 1000 and 2000 procedures, 30 centres should suffice when indications for PCI remain unchanged. In a cost-conscious environment, balanced forces need to come into play, with guidance from the Dutch Society of Cardiology in collaboration with regulatory bodies.

Table 1 Number of PCI centers with and without on-site surgery and number of PCI-procedures in the Netherlands in the period 2000–2011

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011
Centres with on-site surgery	13	13	13	14	16	16	16	16	16	16	16	16
Centres without on-site surgery	0	0	1	2	3	3	3	3	6	9	11	14
Number of PCIs	17,381	19,444	21,532	23,813	28,805	32,198	33,678	34,879	36,367	38,643	40,492	42,123

BHN Netherlands; NVVC; 3 July 2013

References

1. Shahian DM, Meyer GS, Yeh RW, et al. Percutaneous coronary interventions without on-site cardiac surgical backup. N Engl J Med. 2012;366:1814–23.
2. Jacobs AK, Normand SLT, Massaro JM, et al. for the MASS COMM Investigators. Nonemergency PCI at Hospitals with or without On-Site Cardiac Surgery. N Engl J Med. 2013;368:1498–508.
3. Aversano T, Lemmon CC, Liu L. for the Atlantic CPORT investigators. Outcomes of PCI at hospitals with or without on-site cardiac surgery. N Engl J Med. 2012;366:1792–802.
4. Pride YB, Canto JG, Frederick PD, et al. for the NRMI Investigators. Outcomes among patients with ST-segment-elevation myocardial infarction presenting to interventional hospitals with and without on-site cardiac surgery. Circ Cardiovasc Qual Outcomes. 2009;2:574–82.
5. Pride YB, Canto JG, Frederick PD, et al. for the NRMI Investigators. Outcomes among patients with non-ST-segment elevation myocardial infarction presenting to interventional hospitals with and without on-site cardiac surgery. J Am Coll Cardiol Intv. 2009;2:944–52.
6. Nederlandse Vereniging voor Cardiologie: Dutch guidelines for interventional cardiology; Institutional and operator competance and requirements for training. 2004.
7. Mol KA, Rahel BM, Eerens F, et al. The first year of the Venlo percutaneous coronary intervention program: procedural and 6-month clinical outcomes. Neth Heart J. 2013. doi:10.1007/s12471-013-0447-2
8. Wijns W, Kolh P, Danchin N, et al. Guidelines on myocardial revascularization. Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS); European Association for Percutaneous Cardiovascular Interventions (EAPCI). Eur Heart J. 2010;31:2501–55.
9. Widimsky P, Wijns W, Fajadet J, et al. Reperfusion therapy for ST elevation acute myocardial infarction in Europe: description of the current situation in 30 countries. Eur Heart J. 2010;31:943–57.