ELSEVIER

International Journal of Cardiology 132 (2009) 59–65

International Journal of Cardiology

www.elsevier.com/locate/ijcard

Percutaneous coronary intervention without on site surgical back-up; two-years registry of a large Dutch community hospital

J.O.J. Peels [a], R.W.M. Hautvast [a], J.B.R.M. de Swart [a], M.A.J.M. Huybregts [b], V.A.W.M. Umans [a], A.E.R. Arnold [a], G.A.J. Jessurun [c,*], F. Zijlstra [c]

[a] *Department of Cardiology, Medical Centre Alkmaar, Wilhelminalaan 12, PBX 501, 1800 AM, Alkmaar, The Netherlands*
[b] *Department of Thoracic Surgery Free University Medical Centre, Amsterdam, De Boelelaan 1117, PBX 7057, 1007 MB Amsterdam, The Netherlands*
[c] *Department of Cardiology, Thoraxcentre, University Medical Centre Groningen, Hanzeplein 1, PBX 30001, 9700 RB Groningen, The Netherlands*

Received 26 March 2007; received in revised form 18 July 2007; accepted 27 October 2007
Available online 31 January 2008

Abstract

Aims: To assess safety and efficacy of off-site percutaneous coronary intervention (PCI) in The Dutch invasive cardiovascular system.
Methods and results: Descriptive single centre registry of elective and emergency PCI. Setting is a Dutch community hospital, 40 km north of Amsterdam, with an adherent population of 400,000 people. A Clinical follow up of Major Adverse Cardiac and Cerebral Events (MACCE) at 30 days post PCI is performed. The total number of participants eligible for PCI was 781 of whom 545 were men and 236 women.

During a two-year period 781 PCI's were performed of which 298 were emergency and 483 elective. Acute complications occurred in 2.1% of participants. MACCE-free was 86.9% in the group with AMI and 95.8% in the elective group.
Conclusions: Off-site PCI is feasible and safe in The Netherlands on the condition that specific key factors for success are taken into consideration.

Keywords: Off site angioplasty; Community hospital; Outcome; Surgical backup

1. Introduction

At present, percutaneous coronary intervention (PCI) is widely advocated as a therapy of choice for the treatment of acute myocardial infarction (AMI) [1–4]. However, many patients with an acute myocardial infarction are yet treated by thrombolysis within the Dutch cardiovascular system. PCI is restricted to assigned heart centres by state regulation in The Netherlands. To enable PCI to become an easily accessible treatment option for acute myocardial infarction, it was argued that the number of centres that would be able to perform PCI should increase. On the other hand, with the number of heart surgical interventions (HS) stabilised for more than 10 years and a steady increment of the number of PCI's by an annual growth of 10% [source The Dutch Supervisory Commission for Cardiac Interventions, BHN (Fig. 1)], a further increase of the number of heart centres would significantly decrease the number of heart operations per centre. Subsequently, it was proposed that only an increase of sites where PCI's could be performed was required to improve service delivery of Dutch acute cardiovascular care. Furthermore, a slowly progressive number of persons waiting for PCI's in The Netherlands are shown until 2003 (Fig. 2). From 2004 the number of waiting persons declined with the initiation of 4 new PCI programs within geographical blank spots. At present there is no significant waiting list for PCI in the Netherlands.

The aforementioned market driven demand is supported by clinical evidence that primary angioplasty can be performed safely in hospitals without on site surgical back-up [5–17]. To

* Corresponding author. Tel.: +31 50 3612365; fax: +31 50 3614633.
E-mail address: G.Jessurun@thorax.umcg.nl (G.A.J. Jessurun).

0167-5273/$ - see front matter © 2007 Elsevier Ireland Ltd. All rights reserved.
doi:10.1016/j.ijcard.2007.10.037

prove that PCI without surgical back up is feasible and safe in The Netherlands, the Dutch government designated the Medical Centre Alkmaar (MCA) as an experimental PCI centre without in-hospital heart surgery (a so-called off-site PCI centre). At the same time, the Dutch society of cardiology and the working group on intervention cardiology created national guidelines for initiation and operation of PCI centres. As the current Dutch minister of healthcare supports more marketing incentives for optimal elective service delivery, the advisory board of healthcare was requested to analyse and report on the national requirements for Dutch invasive cardiovascular care.

Against these rapid political and environmental changes, we sought to assess a registry on safety and feasibility of an off-site PCI program.

2. Methods

2.1. Organisational preparations

Three experienced intervention cardiologists with an average annual caseload ranging from 250 to 400 were recruited from different heart centres, to ensure a 24-hour on call duty schedule. The MCA was equipped with two complete digital (catheterisation laboratories) cath labs including possibilities for intra-aortic counterpulsation and mechanical ventilation. The nursing staff received a one year cathlab training in a nearby heart centre (The Free University Medical Centre Amsterdam, (VUMC)) prior to initiation of the PCI program. Solid agreements were made with the medical staff of the department of thoracic surgery of an affiliated hospital (VUMC), to which all MCA patients for heart surgery were referred. Like in all Dutch PCI centres, all patients designated for revascularisation therapy were discussed in a heart team that consisted in this case of a cardiothoracic surgeon of the affiliated hospital and an intervention cardiologist of the MCA. Decisions were made by consensus physician's agreement. Emergency PCI's were evaluated afterwards in this heart team. A bailout protocol was designed for scenarios that would require emergency surgery.

During the first off-site operational year, only primary PCI was performed on a 24-hour on-call duty schedule. To maintain an adequate skill level, each intervention cardiologists performed additional elective PCI's in the affiliated heart centre. In the second year all primary and elective PCI's were performed in the MCA without surgical back up on site. All PCI's for acute MI were primarily stented and received upstream glycoprotein IIb/IIIa inhibition by abxicimab.

A study group on this subject had recommended primary PCI as the preferred strategy of clinical management to explore safety and feasibility of off-site PCI. Nonetheless, the number of acute PCI's was too low to be economically remunerative and to ensure an adequate caseload per intervention cardiologist. Therefore, all elective PCI's from the MCA were added to total service delivery to enlarge caseload and make the project economic justifiable.

2.2. PCI technique

PCI was performed by a standard percutaneous technique through the femoral artery or other access site as a secondary alternative. A 6 or 7 French guiding catheter was introduced. In all acute cases patients received upstream abxicimab.

Independent of the degree of urgency a prior hemodynamic assessment, which included the pre-existent left ventricular function, was made to consider whether the insertion of an intra-aortic balloon pump was mandatory [9]. The primary objective of this mechanical pre-treatment was to improve diastolic coronary perfusion and reduce the afterload for a compromised left ventricular function. A secondary objective was to improve collateral recruitment to counterbalance the overall ischemic insult. In addition, the preparation phase included upstream pharmacological pre-treatment by the administration of various drugs such as vasoactive drugs for imminent circulatory failure.

2.3. Inclusion criteria

2.3.1. Patients suffering an AMI

Patients with symptoms of acute myocardial infarction persisting for more than 30 min, unresponsive to aspirin, heparin and nitroglycerin, accompanied by ST-segment elevation of more than 1 mm (0.1 mV) in two or more contiguous electrocardiographic leads, presenting within 6 h after the onset of symptoms were included. Patients were also included with symptom duration of 6 to 48 h if there was evidence of ongoing ischemia. The only exclusion criterium was inaccessibility of all regular arterial access sites. All

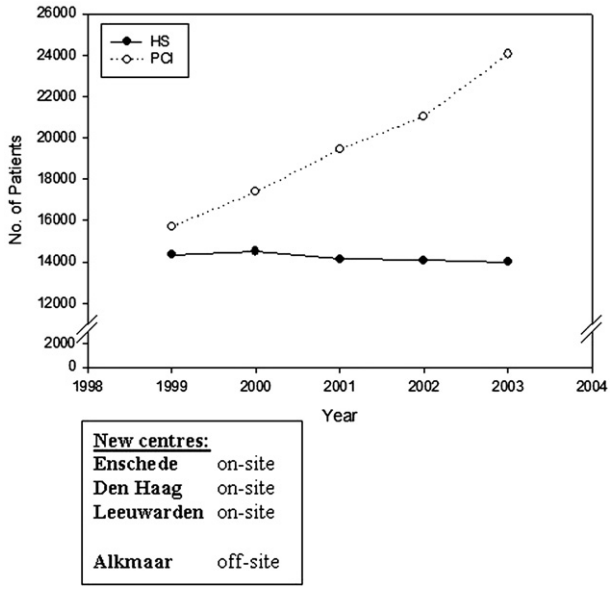

Fig. 1. Number of HS vs. PCI from 1999–2003.