Outpatient percutaneous coronary intervention: Ready for prime time?

Olivier F Bertrand MD PhD, Eric Larose DVM MD, Robert De Larochellière MD, Guy Proulx MD,
Can Manh Nguyen MD, Jean-Pierre Déry MD MSc, Onil Gleeton MD, Gérald Barbeau MD, Bernard Noël MD,
Jacques Rouleau MD, Jean-Roch Boudreault MD, Louis Roy MD, Josep Rodés-Cabau MD

OF Bertrand, E Larose, R De Larochellière, et al. Outpatient percutaneous coronary intervention: Ready for prime time? *Can J Cardiol* 2007;23(Suppl B):58B-66B.

Outpatient practice after percutaneous coronary intervention (PCI) is gaining momentum due to constantly optimizing results. Furthermore, the availability of limited beds to handle the large volume of coronary interventions also promotes outpatient practice. The present report relates the current experience with same-day discharge and defines persisting challenges in promoting accelerated in-hospital turnover. Since the mid-1990s, there have been several reports on same-day discharge following uncomplicated procedures. Overall, the success of outpatient PCI practice is based on a few technological and pharmacological advances. First, the systematic use of stents and potent antiplatelet agents have revolutionized the acute success rates of PCI by virtually eliminating the risks of acute vessel closure within the first 24 h following a successful procedure. Second, the miniaturization of catheter sizes has also simplified access site management, accelerated ambulation time and limited the risks of puncture site bleeding. In this regard, the transradial approach initially described in Canada and later popularized in Europe has transformed the acute care of patients after PCI. Today, however, the practice of transradial PCI still varies largely from country to country. From the literature review, it appears that after a short period of observation (4 h to 6 h), the majority of eligible patients who have undergone uncomplicated coronary stenting can be discharged on the same day. Whereas implementation of same-day discharge to referring centres is simple, home discharge requires the development of structured outpatient programs with dedicated resources to assist the patient and family with short-term logistics, to provide reassurance, to serve as a 'safety net' and, lastly, to promote medication compliance and cardiovascular risk factor management. Further studies are required to better define the cost-minimization effects of outpatient PCI practice, as well as patient perception of fast-track PCI. It is proposed that outpatient PCI will likely continue to expand over the next decade.

Key Words: *Abciximab, Discharge, Percutaneous transluminal coronary angioplasty, Radial, Stent*

Over the past two decades, the number of percutaneous coronary interventions (PCIs) performed worldwide has increased exponentially with currently more than two million interventions performed annually. While the percentage of patients referred for stable angina has remained stable, the increased activity has been primarily due to the increased number of patients referred for acute coronary syndromes. This phenomenon can be explained by improved outcomes associated

L'intervention coronarienne percutanée ambulatoire : sommes-nous prêts à en accroître la pratique?

La pratique des soins externes après une intervention coronarienne percutanée (ICP) gagne du terrain en raison de l'amélioration constante des résultats. De plus, le nombre limité de lits pour faire face au grand nombre d'interventions coronariennes favorise également les traitements ambulatoires. Le présent rapport fait état de la situation actuelle des interventions d'un jour et des difficultés qui subsistent dans la promotion du traitement toujours plus rapide des patients dans les hôpitaux. Depuis le milieu des années 90, il y a eu plusieurs rapports sur la sortie de l'hôpital le jour même après une intervention sans complications. Le succès de l'ICP ambulatoire repose essentiellement sur quelques progrès technologiques et pharmacologiques. Tout d'abord, la pose systématique d'endoprothèses et l'utilisation courante de puissants antiplaquettaires ont considérablement amélioré le taux de réussite des ICP en éliminant presque complètement les risques d'obturation aiguë des vaisseaux au cours des 24 premières heures suivant une intervention réussie. Ensuite, la miniaturisation des cathéters a facilité le traitement des points d'accès, accéléré la prestation des soins ambulatoires et diminué les risques d'hémorragie au point de ponction. À cet égard, l'approche par voie radiale, décrite pour la première fois au Canada, puis appliquée en Europe, a transformé les soins en phase aiguë après une ICP. Aujourd'hui, cependant, la pratique de l'ICP par voie radiale varie considérablement d'un pays à l'autre. D'après l'examen de la documentation, il semblerait que, après une courte période d'observation (4 à 6 h), la plupart des patients ayant subi une pose d'endoprothèses coronariennes sans complications puissent quitter l'hôpital le jour même. Tandis que le retour des malades vers les hôpitaux d'origine ne pose pas de problème, le retour à domicile exige la mise en place d'un programme structuré de soins externes, doté de ressources affectées à cette fin pour aider les patients et leur famille dans l'organisation des soins à court terme, les rassurer, servir de « filet de sécurité » et, finalement, promouvoir le respect du traitement médicamenteux et la prise en charge des facteurs de risque de maladie cardiovasculaire. Il faudrait mener d'autres études pour mieux comprendre les effets de minimisation des coûts de la pratique de l'ICP ambulatoire et la perception des patients à l'égard de l'ICP rapide. À notre avis, l'ICP ambulatoire est appelée à gagner encore plus de terrain au cours de la prochaine décennie.

with fast-track PCI compared with conservative medical management as shown in several large, multicentre, international trials (1).

This increased activity in PCI laboratories is a significant burden for hospital bed turnover and management. Several other disciplines have witnessed the development of outpatient practice, a direct consequence of improved care with planned surgical procedures. Today, outpatient surgeries are

Interventional Cardiology Laboratories, Laval Hospital, Quebec

Correspondence: Dr Olivier F Bertrand, Hôpital Laval, Institut universitaire de cardiologie et pneumologie, affilié à l'Université Laval, 2725, chemin Sainte-Foy, Sainte-Foy, Quebec G1V 4G5. Telephone 418-656-8711 ext 5947, fax 418-656-4544, e-mail Olivier.bertrand@crlh.ulaval.ca

Received for publication March 26, 2007. Accepted June 17, 2007

routinely performed for cholecystectomy and endovascular procedures. Even case reports of same-day home discharge and series of overnight hospital discharge after uncomplicated coronary bypass surgery have been reported (2,3). Experiences with outpatient practice in interventional radiology for renal, peripheral artery or carotid percutaneous intervention have been increasingly reported (4-6).

The present report reviews past and current experiences from Hôpital Laval (Sainte-Foy, Quebec) and other institutions with outpatient PCI by focusing on the safety aspects and the potential benefits, as well as the limitations for patients, staff, hospital management and, ultimately, society.

Percutaneous transluminal coronary angioplasty experience

To develop an outpatient program in the balloon angioplasty era, it was necessary to consider two potentially serious risk categories. First, the ischemic risk is related to acute vessel closure and its morbidity and mortality consequences. Several reports have shown that acute vessel closure can occur in 5% to 20% of cases after percutaneous transluminal coronary angioplasty (PTCA), most of these events occurring during the first 24 h to 48 h post-PTCA (7,8). Beyond 48 h, the incidence of ischemic events has been reported to decrease exponentially (9). This clustering of events during the first 24 h has also been observed after coronary stenting (10). In these early days, the ischemic risk was tightly linked to the clinical presentation and to the angiographic appearance before balloon dilation. The second risk, the bleeding risk, has been largely associated with the standard femoral artery approach and the use of large-sized 7 to 8 French catheters. Vascular complications post-PTCA ranged between 4% and 10%; therefore, meticulous care to obtain hemostasis, including prolonged (overnight) bed rest, was required (11,12).

The increase in PTCA activity prompted Laarman et al (13) to assess the feasibility and safety of same-day discharge after uncomplicated transbrachial PTCA. By selecting very low-risk patients (stable angina) and lesions (side branches of major vessels), they performed PTCA under surgical stand-by in 63 patients. After successful PTCA and an observation period of 2 h, 50 patients (79%) were considered eligible for discharge but remained hospitalized without monitoring until the next morning. No ischemic events occurred in this group of patients. In the group of patients selected for hospitalization, three sustained vessel occlusion (two within 1 h of observation and one 20 h post-PTCA). Despite use of the brachial approach and 6 French diagnostic catheters, bleeding at the puncture site and vascular complications occurred in five patients with two requiring surgical repair. From this preliminary experience, the importance of defining the ischemic risk after PTCA as well as the role of an observation period emerged as important factors.

Knopf et al (14) reported a series of 90 patients randomly assigned to same-day discharge or overnight hospitalization. Of these, 33 patients underwent same-day discharge. No complications occurred after discharge, and a satisfaction survey conducted with patients and relatives showed a high degree of comfort and preference for the same-day discharge strategy. Koch et al (15) studied the role of an observation period of 4 h before discharging patients to their referring centres. Their study reflected the rapid change of PTCA practice because in their beginning experience, the use of 7 to 8 French catheters and balloon angioplasty were routinely used, while after 1994,

use of 6 French catheters and coronary stenting increased steadily (from 9.4% in 1995 to 23% in 1996). During the observation period, repeat angioplasty was required in seven patients (0.4%). After the 4 h observation period, 1680 patients (89%) were discharged to their referring centres. In this group, acute recurrent ischemia was observed in only two patients (0.1%). In the 187 patients who remained hospitalized, the reasons for exclusion were mainly due to suboptimal angiographic results (ie, persisting dissection). In this last group, two patients (1%) died, 51 (27.3%) sustained myocardial infarction (MI) and five underwent urgent repeat angioplasty. From these results, it can be concluded that after uncomplicated balloon angioplasty and a short period of observation, a large majority of patients could be safely discharged the same day. Furthermore, patients at higher risk of complications could be identified at the end of the procedure. Although investigators initially considered stenting as conferring an additional ischemic risk precluding same-day discharge, they later recognized the potential benefit owing to optimized stent deployment techniques and simplified antiplatelet regimen compared with previous heavy anticoagulation.

Experience with coronary stenting

Over the past decade, a series of registries and a few randomly assigned trials with increased percentage of coronary stenting and same-day discharge have flourished (Tables 1 and 2). Having pioneered the use of transradial PCI, Kiemeneij et al (16) were interested in applying this new approach to outpatient practice. They recruited 188 stable patients referred for elective stent implantation. From May 1994 to December 1994, patients eligible for outpatient practice had to have an international normalized ratio greater than 2.5 and had to have received a heparin bolus of 10,000 U and 500 mg acetylsalicylic acid at the beginning of the procedure. Later on, this heavy anticoagulation scheme was replaced by treatment with acetylsalicylic acid and ticlopidine. After a successful and an uneventful PCI, patients were observed for a period of 6 h before discharge. Of the 188 recruited patients, 88 patients had complications and were not eligible for same-day discharge. Of the remaining 100 patients, 92 were discharged home and eight were transferred back to their referring centres. No same-day discharge patients faced any cardiac or bleeding complications within 24 h. Using their previously reported observation period of 4 h, Koch et al (17) reported an update of their experience from January 1995 to May 1997 and studied predictive factors for failure of same-day discharge. Of 1015 patients, 922 (91%) were triaged for same-day discharge to their referring centres and had an uncomplicated outcome. Independent preprocedural significant predictors of failure to same-day discharge were the presence of an ostial lesion, a PTCA of more than one lesion and a restenotic lesion. From the remaining 93 patients, 40 (43%) had a complicated clinical course. It should be emphasized that despite the fact that the stenting rate increased during the study period, its overall use was still quite low (less than 30%). Wilentz et al (18) enrolled stable and unstable patients (acute MI less than 24 h) for stenting by the femoral approach and using collagen-based closure devices. Of 60 initially recruited patients, 55 were effectively discharged the same day, 3 h to 10 h after PCI. No ischemic complications occurred but one patient developed a pseudoaneurysm and had surgical repair. Clément-Major and Lemire (19) reviewed their experience in the province of

TABLE 1
Studies with same-day discharge

Reference	Year	Design	Age, years	Approach	Anticoagulation	French size (% or n)	Enrolled patients, n	Eligible patients, n	Discharged patients
PTCA									
Laarman et al (13)	1991–1992	Registry	59±10*	Brachial	100 U/kg heparin	6 diagnostic	63	50	–
Knopf et al (14)	1993–1995	Random	58±10*	Femoral	10,000 U heparin	6	262	43	33 (77%)
Koch et al (15)	1991–1996	Registry	61±10*	Femoral	5000 U heparin	7–8 (53%)/6 (47%)	1900	1900	1680 (88%)
Stent									
Kiemeneij et al (16)	1994	Registry	60±10*	Radial	10,000 U heparin	6	188	100	92 (92%)
Koch et al (17)	1995–1997	Registry	60±11*	Femoral	5000 U heparin	6	2131	1015	922 (91%)
Wilentz et al (18)	1997–1999	Registry	–	Femoral	80 U/kg heparin	6 (49)/7–8 (11)	60	59	55 (93%)
Clément-Major and Lemire (19)	1997–1999	Registry	–	Radial/femoral	–	–	1856	546	383 (70%)
Ziakas et al (20)	1998–2001	Registry	63±11*	Radial	5000 U–10,000 U heparin	6 (436)/7 (483)	–	2072	943 (46%)
Carere et al (21)	1999	Random	60±11*	Femoral	10,000 U heparin	8	–	50	41 (82%)
Gilchrist et al (31)	1999–2001	Registry	60	Radial	Heparin bolus (ACT 200–300 s) + eptifibatide 1–2 bolus + 6 h infusion	5–6	–	26–	26 (100%)
Slagboom et al (22)	2000	Registry	63	Radial	5000 U heparin PTCA, 10,000 U heparin stent	6	550	155	106 (68%)
Dalby et al (23)	2001	Registry	65	Femoral	Mean 7550 U heparin	6 (56)/8 (14)	98	70	51 (73%)
Blackman et al (24)	–	Registry	60±10*	Femoral	2500 U or 5000 U heparin	6	122	50	45 (90%)
Ormiston et al (25)	2001	Registry	61	Femoral	Bivalirudin	5 (84)/6 (5)/7 (11)	100	85	26 (31%)
Wiper et al (32)	2001–2005	Registry	61±10*	Radial	70 U/kg heparin ± abc bolus-only (216)/ 6–12 h (27)	6 (404)/7 (13)	–	442	367 (83%)
Lasevitch et al (26)	2002–2003	Registry	59±10*	Femoral	70 U/kg heparin	5	–	100	51% home, 46% minimal care
Slagboom et al (27)	2003	Random	60	Radial/femoral	5000 U heparin PTCA, 10,000 heparin stent	6	–	644	375 (58%)
Kumar et al (33)	2003	Registry	55	Radial	70 U/kg heparin ± abc bolus-only	6	–	150	80%
Motwani (28)	–	Registry	43–75†	Radial	Heparin	–	101	66	63 (95%)
McKenna et al (29)	–	Registry	–	Femoral	Heparin	6	–	487	409 (84%)
Yee et al (30)	2004	Registry	56±9*	Femoral	80 U/kg heparin	6–7	75	75	25 (33%)
Bertrand et al (34)	2003–2005	Random	60±10*	Radial	70 U/kg heparin + abc bolus-only	5–6–7	1348	504	443 (88%)

*Mean ± SD; †Minimum to maximum range. abc Abciximab; ACT Activated clotting time; PTCA Percutaneous transluminal coronary angioplasty

Quebec with same-day discharge either home or to referring centres in 539 patients who underwent PCI using the femoral or radial approach. During the course of the study, stents were increasingly used (less than 25% in 1997 to over 75% in 1999). After PCI, 383 patients (71%) were discharged the same day and 156 patients were kept for prolonged observation mostly due to suboptimal PCI results.

The first western Canadian experience with outpatient practice was reported by Ziakas et al (20). Using the transradial approach, they discharged 943 patients the same day after uncomplicated PCI. Their experience included patients with stable and unstable angina and single or multilesion angioplasty with all types of lesion characteristics. A total of 811 patients answered a structured questionnaire. Within 24 h post-PCI, 278 patients (34%) reported one or more minor access site complications (ie, bruising or pain) but no ischemic event. Most important, 28 (3.3%) sought medical advice in the 24 h

following the procedure, and at 30 days, 28 patients (3.5%) visited their family physician and 14 patients (1.7%) had a hospital visit. Overall, 718 patients (89%) stated that they were satisfied with same-day discharge. Carere et al (21) performed a feasibility study in 100 patients randomly assigned to a suture-based femoral artery closure device and same-day discharge or compression with a C-clamp and overnight hospitalization. Same-day discharge was feasible in 41 patients (82%) randomly assigned to a closure device. Failures to same-day discharge were mainly related to access site problems (eight cases); only one patient had persisting chest pain. No ischemic or bleeding events were reported. Before initiating a randomly assigned study comparing same-day discharge with the femoral or radial approach, Slagboom et al (22) performed a pilot phase which exclusively used the transradial approach in 159 patients. This was primarily intended to verify the value of their sets of seven clinical and five angiographic criteria precluding same-day

TABLE 2
Complications after same-day discharge

Reference	Ischemic complications	Bleeding	Other events
PTCA			
Laarman et al (13)	0	Four hematomas (7%)	One false aneurysm (2%), two surgical repair (4%)
Knopf et al (14)	0	0	0
Koch et al (15)	2 (0.1%)		
Stent			
Kiemeneij et al (16)	0	0	
Koch et al (17)	0	—	
Wilentz et al (18)	0	—	One false aneurysm
Clément-Major and Lemire (19)	0	0	
Ziakas et al (20)	One reangiogram	—	28 patients seek medical advice within 24 h
Carere et al (21)			
Gilchrist et al (31)	0	0	
Slagboom et al (22)	0	0	
Dalby et al (23)	0	0	
Blackman et al (24)	One repeat PCI	Three hematomas	One false aneurysm
Ormiston et al (25)	0	0	
Wiper et al (32)	0	38 (9%) small hematomas	One patient died at 72 h and two patients had stent thrombosis at 48 h
Lasevitch et al (26)	0	One hematoma >10 cm	
Slagboom et al (27)	One stent thrombosis and repeat PCI	Five minor hematomas	
Kumar et al (33)	—	—	
Motwani (28)	0	0	
McKenna et al (29)	—	—	
Yee et al (30)	0	Seven groin-oozing	
Bertrand et al (34)	0	Three rectal bleeding plus one drop in hemoglobin (0.8%) plus 24 (4.8%) hematomas >5 cm	

PCI Percutaneous coronary intervention; PTCA Percutaneous transluminal coronary angioplasty

discharge. Using these criteria, 106 patients (67%) were assigned to same-day discharge. In these outpatients, no cardiac or vascular complication occurred during the 4 h to 6 h observation phase or during the first 24 h follow-up. Among patients maintained hospitalized, one patient had an in-lab vessel closure and three others underwent repeat PCI during the observation phase. One patient suffered a transient ischemic attack.

Dalby et al (23) considered 73 patients on a waiting list for elective catheterization as suitable for same-day discharge; with 100% stenting and using a collagen-based femoral artery closure device. Procedural success was obtained in 68 of the 70 patients who underwent PCI. Ultimately, 51 (73%) were successfully discharged on the same-day. No formal criteria were applied to reject patients for same-day discharge, but in most cases, they were either related to angioplasty results (11 cases) or to access site complications (six cases). No ischemic events occurred during the first 24 h in outpatients or registry patients. Of 122 patients with acute coronary syndrome sent by a referring hospital, Blackman et al (24) considered 50 patients as suitable for same-day discharge to the referring hospital. Overall, 45 of these patients underwent PCI with stent implantation and were transferred back to their referring centre on the same day. At 30 days,

one patient had a second PCI due to dissection distal to the first implanted stent. Three patients suffered from significant groin hematoma and one patient developed a pseudoaneurysm. Ormiston et al (25) recruited 100 potential patients representing all comers because only patients with acute MI were excluded. Ultimately, only 26 patients were discharged the same day. Main reasons associated with overnight stay were late afternoon procedures (n=26), social reasons (n=24) and use of glycoprotein IIb/IIIa inhibitors (n=17). There were no ischemic or bleeding complications in patients discharged the same day. Of interest, of the 32 patients who had their procedure completed by 12:00, 19 (59%) were discharged the same day. Using the femoral approach and exclusively 5 French catheters, Lasevitch et al (26) recruited 100 patients scheduled for elective coronary stenting. Exclusion criteria were mostly related to anticipated problems with small size catheters such as severely calcified lesions. Three patients were excluded for same-day discharge (one underwent repeat PCI 15 min postindex stenting). Fifty-one patients were discharged home 8 h to 12 h post-PCI and 46 patients were sent to the minimal care facility (due to afternoon procedures). Of note, 10 patients had minor bleeding at the access site, which was managed by compression and did not prevent same-day discharge. During the first 24 h, no

ischemic events were noted but one patient developed a large hematoma (greater than 10 cm).

Slagboom et al (27) performed a randomly assigned study in 644 patients comparing same-day discharge after the radial or femoral approach. After successful PCI (stenting in 62%), 198 patients (61%) in the radial group and 177 patients (55%) in the femoral group were triaged for same-day discharge using previously defined criteria. Only one ischemic event (stent thrombosis) and five bleeding events (1.1%) occurred after same-day discharge during the first 24 h. Indications for in-hospital prolonged observation were persisting dissection in 28% of patients, prolonged chest pain in 16% of patients and multivessel PCI in 9% of patients. Ischemic and bleeding events occurred more frequently in inpatients including one (0.4%) death, 13 (5.2%) MI, 12 (4.8%) urgent revascularization and 25 (10%) bleeding events compared with outpatients.

The preliminary experience of Motwani (28) in 101 consecutive patients referred for elective PCI was reported in 2003. Thirty-five patients were excluded for same-day discharge strategy before PCI. Using the transradial approach and 94% stenting rate, same-day discharge was obtained in 63 of 66 (95%) patients. One patient sustained vessel closure 20 min post-PCI and the two others could not be discharged for reasons unrelated to PCI. No ischemic or bleeding event occurred after discharge. McKenna et al (29) reported their experience with same-day discharge in 487 patients. Same-day discharge was obtained in 409 (84%) patients and reasons for nondischarge included suboptimal PCI results, use of abciximab and minor access site bleeding. Yee et al (30) assessed the feasibility and safety of same-day discharge after coronary stenting and using a collagen-based femoral artery closure device. Seventy-five low-risk patients were enrolled (single lesion, stable angina). In the first 50 patients, same-day discharge was planned but patients remained hospitalized overnight. In this group, time to ambulation (6 h or less) was obtained in 88% of patients. Hematoma was noted in two patients. In the last 25 patients, time to ambulation (6 h or less) was also obtained in 86% and discharge was performed 10.7 ± 1.3 h after PCI. No ischemic events occurred during the first 48 h of follow-up.

With an increasing rate of stenting and inclusion of higher-risk patients, several authors have demonstrated the feasibility and safety of same-day discharge after uncomplicated coronary PCI. Using clinical judgment and a few angiographic criteria, patients at higher ischemic risk were identified and remained hospitalized. Once hemostasis is completed, patients can be discharged after both the femoral and radial approaches. The use of platelet glycoprotein IIb/IIIa receptor antagonists was still considered to be an exclusion criterion and prohibited same-day home discharge.

Gilchrist et al (31) reported their preliminary experience with 26 patients with stable or unstable angina using the transradial approach, 5 or 6 French catheters and an abbreviated course of eptifibatide. All patients were discharged home after a mean 6.5 h observation period. Wiper et al (32) reviewed their experience with 442 patients referred for elective transradial PCI. Abciximab as bolus-only was used in 216 cases. Successful PCI was obtained in 95% of the cases, and 367 patients (83%) were discharged the same day. Patients were observed for a minimum of 4 h before discharge. Ischemic events occurred in three cases early after PCI, all related to stent thrombosis. The first event occurred 72 h post-PCI and resulted in cardiac death; the other two led to MI and repeat PCI. No major or

minor bleeding events were reported using the thrombolysis in MI classification but 38 patients (9%) developed small hematomas requiring a hospital visit within 24 h. Kumar et al (33) reported their preliminary experience with the transradial approach in 150 consecutive patients recruited over 21 months. Patients referred for elective PCI with noncomplex coronary lesions were eligible. After PCI (98% stenting), same-day discharge was performed in 80% of patients. Patients who were not discharged on the same day were categorized in three groups: access site-related problems (13 cases), suboptimal PCI results (11 cases) and miscellaneous (six cases). During early follow-up, no ischemic or bleeding event occurred in outpatients.

Recognizing the benefit of the transradial approach to achieve rapid hemostasis and to limit the bleeding risk, these authors have shown that same-day home discharge was feasible even with the use of glycoprotein IIb/IIIa inhibitors. In addition to stenting, the optimization of antiplatelet therapy seemed to minimize the ischemic risk. However, it remained unknown whether abciximab bolus-only or an abbreviated treatment with eptifibatide was equivalent to the standard recommended protocols. To extend same-day discharge to patients at high risk, such as patients with acute coronary syndromes, this approach required to be validated in a randomly assigned trial.

From Early Discharge After Transradial Stenting of Coronary Arteries study to 'Contrôle de Qualité pour Faciliter le Départ' program

Before conducting the Early Discharge After Transradial Stenting of Coronary Arteries (EASY) study, discharge of patients the same day after uncomplicated transradial PCI was occurring infrequently in Hôpital Laval and was limited to outpatients living nearby. Decision to discharge relied exclusively on the operator and patient willingness; clinical follow-up was not systematically applied. Furthermore, during that period, the large majority of patients (more than 80%) were treated with glycoprotein IIb/IIIa inhibitors and referring centres were reluctant to accept those patients with ongoing infusions, fearing bleeding complications. Facing a significant increase in PCI activity with persisting bed constraints, it was decided to develop an outpatient program. As a first step, we performed a large randomly assigned trial comparing the two strategies after PCI (34). Protocols were drafted between 2001 and 2002, and funding was sought from several health agencies and the pharmaceutical industry. Reviewing the Evaluation of c7E3 for Prevention of Ischemic Complications (EPIC) study results and the pharmacodynamics of abciximab, we thought that current practice with systematic stenting would allow the use of the abciximab bolus-only strategy and avoid the standard 12 h infusion. At that time (2001), the role of pretreatment with a loading dose of clopidogrel was emerging as an important factor. Therefore, a group including one investigator, one pharmacist, the chief nurse of the catheterization laboratory and two nurses from the cardiology ward visited each referring centre within a radius of 300 km from our tertiary care hospital. During a half-day visit, presentations on the benefits and safety of the transradial and translumbar approaches allowing same-day discharge, on the principles of radial hemostasis, on the importance of clopidogrel pretreatment and loading dose before PCI and on the pharmacology of glycoprotein IIb/IIIa inhibitors were extensively reviewed and discussed.

Enrolment in the EASY study was conducted between October 13, 2003, and April 15, 2005 (34). During that period,

a total of 4621 PCIs were performed. Of these patients, the research staff, including one coordinator and six research nurses, approached 3277 clinically eligible patients who signed the informed consent before the diagnostic catheterization exclusively performed by transradial or transulnar approaches (35). After the diagnostic angiogram, 1348 patients underwent ad hoc coronary stenting and received the bolus of abciximab before the first balloon inflation. A few exclusion criteria were used before diagnostic angiography: patients had post-ST elevation acute MI of less than 72 h, history of ejection fraction less than 30% (left ventriculography is not routinely performed before PCI), intolerance to acetylsalicylic acid or thienopyridines, comorbidities precluding same-day discharge or contraindication to abciximab. After stent implantation, angiographic success was not mandatory but unsuccessful PCI – defined by persisting type B or more dissection, thrombolysis in MI flow less than 3, compromised side-branch (1 mm or greater) or thrombus – precluded patients from random assignment. These patients with unsuccessful PCI were kept in a registry and received a standard 12 h abciximab infusion. All dilated lesions had to be stented except secondary branches of bifurcation lesions or in the case of redilation and brachytherapy for in-stent restenosis (36,37). Clinical complications, such as ventricular fibrillation or hemodynamic collapse during PCI, precluded random assignment. Random assignment occurred at the end of the procedure and in the case of random assignment for overnight hospitalization, a 12 h standard abciximab infusion was initiated in the catheterization suite. Sheaths were removed at the end of the procedure and a hemostatic band was maintained until hemostasis was completed (usually within 2 h). After a 4 h to 6 h observation period, patients randomly assigned to home discharge were visited by the operator and a dedicated research nurse and any complication was noted. After the control visit, patients were discharged with a few written recommendations, a telephone number to call in case of emergency, a plastic bag with tubes for blood tests the next day and a prescription for a control electrocardiogram. Whenever possible, patients in the 12 h infusion group were transferred back to their referring centres 4 h to 6 h after PCI. A telephone contact or hospital visit was performed the next day by the study personnel and any complications were noted in dedicated case report forms.

It should be emphasized that at the time of the present study protocol design, many were concerned with the bleeding risks, while the operators were more concerned with ischemic risk in patients at higher risk. There was also a lack of data in the literature concerning possible negative aspects of early discharge regarding repeat hospitalizations or increased unsolicited medical visits. Nevertheless, these two aspects, while less serious than the usual clinical complications, would have had a negative impact on a same-day discharge program and created much less interest in terms of cost-minimization.

Considering the incidence of other comorbidities or noncardiac-related issues, it was hypothesized that a maximum of 50% of patients referred to the catheterization laboratory would be eligible for same-day discharge. During the study period, we randomly assigned 1005 patients. After PCI, 504 patients received one stent or more, did not present any clinical complication during the procedure or angiographic exclusion criteria and were randomly assigned to home discharge after an observation period of 4 h to 6 h. During this observation period, a 50-year-old patient with de novo angina and

single-vessel disease had received a 3.0×16 mm stent (direct stenting at 20 atm) in a distal right coronary artery. The procedure was uneventful, an excellent angiographic result was obtained and the final activated clotting time was 254 s. Approximately 2 h after the procedure, while in the cardiology ward, the patient developed acute chest pain with severe bradycardia and he was brought back for urgent repeat catheterization. At that time, the right coronary artery showed complete distal occlusion; the vessel was quickly reopened and another stent was implanted with excellent angiographic result. This patient developed a Q-wave inferior MI. Apart from this patient, 60 patients were not discharged as planned and remained hospitalized overnight. Overall, 51 patients remained hospitalized for medical reasons and only 10 patients expressed preference for prolonged in-hospital observation. After discharge, no death or urgent coronary artery bypass graft surgery occurred. One patient did not develop any complications but was adjudicated as having a Q-wave MI based on 30-day electrocardiogram findings. Beyond 24 h, four patients were referred for PCI in a nontarget vessel. In terms of bleeding, three patients had rectal bleeding and one of these required several transfusions. Another patient, adjudicated as having a major bleed, had a drop in hemoglobin of over 3 g/L without external bleeding. Of note, withholding abciximab infusion did not lead to a significant benefit in terms of bleeding risk, mostly because of the extremely low rates in both groups.

Overall, the success of the EASY study reassured operators and attending physicians, further demonstrated the benefits of the transradial approach and was the building block for the development of a structured, clinical, outpatient program. Beyond the safety issues, it became obvious that accelerating patient turnover and limiting in-hospital duration had a major impact on several resources involved in patient care. However, by limiting the interaction time between patients and health care professionals, outpatient practice could also have some negative implications. For example, a young patient admitted for a non-ST elevation acute MI in the early morning can be transferred in the catheterization laboratory at 10:00, receive a stent in his proximal left anterior descending artery at 10:30 and be discharged home at 16:00! As a result, it may be difficult to persuade the patient that he has not been cured of his disease!

To set up the *Contrôle de Qualité pour Faciliter le Départ* program, we have worked on these two aspects, the 'safety-net' and the post-PCI rehabilitation aspects. For the first aspect, a liaison nurse position has been established. On completion of PCI, the nurses's first role consists of verifying with the operator and the referring physician (in case of hospitalized patient) that the patient can be safely discharged home. Then, the nurse meets with the patient and his/her family to organize logistical aspects. This sometimes includes several telephone calls to find a hotel room, arrange transportation or contact family members. During the observation period, a liaison pharmacist checks with the patient, the referring hospital or the pharmacy concerning previous medical therapy and reviews with the operator the list of medications to be taken until the next medical visit. In case of drug-eluting stent implantation, a card emphasizing the importance of combination therapy with acetylsalicylic acid and clopidogrel is also provided to the patient.

Before discharge, the liaison nurse verifies the absence of complications, schedules a telephone contact for the next day and provides the patient with the procedure summary and a

brochure detailing several aspects related to the procedure as well as cardiovascular risk factor management. A list of rehabilitation centres is also provided on request and an appointment with the referring physician within four to six weeks is scheduled. In case of emergency, a phone number is also provided. The next day, the liaison nurse contacts each patient and records any problem.

Since the completion of the EASY study, 707 patients (13%) of a total of 5563 patients who received PCI have been discharged home the same day. Overall, more than 67% of all patients after PCI have been discharged home or transferred back to their referring centre the same day after PCI. Patients who remained overnight in our institution were either referred from remote regions (greater than 300 km) or could not be discharged the same day for logistic reasons. Of the 707 patients, only one was rehospitalized within 24 h with left ventricular dysfunction and later died. This 83-year-old postbypass patient with chronic obstructive pulmonary disease had undergone an uneventful procedure with stent implantation in a saphenous vein graft to a marginal branch. Autopsy showed severe and diffuse pulmonary congestion, localized acute subendocardial necrosis from the posterolateral wall involving papillary muscle and a patent stent. Because no device protection had been used, it was concluded that the patient had suffered distal embolization during the procedure, which led to severe mitral regurgitation due to papillary muscle dysfunction. No patient discharged the same day either home or to referring centres sustained any ischemic complication leading to repeat catheterization or revascularization within 24 h of discharge. Of 707 patients, 118 (17%) received a bolus-only of abciximab during PCI and the remaining patients received heparin-only anticoagulation during PCI. All patients were routinely pretreated with acetylsalicylic acid and clopidogrel before catheterization. After home discharge, no bleeding event was recorded or hospital visit was required within 24 h postdischarge. A single patient was rehospitalized within 24 h post-PCI for noncardiac reasons (car accident). Another patient had a repeat angiogram in another hospital for chest pain three days after the index procedure.

Summary of current experience and perspectives

Over the past 15 years, several reports involving a few thousand patients discharged the same day after PCI have been published. In the early 1990s, the authors privileged low-risk patients usually referred for elective balloon angioplasty. Despite the fact that several clinical and angiographic criteria established before the intervention had been associated with adverse ischemic outcomes after PTCA, operators quickly observed that the immediate angiographic result and the lack of any clinical complications were the most important factors associated with clinical outcome within the first 24 h. At that time, it became obvious that a short observation period (4 h to 6 h) was adequate to triage patients between same-day discharge and overnight hospitalization (17). Of interest, coronary stenting was initially considered to be an exclusion criteria for same-day discharge but was later recognized as providing superior safety compared with balloon angioplasty. Obviously, the outpatient strategy also benefited from a conversion from strong anticoagulation peri- and postprocedure to powerful antiplatelet regimens pre-, peri- and postprocedure. This allowed investigators to enrol higher-risk patients and minimized the ischemic risk. Still, the issues of prolonged bed

rest and access site bleeding risk remained an issue. Some authors using the femoral access and closure devices have described preliminary experience to accelerate ambulation time to discharge patients on the same day (21,30,38). It should be realized that closure devices have not been demonstrated to lower the risk of vascular complications compared with manual compression (39). In that regard, the radial approach offers distinct advantages because it allows immediate ambulation, rapid hemostasis and clearly reduces access site complications and bleeding compared with the femoral approach (40). Conversely, the radial approach offers no distinct benefit over the femoral approach for limiting ischemic risk (40). Therefore, it appears that once hemostasis occurs, as well as after femoral and radial approaches have been completed, patients can be safely discharged. The risks of delayed complications after the femoral approach, such as pseudoaneurysm or fistula, would not be completely prevented by overnight hospitalization.

One unresolved issue is to estimate what percentage of patients from the total volume of PCI of a catheterization laboratory can be ultimately discharged the same day. The use of glycoprotein IIb/IIIa inhibitors with standard 12 h to 24 h post-PCI infusion prohibited the development of same-day home discharge and sometimes limited same-day discharge to referring hospitals. Due to several factors, the use of glycoprotein IIb/IIIa inhibitors worldwide varies widely from less than 5% to greater than 80% of the cases. In the EASY study, it was demonstrated that after uncomplicated coronary stenting, 12 h of abciximab infusion does not confer any additional benefit over abciximab bolus-only (34). Other authors have also reported their encouraging experience using a bolus-only of glycoprotein IIb/IIIa inhibitors (41,42). The importance of postprocedural infusion of glycoprotein IIb/IIIa inhibitors is probably decreasing because the large majority of patients are now pretreated with a loading dose of clopidogrel before catheterization. It has even been argued recently that the benefits of glycoprotein IIb/IIIa inhibitors were confined to higher-risk acute coronary syndrome with positive troponins before catheterization (43). Prudence and judgment are still required in the context of same-day home discharge of higher risk patients because the combined triple therapy with acetylsalicylic acid, clopidogrel and glycoprotein IIb/IIIa has been demonstrated as offering the best protection against myonecrosis post-PCI (44). Indeed, in high-volume catheterization laboratories, patients referred for unstable angina and acute coronary syndromes represent the majority of the patient population. In 2005, the Society for Cardiovascular Angiography and Interventions conducted a survey among 329 of its members to evaluate the practice of same-day discharge in referring centres (45). Of interest, 20% of respondents practiced outpatient PCI for 10% to 30% of their cases and 8% of respondents for 40% to 90% of their cases (45). Overall, the survey indicated that lower-risk patients (stable angina or positive stress test) and simple lesions were targeted. From the current experience, it seems that approximately 50% of the total patient population of a catheterization laboratory may still require hospitalization after PCI for logistic or noncardiac-related causes. Using simple clinical and angiographic criteria, patients eligible for same-day discharge can be triaged safely after an observation period of 4 h to 6 h and 80% to 90% can ultimately be discharged the same day.

While same-day discharge to referring hospitals is quite simple to implement, home discharge involves the allocation of

specific resources to develop a structured program. The challenges of such a large-scale program are not only to ensure patient short-term safety and logistics, but must also include more global aspects to improve patient satisfaction and cardiac health, accelerate return to work and ultimately minimize costs to society. In that regard, transradial PCI offers significant advantages compared with the standard femoral approach (46-48).

ACKNOWLEDGEMENTS: The EASY study was funded by Eli Lilly, Bristol-Myers Squibb/sanofi aventis, la Régie Régionale de Québec and la Corporation de l'Institut de Cardiologie de Québec. Dr Bertrand is a research scholar of the Fonds de la Recherche en Santé du Québec and the holder of the EASY Fund, supported by Cordis and la Corporation de l'Institut de Cardiologie de Québec. The support of Servier to the clinical database is also gratefully acknowledged.

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