www.cardiologyrounds.ca JANUARY 2005 volume X, issue 1

CARDIOLOGY Rounds®

AS PRESENTED IN THE ROUNDS OF THE DIVISION OF CARDIOLOGY, ST. MICHAEL'S HOSPITAL, UNIVERSITY OF TORONTO

Complications of Intra-aortic Balloon Pump: Can we prevent them?

By SANJIT JOLLY, MD, FRCP and GORDON MOE, MD, FRCP

The complications of intra-aortic balloon pump (IABP) often occur in critically-ill patients who are least able to tolerate them. This issue of *Cardiology Rounds* presents several cases illustrating the complications of IABP and describes the incidence of these complications based on a literature review. Strategies for the prevention of IABP complications, such as sheath size and sheathless technique, are reviewed, and practical recommendations for the prevention of IABP complications are discussed.

Illustrative cases

Case #1

A 73-year-old man presented to a small community hospital with chest pain and inferolateral T wave inversion with a positive troponin I. The patient had a previous inferior myocardial infarction (MI) about 15 years ago and a left anterior descending (LAD) artery percutaneous coronary intervention (PCI) 1 year previously. During the current admission, he was transferred to a tertiary centre for cardiac catheterization, which demonstrated an occluded ostial LAD artery and proximal right coronary artery (RCA), and an 80% lesion in the proximal circumflex. The cardiac surgery team was consulted and the patient was transferred to the coronary care unit. He developed chest pain with 2 mm of dynamic ST depression in the inferolateral leads (Figure 1). The cardiac surgery team was again contacted but, due to ongoing surgery that occupied all of the operating rooms (ORs), it was anticipated that there would be a delay of several hours before he could go to the OR. Therefore, the decision was made to insert an IABP to stabilize the patient.

The IABP was inserted at the bedside without fluoroscopic guidance. Since blood could not be withdrawn from the IABP after insertion, the IABP was withdrawn. The patient became hypotensive, but stabilized after initiation of dopamine and norepinephrine. The IABP was subsequently re-inserted with good diastolic augmentation. The patient remained stable and was taken to the OR for emergent coronary artery bypass graft (CABG) surgery.

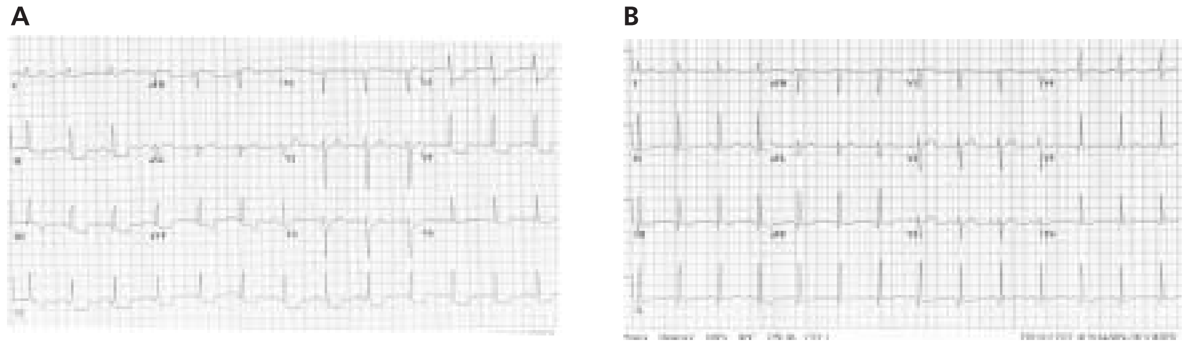
The patient had 4-vessel bypass grafting but, near the end of the operation, it was noted that his abdominal girth had increased and his hemoglobin had dropped precipitously. A vascular surgeon was called to perform an urgent laparotomy and found a perforation of the common iliac artery. Unfortunately, the patient did not survive.

Case #2

A 62-year-old woman presented to a community hospital with an anterior ST segment elevation MI; she received thrombolysis and had persistent ST elevation and hypotension requiring dopamine and norepinephrine. The patient had a history of hypertension and peripheral vascular disease. After transfer to a tertiary care centre, she had an urgent angiogram that demon-

St. Michael's Hospital
30 Bond St.,
Suite 7049, Queen Wing
Toronto, Ont. M5B 1W8
Fax: (416) 864-5941

Figure 1: Examples of electrocardiogram (ECG) changes for Case #1



A) 12-lead ECG showing chest pain in Case #1

B) 12-lead ECG of after resolution of chest pain

strated an occluded LAD artery, which was then stented successfully. The patient had an IABP inserted into the right groin.

The patient had ongoing hypotension and, according to hemodynamic measurements, was in cardiogenic shock. A large right groin hematoma was noted and her hemoglobin dropped from 140 to 70 g/dL. She underwent a computed tomography (CT) scan of the abdomen that revealed a large iliopsoas hematoma with no retroperitoneal extension. The leg with the IABP was noted to be ischemic and a vascular surgeon was consulted. The patient was deemed too unstable to have the IABP withdrawn immediately. Subsequently, the patient's condition improved and the IABP was removed the following day. Unfortunately, that leg became necrotic and required amputation the following week. The patient otherwise continued to improve and was discharged home several weeks later.

To summarize, the first case involved retroperitoneal bleeding due to arterial perforation from an IABP and the second case involved major bleeding and subsequent limb ischemia from an IABP leading to amputation. The following review outlines the prevalence of IABP-related complications, their risk factors, and provides strategies for preventing these complications.

Indications for IABP

In brief, the indications for IABP include cardiogenic shock, refractory ventricular arrhythmias, refractory heart failure, papillary muscle rupture or acute mitral regurgitation, ventricular septal rupture, refractory unstable angina, high-risk PCI, and inability to wean from cardiopulmonary bypass.[1]

Contraindications for IABP use

Absolute contraindications for IABP use include significant aortic insufficiency and aortic dissection. Relative contraindications for IABP use include abdominal aortic aneurysm, severe occlusive femoral or iliac disease, and morbid obesity.[1]

Percutaneous IABP insertion technique

A percutaneous IABP catheter is inserted into the common femoral artery via the Seldinger technique utilizing dilators. The puncture site should be below the inguinal ligament to avoid transperitoneal puncture and, therefore, retroperitoneal hemorrhage. As well, the puncture should be above the profunda femoris to reduce the likelihood of insertion into the superficial femoral artery or other branches which, if entered, will likely occlude these branches and cause ischemia. It is essential that the guide wire used in the insertion passes freely without resistance throughout the procedure and verification of the position under fluoroscopy is recommended.

Epidemiology of complications from IABP

The largest study to date is from the Benchmark Registry that included 16,909 patients from 243 institutions in 18 countries and examined the prevalence of complications from datascope IABPs.[2] In this study, major limb ischemia was defined as a loss of pulse or sensation, or pallor requiring vascular surgery. Minor limb ischemia was defined as loss of pulse that resolved with the removal of the IABP. Major bleeding was defined as bleeding causing hemodynamic compromise requiring blood transfusion or vascular surgery. Mortality due to IABP was defined as death due to vascular perforation or embolism related to the IABP procedure.

In this registry, the mean age of the patients was 66 years and only 12% had previously documented peripheral vascular disease. The top 3 indications for IABP were for support and stabilization, cardiogenic shock, and weaning from cardiopulmonary bypass. Approximately

Table 1: IABP complication rates from the Benchmark Registry[2]

Complication	Incidence (%) (n = 16 909)
IABP-related mortality	0.05%
Any limb ischemia	2.9%
Major limb ischemia	0.9%
Severe access site bleeding	0.8%
Amputation	0.1%
Balloon leak	1.0%

80% of the IABPs were inserted with an arterial sheath and 78% used a 9.5 Fr instead of the smaller 8 Fr-size catheter.

As shown in Table 1, the IABP-related mortality was 0.05%. The prevalence of any limb ischemia was 2.9% and major limb ischemia was 0.9%. The need for amputation from IABP insertion was 0.1%. The mean duration of IABP therapy was 53 hours with a median of 41 hours. The distribution of the settings for IABP insertion was 63% in the catheterization laboratory or fluoroscopy room, 24% in the operating room, and 4% in the ICU. Multivariate analysis revealed that female sex, age >75 years, peripheral vascular disease (PVD) and body surface area (BSA) <1.65 m^2 predicted procedure complications (Table 2).

Cohen et al conducted a large prospective study to examine the prevalence of IABP complications.[3] The study was performed at a single centre and it is useful to highlight his results and compare them with those from the large multicentre registry.[2] The cohort comprised 1119 patients enrolled between 1993-1997.[3] The mean age was 65 years and 8% had a known history of PVD. Of note, all patients had either insertion of 9 Fr (69%) or 11 Fr (30%) size IABP catheters. Physicians were only allowed to participate in this study if they had inserted ≥50 IABP catheters. The major complication rate, defined as embolism or ischemia requiring surgery, bleeding requiring transfusion or surgery, sepsis, balloon rupture, and IABP-related death, was much higher than in the Benchmark Registry, at 11%. IABP-related death was 0.4% and major bleeding was 4.6%, again much higher than in the Benchmark Registry. Finally, the major limb ischemia rate was 3.3%. The higher incidence of IABP complications in this study may be due, in part, to the use of a larger sheath size, and the higher bleeding rate may be due to use of the tearaway sheath that allows bleeding around the catheter when the sheath is removed. Finally, it should be noted that data from the Benchmark Registry is applicable only to Datascope IABP systems.

Table 2: Multivariate predictors of IABP complications from the Benchmark Registry[2]

Risk factor	Odds ratio	P value
PVD	1.97	<0.001
Female	1.74	<0.001
BSA <1.65 m^2	1.45	<0.05
Age >75 years	1.29	<0.05

BSA = body surface area
PVD = peripheral vascular disease

Cohen and colleagues defined a high-risk subgroup for IABP complications to include those with any of the following: known PVD, female sex, BSA <1.8 m^2, cardiac index (CI) <2.2 L/min/m^2, history of stroke/transient ischemic attacks (TIA), or history of diabetes (univariate predictors of IABP complications). These risk factors, in addition to larger catheter size, have been shown to predict IABP-related complications in several studies.[4-8] Patients in the high-risk subgroup (ie, with one of the risk factors) had a 15% incidence of major complications versus 3% in the group without risk factors. In a multivariate analysis, PVD, female sex, low BSA, and history of stroke/TIA were the only risk factors to independently predict complications. The authors developed a simple IABP complication risk model that is outlined in Table 3. They found that with their model, the risk of complications rises dramatically with each additional risk factor. For example, a patient with 4 risk factors has a 75% risk of an IABP complication. This IABP complication risk model may help clinicians estimate the risk of IABP complications in individual patients and use specific methods, such as smaller sheath size, to help reduce the risk of complications.

Prevention of complications

Catheter size: does it matter?

Smaller catheters take less of the cross-sectional area of the common femoral artery and, theoretically, should cause less limb ischemia. The question of whether reducing catheter size reduces IABP complications was addressed in a post-hoc analysis of the Benchmark IABP Registry comparing the incidence of complications in 8.0 Fr versus 9.5 Fr size IABP catheters.[9] This non-randomized comparison was performed between 1997-2000, in a prospective registry of Datascope IABP catheters in 9332 patients who had an IABP inserted in cardiac catheterization laboratories. The majority, 7078 patients, received the larger 9.5 Fr IABP catheters and 2254 received the smaller 8.0 Fr IABP catheters. The endpoints included major and minor limb ischemia, major bleeding, IABP failure, and

Table 3: Risk factors and the cumulative risk for IABP complications[3]
(Risk factors = history of peripheral vascular disease [PVD], female sex, body surface area [BSA] <1.8 m^2, history of stroke/ transient ischemic attack [TIA])

No of risk factors	IABP complications (%) (n = 1119)
0	6.4%
1	18.6%
2	23.1%
3	39.5%
4	75%

Table 4: IABP-related complication rate in smaller (8.0 Fr) vs larger (9.5 Fr) IABP catheters[9]

IABP-related complication	8 Fr catheter size (n = 2254)	9.5 Fr catheter size (n = 7078)
Major limb ischemia	1.6%	2.5%*
Severe access site bleeding	0.8%	0.9%
Unsuccessful IABP therapy	2.9%	1.7%*
Mortality from complication	0%	0.1%

* $p<0.05$

mortality from IABP. Major limb ischemia was defined as ischemia requiring surgical intervention, and major bleeding was defined as bleeding requiring transfusion or surgical intervention. IABP failure was defined as either poor IABP augmentation, a failure of the IABP to deploy, or a balloon leak.

Comparing subjects in both groups, there were no significant differences in baseline characteristics with regards to age, sex, PVD, BSA, indication for insertion, and use of a sheathless technique. The 8 Fr IABP catheters were in place for an average of 5 hours longer than the 9.5 Fr IABP catheters. As shown in Table 4, the incidence of major limb ischemia was 1.6% in the 8 Fr group and 2.5% in the 9.5 Fr group ($p<0.05$), which translates into a relative risk reduction of 36% for major limb ischemia with the 8.0 Fr systems. There was no difference in bleeding rates or mortality related to IABP. The 8.0 Fr had a higher incidence of IABP failure: 2.9% versus 1.7% in the 9.5 Fr group. The 8.0 Fr system has a smaller catheter lumen that is more prone to kinking and clotting than the 9.5 Fr system; therefore, the slightly higher failure rate with the smaller catheter is expected.

In summary, the smaller 8.0 Fr IABP catheter was associated with a lower incidence of limb ischemia, but a higher rate of IABP failure. These data suggest that the use of 8.0 Fr IABP catheters in selected high-risk populations may help reduce the incidence of complications.

Sheathed versus unsheathed

Many clinicians think that a sheathless insertion of an IABP reduces the size of obstruction in the femoral artery and, therefore, reduces the incidence of limb ischemia. A small, retrospective, non-randomized study in 126 patients undergoing percutaneous IABP insertion compared the incidence of complications with sheathed versus unsheathed IABP catheters.[10] Sheathless Kontron IABP 9.0 Fr catheters were compared with Datascope sheathed IABP catheters, of which 54% were 9.5 Fr, 26% 8.5 Fr, and 20% 10.5 Fr. The sheathless group was older, had a higher incidence of diabetes and PVD, and the IABPs were in place an average of 9 hours longer than the sheathed IABPs. The incidence of major limb ischemia was lower in the sheathless group, 2% versus 12% in the sheathed group ($p<0.01$). The heterogeneity in the sheath size for the sheathed group raises the question about whether the benefit was due to differences in sheath size or to the sheathless technique itself.

Gol et al conducted a retrospective study in 449 patients to examine whether sheathless insertion reduced complications.[11] The study included patients undergoing cardiac surgery from a single centre in Turkey who required a percutaneous IABP and used Kontron IABP catheters. Unfortunately, there was no description of the baseline characteristics for the sheathed versus unsheathed cohorts. There were no significant differences reported in the rate of ischemic complications.

Finally, the largest study examining this issue was the Benchmark Registry that performed a multivariate analysis for predictors of limb ischemia in a subset of patients (n=7,078) who had a 9.5 Fr IABP catheter inserted.[9] Sheathed IABP catheter insertion was associated with an odds ratio (OR) of 1.79 ($p<0.01$) for any limb ischemia, but a non-significant trend for increased major limb ischemia (requiring surgical intervention), OR 2.42 ($p=0.062$).[9] The sheathless technique did not independently predict bleeding in this analysis.

In summary, there are potential biases in non-randomized comparisons and it is very likely that patients at higher risk of ischemic complications receive the sheathless insertion. However, sheathless IABP insertion likely lowers the incidence of vascular ischemic complications without a significant increase in bleeding, at least, based on the results of the large Benchmark Registry.

Does IABP procedural volume influence outcome?

A study from the U.S. National Registry of MI attempted to address the question of whether IABP procedural volume influences the prevalence of IABP complications.[12] This retrospective study included 12,730 patients with an MI who required supportive therapy with an IABP. The authors divided hospitals by IABP procedural volume into three tertiles of low- (3.4 IABPs/yr), intermediate- (12.7 IABPs/yr), and high-volume (37.4 IABPs/yr) centres. Regardless of the type of reperfusion therapy (primary PCI or thrombolysis), patients with an MI requiring an IABP had a lower mortality at high-volume IABP centres. Furthermore, in a multivariate analysis, high-volume IABP centres were associated with lower mortality (OR 0.71; 95% CI, 0.56-0.90), and this was independent of baseline patient characteristics and therapies. However, it has previously been shown that PCI volume is linked to outcomes for PCI, so it is likely that there are many confounders in this analysis, including higher PCI volumes and onsite cardiac surgery at the high-volume centres. Therefore, the higher mortality for MI patients with IABPs in low-volume centres cannot be solely attributed to IABP complications. Nevertheless, it is prudent to advise that physicians inserting IABP catheters be proficient. It is logical that IABP procedural volume is linked to the prevalence of IABP-related complications, however, this has not been demonstrated definitively.

Summary

The incidence of major IABP complications is 2.6% with an IABP-related mortality of at least 0.05%.[2] The prevalence of IABP-related limb ischemia is at least 2.9% and severe bleeding related to an IABP is 0.8%.[2] Risk factors for IABP complications include PVD, BSA <1.8 m^2, female sex, and age >75 years. Clinicians should use these risk factors to identify patients at risk for IABP complications. Indeed, patients with all 4 risk factors have a 75% risk of an IABP-related complication.[3]

Smaller IABP catheter size (8.0 Fr) is associated with a lower rate of ischemic complications and sheathless insertion may be associated with a lower ischemic complication rate as well.

Recommendations

Patients who require IABP and have risk factors for IABP complications should have 8.0 Fr IABP catheters as a part of institutionally driven protocols to systematically reduce IABP complications. Only proficient individuals should be inserting IABP catheters. Randomized trials to assess the efficacy of the sheathless technique, smaller catheter size, and universal fluoroscopic-guided insertion to reduce IABP complications would be helpful. Furthermore, there is a lack of randomized trials demonstrating an effect of IABP on outcome. Finally, prompt identification and treatment of IABP complications are critical, as demonstrated by the cases discussed at the start.

Acknowledgement: *Special thanks to Dr. Peter Seidelin, an interventional cardiologist at the University Health Network, Toronto, Canada, for his assistance.*

References

1. Braunwald E, Zipes D, Libby P. *Heart disease*. 6th ed. Philadelphia, PA: W.B. Saunders Company; 1997:602.
2. Ferguson III JJ, Cohn M, Freedman Jr RJ, et al. The current practice from the benchmark registry. *J Am Coll Cardiol* 2001;38: 1456-62.
3. Cohen M, Dawson MS, Kopistanky C, et al. Sex and other predictors of intra-aortic balloon counterpulsation-related complications: prospective study of 1119 consecutive patients. *Am Heart J* 2000;139:282-7.
4. Gottlieb SO, Brinker JA, Borkon AM, et al. Identification of patients at high risk for complications of intra-aortic balloon counterpulsation: a multivariate risk factor anlaysis. *Am J Cardiol* 1984;53:1135-9.
5. Alderman JD, Gabliani GI, McCabe CH, et al. Incidence and management of limb ischemia with percutaneous wire-guided intra-aortic balloon catheters. *J Am Coll Cardiol* 1987;9:524-30.
6. Iverson LIG, Herfindahl G, Ecker RR, et al. Vascular complications of intra-aortic balloon counterpulsation. *Am J Surg* 1987; 154:100-3.
7. Skillman JJ, Kim D, Baim DS. Vascular complications of percutaneous femoral cardiac interventions. *Arch Surg* 1988;123:1207-12.
8. Funk M, Gleason J , Foell D. Lower limb ischemia related to use of the intra-aortic balloon pump. *Heart Lung* 1989;18:542-52.
9. Cohen M, Ferguson III JJ, Freedman Jr RJ, et al. Comparison of outcomes after 8 vs. 9.5 French size intra-aortic balloon counterpulsation catheters based on 9332 patients in the prospective benchmark registry. *Cathet Cardiovasc Intervent* 2002;56:200-6.
10. Tatar H, Cicek S, Demirkilic U, et al. Vascular complications of intra-aortic balloon pump: unsheathed versus sheathed insertion. *Ann Thorac Surg* 1993;55:1518-21.
11. Gol MK, Bayazit M, Emir M, Tasdemir O, Bayazit K. Vascular complications related to percutaneous insertion of intra-aortic balloon pumps. *Ann Thorac Surg* 1994;58:1476-80.
12. Chen EW, Canto JG, Parsons LS, et al. Relation between hospital intra-aortic balloon counterpulsation volume and mortality in acute myocardial infarction complicated by cardiogenic shock. *Circulation* 2003;108:951-7.

Abstracts of Interest

The Current Practice of Intra-aortic Balloon Counterpulsation: Results from the Benchmark Registry

FERGUSON JJ 3RD, COHEN M; FREEDMAN RJ JR, ET AL.

OBJECTIVES: This study presents clinical data from the first large registry of aortic counterpulsation, a computerized database that incorporates prospectively gathered data on indications for intra-aortic balloon counterpulsation (IABP) use, patient demographics, concomitant medication and in-hospital outcomes and complications.

BACKGROUND: The intra-aortic balloon pump (IABP) is widely used to provide circulatory support for patients experiencing hemodynamic instability due to myocardial infarction, cardiogenic shock, or in very high risk patients undergoing angioplasty or coronary artery bypass grafting.

METHODS: Between June 1996 and August 2000, 203 hospitals worldwide (90% U.S., 10% non-U.S.) collected 16,909 patient case records (68.8% men, 31.2% women; mean age 65.9 +/- 11.7 years).

RESULTS: The most frequent indications for use of IABP were as follows: to provide hemodynamic support during or after cardiac catheterization (20.6%), cardiogenic shock (18.8%), weaning from cardiopulmonary bypass (16.1%), preoperative use in high risk patients (13.0%) and refractory unstable angina (12.3%). Major IABP complications (major limb ischemia, severe bleeding, balloon leak, death directly due to IABP insertion or failure) occurred in 2.6% of cases; in-hospital mortality was 21.2% (11.6% with the balloon in place). Female gender, high age and peripheral vascular disease were independent predictors of a serious complication.

CONCLUSIONS: This registry provides a useful tool for monitoring the evolving practice of IABP. In the modern-day practice of IABP, complication rates are generally low, although in-hospital mortality remains high. There is an increased risk of major complications in women, older patients and patients with peripheral vascular disease.

J Am Coll Cardiol 2001;38(5):1456-62.

Relation Between Hospital Intra-aortic Balloon Counterpulsation Volume and Mortality in Acute Myocardial Infarction Complicated by Cardiogenic Shock

CHEN EW, CANTO JG, PARSONS LS, ET AL.

BACKGROUND: Increasing evidence suggests an inverse relationship between outcome and the total number of invasive cardiac procedures performed at a given hospital. The purpose of the present study was to determine if a similar relationship exists between the number of intra-aortic balloon counterpulsation (IABP) procedures performed at a given hospital per year and the in-hospital mortality rate of patients with acute myocardial infarction complicated by cardiogenic shock.

METHODS AND RESULTS: We analyzed data of 12 730 patients at 750 hospitals enrolled in the National Registry of Myocardial Infarction 2 from 1994 to 1998. The hospitals were divided into tertiles (low-, intermediate-, and high-IABP volume hospitals) according to the number of IABPs performed at the given hospital per year. The median number of IABPs performed per hospital per year was 3.4, 12.7, and 37.4 IABPs at low-, intermediate-, and high-volume hospitals, respectively. Of those patients who underwent IABP, there were only minor differences in baseline patient characteristics between the 3 groups. Crude mortality rate decreased with increasing IABP volume: 65.4%, lowest volume tertile; 54.1%, intermediate volume tertile; and 50.6%, highest volume tertile (P for trend <0.001). This mortality difference represented 150 fewer deaths per 1000 patients treated at the high IABP hospitals. In the multivariate analysis, high hospital IABP volume for patients with acute myocardial infarction was associated with lower mortality (OR=0.71, 95% CI=0.56 to 0.90), independent of baseline patient characteristics, hospital factors, treatment, and procedures such as PTCA.

CONCLUSIONS: Among the myocardial infarction patients with cardiogenic shock who underwent IABP placement, mortality rate was significantly lower at high-IABP volume hospitals compared with low-IABP volume hospitals.

Circulation 2003;108(8):951-7.

Upcoming meetings

6-9 March 2005
American College of Cardiology Annual Scientific Sessions
Orlando, Florida
CONTACT: Tel.: 800-253-4636, ext. 694
Fax: 301-897-9745
Email: resource@acc.org

20-24 March 2005
21st Annual Cardiovascular Conference
Fairmont Chateau Lake Louise Hotel
Lake Louise, Alberta
CONTACT: www.acclakelouise.com
Hallmark Meeting Concepts
Tel.: (905) 825-2575
Fax: (905) 825-8127

Change of address notices and requests for subscriptions to *Cardiology Rounds* are to be sent by mail to P.O. Box 310, Station H, Montreal, Quebec H3G 2K8 or by fax to (514) 932-5114 or by e-mail to info@snellmedical.com. Please reference *Cardiology Rounds* in your correspondence. Undeliverable copies are to be sent to the address above. Publications Post #40032303

This publication is made possible by an educational grant from

Novartis Pharmaceuticals Canada Inc.