Complications of
Percutaneous Coronary
Interventions
Complications of Percutaneous Coronary Interventions

Forewords by Joseph S. Alpert, MD, and Antonio Colombo, MD

With 92 Illustrations in 233 Parts, 13 in Full Color
How and when my parents instilled my concern for my many patients
and for those whom others care for, I may never know.
This work is dedicated to you, Mom and Dad.
Wherever you are, be proud of what you continue to do for many, many patients.
Every physician hates to have a patient develop a complication. Nevertheless, we also know that when a problem does develop, one needs a clear corrective strategy to minimize the effect of the complication and thereby prevent a major morbid event. The most frightening of all cardiologic complications occur in the catheterization laboratory. Indeed, Lewis Dexter, one of my mentors, told me about his first, accidental catheterization of the pulmonary artery. When he saw, under the fluoroscope, that the catheter was dancing back and forth in the lung, Dr. Dexter was convinced that he had perforated the patient's heart while trying to thread the catheter through the right atrium to the renal veins. However, after some thought and observation, he realized that he had not encountered a complication; instead he had tripped upon the opportunity to diagnose and understand various forms of heart diseases. Clinical cardiac catheterization had been born!

The 14 chapters in this book have various real-life complications that have occurred during coronary intervention. They also describe various strategies for avoiding or managing them. The chapters take the reader sequentially through a variety of situations, any one of which would make for a potentially “bad day” in the catheterization laboratory. Starting with medication problems, the authors work their way from the groin to the coronary arteries, detailing unpleasant situations and how to deal with them. All types of intervention and every device employed are considered, including balloon angioplasty, guidewires, stents, brachytherapy, and closure devices for sealing off peripheral arterial access. Other forms of complication are also considered, such as the no-reflow phenomenon and early versus late complications. Finally, the legal and liability concerns of these complications are examined, as are resuscitation and the reporting of adverse events.

This highly complete, readable, and useful text will be of inestimable value to catheterization personnel.

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No procedures: no complications.

In most conferences of interventional cardiology, the sessions dealing with "Complications" are usually the ones where few or no empty seats are available. The most effective way to dramatically reduce and truly eliminate the risk for complications is not to perform a procedure. In real life this approach translates into what we call "patient selection." The experience accumulated in almost 30 years of percutaneous coronary interventions has given us some useful information to enable us to estimate the risk of complications according to the characteristics of the patient and of the lesion. A very common evaluation we all perform before any intervention is to estimate the risk versus the benefit of the procedure we plan to perform. A procedure is considered appropriate when the risk of complications is far below the potential clinical advantage. In some circumstances, such as in percutaneously treating a patient with cardiogenic shock, we are ready to accept a very high risk of complications in the face of a much higher risk associated with the natural history of the untreated condition.

Besides these foreseeable complications there are a group of complications that are very rare and almost never occur (less than 1%). Nevertheless, on an "unlucky day" we may experience one of these. These complications are the worst because they are totally unexpected, and they may occur with the operator unprepared and not trained to deal with them (the very reason why this patient, a low-risk case, was selected). The operator not infrequently has an initial sense of bewilderment, which may further delay an effective management.

The truth of the matter is that no matter what strategy an interventional cardiologist is going to use, in no way is he liberated from the occurrence of complications. Perhaps one of the highest risk periods in the practice of interventional cardiology occurs following long intervals in which many procedures were successfully performed and no complications occurred.

The point of this discussion is that familiarity with most complications (never all, as there is always the complication not yet described), their associated factors, their pathophysiology, their treatment, and ways to minimize their occurrence are essential in the education of every interventional cardiologist. These are the reasons that I consider the work of Samuel Butman a laudable contribution to the field. Even though a lot has been written about complications and journals frequently describe case reports and reviews, it is very useful to have a single book that systematically approaches the issue of complications that may occur in performing coronary interventions. It is important to keep in mind that as devices evolve the potential for even newer
complications arises as well. We now treat more complex patients because we feel more experienced and have better devices and because we are not afraid to deal with undilatable lesions or to attempt to reopen total occlusions considered untreatable in the past. The result of this more aggressive approach, which gives more options to patients, is the emergence of new complications or familiar complications presenting in a different way. It is quite different to deal with a coronary perforation in a patient on heparin compared to one receiving IIb/IIIa inhibitors or bivalirudin.

For these reasons there is need for an updated approach to complications. I think this work fulfills these requirements. Each chapter is introduced by a detailed case presentation describing the occurrence of and, at times unsuccessful, solution to a specific complication. A review of the literature with cases, the pathophysiology of the complication, and the various proposed treatments are then presented. There are some important and novel chapters—"Legal Complications of Percutaneous Coronary Procedures" and "Adverse Event Reporting: Physicians, Manufacturers, and the Food and Drug Administration"—interesting for both practitioners and the many ancillary people involved in these procedures. All the contributors are very experienced and provide a reliable and very credible evaluation of each topic.

I cannot conclude this introduction without mentioning that besides my profound interest in reading and learning about complications, I am absolutely delighted to write these words because my association with Sam dates to the time when I was a cardiology fellow at the Veterans Administration Hospital in California and I performed my first angioplasties under his direction. More than anything else, I am happy to see a tool that many interventionalists will find very useful. Careful and critical reading of this book may ultimately help to effectively prevent some complications, and even if the complications occur, the reader may feel more confident and capable of instituting the most appropriate treatment.

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Preface

In the first 125 interventional procedures I performed in the early 1980s, using primitive equipment, no patient had a myocardial infarction, none required urgent surgery, and none died. That run did not last, of course, and now having performed over 2,200 percutaneous coronary interventions, I know better. Perhaps it is simply a wish to pass along the idea of "knowing better" that has led me to this task.

The idea for writing this book came not from a particular untimely event during an interventional procedure. Rather, it arose from a combination of factors: occasional reviews of legal files, where complications occur in laboratories far away and by cardiologists I do not know; events discussed at our weekly conferences; and complications I have witnessed or been a party to.

It appears that at times we are unaware of some of the risks to which we subject ourselves, and more importantly our patients. While most of us would prefer that complications simply not occur, this is not the case. Complications are an unfortunate but real part of percutaneous coronary interventions.

The purpose of this book is to put as many of the complications reported and experienced by many in this field under one cover, to serve as a tool and resource for trainees, for technical staff, for laboratories, and for cardiologists alike. As is true with most things in life, better education and dissemination of the information can only improve on what we do. The authors contributing to this book are dedicated to bettering interventional cardiovascular care by minimizing the number of complications, always a source of angst for all.

This book is organized in a familiar proximal (skin) to distal (coronary intervention) approach, with several additional chapters rounding out its scope. Information into both legal ramifications and government responsibilities provides further insight into the risks and benefits of the devices and the procedure more and more of our patients continue to embrace.

My background as an interventional cardiologist is straightforward. After having learned the basics in the early 1980s, I was proctored, and then I developed a coronary interventional program at the Veteran's Administration Medical Center in Long Beach, California. Later, I moved to Arizona where, as director of the Cardiac Catheterization Laboratories, I developed a state-of-the-art active multivessel interventional program at the University of Arizona in Tucson. We have had an outstanding success rate, combined with a very low complication rate during my tenure as director, nearly 20 years.

I could not have written this book without the open and honest assistance of my coauthors—who all agreed to lead their chapters with an unfortunate case of their own—and the daily support of the excellent CCL staff who are not only well trained but a pleasure to come to in the morning and reluctantly
meet, as we do at times, during the odd hours of the night. My editor at Springer, Robert Albano, and his developmental editor, Stephanie Sakson, were supportive and generous with their time and patience. Finally, a special note of gratitude to Eva, my partner, and a co-author, as well. Next time I will not take my work with me on vacations.

_Samuel M. Butman, MD, FACC, FSNAI_
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1
Introduction

Samuel M. Butman

“Complications: It’s just as important to share the cases that don’t go according to plan”
From the cover of Endovascular Today, Volume 3, July/August 2004

There is gratification in performing a high-risk intervention in a patient wary of general anesthesia, surgery, and a prolonged recovery (Figure 1-1). Unfortunately, this can be easily offset when an unexpected complication occurs during a seemingly straightforward intervention, necessitating additional and unplanned interventions to avert disaster (Figure 1-2). This is the reality of day-to-day percutaneous coronary interventions performed, on average, in 25% of patients undergoing diagnostic coronary angiography.

Why write a seemingly negatively charged book? Which, if any, interventionalists would agree to contribute cases, let alone a chapter? The answer to the first question is simple: With the reality that the majority of procedures are uncomplicated, it is easy to go through training, work in a busy cardiac catheterization laboratory, and practice for some time doing a moderate number of interventions, and not be aware of the myriad of complications that can occur or, more importantly, that may be averted. More information and a greater dissemination of the information can only further improve outcomes—the goal of this book of bad things that can happen to good people.

Indeed, it was somewhat difficult to find experienced cardiologists willing to contribute, not so much due to the subject matter, but because so many of us are simply too busy. However, all agreed with the aim in publishing this book of complications, accepting that they occur, albeit infrequently, that they may be avoidable, and that they are more readily managed when we know more about them. As I write this introduction with all the contributing chapters finalized, novel complications are being reported.

Approximately one million percutaneous coronary interventional procedures were performed in 2003 in the United States, with twice that number performed worldwide. An estimated 7500 interventional cardiologists in the United States and another 11,000 worldwide performed these complex and high-risk procedures in 1500 U.S. and foreign hospitals. The numbers continue to increase with expanding indications, improved tools, and better long-term outcomes with drug-coated stents, which reduce the incidence of restenosis. The incidence of significant adverse events is very low, with recent reports describing overall complication rates between 1% and 5%. There are an increasing number of physicians performing percutaneous coronary intervention, and while many perform a low volume of procedures, success rates of over 97% are still expected.

With hundreds of procedures being performed worldwide daily, even a 2%-3% complication risk is an important consideration to both the physician and the patient involved in a procedure, more so if an actual adverse event occurs during the procedure. Complications range from the minor bruise postprocedure to the rare but life-threatening pulmonary hemorrhage due to glycoprotein IIb/IIIa inhibitor therapy, aortic dissection from an ostial vessel dilatation, or death after failure of resuscitative efforts. This book is a compilation of many published reports, data freely available from U.S. Food and Drug Administration websites, personal experiences of my colleague–authors, and my own database of events, with the hope that knowledge of potential and real missteps and a better identification of the early signs of compromise will lead to even better outcomes for all.

Models of risk prediction and stratification of higher risk patients were reported early in the percutaneous coronary balloon angioplasty experience. These continue to be reported regularly from many sources, reflecting both the growing library of experience and the newer and more novel technologies. While of moderate use in prediction and patient selection, the ever-improving and
changing tools and drugs available have minimized the real effect of these reports on patient selection on a day-to-day basis. Since the advent of coronary stenting, type B and C coronary lesions do not portend the same risk as they did during the era of "plain old balloon angioplasty." Conversely, most clinicians who have experienced severe no-reflow during the treatment of a degenerated vein graft or during the course of an acute infarct vessel angioplasty have learned to both be aware of the potential and, from the literature, know how to treat it. We now have a better understanding of who is at risk and what works to avoid and treat the no-reflow event. The con-
1. Introduction

Continuing reports in our specialty journals, the wisdom of those with large experiences in textbooks on interventional cardiology, and our own clinical experience are all invaluable in affecting the care we provide our patients.

The risks have remained low, but even an occasional bad event should cause us to stop and reconsider what we do. The availability of an alternate therapy, be it medical or surgical, should always be an option considered. Coronary perforations are uncommon today, but there is still a risk as we develop better or more aggressive interventions to open chronic total occlusions. As we begin to more frequently consider interventions in patients with left main coronary artery stenoses, untoward events will continue to occur in the coronary artery, in the groin, or postprocedure and range from nuisance to life threatening. This is an ever-changing landscape with continual improvements and new potential problems as we leave the older technology for newer and improved tools.

Success in the cardiac catheterization laboratory is dependent not only on proper selection of patients, but also on skilled and focused technical staff and better-than-adequate imaging equipment. Better imaging

![Figure 1-2](image)

**Figure 1-2.** (A) Left coronary angiogram in the apical cranial view. High-grade disease is seen in the mid left anterior descending artery just distal to the origin of a diagonal branch. (B) Left anterior oblique cranial view with the intravascular ultrasonographic catheter at the lesion. A second wire is in the diagonal branch. (C) After balloon dilatation with a second, larger, cutting balloon, inadvertently oversized to the proximal vessel from intravascular ultrasound data, there is dissection of the LAD with reduced blood flow. (D) Additional unplanned stents were successfully placed with a good final angiographic result.
equipment is critical, and the manufacturers continue to move forward with us in this regard. The increasing body mass of our aging population, the growing number of procedures being performed, and the need for better visualization as we attack more complex anatomy all demand the best imaging equipment as well as improved wires, balloons, and guide catheters. The catheterization laboratory technical staff may not always make or break a case, but they can assist or distract a physician from the task at hand. How easily an exchange wire is kept in place, rather than inadvertently moved, or how quickly an expanding hematoma or coronary dissection is recognized makes a difference. Having a dedicated, stable, and focused team is key to facile, safe, and more frequently successful outcomes.

A final note to ponder, both ethical and legal, is how we approach our patients before they reach the laboratory, specifically the manner in which they are asked to sign their consent forms. Are our patients being properly informed about the risks and benefits of coronary revascularization, be it percutaneous or surgical? The answer comes from a recent poll of patients. In this report, 42% of the patients could not identify the risk of percutaneous coronary intervention, and a similar number could not identify the possible benefits of the procedure! While the numbers were slightly worse for surgical revascularization, two-thirds could not quantify the risks inherent during percutaneous coronary intervention. One can only wonder what number of interventional cardiologists might fare similarly. This figure should not be surprising given the ad hoc, frequently routine approach of percutaneous coronary intervention today. Do we tell our patients that the risk of coronary perforation and death is higher when we are dealing with a more complex lesion or a total occlusion, or when we are using a bigger balloon or a more complex device? Are we describing the myriad of noncoronary complications that may occur? What about alternative approaches and their risks? Are they honestly and openly discussed with the patient? Would our surgical colleagues agree? Should we postpone a potential same-day intervention when other options exist, or when particularly high-risk anatomy is present? How often do we ask a surgeon to discuss options with the patient before possible percutaneous intervention?

The book is organized in the manner that we perform the interventions, from “skin to skin,” with a few additional chapters. Of note, the chapter on the legal aspects of percutaneous coronary intervention is not meant to be a distraction or cause for alarm, but rather it is aimed at a better understanding of what can and cannot be done to prevent further suffering if an untoward event does occur. Specific approaches to treating complications are dealt with in each chapter to some degree, but are not the focus of this book. They have been described in several general textbooks on coronary intervention. It is the hope of all contributors that anticipating or recognizing a problem or minor mishap earlier as a result of reading this book will lead to less serious adverse events and better outcomes for both our readers and our patients.

References

2 Complications of the Medications

Paul E. Nolan, Jr. and Toby C. Trujillo

In the United States nearly 600,000 percutaneous coronary interventions (PCI) are performed annually. Adjunctive pharmacologic therapies are used to facilitate and assure favorable patient outcomes in the setting of PCI. However, complications, some severe, occur with the use of these adjunctive therapies. This chapter will discuss selected complications, including their prevention and treatment.

1. Case 1. An Unusual Bleeding Complication

A 28-year-old male presented to the emergency department complaining of chest discomfort and shortness of breath that began 1 hour prior to arrival. The past medical history was significant for three orthotopic heart transplantations. He also had a history of mild chronic renal insufficiency. His medications included cyclosporine, azathioprine, prednisone, diltiazem, and pantoprazole. The initial electrocardiographic readings revealed sinus tachycardia at a rate of 105 beats per minute (bpm) and marked ST-segment depression in leads V4-V6. During the ensuing cardiac catheterization, a high-grade coronary stenosis of the left circumflex artery was found and mild pulmonary hypertension was documented. He was given 4000 U heparin intravenously (IV) and a 180μg/kg IV bolus of eptifibatide, followed by a continuous IV infusion at 2.0μg/kg/min. Following angioplasty and implantation of a drug-eluting stent, there was no residual stenosis. The patient was prescribed 325 mg aspirin and 75 mg clopidogrel, after a loading dose of 300 mg was given in the cardiac catheterization laboratory. Baseline laboratory values included hemoglobin of 10.7 g/dL, hematocrit of 31%, platelet count of 249,000/mm³, and a serum creatinine of 1.9 mg/dL. Six hours postintervention, the patient began complaining of shortness of breath, was noted to be hypoxic, and developed hemoptysis of about 100 mL. The eptifibatide infusion was stopped and the patient was transferred to the cardiovascular intensive care unit for observation. The initial chest X-ray revealed haziness throughout both lungs, bilateral pleural effusions, and cardiomegaly. A second X-ray performed 9 hours later revealed alveolar and interstitial edema and an increase in the right pleural effusion. In the ensuing 72 hours, hemoglobin levels fell to 8.7 g/dL and the platelet count fell to 177,000/mm³. The remainder of the hospital course was one of recovery and he was subsequently discharged home with a diagnosis of pulmonary hemorrhage related to eptifibatide.

2. Bleeding Complications

Hemorrhagic complications represent a worrisome, relatively common, acute adverse event associated with PCI and its attendant pharmacotherapy. In clinical trials hemorrhagic complications generally have been classified as major, moderate, or minor according to definitions originally used either in the Thrombolysis in Myocardial Infarction (TIMI) or Global Utilization of Streptokinase or tPA Outcomes (GUSTO) trials. However, these arbitrary definitions, which were originally conceived for thrombolytic trials, may underestimate the true incidence of clinically important hemorrhagic complications following PCI in the modern era of combined anticoagulant and triple antiplatelet therapy. Additional predictors of bleeding include advanced age, female gender, renal impairment, hepatic dysfunction, diabetes, and post-PCI heparin use (Table 2-1). Additional predictors of bleeding include...