Review

Interventional Cardiology

Infectious complications of percutaneous cardiac procedures

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Percutaneous coronary intervention (PCI) and interventional structural heart disease procedures have steadily increased worldwide over the last two decades. Patient infection is a potential complication of percutaneous cardiac procedures, but the incidence is very low due to the use of sterile techniques and percutaneous arterial puncture. Infection can be categorized as occurring at the access site, which includes vascular closure devices, or locally within the implanted device or a cardiac structure. Although rare, endovascular and cardiac infection can be challenging to diagnose and may have catastrophic consequences. In most cases, treatment requires prolonged parenteral antibiotics and surgical intervention. A comprehensive review of all reports of infection related to percutaneous cardiac procedures since 1994 is covered as are the current infection control guidelines.

Keywords: complications • infection • percutaneous coronary intervention • *Staphylococcus aureus* • vascular closure device

Infections are an inherent risk of any invasive procedure or indwelling temporary or permanent device. Fortunately, for percutaneous procedures performed with sterile technique the incidence is rare. Although infection rates may be underestimated by reporting bias or missed diagnosis, a large retrospective study involving over 22,000 cardiac procedures found a bloodstream infection rate of 0.11% [1]. Several potential sources may introduce bacteria to the access site, the blood stream or a remote location. Localized infection can occur at any site of vascular injury such as the access site, or in an implanted device. The factors influencing the pathogenesis of procedure related infections include the virulence of the pathogen, host response, and the properties of the device. In this review, infections related to arterial access, as well as implanted cardiac devices including stents, valves and septal closure devices are covered in detail. In addition, indications for antibiotic prophylaxis and standards for infection control are discussed.

Cardiac catheterization

Diagnostic coronary angiography and percutaneous coronary intervention (PCI) are the most common procedures performed in cardiac catheterization laboratory. In 2010, over 1,000,000 diagnostic cardiac catheterizations and 950,000 PCI procedures were performed in the USA [2]. In the current era, over 95% of PCI is performed with stents, with a predominance of drug-eluting stents (DES) over bare-metal stents (BMS) [3]. A small prospective study of 147 complex PCI patients demonstrated a rate of positive blood cultures of 18% immediately following the procedure and 12% at 12 h. However, in this series, no patients had evidence of clinical infection. This study demonstrates that transient bacteremia is common and generally clears without sequela [4]. A larger retrospective series found PCI related bacteremia in 0.64% of patients [5].

Access site infections

The Swedish physician Sven Seldinger is largely credited for introducing a guidewire

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technique to improve the safety of vascular access. With rare exception, percutaneous venous or arterial cannulation for cardiac catheterization is achieved utilizing a modification of Seldinger's original technique. This procedure effectively places a plastic or composite sheath into a superficial blood vessel allowing catheters to be delivered to cardiac structures [6]. The majority of sheaths placed in the catheterization laboratory are removed at the completion of a procedure or shortly thereafter, which minimizes risk of infection. In the critical care setting where catheters remain inserted for longer periods, the risk of catheter related bloodstream infections is around 2% [7].

Manual compression has long been the method for achieving hemostasis after cardiac catheterization, and arterial infection after cardiac catheterization utilizing this method remains a rare event. Septic endarteritis is an infectious complication of femoral artery cannulation. On literature review, septic endarteritis after femoral artery catheterization and PCI with hemostasis by manual compression has been reported in 20 cases. All of these case reports were associated with certain risk factors such as repeat ipsilateral puncture and prolonged sheath times. Hematoma at the arterial access site can also serve as a nidus for infection. The majority of these infections were caused by staphylococcal infection and required arterial debridement, reconstruction and long-term intravenous antibiotics [8]. Without timely and appropriate treatment, septic arterial aneurysms can rupture or seed additional sites. Septic endarteritis following manual compression after diagnostic catheterization has not been reported. It appears that PCI, perhaps in the context of increased procedural time, provides the increased risk for septic endarteritis. In addition, the use of procedural anticoagulation such as heparin may increase the risk of local infection and bacteremia [8].

Practices that may reduce the risk of septic complications of catheterization include avoidance of access through vascular grafts or surgical sites such as prosthetic hips. Sheaths should not be left in place longer than required. For patients that require staged procedures, the sheath should be removed and alternative access used for the subsequent procedure. There is no data supporting the use of prophylactic antibiotics for catheterization access sites managed with manual pressure.

Vascular closure device infection

Percutaneous vascular closure devices (VCD) have been increasingly used in order to shorten time to ambulation and reduce access site complications in the setting of femoral artery cannulation. Recent data have reported device use in approximately 37% of PCIs and there are significant reductions in vascular complications and the need for blood transfusions [9]. The purported benefits of VCD must be considered against the infectious risks of a foreign body implant. These devices can be broadly separated into suture closure and vascular plugs with collagen or polyethylene glycol. There have been reported cases of septic endarteritis with the use of the Perclose device (Abbott Laboratories, Abbott Park, IL, USA) in diagnostic catheterization. In this setting, it appears that the VCD itself portends the increased infection risk regardless of whether or not coronary intervention was performed.

The Manufacturer and User Facility Device Experience (MAUDE) database is a voluntary reporting system maintained by the US FDA. There appear to be numerous infectious complications entered into this database, which are not reported in the medical literature. All of these cases tend to be similar with delayed presentation of infection (range of 4–28 days), extensive necrosis of the femoral artery requiring reconstruction, and infection with *Staphylococcus aureus*. All of these complications appear to be treated with long-term intravenous antibiotics [10].

The Mayo Clinic performed a retrospective analysis of VCD-related infections between1 January 2000 and 31 December 2003. A total of 46 cases in the medical literature and six cases from their own institution of VCD-related infections were reported. Diabetes mellitus and obesity were the most common comorbidities and *Staphylococcus aureus* was responsible for most (75%) of the infections. Interestingly, Mycotic pseudoaneurysms (22 cases) were the most common complications and most of these patients underwent surgical debridement and reconstructive procedures [11].

Coronary artery stent infections

Stent infection is equally as rare as access site infection but carries more significant morbidity and mortality [12–14]. With the increasing use of DES there is a theoretical increased risk of infection over BMS, in part due to their immunomodulatory properties and delayed endothelialization compared to BMS [15]. Review of the current literature yielded 25 reported cases of coronary stent infection (Table 1) [16–38]. The plurality of infections (48%) was in patients receiving DES followed by BMS (32%). Two patients (8%) developed a coronary infection in the setting of balloon angioplasty. The remainder of patients the stent type was unknown. The most common organism implicated was *Staphylococcus aureus* (80%) followed by *Pseudomonas aeruginosa* (20%).

Table 1. Reported cases of coronary intervention-related infection.

Author (year)	Patient age (years)/sex	Presenting symptoms	Time of onset after procedure	Vessel	Vessel pathology	Organism	Type of stent	Antibiotic therapy	Surgical therapy	Outcome	Ref.
Furtado (2011)	62/M	Fever/angina	2 weeks	LAD	Pseudoaneurysm	*P. aeruginosa*	DES	Yes	Yes	Survived	[36]
Patel (2013)	60/M	Fever	8 weeks	LAD	Coronary aneurysm	MRSA	DES	Yes	Yes	Survived	[29]
Leory (1999)	49/M	Fever	7 days	LAD	Pseudoaneurysm	*P. aeruginosa*	BMS	Yes	Yes	Died	[18]
Bouchart (1997)	38/M	Fever	6 days	LCX	Aneurysm	*P. aeruginosa*	BMS	Yes	Yes	Survived	[17]
Grewe (1999)	54/M	Fever/angina	4 days	LAD	Pericarditis	MSSA	BMS	No	No	Died	[38]
Rensing (2000)	67/M	CP/fever	5 days	SVG	Abscess/mass	*S. aureus*	BMS	Yes	No	Survived	[30]
Bangher (2003)	55/M	Fever	4 days	RCA		CN-staph	BMS	Yes	Yes	Survived	[20]
Golubev (2004)	53/M	Fever	2 days	SVG	Abscess	MSSA	Stent	Yes	Yes	Died	[24]
Singh (2005)	56/M	Fever/MI	4 days	LAD	Aneurysm	MSSA	SES	Yes	Yes	Survived	[19]
Hoffman (2005)	80/M	Fever/chills	5 days	LAD	Abscess	MSSA	Stent	Yes	No	Survived	[21]
Alfonso (2005)	47/M	Fevers	2 days		Mass/abscess	MSSSA	DES	Yes	No	Died	[35]
Schoenkerman (2009)	59/M	Fevers/chills	4 days	LAD	Aneurysm	*S. aureus*	BMS	Yes	No	Died	[32]
Schoenkerman (2009)	54/M	Fevers	2 years	RCA	Aneurysm	*S. aureus*	DES	Yes	Yes	Survived	[32]
Schoenkerman (2009)	68/M	Fevers/CP	4 weeks	LAD, LCX		MSSA	DES	No	No	Died	[32]
Gunther (1993)	66/F	Fever	28 days	RCA	Abscess	MRSA	BMS	Yes	Yes	Survived	[25]
Liu (2003)	72/M	Fever/CP	18 days	LAD	Aneurysm	MSSA	BMS	Yes	Yes	Survived	[28]
Garg (2007)	86/F	CP	16 days	LAD	Aneurysm	MSSA	SES	Yes	No	Died	[23]
Gonda(2007)	75/M	Fever	11 months	RCA	Abscess	MRSA	PES	Yes	Yes	Survived	[16]
Elieson (2012)	66/F	Fever	17 days	RCA	Abscess	MRSA	DES	Yes	No	Died	[22]
Le (2007)	73/M	Fever	3 months	LCX	Pseudoaneurysm	*S. aureus*	SES/PES		Yes	Died	[27]
Jang (2007)	54/M	Fever	4 months	RCA	Perforation	*S. aureus*	PES	yes	Yes	Survived	[26]
Salinas (2007)	43/M	Fever	7 days	RCA	Aneurysm	MRSA	Balloon	Yes	Yes	Died	[31]
Sanakari (2000)	63/F	Fever	1 day	LCX		*S. aureus*	BMS	Yes	No	Survived	[37]
Timist (1993)	66/F	Fever	2 days	RCA	Abscess	*P. aeruginosa*	Balloon	Yes	Yes	Survived	[33]
Wu (2010)	59/M	Fever	NR	LM	Aneurysm	MRSA	DES	Yes	No	Survived	[34]

BMS: Bare-metal stent; DES: Drug-eluting stent; F: Female; LAD: Left anteior descending; LCX: Left circumflex; M: Male; MRSA: Methicillin-resistant *Staphylococcus aureus*; MSSA: Methicillin-sensitive *Staphylococcus aureus*; PES: Paclitaxel-eluting stent; RCA: Right coronary artery; SES: Sirolimus-eluting stent; SVG: Saphenous vein graft.

Risk factors

The etiology of periprocedural infection is unknown; however, there are several risk factors that predispose patients to coronary stent infection. The major risk factors for developing infectious complications post procedure are congestive heart failure, age >60 years old, and procedure related risk factors such difficult vascular access, repeated catheter insertion and duration of sheath retention [17].

Clinical presentation & diagnosis

The diagnosis of coronary artery stent infection presents several challenges. In our review, the most common symptoms are fever and chills and chest pain. However, the nonspecific nature of these symptoms often lead to delay in diagnosis and treatment. Furthermore, the time from stent implant to presentation is also variable, ranging from 2 days to 4 months. A high degree of clinical suspicion, therefore, is required. In the absence of a clear etiology of symptoms stent infection should be considered.

One criteria proposed to aid in the diagnosis of stent infection is the presence of three or more of the following risk factors:

- Placement of a coronary stent within the previous 4 weeks;
- Multiple repeat procedures performed through the same arterial sheath;
- The presence of bacteremia, significant fever, or leukocytosis with no other cause;
- Acute coronary syndrome;
- Positive cardiac imaging [39].

Coronary stent infection manifests in many forms, including coronary artery abscess, aneurysm, and pericarditis. The most common modality used for diagnosis was coronary angiography, but there has been reported use of transthoracic echocardiography, transesophageal echocardiography [17–19], computed tomography coronary angiogram [18,39], cardiovascular magnetic resonance imaging [16], and more recently, PET imaging has been used to diagnosed endovascular stent infection [40].

As evident by this review there is a trend towards higher infection rates with DES. Theoretically, the higher infection rates with DES might be due to impairment of local host defense mechanism and endothelialization of the stent struts by the immunomodulatory drugs released from the stents, which serves as a nidus for infection.

Treatment

The ideal antibiotic duration or mode of treatment for coronary stent infection is unknown. A review by Elieson and colleagues suggested that early-onset infection, defined as <10 days after stent implantation, may be treated with prolonged broad spectrum antibiotics alone. Late-onset infection, defined as ≥10 days after implantation, or major complication, usually necessitate combined surgical and medical therapy [22].

Our contention, based on this case review is that stent infection should be treated similar to infected vascular and valvular prosthesis, where a combined antibiotic and surgical approach is preferred. The goal is total removal of infected material, and subsequent installation of an extra-anatomical or bypass graft. In this review, more than half of the patient survived (60%), and the majority required a combination of both prolonged broad spectrum antibiotic therapy and surgery.

Noncoronary device infections

Permanent implantation of non-coronary devices are being increasingly performed in the cardiac catheterization laboratory including percutaneous heart valves, septal closure devices and endovascular stent grafts. These procedures have a theoretically higher risk of infection compared to intracoronary stents due to larger sheaths, multiple access sites and in some circumstances need for arterial cutdown. In addition, these devices employ prosthetic graft material in addition to a metal alloy.

Transcatheter aortic valve replacement

Infectious complications have been reported with transcatheter aortic valve replacement (TAVR). A recent literature search utilizing MEDLINE-EBSCO and PubMed databases identified ten cases of infective endocarditis (IE) occurring after the TAVR procedure. Most of these IE cases occurred months after the procedure with a mean time to onset of 186 days. The infected valve was the CoreValve (Medtronic CV, Luxembourg) in six of the cases and the Edwards SAPIEN valve (Edwards Lifesciences, CA, USA) in the other four cases. Some of the predisposing factors that these investigators noted included recent PCI, recurrent recent urinary tract infections, probable pneumonia, recent dental procedure, repeated attempts at CoreValve implantation, and mechanical ventilation [41].

The initial clinical symptoms of IE in these TAVR cases included but were not limited to fever, dyspnea, malaise, and elevated inflammatory markers. The echocardiographic findings included vegetation in four of the cases, severe mitral regurgitation with rupture of the anterior leaflet in two cases, left ventricular outflow tract to left atrium fistula in two cases, one case of an echo-free space in the wall of the ascending aorta where the stents of the CoreValve were observed, and

one case there were no echocardiographic findings. In contrast to access site infections, multiple different pathogens were identified including *Staphylococcus* species (three cases), *Streptococcus* species (two cases), and atypical bacteria such as *Enteroccocus faecium*, *Corynebacterium*, and *Moraxella nonliquefaciens*, as well as fungi such as *Histoplasma capsulatum* and *Candida albicans*. Seven patients were treated with antibiotics alone, three required surgery, and in follow-up analysis four patients died [41].

The estimated incidence of IE following TAVR ranges between 0 and 2.3%, which is comparable to surgical prosthetic valve endocarditis incidence of 0.1–4% per year. Despite adequate and aggressive antibiosis and surgical revision, mortality remains high, ranging from 20 to 80% of affected patients [40]. The mechanisms of pathogen exposure include an intraoperative contamination event or a postoperative event from a remote infectious source. Transfemoral TAVR may be achieved via surgical cut-down to the common femoral artery, followed by primary closure at procedure completion or a by a fully percutaneous approach utilizing a VCD. A 2013 study of percutaneous access and closure compared to cut-down revealed that wound infections requiring prolonged antibiotics use or surgical debridement occurred significantly more frequently in the surgical group (0.7 vs 6.7%; p = 0.007) [42]. If a cut-down is utilized, infection control precautions need to be as strict as if the procedure were performed in a surgical suite. Due to the high morbidity associated with IE related to TAVR, clinicians should implement antibiotic prophylaxis directed against skin flora prior to the TAVR procedure. In addition, subacute bacterial endocarditis prophylaxis guidelines for prosthetic cardiac valves should be followed, particularly in the context of an increased risk of IE as a result of procedural aortic insufficiency [43].

Endovascular closure of septal defects

Congenital heart defects including atrial septal defect (ASD) and patent foremen ovale, have indications for closure and are often treated via an endovascular approach; however, there is a paucity of literature that details infectious complications of these procedures. An Italian study analyzed 417 patients that underwent transcatheter occlusion of secundum type ASD between December 1996 and January 2001. Complications were categorized as major and minor. The devices analyzed were the CardioSEAL/STARFlex (NMT Medical, MA, USA) in 159 patients and the Amplatzer Septal Occluder (St Jude Medical, MN, USA) in 258 patients. With respect to infectious complications, there were only two reported cases of IE post transcatheter ASD closure. This study highlights that infectious complications, more specifically IE is an exceedingly rare complication in the transcatheter septal closure era [44]. Prophylaxis against subacute bacterial endocarditis is recommended for 6 months after catheter based closure of congenital heart defects, during the period of device endothelialization [43].

Infection control in the cardiac catheterization laboratory

The standardization of central access procedures has resulted in the widespread use of sterile insertion measures. Many hospitals utilize checklists and involve nursing or other team members during procedures to ensure that not only is the correct procedure being performed, but that an experienced operator is following sterile technique and maximizing barrier precautions. Clinical practice guidelines for infection control in the cardiac catheterization laboratory have been proposed. The Society for Cardiovascular Angiography and Interventions (SCAI) most recently updated guidelines in 2006 [45]. Table 2 outlines the best practices for prevention of infections including patient preparation, access site management, personnel and laboratory cleaning recommendations.

Conclusion & future perspective

Infectious complications of percutaneous cardiac procedures are rare but must be considered in any patient presenting with fevers, chills or bacteremia in the initial 4 weeks following a procedure. There are several clinical and procedural related risk factors for infection including presence of congestive heart failure, age over 60 years, difficult vascular access, sheath duration or repeated catheter insertion. Treatment generally includes prolonged antibiotics and surgical intervention to remove any infected prosthesis. SCAI has proposed guidelines for the prevention of infection and careful implementation of their recommendations may improve patient outcomes. In an era of patient centered medicine and accountability in healthcare, prevention of procedural-related infections is of paramount importance.

Percutaneous procedures performed in the cardiac catheterization laboratory or in a hybrid operating room are increasing in scope and complexity. Concurrent with this growth is the need for adequate training of staff and strict adherence to sterile procedures. Driven in part by financial penalty for nosocomial infections, the infection control field is in constant evolution. A variety of device related factors have been developed and tested with varying results. A recent large meta-analysis revealed a marked reduction in catheter related blood stream infection with the use of antibiotic impregnated or heparin coated catheters [46]. Although conceptually

Table 2. Best practices for infection control.

Patient preparation	Personnel	Laboratory cleaning
• Do not remove hair unless necessary and use a hair clipper as opposed to shaving • Clean skin with 2% chlorhexidine preparation • Use surgical drapes that remain effective barriers when wet • Identify and treat remote infections prior to elective procedures, or postpone procedures until infection has resolved • Use sterile gauze with semipermeable dressing to cover catheter site • Avoid brachial artery cut-down procedures • Antibiotic coverage against skin flora should be used for the diabetic patient utilizing VCD • Do not remove hair unless necessary and use a hair clipper as opposed to shaving	• Adequate hand washing is the most important • Standard precautions • Brushless, waterless alcohol based scrubs are preferred because of less hand irritation, increased efficacy, and immediate bactericidal activity • Masks and surgical caps have not been shown to lower infectious complications of diagnostic cardiac catheterization • Adequate hand-washing is most important	• If visible soiling occurs following a case, surfaces and equipment should be disinfected • After the last procedure of the day, wet-vacuum or mop the floors with a single use mop and an environmental protection agency-registered hospital disinfectant • Air vents should be cleaned at least monthly and ventilation system should ideally provide at least 15 air exchanges per hour of which at least three should be fresh air • Doors to the catheterization laboratory should be kept closed, except as necessary for passage of equipment or personnel • After a catheterization procedure has started, the number of personnel allowed to leave or enter should be kept to a minimum • If visible soiling occurs following a case, surfaces and equipment should be disinfected

VCD: Vascular closure device.
Data taken from [45].

in its infancy, a recent study suggested the incorporation of a novel group of Factor XIIIa (plasma transglutaminase) inhibitors into a lubricious silicone elastomer in order to generate an optimized drug delivery system. In this model, a secondary sustained drug-release profile occurs following an initial burst release for catheters and other medical devices, with the hope that this would reduce the incidence of associated staphylococcal

Executive summary

Infectious complications of percutaneous cardiac procedures are rare
- Procedure-related infections should be considered any in patient presenting with fevers, chills or bactremia in the first 4 weeks postprocedure.

Clinical risk factors of postprocedure infections
- Congestive heart failure.
- Age >60 years old.

Procedure-related risk factors
- Difficult vascular access.
- Repeated catheter insertion.
- Time of sheath retention in the vessel.

Treatment of procedure-related infection
- Prolonged antibiotic use.
- Surgical intervention in some case to remove infected prosthesis.

Infectious control standard
- Adherence to infectious control guidelines proposed by the Society for Cardiovascular Angiography and Interventions can minimize postprocedure infectious complication.
- Use of prophylaxis antibiotics in diabetic patient receiving vascular closure devices.

Future prospective
- Increasing complexity of cardiac catheterization procedure and development of hybrid or requires more stringent adherence to sterile technique.
- Improvement in technology will allow for more sterile delivery of catheterization equipment.

infection [47]. Studies *in vivo* are yet to be performed. Further research aimed at understanding pathogenesis of central venous catheter-related infections is ongoing.

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