Original Studies

Pericardial Covered Stent for Coronary Perforations

Shmuel Chen,1 MD, Chaim Lotan,1 MD, Ronen Jaffe,2 MD, Ronen Rubinshtein,2 MD, Eyal Ben-Assa,3 MD, Ariel Roguin,4 MD, PhD, Boris Varshitzsky,1 MD, and Haim D. Danenberg,1* MD

Objectives: To evaluate initial and long term results of coronary perforation treatment with pericardial covered stent. Background: Iatrogenic coronary perforation is a rare life threatening complication of percutaneous coronary interventions (PCI) occurring in 0.1–0.8% of cases. Covered stents are the mainstay of therapy for coronary perforation. However, polytetrafluoroethylene covered stents are bulky with limited flexibility and thus may not be easy to deliver in difficult anatomy. Therefore, they are reserved to perforations in proximal or mid straight segments where their delivery is relatively easy. The pericardial covered stent is a highly deliverable fully covered stent that may be used to treat coronary perforations. Only a single case has been reported of the use of this stent in its previous version for the treatment of coronary perforation. Methods: The electronic databases of four tertiary medical centers were retrospectively reviewed for cases of coronary perforations in which PCS was used. During a five years period, between 2008 and 2013, 18,364 patients underwent PCI in these centers. Nine cases of perforations for which balloon dilatation was not sufficient and pericardial covered stent was used were recorded. Results: All nine cases were successfully treated with pericardial covered stent. Six of the patients underwent repeated angiography at 2–15 months, and in two of them instent restenosis that warranted repeated angioplasty was observed. One of them was catheterized for NSTEMI 3 months after the covered stent implantation, and stent thrombosis was demonstrated. Conclusions: Pericardial covered stents offer a safe and effective therapy for coronary perforation when balloon inflation and reversal of anticoagulation are insufficient.

© 2015 Wiley Periodicals, Inc.

Key words: pericardial covered stent; coronary perforation; PCI complications

INTRODUCTION

Coronary artery perforation is a rare but potentially fatal complication of percutaneous coronary interventions (PCI), occurring when a dissection or intimal tear completely penetrates the arterial wall leading to either vessel puncture or in more severe cases to vessel rupture [1]. Most cases are caused by distal wire trauma, while balloons and stents responsible for the rest, typically more proximally [2]. Perforations can be classified into three types: Type I, extraluminal crater without extravasation; Type II, pericardial or myocardial blushing or Type III, perforation ≥1 mm diameter with contrast streaming and cavity spilling. Type I is a relatively benign condition, whereas Types II and III can cause a significant accumulation of blood in the pericardial space, which can lead to tamponade and

1Department of Cardiology, Hadassah Hebrew University Medical Center, Jerusalem, Israel
2Department of Cardiology, Lady Davis Carmel Hospital, Haifa, Israel
3Department of Cardiology, Tel Aviv Medical Center, Tel Aviv, Israel
4Department of Cardiology, Rambam Medical Center, Rappaport - Faculty of Medicine, Technion, Israel Institute of Technology, Israel

Conflict of Interest: Drs. Lotan and Danenberg serve as consultants to ITGI.

*Correspondence to: Haim D. Danenberg, MD Heart Institute, Hadassah Hebrew University Medical Center P.O.B 12000, Jerusalem, Israel IL-91120. E-mail: haimd@ekmd.huji.ac.il

Received 29 June 2014; Revision accepted 11 April 2015

DOI: 10.1002/ccd.26011
Published online 00 Month 2015 in Wiley Online Library (wileyonlinelibrary.com)
rapid hemodynamic collapse. Mortality following coronary perforation is high, reported to range from 5.9 to 7.4% [2–4]. Therefore, an urgent intervention is required for these cases. The immediate recommended therapy for prevention of further extravasation is prolonged balloon inflation proximal to the perforation site concomitantly with reversal of anticoagulation. Following failure of this therapy and continuous bleeding, the options are immediate open-heart surgery with its associated risks or intraluminal sealing of the perforation with a covered stent that will and restore a nonbreached vessel wall. The last option is relevant for relatively proximal perforations caused, as mentioned above, by balloon or stent whereas distal perforations usually caused by wire trauma can readily treated by coil embolization.

METHODS

The electronic databases of four tertiary medical centers were retrospectively reviewed for cases of coronary perforations in which PCS was used. During a five years period, between 2008 and 2013, 18,364 patients underwent PCI in these centers. Nine cases of perforations for which balloon dilatation was not sufficient were recorded. All cases were treated with PCS and pericardiocentesis was required in three patients. There were no cases in which surgery or the use of another endovascular technique (such as coil embolization) were required. Six of the nine cases underwent repeated angiography at 2–15 months.

RESULTS

Patients are presented in Table I. All patients but three (#6, 8, 9) were admitted with an acute coronary syndrome. Perforations were treated initially with proximal balloon inflation followed by PCS deployment. Three patients underwent emergent pericardiocentesis during index procedure. Six of the patients underwent repeated angiography at 2–15 months, and in two of them instant restenosis that warranted repeated angioplasty was observed. The restenosis was within the body of the covered stent in both cases. One patient (#5) was catheterized for NSTEMI three months later and stent thrombosis was demonstrated. Three out of these six patients (#2, 6, and 8) were asymptomatic and were catheterized for diagnostic purposes (during TAVI - #2 and 6 and follow up - #8). The covered stents were found to be patent in patients #2 and 6 while in patient #8 the artery (RCA) was occluded at the ostium, proximal to the stent.

DISCUSSION

Coronary perforations are an emergency situation that while rare in current PCI practice may be life threatening and warrants an immediate intervention. The present case series describes the use of the novel pericardial covered stent as a valid option to treat
coronary perforation even in cases with complex coronary anatomy. The coronary anatomy in the cases described was complex in most cases due to vessel tortuosity and presence of calcifications (as detailed below). In case #1, the stent was deployed through a highly tortuous right internal mammary arterial graft and advanced via an existing stent (Fig. 2). Cases #3–4, and 6–8 warranted the crossing of highly calcified tortuous vessels, with (#3, 6-8) or without (#4) an existing stent. In addition to the successful acute results, angiographic follow-up in two patients (#2 and 6) demonstrates good late vessel patency (Fig. 3). Thus, this report highlights this percutaneous therapeutic alternative to coronary perforations as safe and effective in challenging anatomies, reducing the need for emergency surgery.

Efficacy of Covered Stents

Contemporary, coronary perforation is an uncommon phenomenon, thus data regarding the treatment with covered stents is relatively rare and relies on small number of patients. Briguori et al. reported the use of PTFE-covered stents in 11 of 12 patients who had coronary ruptures that were unsuccessfully sealed with prolonged balloon inflations and reversal of anticoagulation. Success rates were up to 91% for Type II and III perforations with low incidence of cardiac tamponade or need for emergency surgery [8].

Stent Thrombosis and Restenosis

The rate of stent thrombosis and restenosis in patients with perforation treated with percutaneous covered stents, is not known. A randomized trial was conducted to compare PTFE-covered stents with bare metal stent for prevention of restenosis and major adverse cardiac events in patients undergoing percutaneous coronary intervention (PCI). The RECOVERS trial, found a higher incidence of 30-day nonfatal myocardial infarction compared to bare metal stents (1.3 vs. 3.4%) [5].

Abbreviations: PCI, percutaneous coronary intervention; RIMA, right internal mammary artery; LAD, left anterior descending; CX, circumflex; DES, drug eluting stent; BMS, bare metal stent; D1, first diagonal; M1, first marginal; NSTE-ACS, non ST elevation acute coronary syndrome.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age/gender</th>
<th>Diagnosis</th>
<th>Location of perforation</th>
<th>Perforation grade</th>
<th>Clinical picture</th>
<th>Covered-stent size D X L (mm)</th>
<th>Angiographic result</th>
<th>Clinical F/U (month/presentation)</th>
<th>Angiographic F/U (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>53/M</td>
<td>NSTE-ACS</td>
<td>Anastomosis RIMA-LAD during PCI to RIMA</td>
<td>II</td>
<td>Chest pain, hypotension</td>
<td>3.0 x 27</td>
<td>Good flow, no perforation</td>
<td>32/Asymptomatic</td>
<td>–</td>
</tr>
<tr>
<td>2</td>
<td>80/M</td>
<td>NSTE-ACS</td>
<td>PCI to Mid LAD (calcified artery)</td>
<td>III</td>
<td>Tamponade</td>
<td>3.0 x 18</td>
<td>Occlusion of D1</td>
<td>11/Asymptomatic</td>
<td>4/Patent</td>
</tr>
<tr>
<td>3</td>
<td>69/F</td>
<td>STEMI</td>
<td>Distal LAD during primary PCI to mid LAD (restenosis, calcified artery)</td>
<td>II</td>
<td>Chest pain, hypotension</td>
<td>3.0 x 18</td>
<td>Good flow, no perforation</td>
<td>15/NSTEMI</td>
<td>15/Instent restenosis</td>
</tr>
<tr>
<td>4</td>
<td>81/M</td>
<td>NSTE-ACS</td>
<td>CX (calcified artery) during PCI</td>
<td>III</td>
<td>Tamponade</td>
<td>3.0 x 23</td>
<td>Good flow, no perforation</td>
<td>4/UA</td>
<td>4/Instent restenosis</td>
</tr>
<tr>
<td>5</td>
<td>51/M</td>
<td>NSTEMI</td>
<td>Proximal LAD (calcified artery) during PCI</td>
<td>II</td>
<td>Asymptomatic</td>
<td>3.0 x 23</td>
<td>Good flow, no perforation</td>
<td>3/NSTEMI</td>
<td>3/Stent thrombosis</td>
</tr>
<tr>
<td>6</td>
<td>84/F</td>
<td>Stable angina</td>
<td>Mid LAD (calcified artery) during PCI</td>
<td>III</td>
<td>Asymptomatic</td>
<td>3.5 x 18</td>
<td>Good flow, no perforation</td>
<td>7/Asymptomatic</td>
<td>7/Patent</td>
</tr>
<tr>
<td>7</td>
<td>78/M</td>
<td>NSTE-ACS</td>
<td>Mid RCA (calcified artery) during PCI with Rotablation</td>
<td>I</td>
<td>Chest pain, hypotension</td>
<td>3.0 x 13</td>
<td>Good flow, no perforation</td>
<td>12/Asymptomatic</td>
<td>–</td>
</tr>
<tr>
<td>8</td>
<td>67/M</td>
<td>Stable angina</td>
<td>Tight lesion in the mid LAD, during PCI</td>
<td>III</td>
<td>Chest pain, hypotension</td>
<td>3.5 x 14</td>
<td>Good flow, no perforation</td>
<td>3/Asymptomatic</td>
<td>2/occluded RCA</td>
</tr>
<tr>
<td>9</td>
<td>66/M</td>
<td>Stable angina</td>
<td>Tight lesion in the mid LAD, during PCI</td>
<td>II</td>
<td>Chest pain, hypotension</td>
<td>3.0 x 23</td>
<td>Good flow, no perforation</td>
<td>4/Asymptomatic</td>
<td>–</td>
</tr>
</tbody>
</table>
respectively) [9]. Nevertheless, restenosis rates at 6-month follow-up, were similar. Another study in which PTFE-covered stents were used in various clinical settings (coronary perforations, aneurysms, degenerated saphenous vein grafts, complex lesions, and in-stent restenosis), found that subacute stent thrombosis and restenosis occurred in 5.7 and 31.6% of the patients, respectively [10]. The relatively higher incidences compared with standard stents may be related to delayed endothelialization and increased susceptibility to thrombus formation in PTFE-covered stents [11]. In theory, the rate of this complications might be lower with pericardial covered stents due to better endothelialization of biomaterial, as was previously shown for pericardial patches which support cell infiltration after implantation into the arterial circulation [12]. Nevertheless, until more data becomes available, treatment with dual antiplatelet therapy for at least 3 months should be considered.

**CONCLUSIONS**

Coronary perforation is a life threatening complication of PCI. Pericardial covered stents offer a safe and effective therapy when balloon inflation and reversal of anticoagulation are insufficient. Our report in real life patients shows that PCSs are highly deliverable in challenging coronary anatomy and thus may be useful for emergency treatment of coronary perforation.

**REFERENCES**


