Percutaneous balloon pericardiectomy: efficacy in a series of malignant and nonmalignant cases

Holger H. Sigusch, Wolff Geisler, Ralf Surber, Marc Schönweß and Jens Gerth

Department of Internal Medicine, Division of Cardiology, Heinrich-Braun-Klinikum, Zwickau, Germany; Department of Internal Medicine, Division of Cardiology, Jena University Hospital, Friedrich-Schiller-University of Jena, Jena, Germany; Department of Internal Medicine, Division of Nephrology, Heinrich-Braun-Klinikum, Zwickau, Germany

ABSTRACT

Objective: In the case of malignant pericardial effusion and cardiac tamponade, balloon pericardiectomy is an established minimally invasive option to the surgical creation of a subxiphoid pericardial window. Percutaneous balloon pericardiectomy effectively drains recurrent pericardial fluid by creating a pleuro(-abdominal-) pericardial communication. Design. A series of 26 patients with underlying malignant (n = 12) and nonmalignant (n = 14) diseases underwent percutaneous balloon pericardiectomy between 2008 and 2021. All interventions were done through a subxiphoid access under local anesthesia. Results. The mean survival in the malignant and nonmalignant groups was 1.2 versus 48.0 months, respectively (p < .001). There were neither severe periinterventional complications nor in-hospital deaths. In two patients with nonmalignant disease the surgical creation of a pericardial window was necessary during follow-up. The originally described procedure was modified by the removal of all catheters at the end of the intervention. The procedure was safe. It prevented immobility and facilitated an early discharge from the hospital. Conclusion. Our experiences show that percutaneous balloon pericardiectomy is a minimally invasive approach to successfully provide palliation in the group of patients with underlying malignant disease. On the other hand, we have shown that this technique is safe and feasible in the treatment of pericardial effusion based on nonmalignant disease. We think thereby that pericardial balloon pericardiectomy can be considered as a less invasive alternative to surgery in both groups of patients.

Introduction

In the case of malignant pericardial effusion and cardiac tamponade, balloon pericardiectomy is a minimally invasive option to the surgical creation of a subxiphoid pericardial window. Percutaneous balloon pericardiectomy effectively drains recurrent pericardial fluid by creation of a pleuro(-abdominal-) pericardial communication [1–14]. The aim in this setting is to facilitate ambulant palliative care of the patients with most often advanced malignant disease. The European guidelines on management of pericardial disease recommend percutaneous balloon pericardiectomy in this context as a class IIb intervention [15]. In nonmalignant pericardial effusion and tamponade, balloon pericardiectomy has been rarely used. This is due to a couple of reasons. First, improved postpericardiectomy management as proposed by Luis et al. lead to fewer recurrences in patients with nonmalignant effusions [15]. Second, surgical alternatives such as the creation of a subxiphoid pericardial window, video-assisted transthoracic pericardial drainage and pericardiectomy are the preferred options for the more resilient patients, not suffering from underlying malignant disease [3].

To our knowledge, there have been no significant reports on the use of balloon pericardiectomy in the context of nonmalignant pericardial disease [15,16]. Irrespective of these earlier findings, our series suggests that the minimal invasive approach may have a role in nonmalignant disease, too.

Methods

Diagnosis and patient selection

The diagnosis of pericardial effusion and cardiac tamponade was made by transthoracic echocardiography according to [15,17]. In addition, each patient underwent computed tomography of the chest to screen for underlying—especially malignant—disease. From 2008 to 2021, 90 patients underwent pericardiectomy at our institution for different reasons (Figure 1). Out of these 90 patients, 26 patients underwent balloon pericardiectomy. Out of these, 12 patients had an underlying malignant cause, whereas 14 patients suffered nonmalignant diseases.
**Pericardiocentesis and balloon pericardiotomy**

Each patient gave his/her written informed consent to pericardiocentesis and pericardiotomy. Ethics approval has been granted by the ethics committee at the Saxon State Medical Association (Dresden, Germany, EK-BR-67/22-1). The procedures were performed via a subxiphoid approach under fluoroscopic guidance in the catheterization laboratory. In all cases, an arterial line for pressure monitoring had been established via the radial artery. Under strictly sterile conditions, local anesthesia (15–20 ml 1% lidocaine) was performed and the pericardiocentesis needle was inserted directly beneath the costal margin slightly to the left of the midline. After making a 1 cm skin incision, the needle was advanced in a 30-degree-angle to the skin-avoiding the liver-pointing toward the left shoulder. Once reaching the pericardial space a 0.035 guidewire was inserted. First, a small (4 or 5 French) sheath was inserted to verify the intrapericardial location of the wire and the sheath. This was done by analysis of hemoglobin concentration and oxygen saturation as well as injection of iodinated contrast. In some cases, agitated saline was injected via the small sheath and intrapericardial contrasting was confirmed by echocardiography. Then, in all cases a 7 French sheath was inserted. A 7 French pigtail catheter was inserted, and the pericardial fluid drained.

In the case of planned balloon pericardiotomy a 14 Gauge needle was placed parallel to the skin to mark the skin level (Figure 2). Balloon pericardiotomy was performed in analgo-sedation using intravenous fentanyl (0.1 mg) and propofol (1 mg per kg body weight) Fentanyl was given at the very beginning. Whereas, propofol was applied just before balloon pericardiotomy. An Amplatz Super Stiff wire (Boston Scientific, Marlborough, MA, USA) was inserted via the pigtail catheter forming an intrapericardial loop. Skin and tissue were dilated using 10–12 F dilators to allow the subsequent passage of the balloon. In all cases, high pressure balloons (Z-MED II, NuMED, Inc., Hopkinton, NY, USA) were used. The diameter of the balloon was between 20 and 25 mm. Hence, the length was always 60 mm to decrease the tendency of the balloon to slip. Under fluoroscopic guidance in a left anterior oblique view (at least 70°), the proximal marker of the balloon was placed just below the skin (needle, see above). Then, one operator must fix the balloon by pulling and avoid a pull in, while the second operator forcefully inflates the balloon using a 50 ml syringe filled with a 5:1 contrast/saline mixture. In the left anterior oblique projection, the level of the pericardium was clearly visible by a waist of the balloon. The selected balloon must be at least once fully inflated (Figure 2). During the inflation it was of utmost importance to avoid an inward pulling of the
balloon to dilate the pericardium. Both parts—the fixing of the balloon and the inflation of the balloon need the application of vigorous force. At the end, balloon and wire were removed and a skin suture placed if necessary. A sterile adhesive tape was applied. The patients were monitored for one hour in the catheterization laboratory area and then transferred to the wards, rarely to the intensive care unit for monitoring. Chest x-ray was performed the same day to exclude pneumothorax. Transthoracic echocardiography was performed the next day and before discharge from the hospital.

**Statistical analysis**

Differences in normal distributed continuous variables were tested with Student’s t-test. Otherwise, the Mann-Whitney U test was used. The relation of dichotomy variables was checked with Person’s χ² analysis. Kaplan Meier survival curves were compared by log rank test. All tests of significance were two sided; a value of \( p < .05 \) indicated a statistically significant difference. The statistical analyses were computed with SPSS version 19.0 (SPSS Inc., Chicago, IL, USA).

**Results**

Details on patient enrollment are depicted in Figure 1. Out of 90 patients undergoing interventions for pericardial effusions, 26 underwent percutaneous balloon pericardiotomy. Baseline characteristics of the patient groups are given in Table 1. Except age, which was significantly lower in the group of patients with a malignant etiology there were no statistically significant differences regarding the baseline variables between the groups. Most patients (\( n = 20 \)) presented with clinical and echocardiographic signs of subacute or chronic cardiac tamponade (Table 2). In six out of 26 cases percutaneous balloon pericardiotomy was done as the primary procedure, 20 cases followed preceding pericardiocentesis with catheter removal.

All procedures were technically successful. There were no periprocedural or postprocedural deaths or severe complications. In one patient, an asymptomatic pneumopericardium developed after the procedure (Figure 2). All patients were discharged from the hospital at a mean interval of 7.5 days after the procedure (Table 2).

The follow-up showed the expected difference of survival between the nonmalignant and malignant groups, which was statistically highly significant (Figure 3(A)). The mean survival in the group suffering malignant causes was 1.2 versus 48.0 months in the group of patients with nonmalignant pericardial effusions, respectively (\( p < .001 \)).

In two patients with underlying nonmalignant disease, the surgical creation of a subxiphoid pericardial window was necessary during follow-up (Figure 3(B)). Therefore, percutaneous balloon pericardiectomy had a long-term success in 12 out of 14 patients with nonmalignant disease.

**Discussion**

Our report shows, that percutaneous balloon pericardiectomy is not only feasible in patients with malignant pericardial effusions but is also a viable therapeutic option in nonmalignant pericardial effusions.

Percutaneous balloon pericardiectomy must be compared regarding efficacy and complications to other approaches as repeated pericardiocentesis, prolonged drainage of
pericardial fluid after pericardiocentesis and surgical procedures, for example, the creation of a subxiphoid pericardial window and video-assisted transthoracic drainage [3,18–20]. Prospectively randomized studies comparing pericardiocentesis and surgical pericardial window in the management of pericardial effusions requiring drainage [3,18]. The largest series reported by Horr et al. showed an in-hospital mortality of 4.4% versus 5.5% in the surgical and pericardiocentesis groups, respectively. The re-accumulation of pericardial effusion was more common in the pericardiocentesis group 24% versus 10%. Both, pericardial window creation and pericardiocentesis were judged as safe and effective treatments in pericardial effusion. More recently, the creation of a pericardial window via video-assisted thoracoscopic surgery (VATS) is increasingly used over other surgical methods [21–23]. It has been suggested that VATS compares favorably to other surgical methods [24]. However, there are no data comparing the creation of a pericardial window by VATS with balloon pericardiotomy. VATS is by far more invasive, requiring general anesthesia and double lumen intubation. Also, it is probably more costly than balloon pericardiotomy [23].

In 1991, the high recurrence rate of pericardial effusions after drainage led to the development of percutaneous balloon pericardiotomy first reported by Palacios et al. [1]. Ziskind et al. described the results of 50 patients recorded in a multicenter registry undergoing percutaneous balloon pericardiocentesis [2]. About 90% of the patients had underlying malignant disease and the mean survival time in this subset of patients was only 3.3 months. The survival in our group of patients with malignant disease was even worse (1.2 months). Following these initial reports, percutaneous balloon pericardiocentesis was mainly applied in patients with malignant pericardial effusions. This was mainly due to the very limited life expectancy of these patients favoring a less invasive procedure [15,25]. Thirty years after these initial reports, the experience with percutaneous balloon pericardiocentesis in patients with nonmalignant disease is still limited. Our small series reports 26 patients with underlying nonmalignant and malignant diseases. In the group of 14 patients with nonmalignant disease, pericardial balloon pericardiocentesis showed an excellent safety profile (no severe

| Table 1. Characteristics of the patients at baseline. |
|---------------------------------------------------|
| All patients $n = 26$                          | Malignant $n = 12$ | Nonmalignant $n = 14$ | $p$ Value |
| Age, years (SD)                                 | 68.3 ± 15.3       | 60.1 ± 16.3           | 75.4 ± 10.4 | .008 |
| Sex (f/m)                                        | 16/10             | 6/6                   | 10/4        | .27  |
| Body mass index (kg/m²)                         | 26.2 ± 4.4        | 24.8 ± 3.6            | 27.5 ± 4.8  | .11  |
| Length of hospital stay (days)                   | 13.0 ± 8.7        | 15 ± 10               | 11.2 ± 7    | .26  |
| Hemoglobin concentration (g/dl)                  | 11.6 ± 1.6        | 11.3 ± 1.6            | 11.7 ± 1.6  | .43  |
| Leucocyte count (10⁹/l)                          | 9.4 ± 4.7         | 10.7 ± 5.6            | 8.2 ± 3.7   | .22  |
| C reactive protein (mg/l)                        | 62.8 ± 59.7       | 72 ± 52               | 54 ± 66     | .24  |

Mean values (standard deviation) were reported continuous and categorical variables, respectively.

| Table 2. Procedural characteristics. |
|--------------------------------------|
| All patients $n = 26$                | Malignant $n = 12$ | Nonmalignant $n = 14$ | $p$ Value |
| Balloon pericardiocentesis as primary procedure (n) | 6/26       | 5/12                   | 1/14       | <.01 |
| Signs of tamponade                   | 20/26      | 8/12                   | 12/14      | .13  |
| Volume of pericardial effusion drained at the time of pericardiocentesis (ml) | 652 ± 60   | 667 ± 252              | 639 ± 305  | .23  |
| Balloon diameter (mm)                | 22.6       | 21.8                   | 23.2       | .09  |
| Length of hospital stay after the procedure (days) | 7.5        | 7.1                    | 8.0        | .92  |

Mean values (standard deviation) were reported continuous and categorical variables, respectively.

Figure 3. Kaplan-Meier Estimates of Death at 48 months. Shown is the probability of survival among patients who underwent balloon pericardiocentesis for pericardial effusion with underlying nonmalignant and malignant diseases. (A) shows the probability of survival in both groups. (B) depicts the probability of survival without surgical pericardiocentesis.
complication or procedure related deaths) and was effective in the prevention of the recurrence of effusion. In 2 out of 14 patients a surgical intervention was necessary during follow-up. Thus, a long-term success rate of 85% has been achieved in this group.

Recurrent pericardial effusion is a common problem in daily clinical practice. In malignant disease, percutaneous balloon pericardiectomy should be considered as a primary alternative to surgery. Considering the very limited life expectancy in this group, this minimally invasive procedure allows to shorten the hospital stay considerably.

Considering the increasing numbers of invasive procedures performed in percutaneous coronary interventions, structural heart disease and device implantation the proper interventional management of complications such as pericardial effusion and tamponade are of increasing importance. The patient population undergoing these interventions is increasingly aged and multimorbid. Therefore, in recurring pericardial effusions after initial pericardiocentesis, percutaneous balloon pericardiectomy can be—rather than surgery—considered an alternative strategy with a high success rate.

We modified the initially by Palacios et al. described procedure by removing all catheter material by the end of the procedure [1]. This is safe, it prevents immobility and facilitates early discharge from the hospital.

Our report is limited by the small number of patients in both groups. The results in the group of patients with underlying malignant disease confirm the data reported by other authors. The short survival in this group shows that a pericardial effusion is a marker of advanced disease. The group of patients with underlying nonmalignant disease shows a far better survival. However, because of the retrospective nature of the data, possibilities for comparisons are limited.

In conclusion, our experience confirms that percutaneous balloon pericardiectomy is a successful minimally invasive approach for palliation in the group of patients with underlying malignant disease. On the other hand, we have shown that this technique is safe and feasible in the treatment of pericardial effusion based on nonmalignant disease. We think that percutaneous balloon pericardiectomy can be considered as a safe and far less invasive alternative to surgery in both settings.

Disclosure statement
No potential conflict of interest was reported by the author(s).

Funding
The author(s) reported there is no funding associated with the work featured in this article.

References
[1] Palacios IF, Tuzcu EM, Ziskind AA, et al. Percutaneous balloon pericardial window for patients with malignant pericardial effusion and tamponade. Cathet Cardiovasc Diagn. 1991;22(4):244–249.
[2] Ziskind AA, Pearce AC, Lemmon CC, et al. Percutaneous balloon pericardiectomy for the treatment of cardiac tamponade and large pericardial effusions: description of technique and report of the first 50 cases. J Am Coll Cardiol. 1993;21(1):1–5.
[3] Allen KB, Faber LP, Warren WH, et al. Percutaneous balloon pericardiectomy: subxiphoid pericardiectomy versus percutaneous catheter drainage. Ann Thorac Surg. 1999;67(2):437–440.
[4] Bertrand O, Legrand V, Kulbertus H. Percutaneous balloon pericardiectomy: a case report and analysis of mechanism of action. Cathet Cardiovasc Diagn. 1996;38(2):180–182.
[5] Chow LT, Chow WH. Mechanism of pericardial window creation by balloon pericardiectomy. Am J Cardiol. 1993;72(17):1321–1322.
[6] Furuikawa A, Itoh A, Nakamura T, et al. [Efficacy of percutaneous balloon pericardiectomy and intrapericardial instillation for the management of refractory pericardial effusion: a case report]. J Cardiol. 2007;50(6):389–395.
[7] Galli M, Politi A, Pedretti F, et al. Percutaneous balloon pericardiectomy for malignant pericardial tamponade. Chest. 1995;108(6):1499–1501.
[8] Jackson G, Keane D, Mishra B. Percutaneous balloon pericardiectomy in the management of recurrent malignant pericardial effusions. Br Heart J. 1992;68(6):613–615.
[9] Jones DA, Jain AK. Percutaneous balloon pericardiectomy for recurrent malignant pericardial effusion. J Thorac Oncol. 2011;6(12):2138–2139.
[10] Maisch B, Ristic AD, Pankuweit S, et al. Percutaneous therapy in pericardial diseases. Cardiol Clin. 2017;35(4):567–588.
[11] Ohike M, Bessho A, Haraoka K, et al. Percutaneous balloon pericardiectomy by the use of inoue balloon for the management of recurrent cardiac tamponade in a patient with lung cancer. Intern Med. 2000;39(12):1071–1074.
[12] Swanson N, Mirza I, Wijesinghe N, et al. Primary percutaneous balloon pericardiectomy for malignant pericardial effusion. Catheter Cardiovasc Interv. 2008;74(4):504–507.
[13] Thanopoulos BD, Georgakopoulos D, Tsoulos GS, et al. Percutaneous balloon pericardiectomy for the treatment of large, nonmalignant pericardial effusions in children: immediate and medium-term results. Cathet Cardiovasc Diagn. 1997;40(1):97–100.
[14] Virk SA, Chandrakumar D, Villanueva C, et al. Systematic review of percutaneous interventions for malignant pericardial effusion. Heart. 2015;101(20):1619–1626.
[15] Adler Y, Charron P, Imazio M, ESC Scientific Document Group, et al. 2015 ESC guidelines for the diagnosis and management of pericardial diseases: the task force for the diagnosis and management of pericardial diseases of the European society of cardiology (ESC)endorsed by: the European association for Cardio-Thoracic surgery (EACTS). Eur Heart J. 2015;36(42):2921–2964.
[16] Luis SA, Kane GC, Luis CR, et al. Overview of optimal techniques for pericardiocentesis in contemporary practice. Curr Cardiol Rep. 2020;22(8):60.
[17] Ristic AD, Imazio M, Adler Y, et al. Triage strategy for urgent management of cardiac tamponade: a position statement of the European society of cardiology working group on myocardial and pericardial diseases. Eur Heart J. 2014;35(34):2279–2284.
[18] Horr SE, Mentias A, Houghtaling PL, et al. Comparison of outcomes of pericardiocentesis Versus surgical pericardial window in patients requiring drainage of pericardial effusions. Am J Cardiol. 2017;120(5):883–890.
[19] Balla S, Zea-Vera R, Kaplan RA, et al. Mid-Term efficacy of subxiphoid Versus transpleural pericardial window for pericardial effusion. J Surg Res. 2020;252:9–15.
[20] Langdon SE, Seery K, Kulik A. Contemporary outcomes after pericardial window surgery: impact of operative technique. J Cardiothorac Surg. 2016;11(1):73.
[21] Georghiou GP, Stamler A, Sharoni E, et al. Video-assisted thoracoscopic pericardial window for diagnosis and management of pericardial effusions. Ann Thorac Surg. 2005;80(2):607–610.

[22] Nataf P, Cacoub P, Regan M, et al. Video-thoracoscopic pericardial window in the diagnosis and treatment of pericardial effusions. Am J Cardiol. 1998;82(1):124–126.

[23] Gokce M, Tilkan OK, Uysal S, et al. Efficacy of uniportal video-assisted thoracoscopic pericardial window creation using two lung ventilation in chronic large pericardial effusions. J Pak Med Assoc. 2020;70(10):1742–1747.

[24] Muhammad MI. The pericardial window: is a video-assisted thoracoscopy approach better than a surgical approach? Interact Cardiovasc Thorac Surg. 2011;12(2):174–178.

[25] Hoit BD. Pericardial effusion and cardiac tamponade in the new millennium. Curr Cardiol Rep. 2017;19(7):57.