

Percutaneous Pericardial Procedures: In-Hospital and One-Year Outcomes

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SUMMARY

Background

Pericardial window has been the conventional treatment for severe pericardial effusion or recurrent cardiac tamponade before the advent of percutaneous balloon pericardiectomy.

Objectives

To analyze our initial experience with pericardial procedures in patients with pericardial effusion.

Material and Methods

A total of 15 consecutive patients underwent percutaneous balloon pericardiectomy due to severe pericardial effusion or cardiac tamponade. Primary success was defined as an effective percutaneous balloon pericardiectomy without the need of a new intervention due to pericardial effusion and absence of major complications during hospitalization. A pericardial biopsy was performed through the same route in 3 patients.

Results

The primary success was achieved in all the procedures. The most frequent complication during hospitalization was pleural effusion. One year after the procedure 7 patients had died due to the underlying condition; none of them had had recurrent pericardial effusion.

Conclusions

In our series of patients, percutaneous balloon pericardiectomy appeared to be a useful and simple technique, with a high rate of success and a low incidence of complications and recurrences. Percutaneous pericardial biopsy might add diagnostic information within the same procedure.

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Key words > Pericardiectomy - Balloon Dilatation - Pericardial Effusion - Cardiac Tamponade

Abbreviations > PBP Percutaneous balloon pericardiectomy

BACKGROUND

Pericardial effusion may occur as the consequence of a variety of conditions including infections, neoplasms and connective tissue diseases. (1)

Patients with pericardial effusion generally present malignant or infectious diseases, and are frequently undernourished and in poor general condition. Previous studies have demonstrated unfavorable outcomes in this population, and survival is strongly

related to the extension of the underlying condition and its etiology. (2-4)

Once the clinical and radiological diagnosis has been established, patients should undergo echocardiography examination to determine the severity of pericardial effusion and to evaluate the presence of signs of cardiac tamponade.

Pericardiocentesis should not be indicated in asymptomatic patients with no hemodynamic compromise, except for fluid examination for diagnostic pur-

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poses in cases of acute bacterial pericarditis, tuberculosis and neoplasms. Pericardial fluid analysis might reveal the presence of a transudate (hydropericardium), exudate, pyopericardium or hemopericardium. (1) Cardiac tamponade is an absolute indication for urgent drainage. (5)

The need for a new pericardiocentesis is between 15% and 40% according to the different authors. (6) Prevention of recurrences of pericardial effusion is controversial and depends mostly on local institution practices. (6) The surgical creation of a pleuropericardial window through a lateral approach or subxyphoid pericardiectomy has been the conventional treatment to prevent recurrent pericardial effusion. Other non-surgical options, such as intrapericardial instillation of cytostatic/sclerosing agents and radiation therapy are currently available.

In 1991, Palacios et al. (7) developed the percutaneous balloon pericardial window (PBPW) technique for patients with severe pericardial effusion or cardiac tamponade to avoid recurrences by creating a pleural and/or peritoneal window, and it emerged as an alternative to the classic surgical pleuropericardial window. The original technique has been modified thereafter. In 1992, Chow (8) described the PBP using the Inoue balloon catheter. Ziskind et al. (9) provided valuable information with their multicenter register of 130 patients. (9) In 1995, Iaffaldano et al. described the double balloon technique. (10) A double-balloon technique with balloons of different length did not show significant differences. (11)

Percutaneous balloon pericardiectomy produces a tear in the parietal pericardium and creates a pleuropericardial or pleuro-abdominal direct communication (Figure 1). Nevertheless, PBP will not remain open indefinitely probably due to progressive autosclerosis between the parietal and visceral pericardium after complete fluid evacuation. (6)

The goal of the present study is to analyze the outcomes of the pericardial procedures performed during an 8-year period in terms of success rate, safety and long-term follow-up in a series of 15 patients undergoing percutaneous balloon pericardiectomy with double balloon technique and pericardial biopsy.

MATERIAL AND METHODS

We conducted a prospective registry of patients undergoing PBP and pericardial biopsy.

The study population included patients referred to the cardiac catheterization laboratory with clinical and echocardiographic signs of cardiac tamponade or severe recurrent symptomatic pericardial effusion with indication of pericardial drainage. Patients were excluded if the attending physicians chose another therapeutic approach. The presence of purulent effusion, clinical suspicion of acute bacterial infection, history of pneumonectomy and coagulation disorders were exclusion criteria for PBP.

From January 2000 to February 2008, 15 patients underwent PBP; pericardial biopsy was also performed in three of them.

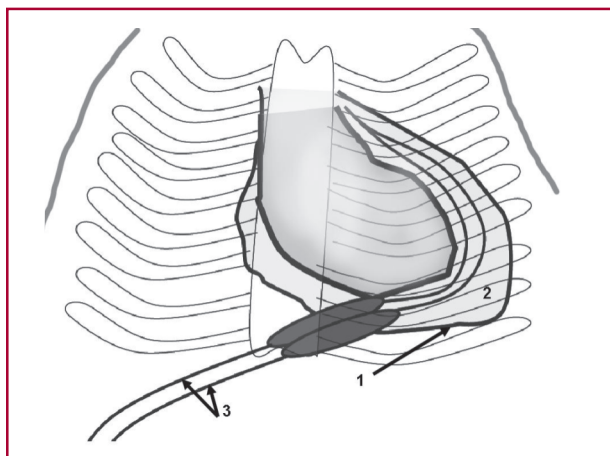


Fig. 1. Schematic illustration of the percutaneous pericardiectomy with double balloon technique. 1: Parietal pericardium. 2: Pericardial space. 3: Balloon catheters inflated to create the pericardial window.

The PBP was carried out using a double balloon technique to create the pericardial window. The procedure was considered successful when the window reached a diameter of approximately 30 mm.

Management strategy was defined as primary when PBP was performed at the time of initial pericardiocentesis, and secondary when PBP was carried out after a recurrence.

The following major events were considered: death, bleeding or persistent pericardial drainage requiring surgery; pericardial effusion, fever, chest pain, pleural effusion and pneumothorax were considered minor events.

Primary success was defined as an effective PBP without the need for a new intervention due to pericardial effusion and absence of major complications during hospitalization. A pericardial biopsy was performed through the same route in 3 patients.

Statistical Analysis

For descriptive statistics, the mean (standard deviation) was used in cases of a normal distribution of variables and the median with its corresponding 25%-75% interquartile range (IQR) were used for variables with a skewed distribution.

Procedure

Percutaneous balloon pericardiectomy (Figure 2)

The technique is relatively safe and simple. It is performed in the catheterization laboratory with minimal discomfort with the patient under local anesthesia and receiving mild sedation with intravenous short-acting benzodiazepines. The subxyphoid area is infiltrated with 1% lidocaine and pericardiocentesis is performed under fluoroscopic guidance. A 0,035" × 150 mm J-tip guidewire is advanced into the pericardial space; the position of the tip should appear looping freely in the pericardial space. A 6 F pigtail catheter is advanced over the guidewire. Intrapericardial pressure is measured. Pericardial fluid is then evacuated and pericardial pressure is measured thereafter. Samples of pericardial fluid are sent for fluid analysis, cytological studies and culturing. A 6 F valved introducer sheath is placed and a second 0,035" × 150 mm J-tip guidewire is advanced. The catheter

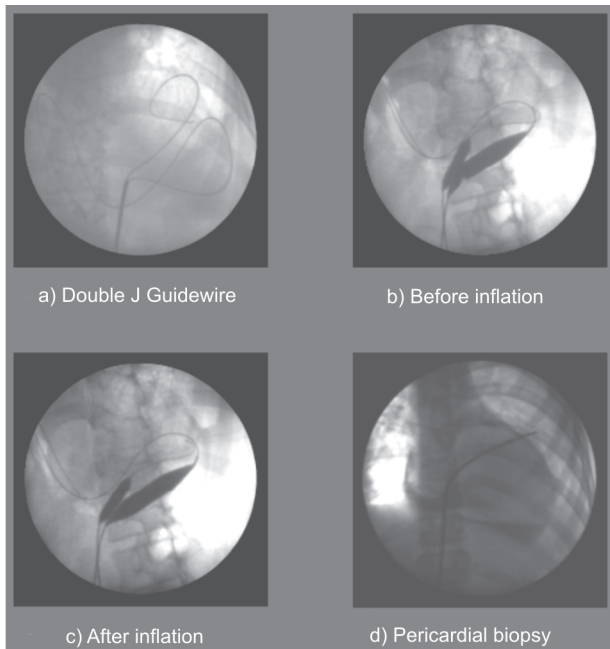


Fig. 2. Pericardiomy and pericardial biopsy images. **A.** Fluoroscopic image with double "J" guidewire in the pericardium. **B.** Image of the double balloon with a notch before inflation. **C.** Image after inflation. **D.** Pericardial biopsy.

is then removed leaving both guidewires in the pericardial space. Two balloon catheters used in angioplasty (crystal balloon, Balt, France) are then advanced. The size of the balloons varies among 12, 15, 18, 20 and 23 mm and they are combined to create a pericardial window of at least 30 mm. As the balloon is inflated, a waist is seen at the pericardial margin, which disappears with full inflation of the balloon as the pericardial window is created. Two to three inflations are performed to assure an adequate opening of the pericardium. The balloon-dilating catheters are then removed, leaving a guidewire in the pericardial space. A new pigtail catheter is then advanced over this guidewire and left for drainage. (10)

The double balloon technique was used in all our patients, and it was considered successful when the window reached a diameter of approximately 30 mm.

A sample for pericardial biopsy was obtained through the same route in 3 patients. A fourth patient who also underwent pericardial biopsy was not included due to the presence of an acute infection.

Pericardial biopsy

A 0.035" J-tip guidewire is advanced through a valved sheath introducer. A Judkins right coronary catheter is advanced over the guidewire into the pericardial space. Then, 5-10 ml of iodinated contrast agent is injected in the pericardial space to help outline the parietal pericardium. The catheter is advanced by orientation of the fluoroscopic image in the anteroposterior view and in the right anterior oblique view until a tent-like image is formed. A 7-F biopsy forceps device (Cordis by Johnson & Johnson, or similar), 104 mm-long is introduced and 6-8 samples are taken along the posterolateral wall. (12)

Patient care after the procedure

After PBE, patients returned to the intermediate care unit. The pericardial catheter remained patent and pericardial drainage volumes were recorded during 24 hours. The catheter was removed when the drainage was less than 75 ml in 24 hours. Two-dimensional echocardiography and chest x-ray were performed within 24 to 48 hours after removal of the pericardial catheter.

Table 1 summarizes the general characteristics of the population and the technical details of the procedure.

Follow-up

Patients were followed-up with medical visits 1 month, 6 months and 1 year after the procedure.

RESULTS (Table 2)

Mean age was 52.5 ± 18 years and 60% were women. Primary and secondary management strategies were indicated in 73% and 27% of cases, respectively. The diagnosis was severe symptomatic pericardial effusion in 67% of cases and cardiac tamponade in 33%. The median volume of pericardial fluid that was drained during the procedure was 800 ml, (25%-75% IQR, 650-1650). Hemopericardium or serosanguineous pericardial effusion occurred in 80% of patients. Pericardial drainage did not last longer than 48 hours.

The most prevailing underlying conditions were neoplasms (46.6%) and chronic infections in 5 cases (33.3%): 3 patients with acquired immunodeficiency syndrome (AIDS), 1 with tuberculosis and 1 with both diseases. Scleroderma (1 patient), congestive heart failure (1 patient) and hypothyroidism (1 patient) were less frequent.

The median duration of the procedure was 85 minutes (percentiles 25%-75%, 80-90).

The primary success was achieved in all the procedures.

No major complications were reported during hospitalization, yet minor complications occurred. Pleural effusion was the most frequent complication (13 patients, 86%); most of them were mild effusions and resolved spontaneously. The time to radiological development of a new left pleural effusion was $2.8 \text{ days} \pm 0.4 \text{ days}$ (2-5). No pleural effusions were reported one month after the procedure. Six patients (40%) complaint of mild chest discomfort and 3 patients (20%) presented self-limited non-infectious fever within the first 24 hours.

The following events were reported during the first year of follow-up (mean 8.5 ± 4.7 months) (Table 1): mild recurrent pericardial effusion (1 patient, 6.65) not requiring a new procedure and 7 deaths related to the underlying diseases (46%).

The three samples referred to histopathological study corresponded to pericardial tissue with unspecified inflammation; in one case, the culture was positive for tuberculosis.

Table 1. General characteristics of the population and the technical details of the procedure and results

N°	General characteristics of the population and the technical details of the procedure							Seguimiento al año	
	Age	Gender	Cause	Intrapericardial pressure before and after the procedure	Fluid characteristics	Biopsy	Drainage duration	Months of survival	Recurrent pericardial effusion
1	33	F	AIDS	B 15 - A 0	Hemorrhagic	No	24 h	9	No
2	60	F	Breast cancer	B 20 - A 0	Hemorrhagic	No	24 h	11	No
3	22	M	AIDS	B 30 - A 0	Hemorrhagic	No	24 h	12	No
4	65	M	Lymphoma	B 25 - A 0	Serosanguineous	No	24 h	6	No
5	61	F	AIDS	B 22 - A 0	Hemorrhagic	No	48 h	1	No
6	66	M	Breast cancer	B 22 - A 0	Serosanguineous	No	48 h	12	Yes
7	35	F	Scleroderma	B 25 - A 0	Serous	No	24 h	12	No
8	78	M	Hypothyroidism	B 20 - A 0	Serous	No	24 h	12	No
9	70	M	Lymphoma	B 20 - A 0	Serosanguineous	No	24 h	12	No
10	70	F	CHF	B 30 - A 0	Serous	No	24 h	1	No
11	45	F	AIDS-TBC	B 25 - A 0	Serosanguineous	Yes	24 h	1	No
12	50	F	Cervical cancer	B 20 - A 0	Hemorrhagic	No	24 h	12	No
13	47	F	Lung cancer	B 25 - A 0	Serosanguineous	Yes	24 h	3	No
14	65	F	Lung cancer	B 20 - A 0	Serosanguineous	No	24 h	12	No
15	21	M	TBC	B 20 - A 0	Hemorrhagic	Yes	24 h	12	No

CHF: Congestive heart failure. AIDS: acquired immunodeficiency syndrome. TBC: Tuberculosis.

Table 2. Results and complications

Mean age	52,5 ± 18 años
Gender F/M	60%/40%
Severe effusion	67%
Cardiac tamponade	33%
Primary management strategy	73%
Previous pericardiocentesis	27%
Neoplasm	46%
Infection	33%
Other	21%
In-hospital complications	
Pleural effusion	86%
- mild	77%
- moderate	23%
Chest discomfort	40%
Fever	20%

DISCUSSION

The main objectives of the management of cardiac tamponade and severe pericardial effusion include the prevention of the major complications related to hemodynamic compromise and of recurrences. The incidence of recurrent pericardial effusion after

pericardiocentesis is 15% to 40% according to different authors. (2, 6) “Blind” pericardiocentesis is not free from complications such as ventricular puncture, laceration of the heart and coronary arteries, arrhythmias, pneumothorax, trauma of abdominal organs, cardiopulmonary arrest and death. In addition, about 10% of these procedures are not successful. (13) A series of 245 echocardiographically-guided pericardiocentesis reported that the procedure was successful in 97% of cases.

In patients with failed pericardiocentesis or with pericardial hematoma (14, 15), two surgical options have been described: the creation of a pericardial window through a subxyphoid approach or through thoracotomy followed by pericardiotomy. Subxyphoid pericardial window is the conventional therapy for cardiac tamponade due to its elevated rate of success (91%) and the low incidence of complications and recurrences. (14) Park et al. compared both surgical techniques and found lower postoperative morbidity for the subxyphoid approach (10% versus 67% for thoracotomy with pericardiectomy). (15) Pericardiectomy is associated with high mortality rate (13%); for this reason, its indication should be limited only for those cases requiring an extensive resection of the pericardium. A less invasive approach should be preferable for extremely ill patients.

Intrapericardial instillation of sclerosing agents as tetracycline, bleomycin, thiotepa and radiopharmaceuticals has proved to prevent recurrences by 30%

to 90% at 30 days without producing adverse effects, except for chest pain associated with the infusion of tetracycline. The incidence of recurrent pericardial effusion was 17% after 1 year of follow-up. Other cytostatic and sclerosing agents might also be useful. (16, 17)

Subxiphoid pericardial window has been the surgical option of choice during the last years due to its low incidence of complications and the possibility of obtaining samples for a pericardial biopsy (18).

Percutaneous balloon pericardiectomy is a therapeutic alternative which developed subsequently. It may be considered the percutaneous variant of surgical subxiphoid pericardial window with the advantage of being a less invasive procedure. Our experience confirms that it is a simple procedure that can be performed in extremely ill patients with low incidence of complications.

The exact mechanism to explain the success of percutaneous pericardiectomy is controversial. In 13 of our 15 patients we found left pleural effusion after the procedure. The frequency of this universal finding suggests that drainage of the pericardial fluid into the pericardial space is one of the main mechanisms that prevent recurrences. Other mechanisms proposed are peritoneal drainage and the inflammatory fusion of the epicardium to pericardium after fluid evacuation. (17, 19, 24)

In our series mean age and population distribution by gender (Table 1) was similar to those reported by a multicenter registry. (20) Neoplasms were the most prevalent underlying conditions in the multicenter registry (85%) and the first cause of pericardial effusion in our series (46%); yet, we found a significant incidence of infections (33%).

Ziskind et al. communicated that PBP was a safe and effective procedure in their first report of 50 patients, with a primary success rate of 92%. (20) We also found a high success rate (100%) We performed primary PBP in 73% of our patients compared to 50% in the multicenter registry; (20) in our opinion, the advantage of a primary management strategy is that it prevents the risk of developing a second pericardial effusion with eventual cardiac tamponade and the need for an urgent pericardiocentesis, as has been recently communicated. (21, 22)

In our series, patients with suspected acute bacterial infection were not eligible for percutaneous pericardiectomy; however, in other study (23) a patient with high operative risk was successfully treated. New studies are necessary to assess the risk/benefit ratio of the procedure in these patients.

In our experience, pleural effusion was the most frequent complication; it resolved spontaneously and was clinically irrelevant. Few series have reported the need for interventions to evacuate pleural effusion. (25)

The multicenter registry (20) did not report recurrent pericardial effusion within 5 ± 5.8 months of follow-up. In other series, Thanopoulos et al. commu-

nicated a survival free from recurrences of 90% at 14 months of follow-up. (26) Our patients who were still alive one year after the procedure had no need for new interventions due to recurrent pericardial effusion.

In patients with cardiac tamponade, short-term survival is related to early diagnosis and treatment; however, long-term survival depends mostly on the prognosis of the underlying condition regardless the type of intervention performed. (6) Despite the primary success of the procedure and the absence of recurrences of pericardial effusion, the long-term prognosis of all our patients was strictly related to the outcomes of the underlying disease. Pericardial effusion was not the cause of death in any of our patients.

The sensitivity of pericardial biopsy under fluoroscopic guidance as a diagnostic test is about 8.3%. When samples are obtained under pericardioscopy, sensitivity increases to 53%. (13, 27) In our study, the etiological diagnosis was made in one out of three cases (33%).

CONCLUSIONS

Percutaneous balloon pericardiectomy is a useful and simple technique, with a high rate of success and a low incidence of minor complications and recurrences. It is a valid therapeutic option for patients with severe pericardial effusion or cardiac tamponade and preferable to the classic pleuropericardial window for critically ill patients; in these patients, the procedure is well tolerated and has low anesthetic and operative risk.

Our experience confirms that PBP may be carried out in a tertiary care center in our country with in-hospital outcomes and long-term results that are similar to those observed in international backgrounds.

Percutaneous pericardial biopsy with local anesthesia might add diagnostic information within the same procedure.

RESUMEN

Procedimientos pericárdicos percutáneos: resultados hospitalarios y en el primer año

Introducción

La ventana quirúrgica pleuropericárdica ha sido el tratamiento convencional del derrame pericárdico grave o taponamiento recidivante hasta el advenimiento de la pericardiotomía percutánea con balón.

Objetivos

Analizar nuestra experiencia inicial en procedimientos pericárdicos realizados en pacientes con derrame pericárdico.

Material y métodos

Se incluyeron 15 pacientes en forma consecutiva tratados con pericardiotomía percutánea con balón por derrame pericárdico grave o taponamiento. Se consideró éxito primario a la pericardiotomía percutánea con balón efectiva

sin necesidad de una nueva intervención por derrame pericárdico y alta hospitalaria sin complicaciones mayores. Por la misma vía se realizó una biopsia pericárdica en 3 pacientes.

Resultados

El éxito primario se alcanzó en todos los procedimientos. En el seguimiento intrahospitalario, el derrame pleural fue la complicación menor más frecuente. En el seguimiento al año se produjeron 7 muertes atribuidas a la enfermedad de base sin que se observaran recidivas de derrame pericárdico.

Conclusiones

En nuestra serie de pacientes, la pericardiotomía percutánea con balón resultó una técnica útil y simple, con una tasa alta de éxito y una tasa baja de complicaciones y recidivas. La biopsia pericárdica percutánea podría agregar información diagnóstica en un mismo procedimiento.

Palabras clave > Pericardiectomy - Balloon dilatation - Pericardial Effusion - Cardiac Tamponade

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