

The Efficiency of Surgical Subxiphoid Pericardial Drainage and Percutaneous Pericardial Drainage in Pericardial Effusions Associated with Cardiac Tamponade

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Rezumat

Eficiența drenajului pericardic subxifoidian chirurgical și a drenajului pericardic percutan în revărsate pericardice cu tamponadă cardiacă

Obiective: Tratamentul optim pentru pericarditele efuzive cu tamponadă cardiacă rămâne controversat. Studiul actual compară rezultatele în urma a dintre cele mai utilizate proceduri de drenaj pericardic: drenajul pericardic subxifoidian (DPSS) și drenajul pericardic percutan (DPPK).

Material și metode: Am realizat un studiu retrospectiv pe o perioadă de 5 ani pentru a analiza rezultatele după DPSS și DPPK la pacienți cu revărsate pericardice ne-traumatice asociate cu tamponadă cardiacă.

Rezultate: Pacienți cu tamponadă cardiacă ne-traumatică au fost tratați prin DPSS (N 138) și DPPK (N 54). N-au fost sesizate diferențe statistice între grupuri în ceea ce privește: vârsta, volumul drenajului și durata drenajului. Etiologia a fost malignă în 72 cazuri și benignă în 120 cazuri. Supraviețuirea la 2 ani a fost ne semnificativă statistic: 55,1% pentru grupul chirurgical și 44,4% pentru grupul percutan, dar a fost o ușoară dominanță a etiologiei maligne în primul grup (38% versus 35%). Supraviețuirea la pacienții cu cito- sau histologie malignă dovedită a fost statistic mai redusă decât la pacienții cu diagnostic malign, dar cu ambele cito- și histologie negative (7% versus 33%). Absența reintervenției la 1 an pentru recurența revărsatului pericardic a fost statistic mai bună în

grupul chirurgical decât în grupul percutan (92,8% versus 79,6%).

Concluzii: DPSS și DPPK pot fi ambele efectuate cu minimă morbi-mortalitate. DPSS pare să scadă riscul de intervenție de drenaj pericardic pentru recurența revărsatului pericardic, dar aduce un avantaj minim pentru diagnosticul de malignitate al revărsatului pericardic față de citologie luată singular.

Cuvinte cheie: tamponadă cardiacă, drenaj pericardic subxifoidian, drenaj pericardic percutan, citologie pericardică, histopatologie pericardică

Abstract

Objectives: The optimal management for pericardial effusions with cardiac tamponade remains controversial. This study compares the results after two commonly performed techniques: subxiphoid surgical pericardial drainage (DPSS) and percutaneous catheter drainage (DPPK).

Material and methods: We conducted a 5-year retrospective study to analyse the outcome after DPSS and DPPK in patients with non-traumatic pericardial effusions with cardiac tamponade.

Outcomes: Patients with non-traumatic cardiac tamponade were treated with DPSS (N=138) and DPPK (N=54). There were no statistical differences between groups regarding: age, drainage volume and duration of drainage. The etiology was malignant in 72 patients and benign in 120 patients. The 2-year survival was statistically non-significant: 55,1% in the surgical group and 44,4% in the percutaneous group, but there was a slight prevalence of malignant diagnosis in the first group (38% versus 35%). The 1-year survival in patients with proved cyto-/histological malignancy was statistically poorer than in

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patients with malignant diagnosis and with both negative cytology and histology (7% versus 33%). The 1-year freedom of re-intervention for recurrence of pericardial effusion was statistically better in the surgical group as in the percutaneous one (92.8% versus 79,6%).

Conclusions: DPSS and DPPK can be both safely performed. DPSS appears to decrease intervention-necessitating recurrence, but it brings a minimal advantage for the malignant diagnosis over cytology alone.

Key words: cardiac tamponade, subxiphoid pericardial drainage, percutaneous pericardial drainage, pericardial cytology, pericardial histopathology

Introduction and Aims

The treatment of pericardial effusions associated with cardiac tamponade (CTa) remains a controversial subject, despite the fact that the first efficient treatment of this affliction was obtained through surgical subxiphoid drainage in 1829 (1).

At present, several pericardial drainage techniques (mini-invasive or invasive) that can be associated with local intrapericardial treatment (sclerotherapy, chemotherapy) (2,3) and (if required) pericardioscopy guided pericardial biopsy (4-11) are practiced, with variable results. However, there are no records of randomized studies comparing the efficiency and complications of these methods in medical literature.

The present study analyses 2 of the most frequent therapies used in pericardial effusions associated with CTa: percutaneous catheter pericardial drainage (PCPD) and surgical subxiphoid pericardial drainage (SSPD).

The specific advantages of SSPD and PCPD respectively are broadly described in specialized treatises (5,6).

The present study compares the results of the two above mentioned therapeutic methods from several points of view: peri-procedural complications and mortality, diagnostic sensibility, survival rate in the first 2 years following the procedure and lack of reintervention need due to the recurrence of pericardial effusion during the first year after the procedure.

Materials and Methods

The study was performed retrospectively, on 192 patients who were successively admitted to and treated within the Army Center for Cardiovascular Diseases and Bucharest Central Military Hospital for pericardial effusion with cardiac tamponade, between January 2005 and December 2011. Consent for conducting the study was received from the above mentioned institutions.

The criteria for inclusion in the study were: echocardiographic and/or clinical diagnosis of pericardial effusion with CTa, first record of surgical pericardial drainage in the patient's history and patient treatment through one of the two methods:

SSPD and PCPD respectively. Patients with traumatic CTa were deliberately excluded from the study.

The CTa was diagnosed in all cases by a cardiology specialist based on clinical signs and symptoms and on the cardiac ultrasound exam. The choice of treatment was made by the cardiologist, usually in collaboration with the thoracic or cardiovascular surgeon. There was no particular protocol followed in directing each patient towards one type of treatment or the other, but the cardiac ultrasound image was in some cases crucial for orienting towards SSPD, if suspicion of pericardial fluid fixing (effusion primarily fixed posteriorly or inferiorly, obvious locations for fixing) was raised.

Surgical registries from the 7 year period during which the study was conducted were consulted. 357 patients with pericardial effusion were identified, on which SSPD or PCPD was performed. After a careful analysis of these patients' clinical files, 165 patients were excluded from the study, based on the following reasons: 29 patients presented pericardial effusion of traumatic aetiology, 105 patients benefited from pericardial drainage interventions (SSPD or PCPD) without presenting clinical or ultrasound imaging signs of CTa, 17 patients required a SSPD reintervention (the first SSPD having been performed prior to the study start date), and in 14 cases the data recorded in the patient files were insufficient. In the end, 192 patients remained to be included in the study.

We divided patients into 2 study groups: one consisting of 54 patients who benefited from PCPD and a group of 138 patients treated through SSPD. These interventions were performed by various cardiologists and surgeons respectively, of the above mentioned surgical specialties.

The technique used in SSPD was a classic one (4-6, 12-14), in most cases performed under local anaesthesia enhanced by sedation. Certain technical details need specifying:

- Disinfecting and application of surgical drapes was often performed before inducing the anaesthesia, in order to allow rapid intervention in case of haemodynamic decompensating;
- 7-9 cm incision centred on the apex of the median xiphoid appendix;
- Routinely performed resection of the xiphoid appendix;
- Routinely performed sampling of a pericardial fragment of 2-4 cm diameter, along with pericardial fluid sampling for cytological, bacteriologic and biochemical analyses;
- Digital checking of the pericardial cavity in order to detect adhesions that were digitally lysed where found;
- Insertion of large diameter pericardial tube (28F), exteriorized through a counterincision in the superior abdominal quadrant, avoiding to exteriorize it through the initial incision - a procedure associated with a higher risk of infection or postoperative incisional hernia;
- Instillation of a sclerosing, chemotherapeutic agent, or creation of a pericardioperitoneal window were not performed as part of the first intervention;

- Pericardial drainage was maintained for a period of time considered appropriate by the treating physician, without there being an established protocol regarding it.

The local anaesthesia procedure used in PCPD is the classic procedure (14,15) and involved the following technical details:

- Ultrasound guided pericardial puncture with an 18-gauge, 8 cm spinal needle with an introducer;
- Placement of a thin soft tip guidewire through the cannula hub after removing the introducer;
- Minimal skin incision at guidewire level;
- Introduction of an intrapleural 8F catheter with multiple lateral vents and a distal vent;
- Securing the catheter to the skin;
- Pericardial drainage was maintained for a period of time decided by the treating physician as well, without there being an established protocol for the procedure;
- Instillation of a sclerosing agent, or local chemotherapy were not performed.

The clinical data of the patients studied were obtained from the patients' clinical and ICU files.

A routine cardiac ultrasound exam was not performed early postoperatively during the patient hospitalization period, this aspect being left at the decision of the treating physician, depending on the resolution or recurrence of cardiac-respiratory symptoms.

Postoperative patient follow-up for the purposes of the study was performed through scheduled surgical consult, 1 month after the procedure, and periodic cardiologic consult (outpatient registers were revised) or through revising new patient files in case of patient readmission to the centre. In

order to obtain the necessary data, the patients' families or GPs were often consulted. The intended aim was to acquire data concerning survival in the first two years after the procedure and reintervention necessity due to recurrence over the first postoperative year. Also, data regarding intra-operative mortality and that during hospital stay, postoperative complications, and pericardial cytological and histopathological exam result were obtained.

Data statistical processing was performed with IBM SPSS programme (version 19). Survival rates and the risk of reintervention due to recurrence were estimated through the Kaplan-Meier curve, and by means of the log-rank test (Mantel-Cox). These data were compared between the 2 patient study groups. With the help of the Cox regression of proportionate hazard patient preoperative characteristics were adjusted in order to compare survival rates and reintervention risks among the 2 groups. Continuous variables were expressed through an arithmetical average rate (M) \pm standard deviation (SD) and were compared to the t Student and the non-parametrical Mann-Whitney (U test) respectively for the two groups. Definite variables were compared by means of the chi square test. For p under or equal to 0.05 the differences were considered to be of statistical relevance.

Results

Clinical and ICU files of all 192 were analysed: 92 men and 100 women with ages between 34 and 81 years old and an age average of 60.8 ± 11.4 years. Peri-procedural variables, divided in the 2 study groups, were statistically compared and presented in *Table 1*.

	SSPD	PCPD	p
Pre-procedural Characteristics of the Two Groups			
Age (years)	61.3 \pm 11.2	59.9 \pm 12.1	0.45
Gender (Feminine)	72 (52.2%)	28 (51.9)	0.97
Clinical CTa	43 (31.16%)	19 (35.19%)	0.60
Pericardiocentesis in history	45 (32.6%)	22 (40.7%)	0.29
Cardiac diseases:	83 (60.14%)	34 (62.96%)	0.72
Respiratory diseases:	78 (56.52%)	32 (59.26%)	0.73
Associated pleurisy	70 (50.7%)	26 (48.1%)	0.75
Intra-procedural Characteristics of the Two Groups			
Intra-procedural mortality	1 (0.7%)	1 (1.9%)	0.49
Cardiac complications:	26 (18.8%)	23 (42.6%)	0.001*
- "Benign" arrhythmias	15 (10.87%)	18 (33.3%)	<0.001*
- HD instability	5 (3.6%)	2 (3.7%)	0.98
- Cardiac arrest (VFib)	6 (4.3%)	2 (3.7%)	0.84
- Myocardial rupture and conversion to median sternotomy	0	1 (1.9%)	0.11
Pneumothorax	0	1 (1.9%)	0.11
Post-procedural Characteristics of the Two Groups			
Global complications	48 (34.8%)	18 (33.3%)	0.84
Cardiac complications	46 (33.3%)	16 (29.63%)	0.62
Respiratory complications	30 (21.74%)	10 (18.52%)	0.62
Wound infection	3 (2.27%)	-	-
Fever > 38C	14 (10.14%)	5 (9.26%)	0.85
Malignant aetiology	53 (38.41%)	19 (35.19%)	0.68
Drainage period (days)	4.26 \pm 1.29	4.17 \pm 1.65	0.67
Drainage volume (ml)	346.3 \pm 158.93	386.04 \pm 191.9	0.15
Hospital stay mortality	18 (13.04%)	11 (20.37%)	0.68

Table 1. Statistical comparison of the main peri-procedural characteristics in the two groups

Table 2. Pericardial cytology and histopathology in patients with neoplastic aetiology divided between the two groups

SSPD (N=53)			PCPD (N=19)			
			(-)	(+)	(-)	(+)
Histopathology	(-)	Cytology (-)	24 (45%)	0	10 (52.6%)	0
		(+)	0	7 (13%)	0	9 (47.4%)
	(+)	Cytology (-)	0	3 (5.6%)	0	0
		(+)	0	19 (39%)	0	0

Statistically relevant differences were observed only in relation to the rate of “benign” intra-procedural arrhythmias (different from ventricular fibrillation, sustained ventricular tachycardia or ventricular flutter), which was higher in the PCPD group. No other statistically relevant differences were noted comparing the 2 groups.

Intra-procedural mortality was minimal (1 patient in each group, without any statistical difference); however, mortality during hospital stay was a relatively high 15.1%, a fact that could be explained by the myocardial suffering that is associated with pericarditis.

In patients with pericardial effusion of malignant aetiology, the accuracy of the neoplastic diagnosis made through cytopathological exam, which in the PCPD group was compared to that of those made through association with histopathological exam of the pericardial sample in the SSPD group. Results are shown in Table 2.

Despite of the 5.6% surplus of patients with histopathological confirmation of a malignant aetiology, the association between a cytological exam and a histopathological one does not appear to significantly increase the diagnostic rate of a malignant aetiology of the pericardial effusion (p=0.582 calculated by means of the chi-square test).

Clinical follow-up had the following end-points: survival during the first two years after the procedure (for which data was obtained from 100% of the patients) and lack of pericardial effusion recurrence requiring reintervention during the first postoperative year (for which data was obtained from 89% of patients, excluding a patient requiring conversion to median sternotomy for iatrogenic myocardial rupture).

Curves of survival during the first two years after the procedure for each group were calculated by means of the Kaplan-Meier method. No statistically relevant differences between the 2 batches were noted (p=0.145 through the

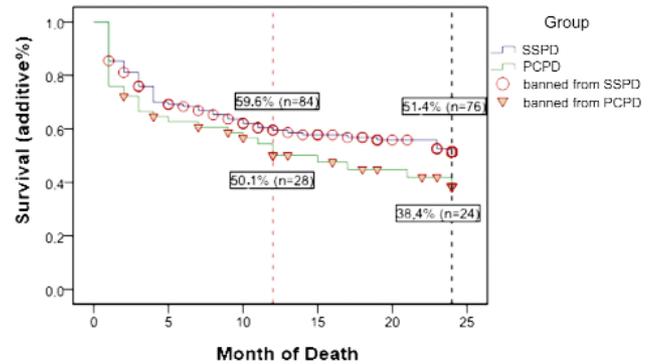


Figure 1. Two year post-operative survival, by groups of patients, through Kaplan-Meier Method (p=0.145 through log-rank test)

Mantel-Cox test). (See Fig. 1)

We adjusted the risk of death during the first 2 postoperative years with the help of the Cox regression for proportionate hazard (See Table 3). No differences related to the risk of death between the 2 pericardial drainage procedures (PCPD or SSPD) were noted. We did observe, however, that the risk of death during the first two postoperative years is statistically linked to the patient’s age at the time of the procedure and to the status of the effusion in terms of malignancy. Thus, patients under the age of 60 years old at the time of the intervention have a 0.56 times lower risk of death during the first 2 years postoperatively than those older than 60 years old at the time of the procedure (p=0.017). Also, patient with a benign aetiology of pericardial effusion have an 0.26 times lower rate of death during the first two years after the intervention than those with a malignant aetiology (p=0.07).

Table 3. Adjusting confusion factors due to various postoperative patient characteristics when comparing the risk of death in the first two years post-procedure

	B	p value	Exp(B)	95% Confidence Interval Limits for Exp(B):	
				Inferior	Superior
SSPD Group	-.193	.412	.824	.519	1.308
Benign aetiology	-1.338	.007*	.262	.099	.699
Pericardiocentesis	.366	.465	1.442	.541	3.846
Lack of clinical CTa	-.106	.817	.900	.366	2.209
Pleurisy	.228	.730	1.256	.344	4.586
Lack of respiratory complications	-.098	.874	.906	.269	3.054
Lack of cardiac complications	-.675	.127	.509	.214	1.212
Age < 60 years	-.578	.017*	.561	.349	.902

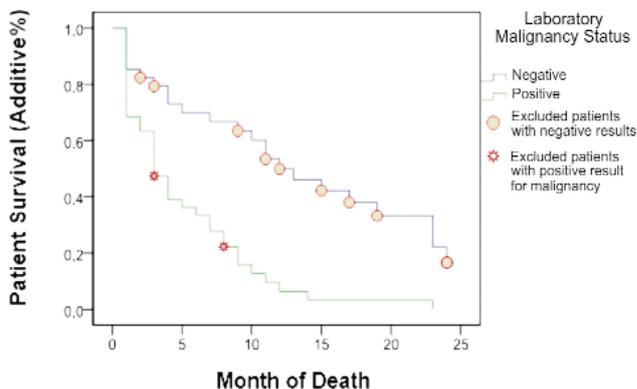


Figure 2. First two-year post-procedure survival curves, comparison between patients with positive or negative laboratory results, for malignancy

We made a comparison between the survival rates of the 72 patients bearing malignant aetiology of the pericardial effusion, according to the cytological or histopathological result conclusive of malignancy. We thus obtained two groups: the positive batch (positive malignant cytological or histopathological exam) and the negative batch (negative pericardial cytological or histopathological exams). The survival curves for the two batches, estimated by means of the Kaplan-Meier method, have shown, through comparison by means of the log-rank test, a significantly higher rate of survival in the negative group ($p < 0.001$) compared to the positive group (16.6% survival rate compared to 0% in the positive group). (See Fig. 2)

The analysis of the period of time throughout which reintervention through pericardial drainage for effusion recurrence during the first year postoperatively was not necessary, compared among the 2 groups and estimated by means of the Kaplan-Meier method, showed a statistically relevant difference ($p = 0.034$ by means of the Mantel-Cox log-rank test) in favour of the PCPD group. (See Fig. 3)

By means of the Cox regression for proportionate hazard, a relative risk 6.38 times higher in the PCPD group than in the SSPD one in terms of reintervention due to effusion recurrence in the first postoperative year was confirmed (confidence interval: 1.21-38.49, with $p = 0.029$). Also, the

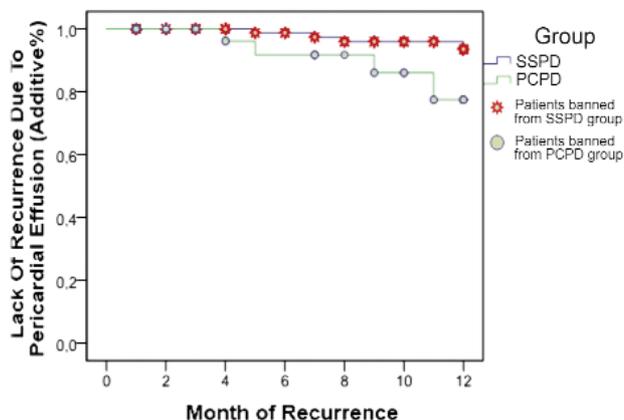


Figure 3. Lack of reintervention for pericardial effusion recurrence, comparison between the 2 groups ($p = 0.023$ through Mantel-Cox test)

relative risk for reintervention was 0.05 times lower in patients with malignant aetiology of the effusion than in those with a benign one ($p = 0.025$). (See Table 4)

Discussions

The present study compared two of the most frequently performed therapeutic-diagnostic techniques for pericardial effusions.

The analysis of the main pre-procedural characteristics of the two patient groups did not reveal any statistically relevant differences, the two groups being relatively even from this point of view (See Table 1 again).

The diagnosis of pericardial effusion of malignant aetiology was established for the present study for all patients with a history of neoplastic processes (whether active or in remission), regardless of the cytological or histopathological laboratory results, if no other aetiology for the effusion could be found after the conclusion of all relevant medical investigations. It is to be remarked that there are studies incriminating a malignant aetiology only when it is confirmed by a cytological or histopathological exam. (16). We believed, as the majority of other authors, that excluding patients with

Table 4. The contribution of various preoperative characteristic in the recurrence of pericardial effusions requiring reintervention

	B	p value	Exp(B)	95% Confidence Interval Limits for Exp(B):	
				Inferior	Superior
Cardiac	1.932	.229	6.902	.296	161.119
PCPD Group	1.921	.029*	6.830	1.213	38.468
Pleurisy	12.080	.942	1.763	.000	2.772
Respiratory	-19.798	.905	.000	.000	2.392
Clinical CTa	10.970	.889	5.811	.000	8.271
Pericardiocentesis in history	-.128	.999	.880	.000	6.870
Benign aetiology	-3.013	.025*	.049	.004	.690
Age > 60 years	.461	.606	1.585	.275	9.135

negative cytological and histopathological exams from the neoplastic aetiology group would represent a selection error (2, 7,12,13-16,17). Paraneoplastic pericardial effusions can appear through various mechanisms, not only through metastasis; also, the possibility of a false negative biopsy result must be taken into account. A reverse pathway of malignant cell dissemination after the invasion of the mediastinum ganglia would require a larger invasion of the visceral pericardium, rich in lymphatic vessels, than of the parietal one, which was submitted to the biopsy exam (18).

Confirmation of malignancy of the pericardial effusion through laboratory (cytological or histopathological) exams in patients with a diagnosis of malignant pericardial effusion was obtained in the present study in 53% (N=38) of cases. The rate of confirmation of pericardial malignancy in patients with malignant affliction (active or in remission) is recorded in various studies to be between 50-79% (2,7,15-17). The diagnostic success in determining the malignant aetiology of the pericardial effusion through pericardial biopsy associated with cytological analysis would be minimal, according to the present study and to various other data recorded in medical literature (17). In the SSPD group, a positive malignant result was obtained through pericardial biopsy in 44.6% of the patients, while cytological exams were positive in 52% of the patients with prior diagnosis of cancer. By combining the 2 methods a minimal increase of the rate of malignant pericarditis was obtained, increasing to 57.6%. 3 patients (5.6%) obtained additional confirmation through histopathological exam; the association of the histopathological exam to the cytological one in diagnosing the malignant aetiology of the pleural effusion had no statistical relevance, being measured with the chi-square test to be $p=0.582$. This fact casts a shadow of doubt over the utility of SSPD in diagnosing a malignant aetiology through „a l'aveugle” pericardial biopsy. There are some authors, however, who recorded better results of diagnosing malignancy through pericardioscopy guided pericardial biopsy associated with SSPD (11).

An attentive analysis of Fig. 2 indicates that recurrences of pericardial effusions requiring reintervention develop 4 months after the first intervention, regardless of the drainage procedure performed. Moreover, patients with malignant aetiology of pericardial effusions required a reintervention for fluid drainage after an average of 6.6 months after the procedure, comparing to the global average of 7.6 months post-procedure for other pericardial effusions.

The present study has shown that determining the malignant aetiology of a pericardial effusion through laboratory exams (cytological or histopathological) has prognostic repercussions on the first two-year post-procedure survival rate. This fact was proved by another study as well (7) and could represent an argument in favour of indicating PCPD as a method of first intention, as opposed to SSPD in patients with neoplastic aetiologies and low (under 6 months) life expectancy, as the risk of recurrence is extremely reduced for a period of time of under 6 months after the procedure.

Survival in the first two years after the procedure was not

statistically different when comparing the 2 procedures (SSPD or PCPD), being influenced significantly only by some postoperative characteristics of the patients: their age at the time of the intervention and the presence of a malignant aetiology of the pericardial effusion. The result is in accordance with that of other recent studies. (7,12)

The risk of reintervention for recurrence of pericardial effusion in the first year after the procedure was higher in patients with malignant aetiology than in those with a benign one ($p=0.025$). The result is in accordance with those published by Paterson A. et al (7) in 2003, also taking into account that the current study included a slightly higher number of patients with malignant aetiology in comparison to study (7) (37% versus 32%). The risk of reintervention due to recurrence is significantly lower in the SSPD group (6.4% in the SSPD batch, compared to 22.6% in the PCPD batch), even despite a certain predominance, statistically irrelevant, of a malignant aetiology in this group (38.41% versus 35.19%). The result is in accordance with previously published studies, there being recorded in medical literature first-year post-procedure recurrences with an average of 0-30% in the PCPD group, and 0-9% in the SSPD group (2,3,7,10,16,19-31); however, a large number of these studies do not present a comparative analysis of the 2 pericardial drainage methods (2,7,16,18-28,30).

It has also been observed that SSPD in association with general or local anaesthesia did not determine a higher rate of morbidity-mortality than PCPD. Intra-procedural mortality was minimal in both interventions (1 intra-procedural death was recorded in both groups, with no statistical relevance), and intra-procedural morbidity was also minimal. During PCPD “benign” arrhythmic complications were recorded more frequently ($p<0.001$). These arrhythmias often required the administration of an antiarrhythmic, but very often converted spontaneously. Hospital stay mortality was slightly higher in the PCPD group (20.37% versus 13.04%), but with no statistical relevance ($p=0.20$). A detailed analysis of this mortality should be conducted in a structured manner, based on the cause of death and on a stratification of the patient preoperative risk. The retrospective data at our disposal did not allow a further expanded analysis on this subject.

The limits of the current study are represented by the lack of randomization of the 2 procedures and, of course, possible cases of cardiac tamponade as a cause of death in those patients that survived their hospital stay, a fact that could affect the rate of reintervention for pericardial effusion recurrence.

Conclusions

- Both procedures (SSPD and PCPD) can be performed with a minimal intra-procedural morbidity-mortality rate. PCPD was, however, associated with a statistically significant higher rate of development of “benign” intra-procedural arrhythmias (other than ventricular flutter/fibrillation, sustained ventricular tachycardia). Hospital stay mortality was not statistically different when comparing the 2 pericardial drainage techniques;

- Survival in the first two years after the procedure did not depend on the type of procedure performed for the pericardial drainage, but was negatively influenced by a malignant aetiology of the effusion and an age of over 60 years at the time of intervention;
- cytology and/or histopathology positive for pericardial malignancy are definite negative ad vitam prognostic factors;
- the diagnostic gain in determining a malignant aetiology of a pericarditis through pericardial biopsy associated with cytological exam, without pericardioscopy guidance, during SSPD is minimal, without any statistical relevance;
- Pericardial effusion recurrence requiring reintervention in the first post-operative year is more frequent among cases with malignant aetiology than in benign cases, and more frequent after PCPD than after SSPD. Usually, pericardial effusion recurrence requiring pericardial drainage reintervention appears after 4 post-operative months, with an average of 6.6 months in cases with malignant aetiology, and 7.6 months in patients with recurrence, regardless of the aetiology.

Corroborating these data, in patients with malignant aetiology of pericardial effusion and low life expectancy rate (under 6 months or estimated according to a malignant pericardial malignancy in the patient history), one will prefer PCPD due to its minimum risk of recurrence within this period of time, thus avoiding the stress of anaesthesia and surgery, and given the lack of utility of performing a diagnostic SSPD in this clinical context.

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