Scientific letters

Expert center and balloon pulmonary angioplasty network program in chronic thromboembolic pulmonary hypertension: safety and effectiveness of a pioneering experience

Centro experto y angioplastia pulmonar en red en hipertensión pulmonar tromboembólica crónica. Eficacia y seguridad de una experiencia pionera

To the Editor,

Although the prognosis of chronic thromboembolic pulmonary hypertension (CTEPH) is poor, its survival has been improved by thromboendarterectomy surgery and balloon pulmonary angioplasty (BPA). Clinical practice guidelines[1] and consensus documents[2] state that BPA should be performed in high-volume expert centers to guarantee good outcomes and a low rate of complications. In Spain, these criteria are met by just 2 expert centers, services, and units (RCSUs), designated in 2015 by the Spanish Ministry of Health for this disease.[3] The objective of this designation is to guarantee equitable access and high-quality, safe, and efficient care for patients with diseases requiring a high level of specialized care and to therefore concentrate patients in a small number of centers. However, this situation needs to be reconsidered due to the growing demand for this procedure and long waiting times in the RCSUs, the increasing interest of non-RCSU centers in performing BPA, and the long distances travelled by patients from other autonomous communities to the RCSUs. In this regard, the consensus document of the European Respiratory Society proposes that BPA procedures be permitted in nonexpert centers, under the guidance of an expert center.[4] Here, we present the results of a pioneering experience that includes the performance of BPA in nonexpert centers through a network protocol coordinated with a referral RCSU.

The multidisciplinary CTEPH unit in our RCSU has been a pioneer in Spain in the teaching of the BPA procedure via theoretical and practical courses and training stays in the unit. In addition, a collaborative network program was developed

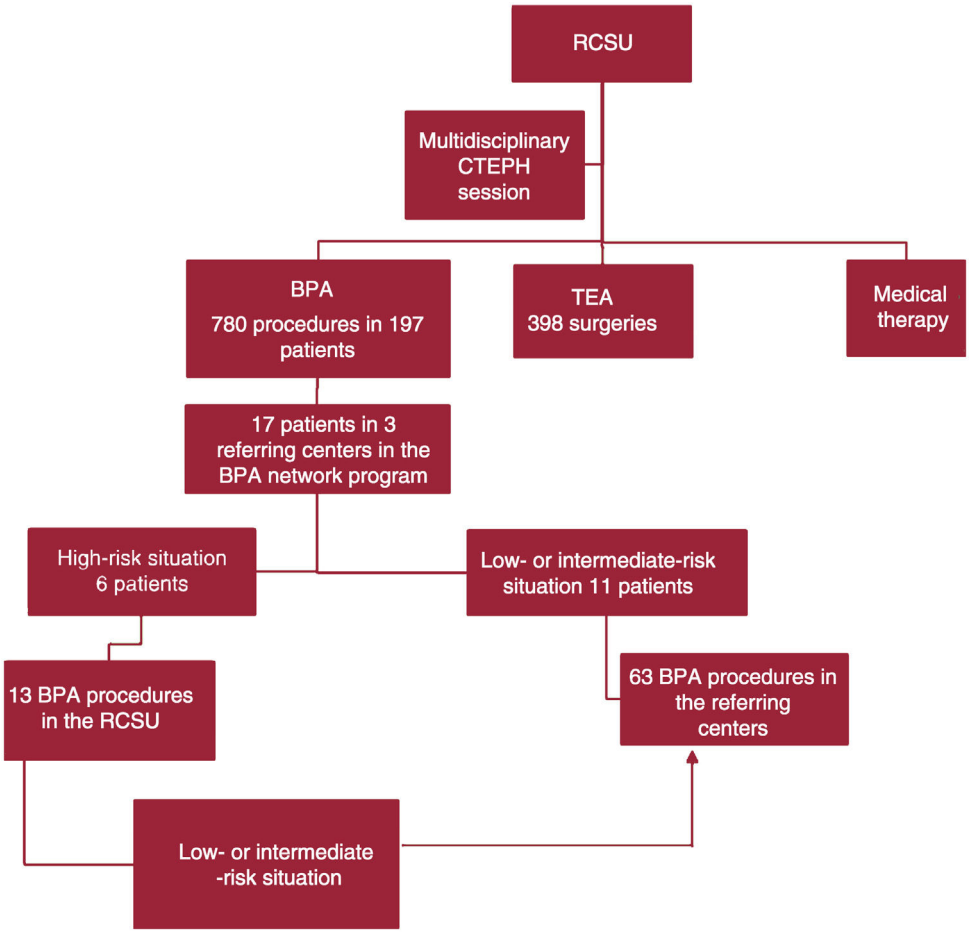

Figure 1. Pulmonary angioplasty network program. BPA, balloon pulmonary angioplasty; CTEPH, chronic thromboembolic pulmonary hypertension; RCSUs, expert centers, services, and units; TEA, thromboendarterectomy.

Table 1
Protocol and results of the pulmonary angioplasty network program

Protocol for a CTEPH network conducted in collaboration with an RCSU for the development and implementation of a pulmonary angioplasty program in referring centers	
Patients indicated for BPA in an RCSU	High-risk patients according to European Society of Cardiology guidelines[1] Patients requiring intravenous dobutamine or epoprostenol before BPA Patients with high-risk hemodynamic parameters: severely reduced cardiac index $\leq$ 1.8 L/min/m^2 or severely elevated mean pulmonary pressure or pulmonary vascular resistances ($\geq$ 45 mmHg or $\geq$ 10 WU) Patients with elevated technical complexity (severely dilated and tortuous pulmonary arteries, patients with residual post-TEA pulmonary hypertension)
Patients indicated for BPA in a referring center	Patients who, in the initial assessment, do not meet treatment criteria in the RCSU Patients who, after 2 or 3 BPA procedures, transition to low or intermediate risk
Prerequisites of the referring center for BPA initiation	Availability of a working unit/group for pulmonary hypertension Possible implementation of extracorporeal membrane oxygenation Availability of at least 1 interventional cardiologist with knowledge of the BPA technique and its complications
Initiation of BPA instruction in the referring center	Performance of the first 10 BPA procedures under guidance in the referring center

Characteristics, complications, and results of the BPA program in the referring centers								
	BPA performed in an RCSU/BPA in referring center	Patients in the BPA program	Completed/in process/interrupted	Starting year	Complications	Peri-BPA deaths	Other major complications	Reason for BPA
Referring center 1	2/30	7 patients 85% women Mean age, 71 (46-86) y	6/1/0	2017	32% of procedures: 1 catheter dissection 6 hemoptysis episodes (3 in 1 patient) 2 mild reperfusion edemas 1 femoral hematoma	No	No	• Distal involvement, 3 patients • Distal involvement + comorbidity in 4 patients ($>$ 80 y)
Referring center 2	6/21	6 patients 50% women Mean age, 69 (58-78) y	4/1/1	2021	27% of procedures: 6 hemoptysis episodes in 2 patients 2 catheter/guidewir e/balloon dissections 1 mild reperfusion edema 1 contrast allergy	No	No	• Post-TEA (n = 1) • Distal involvement (n = 2) • Distal involvement and high surgical risk (n = 3)
Referring center 3	5/12	4 patients 50% women Mean age, 79 (77-86) y	3/1/0	2021	8% of procedures: 1 hemoptysis due to distal perforation, self-limiting	No	No	• Distal involvement in all 4 patients (2 patients $>$ 85 y)

Program results				
	Baseline	End	% improvement, mean (95%CI)	*P*
Mean pulmonary arterial pressure, mmHg	46.8 $\pm$ 15.1	30.2 $\pm$ 6.0	35.7 (19.2-52.1)	$<$ .001
Pulmonary vascular resistance, WU	9.6 $\pm$ 5.3	3.8 $\pm$ 1.7	60.4 (28.1-92.7)	$<$ .01
Cardiac index, L/min/m^2	2.1 (1.9-2.4)	2.6 (2.2-2.8)	23.8	.03
NT-proBNP, pg/mL	1197 (606-3096)	202 (124-363)	83.1	.02
6-min walk test, m	308.8 $\pm$ 87.2	400.0 $\pm$ 107	29.8 (–0.12 to 69.8)	.10
World Health Organization functional class, % I/% II/% III/% IV	I: 0.0 II: 17.7 III: 58.8 IV: 23.5	I: 35.3 II: 47.0 III: 17.7 IV: 0.0	Not applicable	$<$ .01

95%CI, 95% confidence interval; BPA, balloon pulmonary angioplasty; NT-proBNP, N-terminal pro-B-type natriuretic peptide; RCSUs, expert centers, services, and units; TEA, thromboendarterectomy.

with centers that refer patients to our RCSU and would like to begin conducting BPA in order to enable the referring centers to autonomously perform BPA after a training period overseen by our RCSU. The ultimate aim of this collaboration is to secure uniform therapeutic opportunities for patients with CTEPH, whether they are managed in referring centers or in the RCSU, and to guarantee high-quality and safe treatments. Accordingly, we developed a protocol-based collaborative network program (table 1). The main prerequisite of this program is that all patients be presented in a multidisciplinary session in the RCSU to determine each patient's optimal therapy. If BPA is chosen, any low- or intermediate-risk procedures can be performed in the referring centers after a period of guided training (figure 1). A second precondition of the program is that the "nonexpert" center be equipped with a pulmonary hypertension unit experienced in the diagnosis and pharmacological management of pulmonary hypertension, including the use of drugs with complex administration protocols, as well as experience with the intensive care management of possible BPA-associated complications.

Currently, this BPA program in referring centers and coordinated with the RCSU is in operation in 3 centers in autonomous communities distinct from that of our RCSU. Interventional cardiologists in these centers underwent a theoretical/practical course on BPA in our RCSU, conducted the first 10 BPA procedures in their centers under the guidance of an interventional cardiologist from the RCSU, and now independently perform low- and intermediate-risk procedures in their centers. The present work has been conducted in accordance with international recommendations on clinical research and has been approved by the ethics committee of our center. Informed consent was obtained from all patients and stored.

All patients included in this BPA network program were presented in a multidisciplinary CTEPH session in our RCSU in which the appropriate therapeutic option was selected for each patient in conjunction with the referring physicians. The first procedures were performed in our RCSU for high-risk patients or those with elevated technical complexity, so that 13 of the 63 procedures were performed in the RCSU while the remainder were performed in the referring centers (figure 1). The results of this program are shown in table 1. The data show similar clinical, hemodynamic, and biomarker improvements to those published for the first 46 patients who underwent BPA in our RCSU.[5] The periprocedural complication rate in the referring centers was also similar to or lower than that described for our RCSU series.[5] All complications were mild (table 1), with no periprocedural deaths, confirming that the network BPA program is safe for patients.

In conclusion, the preliminary results indicate the feasibility of this novel network protocol for CTEPH, which includes the performance of pulmonary angioplasty in nonexpert centers and conducted in a network coordinated with the referral RCSU for low- and intermediate-risk patients. The preliminary results demonstrate that this approach could be safe and effective. This type of tutored pulmonary angioplasty program in referring centers would additionally reduce procedural delays and improve the efficient management of this disease.

FUNDING

The present work has not been funded by any organization.

ETHICAL CONSIDERATIONS

The present work has been conducted in accordance with international recommendations on clinical research and has been approved by the ethics committee of our center. Informed consent was obtained from all patients and stored. The sex distribution of the population is balanced. Possible sex and gender biases have not been analyzed due to the small sample size.

STATEMENT ON THE USE OF ARTIFICIAL INTELLIGENCE

Artificial intelligence has not been used to draft this article.

AUTHORS' CONTRIBUTIONS

M. Velázquez Martín contributed to the conception and drafting of the manuscript. N. Maneiro Melón managed the data analysis and interpretation. A. Gómez Menchero, R. González Ferreiro, and A. Andrés Morist contributed to the data acquisition. P. Escribano Subias contributed to the conception of the work. All authors have performed a critical review of the intellectual content and have approved the final version of the manuscript. Similarly, all authors agree to be accountable for all aspects of the work and to investigate and resolve any questions related to the accuracy or veracity of any part of the work.

CONFLICTS OF INTEREST

None.

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Available online 26 January 2024

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https://doi.org/10.1016/j.recesp.2023.12.012

Usefulness of remote pulmonary arterial pressure monitoring in patients with advanced heart failure listed for HT

Utilidad de la monitorización a distancia de la presión arterial pulmonar de pacientes con insuficiencia cardiaca avanzada en lista de TxC

To the Editor,

Pulmonary hypertension (PHT) is a common finding in patients with heart failure (HF) and has prognostic relevance.[1] Increasing pulmonary congestion resulting from HF is accompanied by adaptive changes in the pulmonary circulation (remodeling of the vasculature and extracellular matrix) that lead to increased pulmonary vascular resistance (PVR) and combined precapillary and postcapillary PHT, which is frequent in patients with advanced HF.[2] Medical treatment guided by remote pulmonary arterial pressure monitoring (RPAPM) based on the wireless CardioMEMS device (Abbott, United States) implanted in the pulmonary artery reduces HF hospitalizations[3,4] and significantly decreases PHT.[5] CardioMEMS comprises the following components: a sensor with a pressure-sensitive capacitor that is placed inside a branch of the pulmonary artery using right cardiac catheterization (RCC); an electronic system that receives the pressure signal and transmits it on activation by the patient; and a software application that enables interpretation of the signal (figure 1). Readings taken via RCC in the implant help set hemodynamic targets to guide treatment.

Evaluation of PHT is a key element in pretransplant work-up. Irreversible PHT, defined as systolic pulmonary artery pressure >50 mmHg and PVR >3 Wood units or a transpulmonary gradient >15 mmHg, is considered a contraindication for isolated heart transplant. This assessment is performed using RCC and, in the case of PHT, requires the patient to initiate drug therapy to reverse the increase in PVR (diuretics, inotropic agents, or pulmonary vasodilators such as prostaglandins, phosphodiesterase 5 [PDE5] inhibitors, and endothelin receptor antagonists) or be implanted with a left ventricular assist device.[6] The hemodynamic status of patients on the transplant waiting list should be re-evaluated periodically using RCC (generally every 3-6 months). Nevertheless, given the high frequency of decompensation in these patients and the unforeseeable nature of transplant scheduling, such a strategy may be insufficient for predicting the grade of PHT at transplant, with an increase in the posttransplant risk of right-sided HF. Studies evaluating the effectiveness of RPAPM devices show that patients in New York Heart Association functional class IV are underrepresented and that transplant candidates are excluded.[3] However, RPAPM could prove useful in these patients, since it enables closer monitoring and treatment adjustment. This report aims to review preliminary experience in the use of RPAPM to guide the treatment of patients on the heart transplant waiting list.

The CardioMEMS RPAPM program at our center was started in September 2019. The system was implemented in 5 waiting list patients between November 2020 and October 2023. Pulmonary arterial pressure (PAP) readings were evaluated twice weekly by a physician from the HF unit. If the hemodynamic targets changed

Figure 1. CardioMEMS monitoring system. A: implantable sensor. B: patient electronic system. C: computer interface of the monitoring system.