Canadian Journal of Cardiology 35 (2019) 193–198

Clinical Research

Shortening Hospital Stay Is Feasible and Safe in Patients With Chronic Thromboembolic Pulmonary Hypertension Treated With Balloon Pulmonary Angioplasty

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ABSTRACT

Background: There is no consensus on the length of hospital stay (LOHS) and post-interventional management after balloon pulmonary angioplasty (BPA) in patients with chronic thromboembolic pulmonary hypertension (CTEPH). We examined temporal trends with respect to LOHS and requirement for intensive care for BPA and their relationship with the incidence of BPA-related complications.

Methods: From November 2012 to September 2017, a total of 123 consecutive patients with CTEPH who underwent BPA were enrolled (age: 66.0 [54.0 to 74.0], World Health Organization [WHO] functional class II/III/IV; 27/88/8). Patients were divided for analysis into 3 groups according to the date of their first BPA: early-, middle-, and late-phase groups.

Results: Mean pulmonary arterial pressure decreased from 36.0 (29.0 to 45.0) to 20.0 (16.0 to 22.0) mm Hg after BPA ($P < 0.001$). The LOHS was 41.0 (31.0 to 54.0) days in total including all sessions and 6.6 (6.0 to 7.9) days/session. Despite no significant differences in age, baseline hemodynamics, and laboratory data among the 3 groups, there was a significant reduction in LOHS (7.9 [7.0 to 9.5], 6.5 [6.1 to

RÉSUMÉ

Introduction : Il n'y a pas de consensus sur la durée du séjour hospitalier (DSH) et la gestion post-intervention après angioplastie pulmonaire par ballonnet (APB) chez les patients atteints d'hypertension pulmonaire thromboembolique chronique (HPTEC). Nous avons examiné les tendances temporelles en matière de DSH et les besoins en soins intensifs pour l'APB et leur relation avec l'incidence de complications liées l'APB.

Méthodes : Entre novembre 2012 et septembre 2017, un total de 123 patients successifs atteints d'HPTEC et traités par APB ont été inscrits (âge: 66,0 [54,0 à 74,0], classe fonctionnelle II/III/IV de l'Organisation mondiale de la Santé [OMS]; 27/88/8). Pour l'analyse, les patients ont été divisés en 3 groupes en fonction de la date de leur première APB : groupes de phase précoce, intermédiaire et avancée.

Résultats : La pression artérielle pulmonaire moyenne a diminué de 36,0 (29,0 à 45,0) à 20,0 (16,0 à 22,0) mm Hg après l'APB ($P<0,001$). La DSH était de 41,0 (31,0 à 54,0) jours, toutes séances confondues, et de 6,6 (6,0 à 7,9) jours/séance. Malgré l'absence de différence significative entre l'âge, les paramètres hémodynamiques

Optimizing the length of hospital stay (LOHS) and the need for intensive care unit stay for catheter interventions is important to minimize the use of medical resources and procedural costs, without jeopardizing safety.[1-3] Increasing evidence for the efficacy of balloon pulmonary angioplasty (BPA) in improving the hemodynamics and exercise capacity of patients with chronic thromboembolic pulmonary hypertension (CTEPH) is available.[4-10] However, there are no data regarding the current trends in LOHS and use of the intensive care unit for BPA.

The learning curve associated with the introduction of a new procedure might be associated with a reduction in the LOHS as well as efficient use of the intensive care unit. As an example, with increasing experience of the operators in performing transcatheter aortic valve implantation, a reduction in LOHS was feasible, and intensive care unit stay could be avoided in select patients.[1,11] The statement by the Japanese Circulation Society[12] about BPA for CTEPH published in 2014 recommended stay in the intensive care unit under the monitoring of Swan Ganz catheter according to the previous reports.[5,6,13] However, owing to the decrease in the incidence of complications of BPA with the improvement in techniques in recent times,[7] LOHS and the need for stay in the intensive care unit for BPA might be changing in real-world practice.

In this study, we aimed to examine the contemporary trends in LOHS and provision of intensive care unit stay for BPA and their relationship with the incidences of BPA-related complications.

Received for publication October 25, 2018. Accepted December 3, 2018.

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See page 197 for disclosure information.

https://doi.org/10.1016/j.cjca.2018.12.001

7.3], 6.0 [5.3 to 6.5] days/session, $P < 0.001$) and use of intensive/high care unit (100%, 93%, 46%, $P < 0.001$). The reduction in LOHS and intensive/high care unit use did not affect the occurrence of BPA-related complications.

Conclusions: **Increasing experience with BPA was associated with a reduction in LOHS and the use of intensive/high care unit, but no change was noted in the rate of BPA-related complications. These findings suggest that the reduction in both LOHS and use of the intensive care unit for BPA is feasible and does not jeopardize the safety of the procedure.**

de base et les données de laboratoire des 3 groupes, il y avait une réduction significative de la DSH (7,9 [7,0 à 9,5], 6,5 [6,1 à 7,3], 6,0 [5,3 à 6,5] jours/séances, $P<0,001$) et de l'utilisation d'unité de soins intensifs (100 %, 93 %, 46 %, $P <0,001$). La réduction de la DSH et de l'utilisation d'unités de soins intensifs n'a pas eu d'incidence sur le taux de complications liées à l'APB.

Conclusions : **L'expérience accrue de l'APB était associée à une réduction de la DSH et à l'utilisation d'unités de soins intensifs, mais aucun changement n'a été observé dans le taux de complications liées à l'APB. Ces résultats suggèrent que la réduction à la fois de la DSH et de l'utilisation d'unité de soins intensifs pour l'APB est réalisable et ne compromet pas la sécurité de la procédure.**

Methods

In this single-centre retrospective study, we used data from 125 patients with CTEPH who underwent BPA at Keio University Hospital between November 2012 and September 2017. The diagnosis of CTEPH was based on the visualization of confirmed pulmonary thromboembolism on contrast-enhanced lung computed tomography (CT), perfusion lung scintigraphy, and pulmonary angiography after ruling out collagen vascular disease, parenchymal lung disease, left heart abnormality, and other systemic diseases by blood tests, pulmonary function tests, and echocardiography.[14] Mean pulmonary artery pressure (PAP) $\geq$ 25 mm Hg was confirmed on initial assessment during the right heart catheterization (RHC). The indications for BPA were (1) World Health Organization (WHO) functional class $\geq$ II and (2) patients' understanding of the interventional procedures and possible complications and signing the informed consent of their own free will. Although pulmonary endarterectomy (PEA) was considered in all patients, they were subjected to BPA because of the following reasons: (1) peripheral type of lesion; (2) inoperability because of advanced age, poor physical condition, or high-risk of general anesthesia (ie, right heart failure and several comorbidities); (3) patient refusal to undergo PEA; or (4) residual pulmonary hypertension after PEA. Two patients were excluded because they underwent PEA between the BPA sessions. In all, 123 patients who completed all the BPA sessions were evaluated. All sessions were performed by 1 of the authors (T. Kawakami). All patients provided written informed consent, and the institutional review board of Keio University Hospital approved the BPA and analysis of clinical data.

The BPA procedure was performed in staged multiple sessions at intervals of a few days to weeks, during 1 or several hospitalizations, as previously described.[15] All patients underwent RHC for the measurement of right atrial pressure (RAP) and PAP prior to and 1 week after BPA. The cardiac output (CO) was determined by the Fick technique using assumed oxygen consumption. The pulmonary vascular resistance (PVR) was calculated by subtracting the pulmonary capillary wedge pressure from the mean PAP and dividing it by the CO. Biomarkers, such as brain natriuretic peptide (BNP) and high sensitivity-troponin T (hs-TnT) levels, were also assessed before and 1 week after BPA, as previously described.[9] Patients were divided into 3 groups according to date of their first BPA procedure: early- (November 2012 to May 2014, n = 41), middle- (June 2014 to July- 2015, n = 41), and late-phase groups (August 2015 to June 2017, n = 41) for comparison.

Total LOHS was calculated as the sum of LOHS for all BPA sessions. Mean LOHS per session was calculated by dividing the total LOHS by the number of sessions. We collected the data of use of chest CT and intensive/high care unit stay. The intensive/high care unit allowed continuous monitoring of the electrocardiogram (ECG), oxygen saturation, and urine output as well as hemodynamic monitoring (Swan-Ganz catheter) and support (percutaneous cardiopulmonary support [PCPS]), and respiratory support (invasive and noninvasive ventilation assistant) if necessary. Patients who were not admitted to the intensive/high care unit were admitted in the general ward of the cardiology department for standard medical care with continuous monitoring of ECG on the day following the BPA; oxygen saturation was monitored for the entire duration of hospital stay. The need for CT and stay in the intensive/high care unit after BPA was determined by the treating physicians. The data on BPA-related

Table 1. **Baseline characteristics and procedure**

	Overall population (N = 123)	Early phase (N = 41)	Middle phase (N = 41)	Late phase (N = 41)	*P* value
Age, years	66.0 (54.0-74.0)	63.0 (54.0-74.5)	67.0 (48.5-75.0)	68.0 (57.0-74.0)	0.486
Male, n (%)	43 (35.0)	13 (31.7)	15 (36.6)	15 (36.6)	0.867
eGFR, mL/min/1.73m^2	60.5 ± 19.0	61.7 ± 17.5	60.5 ± 19.8	59.3 ± 20.0	0.855
WHO III or IV, n (%)	96 (78.0)	32 (78.0)	35 (85.4)	29 (70.7)	0.278
WHO IV, n (%)	8 (6.5)	3 (7.3)	4 (9.8)	1 (2.4)	0.392
HOT at daytime, n (%)	81 (65.9)	24 (58.5)	31 (75.6)	26 (63.4)	0.244
Number of target vessels, n	14.0 (12.0-16.0)	14.0 (13.0-16.0)	13.0 (11.0-15.0)	16.0 (14.0-17.0)	< 0.001
Number of total sessions, n	6.0 (5.0-8.0)	6.0 (4.5-8.0)	6.0 (4.5-8.0)	6.0 (5.0-8.0)	0.671
Contrast agent dose, ml/session	206 ± 44	215 ± 41	189 ± 43	213 ± 44	0.012

Data are mean ± standard deviation, median (with interquartile ranges) or absolute values with percentages. eGFR, estimated glomerular filtration rate; HOT, home oxygen therapy; WHO, World Health Organization.

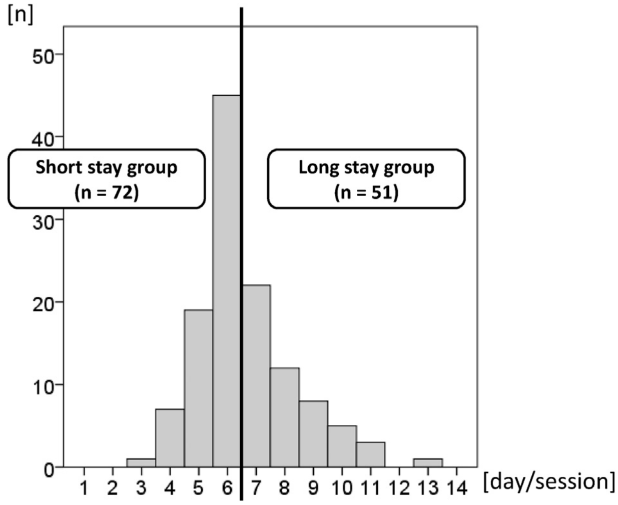

Figure 1. Distribution of the length of hospital stay.

complications—such as pulmonary injury, contrast-induced nephropathy (CIN), the need for hemodialysis, PCPS or intubation, and death—were collected. Total medical costs during each hospitalization were calculated using the administrative data, based on the cost for each patient's consumption of resources. The cost in this study included only direct costs, including fees for consultation, drugs and intravenous fluids, laboratory and radiologic testing, treatment and operation, rehabilitation, hospital room and nursing, blood transfusions, and anesthesia services.

Normally distributed data were expressed as mean ± standard deviation, nonparametric data as median (with interquartile ranges), and categorical data as absolute values and percentages. Significant differences were determined using the Wilcoxon matched-pairs signed rank test, and Pearson's χ^2 test, 1-way analysis of variance (ANOVA), and Kruskal−Wallis tests, as appropriate. For multivariate analysis to assess the independent determinants of LOHS, the variables included in the model were age, gender, WHO functional class, estimated glomerular filtration rate (eGFR), and the date of first BPA procedure. A P value of < 0.05 was considered to be statistically significant. Statistical analyses were performed using SPSS version 24 (SPSS Inc, Chicago, IL).

Results

The baseline characteristics of the 123 patients enrolled are detailed in Table 1. The population was predominately female, with a median age of 66.0 (54.0 to 74.0) years. The number of target vessels per patient was 14.0 (12.0 to 16.0). BPA was performed in multiple sessions to prevent the complications of pulmonary injury, CIN, and excessive radiation exposure, with 6.0 (5.0 to 8.0) sessions performed per patient. A significant improvement in RAP, PAP, and PVR was observed after BPA (mean RAP: from 6.0 [4.0 to 9.0] to 2.0 [0.0 to 3.0] mm Hg, $P < 0.001$, mean PAP: from 36.0 [29.0 to 45.0] to 20.0 [16.0 to 22.0] mm Hg, $P < 0.001$, PVR: from 541 [389-933] to 272 [202-336] dynes sec cm^{-5}, $P < 0.001$). There was no difference in the CO before and after the BPA (from 3.5 [2.9 to 4.6] to 3.8 [3.2 to 4.5] L/min, $P = 0.253$). Biomarkers also decreased after the BPA (BNP: from 53.2 [24.0 to 240.5] to 24.7 [15.2 to 43.4] pg/mL, $P < 0.001$, hs-TnT: from 11.0 [7.0 to 21.0] to 10.0 [6.0 to 15.0] ng/L, $P < 0.001$). The total LOHS for each patient for all sessions of BPA was 41.0 (31.0 to 54.0) days and 6.6 (6.0 to 7.9) days/session. Of 123 patients, 72 were classified into the short-LOHS group (< 7 days/session), and the rest were in the long-LOHS group (≥ 7 days/session) (Fig. 1).

Table 2. Hemodynamics parameters and biomarkers before and after BPA

	Overall population (N = 123)	Early phase (N = 41)	Middle phase (N = 41)	Late phase (N = 41)	P value
Mean RAP, mm Hg					
Baseline	6.0 (4.0 to 9.0)	6.5 (4.0 to 9.0)	6.0 (4.0 to 8.0)	5.0 (3.0 to 8.0)	0.379
Post-BPA	2.0 (0.0 to 3.0)	2.0 (0.5 to 3.0)	2.0 (0.5 to 3.0)	2.0 (0.0 to 2.5)	
Change from baseline	−4.0 (−6.3 to −2.0)	−5.0 (−7.0 to −2.3)	−4.0 (−6.0 to −2.0)	−3.0 (−6.0 to −1.0)	0.417
Mean PAP, mm Hg					
Baseline	36.0 (29.0-45.0)	35.0 (30.5-44.5)	39.0 (30.0-47.5)	35.0 (28.0-42.5)	0.264
Post-BPA	20.0 (16.0-22.0)	18.0 (16.0-22.0)	21.0 (18.0-22.0)	19.0 (16.0-22.5)	
Change from baseline	−17.0 (−24.0 to −11.0)	−17.0 (−24.5 to −12.5)	−18.0 (−26.0 to −9.0)	−15.0 (−22.0 to −9.5)	0.450
CO, L/min					
Baseline	3.5 (2.9-4.6)	3.5 (2.9-4.5)	3.3 (2.8-4.6)	3.6 (3.0-4.9)	0.621
Post-BPA	3.8 (3.2-4.5)	3.6 (3.1-4.3)	3.9 (3.0-4.7)	3.8 (3.3-4.5)	
Change from baseline	0.2 (−0.5 to 0.8)	0.1 (−0.4 to 0.6)	0.1 (−0.5 to 0.9)	0.3 (−0.8 to 0.9)	0.920
PVR, dynes·sec·cm^{-5}					
Baseline	541 (389-933)	494 (400-965)	598 (414-1018)	558 (349-797)	0.636
Post-BPA	272 (202-336)	267 (176-333)	294 (198-346)	252 (212-336)	
Change from baseline	−295 (−628 to −153)	−240 (−715 to −135)	−384 (−615 to −145)	−295 (−597 to −157)	0.775
BNP, pg/mL					
Baseline	53.2 (24.0-240.5)	39.8 (21.6-127.3)	70.0 (23.3-355.8)	85.2 (33.6-282.8)	0.116
Post-BPA	24.7 (15.2-43.4)	20.3 (14.9-37.1)	30.4 (16.1-50.0)	24.3 (13.9-43.9)	
Change from baseline	−23.5 (−178.3 to 0.0)	−12.7 (−109 to 2.3)	−33.0 (−304.7 to −0.1)	−30.0 (−194.4 to −2.2)	0.168
Hs-TnT, ng/L					
Baseline	11.0 (7.0-21.0)	13.0 (6.5-17.5)	11.0 (6.0-22.0)	12.0 (7.0-20.5)	0.867
Post-BPA	10.0 (6.0-15.0)	8.0 (6.0-13.5)	11.0 (5.0-17.0)	11.0 (6.5-14.5)	
Change from baseline	−1.0 (−7.0 to 1.0)	−1.0 (−6.5 to 0.0)	−1.0 (−7.0 to 0.5)	−1.0 (−7.0 to 1.0)	0.986

Data are median (with interquartile ranges).

BNP, brain natriuretic peptide; BPA, balloon pulmonary angioplasty; CO, cardiac output; hs-TnT, high sensitivity-troponin T; PAP, pulmonary arterial pressure; PVR, pulmonary vascular resistance; RAP, right atrial pressure.

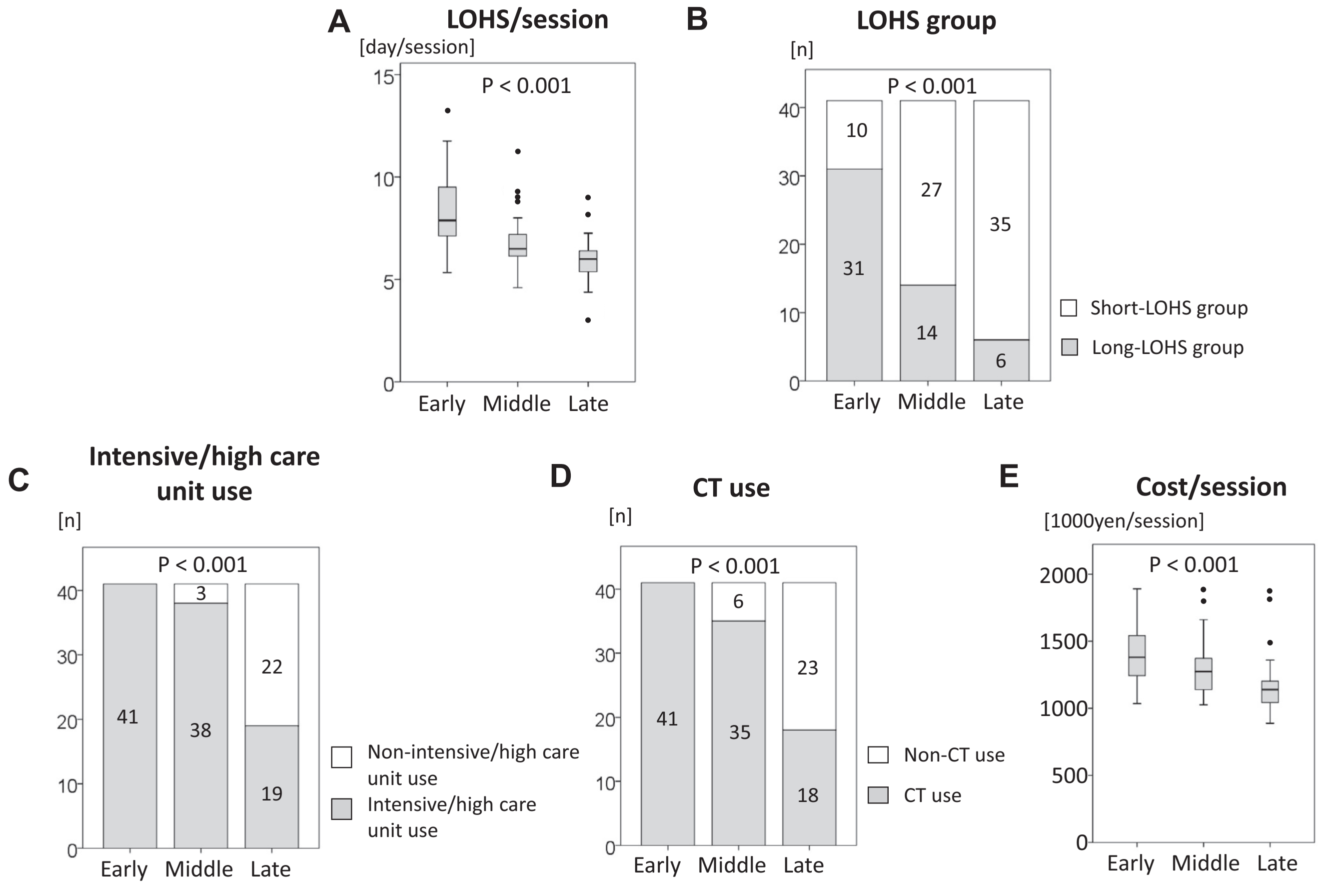

Figure 2. Time trends of length of hospital stay (LOHS) per session (**A**), numbers of patients in short- and long-LOHS groups (**B**), use of intensive/high care unit per patient (**C**), use of chest computed tomography (CT) per patient (**D**), and medical cost per session (**E**). **Bars** denote medians, **boxes** denote interquartile ranges, **whiskers** denote ranges excluding statistical outliers (**bullets**) (> 1.5 box lengths from either the 25th or 75th percentiles).

Baseline characteristics, procedural data, hemodynamic data, and biomarkers according to the date of the first BPA are shown in Tables 1 and 2. There was no significant difference in age, WHO functional status, hemodynamic data, or biomarkers among the 3 groups. The change in hemodynamics and biomarkers after BPA in the three groups are shown in Table 2. Improvement in RAP, PAP, PVR, and levels of BNP and hs-TnT did not differ among the groups.

Figure 2 shows the trends in LOHS, use of intensive/high care unit and chest CT, and the medical cost. There was a significant reduction in the LOHS (early phase: 7.9 [7.0 to 9.5], middle phase; 6.5 [6.1 to 7.3], late phase; 6.0 [5.3 to 6.5] days/session, $P < 0.001$) as well as reduction in use of intensive/high care unit and chest CT, and medical cost. The reduction in the length of intensive/high care unit stay (1.0 [0.8 to 1.0], 0.6 [0.3 to 0.9], 0.0 [0.0 to 0.3] days/session, $P < 0.001$) and frequency of chest CT (1.3 [1.1 to1.4], 0.6 [0.3 to 0.9], 0.0 [0.0 to 0.7] /session, $P < 0.001$) was also observed. Multivariate regression analysis demonstrated that only the early phase of the procedure was significantly associated with long-LOHS (Table 3). The reduction in LOHS had no effect on the incidence of BPA-related complications (ie, pulmonary injury, CIN, severe

Table 3. Multivariate analysis of long hospital stay group

	Model 1		Model 2	
	OR (95% CI)	*P* value	OR (95% CI)	*P* value
Age	1.02 (0.98-1.06)	0.354	1.02 (0.98-1.06)	0.195
Gender: male	0.75 (0.28-1.96)	0.552	0.81 (0.32-2.06)	0.659
eGFR	0.99 (0.96-1.02)	0.574	0.99 (0.96-1.01)	0.337
Date of first BPA procedure, per tertile increment	0.21 (0.11-0.38)	< 0.001	0.21 (0.11-0.38)	< 0.001
WHO IV	10.5 (0.92-118.9)	0.058		
WHO II			0.67 (0.22-2.07)	0.485

Standard covariates = age, gender, eGFR, date of first BPA procedure. Model 1 = standard covariates + WHO IV. Model 2 = standard covariates + WHO II.
BPA, balloon pulmonary angioplasty; CI, confidence interval; eGFR, estimated glomerular filtration rate; OR, odds ratio; WHO, World Health Organization.

Table 4. In-hospital complications

	Early phase (N = 41)	Middle phase (N = 41)	Late phase (N = 41)	*P* value
CIN, n/patient (%)	3 (7.3)	3 (7.3)	4 (9.8)	0.897
Pulmonary injury, n/patient (%)	10 (24.4)	10 (24.4)	8 (19.5)	0.831
Hemodialysis, n/patient (%)	0 (0)	0 (0)	0 (0)	-
Death, n/patient (%)	0 (0)	0 (0)	0 (0)	-
PCPS, n/patient (%)	0 (0)	0 (0)	0 (0)	-
Intubation, n/patient (%)	0 (0)	0 (0)	0 (0)	-
Rehospitalization, n/patient (%)	0 (0)	0 (0)	0 (0)	-

Data are absolute values with percentages.
CIN, contrast-induced nephropathy; PCPS, percutaneous cardiopulmonary support.

pulmonary injury needing intubation, CIN requiring hemodialysis, cardiopulmonary collapse requiring PCPS, all-cause death, and rehospitalization due to BPA-related complications) (Table 4). The incidence of pulmonary injury per session in each phase were 6.3% (early phase: 17/272), 7.8% (middle phase: 20/257), and 3.9% (late phase: 10/256), respectively.

Discussion

In this study, there was a significant reduction in LOHS and stay in the intensive/high care unit despite no significant differences in the patient profiles during the observation period. The shortening of LOHS had no impact on the incidence of pulmonary injury, CIN, and all-cause death.

The details of LOHS and use of medical resources for BPA have not been elucidated so far. To our knowledge, only 1 study evaluated the LOHS for BPA; median LOHS for BPA was 9 days/session in 70 patients with CTEPH enrolled from 2009 to 2013,[16] which is similar to the data we obtained during the early phase. In terms of the length of intensive care unit stay, Yanagisawa et al. suggested the need for a 1-day stay in the intensive care unit stay for day after BPA.[16] When BPA was introduced in our institute in 2012, all patients were routinely managed in the intensive/high care unit after BPA to monitor hemodynamics and to provide noninvasive positive pressure ventilation to prevent pulmonary injury.[6] The novelty of our study is that we revealed a significant reduction in LOHS and stay in the intensive/high care unit with no effect on the BPA-related complications for the first time. These findings indicate that a reduction in LOHS and use of intensive/high care unit is not only feasible but also safe. In addition, the use of CT after each BPA procedure, which was common in other high-volume centers,[6] was also decreased in our study, leading to lower medical costs.

There were concerns about the likely increase in BPA-related complications by decreasing the intervals between the sessions and providing no intensive care unit stay. Reperfusion pulmonary injury is the leading complication of PEA, which is the standard treatment for CTEPH.[17] Although it is difficult to compare the complication profiles for BPA and PEA because of different subject populations, the increase in the pulmonary flow grade after BPA also increases the risk of pulmonary injury.[18] Hence, there is a concern that the increase in pulmonary flow for a short interval might increase the risk of pulmonary injury. Multiple exposures to contrast media is known to be a risk factor for CIN.[19,20] Furthermore, not providing stay in the intensive care unit might delay the management of BPA-related complications. However, the incidence and aggravation (ie, the need for PCPS, intubation, and hemodialysis) of these complications remained unchanged during the observation period. Most lung injuries are considered to be a consequence of pulmonary vascular injury related to the procedure.[8,21] We need to consider with caution the possibility of further shortening the LOHS with the improvement in BPA techniques.

Shortening LOHS and avoiding stay in the intensive care unit in the subpopulation of patients undergoing catheter interventions is another important topic for research. For example, in patients undergoing transcatheter aortic valve implantation, unstable hemodynamic compensation was associated with prolonged hospitalization.[1] In BPA, poor functional status (ie, WHO IV class) tended to be associated with longer LOHS in our study. The patients at high risk for BPA (eg, severe right heart failure or multiple comorbidities)[22] need to be monitored carefully after the procedure. A general strategy to reduce the LOHS might be inappropriate, and the evaluation of these high-risk patients should be considered in a future study.

This study had several limitations. First, the number of patients was small, which might reduce the statistical power. Especially, patients with WHO IV were only 6.5% of the cohort, and our conclusion might not be applicable in these patients as previously discussed. Second, our findings were based on the observations at a single institution. Despite the European Society of Cardiology/ European Respiratory Society guideline[14] and the Japanese Circulation Society[12] recommendation to perform BPA in experienced and high-volume CTEPH centres, the details of LOHS and use of medical resources for BPA are not mentioned; these factors could vary in each centre and by operator. We need to investigate the current trends of LOHS as well as the use of medical resources in a multicentre registry, and standardization will be necessary in the future.

Conclusions

Increasing experience with BPA was associated with a reduction in LOHS and stay in the intensive care unit. These did not have any effect on BPA-related complications.

Disclosures

The authors have no conflicts of interest to disclose.

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