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# Survival Predictors in Pulmonary Arterial Hypertension Patients Undergoing Balloon Pulmonary Angioplasty

**Farhat Ullah Khan[1], Zeeshan Afzal[1], Syed Ahsan Akhtar[1], Muhammad Hafeez[1], Tashfeen Irtaza Khan[1]**

[1]Department of Cardiology, Hayatabad Medical Complex, Peshawar, Pakistan

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**Corresponding Author:** Dr. Zeeshan Afzal,
Department of Cardiology, Hayatabad Medical Complex, Peshawar, Pakistan.
Email: zeeshanhunk07@gmail.com

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## ABSTRACT

**Introduction**: Chronic thromboembolic pulmonary hypertension (CTEPH) is a severe complication of pulmonary embolism that leads to progressive right heart failure and death if untreated. Balloon pulmonary angioplasty (BPA) has emerged as a promising intervention for patients with inoperable or residual disease post-pulmonary endarterectomy. **Objective**: To identify predictors of short-term survival in pulmonary arterial hypertension patients undergoing BPA. **Materials and Method:** This prospective observational study was conducted at Department of Cardiology, Hayatabad Medical Complex, Peshawar from January, 2023 to June 2023. Fifty-two patients with confirmed inoperable or residual CTEPH underwent BPA. Hemodynamic and clinical parameters were assessed pre- and post-procedure, and survival was evaluated at six months. **Results**: Survival at six months was 88.5%. Post-procedural mean pulmonary artery pressure <35 mmHg, baseline cardiac index ≥2.0 L/min/m², and absence of vascular injury during BPA were independent predictors of survival. Significant improvements were observed in mPAP, PVR, and WHO functional class. **Conclusion**: BPA significantly improves survival and clinical status in selected PAH patients. Early hemodynamic response and procedural safety are key survival predictors.

## INTRODUCTION

Chronic thromboembolic pulmonary hypertension (CTEPH) is defined as high blood pressure occurring within the pulmonary arteries that cannot be considered persistent, progressive, and severe without treatment and is caused by organized thrombi, thereby increasing pulmonary vascular resistance, and which, if not treated, can lead to right heart failure. The reference standard of treatment has hitherto been considered to be pulmonary endarterectomy (PEA), which is a surgical procedure that has the possibility of being curative. Nevertheless, a considerable number of patients are staged as unbeatable due to lesion location or general health condition. Balloon pulmonary angioplasty (BPA) was researched for these patients as a more effective intervention. It has been widely used globally, and the procedural techniques are still changing (1). They revealed that BPA positively affects the hemodynamics, functional status, and quality of life of patients with CTEPH, yet the treatment carries certain risks as well. It consists of the opening of the obstructed pulmonary arteries by the use of balloon catheters, a method that has advanced in the last decade, resulting in fewer complications and high efficiency of the procedure (2).

However, BPA is still complex in technicality, and deciding about the outcomes is an effort that is required at clinical levels. Hopefully, the patient can figure out which factors affect survival and response to treatment as more use is made of the procedure. More recent work of investigators seeking to reduce morbidity and mortality of patients who underwent BPA has involved determining procedural and clinical characteristics that are associated with this risk and survival (3). Several measures, such as baseline hemodynamic studies, the lesion characteristics, and the procedural approaches that are adopted, have been pointed out as determining factors for the outcomes of BPA. For example, early changes in hemodynamics after the first BPA sessions have been correlated with long-term outcomes, which means that early behavioral improvements may be

considered as prognostic factors for survival (4). Nevertheless, when long-term results comparing BPA with PEA have been presented, the latter remains superior in operable cases, whereas, in patients with inoperable disease, BPA offers at least similar survival advantages (5).

Exercise tolerance and other measures of functionality have also been used as measures of survival in lieu of longevity data. However, one study showed that improving the six-minute walk distance (6MWD) after BPA improved long-term survival, indicating that functional measures should be incorporated into prognostic models. Moreover, advanced tools have been derived from nomograms for diagnosing hemodynamic response following BPA, which integrates data, including mean pulmonary artery pressure and cardiac index (Petersen et al., 2017). Despite these advancements, such applications to the actual clinical practice of delivering medicine are still under development but have great potential in personalizing the patient's therapy. More recently, data on the multicenter registry have also confirmed the writing-off of BPA, evidencing its efficacy in terms of positive changes in pulmonary hemodynamics and survival rates in various groups of patients. Such conclusions have proved the significance of procedural expertise and patient selection, more particularly since procedural volumes and operator experience are directly connected to the result (8).

However, it should also be admitted that BPA is not without danger or risk associated with its utilization. Vascular complications such as pulmonary artery rupture and reperfusion edema, despite being less common with the evolution of technology, are significant risks. Their early recognition and control are important for reducing adults' morbidity and mortality rates (9). As an essential component of the management of CTEPH, there have been concerns and doubts about whether PEA also occupies the same position. Even though PEA is definitive in central-type CTEPH, BPA is helpful when CTEPH is distal or in patients with contraindications towards surgery. The interplay of these interventions has compelled academics to reconsider the clinical practices, which have been considered the standard of care for CTEPH (10). Data obtained from BPA registries have confirmed the durability of those outcomes, as well as survival and hemodynamic data comparable to the ones with PEA in specific subsets of patients (11).

Technological enhancements, as well as refinement of the procedures used, have greatly enhanced BPA results. Every from the choice of balloon to the imaging guidance has been designed and developed to improve the safety of the process and effectiveness of treatment. These modifications have provided better results in acute settings but also cut radiation dose and procedural time, making BPA a more friendly approach in large volume centers. However, the presence of elevated pulmonary arterial pressure after the procedure remains a prognostic problem. Therefore, the survival rate for patients who have undergone BPA was found to be significantly lesser in the cases where PA pressures were elevated and remained high even after a successful procedure (13). Several trials that have compared the effects of BPA and PEA based on objective parameters have shown that these two modalities have almost similar positive effects on the hemodynamics and functional class of the patient, but as usual, patient selection to the modality is the key to the best outcome.

Furthermore, this treatment has been proven effective even in elderly and high-risk patients who were thought to be unable to be treated (14). Despite this, complete revascularization by BPA, despite being promising, remains an ambitious task. However, it was able to be tried and tested in pilot subjects, which broadened interventional therapy in CTEPH even further (15). Lastly, balloon pulmonary angioplasty has shifted from being a research therapy to one of the standard therapies for CTEPH patients. Therefore, it is imperative to recognize survival indicators as the use of ECMO continues to increase and to improve patient outcomes. Further research and clinical experience in the present and future will enhance the knowledge of such factors and give clinicians appropriate guidance to start and avoid therapy that is fatal in patients with this complex disease.

### Objective

To determine the predictors of mortality in patients of Pulmonary Arterial Hypertension treated with balloon pulmonary angioplasty in a tertiary care hospital in Karachi, Pakistan.

## MATERIALS AND METHODS

**Design:** Prospective Observational Study.

**Study setting:** The study was carried out at Department of Cardiology, Hayatabad Medical Complex, Peshawar.

**Duration:** The study duration was from January, 2023 to June 2023.

### Inclusion Criteria

The study involved patients 18 years of age and above with a confirmed BPA-deliverable diagnosis of CTEPH or persistent/recurrent PAH after pulmonary endarterectomy. The diagnosis was made using right heart catheterization, ventilation-perfusion scan, and CT pulmonary angiogram. The patients had to be clinically stable and capable of giving their informed consent.

### Exclusion Criteria

Patients with significant comorbidities, such as chronic liver or renal disease, hypertension that is uncontrolled at the time of recruitment, active infection, or malignancy, were excluded. Furthermore, patients who

refused the operation or who could not be traced at the time of follow-up were excluded.

**Methods**

All patients received a clinical review, right heart catheter, transthoracic echocardiography, and computed tomography pulmonary angiogram to identify thromboembolic disease location. Interventional procedures in fluoroscopic management were preceded by a staged BPA format that was performed in the laboratories. These balloon catheters were well chosen to be used in the right sizes to aid in selective dilation of these lesions while at the same time minimizing complications like vascular damage. Demographic data, blood pressure, mean pulmonary artery pressure, pulmonary vascular resistance, and cardiac index were recorded before and on completion of each BPA session. The patients in this study were followed from the time that they were hospitalized up to intervals after the procedure. Some parameters collected included demography, comorbidities, functional class, and details of the procedures performed. The patient's status at the end of the sixth month was determined, and predictors of death were evaluated. Some other manifestations that were also observed included reperfusion pulmonary edema, hemoptysis, and vascular injury. Hence, simple chi-square tests were applied to assess the relationship between various characteristics, use of BPA, and survival rates post-procedure.

## RESULTS

A total of 52 patients with pulmonary arterial hypertension undergoing balloon pulmonary angioplasty (BPA) were enrolled during the study period. The mean age of the patients was 47.6 ± 12.4 years, with 30 (57.7%) being female. Most patients (69.2%) were in WHO functional class III at baseline, while the remainder were in class II or IV. The majority had inoperable chronic thromboembolic pulmonary hypertension (CTEPH), and a small subset had residual or recurrent disease following pulmonary endarterectomy. Baseline hemodynamic parameters revealed a mean pulmonary artery pressure (mPAP) of 43.2 ± 8.7 mmHg and pulmonary vascular resistance (PVR) of 6.9 ± 2.1 Wood units.

Table 1 summarizes the baseline clinical and hemodynamic characteristics of the study population.

**Table 1**

*Baseline Clinical and Hemodynamic Characteristics (n=52)*

| Variable | Value |
|---|---|
| Age (years) | 47.6 ± 12.4 |
| Female (%) | 57.7 |
| WHO Functional Class II/III/IV | 19.2% / 69.2% / 11.5% |
| Mean PAP (mmHg) | 43.2 ± 8.7 |
| PVR (Wood units) | 6.9 ± 2.1 |
| Cardiac Index (L/min/m²) | 2.1 ± 0.4 |
| NT-proBNP (pg/mL) | 1280 ± 634 |

Each patient underwent an average of 3.2 ± 1.1 BPA sessions. The procedure was technically successful in all cases, with significant improvement in hemodynamics and functional capacity noted over time. At six months, survival was achieved in 46 (88.5%) patients, while 6 (11.5%) patients died due to complications such as pulmonary hemorrhage, right heart failure, or sepsis. Patients who survived showed significant improvement in mean pulmonary artery pressure and functional class.

**Table 2**

*Hemodynamic and Functional Changes Post-BPA*

| Parameter | Baseline | Post-BPA (6 months) | p-value |
|---|---|---|---|
| Mean PAP (mmHg) | 43.2 ± 8.7 | 34.1 ± 6.3 | <0.001 |
| PVR (Wood units) | 6.9 ± 2.1 | 4.2 ± 1.7 | <0.001 |
| Cardiac Index (L/min/m²) | 2.1 ± 0.4 | 2.6 ± 0.5 | <0.001 |
| WHO Functional Class III (%) | 69.2 | 34.6 | <0.001 |

Multivariate logistic regression identified three independent predictors of six-month survival: post-BPA mean PAP < 35 mmHg (p=0.003), baseline cardiac index ≥ 2.0 L/min/m² (p=0.01), and absence of vascular injury during BPA (p=0.04). Patients with all three favorable predictors had a 96.2% survival rate compared to 66.7% among those without.

**Table 3**

*Independent Predictors of Six-Month Survival*

| Predictor | Odds Ratio | 95% CI | p-value |
|---|---|---|---|
| Post-BPA mPAP < 35 mmHg | 4.8 | 1.7–13.6 | 0.003 |
| Baseline Cardiac Index ≥ 2.0 | 3.6 | 1.3–10.1 | 0.010 |
| No Vascular Injury During BPA | 2.9 | 1.1–7.9 | 0.040 |

These findings suggest that early hemodynamic response and procedural safety are critical determinants of survival following BPA in PAH patients.

## DISCUSSION

Balloon pulmonary angioplasty, or BPA, is a catheter-based procedure that is used in patients with CTEPH who are not suitable for surgery or those who are not relieved by surgery or PEA. The research results presented here support the efficacy and safety of BPA in increasing survival rates and functional status alongside enhancing the hemodynamic condition of a specific sample of patients with PAH. BPA is confirmed by evidence from all around the world as providing a considerable element of clinical advantage, having the provision of liver transplantation in that technique focuses on experienced centers, and the survival effect is considerably determined by the procedural and physiological relevant factors (1). The respective LVEF at 6 months post BPA in study was 88.5%, which is in accordance with those interpreted by other researchers in

multicenter registries and time series (2). Ito et al. stated that procedural safety was the hallmark of outcomes, and some of the predictors of adverse events included vascular injury.

The results of this study support this assertion since no vascular injury was found to be an independent predictor of patient survival. Piliero et al. also reported to other authors that there is a gradual reduction in the complication rates during BPA because of the improvements in the technique as well as a more careful patient selection process, some of which was reflected in the center where the complication rate observed was comparatively low. Also, in the present research study, the findings are further portraying a marked alteration of the value of both the mPAP and the PVR subsequent to the BPA. These hemodynamic changes are supported by Kennedy et al., who, in their meta-analysis, showed a marked decrease in mPAP and PVR with BPA regardless of the population group (3). These are not only useful from a physiological perspective but are definitely linked closely with the primary indicators of efficacy and survival. Li et al. showed that early morbidity is associated with late survival, and this underlines the conclusion that post-BPA mPAP less than 35 mmHg is an independent predictor of survival (4).

The other significant discovery made in the study was that of the baseline CI as a marker of prognosis. Survival was mainly identified in patients with a CI of $\geq$ 2.0 L/min/m$^2$, which, in harmony with other researchers, noted the significance of right ventricular function as well as CI toward BPA (5). Yang et al. As for the Role of BPA and PEA in the treatment of CTEPH, both interventions have the potential to increase long-term survival rates in patients, yet it was stated that patient heterogeneity factors, particularly cardiac function, should determine the strategy applied (5). Furthermore, the increase in exercise tolerance, which is usually reflected by the 6MWD, has close ties to survival. Daigo et al. explained how gains of function after BPA are due to enhancement in right ventricular after-load, while the indices could act as survival proxies (6), fully supporting the findings of improved WHO functional class.

Several studies have offered predictive models as well as nomograms that can help clinicians forecast BPA results. Xin et al. have worked on a new stage 2 BPA response model regarding patient's baseline hemodynamic and clinical data (7). The turn of recognizing both the mPAP and CI during the follow-up as additional predictors also supports the use of such models in clinical practice. These large registries have helped in replicating the above predictors across different large centers and patient populations, as done by Darocha et al. It provides a consistent hemodynamic improvement, confirming that BPA, when properly done, is a safe and effective solution to surgery. Several issues are still limiting risks that mandate attention and include pulmonary artery injury and reperfusion edema that may cause serious morbidity or mortality. Ejiri et al. discussed current management strategies for these complications and stated that early identification and supportive care increase survival rates (9).

The study supports this view well, and the result that conferred the absence of vascular injury routinely led to a far higher survival rate. It underlines caution regarding the value of procedural experience and the technique. Discussing its relative role to PEA, the authors highlight further the role of BPA, especially with the new evidence cited that supports BPA in the management of distal or surgically inaccessible lesions. Taniguchi et al. examined the role of both interventions, and it can be concluded that similar to many severe pulmonary diseases, CTEPH may not necessarily be fatal thanks to improvements in the two strategies (10). This was also expressed by Delcroix et al. in the worldwide CTEPH registry, where there was no significant difference in mortality rate between PEA and BPA groups in selected patients (11). This is in line with the presented study results suggesting that BPA can provide survival benefits in cautiously selected patients who are not surgical candidates.

Another factor that has brought about improvements in outcomes is the refinement of BPA techniques and adjunct technologies. The procedural changes that Mahmud et al. proffered for improving safety and efficacy are imaging for better lesion identification as well as low-pressure ballooning (12). Nevertheless, PH management after BPA remains a clinical issue even after the procedure is done. Kallonen et al. have shown that persistent pulmonary hypertension after PE was associated with mortality, and a similar situation might be valid in BPA (13). That the post-BPA mPAP < 35 mmHg predicts survival implies that targets of hemodynamic parameters should be closely monitored even after the procedure is concluded as a success. Studies such as the one by Masaki et al. have started establishing the type of patents that will benefit more from the use of BPA or PEA (14). They reported that both therapies are efficacious, but the best results should be aimed at matching the patients to the intervention.

Further, Fujii and colleagues used BPA to evaluate the practicality of complete revascularization and affirmed that further intervention is feasible and safe when done carefully to help enhance the prognosis without worsening the risks (15). These observations argue for a modified application of the concept of precision medicine for CTEPH, regarding the choice of the procedure, its timing, and dosage based on specific patient characteristics. Lastly, the work confirms that BPA has utility as an effective treatment modality in certain patients with inoperable or persistent CTEPH. The areas of the study showed post-BPA survival predictors, including early hemodynamic response,

preserved cardiac index, and procedural safety. They should be considered when assessing the patients and monitoring them later on. Therefore, BPA needs to incorporate the continuation of predictive tools and the combination of multidisciplinary teams for the decision-making process to improve the results and increase the possibilities of performing this lifesaving procedure.

## CONCLUSION

Balloon pulmonary angioplasty (BPA) has shown a number of therapeutic advantages in treating patients suffering from pulmonary arterial hypertension due to inoperable or persistent more than chronic thromboembolic disease. This paper focuses on the enhancement of hemodynamic features, functional class, and short-term survival after BPA. These include post-procedural mean pulmonary arterial pressure of <35 mmHg, the baseline cardiac index of ≥2.0 L/min/m², and the absence of vascular injury where it was applicable. As understood from these results, close patient selection, procedural techniques, and close patient supervision after the procedure are important. Therefore, BPA can be considered a valid and effective treatment modality, especially for patients with distal or operative inaccessible disease. Despite the remaining techniques and predictive tools under development, BPA is on the right track to becoming the go-to approach to the management of CTEPH. Multicenter research with a larger sample size and a longer observation period is required to identify additional factors that might significantly affect survival and help tailor individualized treatment.

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