Pleurodesis using autologous blood: a new concept in the management of persistent air leak in acute respiratory distress syndrome

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Abstract
Objective: Pneumothorax is present as a frequent complication in acute respiratory distress syndrome (ARDS). Persistent air leak (PAL) prolongs pneumothorax in 2% of cases of ARDS, increasing the rate of mortality by 26%. Pleurodesis using autologous blood (PAB) is an effective method in cases of oncological pulmonary surgery. The goal of this study was to compare PAB with the conventional drain and water seal in the management of PAL in patients with ARDS and pneumothorax.

Design: The study was a case-control, prospective, nonrandomized one comparing 2 groups subjected to artificial pairing (1:1).

Setting: The study took place at the Torrecardenas Hospital (Andalusian Health Service, Almería, Spain).

Patients: Participants were 2 groups of 27 patients, all with ARDS, pneumothorax, and PAL.

Interventions: One group received conventional treatment whereas the other received PAB.

Main results: The severity of the conditions of both groups is homogeneous, shown by sex; age; Murray, Marshall, and Acute Physiology and Chronic Health Evaluation II scores; and etiology of ARDS. The patients in the PAB group had a shorter stay in the ICU, shorter weaning time (WT), and lower death rate. The average differences between the groups were 11 days less WT (adjusted odds ratio [OR] = 0.1) and 9 days less on average.
time spent in the ICU (adjusted OR = 0.24). The death rates in the PAB group and the control group were 3.7% and 29.6%, respectively (adjusted OR = 0.6).

Conclusions: The use of PAB makes possible a decrease in ventilator WT and a shorter stay in the ICU, with a resulting increase in functional recuperation and decrease in patient mortality.

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1. Introduction

The incidence of acute respiratory distress syndrome (ARDS) varies greatly from 1.5 to 13.5 for every 100,000 inhabitants [1], with the mortality rate oscillating between 30% and 80% [2-6]. The need for mechanical ventilation is associated with barotrauma [7], nosocomial pneumonia, and multiorgan failure. Other complications may occur depending on the duration of the process [8].

The duration of ARDS in patients without pneumothorax is approximately 7 days as compared with 15.3 days in those with pneumothorax [9]. The incidence of pneumothorax is, generally, approximately 30%, with the mortality rate being 66% compared with 40% without pneumothorax and the incidence increasing with the duration of the process [9].

The persistent air leak (PAL) makes the resolution of pneumothorax more difficult in 2% of cases, increasing the mortality to 92%. This normally appears between the 7th and 10th days [2,10].

There is no controlled prospective study on the management of PAL in cases of ARDS [11]. The treatment strategy for the resolution of PAL consists of measures aimed at reducing the effusion of air [12-18], bronchoscopic techniques to locate and occlude the fistula, surgical abrasion techniques (scarring via laser, incision/abrasion, video-assisted thorascopic surgery), and pleurodesis by means of chemical irritation of the pleura (talc, tetracycline, bleomycin) [14-17].

The advantage of any therapeutic option in the treatment of PAL over another has not been proven [18]; in the case of multiple air leaks, which frequently occur in cases of ARDS, surgical and bronchoscopic techniques are very limited [12-18]. Because we do not have an optimal strategy at the moment and it is the conventional chest tube with water seal that is used exclusively, we propose non-irritant pleurodesis using autologous blood (PAB) [19-23] as a solution.

The objective of this study was to analyze the effectiveness of PAB as compared with chest tube drainage with water seal in mechanically ventilated patients with ARDS and PAL.

2. Patients and methods

2.1. Subjects and setting

The study took place at the Torrecardenas Hospital (Andalusian Health Service, Almería, Spain), which has an intensive care unit (ICU) with 400 patients per year receiving mechanical ventilation for medical and surgical pathologies. All the patients included in the study were ventilated (Servo Computer Module 990; Siemens Group, Madrid, Spain); ventilation management was established following the guidelines of the Critical Care Society [24].

For our study, we considered patients with ARDS, pneumothorax, and PAL receiving mechanical ventilation. Acute respiratory distress syndrome was defined according to Euro-American Consensus Conference criteria: arterial oxygen-to-inspired oxygen concentration ratio (PaO₂/FI₂O₂) lower than 26.3 kPa, diffuse radiographic infiltrates on chest film, and clinical criteria consistent with normal left atrial pressure [25]. Pneumothorax was defined as free air within the pleural space [26]. In this study, we considered PAL as the air leak that persists after a chest tube had been connected to a water seal system for 24 hours [2,10].

2.2. Ethical treatment

With regard to ethical treatment, the argument for the use of PAB was based on compassionate therapeutic considerations. The study was approved by the hospital ethics and clinical research commission. The possibility of nonrandomization was accepted by the commission. The study lasted for 4 years, from January 1999 to December 2002.

2.3. Study protocol

The inclusion criteria for the study were as follows:

- Patients older than 18 years who have ARDS (>2 points, Murray score) [27];
- Patients who were mechanically ventilated;
- Patients with pneumothorax and PAL after a chest tube had been connected to a water seal system for 24 hours [2,10]; and
- Patients whose visceral-parietal pleurae distance was less than 2 cm.

The exclusion criteria were as follows:

- Patients with a chronic pulmonary disease;
- Patients with a serious head injury (Glasgow Coma Scale score < 9) [28];
- Patients with hemothorax; and
- Patients with ribcage instability.

The exclusion criteria were based on variables that could cause a confusion bias as a result of the prolongation of
When a patient met the inclusion criteria, he or she was assigned to 1 of 2 therapeutic options: conventional treatment or PAB.

2.3.1. Control group
The conventional treatment involved insertion of a conventional intercostal drainage tube with water seal. This sterile procedure requires knowledge of the location of the pneumothorax for the correct placement of a tube, ranging in size from 24 to 28 Fr. The tube was introduced through a 2-cm transverse surface incision in the selected intercostal space. When the tube was in place, it had to be confirmed that all the holes were within the pleural space; then, the tube was connected to the water seal system. The indication for removal of the chest drain was the resolution of the pneumothorax when there were no more air leaks.

2.3.2. Case group
The intervention involved PAB, using the drainage and its intrapleural placement. The technique recommended in this article consists of between 50 and 75 mL of autologous blood, without anticoagulants, administered to a patient through the existing chest tube. The only requisite for this procedure was radiological confirmation of the approximation of both the parietal and visceral pleurae. Once the blood had been administered, the drainage system was connected to a water seal. The patient had to be rotated laterally, once each, to both the right and left sides, immediately after administration to distribute the blood in the pleural cavity, because the distribution of the fistulas was unknown. The criteria for chest tube removal were the same as those for without pleurodesis.

The qualitative variables studied were as follows:

- Sex
- Acute renal failure (defined clinically by sudden disruption [hours or days] of previously normal or stable kidney function)
- Hemodynamic instability (defined as those episodes of hypotension that need infusion of inotropic drugs and/or fluid for normalization)
- Tracheostomy (we considered in this study that 11 days seems to be the optimal time to convert from tracheal tube to tracheostomy in those patients who need prolonged mechanical ventilation)
- Others (gastrointestinal hemorrhage, malnutrition, deep vein thrombosis, critical neuropathy of the patient, catheter infections)
- Death (when the patients were in the ICU or in other hospital departments); the death rate was measured for 1 year from the beginning of the study

The quantitative variables studied were as follows:

- Age in years
- Murray score [27]
- Marshall score [29]
- Acute Physiology and Chronic Health Evaluation (APACHE II score) [30]
- $\Delta^2$ in the alveolar-arterial (Aa) gradient of O$_2$ (PaO$_2$/FiO$_2$)
- $\Delta$ in compliance expressed in mL/cm H$_2$O
- $\Delta$ in positive end expiratory pressure (PEEP)
- $\Delta$ in respiratory rate (RR)
- $\Delta$ in plateau pressure (PP)
- $\Delta$ in tidal volume (TV)
- Seal time (ST) in days (the time from when a patient was included in the study until chest tube removal)
- Weaning time (WT) in days (the time from when a patient was included in the study until the patient was removed from mechanical ventilation)
- Time in the ICU in days (the time from when a patient was included in the study until discharge from the ICU)
- Number of nosocomial pneumonias (for our study, this was defined as a diagnosis of pneumonia in patients more than 48 hours after hospital admission in the absence of pulmonary symptoms [10 days before admission])

2.4. Design
The study was a case-control, nonrandomized sampling of 2 groups of patients with ARDS and pneumothorax receiving artificial 1:1 pairing according to the degree of severity (APACHE II [30] and consensus criteria from the Murray score of ARDS [27] and Marshall score [29]), sex, age, and etiology of ARDS. The control group was composed of patients who had been treated with drainage and water seal; the case group, of those treated by PAB.

2.5. Follow-up
A telephone evaluation was carried out approximately 1 year after discharge to evaluate each patient’s condition and respiratory function and capacity, basing results on the dyspnea rate. In addition, hospital ward and postdischarge death rates were estimated.

2.6. Statistical analysis
The statistical analysis was based on the Kolmogorov-Smirnov test to check the normality of the samples,
McNemar statistics for the bivariate analysis of qualitative variables, and the Wilcoxon signed rank test for the quantitative variables. To show the homogeneity in both groups, we used the same tests, McNemar test and Wilcoxon signed rank test, that were applied to the control group on internal validity for the pairing criteria, sex, age, APACHE II score [30], etiology of ARDS, Marshall score [29], and Murray score [27]. Multivariate analysis, with binary logistic regression, was used for evaluation of the death rate, WT, and ICU time as different independent predictive factors for those that are significant values in the bivariate analysis or of clinical importance. Therefore, the exploration of PAB as a factor associated with death rate, WT, and ICU time was developed by the consideration of the WT and ICU time as new categorical variables, taking the median values of WT and ICU time as a limit for division in 2 intervals, short-term and long-term intervals, in each variable. A P value of <0.05 was statistically significant and the potency was 80%. The categorical variables are shown in number of patients and percentage values; the continuous variables values, in median and range values. In addition, for the different independent variables in the multivariate analysis, the crude and adjusted odds ratio (OR) values and their 95% confidence intervals (CIs) are shown.

### 3. Results

The patients included in both groups belong to same population. Each group was composed of 27 patients (N = 54). The control group and the case group had the same male/female ratio (12:15); the median age in the control group was 44 years (range = 19-78 years) and that in the case group was likewise 44 years (range = 24-73 years), with no statistically significant difference. The median APACHE II score in the control group was 24 (range = 18-30) and that for the case group was likewise 24 (range = 18-34), with no statistically significant difference. In the case of the Marshall test, the median score was 17.8 in the control group (median = 17; range = 14-22), with no statistically significant difference with regard to the case group. The Murray median score was 3 (range = 2-4), with the values being the same in both groups, showing no statistically significant difference. At this point, the results allow us to show that there was no difference between the 2 groups, both being homogeneous (Table 1).

In comparing the 2 groups that underwent 1:1 pairing, the different progressions of respiratory parameters were examined. These were respiratory system compliance, Aa gradient O2, PEEP, RR, PP, and TV. These factors reveal the state of gaseous exchange and respiratory function and include those with a direct relation to the appearance of pneumothorax. Equally, the WT and ST and stay in the ICU were compared, all being determinants of the mortality rate and functional recuperation. The number and nature of intercurrent complications, the death rate, as well as the need for tracheostomy are equal determinants of the progression of lung recuperation.

In this way, it can be seen by way of the Wilcoxon signed rank test that the group treated with PAB, in comparison with the group receiving treatment with a thoracic drain and water seal only, shows a statistically significant improvement in the

### Table 1  Patient information and group homogeneity

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>PAB group</th>
<th>Statistical significance (P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male/female ratio</td>
<td>12:15</td>
<td>12:15</td>
<td>n = 27; &lt;1.0a</td>
</tr>
<tr>
<td>Age (y) [median (range)]</td>
<td>44 (19-78)</td>
<td>44 (24-73)</td>
<td>Z = −1.01; &lt;3.1b</td>
</tr>
<tr>
<td>APACHE II [median (range)]</td>
<td>24 (18-30)</td>
<td>24 (18-34)</td>
<td>Z = −0.26; &lt;7.9b</td>
</tr>
<tr>
<td>Murray score [median (range)]</td>
<td>3 (2-4)</td>
<td>3 (2-4)</td>
<td>Z = −0.25; &lt;7.9b</td>
</tr>
<tr>
<td>Marshall score [median (range)]</td>
<td>17 (14-22)</td>
<td>17 (14-24)</td>
<td>Z = −0.46; &lt;6.4b</td>
</tr>
</tbody>
</table>

* a McNemar test.
* b Wilcoxon signed rank test.
* Ref. [31].
* Ref. [28].
* Ref. [30].

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**Fig. 1**  Death rate differences.
death rate, WT and ST, and parameters of gaseous exchange, the means for the control group being different.

The death rates were shown to be statistically different between the PAB group and the control group, at 3.7% and 29.6%, respectively (Fig. 1; Table 2). The results in the multivariate analysis of independent predictive factor PAB for the death rate are as follows: crude OR = 0.091/95% CI = 0.011-0.793 and adjusted OR = 0.6/95% CI = 0.02-0.822 (Table 4).

Equally, the rate of hemodynamic instability was different between the groups, with 25.9% in the PAB group vs 55.6% in the control group.

With regard to the need for tracheostomy, the difference between the groups was statistically significant, with 66.7% in control patients vs 25.9% in case patients.

Regarding complications from PAB, during the patients’ entire hospital stay, fever was present in 3.4% of cases, with a 5.1% recurrence rate. There was no incidence of adverse effects such as clinically significant thoracic pain or decreases in lung capacity (Table 2).

The progression of ST and WT and the length of stay in the ICU demonstrate a statistically significant reduction in the PAB group with respect to the control group when compared using the Wilcoxon signed rank test.

The average differences between the groups were 8 days less ST, 13 days less on average time spent in the ICU (Fig. 2), and 11 days less WT (Fig. 2) (Table 3). These differences remain in the multivariate analysis: in the predictive equation about short ICU times for PAB as an independent factor with a crude OR of 0.052 (95% CI = 0.013-0.204), the adjusted OR was 0.04 (95% CI = 0.01-0.29). Equally, the multivariate analysis supports the statistical significance for the equation of WT: with a crude OR of 0.05 (95% CI = 0.01-0.49) for PAB as an independent predictive factor and an adjusted OR of 0.1 (95% CI = 0.01-0.45) (Table 4).

The presence of respiratory tract infections in our study was also shown to be less in the PAB group as opposed to the group receiving treatment with a thoracic drain and water seal; however, this was not statistically significant, with the respiratory tract infection rates in the control group vs the case group being 7.4% vs 33.3% (1 event), 44.4% vs 29.6% (2 events), and 22.2% vs 7.4% (3 events), the values not being significant statistically. In cases with acute renal failure as the intercurrent complication, nevertheless, the smaller numbers were still clinically significant. In the same way, there was no statistically significant difference between the case and control groups with regard to gastrointestinal hemorrhage, malnutrition, deep vein thrombosis, critical neuropathy of the patient, and catheter infections (all inside the variable “Others”) (Table 2).

Finally, the respiratory effort and the risk of pneumothorax diminished significantly in the PAB group as opposed to the control group, as shown by the bivariate analysis with the Wilcoxon signed rank test: a difference in the decrease of Δ compliance of 17 mL/cm H2O in the PAB group as compared with the control group and a difference in the variation of the PEEP means of 3 cm H2O, decreasing in the PAB group as compared with an increase in requirements for the control group. In the same way, the difference of the means of Δ RR was 6 rpm, decreasing in the PAB group as opposed to an increase in the control group, and the difference of PP means was 4 cm H2O, decreasing in the PAB group and increasing in value in the control group. There was a concomitant increase in the difference of the

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Table 2  Events during progression

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>PAB group</th>
<th>McNemar test significance ((P))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respiratory tract infection [n (%)]</td>
<td>20 (74.1)</td>
<td>19 (70.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Acute renal failure [n (%)]</td>
<td>15 (55.6)</td>
<td>12 (44.4)</td>
<td>NS</td>
</tr>
<tr>
<td>Hemodynamic instability [n (%)]</td>
<td>15 (55.6)</td>
<td>7 (25.9)</td>
<td>n = 27; (&lt;.039)</td>
</tr>
<tr>
<td>Tracheostomy [n (%)]</td>
<td>18 (66.7)</td>
<td>7 (25.9)</td>
<td>n = 27; (&lt;.013)</td>
</tr>
<tr>
<td>Other alterations* [n (%)]</td>
<td>19 (70.4)</td>
<td>13 (48.1)</td>
<td>NS</td>
</tr>
<tr>
<td>Death [n (%)]</td>
<td>8 (29.6)</td>
<td>1 (3.7)</td>
<td>n = 27; (&lt;.039)</td>
</tr>
</tbody>
</table>

NS indicates not significant.

* For example, vein thrombosis, gastrointestinal hemorrhage, malnutrition, infections caused by a catheter, and effects caused by the use of muscle relaxant.
means for decrease in $\Delta$ TV of 156 mL in the PAB group as compared with the control group (Table 3).

4. Discussion

With an incidence of up to 13.5 for every 100,000 inhabitants, ARDS is the cause of 9% of admissions in ICUs [1,31]. The death rate varies between 30% and 40%, with the most frequent causes being multiorgan system failure and sepsis [2-6]. This rate increases to 66% when pneumothorax is present, also increasing the duration of the process from 7 to 15.3 days [9]. Furthermore, pneumothorax continuing after 24 hours of water seal drainage, present in 2% of all cases of ARDS, results in a mortality rate of 92% (26% more than cases with pneumothorax only) [32].

The prolongation of mechanical ventilation owing to PAL brings a higher incidence of nosocomial pneumonia and multi-system failure and leads to various complications derived from the use of relaxants, gastrointestinal hemorrhage and malnutrition [7], contributing to an increased mortality rate or a worsening of functional recuperation.

Various strategies directed at reducing air leak (differential ventilation, increased frequency of ventilation, occlusion of the thoracic tube during inhalation, and even the application of high levels of PEEP) [12-18] have not demonstrated much usefulness, and, in fact, there is no existing evidence to show that they affect rates of mortality or improve patients’ condition [33].

The bronchoscopic techniques to locate and occlude the fistula via a cylinder (Fogarty or Swan-Ganz) or via the use of various substances (fibrin, autologous coagulum, tissular gel, etc) [13] are expensive, complex, and not shown to be useful for affected patients because of the multiple characters of PAL and the precarious vital reserves of patients [12-18].

Also available are surgical abrasion techniques (scarring via laser, incision/abrasion, video-assisted thorascopic surgery), the objective of which is to resolve the fistula by way of mechanical pleurodesis or bullectomy, but with the same limitations as those for bronchoscopic techniques.

On the other hand, chemical abrasion of the pleura with t alc, being the most widely studied and most efficient agent in patients with severe pleural effusion, is a complex process [34,35]. Its use is not standardized, and it has a recurrence rate of 25% in the treatment of oncology patients. Its application in cases of ARDS with pneumothorax is not supported in present medical literature [32].

Currently, the treatment of pneumothorax in ARDS is limited to insertion of a chest tube with water seal. There is no optimal therapeutic option available for routine use because of the limitations of precariousness of patients’ conditions, the frequent presence of multiple fistula processes, and, finally, the absence of evidence on this subject in medical literature.

The importance of ST and WT on mortality and functional recuperation in these cases shows that the exclusive use of thoracic drainage is not sufficient as a therapeutic strategy in resolving pneumothorax.

At this point, PAB is a simple, cheap, and effective method for a limited group of oncology patients undergoing extensive lung removal and suffering from PAL [19-22,36]. Thus, PAB is shown to be an alternative to the thoracic drain with water seal, in the absence of other viable therapeutic interventions, in patients with ARDS and pneumothorax.

Our study involves 2 groups characterized by the homogeneity of the patients, based on pairing them by age, sex, APACHE II score [30], Marshall score [29], and Murray score [27]. The case group was treated with chest tube and PAB; the control group, with chest tube and water

<table>
<thead>
<tr>
<th>Table 3</th>
<th>Respiratory values</th>
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<tr>
<td></td>
<td>Control group [mean (range)]</td>
</tr>
<tr>
<td>$\Delta$ D(Aa)O$_2$ (mm Hg)</td>
<td>70 (40 to 130)</td>
</tr>
<tr>
<td>$\Delta$ Compliance (mL/cm H$_2$O)</td>
<td>8 (0 to 12)</td>
</tr>
<tr>
<td>$\Delta$ PEEP (cm H$_2$O)</td>
<td>2 (−4 to 5)</td>
</tr>
<tr>
<td>$\Delta$ RR/min</td>
<td>3 (0 to 6)</td>
</tr>
<tr>
<td>$\Delta$ PP (cm H$_2$O)</td>
<td>4 (−15 to 12)</td>
</tr>
<tr>
<td>$\Delta$ TV (mL)</td>
<td>20 (0 to 125)</td>
</tr>
<tr>
<td>ST (d)</td>
<td>10 (4 to 16)</td>
</tr>
<tr>
<td>WT (d)</td>
<td>16 (8 to 26)</td>
</tr>
<tr>
<td>ICU time (d)</td>
<td>29 (16 to 47)</td>
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<table>
<thead>
<tr>
<th>Table 4</th>
<th>Factors associated with death, ICU time, and WT</th>
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<tr>
<td></td>
<td>Adjusted OR</td>
</tr>
<tr>
<td>Death</td>
<td>PAB 0.6</td>
</tr>
<tr>
<td>Age</td>
<td>1.101</td>
</tr>
<tr>
<td>ICU time</td>
<td>PAB 0.24</td>
</tr>
<tr>
<td>TV</td>
<td>1.046</td>
</tr>
<tr>
<td>WT</td>
<td>PAB 0.1</td>
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Multivariate analysis.
Pleurodesis using autologous blood

seal exclusively. Although the patients were nonrandomized owing to ethical limitations, this homogeneity allows us to affirm that the differences in respiratory parameters, hemodynamic instability, death rate, stay in the ICU, and WT as well as ST found between the groups could not be exclusively explained by the differences in the severity of the condition of the patients.

The results show, for those patients treated by PAB, that the ST, WT, and stay in the ICU are shorter than the time spent by the control group patients. Equally, the TV, PP, and PEEP required were less in the case group with respect to the control group.

Finally, the results show less incidence of hemodynamic instability, less need of tracheostomy in the weaning process, and, most importantly, a decrease in death rate in the case group as compared with the control group.

Our pleurodesis technique shows a clear advantage over exclusive use of chest drain and water seal for better association with a short stay in the ICU, less WT, and lower death rate. The bivariate analysis allows us to affirm that the PAB group shows an improvement in respiratory parameters; a smaller number of events of hemodynamic instability; less need for tracheostomy; shorter WT, ST, and stay in the ICU; and a lower death rate. From the multivariate analysis, we feel that a very strong association exists between the independent predictive factor PAB and a lower death rate, shorter WT, and shorter stay in the ICU.

The death of one patient in the PAB group was caused by an arterial lesion resulting from the tracheotomy cannula, which was discovered during autopsy.

During the subsequent telephone assessment, patients in both groups stated complete recovery from their respiratory ailment and claimed not to have suffered any further problem during that time.

The advantage of our therapy, as opposed to the conventional use of the chest tube exclusively, is the reduction of time required for optimal functional respiratory recuperation in patients with pneumothorax and ARDS receiving mechanical ventilation. Moreover, the death rate may be lower in these cases. However, the possibility of empyema as a serious complication could prolong the time required for resolving the process and increase the death rate.

4.1. Study limitations

Nevertheless, it is necessary to evaluate the results for the PAB group carefully because of the small number of patients and nonrandomization. In our opinion, the results of this study are limited by the lack of patient numbers and absence of serious complications in the PAB group. For the study design, the configuration of multivariate analysis is based more on exploratory than on predictive objectives. Moreover, there are important ethical limitations caused by the absence of previous studies on this technique and its use. Further studies could lead to completion and improve current results and conclusions. Further controlled and randomized studies with larger numbers of patients would be required and might prove interesting.

5. Conclusion

In our patients, the use of PAB led to an improvement in both respiratory parameters and mechanical ventilation, making it possible to decrease the ventilator WT and allowing a shorter stay in the ICU, with a resulting increase in functional recuperation and decrease in patient mortality.

Acknowledgment

We thank the ICU nursing team of the Torrecardenas Hospital for their help.

References


