

Evaluation of chest seal performance in a swine model. Comparison of Asherman vs. Bolin seal

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Running title: Experimental Chest seals comparison

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ABSTRACT

INTRODUCTION: Chest seals are externally applied devices used to treat an open pneumothorax. There is concern that chest seals used for treatment of an open pneumothorax can fail due to coagulation or malfunction of the external vent and poor skin adherence. Chest seal failure may lead to respiratory compromise or the development of a tension pneumothorax. The objective of this project was to compare the efficacy and adhesive capacity of two chest seals: Asherman and Bolin.

METHODS: An open pneumothorax model in the swine (30 kg) was developed to test the performance of Asherman (n=8) and Bolin (n=8) seals based on hemodynamic and ultrasonographic changes following intrathoracic air and blood infusion. Seal adherence measured on a scale from 0 (poor) to 3 (good) was tested on dry skin and skin soiled with blood.

RESULTS: After standardized perforation of the chest cavity and aperture blocking, an air infusion of 372 (214 ml) was sufficient to reduce MAP by 20%. Both chest seals prevented a significant fall in MAP after infusion of 1500 ml air into the chest cavity, and had similar adherence scores (2.6 (0.8) and 2.8 (0.6)) on dry skin. However, on blood soiled skin the Bolin seal had a higher score (2.7 (0.6) vs. 0.4 (0.7); $p < 0.01$). Ultrasound did not yield interpretable results to differentiate between Asherman and Bolin seals.

CONCLUSIONS: The Bolin and Asherman chest seals were equivalent in preventing the development of a tension pneumothorax in this open pneumothorax model. However the Bolin chest seal demonstrated stronger adherence in blood soiled conditions.

KEY WORDS: Chest seal, pneumo-thorax, injury, seal adhesion.

INTRODUCTION

Damage to the respiratory system by lung perforation accounts for 5% of battlefield injuries. Open pneumothorax is defined as a collapse of the lung with an associated chest wall defect that allows communication of the pneumothorax with the exterior. With an open pneumothorax, air is entrained in the chest cavity during inspiration and exits the wound upon exhalation. Since air may preferentially enter the chest cavity and not the lung itself, an open pneumothorax may lead to respiratory failure^{3,5}. Treating an open pneumothorax necessitates evacuating air from the chest cavity while not allowing external air to enter.

One temporizing approach to treating an open pneumothorax is achieved with bandages secured on three sides¹ to allow air to escape from the chest while preventing external air from entering. This concept has led to modern day “chest seals” that are manufactured one-way valve adhesive devices placed over a chest wound to allow air and blood to escape while preventing the re-entry of either (Fig. 1A)^{5,8}. In remote settings where evacuation delay is frequent, treatment consists of the application of a device that allows thoracic cavity air to escape while obstructing any external air from entering. Concerns for chest seal failure include poor adhesion to the chest wall, intra-thoracic events (i.e. blood clotting causing valve obstruction) and wounds that may prohibit or obstruct free communication with the chest seal device.

If air is prevented from exiting the chest cavity by a one-way tissue flap or malfunctioning chest seal, the intrathoracic retention of air may result in hemodynamic compromise (tension pneumothorax). Mortality due to tension pneumothorax is between 58-77% if left untreated^{3,7}.

The two currently available chest seals are the Asherman and Bolin. The Asherman package (Rüsch; Duluth, GA) consists of a one-way valve adhesive seal with a 2.5 cm long and flat extension (vent, 15 cm base diameter) (Fig. 1A). The Bolin package (Polymer Science;

Monticello, IN) is a 3-valve device (15 cm base diameter polyurethane base) with a hydrogel adhesive base (Fig 1B). Both packages contain a 10 cm x 10 cm gauze dressing to swipe the wound before placement.

Systematic testing of these 2 chest seals using controlled models has not been reported. We used an established swine model of tension-pneumothorax to examine and compare the performance of these two chest seal devices.

The hypothesis tested whether the more recent Bolin chest seal performs as well or better than the original Asherman seal. Effectiveness was measured on the basis of: 1) Adhesive performance of the seal to the skin; 2) Survival and respiratory/hemodynamic responses for 30 min following lung perforation; and 3) an ultra sound imaging for lung apposition^{4,9}.

MATERIALS AND METHODS

a) Lung injury and chest seal procedure.

The experiments reported herein were conducted according to the principles set forth in the *Guide for the Care and Use of Laboratory Animals*, Institute of Laboratory Animals Resources, National Research Council, National Academy Press, 1996. The study was approved by the Naval Medical Research Center/Walter Reed Army Institute of Research Institutional Animal Care and Use Committee; all procedures were performed in an animal facility approved by the *Association for Assessment and Accreditation for Laboratory Animal Care International* (AAALAC).

Thirty kilogram Yorkshire swine (n=16) were sedated by intramuscular injection of Ketamine (30 mg/kg). Anesthesia was maintained with inhalational isoflurane (~2%). Under

aseptic technique catheters were placed in the carotid artery and internal jugular vein via surgical cut down for continuous monitoring of blood pressure, and a pulmonary artery catheter (Swan) was inserted to monitor hemodynamic variables and collect blood samples. Animals breathed spontaneously without pressure support throughout the experiment.

b) Open pneumothorax model.

While the animal was in a supine position with the right front leg gently pulled forward, an incision through the dermis was made over the 5th intercostal space just inferior to swine axilla. Being careful not to injure the lung, a hole was created by blunt dissection into the adjacent pleural cavity. A 10 ml syringe, previously cut to a barrel length of 3 cm, was inserted into the pleural cavity through the hole, such that the flange rested on the skin surrounding the wound. Pneumothorax was confirmed by visualizing the collapsed lung in the pleural space and hearing the movement of air (in and out) during the respiratory cycle. This created a standard communication tract from the chest cavity to the skin with the syringe plunger to be used as the seal. Next a 9-Fr-ga angiocatheter (PAC; Edwards Life Sciences, Irvine, CA.) was placed through the chest wall approximately 10 cm from the aperture in the thoracic cavity via a modified Seldinger technique¹⁰. This allowed air and blood injection in the chest cavity.

To demonstrate the amount of injected air that would cause hemodynamic compromise (i.e. reduction of blood pressure), such as might be encountered with chest seal valve failure, the modified syringe barrel positioned in the chest wall was closed with its plunger, and air was injected by 60 ml aliquots into the thoracic cavity through the 9-Fr angiocatheter to a maximum volume of 50 ml/kg (1500 ml). This was discontinued by removing the plunger when the mean arterial pressure (MAP) decreased by 20% from baseline, or heart rate increased by 20% from

baseline. The animal was observed for a 15 minute recovery period after MAP returned to baseline.

The chest seals were then block randomized in groups of two and the chest seal placed over the chest wound. The objective being to test valve efficacy to evacuate air, seals were trimmed to accommodate the swine torso if necessary and edges were secured with tape to ensure 100% adherence to the skin. As previously described, air was injected by increments of 60 ml to a maximum of 50 ml/kg. Hemodynamic signs were monitored and recorded with an *a priori* stopping point of a 20% MAP decrease or heart rate increase of 20% from baseline indicative of tension pneumothorax. Gentle manual suction was applied to the introducer angiocatheter to remove any excess air from the thoracic cavity followed by a 15 min stabilization period. Finally, in an effort to evaluate the efficiency of the chest seals to evacuate air in the presence of blood in the chest cavity, 240 ml of fresh blood was collected from the arterial line and injected immediately into the chest cavity via the 9-Fr angiocatheter. After 5 min stabilization, 50 ml/kg (1500 ml) of air was injected in the chest cavity in 60 ml aliquots. Hemodynamic signs were again monitored and recorded until MAP decreased 20% or heart rate increased 20% from baseline. Survival was determined within the following 15 min. At the end of the experimental series animals were euthanized by 100 mg/kg Euthasol solution by IV injection.

c) Adherence

Adherence of the chest seal was tested with upper abdominal placement on dry skin and skin soiled with blood. Soiled conditions consisted of 10 ml blood smeared on the skin, sufficient to cover the surface area of the seal then wiped off by one 10 x 10 cm gauze as provided in the seal package. After placement, adhesion was tested by pulling the seal by the

vent or by the 3 valves. Skin adherence was scored on a scale of 0 (poor) to 3 (good), similar to that described by Khan and Peh⁶. Briefly, 0 is for no adherence (the seal is easily removed from the skin), 1 for poor adherence (the seal is easily removed with light force), 2 for a moderate adherence (the seal is still partially adherent do the skin), and 3 for firm adherence (no removal of the seal without strong deliberate power). To calculate the surface area remaining covered by the seal after the adhesion test, the seal was marked for the adherent surface and documented by a photography that was xeroxed. The marked area was then cut and measured by paper weight technique.

d) Ultra sound measurement

Prior and subsequent to each intervention and monitoring, an ultrasound scan using the Sonosite Titan (Sonosite, Bothell, WA) with a 4-2 MHz microcurved array transducer at a depth of 10 cm was recorded. Images were recorded by a trained investigator at 3 standardized placement points on the chest (Fig. 2). Images and 2-D data were video taped in real-time and the images reviewed by an investigator blinded to the study^{4,9}. Images were analyzed for lung sliding and “sea-shore sign”. Lung sliding illustrates whether the lung surface is touching the chest wall surface. When air is in the thoracic cavity (outside of the lung) it is seen by ultrasound as an absence of lung sliding and an absence of the 2-D “seashore sign”. The presence or absence of lung sliding is likely to be different in each location and taken together may be a rough quantitative indicator of the amount of air in the thoracic cavity. A score of one (1) was given if the measure of lung apposition was noted in each of three areas (minimum score 0, maximum 6). Comparison between groups was based on this scoring strategy.

e) Data Analysis/Statistics

Data analysis of skin adherence (score 0-3), and lung expansion were analyzed using Wilcoxon rank sum test or Student's *t*-test. A difference of 1 in this adherence test will be detected with a power of 80% and a level of significance of 95% using a sample size of 12. A sample size of 8 is sufficient to detect efficacy of the chest seals to prevent pneumothorax (power 95%). A comparison of independent survival rates was performed with Fisher's exact test. Respiratory and hemodynamic data generating continuous variables measured at only one or two time points was analyzed with Analysis of Variance methods. Statistical results were determined significant at $p \leq 0.05$. Randomization scheme for the 2 seals (Asherman, Bolin) was designed by a block randomization list (block size of 2) generated by nQuery. Results are expressed as mean \pm standard deviation (S.D.)

RESULTS

Hemodynamics

Animal weight averaged 29.8 (1.9) kg with initial MAP 61.2 (6.7) mmHg. After perforation of the chest cavity and insertion of the syringe plunger to obstruct air flow, infusion of 372 (214) ml of air was sufficient to induce a 20% MAP drop (Table 1). It was found that both chest seals prevented a significant fall in MAP after the maximum (1500 ml) air infusion to the chest cavity. After withdrawal of blood (240 ml), MAP dropped and because blood injection to the chest cavity was concurrent to collection there was no time for MAP stabilization. Nevertheless, there was no further decrease of MAP after injection of 1500 ml of air regardless of the seal used. We noticed an increased mean pulmonary artery pressure (MPAP) after the first air injection from 12.6 (3.2) to 24.7 (8.2) mmHg. Subsequently MPAP decreased but never returned to baseline, nor did it increase after injection of air, or blood and air, when either seal was in place (17.0 (5.2) vs. 17.0 (2.6) mmHg for the Asherman and Bolin seal, respectively). Increased heart rate was only noticeable when blood was withdrawn. All animals survived the duration of the experiment (~ 65 min) following pneumothorax and seal application.

Figure 3 illustrates the events and changes in hemodynamics during the creation and treatment of the pneumothorax in a typical experiment. MAP increased slightly and then remained stable after chest perforation. It dropped significantly after creation of tension pneumothorax and MAP was rapidly restored after release of the tension pneumothorax and remained fairly stable following the air injection after seal placement. End tidal CO₂ increased following chest perforation and pneumothorax but decreased thereafter. Blood collection at the end of the experiment resulted in a MAP decrease and HR response that was not worsened by

additional air injection with either seal. Also pulmonary pressure and cardiac output remained stable.

Adherence

There was no difference between the scores for adherence to dry skin; Bolin seal 2.6 (0.8) vs. Asherman seal 2.8 (0.6) . On the blood soiled surface the score remained similar to the dry skin for the Bolin seal (2.7 (0.6)), whereas it significantly dropped for the Asherman seal (0.4 (0.7); $p < 0.001$). Peeling the seals off the dry skin was similar for both seals, however on soiled skin the Asherman could be easily detached (2.6 (0.6) vs. 0; $p < 0.001$) (Table 2).

Ultrasound

Thirteen animals were scanned with ultra sound (Asherman (n=6) and Bolin (n=7)). They show adequate and similar baseline images for evaluation with maximum scoring. Three animals were not imaged due to non-availability of ultrasonographic equipment. All 13 baseline images showed normal lung apposition demonstrating lung sliding and “seashore sign” in all three areas measured (score 6/6). After air or air/blood injection into the chest cavity, only 2 animals showed any signs of lung apposition, one in the Bolin group scoring 1/6 and one in the Ashernan group scoring 2/6. Given the small number (n=2) for reliable lung apposition measurements, these were not statistically compared.

DISCUSSION

Emergency rescue care for an open pneumothorax consists of oxygen supplementation, ventilatory support, and chest wound dressings that serve as a one-way valve for evacuating intrathoracic air and preventing a tension pneumothorax¹. Modification of design for chest seals was previously based on anecdotal reports of seal failure. Chest wound dressings and needle thoracocentesis require training and may lead to unsuccessful treatment depending on needle length and patient pathology². Chest seals remedy these problems by a one-way tube valve that allows thoracic air release. However, regardless of how efficiently a seal prevents respiratory failure or tension pneumothorax, if adherence is compromised, it may be rendered useless

The systematic evaluation of such device modifications was the objective of this study by testing chest seal valve efficacy and the adhesive properties of two seals. To test valve function our first approach was to create an open wound and bronchopleural fistula. Initial attempts (n=3, not reported here) were problematic in that the wounds created were difficult to standardize and commonly appeared to form one-way tissue flaps that resulted in tension pneumothorax. The use of a modified plastic syringe allowed a standardized wound to be created as well as preventing the development of tissue flaps. In this model we found that hemodynamic parameters were a reliable indicator of chest seal valve function.

The chest seals tested did not demonstrate any differences in evacuating air introduced in the extrapleural cavity through a separate catheter. Both seals performed similarly even in the presence of intra-thoracic blood. Similarly, both seal valves efficiently prevented the development hemodynamic compromise from tension pneumothorax physiology that could have resulted from increased intrathoracic pressure and decreased venous filling of the right heart. Though ultrasonography suggested that neither device was associated with normal lung inflation, the amount of air retained appeared to have no significant effect on hemodynamics. It was also

reassuring that hemodynamic function remained stable even when additional blood was introduced into the chest cavity (after the initial decrease of MAP due to systemic blood loss). We feel that the spontaneously breathing animal and standardized wound provided an accurate assessment of the chest seal valves in conditions similar to those encountered in austere environments.

Though valve function for both devices appeared adequate and equivalent, adherence of the devices showed significant differences. The Bolin seal was superior adhering to skin, especially in the presence of blood soiling. The abdomen of the swine is relatively free of hair and a good model for adherence performance. However, it should be noted that pig skin may not accurately represent human skin in terms of thickness and pilosity. It is important to report that a chest seal is primarily used when a lengthy evacuation is anticipated. Such scenarios occur in military combat and extreme sport environments. The excellent adhesion performance by hydrogel layered on a rugged polyurethane disc structure found with the Bolin seal allows easy relocation of the seal, even on soiled surfaces. In addition to the premium adhesion of the Bolin seal, it offers the advantage of a 3-valve seal which avoids a long vent (as in the Asherman seal) that could more easily kink after application, obstructing air evacuation.

We have developed a model for testing the efficacy of evacuating extrapleural thoracic air in an open pneumothorax model that focused on limiting hemodynamic compromise. This model appears suitable for device testing as the chest opening, intrathoracic air, and blood injections were standardized. Ultrasonography did not yield additional information to our device testing and may not be a necessary part of similar evaluations. Additional ways to standardize the amount of time that blood is in contact with the seal would further improve this model. Overall, the model showed encouraging results for evaluating chest seals and may be used to evaluate other treatment options for open pneumothorax and their applications in austere situations.

CONCLUSION

We have developed a standardized spontaneously breathing open pneumothorax swine model. Device testing in this model relied on hemodynamic changes that were easily monitored. The Asherman and Bolin chest seal valves have similar effectiveness in evacuating intrathoracic air, but the Bolin seal offers superior adhesive properties.

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REFERENCES

1. American College of Surgeons, committee on Trauma. Advanced Trauma Life Support, ISBN: 9781880696149, ACS 7th edition, 2004.
2. Britten S, Palmer SH, Snow TM. Needle thoracocentesis in tension pneumothorax: insufficient cannula length and potential failure. *Injury* 1996; 27(5):321-2.
3. Fleming WH, Bowen JC. Early complications of long-term respiratory support. *J Thor Cardiovasc Surg* 1972; 64(5):729-38.
4. Hamilton DR, Sargsyan AE, Kirkpatrick AW, et al. Sonographic detection of pneumothorax and hemothorax in microgravity. *Aviat Space Environ Med.* 2004; 75(3):272-7.
5. Hodgetts TJ, Hanlan CG, Newey CG. Battlefield First Aid: a simple, systematic approach for every soldier. *J R Army Med Corps.* 1999; 145(2):55-9.
6. Khan TA, Peh KK. A preliminary investigation of chitosan film as dressing for punch biopsy wounds in rats. *J Pharm Pharm Sci.* 2003; 6(1):20-6.
7. Peoples GE, Gerlinger T, Craig R, Burlingame B. Combat casualties in Afghanistan Cared for by a single forward surgical team during the initial phase of operation Enduring Freedom. *Mil Med* 2005; 170(6):462-8.
8. Rathinam S, Steyn RS. Management of complicated postoperative air leak - a new indication for the Asherman chest seal. *Interact Cardiovasc Thorac Surg.* 2007; 6(5):
9. Sargsyan AE, Hamilton DR, Nicolaou S, et al. Ultrasound evaluation of the magnitude of pneumothorax: a new concept. *Am Surg* 2001; 67(3):232-5.
10. Singh K, Loo S, Bellomo R. Pleural drainage using central venous catheters. *Crit Care* 2003; 7(6):R191-4.

Figures

Figure 1.

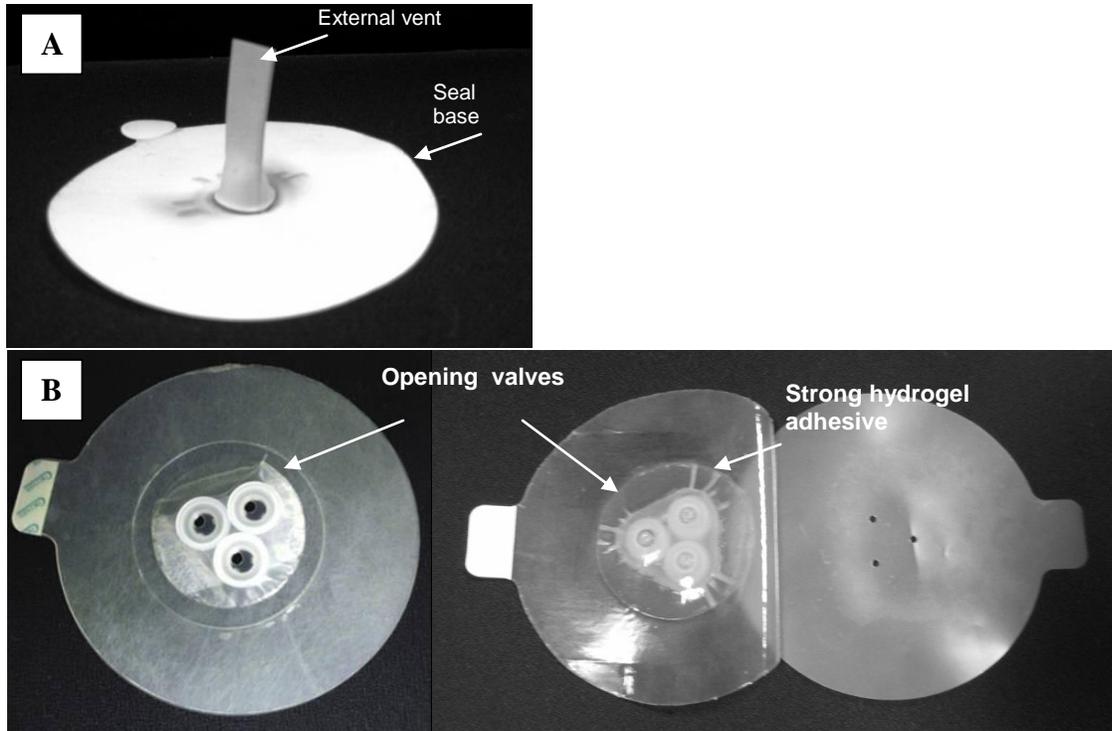


Figure 2.

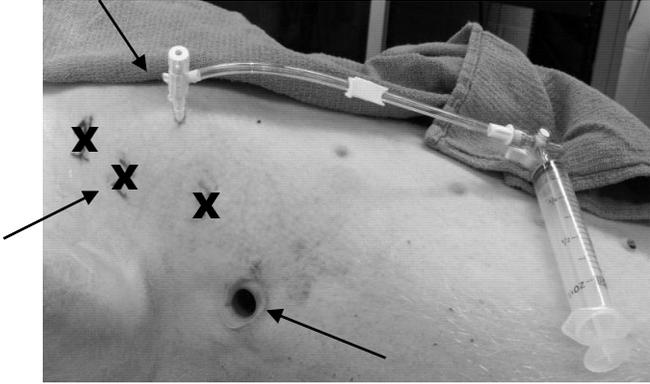
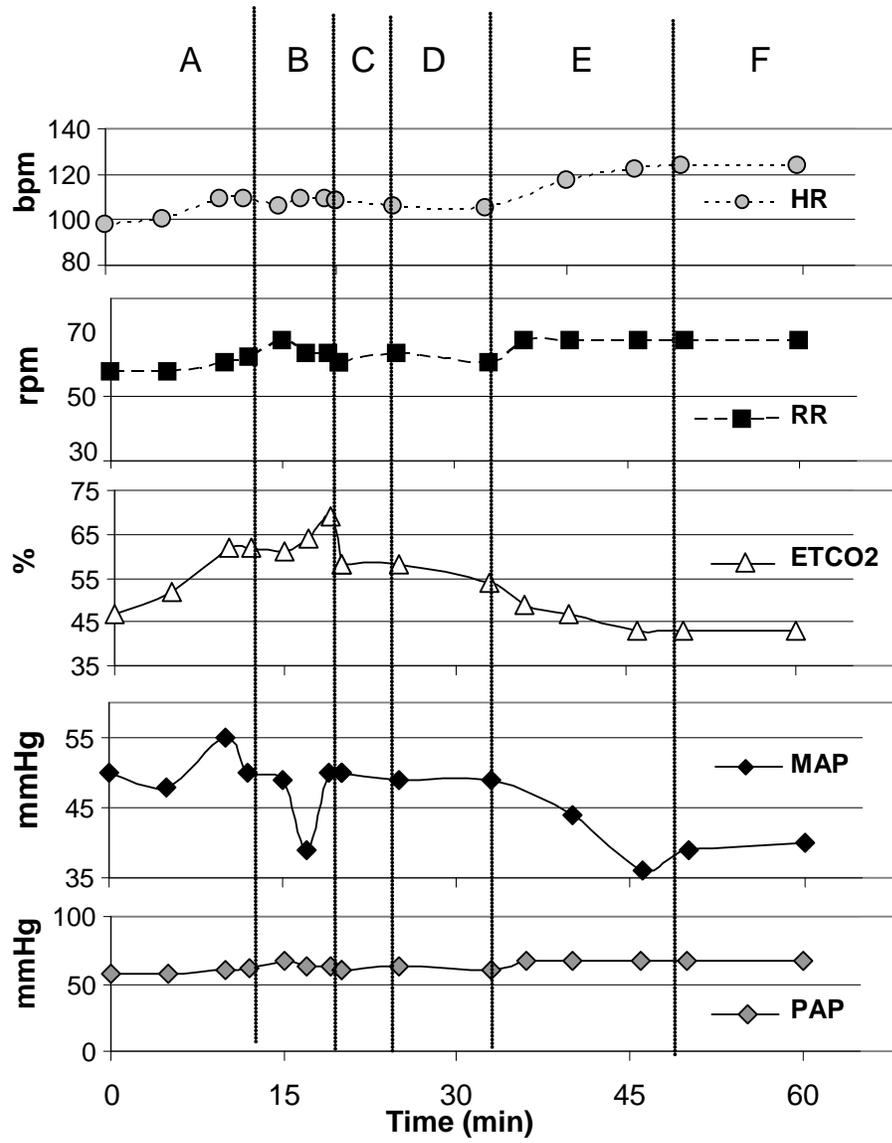


Figure 3.



Legends

Figure 1: **A:** Asherman tube chest seal, **B:** Bolin 3-valve chest seal, both with a 15 cm diameter adhesive base- unopened and opened view.

Figure 2. Illustration of the *in situ* catheter for injection of air and blood, and the syringe barrel aperture for pneumothorax creation. Arrows indicate respectively the 3 thoracic placements (X) for imaging of pneumothorax by ultrasound.

Figure 3. Representative example for hemodynamics changes during the different steps of the pneumothorax induction model A: Chest incision, placement of syringe barrel and chest catheter, B: Injection of air and creation of pneumothorax, C: Seal application, D: Injection of 1500 ml air, E: Injection of 240 ml blood, F: Injection of 1500 ml air. Parameter monitored: HR; heart rate, ETCO₂: end tidal CO₂, RR; respiration rate, MAP: mean arterial pressure, PAP: mean pulmonary arterial pressure.

Table 1: Air injection to induce pneumothorax: Results are expressed as mean \pm standard deviation (S.D.)

Pneumothorax Aperture covered by:	Syringe Plunger (n=16)	Asherman Seal (n=8)	Bolin Seal (n=8)
Air injection without blood	372 (214) ml ¹	1500 ml ²	1500 ml ²
Air injection after 240 ml blood	n/a	1500 ml ²	1500 ml ²
Survival	n/a	100%	100%

¹ Volume of air injected in the chest to achieve 15 – 20% MAP decrease

² Maximal volume of air injected in the chest with no MAP or HR decrease

Table 2: Adherence test of the seals on dry and soiled skin:

Adhesion score		Asherman seal	Bolin Seal	P
		n = 12	n = 12	
Dry skin	Adherence	2.8 (0.6)	2.6 (0.8)	0.55
	Ease to peel off	2.3 (0.7)	2.2 (1.0)	0.63
	Surface covered	92.6 (10.3)	92.0 (12.2)	0.91
Soiled skin by blood	Adherence	0.4 (0.7) *	2.7 (0.7)	<0.001
	Ease to peel off	0 (0) *	2.6 (0.6)	<0.001
	Surface covered	6.0 (13.1) *	83.0 (23.3)	<0.001

Results are expressed as mean \pm standard deviation (SD) and Wilcoxon test was used to compare Asherman and Bolin seals on soiled skin. * also denotes adherence difference for the Asherman seal on dry and soiled skin.