Technical report

A pleural vacuum relief device for pleural drain unit use in the hyperbaric environment

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Abstract

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Introduction: When a standard water-seal pleural drain unit (PDU) is used under hyperbaric conditions there are scenarios where excessive negative intrapleural pressure (IPP) and/or fluid reflux can be induced, risking significant morbidity. We developed and tested a pleural vacuum relief (PVR) device which automatically manages these risks, whilst allowing more rapid hyperbaric pressure change rates.

Methods: The custom-made PVR device consists of a one-way pressure relief valve connected in line with a sterile micro filter selected for its specific flow capacity. The PVR device is designed for connection to the patient side sampling port of a PDU system, allowing inflow of ambient air whenever negative pressure is present, creating a small, controlled air leak which prevents excessive negative pressure. The hyperbaric performance of a Pleur-Evac A-6000 intercostal drain was assessed with and without this added device by measuring simulated IPP with an electronic pressure monitor connected at the patient end of the PDU. IPP readings were taken at 10, 15, 20 and 30 cmH_2O of suction (set on the drain unit) at compression rates of 10, 30, 60, 80, 90 and 180 $kPa·min^{-1}$ to a pressure of 280 kPa.

Results: At any compression rate of > 10 $kPa·min^{-1}$, the negative IPP generated by the Pleur-Evac A-6000 alone was excessive and resulted in back flow through the PDU water seal. By adding the PVR device, the generated negative IPP remains within a clinically acceptable range, allowing compression rates of at least 30 $kPa·min^{-1}$ with suction settings up to -20 cmH_2O during all phases of hyperbaric treatment.

Conclusions: The PDU PVR device we have developed works well, minimising attendant workload and automatically avoiding the excessive negative IPPs that can otherwise occur. This device should only be used with suction.


Introduction

Proprietary water-seal pleural drain units (PDUs) are the preferred method for chest drainage of pneumothorax, empyema, blood or fluid during in-hospital care. On occasions, patients with an intercostal catheter (ICC) and a PDU will require hyperbaric oxygen treatment (HBOT) to manage a coexistent condition, such as decompression illness (DCI), cerebral arterial gas embolism (CAGE) or necrotizing fasciitis. The designs of PDUs incorporate multiple air-filled spaces on either side of a water trap and these are affected by hyperbaric exposure in ways that depend upon whether the unit is on suction or not, and whether the patient has a pleural air leak or not. A key performance requirement for pleural drain systems is the avoidance of excessively negative intra-pleural pressure (IPP) as this may result in lung injury and potentially worsening of a trans-pulmonary air leak.[1] Although these units have manual and automatic pressure relief systems designed to prevent excess negative pressure, the automatic relief settings are generally quite high. Further,

some hyperbaric scenarios result in a bubbling backflow of water-seal fluid towards the patient, for example during fast compression for CAGE, and this risks contamination of what should be the sterile side of the system. To safely manage a patient with a PDU during HBOT, close observation is necessary and a number of modifications must be made to standard pleural drainage system care. To avoid potential complications arising from use of a proprietary PDU, many hyperbaric units and hyperbaric texts recommend that a PDU be disconnected with the substitution of a Heimlich valve during HBOT.

Previous studies have shown that PDUs from different manufacturers show variations from the prescribed to the actual delivered intra-pleural pressure (IPP).[2,3] Our group has previously tested the function of one PDU (Atrium Oasis Dry Suction 3600 Chest Drain) under hyperbaric conditions; this device proved to be dramatically affected by pressure changes.[4] However, safe use in an hyperbaric environment was possible if no suction was applied during pressurisation

Figure 1

A schematic of the Pleur-Vac A-6000 pleural drainage unit (PDU) and of the experimental set up including the pleural vacuum relief (PVR) device
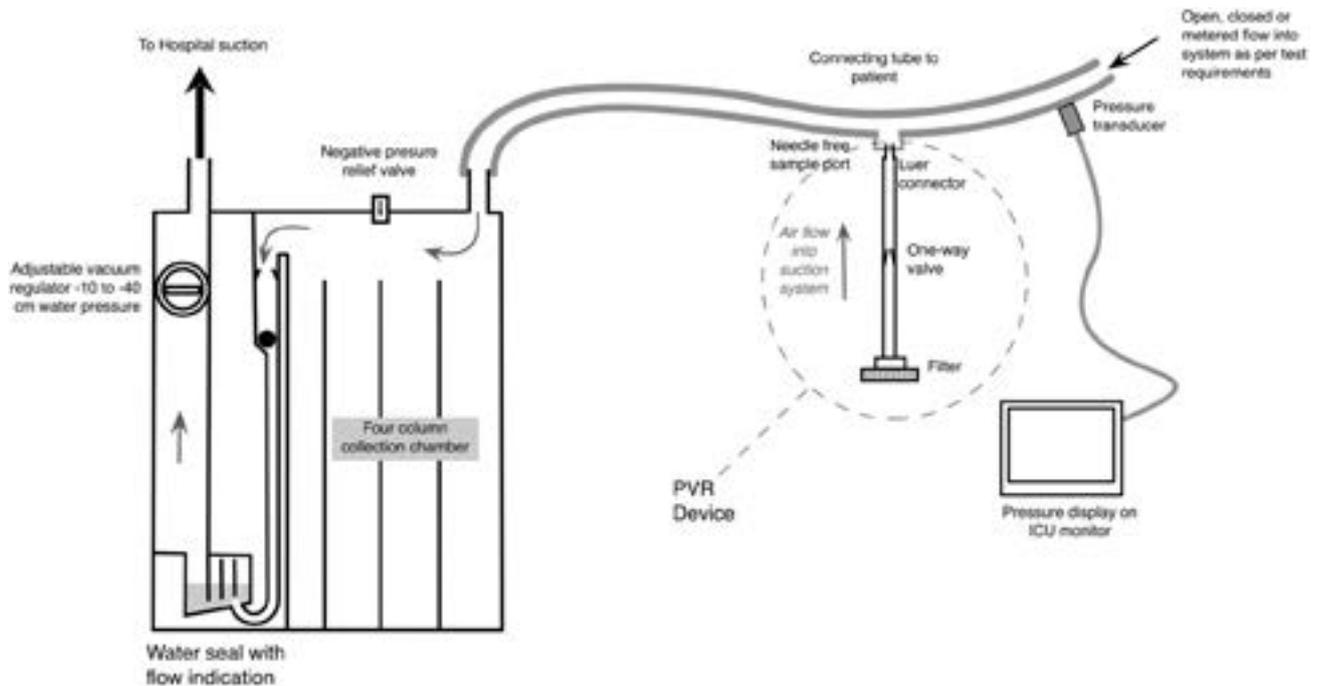
and if the rate of pressurisation was limited to 10 kPa·min[-1] or less. Under these conditions the water-seal was maintained and the column of water making the seal did not back flow into the collection chamber.[5]

As the construction details of different PDUs vary significantly, the performance characteristics of any one particular model cannot be assumed to be the same as for other similar devices.[4] Currently our institution predominantly uses the Pleur-Evac® A-6000 PDU from Teleflex. In this device the degree of suction is controlled by an inbuilt regulator with the desired suction selected via a crude rotary dial. A water seal chamber indicates the negative pressure delivered on the patient side of the device, with bubbles through the water seal chamber indicating the rate of any air leakage present. The PDU collection chamber is a closed volume, so that when the ambient pressure increases, vacuum/negative pressure will develop in the collection chamber unless this is relieved by inflow of gas or fluid. In the absence of an air leak from the patient, the only inflow route for this gas is via back flow through the water seal (Figure 1). While for many patients removal of suction during pressurisation may be clinically acceptable, it is usually considered optimal to maintain stability of the IPP at all times by maintaining the suction to the PDU during all phases of HBOT.

The strategy recommended by the manufacturer for avoiding excess negative pressure is to manually operate the negative pressure relief valve located on top of the unit. Although this does work during pressurisation, there are several disadvantages: the patient attendant becomes occupied physically and mentally with keeping the PDU vented, to the detriment of attending to other matters, and negative IPP pressure can disappear when the valve is open for prolonged periods, risking lung collapse. These problems are multiplied when more than one PDU is present.

Our clinical experience with patients with pleural air leaks and PDUs on suction suggested that keeping the PDU on regulated suction with an artificially provided and controlled 'air leak' might mitigate the potential problems associated with PDUs in hyperbaric situations. This would enable continuance of suction and the desired low level negative IPP pressure in patients without pleural leaks throughout the various phases of hyperbaric treatment. After a prototype device appeared to work in crude testing, we refined the concept, and undertook detailed testing of the new device by comparing the performance of the Pleur-Evac A-6000 with and without the pleural vacuum relief device across a range of pleural drainage and hyperbaric settings.

Aims

We hypothesised that a custom-made pleural vacuum relief (PVR) device inserted into the patient tube side of a PDU via its needleless sample site (an auto-sealing 'Luer-Lock' style push-and-twist connection) would allow passive, controlled introduction of ambient air into the PDU system whilst the PDU was on suction, ensuring that the desired low levels of negative pressure would not become excessive, thus allowing for intervention-free operation of the ICC

Figure 2
The custom-made pleural vacuum relief (PVR) device will be inserted into the patient tube side of a pleural drainage unit (PDU) via the PDU's needleless sample site
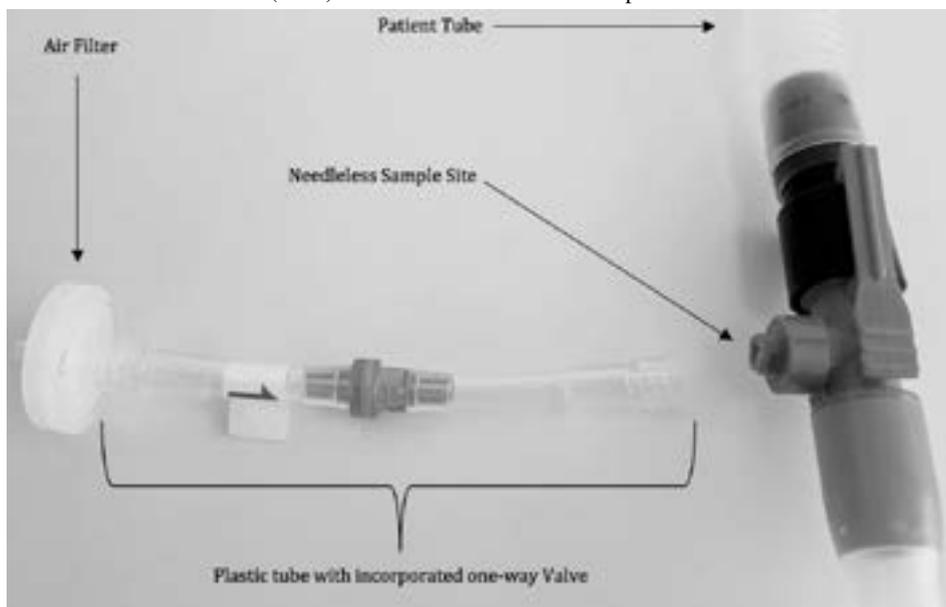
and PDU during all phases of HBOT. We tested the ability of the PVR device to allow the PDU to remain on suction and maintain a safe IPP throughout hyperbaric exposure during both normal and elevated pressurisation rates.[5] As the testing process involved use of the Pleur-Evac A-6000 PDU with and without the PVR device, we are also able to report details of the hyperbaric performance of the Pleur-Evac A-6000 PDU.

Methods

This study did not involve human or animal subjects and, therefore, was not subject to ethics committee approval or application. Testing was performed on a single Pleur-Evac A-6000 PDU device of the type currently used in The Alfred Hospital Department of Intensive Care and Hyperbaric Medicine, Melbourne. The drain tube normally connected to the patient was connected to an electronic pressure monitor (Edwards Life sciences, Pressure Monitoring Kit with TruWave Disposable Pressure Transducer, Ref: PX212) to measure the generated pressure at the patient end of the drain tube. It was assumed that this would equate to the IPP in a patient without a pleural leak. The pressure transducer accuracy was verified with a calibrated test instrument (Druck® DPI 705 Digital Pressure Indicator, Rep: 107953, s/n: 70526859, calibrated: 25/10/2012). Pressure readings were taken by connecting the pressure transducer via a chamber penetration to a Phillips IntelliVue MP70 monitor external to the chamber, so that no staff were required to be pressurised in the hyperbaric chamber during the study. Pressure readings were read from the monitor visually and transcribed onto an Excel spreadsheet (Microsoft® 2004). A schema of the experimental set up is presented in Figure 1.

The PDU was set up as per the manufacturer's instructions with the water seal chamber filled to the 'fill line'. The PDU suction port was connected via standard medical suction tubing to the hyperbaric chamber wall suction outlet set to maximum (The Alfred Hyperbaric Service chamber is a TGA-approved chamber and, as such, all gas and suction supplies conform to the appropriate Australian gas standard AS 2896-2011). In this configuration, the PDU suction level is controlled by the suction regulator incorporated into the PDU as per manufacturer recommendations.

The PVR device (Figure 2) allows a small flow of ambient air to be entrained throughout the various phases of a typical HBOT treatment whenever the PDU is on suction, unless the patient were to have a very large pleural air leak. The flow of air through the device is limited by the flow resistance properties of the device such that with the suction connected, sufficient continuous flow is maintained through the PDU to prevent the development of excessive negative pressure within the PDU collecting chamber while still maintaining the desired negative ICC pressure within clinically acceptable values. With continuous bubbling occurring through the water trap, it becomes easy to verify that the system is working satisfactorily.

The PVR device consists of a non-return valve and a small microbiological filter in line. Selecting the optimal filter involved bench testing over a dozen types of filters using the NATA-certified PTS2000 flow bench tester to determine pressure drop characteristics across each filter. The PALL Life Sciences Acrodisc® CR 25 mm syringe filter with 1µm PTFE membrane, (PN S4226, Lot 21683800) was selected as this provided the appropriate properties when incorporated

into our PVR device.[6,7] The controlled leak results in only a small, inconsequential reduction in the negative pressure at the ICC end of the patient tube during steady-state pressure conditions. Should the patient cough, back flow through the PVR is prevented by the presence of a one-way valve. The disposable device is easy to assemble and connect to the PDU. During compression, a whistling noise is commonly heard coming from the device, which gives a supplementary auditory confirmation that the PVR valve is working.

Having refined the PVR device, we undertook testing with a pressure-monitored PDU during various suction and hyperbaric pressure scenarios in the hyperbaric chamber (FETL-24, Fink Engineering, Melbourne, Australia). The suction conditions examined were:

- suction tubing connected to the chamber suction, with suction switched off ('no suction');
- suction tubing connected to the chamber suction, with suction switched on, regulated by the PDU's adjustable suction regulator to 10, 15, 20 and 30 cmH_2O of suction (30 cmH_2O was only tested at 30 $kPa\cdot min^{-1}$ pressurisation rate).

The hyperbaric chamber rates of pressure change used were:

- compression at 10, 30, 60, 80, 90 and 180 $kPa\cdot min^{-1}$ to 280 kPa;
- decompression was conducted at 60 $kPa\cdot min^{-1}$ for all tests.

The nominated compression rate for all Royal Navy/US Navy treatment tables (until the latest iteration of the USN dive manual) has been 180 $kPa\cdot min^{-1}$. Anecdotally, most clinical hyperbaric services pressurize at slower rates than this with many commercial and civilian chambers not physically capable of this compression rate. At the Alfred the routine compression rates are:

- Standard treatment table (TT) 10 $kPa\cdot min^{-1}$;
- ICU TT 30 $kPa\cdot min^{-1}$;
- Diver emergency TT 180 $kPa\cdot min^{-1}$.

The level of negative pressure within the ICC connection (simulated IPP) was recorded every 5, 15, 30 or 60 seconds depending upon the pressurisation rate being studied.

For the 30 $kPa\cdot min^{-1}$ pressurisation rate, we also conducted measurements with an ICC tubing air leak to simulate a bronchopleural fistula. Fistula flows of 1, 2.5 and 5 $L\cdot min^{-1}$ were simulated. This was conducted by using a chamber oxygen outlet connected via a low-flow flow meter and a Y-connector to the patient tube.

The outcome measures were:
- simulated intra-pleural pressure (IPP);
- displacement distance of the underwater seal column towards the ball valve.

An initial 'proof of concept' series of tests was performed which demonstrated a very low inter-test variance in measured values of IPP between different 'runs' of the same pressurisation profile. As such, it was decided that three 'runs' for each set of conditions would provide adequate data to calculate mean IPP values for that set of conditions. A pilot study had shown that pressure readings in other areas of the ICC system were not relevant to the delivery of the correct IPP.[4]

Results

NO SUCTION, NO PVR DEVICE

At a compression rate of 10 $kPa\cdot min^{-1}$ without suction, the negative IPP rose without backflow of the underwater seal fluid into the collection chamber. In this test, the IPP increased to -26 cmH_2O during the first minute (the negative pressure in the patient tube increased as increasing ambient pressure led to a decrease of air volume in the collection chamber) without breakdown of the water seal, then stabilised around -22 cmH_2O until the ambient pressure reached 280 kPa. The IPP then remained stable at pressure, before coming back to zero and then becoming slightly positive during decompression. At all compression rates faster than 10 $kPa\cdot min^{-1}$, the flow of gas backwards into the collecting chamber forces the water in the underwater seal up the column and past the ball valve into the collecting chamber potentially compromising the seal should too much fluid be lost.

NO SUCTION, WITH PVR DEVICE

At the compression rates of 10, 30, 60 and 180 kPa/min with no suction applied and with the PVR device in place, the profiles of the IPP pressure curves followed a similar pattern in each test. During compression, the IPP rapidly became more negative, then stabilised while at 280 kPa. During decompression the negative IPP decreased with the decrease in pressure in the chamber, returning to baseline (zero) after completion of decompression. At each compression rate no backflow of the water column making the seal was noted. Maintenance of this volume is essential for correct functioning of the device. The maximum negative IPP pressure recorded was dependent upon the compression rate, -9, -16, -28 and > -42 cmH_2O at compression rates of 10, 30, 60 and 180 $kPa\cdot min^{-1}$ respectively. A negative pressure of -42 cmH_2O was the maximum our chosen electronic pressure transducer could measure. It was observed that the suction delivered to the patient tube was more negative than the suction regulator setting on our ICC drain in all phases of the HBOT cycle.

WITH SUCTION, WITH PVR DEVICE

In all suction conditions and at all compression rates tested with the PVR device in place, the water seal was preserved. At compression rates of 10 and 30 $kPa\cdot min^{-1}$ and with

Figure 3
Average intrapleural pressure (IPP) during all phases of the pressurisation cycle; compression rate 30 kPa·min⁻¹;
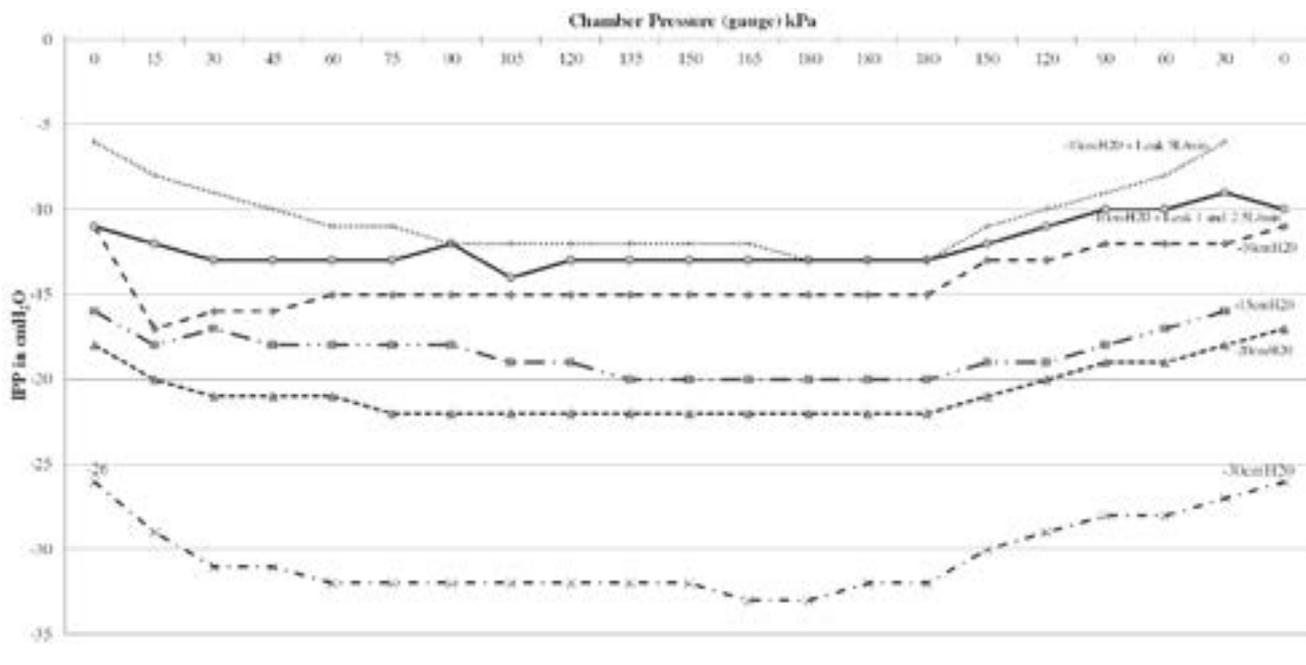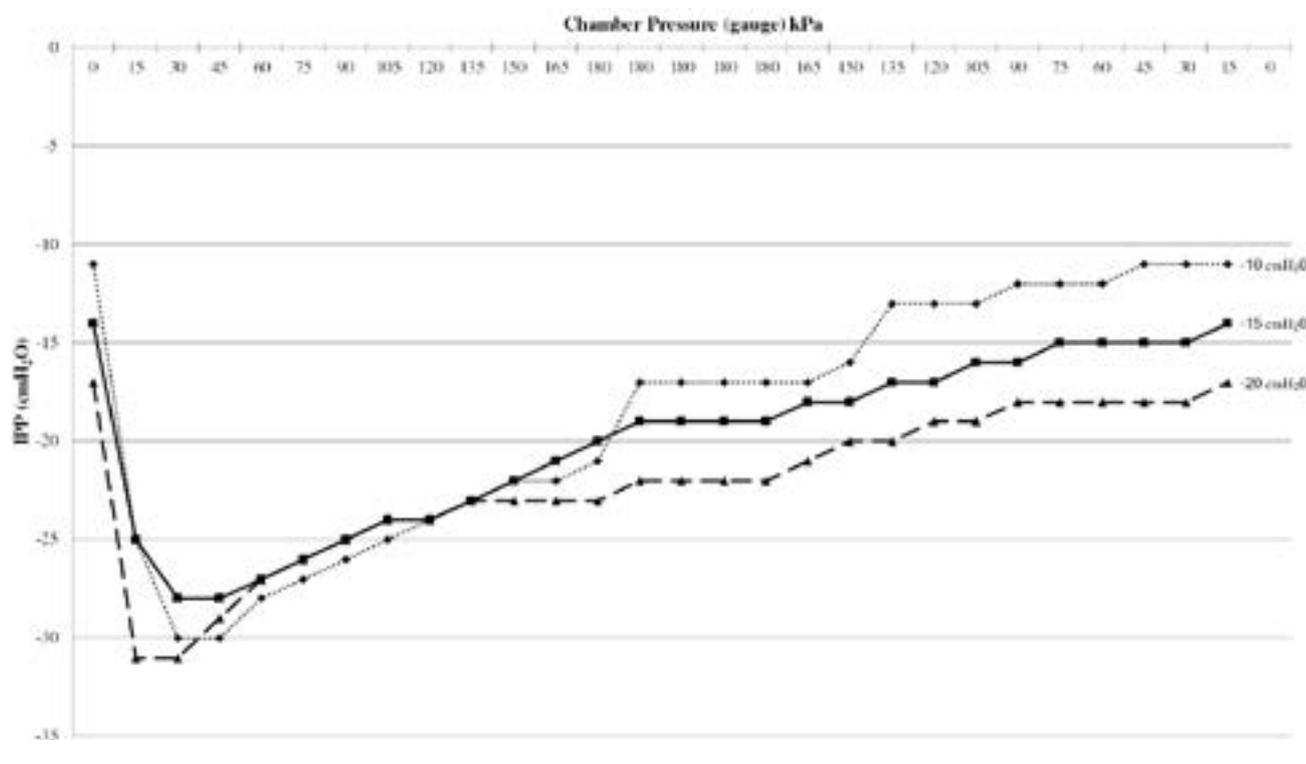decompression rate 60 kPa·min⁻¹, with and without leak

Figure 4
Average intrapleural pressure (IPP) during all phases of the pressurisation cycle; compression rate 60 kPa·min⁻¹;
decompression rate 60 kPa·min⁻¹

variation of the suction setting from -10 to -20 cmH$_2$O (and -30 cmH$_2$O at 30 kPa·min⁻¹), there was only a slight fall in the initial IPP values and in the maximum negative values. Changes during 30 kPa·min⁻¹ compression are shown in Figure 3. Overall, the negative IPP generated remained much closer to the regulator suction setting on the PDU. With a compression rate of 60 kPa·min⁻¹ a somewhat larger initial fall in IPP occurred but did not exceed -30 cmH$_2$O and was the same for all suction settings tested (Figure 4).

At the maximum compression rate tested of 180 kPa·min⁻¹ the initial pressure drop was greater and exceeded the -42 cmH_2O limit of the electronic pressure monitor display for the two suction settings of -10 and -20 cmH_2O. The maximum compression rate at which the IPP did not exceed -42 cmH_2O with a suction setting of -10 cmH_2O was found to occur with a compression rate of just under 90 kPa·min⁻¹.

WITH SUCTION, WITH PVR DEVICE, WITH AIR LEAK

At the compression rate of 30 kPa·min⁻¹ with the suction set to -10 cmH_2O, air was allowed to enter the patient tubing in a regulated fashion to simulate a bronchopleural fistula. The test results demonstrated very stable IPP during all phases of the HBOT with the measured negative IPP falling below the set suction on the ICC drain only with a simulated pleural air leak of 5 l·min⁻¹. However , the IPP remained negative at around -6 cmH_2O during the initial and final phases and not exceeding -12 cmH_2O overall (Figure 3).

Discussion

It is optimal for most intensive care interventions, including thoracic drainage if present, to be continued throughout HBOT and during transfers when technically feasible rather than disconnecting and replacing them with alternative technology. Continuous intrapleural suction, particularly during decompression, is critically important in treating pneumothorax which will otherwise expand, potentially leading to a tension pneumothorax. The PDU study previously undertaken on the Atrium Oasis Dry Suction 3600 chest drain showed significant variations in the degree of negative IPP generated during compression and decompression.[4] Acceptable levels of IPP were only achievable when compression rates were very slow and when suction was discontinued during compression. Given also the potential for backflow of the underwater seal fluid into the collection chamber and subsequent loss of the seal, there is a requirement for the chamber attendant to monitor the PDU water-seal during compression, a period which already involves heavy task loading, especially in high-acuity patients.

We have confirmed that the Pleur-Evac A-6000 ICC drain is generally safe to use if the same procedures are used as those recommended previously,[4] that is, without suction during compression and with the compression rate limited to 10 kPa·min⁻¹.

Our primary aim was to develop a safe, cheap and easy-to-use system which would minimise the risk of excessive negative intra-pleural pressures whilst allowing normal operation of proprietary PDUs, including continuity of suction, during all phases of HBOT. This device would ideally require minimal or no intervention by staff and would allow rates of compression faster than 10 kPa·min⁻¹. The introduction of this PVR device has allowed the use of

standard treatment tables in our institution when a PDU is present and has markedly reduced inside attendant workload in critically ill patients. Also, this device does not modify or change the intended use of the PDU in any way.

A valid criticism of this type of device is that it can allow air to flow into the pleural cavity in the absence of suction. This scenario was tested as a potential 'failure mode'. The internal resistance within the PVR device will prevent rapid re-accumulation of a pneumothorax in the event of suction being disconnected before the PVR has been removed but it is imperative that staff are educated about safe use of the device and that there is strict adherence to protocols and checklists. We require removal and disposal of each PVR at the conclusion of each hyperbaric session and prior to transport back to the ICU.

Even with the use of our PVR device, the negative IPP generated during hyperbaric compression was always higher than the set suction on the suction regulator setting of the ICC drain. Normal intrapleural pressures vary between -8 to -3.4 cmH_2O but can transiently exceed -54 and +70 cmH_2O in extreme inspiration and expiration respectively.[5] There is no clear evidence in the medical literature on what should be the maximum therapeutic intrapleural negative pressure.[3] Some authors recommend up to -40 cmH_2O in some cases, but the therapeutic settings most commonly used seem to range from -10 to -30 cmH_2O. It is thought that higher suction settings generating substantial negative IPP can potentially worsen a pleural leak or even trap lung parenchyma in chest tube holes, leading to lung injury. From an overall perspective, a target maximum IPP of -30 cmH_2O seems reasonable.

Assuming this, and using our custom PVR device, we could recommend using the Pleur-Evac A-6000 ICC drain at rates of compression up to 60 kPa·min⁻¹ with the suction regulator set at a maximum of -20 cmH_2O. In this setting, the IPP will reach, on average, a maximum of -31 cmH_2O for less than 30 seconds, before returning progressively back to the set value, and staying in the safe pressure range (Figure 4). However at compression rates beyond 60 kPa·min⁻¹, an initial increase in the negative IPP to greater than -30 cmH_2O was observed. To minimise the risk of an undesirable increase in negative pressure, and to maintain a more stable IPP throughout the HBOT, compression rates of between 10 and 30 kPa·min⁻¹ should be used. At these rates, the IPP varies no more than -5 cmH_2O and remains very stable throughout the compression period (Figure 3).

The simulation of an air leak did not compromise the function of the PVR device, suggesting that if the patient were to have a bronchopleural fistula, the use of our device under hyperbaric conditions should still ensure delivery of the necessary ICC suction. In practice, it would be rare for a patient with an air leak of 5 L·min⁻¹ to undergo HBOT

rather than to receive surgical intervention before therapy. In comparison with the pressure curves without a simulated pleural air leak, the IPP was more stable when a pleural air leak was simulated (Figure 3). This is presumably due to the air leak playing the same role as our PVR device in ensuring unidirectional airflow through the PDU during compression, preventing generation of excessive negative pressure as the air in the collection chamber is compressed.

The choice of sterile air filter was critical to the development of the device. Many different types of filters (PTFE, PES, PVDF, etc.) with different properties (hydrophobic, hydrophilic), pores sizes (in μm) and filter surface areas (in mm diameter) are available commercially. Our final selection was based on a compromise between good filtration properties and the necessary flow resistance to permit enough ambient air to enter into the PDU collection chamber to modulate negative pressure during compression and the maintainance of a safe bacterial filtration capability and avoiding an excessive air leak. A 25 mm filter with an hydrophobic PTFE membrane with pore size of 1 μm ensures good anti-bacterial and anti-viral properties.[6,7] The PALL filter selected is primarily designed for use with liquids and the filtration capabilities of such membranes are about ten times more efficient in air than in liquid owing to electrostatic charges in the membranes that attract airborne particles and organisms at the surface of the membrane and also to the walls of the pores. Secondly, the pore size is sufficiently small that Brownian motion becomes relevant, with small particles not travelling on straight trajectories when carried in air, making it difficult for them to progress through the thickness of a filter without becoming trapped in the matrix of the filter.[6]

There are some caveats on the use of the PVR device in the clinical setting. In particular, the PDU must be connected to the chamber's suction system and confirmed to be under suction before the PVR can be connected. While the controlled leak from the PVR is small, the application of the device prior to the application of suction to the PDU could nevertheless result in the patient's lung collapsing. Similarly, the device must be removed from the patient-tube prior to the PDU being removed from the chamber suction system at the end of the treatment. With appropriate staff training and protocols in place, this has not proven to be an issue in the clinical setting in our institution.

Conclusions

The use of a PDU under hyperbaric conditions normally requires significant intervention from staff and reduced compression rates to prevent an unacceptable increase in IPP during variations in ambient pressure. While the Pleur-Evac A-6000 ICC drain can be used safely in hyperbaric chambers without suction (during compression) and at a maximum compression rate of 10 kPa·min[-1], the use of our PVR device allows for the IPP to remain within an acceptable range without intervention from the staff during all phases of HBOT, including at compression rates up to 60 kPa·min[-1] with continuation of pleural suction at settings up to -20 cmH$_2$O. For routine treatments, we would recommend a compression rate of 30 kPa·min[-1], where the generated IPP is most stable. Finally, it is important to remember that during decompression it is highly desirable for any ICC drain to be on suction in order to avoid the complication of an expanding pneumothorax. A critical practice point is that if the PVR device is to be used, the PDU must be on suction before it is attached and the device removed before taking the patient off suction for transport.

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