Xpand chest drain: assessing equivalence to current standard therapy – a randomised controlled trial

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Summary

Background. Penetrating chest trauma is a leading cause of admission to South African emergency departments. The resultant pneumo-/haemothoraces are currently routinely treated by means of standard underwater bottle drainage. A South African company, Sinapi Biomedical, recently launched the Xpand chest drain. This device incorporates a one-way valve with a fluid reservoir and permits the detection of an air leak, as well as intrapleural pressure differences.

Aim. To prove equivalence of the Xpand chest drain compared with standard underwater bottle drainage.

Methods. In a non-blinded randomised control trial 67 patients with radiological proof of a pneumo- or haemothorax following penetrating chest trauma were divided into two groups. One group received standard underwater drain treatment and the other group had the Xpand chest drain inserted. Time from placement of drain to removal of drain (following radiological proof of resolution) was compared between the two groups.

Results. The underwater drain group (N = 34) had drainage periods varying from 6 to 280 hours with an average of 81.47 hours, while the Xpand group (N = 33) had drainage periods varying from 13 to 151 hours with an average of 61.04 hours ($p = 0.088$).

Conclusions. Although there was a definite improvement in drainage time with the Xpand chest drain, the difference did not reach statistical significance. We have, however, proven that the Xpand chest drain is as effective as a standard underwater drain in treating the sequelae of penetrating chest trauma and therefore recommend it as an alternative to current standard therapy.

Penetrating chest trauma is one of the leading causes of admission to South African emergency departments. This places a strain on all trauma facilities and the health budget in general. Days absent from work also have economic implications. It is therefore imperative that we continually reassess our current treatment modalities and search for more cost-effective means of treatment.

Underwater seal drainage was first described by Playfair[1] in 1875 and has become the standard form of chest drainage throughout the world. In South Africa the underwater drain (UWD) is the most common device used for chest drainage (estimated at 98%). It consists of tubing and a glass or plastic bottle filled with 300 - 500 ml of sterile water. The end of the tubing is positioned 5 cm beneath the water level, allowing air and liquid to exit but not re-enter the pleural space. The UWD has the following disadvantages:

- Retrograde flow of fluid may occur if the bottle is raised sufficiently
- Clamping of the drain may result in a tension pneumothorax
- The opening pressure of the 'valve' is inconsistent because of varying liquid levels in the bottle
- Risk of exposure of nursing staff to bodily fluids either by leakage from 'open to air' system or breakage of glass bottle (with associated risk to patient)
- Bulky bottle restricts patient movement and increases risk of spillage
- When low-pressure suctioning is used, a second (and sometimes third) bottle is used, adding to bulk and patient immobility.

The Xpand chest drain is an external medical device made of plastic that incorporates a fluid reservoir, a one-way valve and an air-leak detection system. It is connected to a thoracic intrapleural catheter to allow drainage of fluid and air from the thoracic cavity. The Xpand drain has the following advantages over a UWD:

- Smaller, lighter device ensures greater patient mobility and comfort
- Makes use of a positive sealing one-way valve that, unlike the UWD, functions irrespective of the orientation or positioning of the device relative to the lungs
- The one-way valve maintains a constant opening pressure (< 3 cm H_2O)
- 'Closed system' fluid drainage (reservoir of 200 ml conected to a 2 000 ml drainage bag) prevents exposure of body fluids to nursing staff
- Fast, easy attachment to any size chest catheter without the need to add water

- Large diameter connector and flutter valve allows fluids and blood clots to exit freely
- Simple visual air-leak detection system
- Simple visual intrapleural pressure monitoring system
- No clamping of tubing required
- Direct attachment of low-pressure suction and maintenance of negative pressure even after suction removal
- Cost-effective – negates need for bottle changes and therefore reduces sterilisation costs.

In theory then, the Xpand chest drain (Figs 1 and 2) has numerous advantages over the current standard UWD. The one-way valve used in the Xpand device was evaluated in an animal trial undertaken by Professor André Coetzee, Head of the Department of Anaesthesiology and Critical Care at Stellenbosch University, in 2002 and found to be 100% effective. Samples of the Xpand device have been used under strictly controlled conditions in the departments of Cardiothoracic Surgery, Trauma Surgery and Paediatrics at Tygerberg Hospital with good results. No formal trial had been done on the Xpand device and we therefore embarked on this study to test equivalence and to investigate superiority of the Xpand chest drain over current standard therapy with regard to:

- Ability to effectively drain pneumo-/haemothoraces caused by penetrating trauma
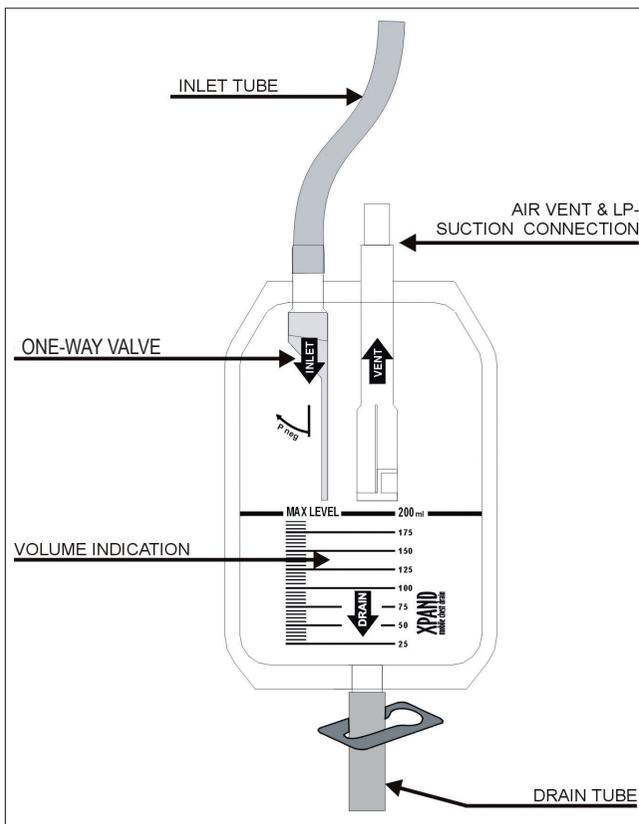- Length of hospital stay.

Fig. 1. Schematic representation of Xpand drain.

Fig. 2. Sinapi Xpand® drain.

Methods

Patients

All patients 18 years or older presenting with a history of penetrating chest trauma and radiological proof of a haemo- or pneumothorax were eligible for the trial.

Exclusion criteria were:
- The haemodynamically unstable patient
- Altered level of consciousness whether due to head injury or intoxication
- Patients with other injuries that would impede mobility or require bed-rest.

Adverse events were defined as the following:
- Mechanical failure of Xpand device
- Inability to drain pneumo-/haemothorax effectively
- Pneumonia
- Empyema
- Clotted haemothorax
- Persistent air leak
- Tension pneumothorax.

The study protocol and consent procedure were approved by the Human Trials Ethics Committee of Stellenbosch University, Tygerberg, South Africa. Written informed consent was obtained from all patients before entry.

Study design

The study was a randomised non-blinded controlled trial conducted at the Trauma Department of Tygerberg Academic Hospital. Patients were randomised into either the Xpand system group or the standard UWD group by means of their folder numbers (last digit even numbers – Xpand device v. last digit odd numbers – standard UWD).

A thoracic catheter was inserted as per standard Advanced Trauma Life support (ATLS) technique and then connected to the appropriate drainage device. Chest radiographs to confirm position were taken after placement of thoracic catheters. All patients were admitted to the trauma short-stay ward. Our ward has no beds, only chairs, so as to ensure maximum mobility during admission. Patients were evaluated on a daily basis. The decision to remove the drain was made when clinical examination pointed to a fully expanded lung or less than 50 ml of fluid had drained in the previous 24 hours. Prior to removal a chest radiograph was taken to document resolution of pneumo-/haemothoraces.

Outcome assessment

Primary outcomes were the assessment of the safety of the Xpand drain and the time from placement to removal of drain compared with current standard therapy. The occurrence of any adverse events, as described previously, was also recorded. Any form of further follow-up was unfortunately impossible because of the poor socio-economic circumstances of our patient population.

Statistical analysis

Data were expressed as mean and standard deviation (SD). The two groups were compared by means of a pooled Student's t-test and one-way ANOVA and results were confirmed by a Mann-Whitney non-parametric rank test and a Bootstrap test.[2]

Results

The number of patients treated with the trial device was 37, but 4 were excluded for the following reasons:
- 1 patient underwent thoracotomy for thoracic duct injury
- 1 patient underwent laparotomy for acute abdomen
- 2 patients underwent laparoscopy to exclude diaphragmatic injuries.

A total of 67 patients satisfied our inclusion criteria and were enrolled in the trial after informed consent was obtained. These patients were randomised to either the Xpand drain group (N = 33) or the standard UWD group (N = 34). Radiological review revealed that in the standard UWD group 13 patients had simple pneumothoraces and 21 mixed haemo-/pneumothoraces while in the Xpand group 14 had simple pneumothoraces and 19 mixed haemo-/pneumothoraces.

Fig. 3 gives a visual comparison of the Bootstrap[2] 95% confidence intervals for total hours.

The Xpand group had a mean (± SD) drainage time of 61.04 (± 29.24) hours while the standard UWD group time was 81.47 (± 61.40) hours. These groups do not differ significantly (p = 0.088). In the Xpand group 4 patients developed a persistent air leak requiring low-pressure suction for a mean of 31 (± 8.24) hours, while in the standard UWD group 5 patients developed a persistent air leak requiring low-pressure suction for a mean of 91.2 (± 57.3) hours.
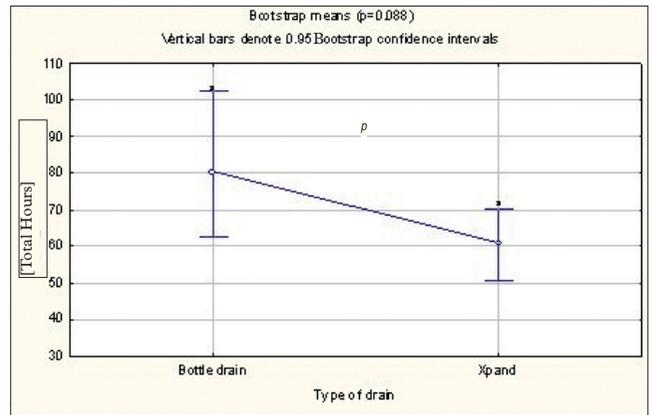

Fig. 3. Bootstrap analysis graph.

Again these groups do not differ significantly (p-values 0.08 (t-test) and p = 0.09 (Mann-Whitney non-parametric).

One patient treated with a standard bottle UWD developed an empyema and was referred to the cardiothoracic surgery department for surgical management.

There were no reported episodes of equipment failure in either group.

Discussion

Penetrating chest trauma is common in the South African population (10% of our total trauma population) and therefore effective and efficient methods of management are required to ensure short hospital stay and minimal complications.

For a truly objective assessment of the effectiveness of both systems we may ideally have needed to do serial chest radiographs to evaluate lung expansion. Unfortunately the inherent lack of manpower and resources in the state health system precluded this. There was one significant confounding variable: the daily clinical evaluation was done by the treating doctors who work on a shift system and was therefore at best a subjective exercise as the primary researcher did not have control over this variable. This probably resulted in some drains being left *in situ* for longer than necessary, but this would have been applicable to both groups. Doing chest radiographs pre-removal ensured that no drain was removed too soon. While waiting for X-rays some patients may have experienced an unnecessary delay in drain removal; again this would apply to both groups. We accept that recent small studies from the groups at Johannesburg[3] and Baragwanath[4] hospitals, however, do not show a need for routine X-rays in all such patients, as do studies from other centres.[5]

Owing to the lack of proper follow-up, we cannot comment on the incidence of long-term complications.

Our results showed a marked improvement in recorded drainage time with the Xpand system over the standard UWD. The factors that might have played a role in achieving this improvement are discussed below.

Heimlich first described the use of a one-way valve to treat pneumothoraces in 1968.[6] Since then various adaptations of the Heimlich valve and new devices based on a one-way valve have been described in the literature and undergone clinical testing. The results of these trials mirror our results as they have mostly also shown equivalence[7,8] or been in favour[9-13] of the one-way valve systems.

Consensus appears to be that the improvement in mobility gained by using a one-way valve system is central to its suc-

cess in achieving faster lung expansion,[14-17] earlier chest drain removal and earlier hospital discharge.

Secondly, the lower and more constant opening pressure of the one-way valve compared with the UWD (where the varying amount of fluid in the tube determines the valve opening pressures) will also enhance air and fluid drainage from the pleural space and further improve lung expansion.[13] Recent advances in ambulatory chest drainage systems (incorporating one-way valves) have led to more patients with pneumothoraces[12,15,18-26] and even pleural effusions[27] being discharged with drains in situ to be further managed as outpatients and thus avoiding prolonged and expensive hospitalisation. This might well be applicable to a carefully selected group of stable patients with isolated traumatic simple pneumothoraces. However, because of the poor socio-economic circumstances of the majority of our patients we cannot see this as a viable strategy for us in the short term, but it is definitely a topic for future research. The incidence of empyema following chest tube placement is very low (1 - 4%).[28-33] Studies have shown low evidence of ascending infection via the chest tube[28,29,31] and that lack of early pleural drainage or prompt pleural apposition (the so-called retained haemothorax) increases the risk of empyema.[28,29,34-39] It follows then that any device (such as the Xpand) that improves pleural drainage and pleural apposition will also lead to a decrease in the risk of empyema.

Despite these benefits, there has been a reluctance to embrace this 'new' technology, especially in South Africa. The reason for this is unclear, but might be that the purpose-built drainage systems are generally more expensive than a standard UWD.

However, when one takes into consideration the shorter hospital stay, the reduction in sterilisation costs and the reduced workload of nursing staff, these devices are in the long term probably a more cost-effective option. We hope that the results of our trial will help to promote the use of this exciting 'new' technology as an alternative to underwater drainage in the treatment of the sequelae of penetrating chest trauma.

Conclusion

Our results showed a marked improvement in average drainage time using the Xpand system. Unfortunately, this difference did not reach statistical significance. We can, however, confidently state that the Xpand system is as safe and effective as current standard underwater drainage and can recommend its use in the treatment of the sequelae of penetrating chest trauma.

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