# Randomized clinical trial of pigtail catheter versus chest tube in injured patients with uncomplicated traumatic pneumothorax

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**Background:** Small pigtail catheters appear to work as well as the traditional large-bore chest tubes in patients with traumatic pneumothorax, but it is not known whether the smaller pigtail catheters are associated with less tube-site pain. This study was conducted to compare tube-site pain following pigtail catheter or chest tube insertion in patients with uncomplicated traumatic pneumothorax.

**Methods:** This prospective randomized trial compared 14-Fr pigtail catheters and 28-Fr chest tubes in patients with traumatic pneumothorax presenting to a level I trauma centre from July 2010 to February 2012. Patients who required emergency tube placement, those who refused and those who could not respond to pain assessment were excluded. Primary outcomes were tube-site pain, as assessed by a numerical rating scale, and total pain medication use. Secondary outcomes included the success rate of pneumothorax resolution and insertion-related complications.

**Results:** Forty patients were enrolled. Baseline characteristics of 20 patients in the pigtail catheter group were similar to those of 20 patients in the chest tube group. No patient had a flail chest or haemothorax. Pain scores related to chest wall trauma were similar in the two groups. Patients with a pigtail catheter had significantly lower mean(s.d.) tube-site pain scores than those with a chest tube, at baseline after tube insertion ( $3 \cdot 2(0.6)$ ) *versus*  $7 \cdot 7(0.6)$ ; P < 0.001), on day 1 ( $1 \cdot 9(0.5)$ ) *versus*  $6 \cdot 2(0.7)$ ; P < 0.001) and day 2 ( $2 \cdot 1(1.1)$ ) *versus*  $5 \cdot 5(1 \cdot 0)$ ; P = 0.040). The decreased use of pain medication associated with pigtail catheter was not significantly different. The duration of tube insertion, success rate and insertion-related complications were all similar in the two groups.

**Conclusion:** For patients with a simple, uncomplicated traumatic pneumothorax, use of a 14-Fr pigtail catheter is associated with reduced pain at the site of insertion, with no other clinically important differences noted compared with chest tubes. Registration number: NCT01537289 (http://clinicaltrials.gov).

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#### Introduction

Chest injuries are common following blunt and penetrating trauma. Fewer than 10 per cent of blunt injuries and 15-30 per cent of penetrating injuries require surgical management<sup>1</sup>. Most can be managed with tube thoracostomy to expand the lung (pneumothorax) or to drain blood (haemothorax)<sup>2</sup>. Although tube thoracostomy is fairly effective, it can be associated with complications such as malpositioning, malfunction, or injury by insertion through the diaphragm or liver<sup>3-5</sup>. The standard tube size

has usually been 32-40 Fr. Insertion of such a large-calibre tube requires a cut-down technique, can be traumatic, and is often associated with significant pain and discomfort.

Pigtail catheters, originally used by cardiologists to drain chronic pericardial effusion<sup>6</sup>, were later modified and adapted for pleural drainage<sup>7</sup>. Because of their small size and reduced trauma during placement, patients may experience significantly decreased pain and discomfort. Pigtail catheters are frequently used in the paediatric population<sup>8–10</sup>, as well as in adult, non-traumatic situations<sup>11–17</sup>. Only a few studies have considered pigtail

catheter placement in injured adult patients<sup>18,19</sup>, with placement usually performed by interventional radiologists rather than by trauma surgeons at the bedside.

Pigtail catheters inserted at the bedside have similar efficacy to traditional chest tubes<sup>20,21</sup>. However, the effect of tube size on insertion-related or tube-site pain is not known. One study<sup>22</sup> of chest drains inserted for pleural infection concluded that a smaller tube (14 Fr or less), compared with a larger tube (15 Fr or above), was associated with less tube-site pain, both during insertion and while in place. Although reduced tube-site pain is commonsense clinical knowledge, few studies have attempted to quantify chest tube-related pain or evaluate methods to reduce the pain<sup>23,24</sup>. To explore further the benefits of the smaller pigtail catheters, a study was undertaken to test the hypothesis that pigtail catheters would be associated with less tube-site pain than chest tubes.

## **Methods**

This study was registered with ClinicalTrials.gov (identifier: NCT01537289). It was also approved by the institutional review board of the University of Arizona. All patients, or their next of kin, provided informed consent before inclusion in the trial.

### Patient inclusion and exclusion

Patients eligible for the study were injured patients evaluated at the University of Arizona, a level I trauma centre, between July 2010 and February 2012. The catchment area of the Arizona trauma centre is more than 1 million population, and annual trauma volume averages 5000 patients, of whom 10–15 per cent have chest wall trauma. Eligibility criteria included: age at least 18 years, traumatic pneumothorax requiring chest tube insertion (but not as an emergency), and patient conscious and able to report pain. Patients were excluded if they refused to participate, could not respond to the pain assessment, were prisoners, were found also to have haemothorax after tube insertion.

The criteria for tube insertion were not standardized. In general, for penetrating trauma a tube was inserted for pneumothoraces with a volume greater than 10 per cent (of estimated thoracic volume on imaging). For blunt trauma, a tube was preferred for pneumothorax volume of less than 10 per cent that showed a progression on a followup anterior-posterior chest X-ray. Occult pneumothorax, for example a pneumothorax detected only on computed tomography (CT) and not on chest X-ray, was approached in the same way. Tubes were not inserted prophylactically because patients were on (or would be placed on) temporary positive airway pressure ventilation. The final decision to enrol the patient into the study, as well as the timing of tube insertion, was left to the managing clinician.

## Randomization

Patients were randomized to one of the two treatment groups using a sealed envelope method. The envelopes were prepared by inserting 20 labels of pigtail catheters or chest tubes, and shuffled at random. The patient was randomized to the assigned envelope, either a 14-Fr pigtail catheter (Cook Critical Care, Bloomington, Indiana, USA) or a 28-Fr chest tube.

# Data collection

Baseline characteristics included: age, sex, mechanism of injury (blunt *versus* penetrating), number of rib fractures based on chest X-ray findings, presence of flail segments, presence of pulmonary contusion, the Injury Severity Score (ISS) and the chest Abbreviated Injury Scale (c-AIS) score. Primary outcome measures were: pain at the tube site and the daily intravenous pain medication usage. Secondary outcomes included: success rate (defined as no requirement for a second tube insertion) and tube insertion-related complications. Tube duration and hospital length of stay were also recorded.

# Placement of chest drains

Both pigtail catheters and chest tubes were inserted at the bedside by the attending trauma surgeon or by a surgical resident under the supervision of the in-house attending trauma surgeon. One per cent lidocaine was given for local anaesthesia, along with an intravenous morphine injection



Fig. 1 Pigtail catheter inserted laterally

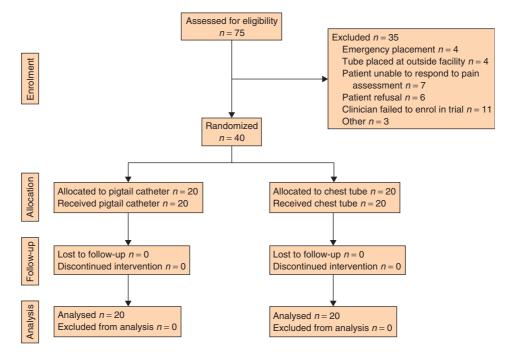


Fig. 2 CONSORT diagram for the trial

Table 1 Demographic data

	Pigtail catheter (n = 20)	Chest tube $(n=20)$	P‡
Age (years)*	46(4)	46(4)	0.992§
Sex ratio (M : F)	17:3	16:4	0.683
No. with blunt trauma	17 (85)	16 (80)	0.683
ISS*	14.5(1.1)	12.2(1.2)	0·163§
Chest AIS†	3 (2-4)	3 (1-4)	0.285¶
No. of rib fractures†	1.5 (0-5)	1.5 (0-5)	0.912¶
Pulmonary contusion	5 (25)	5 (25)	1.000
Flail segment	0 (0)	0 (0)	-

Values in parentheses are percentages unless indicated otherwise; values are \*mean(s.d.) and †median (i.q.r.). ISS, Injury Severity Score; AIS, Abbreviated Injury Scale.  $\ddagger \chi^2$  test, except §Student's *t* test and ¶Wilcoxon rank sum test.

for systemic analgesia, although the amount and quantity were not protocolized. The pigtail catheter was inserted using the modified Seldinger technique at the second or third intercostal space anteriorly, or in the fourth or fifth intercostal space laterally, according to the attending surgeon's preference. Traditionally, when a pigtail catheter is placed for pneumothorax, surgeons have preferred the anterior approach because the air rises to the top. However, as pigtail catheters are being used more like chest tubes, and with the assumption that the lateral approach may involve a shorter distance through the chest wall, many surgeons have started placing pigtail catheters laterally (*Fig. 1*). Chest tubes were inserted by the traditional cut-down method in

#### Table 2 Comparison of outcomes between groups

	Pigtail catheter (n = 20)	Chest tube $(n=20)$	P¶
NRS score for chest wall pain* Day 0 Day 1 Day 2‡ Total pain medication usage (units)*§	6·1(0·6) 5·5(0·5) 4·2(1·1)	6·0(0·8) 5·9(0·7) 5·9(1·0)	0·917 0·652 0·274
Day 1 Day 2 Success rate Insertion-related complication Duration of tube insertion (days)† Duration of hospital stay (days)†	10·3(2·4) 5·0(2·6) 19 (95) 2 (10) 2 (2-3) 4 (3-7)	15.4(3.4) 8.6(2.5) 18 (90) 2 (10) 2 (2-6) 4 (3-7)	0.227 0.323 0.554# 1.000# 0.172** 0.863**

Values in parentheses are percentages unless indicated otherwise; values are \*mean(s.d.) and †median (i.q.r.). ‡Nine *versus* 14 patients for pigtail catheter and chest tube respectively. §1 unit = 1 mg morphine or 25 µg fentanyl or 0·1 mg hydromorphone hydrochloride per 24 h. NRS, numerical rating scale. ¶Student's *t* test, except  $\#\chi^2$  test and \*\*Wilcoxon rank sum test.

the fourth or fifth intercostal space laterally. Chest X-ray was performed after each procedure to evaluate the tube position and confirm the resolution of pneumothorax.

To maintain consistency in initial tube management, the study protocol required the tube to be left on suction for at least 24 h. After that, tube management was left to the attending trauma surgeon's discretion. In general, chest X-ray after 24 h showed resolution of pneumothorax. The tube was placed on water-seal; chest X-ray was repeated within 4-6 h and, if there was no recurrent pneumothorax, the tube was removed and the final chest X-ray performed within 4-6 h.

## Pain measurements

Before tube insertion, the investigator who was not involved with the insertion obtained the baseline (day 0) chest wall pain score, using a numerical rating scale (NRS)<sup>25</sup>. Validity of the NRS, in which patients are asked to rate their level of pain subjectively on a scale ranging from 1 (least pain) to 10 (worst pain), is as good as that of the more commonly used visual analogue scale (VAS) scoring system<sup>26,27</sup>. After tube insertion, the investigator waited for 1-2h for the local anaesthetic effect to subside, and then obtained the baseline (day 0) tube-site pain score, again using the NRS. Scores for both general chest wall and tube-site pain were obtained on days 1 and 2 (by the patient's nurse, who was blinded to the trial), and the total amount of intravenous pain medication used per 24 h was recorded. Pain score measurement was stopped after 2 days because most tubes had been removed by this time.

## Use of pain medication

Pain medication usage (units per 24 h) was calculated using the following formula: 1 unit = 1 mg morphine or 25  $\mu$ g fentanyl or 0.1 mg hydromorphone hydrochloride. Most patients received intravenous pain medication in the form of intermittent bolus or continuous administration. No patient received an epidural analgesia for pain. Oral pain medication was allowed, but was not included in the pain medication usage because patients usually did not make the transition from intravenous to oral pain medication until later in the hospital course.

#### Primary and secondary outcomes

Primary outcomes were: tube-site pain after tube insertion (days 0, 1 and 2) and total intravenous pain medication usage. Secondary outcomes were: success rate of pneumothorax resolution and tube insertion-related complications.

## Statistical analysis

To evaluate and analyse pain, the assumption was made that chest tubes are associated with a score of 10 (100 per cent) on a pain scale of 0-10 and that pigtail catheters, to be clinically relevant, should reduce the pain score by 50

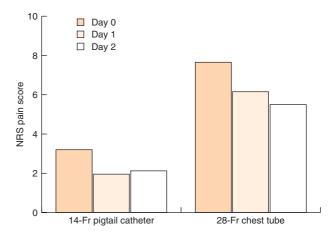
per cent<sup>28</sup>. With two-sided  $\alpha = 0.05$  and 90 per cent power, and a possible 10 per cent drop-out rate, it was calculated that the required sample size was 40.

Continuous data are expressed as mean(s.d.) or median (i.q.r.). Categorical data are expressed as proportions. For between-group comparisons, Student's *t* test was used for continuous normally distributed data, the Wilcoxon rank sum test for non-normally distributed data, and  $\chi^2$  test for proportional data. For statistical analysis, STATA<sup>®</sup> version 12 (StataCorp LP, College Station, Texas, USA) was employed. Two-sided  $P \le 0.050$  was considered statistically significant.

## **Results**

Of 75 patients who were screened, 40 were enrolled, 20 patients in each group (*Fig. 2*). There were no significant differences in baseline characteristics between the two groups (*Table 1*). In the pigtail catheter group, nine catheters were placed anteriorly and 11 laterally.

Baseline chest wall pain was similar in the two groups (*Table 2*), but mean(s.d.) tube-site pain was significantly lower following pigtail catheter insertion at baseline (day 0:  $3 \cdot 2(0 \cdot 6)$  versus  $7 \cdot 7(0 \cdot 6)$  for chest tube;  $P < 0 \cdot 001$ ), and on day 1 ( $1 \cdot 9(0 \cdot 5)$  versus  $6 \cdot 2(0 \cdot 7)$ ;  $P < 0 \cdot 001$ ) and day 2 ( $2 \cdot 1(1 \cdot 1)$  versus  $5 \cdot 5(1 \cdot 0)$ ;  $P = 0 \cdot 040$ ) (*Fig. 3*). Daily 24-h pain medication usage for the first 2 days was lower for patients in the pigtail catheter group, but the difference was not statistically different (*Table 2*). Success rates were similar in the two groups. Insertion-related complications were minor and similar in the two groups, and included



**Fig. 3** Mean numerical rating scale (NRS) tube-site pain score, by day after insertion, in patients with traumatic pneumothorax treated with a 14-Fr pigtail catheter or 28-Fr chest tube. P < 0.001 on days 0 and 1, P = 0.040 on day 2 (Student's *t* test)

extrapleural tube placement (1 in each group) and tube dislodgement (1 in each group).

#### Discussion

This study found that 14-Fr pigtail catheters were associated with a greater than 50 per cent reduction in tube-site pain compared with 28-Fr chest tubes, both after insertion and for the following 2 days. Total 24-h pain medication usage was also lower for patients in the pigtail catheter group, although the difference was not statistically significant.

Previously, only one study<sup>29</sup> on the effect of tube size on pain intensity has been conducted, with no difference in tube-site pain demonstrated. However, that study compared 28–32-Fr with 36–40-Fr chest tubes, thus essentially still comparing a large-bore chest tube, with a large-bore chest tube, using a cut-down insertion technique (*versus* a percutaneous insertion). That study also measured pain intensity at one point in time (1 h after insertion) using a VAS pain score; the present study continued to assess pain intensity until the tube had been removed.

Another patient series<sup>22</sup> studied the effect of tube size on pain intensity, but did not include injured patients. In that study, tubes were inserted for pleural infection, and smaller tubes (14 Fr or less) were associated with less tubesite pain, both at insertion and while in place, compared with tubes greater than 14 Fr in size. However, the authors did not specify at what point in time the pain measurement was obtained and used a verbal rating scale (VRS) to assess pain. The VRS is considered less reliable and less sensitive because it is based on four pain categories: none, mild, moderate and severe<sup>25</sup>. In contrast, the NRS pain score is a numerical scale, similar to the standard VAS score. However, NRS is less cumbersome and easier for nursing staff to use<sup>26,27</sup>.

Several reasons may be proposed to explain why pigtail catheters are associated with less tube-site pain. First, there may be increased tissue trauma as a result of chest tube insertion<sup>22–24</sup>. This may explain why one study<sup>29</sup> reported no difference in the pain intensity between two differently sized chest tubes (28–32 *versus* 36–40 Fr), as the same cutdown technique was used for both groups. Second, the straight, inflexible, stiff-tipped design of chest tubes may cause pleural irritation, although in the present authors' experience this is generally observed only with patient movement. Hence, in one study<sup>24</sup>, the pain rating was assessed by asking patients to move their arms. Pain during movement was not assessed in the present study, as all patients experienced chest wall trauma pain.

Despite having similar success rates and insertionrelated complications, the present study was not powered to compare the efficacy (success/failure rate) of the pigtail catheter and the chest tube. In two previously published larger series, the authors demonstrated similar success rates for both traumatic pneumothorax<sup>20</sup> and haemothorax<sup>21</sup>. Unlike the situation with haemothorax, most members of the trauma faculty in the authors' institution are now comfortable using pigtail catheters as the first-line management for simple, uncomplicated pneumothorax.

Complications, such as infection, were not applicable in the present study because the duration of tube insertion was short. A recent multi-institutional study of risk factors for the development of retained haemothorax and empyema suggested that pneumothorax, as an indication for tube insertion, was not a risk factor for infectious complications<sup>30,31</sup>. The role of antibiotic prophylaxis remained inconclusive, despite a recent meta-analysis<sup>32</sup> suggesting a benefit.

A strength of the present study is its prospective and randomized design. The pain rating assessment was captured by personnel who were unaware of the treatment allocation and not directly involved in the study. A limitation of the study is the use of the pain score as an endpoint measurement, and its repeatability. Pain score measurements are necessarily subjective, and are influenced by the situation and environment, as well as the patient's expectations, attitude and personality<sup>25</sup>. Although total intravenous pain medication usage was employed as a parallel primary endpoint, this does not necessarily provide an absolute measure of the difference between use of pigtail catheters and chest tubes. Intravenous pain medication usage may be affected by multiple factors other than local chest wall pain, including psychological components and other bodily injuries. However, the two groups had similar c-AIS and ISS scores. Oral pain medication usage was not reported because most patients requested analgesia via the intravenous route, especially during the first 24-48 h, and because of the difficulty in converting and comparing the dosage of different oral agents.

## **Disclosure**

The authors declare no conflict of interest.

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