A randomised controlled trial of intrapleural balloon intercostal chest drains to prevent drain displacement

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SVK, NMR and RMM conceived and designed the study. RMM prepared the ethics protocol. RMM, EM, RB, JPC, CD, RP, TS, MC, SJ, DM, SA, MS, NAM, MG, GC, CO, JL, MN, DDF, KP, NAM, SG, GR, LB, MM, RJH, NMR and SVK were involved in recruitment and data collection. RMM, RJH, SG and NMR analysed the data and performed statistical analyses. SVK, RFM, KGB, PLS, NMR provided materials and expert knowledge. SVK, RFM and NMR supervised the study. RMM and NMR wrote the first draft of the manuscript. All authors revised and approved the final version of the manuscript. RMM, NMR and SVK are guarantors of the manuscript.

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ABSTRACT

Background

Chest drain displacement is a common clinical problem, occurring in 9-42% of cases and results in treatment failure or additional pleural procedures conferring unnecessary risk. A novel chest drain with an integrated intrapleural balloon may reduce the risk of displacement.

Methods

Prospective randomised controlled trial comparing the balloon drain to standard care (12F chest drain with no balloon) with the primary outcome of objectively-defined unintentional or accidental chest drain displacement.

Results

267 patients were randomised (primary outcome data available in 257, 96.2%). Displacement occurred less frequently using the balloon drain (displacement 5/128, 3.9%; standard care displacement 13/129, 10.1%) but this was not statistically significant (Odds Ratio (OR) for drain displacement 0.36, 95% CI 0.13 to 1.0, χ^2 1df=2.87, p=0.09). Adjusted analysis to account for minimisation factors and use of drain sutures demonstrated balloon drains were independently associated with reduced drain fall out rate (adjusted OR 0.27, 95% CI 0.08 to 0.87, p=0.028). Adverse events were higher in the balloon arm than the standard care arm (balloon drain 59/131, 45.0%; standard care 18/132, 13.6%; χ^2 1df=31.3, p<0.0001).

Conclusion

Balloon drains reduce displacement compared with standard drains independent of the use of sutures but are associated with increased adverse events specifically during drain removal. The potential benefits of the novel drain should be weighed against the risks, but may be considered in practices where sutures are not routinely used.

Words: 243

INTRODUCTION

Chest drain insertion is one of the most commonly performed medical procedures, with an estimated 15,000 per year conducted in the UK (1). Chest drain displacement remains a major issue, and can result in treatment failure (2) or the need for replacement (3). The frequency of chest drain displacement is between 9 and 42% (2, 4) but these figures do not always account for drains that displace to the extent that they are unusable, but remain within the chest cavity. The TIME1 trial (2), assessing pleurodesis in malignant pleural effusion, demonstrated 8% of patients did not receive talc due to drain displacement, which resulted in unnecessary hospital admissions and invasive procedures (5). In pneumothorax treatment, displacement of drains may result in subcutaneous emphysema, tension pneumothorax and treatment failure (6).

External measures, such as suturing and bespoke dressings, have been used but do not completely prevent drain displacement. A single centre retrospective study (7) demonstrated reduction in displacement with sutures (14.8% non-sutured displacement, 6.6% sutured, p=0.04). A non-comparative study assessing external fixation devices which secure the drain to the skin using adhesive (8) reported displacement rates below that in the published literature (2, 4). Locking pigtail catheters have been used, but may be associated with intercostal vessel laceration (9). There is thus a clear need for a safe, robust and proven method of chest drain fixation.

Internal fixation within the pleural space is a potential solution. Urinary Foley catheters have been used in the pleural space (10), with the balloon inflated within the thoracic cavity. Although the technique was reported to be effective, the study was retrospective and non-comparative, the only complication data reported was empyema, and no validated measures of pain or other outcome were used (10).

On the above basis, a bespoke chest drain was designed with an integrated intrapleural balloon to be inflated once the drain was in the pleural cavity. A small non-comparative pilot study demonstrated no drain displacement in 19/20 cases (11).

This study was a prospective randomised controlled trial using the dedicated balloon intercostal drain (Figure 1) to assess whether it was effective at preventing drain displacement and safe compared with routinely used chest drains.

METHODS

Trial design

The BASIC trial (multicenter open label, randomised, controlled trial of use of a dedicated balloon intercostal chest drain) compared standard 12F intercostal drains and the 12F balloon drain, with the primary outcome of drain displacement. The study was funded by the Royal Brompton and Harefield Hospitals Charity. Trial design, implementation, analysis, and manuscript preparation were performed by the trial investigators, and independent of all funders. Further details in the online supplement.

Participants

Participants were recruited from 19 hospitals in the United Kingdom and randomized to receive either a balloon intercostal drain or a conventional drain. Inclusion criteria were 1) Any clinical indication for a small-bore chest drain, 2) Aged 18 years or over, 3) Able to provide informed consent. Exclusion criteria were 1) Any clinical indication for a large bore (>14F) chest drain or frank haemothorax, 2) Pleural effusion or pneumothorax on radiological assessment (CXR, CT or ultrasound) considered to be too small to place an intercostal drain, 3) Indication for chest drain drainage where the drain was expected to be required for less than 24 hours and 4) Contraindication to chest drain insertion or where enrolment to the trial would delay clinical care in an emergent situation.

Enrolment and randomisation

Participants were randomly assigned in a 1:1 ratio to either balloon drain or standard care, conducted through a centralised, web-based system using a computer-generated minimization algorithm. Minimization factors were 1) Recruiting centre and 2) Indication for chest drain insertion (suspected or confirmed malignancy, pleural infection, pneumothorax, or other indication).

Interventions

Balloon Drain

The balloon drain insertion pack included a 16F dilator, in addition to the standard 14F dilator, which was used to widen the tract. The balloon drain was inserted to a depth to ensure the balloon was within the pleural space before inflation (at least 10cm plus skin to pleura depth).

The balloon drain was inflated using 5mls sterile water through an external port after insertion which was aspirated prior to removal. The drain could be sutured in place at the discretion of the operator, and a bespoke dressing was provided as per a trial specific procedure. In the instance of failed insertion of the balloon drain, a standard chest drain was inserted.

Prior to drain removal, the 5mls sterile water was aspirated from the balloon and the volume of fluid obtained from the balloon documented. Post removal, the balloon was re-inflated outside the chest cavity to assess balloon integrity.

Standard care

Standard (12F) drains were inserted to at least 12cm to match the depth of insertion of balloon drains. All standard drains were secured with one suture and a bespoke drain dressing. Once the drain was inserted, ongoing management of the drain was identical to that in the balloon arm (see trial specific instructions, supplementary file).

Outcomes

The primary outcome was the proportion of chest drains which were unintentionally or accidentally displaced. This was defined pre-hoc as <u>any</u> of the following:

- Drain fell out of the pleural cavity completely
- Drain displaced such that side holes were no longer in the pleural cavity
- Drain confirmed to be displaced from the pleura cavity by any radiological investigation (chest x-ray, ultrasound or CT)
- Drain displaced to any degree such that the displacement stopped adequate function
- Drain withdrawn by an amount deemed to be significant by the local PI.

Patients who died with the drain in situ were assumed to have non-displaced drains.

Secondary outcomes were

- Time to drain displacement
- Clinical consequences of displacement
- Visual Analogue Score (VAS) 100mm for chest pain
- Analgesia requirements

- Requirements for radiological investigations to assess drain placement or function
- Length of hospital stay
- Need for further ipsilateral pleural procedures
- Adverse events (including death and readmissions)
- A per protocol analysis of drain displacement.

Study assessments

All baseline data, drain insertion information, daily analgesia requirement, radiological investigations, adverse events and displacement outcome were recorded on an electronic database. A daily record of pain (100mm VAS score) was undertaken at baseline and for the first 5 days and after chest drain removal.

Follow up

Patients were followed up for 30 days after completion of treatment (drain removal) to assess for complications, additional interventions, readmissions or death.

Sample size

The sample size calculation assumed a rate of displacement of 20% (2, 4) in the standard care arm and 5% in the balloon arm (11). Using these assumptions, with a significance level of 5% and power of 90%, and an expected patient withdrawal rate of 2%, a total of 136 patients were required.

A planned interim assessment of displacement rate in the standard care arm was conducted after 50 patients were randomised to check sample size calculation assumptions for the standard care arm alone (i.e. no comparison was made with the intervention arm). This showed a lower than expected displacement rate in the standard care arm (12%), and on this basis, the sample size was increased to 267.

Analysis

A statistical analysis plan (SAP) was approved and signed off by the trial steering committee prior to data lock and analysis (see online supplement).

Analyses were conducted on an intention to treat (ITT) basis. The drain displacement proportion (primary outcome) was compared using the χ^2 test and used a continuity correction. A pre-planned sensitivity analysis used a logistic regression model which adjusted for the minimisation factors and any baseline imbalances as per the SAP.

For secondary outcomes, χ^2 analysis was used for all categorical outcomes and the Mann-Whitney U test was used for continuous and ordinal outcomes. The time study drains were in situ and time to drain displacement were counted in thirds of days and analysed using Cox proportional hazards regression. A predetermined level of significance was set at 5%.

Pre-specified subgroup analysis was conducted on the minimisation categories (indication for chest drain: malignant pleural effusion, pleural infection, pneumothorax, or other). A per protocol analysis of the primary outcome was conducted as a planned secondary analysis, including only cases where the intended drain was inserted and where the balloon was fully inflated. Adjusted analyses were conducted using pre-specified parameters including the minimisation variables.

Results

Recruitment and data completion

After assessing a total of 490 potentially eligible patients, the target of 267 (100%) patients was recruited. The study recruited between 07 March 2018 and 13 November 2019 (Figure 1). Of the 267 patients randomised, 4 (1.5%) were ineligible due to lack of clinical need for chest drain insertion and were withdrawn from the study. Therefore, 263 patients were randomised: 131 were assigned to balloon drain and 132 to standard care. Two patients withdrew consent during the study (one in each arm) but allowed data collected to be used.

Baseline demographics

Of the 263 patients, median age was 71 years; 146 were male (55.5%). The majority had known or suspected malignant pleural effusion (144, 54.8%), and baseline characteristics were well balanced (Table 1).

Chest drains were inserted in a dedicated procedure room (229/262: 87.4%), or respiratory ward (33/262: 12.6%), and the majority used ultrasound guidance (90.4%) (Online Supplement Table 1). In total, 89% of balloon drains and 100% of standard drains were sutured (Online Supplement Table 1). Insertion of the intended drain was successful in 119/131 (90.8%) in the balloon arm and 129/132 (97.7%) in the standard care arm (χ^2 1df=5.8, p=0.03). In total, 10 patients in the balloon arm received a standard chest drain.

Primary outcome

Displacement information was available in 257/263 (97.7%) patients. Primary outcome data was not available in 6/263 patients due to: withdrawal from the study (n=2) and failure to insert any drain (n=4).

Unadjusted ITT analysis of the primary outcome demonstrated a lower frequency of displacement in the balloon drain arm (balloon drain displacement 5/128, 3.9%; standard care displacement 13/129, 10.1%) which was not statistically significant (Odds Ratio (OR) for drain displacement 0.36, 95% CI 0.13 to 1.0, χ^2 1df=2.87, p=0.09). The use of sutures was the only baseline imbalance and the only additional factor which needed to be accounted for as per the SAP. Adjusted ITT analysis to account for minimisation factors and use of drain sutures demonstrated that balloon catheters were

independently associated with reduced drain displacement (adjusted OR 0.27, 95% CI 0.08 to 0.87, p=0.028).

Time to drain displacement was shorter in the standard care arm than in the balloon drain arm (Online Supplement Figure 2) but this was not statistically significant (Log Rank test (Mantel-Cox), χ^2 1df=3.50, p=0.062).

Of patients meeting the primary outcome (drain displacement), a larger proportion were displaced (13/18, 72.2%) than fell out of the chest cavity (5/18, 27.8%). There were no clinical consequences of displacement in 10 patients (one balloon arm, nine standard care), four patients failed to complete treatment (one balloon arm, three standard care) and three required further procedures (all balloon arm) due to displacement (Table 2).

Secondary outcomes

Adjusted per protocol analysis (including only those who had the allocated drain successfully inserted and, in the balloon arm, the balloon inflated) demonstrated balloon catheters were independently associated with a reduced drain displacement rate (adjusted OR 0.21, 95% CI 0.05 to 0.81, p=0.023).

The use of sutures was associated with a lower rate of drain displacement in both the intention to treat (adjusted OR 0.12, 95% CI 0.02, 0.59, p=0.008) and per protocol analyses (OR 0.09, 95% CI 0.02, 0.50, p=0.006). There were no significant differences between treatment arms in total length of hospital stay, number of radiological investigations, subsequent pleural procedures, re-admissions or mortality (Table 3 and 4).

Adverse Events and Pain

The adverse event (AE) rate was higher in the balloon arm than the standard care arm (balloon drain 59/131, 45.0%; standard care 18/132, 13.6%; χ^2 1df=31.3, p<0.0001). There was one unexpected drain-related serious adverse event (SAE) in the balloon arm (pulmonary oedema requiring intensive care unit admission). Other SAEs were expected and related to underlying medical conditions, including readmission or death, and there was no significant difference between treatment arms (Table 4). The majority of AEs were related to difficulties in drain removal, and none met the criteria for seriousness. Excluding drain removal difficulties, there was no significant difference in patients experiencing AEs between the arms (balloon 16/131, 12.2%; standard care 16/132, 12.1%; χ^2 1df=0.0, p=0.98).

At the time of removal, pain was recorded by the investigators in 21/131 (16%) of patients in the balloon arm and 1/132 (0.8%) in the standard care arm (Fisher exact p<0.001). In pain VAS scores recorded by the patients, there was no difference between treatment groups in pain or analgesia use at any time point(Figure 3, Tables 5 and 6).

Balloon fixation and integrity

In the 91 patients where there was a record of balloon integrity, 9 (9.9%) were concluded to have had a faulty valve.

Five balloon drains were displaced. Of these, 3 were not sutured: in 1 the balloon had not remained inflated, and balloon integrity data was unavailable in the other 2 cases. The remaining 2 cases were sutured; in one the balloon had not remained inflated and in the other, there was no documentation of the volume of fluid removed at deflation.

DISCUSSION

This prospective multicentre, open-label, randomised controlled trial compared balloon drains to standard drains using clinically relevant outcomes. It is the first prospective trial to use a pre-hoc and objective definition for drain displacement, including any relevant outcome which adversely affected patient care, and is thus clinically applicable.

The unadjusted (ITT) analysis demonstrated a lower rate of displacement in the balloon arm (3.9%) compared with standard care (10.1%) (OR for drain displacement 0.36, 95% CI 0.13 to 1.0). The pre-hoc and statistically robust adjusted (ITT) analysis demonstrated a significant and independent reduction in drain fall out rate using the balloon catheter (adjusted OR 0.27, 95% CI 0.08 to 0.87, p=0.028) and sutures (adjusted OR 0.12, 95% CI 0.02, 0.59, p=0.008). Although per protocol analysis is likely to be biased in favour of the intervention in a superiority trial, the per protocol analyses results were in the same direction as the ITT analyses. Taken together, these data suggest that use of the balloon catheter and use of sutures significantly and independently reduce displacement rates.

Sample size assumptions used in this trial were based on interim review of the displacement rate in the standard care arm after 50 patients were recruited suggesting a 12% displacement rate, whereas the final study results demonstrated a lower displacement rate. The lower displacement rate in the standard care arm, which we assume is related to the use of an objective and prospectively defined outcome, suggests that the reason the unadjusted analysis did not show formal statistical significance at the conventional threshold ($p<0.05$) is likely due to the study being underpowered to detect this difference. However, it should be noted that the displacement rate in the standard care arm remains clinically important, with 1 in 10 patients experiencing displacement.

The demonstrated effect size in reducing drain fall out rate (6.2% absolute difference, 63% relative difference, OR 0.36) is large, and clinically significant. If the detected difference is real, the balloon drain reduces drain fall out events by 2.8 fold. The Kaplan-Meier analysis suggests that the reduction in drain fall out rate occurs from day three onwards, and that drain displacement is a more important clinical entity in patients who are likely to need drains for a longer (>48 hour) period, noting that patients likely to require a chest drain for less than 24 hours were excluded from this study.

To remain pragmatic, the trial protocol allowed clinicians to choose whether to use sutures with balloon drains, but mandated their use with “standard care” drains. Clinicians were 100% compliant with the use of sutures in standard drains, whereas 89% chose to use sutures with the balloon drain. The purpose of this trial was to assess whether the balloon drain was associated with less frequent clinically important displacement, rather than as a replacement for a suture which is commonly used

by interventional pulmonologists for small bore (<14F) chest drains. However, many practitioners may not regularly use sutures for chest drains. Given that the results demonstrate a reduction in drain fall out rate independently with both balloon drain and suture use, it is likely that if the study was repeated without suture use in either arm, balloon drain use would be associated with a greater reduction in displacement rate, as it may be assumed fall out rate would be increased in the standard care arm.

A number of balloon drains (9/91, 9.9%) used early in the study had a fault with the valve which led to the balloon deflating while still in situ. Of the five balloon drains which displaced, in all cases either the balloon integrity had been compromised or there was missing data regarding volume of fluid removed on deflation. No balloon drain displacement occurred in cases where the drain had been functioning optimally.

Although the balloon drain was associated with significant displacement reduction, insertion and removal were more difficult than with standard drains, and this is likely due to the presence of a ridge on the drain surface where the non-inflated balloon is fixed. Despite difficulties with drain removal and pain being reported by investigators who were not blind to treatment allocation, there were no differences in patient reported VAS pain scores at the time of drain removal. However, there was a significantly higher rate of AEs in the balloon arm, the majority of which were associated with drain removal. Although there were no severe or serious events related to drain removal in this study, the possibility of complications in a larger population should be considered.

Given these study results, should a balloon drain now be used preferentially in the pleural space to prevent drain displacement? Our results demonstrate that use of an intrapleural balloon is effective in preventing drain displacement, independent of the use of sutures. The overall drain displacement rate using standard drains is around 10% when sutures are used, and therefore the benefits of balloon drains should be balanced with the minor risks of removal. In clinical situations where sutures are not used, or where displacement of the drain would have a profound effect on management (e.g. intended talc pleurodesis or chest drains in the intensive care unit), the balloon drain may have advantages and should be considered.

Conclusion

Chest drains with an integrated inflatable intrapleural balloon reduce displacement compared with standard drains, independent of suture use, but are associated with increased frequency of insertion and removal difficulties and increased non-serious adverse events. Such drains may have a role in

practices where sutures are not routinely used, or where drain displacement would be associated with significant clinical risks, but our data do not support their use in routine clinical practice.

References

1. Hooper C, Maskell N. British Thoracic Society national pleural procedures audit 2010. Thorax. 2011;66(7):636.
2. Rahman NM, Pepperell J, Rehal S, Saba T, Tang A, Ali N, et al. Effect of Opioids vs NSAIDs and Larger vs Smaller Chest Drain Size on Pain Control and Pleurodesis Efficacy Among Patients With Malignant Pleural Effusion: The TIME1 Randomized Clinical Trial. Jama. 2015;314(24):2641-53.
3. Struck MF, Ewens S, Fakler JKM, Hempel G, Beilicke A, Bernhard M, et al. Clinical consequences of chest drain malposition in trauma resuscitation: single-center experience. European journal of trauma and emergency surgery : official publication of the European Trauma Society. 2019;45(4):687-95.
4. Hooper CE, Welham SA, Maskell NA. Pleural procedures and patient safety: a national BTS audit of practice. Thorax. 2015;70(2):189-91.
5. Clive AO, Jones HE, Bhatnagar R, Preston NJ, Maskell N. Interventions for the management of malignant pleural effusions: a network meta-analysis. The Cochrane database of systematic reviews. 2016(5):Cd010529.
6. Aghajanzadeh M, Dehnadi A, Ebrahimi H, Fallah Karkan M, Khajeh Jahromi S, Amir Maafi A, et al. Classification and Management of Subcutaneous Emphysema: a 10-Year Experience. The Indian journal of surgery. 2015;77(Suppl 2):673-7.
7. Asciak R, Addala D, Karimjee J, Rana MS, Tsikrika S, Hassan MF, et al. Chest Drain Fall-Out Rate According to Suturing Practices: A Retrospective Direct Comparison. Respiration; international review of thoracic diseases. 2018;96(1):48-51.
8. Yang MX, Ault MJ. A Punctureless and Secure Method of Chest Drain Fixation. Annals of emergency medicine. 2018;72(1):106-7.
9. Kim H, Cho Y, Suh GY, Yang J, Jeon K. Subclavian Artery Laceration Caused by Pigtail Catheter Removal in a Patient with Pneumothorax. Korean Journal of Critical Care Medicine. 2015;30:119.
10. Ben-Nun A, Best LA. A simple method of using a Foley catheter to drain pleural effusion. Surgery today. 2008;38(8):769-70.
11. Ross S, Ali H, Allsop L, Ali N, Kemp S. P15 A pilot study of a dedicated ballooned intercostal drain. Thorax. 2016;71(Suppl 3):A91-A2.

Tables and Figures

Table 1. Demographics and baseline data

	Balloon Drain n= 131	Standard care n= 132
Age in years (median, IQR)	71 (59-79)	71 (59-79)
Gender (M:F) ǂ	72:58	74:58
Size of effusion (in n patients)	n=130	n=130
• **None***	7 (5.4%)	8 (6.2%)
• **Small**	4 (3.1%)	4 (3.1%)
• **Moderate**	50 (38.5%)	50 (38.5%)
• **Large**	69 (53.1%)	68 (52.3%)
Side of intervention (L:R) ǂ	57:71	53:77
Current malignancy	68/129 (52.7%)	65/132 (49.2%)
Past Medical History		
• **Cardiovascular**	64 (48.9%)	67 (50.8%)
• **Respiratory**	49 (37.4%)	38 (28.8%)
• **Abdominal**	21 (16.0%)	23 (17.4%)
• **Malignancy**	34 (26.0%)	28 (21.2%)
• **Musculoskeletal**	18 (13.7%)	14 (10.6%)
• **Endocrine**	26 (19.8%)	22 (16.7%)
• **Other**	35 (26.7%)	27 (20.5%)
Indication for chest drain insertion:	n=131	n=132
• **Pleural Infection****	27 (20.6%)	28 (21.2%)
• **Malignant pleural effusion****	72 (55.0%)	72 (54.5%)
• **Pneumothorax**	12 (9.2%)	14 (10.6%)
• **Other**	20 (15.3%)	18 (13.6%)
Ultrasound appearances of pleural fluid (when present):	n=120	n=117
• **Unseptated**	90	86
• **Mildly septated**	14	12
• **Moderately septated**	8	9
• **Heavily septated**	8	10
Number of previous pleural interventions:	n=130	n=131
0	63 (48.5%)	74 (56.5%)
1	52 (40.0%)	41 (31.3%)
2	11 (8.5%)	13 (9.9%)
≥3	4 (3.1%)	3 (2.3%)
Increased bleeding risk***	20/131 (15.3%)	21/132 (15.9%)
Baseline pain Visual Analogue Score (VAS) mm (mean, SD)	n=112 17.3 (25.0)	n=109 19.8 (28.46)

Data presented as n (%), unless otherwise stated. *due to pneumothorax, **known or suspected Other; unknown aetiology, transudates, reactive effusions, chylothorax

***Due to antiplatelet or anticoagulant therapy, thrombocytopenia or coagulopathy

ǂMissing data; Gender – 2, Side of Intervention 5

Table 2. Drain displacement and clinical consequences

	Balloon Drain (n=131)	Standard care (n=132)	Statistical analysis*
Drain completely fell out	2 (1.5%)	3 (2.3%)	p=1.0
Displaced, then removed	3 (2.3%)	10 (7.6%)	p=0.08
• **Holes not in pleural cavity**	1	3	
• **Radiological evidence of displacement**	2	4	
• **Withdrawn and not adequately functioning**	0	4	
• **Withdrawn a significant amount**	1	3	
Consequences of displacement			
• **None**	1 (0.8%)	9 (6.9%)	p=0.02
• **Failure to complete treatment**	1 (0.8%)	3 (2.3%)	p=0.62
• **Further pleural procedures**	3 (2.3%)	0 (0%)	p=0.12
• **Other****	0 (0%)	1 (0.8%)	p=1.0

*Fishers exact test **persisting pneumothorax which did not require drainage

Table 3. Secondary outcomes

	Balloon Drain (n=129)	Standard care (n=130)	Statistical analysis
Time study drain in situ, days (median, IQR)	n=124 4 (2.7,6.0)	n=124 4 (2.7,6.0)	p=0.98 (Mann Whitney)
Time any drain in situ*, days (median, IQR)	n=129 5 (3-7)	n=128 5 (3-7)	p=0.34 (Mann Whitney)
Additional radiology needed	(n=129)	(n=130)	
Additional CXR	59	59	p=0.45
• **Median number of CXRs**	1 (1-2)	1 (1-2)	(Mann Whitney)
Additional CT	6	11	χ^2= 1.53, 1df, p=0.22
Subsequent pleural interventions	29/129 (patients) 35 (interventions)	34/128 (patients) 41 (interventions)	
• **Aspiration**	4	9	
• **Chest Drain**	10	7	
• **IPC**	13	9	χ^2 = 0.58, 1df, p=0.45
• **Thoracoscopy**	0	3	
• **Thoracic Surgery**	6	8	
• **Other****	2	4	
• **Unknown**	0	1	
Length of stay post drain insertion* **	n=123	n=129	p=0.39
Median (IQR)	6 (3-11)	7 (4-11)	(Mann Whitney)

*including both the study drain and any subsequent drains inserted **IPC removal, pleural biopsy, pleurodesis ** within 30 days of insertion

CXR – chest radiograph, CT – computed tomography, IPC – indwelling pleural catheter

Table 4. Adverse events

	Balloon Drain n=131	Standard care n=132	Statistical analysis
No. of failed initial insertions • **Alternative drain inserted** • **Associated adverse event**	12 (9.2%) 10 (7.6%) 1 (0.8%)	3 (2.3%) 1 (0.8%) 0 (0%)	χ^2= 5.8 p=0.016
Failure to maintain balloon inflation	9/91 (9.9%)	N/A	
Number of patients experiencing adverse events	59/131 (45.0%)	18/132 (13.6%)	χ^2 = 31.3 p<0.0001
Number of adverse events (individual events)	64	22	
Procedure complications • **Bleed** • **Vasovagal** • **Pneumothorax (including ex-vacuo)** • **Drain site leakage**	 0 (0%) 3 (2.3%) 3 (2.3%) 5 (3.8%)	 1 (0.8%) 2 (1.5%) 9 (6.8%) 0 (0%)	
Post procedure complications • **Site infection** • **Pleural infection** • **Reperfusion pulmonary oedema** • **Surgical emphysema** • **Other***	 1 (0.8%) 1 (0.8%) 1 (0.8%) 0 (0%) 2 (1.5%)	 2 (1.5%) 1 (0.8%) 0 (0%) 4 (3%) 1 (0.8%)	
Difficulty during removal of drain** • **Deflating balloon** • **Removing from chest** • **Fracture** • **Pain** • **Extra incision needed**	48 (36.6) 19 (14.5%) 36 (27.5%) 0 (0%) 21 (16%) 5 (3.8%)	2 (1.5%) 0 (0%) 1 (0.8%) 0 (0%) 1 (0.8%) 0 (0%)	
Serious adverse events • **Number of patients re-admitted within 30 days of drain removal** • **Death within 30 days from removal or died with drain in situ** • **Drain related deaths** • **Other SAEs (not death or re-admission)**	 28/125 (22.4%) 15/130 (11.5%) 0 (0%) 1 (0.8%)	 29/124 (23.4%) 19/131 (14.5%) 0 (0%) 0 (0%)	 χ^2 = 0.03 p=0.85 χ^2 = 0.51 p=0.48

* Incomplete inflation/deflation or equipment malfunction **Physician reported

Table 5. VAS scores (n=216, where data available)

	Balloon (n=112)	Standard care (n=104)	Significance (Mann Whitney U test)
Day 0 – pm	n=108 29.4 (9.3-69.1)	n=102 44.3 (10-76.3)	p=0.33
Day 1 - am	n=112 22 (7-46)	n=104 22 (6.8 – 57.5)	p=0.69
Day 1 - pm	n=106 23 (5-45.8)	n=97 15.8 (4-52.6)	p=0.94
Day 2 - am	n=105 16 (5-37.4)	n=95 14 (4-41)	p=0.67
Day 2 - pm	n=91 22 (4.4 – 43)	n=89 10.8 (4.5 – 35.5)	p=0.35
Day 3 - am	n=85 16 (4.6 – 30.5)	n=83 10.3 (4.3 – 26.5)	p=0.36
Day 3 – pm	n=72 13.25 (5-31.2)	n=72 9.13 (4.15 – 31)	p=0.50
Day 4 – am	n=63 11.5 (3-27)	n=63 9 (3-31.5)	p=0.62
Day 4 – pm	n=58 9.5 (3 – 36.8)	n=56 7.3 (2.6-32.3)	p=0.33
Day 5 - am	n=53 9.5 (3.88 – 21)	n=49 8 (3.9 – 24.3)	p=0.98
Day 5 - pm	n=47 8 (3-34.5)	n=40 7.7 (3.2 – 20.5)	p=0.87
Post removal	n=92 7.35 (2-36.9)	n=75 6.0 (1.5 – 16.8)	p=0.15

In mm, median, IQR.

Table 6. Analgesia requirements

	Balloon (n=129)	Standard Care (n=130)	Significance
Paracetamol	111 (86.0%)	119 (91.5%)	χ^2 = 2.0, p=0.16
NSAIDs	10 (7.8%)	10 (7.7%)	χ^2 <1.0, p=0.99
Opiates	104 (80.6%)	100 (76.9%)	χ^2 = 0.5, p=0.47
Other*	6 (4.7%)	4 (3.1%)	χ^2 = 0.4, p=0.51

NSAIDs = non-steroidal anti-inflammatory drugs, *gabapentin, pregabalin, lidocaine patch, ketamine, clonazepam and buscopan

Figure 1 – Inflated Balloon Catheter

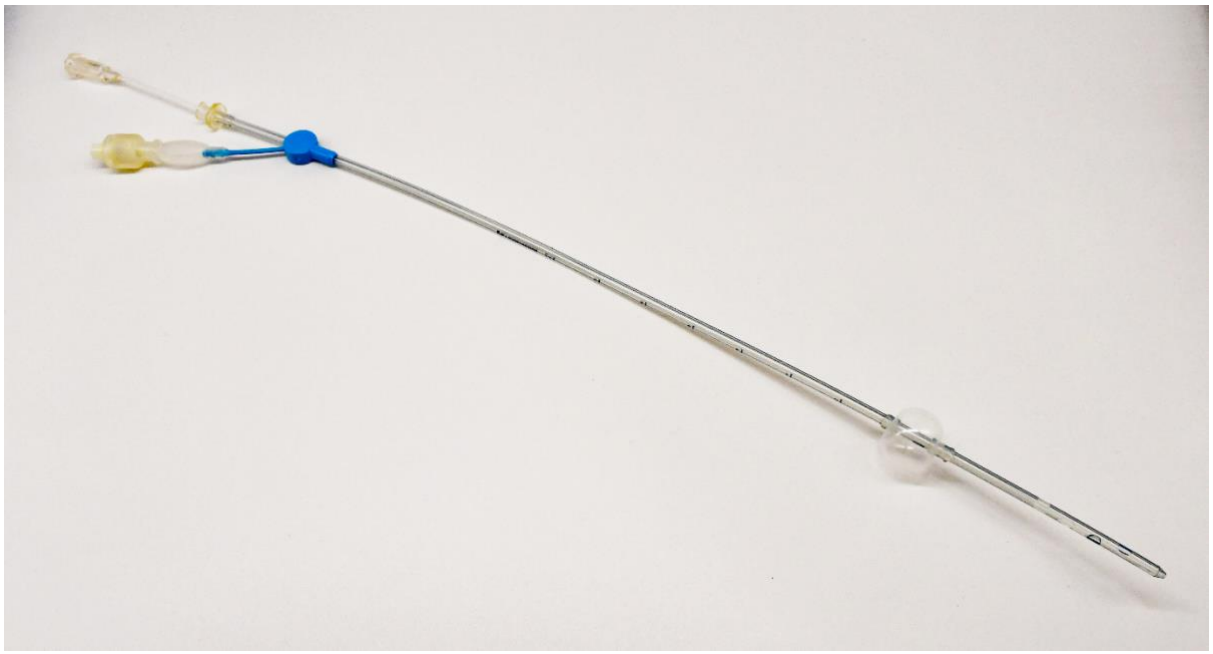
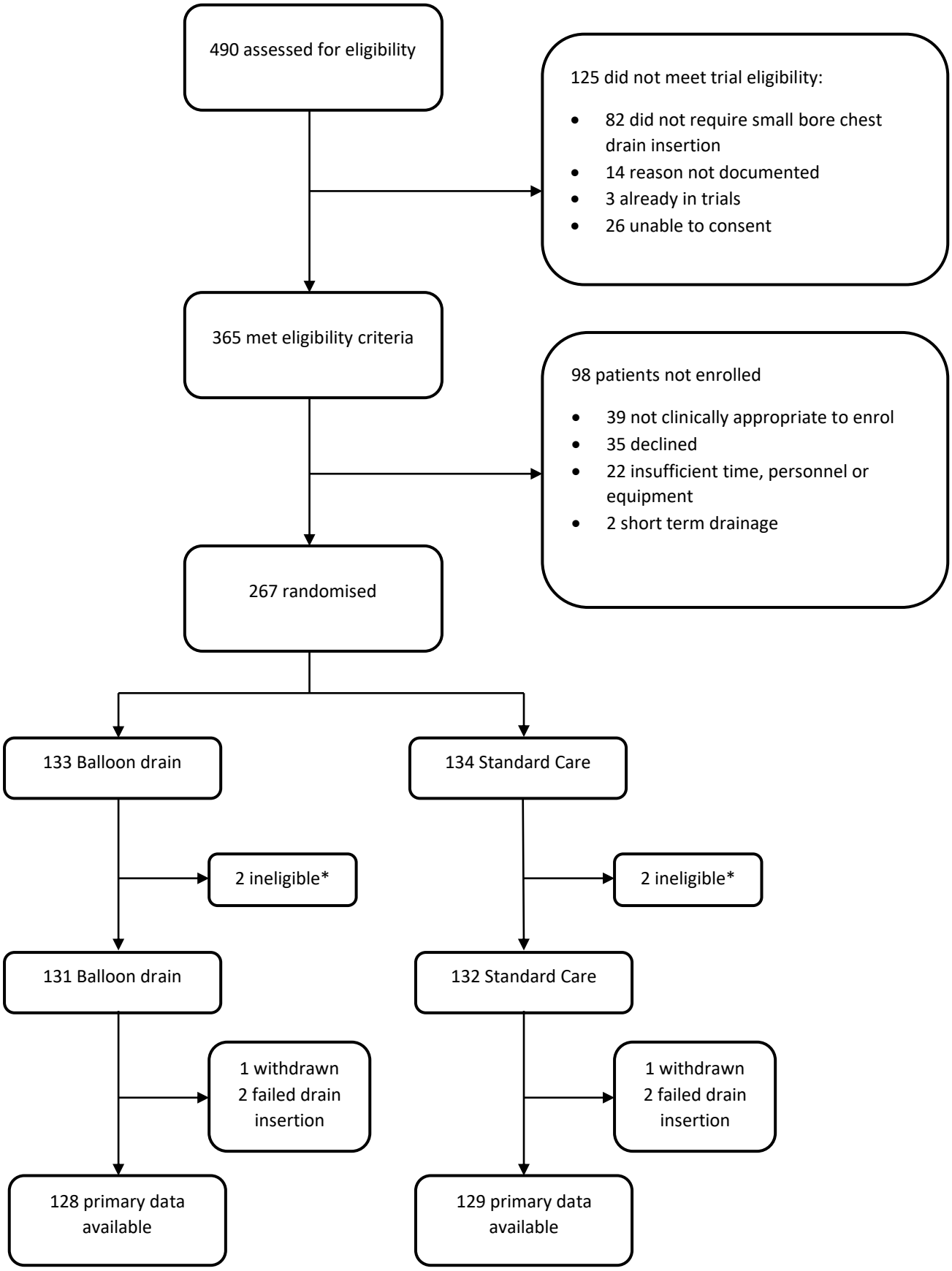


Figure 2 – Consort Diagram



*Four patients were deemed to be ineligible after randomisation as a repeat ultrasound assessment did not demonstrate sufficient fluid for drain insertion.

Figure 3. Daily VAS Scores