Feasibility and effectiveness of the Passio™ digital drainage system in reducing chest pain during IPC pleural drainage

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Conflicts of Interest

- APR Medtech provided 10 Passio IPC starter kits
- Not involved with evaluation

Background

- Passio™ pump drainage system
  - Manufactured by Bearpac Medical in the US
  - Supplied by APR Medtech in the UK

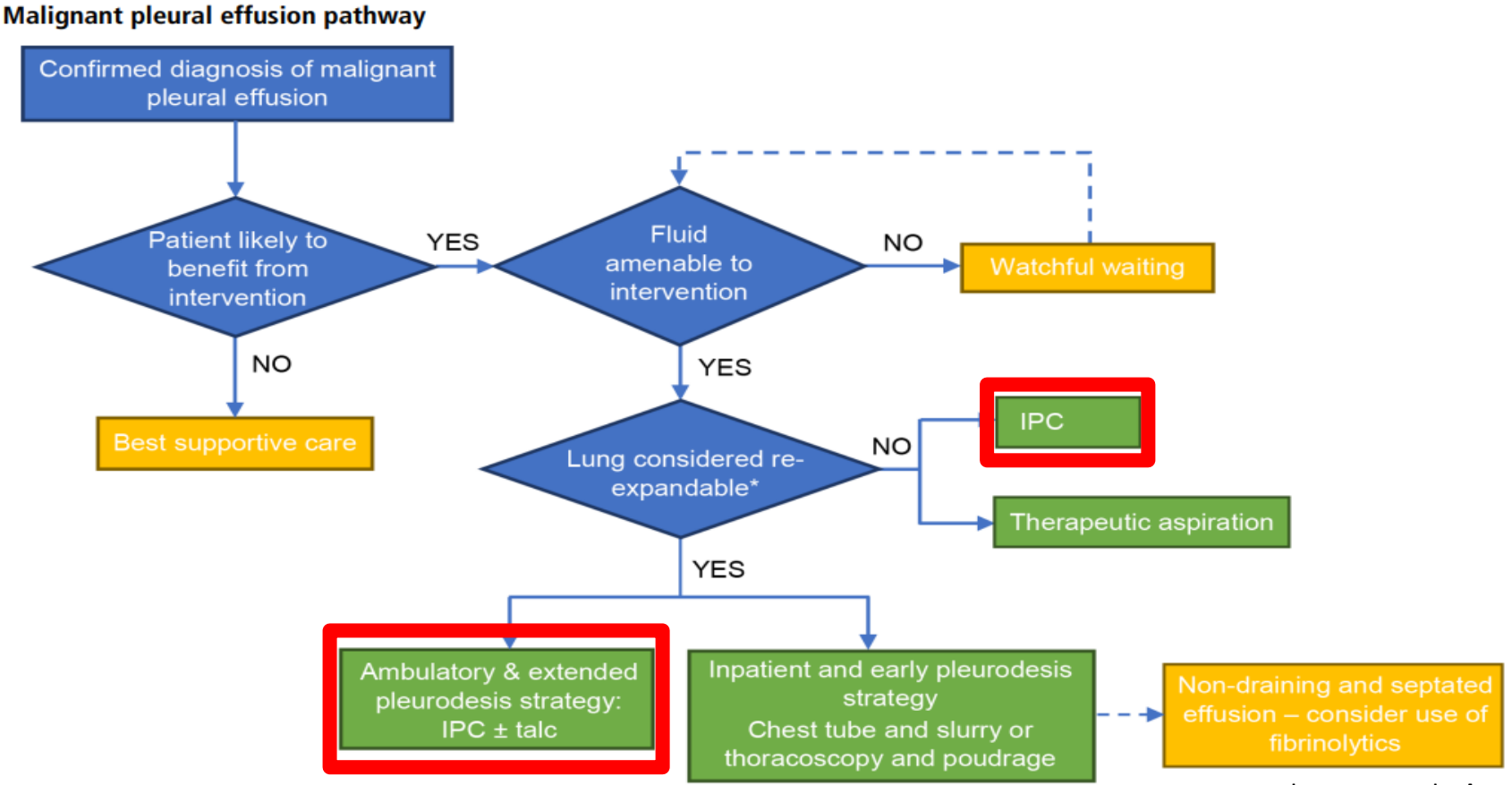
- Uses a battery-operated handheld pump which allows drainage at a lower pressure at variable flow rates

- Device trialled in five patients at Glenfield Hospital, Leicester

- Device was previously trialled in 2022/2023 and had issues with device failure, valve failure and IPC blockage. Manufacturer rectified the problems and issued a new batch of pumps and valves.

IPC as 1st line management for Malignant Pleural Effusion (MPE)

British Thoracic Society Guideline for pleural disease



Roberts M et al. **Thorax 2023**

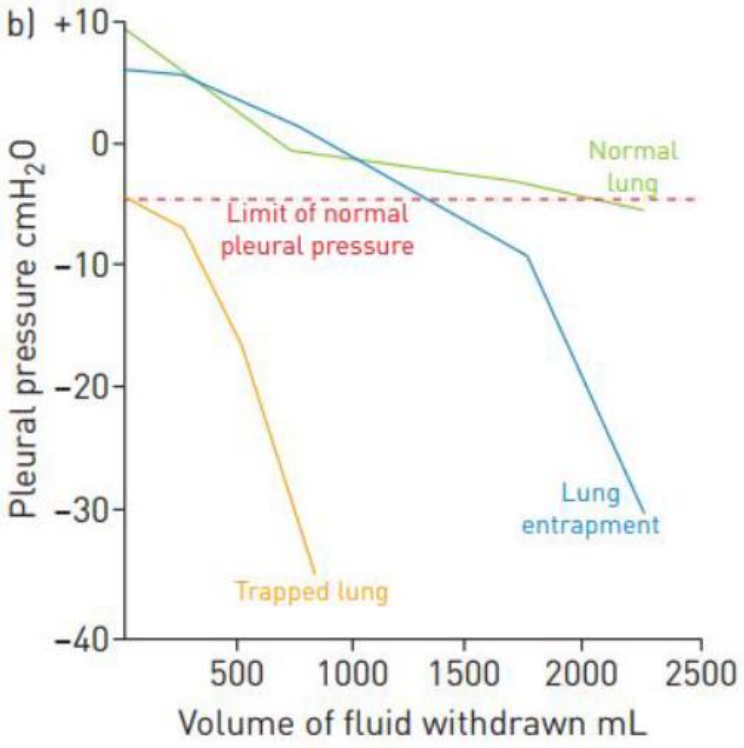
Drainage associated pain

- Drainage can be associated with pain towards the end [1]
- 36% of patients experience discomfort with home drainage [2]
- Managed with analgesia, revised drainage protocol or elimination of vacuum with underwater seal

1. Lui MMS et al. **BMJ Resp Res** 2016
2. Mitchell MA et al. **Thorax** 2023

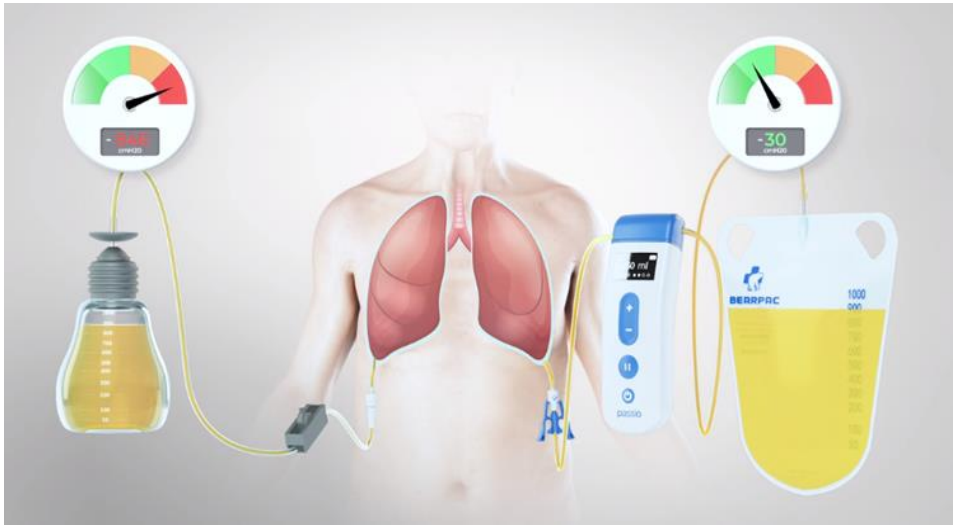
Drainage associated pain

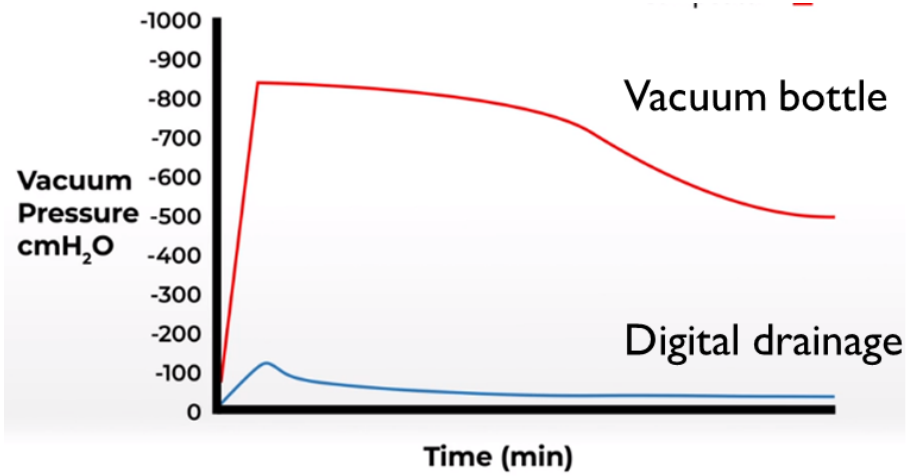
- Could be due to a rapid decrease in pleural pressure[1]
- Vacuum bottles can have a starting pressure as low as -950 cmH_2O
- **Could lower pressure drainage help with drainage-associated pain?**



1. Huggins T et al. **Respirology** 2017
2. Bhatnagar R et al. **Eur Resp Rev** 2016

Passio™ pump drainage system





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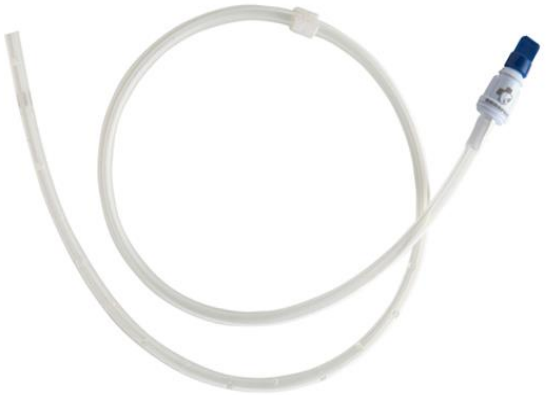
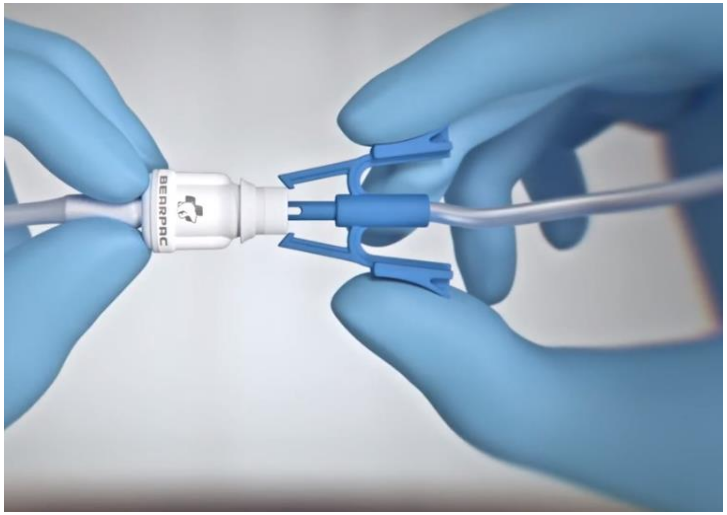
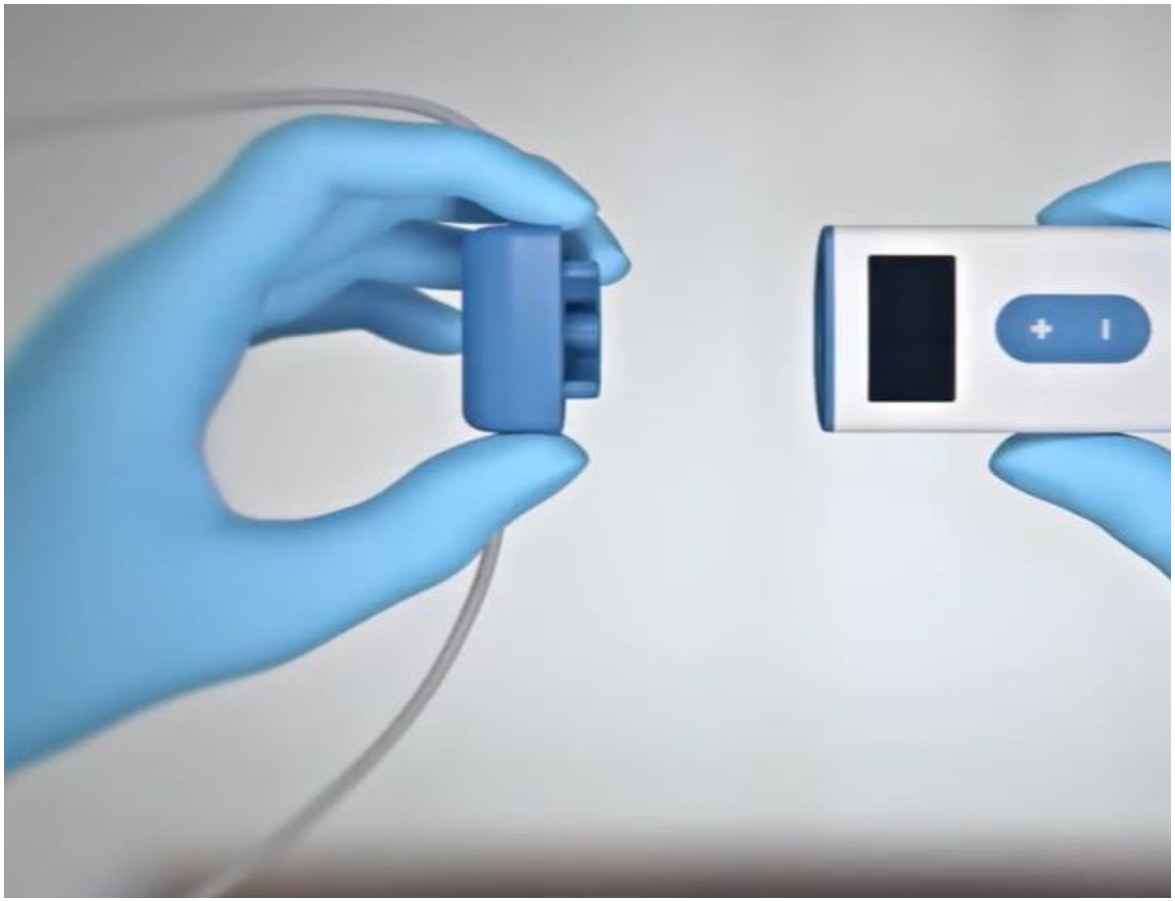
Passio™ pump drainage system







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Passio™ pump drainage system

Drainage at variable flow rates

Speed	Flow rate (ml/min)
1	50
2	100
3	150
4	200

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Passio™ pump drainage system

Lower pressure drainage

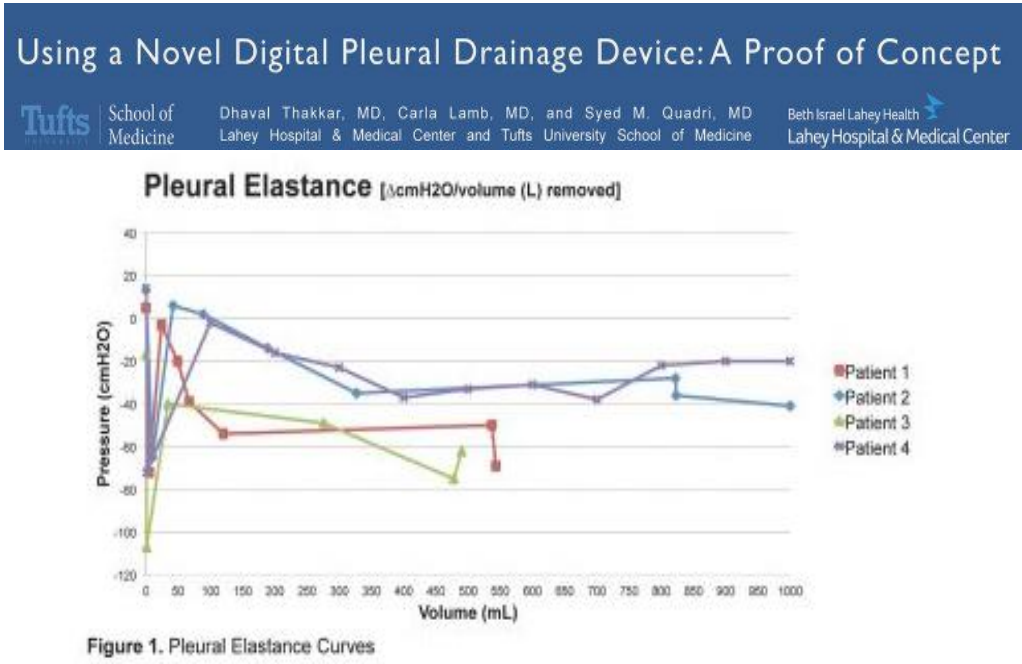
- Mean pressure at priming

  -82.5 cmH2O

- Mean pressure at end of drainage

  -45.5 cmH2O

- No objective assessment of pain



Thakkar D et al. **ATS** 2019

Aims and Objectives

- Evaluate pain levels experienced during IPC drainage with a standard vacuum drainage bottle.
- Assessed whether a digitally controlled pleural drainage system (Passio™) could offer a viable alternative to patients who experience pain during drainage.

Methods

- All patients who had an IPC between November 2023 - April 2024 (n=27) were included.

- A questionnaire was given to complete during the first two weeks after insertion. Pain severity was assessed using a 100mm Visual Analogue Scale (VAS) at 4 points during drainage-
    - Before drainage
    - Mid-drainage
    - End of drainage
    - 10 minutes after end of drainage

- Questionnaires were reviewed at the routine 2-week post-IPC insertion appointment to assess drainage-related pain and if present, the existing IPC valve was replaced with a Passio^{TM} valve (n=5).

- A questionnaire was given to assess VAS scores post- Passio^{TM} valve change.

Results- Demographics

- Total No. of Patients= 27

- Gender-
  - Male- 16 (59%)
  - Female- 11 (41%)

- Mean Age- 70

- Non-Expandable Lung- 10 (37%)

- Degree of pleural apposition-
  - <25%--------- 4 (14.8%)
  - 25-50%------- 2 (7.4%)
  - 50-75%------- 2 (7.4%)
  - >75% --------19(70.4%)

Diagnosis	n
Lung Cancer	8
Mesothelioma	6
Breast Cancer	5
Renal	1
Benign Pleuritis	2
Cancer of unknown primary	1
Sarcoma	1
Lymphoma	2
Ovarian	1

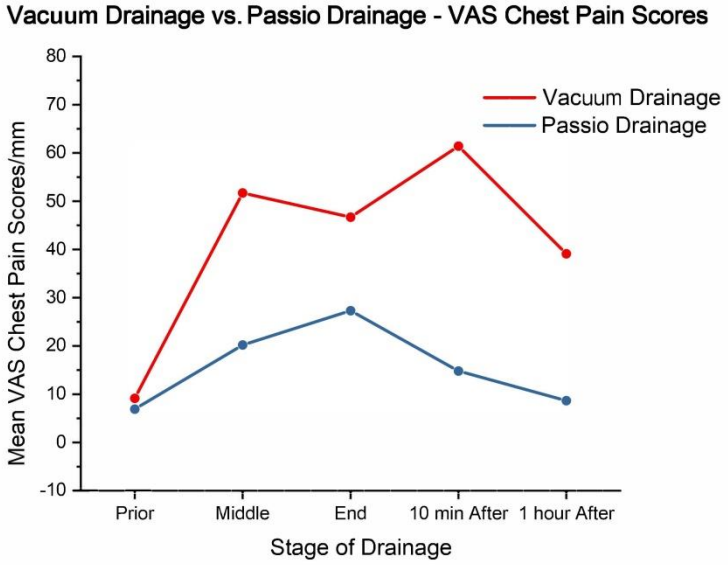
Results- Vacuum Drainage

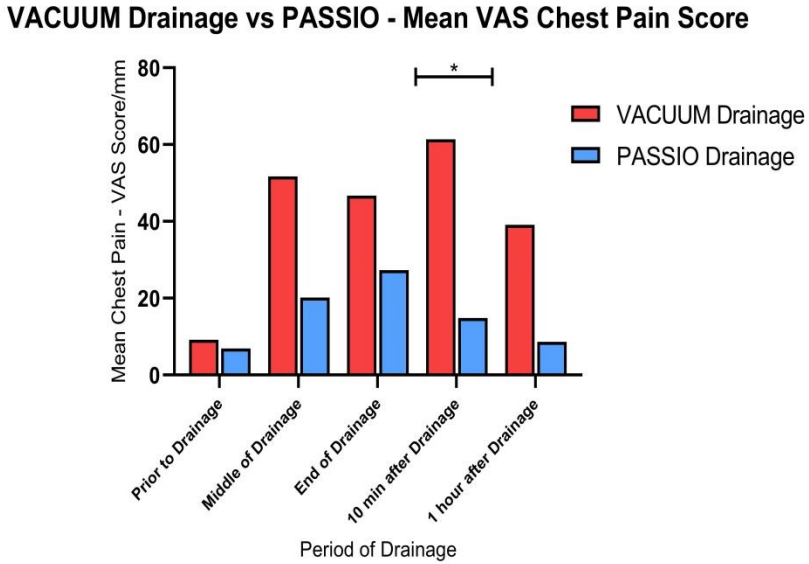
- Analgesia-
  - Yes- 16 (59%)
  - No- 11 (41%)
- Cough during drainage
  - Yes- 11 (41%)
  - No- 16 (59%)
- Slowing down drainage improved pain and coughing-
  - Yes- 9 (82%)
  - No- 2 (18%)

Vacuum Drainage (n=27)	
	Chest Pain VAS Score
Prior to Drainage (mm)	10.53mm ± 2.73
Middle of Drainage (mm)	19.86mm ± 5.15, P=0.29
End of drainage (mm)	20.86mm ± 5.87, P=0.29
10 mins after the end of drainage (mm)	13.28mm ± 4.17, P=0.35

Results- Post- Passio™

Post-Passio Valve Change (n=5)		
	Vacuum Drainage (n=5)	**Post-Passio (n=5)**
Prior to Drainage (mm)	9.16mm ± 4.01	6.91mm ± 2.45, P= 0.79
Middle of Drainage (mm)	51.68mm ± 16.29, P=0.13	20.15mm ± 9.34, P=0.25
End of drainage (mm)	46.68mm ± 19.45, P=0.19	27.28mm ± 12.69, P=0.84
10 mins after the end of drainage (mm)	61.38mm ± 9.81, P=0.06	14.81mm ± 3.33, P=0.0079
1 hour after the end of drainage (mm)	39.12mm ± 15.72, P=0.99	8.66mm ± 2.44, P=0.42





Results- Post- Passio™

- No complications
- No pump/valve failures
- No admissions related to Passio™ valve complications
- 100% patient satisfaction

Limitations

- Small sample size
- Single-centre
- Volume discrepancy between handheld pump reading and the actual volume of fluid drained in the bag

Future..

Bearpac Medical Announces AESOP trial launch at North Bristol NHS Trust to assess experience, safety, and outcomes of the Passio™ Pump Drainage System.

Michael Pichel / 2024-09-27

News from Bearpac Medical!

ISRCTN16390322

- Single centre, crossover, non-blinded 1:1 randomised controlled trial.
- Participants will be randomised to IPC insertion with either a Passio™ catheter or a standard catheter (BD PleurX™).
- Primary objective- Evaluate safety, efficacy and tolerability of the Passio™ Pump Drainage System in comparison to the BD PleurX™ Pleural Catheter System.
- Secondary objective- Evaluate the overall experience of the Passio™ Pump Drainage System from a patient perspective.

AESOP

(**A**ssessing **E**xperience, **S**afety, and **O**utcomes of the **P**assio Pump Drainage System**)**

Conclusions

- Our feasibility study has shown that controlled pleural drainage using a digital drainage device such as Passio™ may have a role in IPC patients who experience pain with vacuum bottle drainage, especially in those who have NEL

- Safe with no complications encountered

- More robust data in the form of RCT trials needed to draw firm conclusions

Thank You For Your Attention

Our Team

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