ORIGINAL ARTICLE

Ambulatory treatment in the management of pneumothorax: a systematic review of the literature

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ABSTRACT

Introduction Spontaneous pneumothorax (SP) is broken down into primary (PSP: no known underlying lung disease), secondary (SSP: known lung disease) and from trauma or iatrogenic pneumothorax (IP). Current treatments include a conservative approach, needle aspiration, chest drain, suction and surgery. A Heimlich valve (HV) is a lightweight one-way valve designed for the ambulatory treatment of pneumothorax (with an intercostal catheter).

Methods We performed a systematic review across nine electronic databases for studies reporting the use of HV for adults with pneumothorax. Randomised controlled trials (RCT), case control studies and case series were included, unrestricted by year of publication. Measures of interest included the use only of a HV to manage SP or IP, (ie, avoidance of further procedures), successful treatment as outpatient (OP) and complications.

Results Eighteen studies were included reporting on the use of HV in 1235 patients, 992 cases of SP (of which 413 were reported as PSP) and 243 IP. The overall quality of the reports was moderate to poor with high risk of bias. Success with HV alone was 1060/1235 (85.8%) and treatment as OP successful in 761/977 (77.9%). Serious complications are rare. Long-term outcomes are comparable with current treatments.

Conclusions High-quality data to support the use of HV for ambulatory treatment of pneumothorax is sparse. The use of HV in such circumstances may have benefits for patient comfort, mobility and avoidance of hospital admission, with comparable outcomes to current practice. There is urgent need for a carefully designed RCT to answer his question.

Key messages

What is the key question?

- Controversy exists with the optimal management of pneumothorax, and Heimlich valves (HV) with an intercostal catheter may offer an alternative to current conventional therapy. We performed a systematic review to examine the existing data for effectiveness and safety for the use of HV in spontaneous and iatrogenic pneumothorax.

What is the bottom line?

- Quality reliable data is sparse, but there is enough to suggest that HV for pneumothorax may be effective and safe in the ambulatory treatment of pneumothorax with avoidance of further procedures in the majority of cases.

Why read on?

- The ambulatory management of pneumothorax is attractive as it is likely to improve comfort and mobility, and reduce or avoid hospital admission, with comparable outcomes to current treatments.

INTRODUCTION

Pneumothorax is defined as the presence of air in the pleural space.[1] It was first described by Itard in 1803, and treatment with needle aspiration (NA) then described by Bell in 1804.[2] Spontaneous pneumothorax (SP) is broken down into primary (PSP: no known underlying lung disease), secondary (SSP: known lung disease) and non-spontaneous from trauma or iatrogenic pneumothorax (IP: most commonly from subclavian vein catheterisation and transthoracic biopsy[3]). In the USA, the incidence of PSP presenting to hospital is 7.4/100 000 for men and 1.2/100 000 for women per year, and for SSP 6.3/100 000 (men) and 2.0/100 000 (women) per year.[4] In the UK, between 1950 and 1997, the incidence of SP (PSP and SSP combined) in those presenting to hospital was 16.7/100 000 for men and 5.8/100 000 for women per year.[5] When combined with new presentations to primary care, the rates rise to 40.7 (men) and 15.6 (women) per 100 000 per year.[5] SP classically affects men more than women (ratio 2.5:1)[5 6] and those with 'ectomorphic' body habitus.[1] PSP carries a very low mortality with most cases of death from SP occurring above the age of 55 years,[5] suggesting that the majority of these cases are likely to have SSP with underlying lung disease. The underlying pathological cause of SP is likely to be the rupture of small bullae or blebs (so-called 'emphysema-like changes') on the pleural surface, which allows egress of air from the lung into the pleural space.[7]

Despite recognition of pneumothorax for more than 200 years, there still remains significant controversy and a wide variation in treatment both nationally and internationally.[8–11] The poor consensus in recommended management of SP is highlighted by three international guidelines (the American College of Chest Physicians Delphi consensus statement from 2001,[12] the British Thoracic Society guidelines 2010[8] and the Belgian Society of Pulmonology guidelines 2005[13]) contrasting sharply in many aspects of proposed treatment, and these international bodies do not even agree on a definition of

size of pneumothorax. Many experts increasingly argue that treatment options for PSP should concentrate more on patient-orientated aspects, such as symptoms, rather than chest x-ray (CXR) appearances.[9] The approach of managing PSP based on clinical and symptomatic criteria as compared with CXR appearance, is currently being examined in a large Australasian randomised controlled trial.[14] The lack of clear consensus in treatment likely contributes to both the poor adherence to guidelines and wide variations in practice that are observed worldwide.

Conventionally, the recognised treatment options for SP include a conservative approach (ie, observation alone) for small SP, NA of air from the pleural cavity, or placement of an intercostal chest tube (ICT) connected to an underwater seal.[8 12] Persistent air leak can be managed with the use of an ICT with underwater seal connected to suction (a practice with little evidence base) and, after prolonged air leak, surgery to repair or resect the damaged lung followed often by pleurodesis (the iatrogenic induction of pleural fibrosis) is advocated.[8 12] NA alone has been demonstrated to carry a highly variable success rate of 30–80%[8]; after NA failure, with current accepted approaches, admission for inpatient treatment is required for persistent pneumothorax.

Ambulatory treatments for some diseases are desirable for healthcare institutions not least for the potential financial implications of inpatient bed-days saved. The treatment of SP, and in particular PSP would lend itself well to outpatient (OP)-orientated management; patients are generally young, with few or no comorbidities, and the condition itself caries a low morbidity and mortality.[5] This is not a new concept, with reports in the literature dating back to 1973[15] advocating the use of a Heimlich flutter valve (HV: a lightweight one-way valve specifically designed for the ambulatory treatment of pneumothorax[16]) attached to an intercostal catheter with patients managed out of hospital. This approach is very attractive to patients as it does not involve connection to a drain bottle, and thus, encourages mobility and ability to more comfortably perform common activities of daily living.[17 18]

This systematic review was designed to concisely assess the published literature to examine the evidence for the use of Heimlich valves (HVs) in the management of adults with pneumothorax as compared with conventional approaches and, furthermore, to establish if such management can be safely and effectively performed in an OP environment.

METHODS

We used a systematic review methodology based on the PRISMA[19] approach and principles. As the authors were aware that high-quality trials data is lacking in this subject field, we specifically allowed consideration of case series within the summation of the literature.

Eligibility criteria

Studies were considered eligible for inclusion with the following criteria: adult patients with spontaneous (primary and secondary) and IP; interventions consisting of conservative approach, NA, ICT, catheter and HV; comparator with any one of the above; outcome: an assessment of the efficacy or reported success of the treatment modality; randomised controlled trials (RCTs), case control study, case series. Exclusions consisted of the following: letters, editorials and studies examining pneumothorax post-thoracic surgery or traumatic pneumothorax. Studies involving postsurgery cases with a clear delineation of outcomes between SP and surgery cases were permitted.

Sources of information

The search strategy included several data sources unrestricted by years of publication although the full text of the study must have been in English. The literature search included the following electronic (online) databases: Cochrane Library (including the Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Databases of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Heath Technology Assessment (HTA) database, National Health Service (NHS) Economic Evaluation database (EED)), Medline (through Pubmed interface), Embase, and Web of Science.

Searches were conducted between 5 April and 15 May 2012. We used the following search terms, adapted for each database as appropriate

- (Drainage OR thoracic drainage OR ambulatory care OR catheters OR catheterisation OR aspiration OR needles OR needle OR manual OR simple OR spontaneous (MeSH terms), with HV (all fields)) AND
- (pneumothorax (MeSH term) OR pneumothoraces (all fields)) AND
- (clinical trial OR randomised controlled trial OR comparative study OR evaluation OR case report (publication type)).

In addition to electronic database scrutiny, we hand-searched textbooks and reference lists of included studies and articles. Lead authors and subject experts were contacted to establish any unpublished grey literature. We included any studies fulfilling the above criteria, and then independently screened and assessed each article identifying those potentially relevant. Studies were reviewed in three stages based on the title, abstract, and then full text with consensus sought at each stage of review. Two authors (FJB and NAM) independently performed the literature search and assimilation of suitable reports. The protocol utilised for the study is available in the supplementary material online.

Data collection process

For selected studies, data were extracted onto an electronic form (Microsoft Excel 2010, Microsoft Corp, USA). Extracted information included: authors, year, geographical area, sample size, nature of pneumothorax (primary, secondary, iatrogenic, mix), intervention type(s), any control/comparator measures, outcomes reported—for each intervention, timescale of assessment, reported complications, study type, assumptions/simplifications.

Quality—risk of bias in individual studies

The overall quality of each study was judged independently by the two authors (FJB and NAM) including assessment of study type, internal validity, generalisability, heterogeneity and precision.

For comparative experimental studies we assessed the adequacy of sequence generation, allocation concealment, blinding, completeness of data, outcome reporting and baseline comparability.

Measures of interest

The primary measure of interest was use only of a HV (with intercostal catheter) to manage the pneumothorax, that is, avoidance of larger ICT and/or surgery; this outcome forms the definition of 'overall success' within the presentation of results.

Additional measures of interest were as follows: where applicable—use of a HV to facilitate only *outpatient-based* treatment; use of HV for different types of pneumothorax (PSP/SSP/IP)

need for surgery; recurrence rate (more than 1 week after treatment); financial assessment/implications; reported complications with 'serious' complication defined by the following: death, life threatening or serious injury, need for hospital admission, or prolonged admission, persistent or significant disability or incapacity. For financial considerations, due to variance in currency and wide difference in dates of studies, a cost ratio was calculated, rather than using original costs reported.

Synthesis of results

Where possible, estimates of effect were collated across the selected studies. Due to the wide heterogeneity and non-comparative nature of the studies, a simple proportion of each outcome of interest was calculated.

RESULTS

Eighteen studies from nine countries over a period of four decades reporting on the use of a HV in 1235 patients were eligible for review. Figure 1 presents a flow chart for full breakdown in the identification of suitable studies. This included two RCTs[20 21] and three prospective series,[17 18 22] the rest were retrospective case series.[15 23–34] There were 992 cases of SP (of which 413 were reported as PSP) and 243 IP. Two studies included reports on postsurgical patients, from which the results were clearly separated from SP and IP, allowing inclusion.[18 24] Table 1 provides a summary of included reports.

Risk of bias assessment

As all but two of the studies available were case series, the overall quality assessment of the assimilated data was assessed as moderate to poor, with a high risk of bias.

Primary and secondary outcomes

Data synthesis on outcomes was not possible. The two randomised controlled studies included had different comparators with use of HV against NA,[20] and HV against ICT,[21] prohibiting further evaluation. Therefore, we provide a narrative synthesis. Table 2 provides a summary of key outcomes. Reported overall success (use of HV with no further intervention) was 85.8% (95% CI 83.7 to 87.7). Thirteen studies describe the use of a HV in an OP setting with a reported success rate of 77.9% (95% CI 75.2 to 80.4).[18 20 22–30 33 34]

Variance in management and approach

There was a wide variance on methodological approach within the reports. Seven studies clearly stated a conservative approach

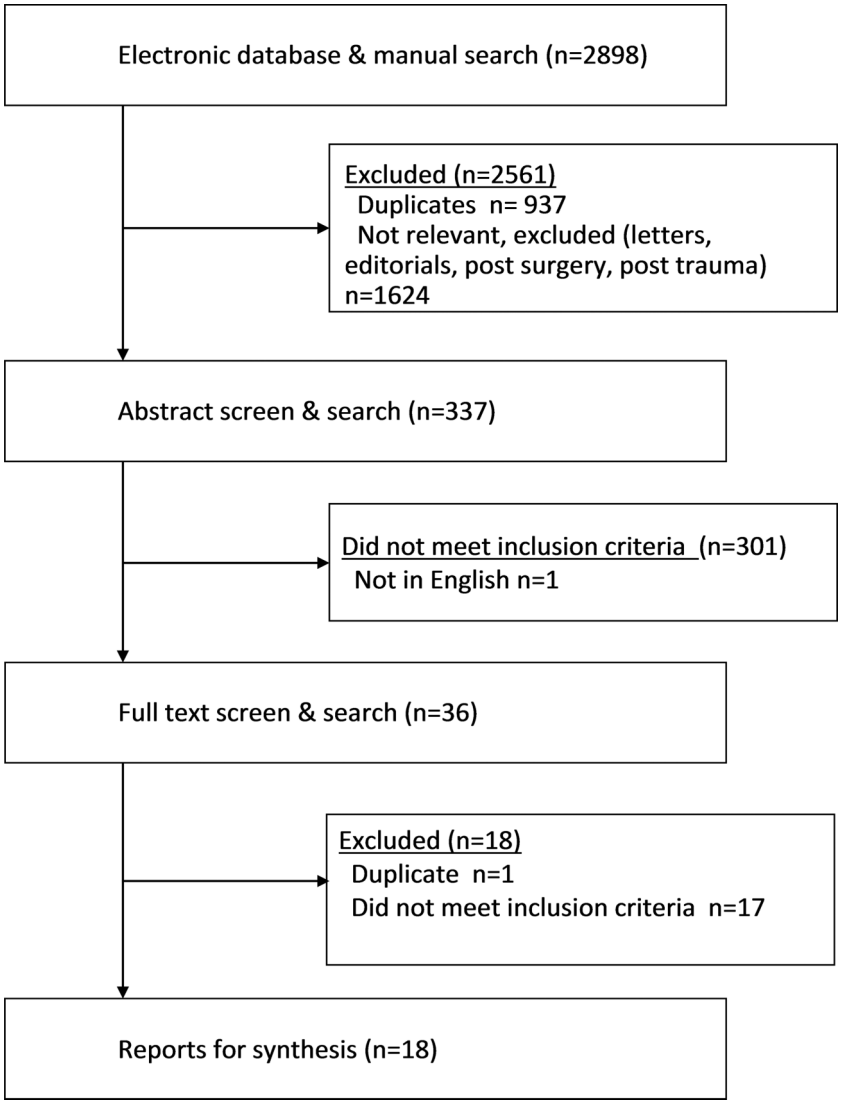

Figure 1 PRISMA flow diagram of evidence synthesis.

Table 1 Summary and characteristics of studies included

Authors	Year	Study design	Outcome	Intervention n=	Pneumothorax type	Exclusions	Setting	Quality
Ho *et al*	2011	RCT	Need for second procedure	25 (23 controls)	PSP	Tension pneumothorax, trauma, pleural effusions, SSP, bleeding disorders	Single centre. Singapore	Very good
Roeggla *et al*	1996	RCT	Need for second procedure	19 (13 controls)	SP—not defined	None stated	Single centre. Austria	Moderate
Vallee *et al*	1988	Prospective series	Re-expansion	37	PSP (19), SSP (18)	Need for mechanical ventilation, hydrothorax, tension pneumothorax	Single centre. USA	Good
Marquette *et al*	2006	Prospective consecutive cases	Re-expansion	41	PSP	Previous pneumothorax	Single centre. France	Good
Dernevik *et al*	2003	Prospective series	Treatment as outpatient	55	PSP (35), SSP (20)	None stated	Single centre. Sweden	Moderate
Lai *et al*	2012	Retrospective case-note review	Need for second procedure	55	PSP	Tension pneumothorax	Single centre. Singapore	Poor
Ponn *et al*	1997	Retrospective series	Treatment as outpatient	240	PSP (96), SSP (80)	Pleural effusion, pleural infection	Single centre. USA	Poor
Hassani *et al*	2009	Retrospective case series	Re-expansion	62	PSP	SSP, IP, postsurgery, traumatic, tension pneumothorax, effusion	Single centre. Canada	Moderate
Campisi *et al*	1997	Retrospective case series	Treatment as outpatient	14	PSP (13), SSP (1)	None stated	Single centre. USA	Poor
Cannon *et al*	1981	Retrospective series	Treatment as outpatient	41	PSP (34), IP (7)	None stated	Single centre. USA	Poor
Mercier *et al*	1976	Case series	Treatment as outpatient	226	PSP (174), SSP (52)	None stated	Single centre. Canada	Poor
Page *et al*	1975	Retrospective case series	Treatment as outpatient	104	PSP	None stated	Single centre. Canada	Poor
Conces *et al*	1988	Retrospective case series	Re-expansion	84	PSP (14), IP (66)	None stated	Single centre. USA	Poor
Bernstein *et al*	1973	Retrospective case series	Re-expansion	18	SP—not defined	None stated	Single centre. UK	Poor
Minami *et al*	1992	Prospective case series	Re-expansion	71	SP—not defined	IP	Single centre. Japan	Moderate
Martin *et al*	1996	Retrospective case series	Re-expansion	84	PSP (11), SSP (21), IP (52)	hydropneumothorax, tension pneumothorax, need for mechanical ventilation	Single centre. USA	Moderate
Choi *et al*	2007	Retrospective case series	Treatment as outpatient	47	PSP (43), SSP (4)	Trauma, hydropneumothorax, pleural infection	Single centre. Korea	Moderate
Gupta *et al*	2008	Retrospective case series	Treatment as outpatient	191	IP	None stated	Single centre. USA	Moderate

Intervention, use of a HV for treatment of a pneumothorax; IP, iatrogenic pneumothorax; PSP, primary spontaneous pneumothorax; RCT, randomised controlled trial; SP, spontaneous pneumothorax; SSP, secondary spontaneous pneumothorax.

to small PSP.[17 20 27–31] Algorithms for active treatment varied from placement of a catheter with HV followed by NA,[22 30] HV plus underwater seal,[28 29] HV plus suction,[25] or HV with no further action.[17 20 21 27 31] Several series did not discharge patients from hospital unless there had been objective improvements in CXR appearances of the pneumothorax by whatever means.[23 25 28 29 33 34]

The size of intercostal catheter used varied at 5.5–20 F tubes, with the older reports favouring larger tubes; all the reports in the last 10 years used catheters less than 12F. Anatomical placement of the tubes varied between the second intercostal space, midclavicular line and fifth intercostal space, anterior midaxillary line.

Table 2 Overall outcomes from all studies

Outcome measure:	n/N=	%	95% CI
Success with HV alone:			
All cases	1060/1235	85.8	83.7 to 87.7
As outpatient	761/977	77.9	75.2 to 80.4
PSP	344/413	83.3	79.4 to 86.6
SSP	110 124	88.7	81.9 to 93.4
Iatrogenic pneumothorax	237/243	97.5	94.7 to 98.9
Need for surgery (all HV cases)	119/1181	10.1	8.5 to 11.9
Reoccurrence (all HV cases: 6–31 months follow up)	40/266	15.0	11.2 to 19.8

'Success' is defined as the 'use only of a HV (with intercostal catheter) to manage the pneumothorax, that is, avoidance of larger ICT and/or surgery' with all studies having variable designs and management algorithms.
HV, Heimlich valve; PSP, primary spontaneous pneumothorax; SSP, secondary spontaneous pneumothorax.

Need for surgery

All but two studies[18 21] presented outcome data for patients requiring surgery for persistent pneumothorax. For all patients treated with HV, 119/1181 (10.1%) required surgical intervention, usually for persistent air leak. Protocol and methodological approach as to the appropriate timing and indication for surgery varied widely. One study from Korea reported a remarkably high requirement for surgery of 26/47 (55.3%)[33] with little explanation, although the use of suction was not commented upon.

Financial

Four studies reported healthcare economic utilisation, with data for three usable. One study[22] compared the use of HV in inpatients as compared with standard inpatient ICT and reported a cost ratio of 1:3. The same study examined the cost of NA versus inpatient ICT, and reported a cost ratio of 1:7. Two studies[27 33] compared the use of OP HV with inpatient ICT reporting cost ratios of 1:3.5 and 1:5.

Recurrence

Data on long-term recurrence of pneumothorax after HV treatment was presented in five studies. Reported recurrence rates varied between 11% and 24% with follow-up periods between 6 months and 31 months.[15 17 25 33] One study reported a recurrence rate after HV use of 7% with no follow-up period stated.[32]

Complications

Serious complications were rare, and no deaths were reported as a consequence of HV treatment. Table 3 presents a summary of data on complications.

DISCUSSION

This is the first systematic review to examine the evidence for the use of HV in the treatment of pneumothorax. Despite nearly 40 years of reports in the literature, quality evidence to support the use of HV for pneumothorax remains sparse with just one good-quality randomised controlled trial to accompany more than a thousand other reported cases. Despite mixed methodology and a high risk of reporting bias, there is enough data to support the notion that HV might be useful in the treatment of non-traumatic pneumothorax with reasonable treatment success on varied parameters in the studies assessed. This treatment has the potential for significant improvements in the treatment of pneumothorax, pending the results of well designed and conducted comparative studies.

The use of a HV attached to a secure intercostal catheter would potentially facilitate ambulatory treatment of pneumothorax and plausibly, in selected individuals' OP-based care. Indeed this management option has been attempted in the vast majority of cases we have identified, with reported success in 761/977 (77.9%; 95% CI 75.2 to 80.4). Strategy varied widely as to when a patient was discharged after initial placement of the ICT and HV. Nevertheless, given the young age group, minimal comorbidity and low mortality associated with PSP,[5] there is now persuasive evidence to support further research as to the usability and safety of this approach.

Table 3 Reported complications from all studies (n=1235)

Complication	n=
Death	0
Visceral puncture/injury	0
Haemothorax (all managed conservatively)	4
Incorrect connection—tension pneumothorax	1
Local cellulitis	1
Tube blockage with exudate	2
HV/catheter dislodged	8
Pain after insertion	1
Surgical emphysema	4

HV, Heimlich valve.

In cases where there was clear delineation between PSP and SSP, there appears to be similar success rates with the use of HV (PSP 344/413 (83.3%; 95% CI 79.4 to 86.6) and SSP (110/124 (88.7%; 95% CI 81.9 to 93.4)), although the likelihood of selection bias in SSP cases in particular is high, with more severe or sick cases likely not to be selected for this innovative treatment. IP appears to have a good success rate with a HV (reported as 97.5%; 95% CI 94.7 to 98.9), which again may be biased by selection, or that these patients usually improve well, anyway, as there is frequently no ongoing air leak.

Complications

In considering the case for the use of HV in the management of pneumothorax, it is important to consider the complications associated with their use; table 3 lists the significant complications reported from the studies. With consideration for likely marked limitations with bias and under-reporting, there are no deaths and no visceral punctures reported, with the most common problem appearing to be tube blockage or dislodgement. Despite the frequent use of larger drains in the older reports there were few reports of significant pain. These data should be compared with known complications with insertion of chest drains where more serious harm and pain is well recognised,[8] with a recent British Thoracic Society pleural procedures audit from the UK stating 25% of patients reported significant pain after insertion of a chest drain for pneumothorax.[35]

Recurrence and need for surgery

The indications for, and timing of, surgery in the management of SP remains controversial with little evidence base to support practice, and there was a wide spectrum of timing and indications in the studies examined for this review. The rates of those deemed to require surgery in this report (10.1%) are comparable with reports from randomised trials examining NA versus tube drainage for SP.[36–39] Similarly, long-term recurrence rates reported in the HV studies (15.0%, range 7–24%) are also similar to those reported elsewhere in the literature (22–29%).[36–39] It is important to note that the use and timing of surgery for management of SP is controversial, with Chee *et al* reporting on 115 patients with SP where 97% of PSP and 79% of SSP with persistent air leak resolved spontaneously with tube drainage alone, with no mortality in the groups.[40] Current guidelines suggest consideration of surgical referral with persistent air leak, or failure of lung re-expansion, at 3–5 days after presentation.[8]

Implications for healthcare resources

There is little reliable data from this review to confidently state a possible healthcare economic benefit from the use of HV to avoid hospital admission, although two studies suggest a benefit in favour of HV use compared with ICT as an inpatient.[27 33] In 2005/2006, hospital episode statistics report 5954 finished consultant episodes for PSP in England.[41] If half the attempts at treatment with NA are successful[8] this suggests that upwards of 3000 patients with PSP will be admitted for ICT each year, with a mean length of hospital stay of 5 days.[36 39] Assuming HV is successful in the treatment of pneumothorax in approximately 80% of cases, the adoption of this treatment could save nearly 12 000 bed days per year in England alone. A detailed economic analysis of healthcare utilisation of possible benefits should be integral to future prospective studies.

Limitations

Overall, the data quality for this systematic review is fairly poor, with a high risk of reporting bias and, therefore, interpretation of these results in this study should be guarded. After direct communication with the author seeking clarity with RCT design, just one report may be regarded as very good quality[20] although a prospective consecutive case series of 42 patients also provides useful data, albeit with no control group.[17] Both these reports present comparable outcome and safety data to the rest of the reports in this review.

SUMMARY

After 40 years of reports using HVs in the ambulatory care of SP, reliable, quality data are sparse. The use of HV in such circumstances may have benefits for patient comfort, mobility and avoidance of hospital admission, with comparable outcomes to current practice, although the current published literature cannot reliably inform this. There is an unmet need to examine the potential for ambulatory treatment of SP with high-quality RCTs required to provide reliable data on outcomes, health-related quality of life, total days hospitalised and pain scores to inform future management.

Contributors FJHB conceived the project, performed data collection, analysis, synthesis and manuscript preparation. NAM performed data collection, analysis and manuscript preparation.

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Competing interests FJHB has received reimbursement for travel expenses to medical conferences from Rocket Medical, and has worked on the advisory board for CareFusion. NAM has received research funding from Novartis and CareFusion, and has worked on the advisory board for CareFusion.

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AMBULATORY TREATMENTS AND THE USE OF HEIMLICH FLUTTER VALVES IN THE MANAGEMENT OF PNEUMOTHORAX - A SYSTEMATIC REVIEW OF THE LITERATURE

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1.0 ABSTRACT

International guidelines differ on the management of spontaneous pneumothorax. There is no agreed consensus and local and National practice differs widely.

The use of needle aspiration (NA) is well established in the treatment of spontaneous pneumothorax but the success rate varies in audits and clinical trails of between 30-80%. After NA, conventionally, the next step is usually to place an intercostal tube (ICT) which requires admission to hospital.

Heimlich valves (HV) offers a potential alternative to ICT by allowing the patient to remain ambulant and potentially be treated as an outpatient. Ambulatory care is an attractive option because it is likely to offer financial benefits, although this has not been reliably demonstrated.

This systematic review was conceived in order to comprehensively assess the evidence base for efficacy and safety in the use of HV in the treatment of pneumothorax.

2.0 INTRODUCTION

Pneumothorax is defined as the presence of air in the pleural space[1]. It was first described by Itard in 1803 and treatment with needle aspiration then described by Bell in 1804[2]. Spontaneous pneumothorax (SP) is broken down into primary (PSP: no known underlying lung disease), secondary (SSP: known lung disease) and non-spontaneous from trauma or iatrogenic (IP: most commonly from subclavian vein catheterisation and transthoracic biopsy[3]). In the USA, the incidence of PSP presenting to hospital is 7.4/ 100,000 for males and 1.2/100,000 for females per year, and for SSP 6.3/100,000 (males) and 2.0/100,000 (females) per year[4]. In the UK between 1950-1997 the incidence of SP (PSP and SSP combined) in those presenting to hospital was 16.7/100,000 for males and 5.8/100,000 for females per year[5]. When combined with new presentations to primary care, the rates rise to 40.7 (men) and 15.6 (women) per 100,000 per year[5]. SP classically affects males more than females (ratio 2.5:1)[5,6] and those with 'ectomorphic' body habitus[1]. PSP carries a very low mortality with most cases of death from SP occurring above the age of 55 years[5], suggesting that the majority of these cases are likely to have SSP with underlying lung disease. The underlying pathological cause of SP is likely to be the rupture of small bullae or blebs (so called 'emphysema like changes') on the pleural surface, which allows egress of air from the lung into the pleural space[7].

Despite recognition of pneumothorax for more than 200 years there still remains significant controversy and a wide variation in treatment both Nationally and Internationally[8-11]. The poor consensus in recommended management of SP is highlighted by the two leading International guidelines (the American College of Chest Physicians Delphi consensus statement from 2001[12] and British Thoracic Society guidelines 2010[8]) contrasting sharply in many aspects of proposed treatment. These two International bodies do not even agree on a definition of size of pneumothorax - although many experts increasingly argue that treatment options for PSP should concentrate more on patient-orientated aspects such as symptoms, rather than chest X-ray appearances[9]. The lack of clear consensus in treatment likely contributes to both the poor adherence to guidelines and wide variations in practice that are observed worldwide.

Conventionally, the recognised treatment options for SP include a conservative approach (i.e. observation alone) for small SP, needle aspiration (NA) of air from the pleural cavity, or placement of an intercostal chest tube (ICT) connected to an under water seal[8,12]. Persistent air leak can be managed with the use of an ICT with under water seal connected to suction (a practice with little evidence base) and, after prolonged air leak, surgery to repair or resect the damaged lung followed often by pleurodesis (the iatrogenic induction of pleural fibrosis) is advocated[8,12]. NA alone has been demonstrated to carry a highly variable success rate of 30-80%[8], after NA failure, with current accepted approaches, admission for inpatient treatment is required for persistent pneumothorax.

Ambulatory management of a range of diseases is desirable not least for the financial implications for health care institutions of inpatient bed-days saved. The treatment of SP, and in particular PSP would lend itself well to outpatient-orientated management; patients are generally young, with few or no comorbidities and the condition itself caries a low morbidity and mortality[5]. This is not a new concept, with reports in the literature dating back to 1975[13] advocating the use of a Heimlich flutter

valve (HV: a lightweight one way valve specifically designed for the ambulatory treatment of pneumothorax[14]) attached to an intercostal catheter with patients managed out of hospital. This approach is very attractive to patients as it does not involve connection to a drain bottle, and thus encourages mobility and ability to more comfortably perform common activities of daily living[15,16].

This systematic review is designed to concisely assess the published literature to examine the evidence for the use of Heimlich valves in the management of adults with pneumothorax as compared to conventional approaches and, furthermore, to establish if such management can be safely and effectively performed in an outpatient environment.

3.0 AIMS & OBJECTIVES

The aim of this systematic review is to comprehensively assess the available evidence base for the use of Heimlich valves in the management of pneumothorax.

4.0 METHODS FOR SYSTEMATIC REVIEW

4.1 Eligibility of studies

Studies will be considered for inclusion with the following criteria:

Population:	Patients with spontaneous pneumothorax (including primary, secondary, iatrogenic)
Intervention:	Conservative, needle aspiration, intercostal chest tube (ICT), catheter and Heimlich valve (HV).
Comparator:	Any one of the above
Outcome:	An assessment of the efficacy / success of the treatment modality
Study:	Randomised controlled trials, case control study, case series
Years:	Unrestricted
Language:	English (full text)
Exclusions:	Letters, post thoracic surgery, traumatic pneumothorax;

4.2 Sources of information

The literature search strategy will include several data sources unrestricted by years of publication although the full text of the study must be in English. The literature search will include the following

electronic (online) databases: Cochrane Library (including the Cochrane Central Register of Controlled Trials (CENTRAL), Cochrane Databases of Systematic Reviews (CDSR), Database of Abstracts of Reviews of Effects (DARE), Heath Technology Assessment (HTA) database, NHS Economic Evaluation database (EED)), Medline (through Pubmed interface), Embase, and Web of Science. Additionally, textbooks and reference lists from the studies identified will be scrutinised. Online clinical trials sites such as clinicaltrials.gov will also be scrutinised.

4.3 Search strategy

The search strategy will include some or all of the terms detailed below. Investigators will adapt and refine the search according to the search results.

Mesh terms:	"Pneumothorax", “Ambulatory Care", “drainage”, “thoracic drainage”, “catheters”, “catheterisation”, “aspiration”, “needle(s)”, “manual”, “simple”, “spontaneous”
Additional terms	“heimlich valve” (all fields)
Publication type:	"Randomized Controlled Trial”, clinical trail”, “comparative study”, “evaluation”, “case report”
Excluding:	Mesh terms - “thoracic surgery”, “thoracic Surgery”

FJB and NAM will perform independent searches and compare findings.

4.4 Study selection – process

The selection process will include: screening and assessment of the of title, abstract, then full report if applicable. FJB and NAM will perform independent assessments of the eligibility of the studies. Conflict will be dealt with by discussion and agreement; if required an independent third party will mediate.

4.5 Data collection process

Data will be placed on to a bespoke database (Microsoft Excel 2010, Microsoft Corp, USA).

4.6 Data items – variables sought

Confirmation of type of pneumothorax (with breakdown if possible: PSP / SSP/ IP), exclude trauma, post surgical

Intervention type(s) - Conservative, needle aspiration, intercostal chest tube, catheter and Heimlich valve.

Any control / comparator measures

Outcomes reported – for each intervention as appropriate. Per section XXXX

Study type (RCT / case series / case report)

Funding sources

Assumptions / simplifications

4.7 Risk of bias in individual studies – study or outcome

This will be assessed on individual study basis taking into account the study design, internal validity, population sample, interventions assessed, outcomes and generalizability of the findings.

4.8 Synthesis of results – method of data handling

Where possible an overall assessment of 'success' with Conservative / NA / HV / ICT will be made. This will likely involve a composite endpoint owing to multiple reported outcomes measures and assessments .

4.9 Risk of bias across studies – may affect the cumulative evidence

If an appropriate number of eligible studies can be identified (~>10) we will create a funnel plot and perform Chi square analysis to assess the degree of any bias present.

5.0 SUMMARY OUTCOME MEASURES

4.1 Primary Outcome:

(a) Use only of the HV device to manage the pneumothorax, i.e. avoidance of ICT and/or surgery

4.2 Additional analyses (**s**econdary outcomes)

(b) use of the HV device to facilitate only *outpatient based* treatment,

(c) Recurrence rate and numbers undergoing surgery

(d) financial assessment

(e) Reported complications – 'serious' complication defined by the following, death or serious injury, need for hospital admission, or prolonged admission, lasting disability.

6.0 STUDY ADMINISTRATION

6.1 Research ethics approval

As this study does not deal directly with patients, patient's confidential information or data there is no requirement for ethics approval.

6.2 Financial support

No financial support is required for this study. Time spent by investigators will be as part of dedicated research sessions from respective host institutions.

7.0 DISSEMINATION OF FINDINGS

The results of this study will be submitted to a high impact medical journal for publication, with abstracts submitted for national and international respiratory meetings as appropriate.

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