# 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.

## 8.0 REFERENCES

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