Clinical evidence compendium

For managing recurrent pleural effusion or malignant ascites

A summary of the clinical evidence supporting the use of indwelling pleural and peritoneal catheter (IPC) systems

BD

Dear Reader,

Every day, patients with recurrent pleural effusion or malignant ascites need drainage. This aims to relieve associated symptoms and to significantly enhance the patient's quality of life. Treatment should provide safe, effective management and avoid severe complications, such as infection, blockage and catheter failure.

Becton, Dickinson and Company (BD) is committed to continuing the advancement of palliative options for patients with pleural effusion and malignant ascites. Since 1997, the PleurX™ catheter system has offered compassionate care to more than 400,000 patients with pleural effusion and malignant ascites in over 50 countries. It has been studied in more than 50 clinical articles, and referenced in more than 35 peer-reviewed journal articles. The PleurX catheter system is a clinically proven solution to palliate this fragile patient population.

This summary was compiled to facilitate the reader in accessing the literature pertinent to the use of the indwelling pleural and peritoneal catheter (IPC) in both the pleural and peritoneal space. All studies in this compendium were found via a literature search and the summaries are provided as a courtesy to you, the reader.

All information in this summary was current as of September 26, 2017 and BD is not liable for any inaccuracies therein.

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This compendium contains highlights from the clinical papers listed below.

Please contact your local BD representative should you require any more information or if you have any questions regarding the compendium or PleurX catheter.

Managing pleural effusion

Managing malignant ascites

Identification of clinical factors predicting PleurX catheter removal in patients treated for malignant pleural effusion

Study author(s)

William H. Warren, Anthony W. Kim and Michael J. Liptay

Publication

Eur J Cardiothorac Surg 2008
DOI: 10.1016/j.ejcts.2007.10.002

Study design (level of evidence)

Case-controlled study

Study location

United States

Study objective

To identify the clinical predictors of catheter removability after spontaneous pleurodesis

Study length

8 years

Study protocol

- Retrospective review of patient records
- Patients were assigned to one of four groups based on primary neoplasm site
- Assessed clinical parameters' influence on catheter removability after spontaneous pleurodesis

Patient population

263 patients with malignant pleural effusion

Study limitations

- Sample sizes vary considerably between groups
- Study spanned 8 years – results do not account for refinements to the catheter insertion procedure

Part of CF03451. Issue 1 Sept 2017.

Study findings

59% of catheters (n=173) were removed after achieving spontaneous pleurodesis

– 70% spontaneous pleurodesis rate among patients with breast and gynaecological cancer

<2% infection rate **<4%** catheter blockage rate

29 days mean catheter indwelling time to achieve spontaneous pleurodesis

Predictors of catheter removability:

– breast or gynaecological cancer

– pleural fluid malignancy

– no trapped lung

Key points

Successful spontaneous pleurodesis resulted in catheter removal for most catheter insertions

PleurX catheters were extremely well tolerated with very low levels of infection and catheter blockage

Patients preferred to keep the catheter in than to risk fluid re-accumulation, emphasising its excellent tolerability

The catheter palliates patients with trapped lung or persistent pleural fluid accumulation, where alternative treatments are likely to fail

Study conclusions

PleurX catheters alleviate unpleasant symptoms of malignant pleural effusion, with few complications

Patients with malignant pleural effusion commonly achieve spontaneous pleurodesis with the PleurX catheter

Single-center experience with 250 tunnelled pleural catheter insertions for malignant pleural effusion

Study author(s)
Alain Tremblay and Gaëtane Michaud

Publication
CHEST 2006
DOI: 10.1378/chest.129.2.362

Study design (level of evidence)
Case-controlled study

Study location
Canada

Study objective
To describe the use of the PleurX catheter for managing dyspnoea in malignant pleural effusion in a large group of patients

Study length
3 years

Study protocol
- A monocentric, retrospective analysis of sequential tunnelled pleural catheter insertions
- All patients underwent tunnelled pleural catheter (PleurX) insertion

Patient population
223 patients with malignant pleural effusion

Study limitations
- Results need to be confirmed in a multicentric study
- Lack of symptom control studies makes comparing the research difficult

Part of CF03451. Issue 1 Sept 2017.

Study findings

96% symptom relief at 2-week follow-up

144 days median overall survival time after insertion

89% catheter insertions achieved symptom control (n=222)

- 39% achieved complete symptom control (n=97)
- 50% achieved partial symptom control (n=125)
- 4% achieved no symptom control (n=9)

4% of catheter insertion procedures failed (n=10)

43% insertions achieved spontaneous pleurodesis (n=103)

90% of successful insertions needed no repeat procedures

56 days mean catheter indwelling time

8% of patients had symptomatic loculations (n=21)

4% of patients had asymptomatic loculations (n=10)

Key points

Long-lasting spontaneous pleurodesis in most patients, repeat procedures were rarely required

The PleurX catheter successfully palliates malignant pleural effusion and facilitates outpatient management

Almost all patients reported symptom relief 2 weeks after insertion

Low rates of procedure failure, complications and infections

Study conclusions

Patients had an overall median catheter indwelling time of 144 days, with low complication rates

The PleurX catheter should be considered as first-line treatment for patients with symptomatic malignant pleural effusion and dyspnoea

Management of malignant pleural effusions using the PleurX catheter

Study author(s)

William H. Warren, Robert Kalimi, Lisa M. Khodadadian and Anthony W. Kim

Publication

Ann Thorac Surg 2008
DOI: 10.1016/j.athoracsur.2007.11.039

Study design (level of evidence)

Case-controlled study

Study location

United States

Study objective

To investigate the efficacy of the PleurX catheter in palliating patients with malignant pleural effusion

Study length

5 years

Study protocol

- Monocentric, retrospective review of medical records
- Patients had indwelling tunnelled pleural catheters (PleurX) inserted

Patient population

202 patients with malignant pleural effusion

Study limitations

- Single-center study with no randomisation
- The efficacy of the PleurX catheter was not compared with any other treatment for malignant pleural effusion

Part of CF03451. Issue 1 Sept 2017.

Study findings

100% success rate in palliating patients' symptoms

0 complications during catheter insertion

21% of patients (at least) asked to keep their catheter in even after drainage had subsided

<2% infection rate and <5% blockage rate

4% fluid re-accumulation rate after catheter removal (n=5)

97% patient compliance with drainage schedule (n=196)

Infection was less common in patients with breast and gynaecological cancer compared with other cancers

Catheter indwelling time >100 days was most common in patients with trapped lung (p=0.001)

Key points

Extremely high patient compliance with drainage schedule and acceptance of the PleurX catheter

The PleurX catheter provided comfort and long-term control of malignant pleural effusion, with few complications

The PleurX catheter enables outpatient management of malignant pleural effusion, unlike many alternatives

60% catheter removal with very low rate of fluid re-accumulation, even in patients with trapped lung

Study conclusion

PleurX catheters effectively palliate patients with malignant pleural effusion on an outpatient basis with high compliance and favourability among patients

Phase III intergroup study of talc poudrage vs talc slurry sclerosis for malignant pleural effusion

Study author(s)

Carolyn M. Dresler, Jemi Olak, James E. Herndon, *et al.*

Publication

CHEST 2005
DOI: 10.1378/chest.127.3.909

Study design (level of evidence)

Randomised control trial

Study location

France

Study objective

To demonstrate the efficacy, safety and appropriate delivery method of talc for sclerosis in treating malignant pleural effusion

Study length

4 years

Study protocol

- Prospective, randomised trial
- Patients received either talc poudrage (insufflation) or talc slurry
- Primary endpoint: percentage of patients whose lung initially re-expanded >90% and who had a successful pleurodesis at 30 days after treatment
- Secondary endpoints: time to effusion recurrence, complications and toxicity frequency, and lung re-expansion ability

Patient population

501 patients with malignant pleural effusion

Study limitations

- Previous studies had a smaller sample size and often defined effusion 'recurrence' differently
- Variable follow-up period
- Further work is needed to define the aetiology and risk of respiratory failure due to talc instillation

Part of CF03451. Issue 1 Sept 2017.

Study findings

78% success rate using talc insufflation

71% success rate using talc slurry

Talc insufflation was significantly more successful than talc slurry in patients with >90% lung re-expansion before treatment (67% *vs* 56%; p=0.045)

4% treatment-related death rate for both talc insufflation and slurry

No significant difference in talc delivery efficiency between talc insufflation and talc slurry among all treated patients (p=0.169)

Patients who had talc insufflation more commonly experienced respiratory complications and failure (p=0.007)

Insufflation gave more comfort (p=0.019), medical safety (p=0.013), and pain relief (p=0.07) than slurry

Groups had similar time for recurrence of effusion

Key points

Pleurodesis rates for talc insufflation and slurry are lower than previously reported trials

Causes of treatment-related death and severe respiratory complications were unpredictable

Similar 30-day success rates between talc delivery methods

Talc slurry is simpler, less invasive and lower risk than talc insufflation

Study conclusions

Efficacy for both talc insufflation and talc slurry were lower than previously reported

For patients with lung or breast cancer, talc insufflation was better than talc slurry at preventing recurrence of malignant pleural effusion

Talc pleurodesis through indwelling pleural catheters for malignant pleural effusions: retrospective case series of a novel clinical pathway

Study author(s)

Liju Ahmed, Hugh Ip Deepak Rao, Nishil Patel and Farinaz Noorzad

Publication

CHEST 2014
DOI: 10.1378/chest.14-0394

Study design (level of evidence)

Case-controlled study

Study location

United Kingdom

Study objective

To examine safety and efficacy data of patients with malignant pleural effusion undergoing talc pleurodesis through the PleurX catheter

Study length

2 years

Study protocol

Monocentric, retrospective review of safety and efficacy from patient records

Patient population

24 patients with a malignant pleural effusion

Study limitations

- Monocentric study with a small sample size and no control group
- No objective records of symptom improvement because of retrospective study design
- Inconsistent timings of pleurodesis assessment
- Results need to be confirmed in a multicentric study

Part of CF03451. Issue 1 Sept 2017.

Study findings

92% of patients achieved successful pleurodesis (n=22)

92% of patients had the catheter inserted on an outpatient basis (n=22) and **100%** of these patients were successfully discharged the same day

21% overall complications rate (n=5)

13% major complications rate (n=3)

– Major complications: hydropneumothorax, empyema and recurrent effusion

Key points

The PleurX catheter allows long-term drainage for patients with trapped lung, where talc pleurodesis usually fails

Complications with the PleurX catheter were rare, with no blockages following talc instillation

Giving talc slurry through the PleurX catheter is safe and effective in an outpatient setting

PleurX catheter insertion requires no hospital admission

Study conclusion

Unlike most chest drain procedures, talc pleurodesis through the PleurX catheter enables safe and effective management of malignant pleural effusion in an outpatient setting

Indwelling tunneled pleural catheters for management of hepatic hydrothorax. A pilot study

Study author(s)

Alexander Chen, Jennifer Massoni, Diana Jung and Jeffery Crippin

Publication

Ann Am Thorac Soc 2016
DOI: 10.1513/AnnalsATS.201510-688BC

Study design (level of evidence)

Cohort study

Study location

United States

Study objective

To evaluate the feasibility of using the indwelling tunnelled pleural catheter to mange hepatic hydrothorax

Study length

6 weeks

Study protocol

- Monocentric, prospective feasibility study
- Patients had indwelling tunnelled pleural catheters (PleurX) inserted

Patient population

24 patients who were candidates for liver transplantation

Study limitations

- Small sample size as hepatic hydrothorax among patients with cirrhosis is rare

Part of CF03451. Issue 1 Sept 2017.

Study findings

33% of patients (n=8) achieved spontaneous pleurodesis with no fluid re-accumulation, in a mean time of 132 days

100% of PleurX catheters were successfully removed without re-accumulation of pleural fluid

0 patients required further drainage procedures after removal

17% (n=4) had pleural fluid infection

- 3 patients needed their catheter removed because of pleural fluid infection
- No patients had catheter-site cellulitis

Key points

Indwelling pleural catheters successfully controlled the symptoms of hepatic hydrothorax in patients awaiting liver transplantation

Similar spontaneous pleurodesis rates in catheters inserted for hepatic hydrothorax and malignant pleural effusion, but infection rate may be higher

Study conclusion

The PleurX indwelling tunnelled pleural catheter may be successfully and safely used in patients with benign pleural effusion to control hepatic hydrothorax

Management of malignant pleural effusion: a cost-utility analysis

Study author(s)

Majid Shafiq, Kevin D. Frick, Hans Lee, *et al.*

Publication

J Broncho Interv Pulmonol 2015
DOI: 10.1097/LBR.0000000000000192

Study design (level of evidence)

Systematic review

Study location

United States

Study objective

To perform a cost–utility analysis of different interventions for managing malignant pleural effusion

Study length

Not applicable

Study protocol

- A cost–utility analysis combining current published findings with data from the US Federal Health insurance Program (Medicare)
- Incremental cost-effectiveness ratios were determined over 6 months for five interventions: tunnelled pleural catheters, repeated thoracentesis, talc slurry, talc poudrage and rapid pleurodesis protocol

Patient population

Adults with malignant pleural effusion and had undergone therapeutic thoracentesis

Study limitations

- This model assumes patients are being treated in an outpatient setting
- The analysis is based on population averages, and so may not apply to individual patients

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Study findings

A tunnelled pleural catheter had an incremental cost-effectiveness ratio of **$45,747** per quality-adjusted life-year over repeated thoracentesis

Repeated thoracentesis was the least effective intervention

Rapid pleurodesis protocol was not cost-effective

Talc pleurodesis was the most expensive intervention, but was no more effective

Key points

The tunnelled pleural catheter is the most cost-effective treatment for malignant pleural effusion

Study conclusions

The tunnelled pleural catheter is the most cost-effective and convenient procedure in patients with malignant pleural effusion

The tunnelled pleural catheter is the intervention of choice for patients with malignant pleural effusion and an expected survival of around 6 months

Prospective evaluation of the PleurX catheter when used to treat recurrent ascites associated with malignancy

Study author(s)

Angi Courtney, Albert A Nemcek Jr, Stefanie Rosenberg, *et al.*

Publication

J Vasc Interv Radiol 2008
DOI: 10.1016/j.jvir.2008.09.002

Study design (level of evidence)

Cohort study

Study location

United States

Study objective

To assess safety and quality of life (QoL) outcomes with the PleurX catheter when managing recurrent ascites in patients with advanced abdominal ascites

Study length

1 year

Study protocol

- Multicentric, prospective study
- Patients underwent drainage sessions with the PleurX catheter
- Assessed QoL using the Memorial Symptom Assessment Survey and Subjective Significance Questionnaire

Patient population

34 patients with non-hepatic abdominal ascites

Study limitations

- Small sample size
- Limited ascites-specific instruments for measuring QoL
- The study excluded subjects with cirrhosis, so cannot be generalised to all patients with malignant ascites

Part of CF03451. Issue 1 Sept 2017.

Study findings

100% success rate for catheter insertions without procedural complications

85% of patients experienced no catheter failures (n=29)

Significantly reduced bloating and abdominal discomfort from baseline in patients at 2 and 8 weeks ($p<0.05$)

83–100% of patients said their ascites was well controlled each week

No procedure-related deaths

56% of patients reported improved QoL 1 week after insertion

15% of patients experienced catheter failure (n=5), of which 9% of patients (n=3) had interventions

The most common adverse event was ascites leakage (21%), but the leak reduced as the tunnel matured

Key points

The PleurX catheter successfully treats recurrent malignant ascites without significant rates of complication, failure or discomfort

The PleurX catheter relieves symptoms and improves QoL for patients with end-stage malignancy

The catheter offers an alternative to percutaneous peritoneal venous shunting

Study conclusions

The PleurX catheter relieves malignant ascites-related discomfort and symptoms

The PleurX catheter has low rates of serious adverse clinical events and catheter failure

Tunneled peritoneal drainage catheter placement for refractory ascites: single-center experience in 188 patients

Study author(s)

Matthew P. Lungren, Charles Y. Kim, Jessica K. Stewart, *et al.*

Publication

J Vasc Interv Radiol 2013
DOI: 10.1016/j.jvir.2013.05.042

Study design (level of evidence)

Case-controlled study

Study location

United States

Study objectives

To assess the safety and success of the PleurX catheter for managing refectory ascites

Study length

6.5 years

Study protocol

- Large, monocentric, retrospective review of medical records
- Patients had tunnelled peritoneal drainage catheters (PleurX) inserted

Patient population

188 consecutive patients with refractory ascites

Study limitations

- This study is a retrospective analysis of a relatively small patient population
- The catheter survival days may have been underestimated in 6% of patients whose death could not be determined
- No standardised grading to determine quality of life improvement

Part of CF03451. Issue 1 Sept 2017.

Study findings

100% success rate for catheter insertions

Patients had the catheter inserted for up to **796 days** (~2 years, 2 months)

0.3 complications per year

7.3% of catheter insertions had complications

No procedure-related deaths or major complications occurred

60 days mean catheter survival

Pancreatic cancer predicted catheter malfunction (p=0.007)

Key points

The PleurX catheter successfully managed refractory ascites

The PleurX catheter had very low rates of catheter malfunction (2.5%)

Cellulitis and peritonitis was rare among patients

Study conclusion

Patients with refractory ascites who were treated with the PleurX peritoneal catheter underwent successful insertion and had few complications

PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites: a NICE Medical Technology Guidance

Study author(s)

Judith White and Grace Carolan-Rees

Publication

Appl Health Econ Health Policy 2012
DOI: 10.2165/11634720-000000000-00000

Study design (level of evidence)

Guideline

Study location

United Kingdom

Study objective

To compare the cost-effectiveness of the indwelling PleurX peritoneal catheter drainage system with large-volume paracentesis in patients with treatment-resistant, recurrent malignant ascites

Study length

Not applicable

Methodology (cost analysis)

- Evaluated costs per patient
- Compared costs and patient impact of catheter use in the community setting with that of inpatient and outpatient large-volume paracentesis

Patient population

Patients with treatment-resistant, recurrent malignant ascites

Study limitations

- This evidence is based on observational studies, and there is currently very limited data available comparing the PleurX peritoneal catheter drainage system with other interventions

Study findings

The PleurX peritoneal catheter and drainage system is more cost effective than inpatient large-volume paracentesis:

- Estimated cost per patient for PleurX is £2,466 compared with £3,146 for inpatient large-volume paracentesis and £1,457 for outpatient large-volume paracentesis
- PleurX peritoneal catheter saves around

  £679 per patient compared with inpatient large-volume paracentesis
- Cost savings associated with the PleurX peritoneal catheter drainage system depend heavily on reducing hospital stay

NICE recommendations

The PleurX peritoneal catheter drainage system should be considered for patients with treatment-resistant, recurrent malignant ascites

Enables early and frequent treatment in the community, reducing treatment waiting times

The clinical evidence suggests that the PleurX peritoneal catheter drainage system:

- is clinically effective with a low complication rate
- could improve quality of life
- enables early and frequent treatment in the community, reducing treatment waiting times

Study conclusions

NICE concluded that the PleurX peritoneal catheter drainage system may improve quality of life, and is a clinically safe and effective palliative therapy for treatment-resistant, recurrent malignant ascites

Switching from inpatient large-volume paracentesis to the PleurX peritoneal catheter saves around £679

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