Clinical Management of Malignant Ascites and Pleural Effusions

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Objectives

- Review pathophysiology of malignant ascites and pleural effusions.
- Discuss various treatment options for malignant ascites and pleural effusions with attention to benefits and limitations.
- Identify appropriate candidates for the PleurX catheter, both for use in the peritoneum and in the pleural space.

Peritoneal Anatomy

- Normally, less than 50ml of peritoneal fluid
- Fluid exchange rate of 500ml/hour
- Low protein
- Lubricates organs

Pathogenesis of Malignant Ascites

Enck, Am J Hosp Palliat Care 2002;19:7-8
Causes of Malignant Ascites

- Over 80% Caused By:
  - Ovarian
  - Pancreatic
  - Colon
  - Uterine
  - Breast
  - Lung
  - Lymphoma
  - Other GI tract
  - Tumor of unknown primary

Malignant Ascites

- Symptoms
  - Pressure/discomfort
  - Early satiety
  - Dyspnea
  - Nausea/vomiting
  - Limited mobility
  - Lower extremity edema

Prognosis

- GI malignancy + ascites
  Median survival = 1-4 months
- Ovarian primary + ascites
  Median survival >300 days

CT/US Images

- Ascites

Treatment Options

- Repeat large volume paracentesis (LVP)
- Peritoneal drainage catheters (pigtail catheters)
- Peritoneovenous shunts
- Subcutaneous ports
- Tunneled catheters (PleurX®)

Large Volume Paracentesis

- Temporary solution
- Multiple needle sticks
- Can develop loculations
- Frequent trips to the hospital
- Resource utilization
- Generally safe
  (avoid epigastric vessels)
Non-Tunneled Drains

Pigtail catheters
- Complication rates up to 35%
- Patient continuously connected to drainage bag
- Reserve for patients with short life expectancy (weeks)

Tunneled Ports

- Subcutaneous
- Several disadvantages:
  - high rates of infection
  - requires nursing support
  - painful access
  - obstruction

Peritoneovenous Shunts

Advantages:
- retention of protein-rich fluid
- no external drainage devices
Disadvantages:
- blockage
- thrombosis
- pulmonary edema
- seroma formation
- leakage
- DIC
- pulmonary tumor embolus

Tunneled Catheter

- PleurX® Catheter
- FDA approved for malignant ascites and pleural effusions
- 15.5 French, 66 cm silicone catheter
- One way valve

PleurX®

- Drainage by patient, family member or caregiver
- Short learning curve
- Spend more time at home -- less at the hospital
- Patient in control
- Not connected to bottle unless draining/not gravity dependent
- Insurance pre-authorization for supplies
- Supplies mailed to patient’s home

Patient Selection for the PleurX® Catheter

- Does patient get symptom relief with paracentesis?
- Loculated ascites?
- Is chemotherapy likely to resolve ascites?
- Life expectancy of patient?
- Family support?
- Hospice bound?
Hospice Set-Up

- $100/day for DRE
- Drainage line and cap
- Portable suction device -- included in daily costs

PleurX® Catheter

- Case History
  - 51 year old woman with ovarian cancer
  - 121 total LVP (4–6 liters per LVP) in 10 months
  - APD drain placed—peritonitis within one week
  - PleurX catheter placed: no further need for LVP or other catheters until death 4 months later

Pleural Physiology

- Normally 5-20 mL fluid
- Fluid passes thru visceral and parietal pleura at a rate of 5 to 10 L/day
- Relatively protein-free
- Reabsorbed by lymphatic drainage

Hausheer & Yarbro, Semin Oncol 1995; 12:74–75

Pleural Effusions

- Transudative
  - Accumulation of proteinaceous material in pleural space
  - Causes: Pneumonia, Malignancy, PE
- Exudative
  - Imbalance between oncotic and hydrostatic pressures
  - Causes: CHF (90%), Cirrhosis, Nephrotic Syndrome

Transudative v.s. Exudative

- Dx Thoracentesis:
  - LDH, Protein, pH, Gram Stain/Cx & Cell Count, +/- cytology
- Light’s Original Criteria- Exudative
  - Protein fluid:serum > 0.5,
  - LDH fluid:serum > 0.6, or
  - Fluid LDH > 2/3 upper limit of serum normal

Malignant Pleural Effusion Pathophysiology

- Multiple causes
- Most important for MPE:
  - Lymphatic drainage blocked by tumor cells
  - Pleural metastases (increased oncotic pressure of pleural fluid)

Causes of Malignant Pleural Effusions:

- Lung 17-56%
- Breast 15-38%
- Lymphoma/Leukemia 6-17%
- Ovarian 7-16%
- Gastric Carcinomas 3-6%

- 2/3 found in women due to breast and gynecologic malignancies


Clinical Aspects

- Dyspnea (>1/2 of patients)
- Pain (usually dull)
- Cough
- Generalized systemic symptoms
  - Malaise, anorexia, fatigue

Pleural Effusion

Characteristics of Fluid

- Malignant Pleural Effusions
  - Often bloody
- Chylothorax suggests mediastinal nodal involvement


Prognosis

- Average survival time 3 to 6 months
- Mortality 54% at 1 month
  - 84% at 6 months
- 9.6 months in patients whose malignant effusion first sign of cancer

Management Options

Control of pleural effusion-things to consider:
- Palliative goals
- Patient condition/prognosis
- Risk/likely benefit
- Longer survival expectancy may warrant more aggressive therapy
- Patient preferences

Treatment Options

- Therapeutic thoracentesis
- Chest tube alone
- Chest tube with chemical pleurodesis or talc slurry
- VATS with talc poudrage
- Tunneled catheter (PleurX®)

Therapeutic Thoracentesis

- Diagnostic
- Does patient get relief?
- Does lung re-expand?
- Drawbacks:
  - loculations
  - multiple needle passes
  - exposure to CXR
  - potential pneumothorax
  - thoracentesis alone has 97% recurrence rate at one month

Chest Tube Drainage Alone

- Pleural fluid drained via large French chest tube
- Requires hospital stay for up to a week
- Painful
- Patient less mobile
- Fluid typically comes back
- Remove tube when drainage less than 30-50cc/day

Chest Tube with Pleurodesis

Goal:
- Approximation of visceral and parietal pleural surfaces
- Introduction of sclerosing agent
  - inflammation (pleuritis)
  - fibrosis

Pleurodesis

- Done via large surgically placed chest tube or 16 Fr tube placed by IR
- Chemical pleurodesis (painful)
  - Bleomycin (60 U in 100ml NS)
  - Doxycycline (500 mg in 100ml NS)
- Talc slurry (fevers)
- Hospital stay

Hausheer & Yarbro, Semin Oncol 1985; 12:54-75
**VATS**

- Video Assisted Thoracoscopic Surgery
- Advantages:
  - Excellent distribution of agent
  - Mechanical abrasion
  - Can lyse adhesions
  - Obtain biopsy
- Disadvantages:
  - Must have healthy patient
  - Hospitalization
  - GA

**Tunneled Catheter**

- i.e. PleurX and Aspira
- Palliation of dyspnea
- Auto-pleurodesis
- Placed under moderate sedation
- Easily done as an outpatient
- Patients are able to drain at home

**Patient Selection for the PleurX®**

- Relief of symptoms with thoracentesis?
- How long since last tap?
- Multiple loculations?
- “Trapped lung”
- VATS or talc pleurodesis in the past?
- Family support?

**PleurX® loculation**

- One-way valve
- Accessed with a special tip that is attached to the drain-line

**Catheter Management**

- The patient or caregiver will use these vacuum bottles to drain the pleural effusion.

- The cap is placed on the valve to keep the access point sterile.
Steps to PleurX® Approval

Patient Good Candidate for PleurX?

Fax Insurance form to Cardinal Health. Allow 3-5 business days.

Cardinal Health obtains insurance approval. Communicates cost to referring MD.

Schedule procedure once approved.

Your Practice Needs A Champion!

- Truly successful programs have a point person
- Patient selection
- Insurance pre-approval for supplies
- Trouble shooting
- Communication with referring MDs
- Patient advocate
- MDs are too busy
- Need a mid-level provider or a nurse to be the champion!

Patient Education

- Ideally, have patient view video prior to procedure
- Family needs to be present
- Demonstrate, then have family member practice
- Discharge instructions
- Video to take home

Patient Education

- Clean procedure -- not sterile
- Positive reinforcement
- Contact person for issues -- including after hours/weekends

Discharge Instructions

- Pleural
  - 1 Liter max/day
  - Less than 30-50 cc for 3 consecutive drainages, contact MD
  - Keep dry
  - No soaking in bathtub, hot tub, swimming

- Peritoneal
  - 2 Liters max/day
  - Less than 100cc for 3 consecutive drainages, contact MD

Pearls

- Ascites leak
  - Insert medial and superior
  - Frequent dressing changes to keep dry
  - Drain 2L/day

Drawing courtesy S Rosenberg, PA-C
Pearls

- Occlusion
  - tPA (4-6cc/20cc NS)
  - Wire manipulation
  - Order CT - look for tumor, fenestrations, fluid volume

Safety and Effectiveness of the PleurX® Catheter When Used to Treat Malignant Ascites

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Materials and Methods

- PleurX pleural fluid and ascites
  - 15.5 Fr, 66 cm fenestrated, silicone catheter with one-way valve and polyester cuff
  - Investigational device had longer non-fenestrated (subcutaneous) portion

Objectives

- Primary:
  - Determine length of time the PleurX® system can function in patients with malignant ascites.

- Secondary:
  - Measure the degree of symptom relief.
  - Assess usability in the home care setting.
  - Measure complication frequency.
Materials and Methods

• Study Design
  • Multicenter, prospective, observational single-arm
  • Inclusion criteria:
    2 or more paracenteses within 30 days
    Malignancy with abdominal involvement
  • Exclusion criteria:
    ESRD on dialysis
    Non-malignant hepatic or nephrotic disease
    Responsive to treatment of the primary malignancy
    Peritoneal infection or loculation
    Peritoneal chemotherapy or immunotherapy
    Intra-abdominal radiation therapy

Timeline of Protocol

Day 2-3: Supervised drainage
Week 1: Phone fu SSQ

Week 2: Clinic, MSAS, SSQ
Week 3-7: Weekly phone fu

Week 8: Clinic, MSAS, SSQ
Week 9-11: Weekly phone fu
Week 12: Clinic, Labs, MSAS, SSQ

Materials and Methods

• Study Group
  • 36 patients initially consented
  • 34 received device
  • Placement in IR
  • Antibiotics in majority
  • Local anesthesia (Lidocaine) and/or moderate sedation
    (Fentanyl and Versed) in all

Results

DEMOGRAPHICS:
Age 64.3 years (40-81)
Gender 13 males (38%), 21 females (62%)
Cytology 11/20 (55%) positive for malignancy
Chemotherapy at enrollment 13 (38%)
Current Ascites treatment Diuretic therapy (n=10)
Salt restriction (n=2)

MALIGNANCY TYPE:
Pancreatic 6 (18%)
Breast 6 (18%)
Colon 5 (15%)
Ovarian 3 (9%)
Carcinoid 3 (9%)
Liver 2 (6%)
Appendix 1 (3%)
GIST 1 (3%)
Mesothelioma 1 (3%)
Other Non-GI 6 (18%)

Results

• Catheter Placement
  • Technical Success: 100%
  • One minor complication (epigastric vein injury)
  • No albumin or colloidal volume expander
  • Imaging
    • US and Fluoro 91%
    • US only in 6%
    • CT and US 3%

• Catheter Function
  • 85% with excellent function at last fu or death
    5 (15%) had resolution of ascites
    3 catheters removed
  • 6 (15%) had loss of function
Results

- Drainage Sessions
  - 440 drainage sessions
  - Median drainage sessions per patient: 17 (5 to 56)
  - Mean volume per session: 1525 cc (410 to 2452 cc)

Results

- Ease of Use
  - No problems: 372 of 440 sessions (85%)
  - 15% of sessions with 1 or more problems
    - “more than minimal pain or discomfort”
    - residual full feeling
    - problems with vacuum bottle
    - difficulty with performance of procedure
  - No patient needed to stop procedure due to procedural difficulties

Results

- Symptoms (MSAS)
  - Ascites related symptoms
    - "feeling bloated"
      - Symptom: feeling bloated
      - 2 wks: p=0.0001
      - 8 wks: p=0.0059
      - 12 wks: NS
    - "abdominal discomfort"
      - Symptom: abdominal discomfort
      - 2 wks: p=0.0001
      - 8 wks: p=0.0100
      - 12 wks: NS

Results

- Symptoms of hypovolemia/hypoalbuminemia NS

Results

- Symptoms (SSQ)
  - 56% described better overall quality of life at 1 week
  - 35% at 2 weeks
  - 44% at 8 weeks
  - 28% at 12 weeks

Results

- Laboratory Values
  - Na+, K+, Total Protein, Albumin, BUN, Cr
  - All patients had albumin values below normal at baseline
  - NS between baseline and 12 weeks

Results

- Adverse Events
  - No adverse events of any kind in 14 (41%)
  - Most frequent adverse event: ascites leakage in 7 (21%)
  - Peritonitis in one patient (3%) (one questionable case)
  - Severe adverse events 3 (9%)
    - Severe pain during drainage
    - Sudden dyspnea and coughing several hours post-placement
    - Anemia severe enough to require transfusion
Patient Survival

- N = 29 deaths
- Mean survival = 41.34 days
- Median survival = 30 days (95% CI 15-48)

Limitations

- SSQ measures overall QOL not ascites specific QOL
- 4 patients entered with only a single paracentesis within 30 days prior to catheter placement (protocol deviation)

Conclusions

- PleurX® catheter for use in malignant ascites:
  - improves ascites-related symptoms
  - permits home use
  - few adverse events or catheter failures
  - lab values stable

Conclusion

- Malignant ascites and effusions are recurrent
- The PleurX® catheter enhances the patient’s quality of life
- PleurX® now an option for Hospice patients
- High patient satisfaction