Surgical Palliative Care

Robert S. Krouse, MD
Disclosures

Nothing to Disclose
Case Presentation

• August 2007 - LAR for low rectal cancer

• January 2009: Pelvic exenteration for recurrence
  – Peritoneal implants
Case Presentation-
“Conservative” Treatment

- May 2009: 1\textsuperscript{st} episode partial SBO
- Multiple hospitalizations- IV hydration, NG tube, Octreotide
- Progressively less responsive to medical management
Case Presentation - CT
Case Presentation - Invasive Treatments

- Admitted to hospital mid-July 2009
  - PEG to decompress stomach along with conservative measures
    - Minimal benefit

- August 2009: OR
  - Carcinomatosis
  - Mucinous mass in the pelvis
  - Small bowel bypass
Case Presentation-
Course after OR

• Never able to consistently eat/bowel function
• Never able to go home
• Small bowel fistula
• Died in in-patient hospice POD# 30
MBO is a relatively common palliative care problem

- 43% palliative surgical consults (Badgwell, Supp Care Ca, 2009)
- 64% small bowel obstructions (Badgwell, J Pall Med, 2011)
- 5-43% of patients with advanced primary or metastatic intra-abdominal malignancy
  - 5-51% of patients with ovarian cancer (~22,000/yr)*
  - 10-28% of patients with colorectal cancer (~135,000/yr)*
  - Other intraperitoneal primaries (bladder, cervix, gastric, pseudomyxoma peritonei)
  - Non-intraperitoneal primaries (lung, breast, melanoma)

*Siegel RL, CA Cancer J Clin, 2017
There is no defined algorithm for care for most patients with MBO
MBO Treatments

• Small bowel obstruction (N=122)
  - Surgical treatment (25%)
  - Endoscopic or IR procedures (24%)
  - Nonoperative/Nonprocedural management (52%)

• Large bowel obstruction (N=28)
  - Surgical treatment (57%)
  - Endoscopic or IR procedures (18%)
  - Nonoperative/Nonprocedural management (25%)

When is the optimal approach for MBO unclear?

- Ascites
- Carcinomatosis
- Multiple obstructions
- Palpable intra-abdominal mass
- Diffuse metastatic disease
- Recurrent MBO
- Multiple medical problems
- History of multiple intra abdominal operations
Symptom Management Approach for MBO

- Nasogastric decompression
- Hydration
- Opioids
- Anti-emetics (haloperidol, odansatran, prochlorperazine, etc.) - 30% complete relief of emesis
- Octreotide - 75-100% response rate
- Anti-cholinergics (Scopolamine)
- Steroids
- TPN
OCTREOTIDE

- SC and IV
- Duration of 8-12 hrs
- Inhibition of release of GI hormone (VIP)
- Reduction of GI secretion and motility
- Decrease in splanchnic flow
- Increase in absorption of water and salts

Mercadante et al, JPSM, 1994
OCTREOTIDE IN BOWEL OBSTRUCTION

- Prevention of bowel obstruction in intermittent or subobstructive states (Mercadante, JPSM, 1997)

Can anti-secretory agents be beneficial in the pre-operative setting of MBO?

• Somatostatin may obviate the need for surgery in some patients with bowel obstruction (from 44% to 22%) with no deleterious effects (Bastounis, Hepatogastroenterol, 1989)

• Octreotide may lead to decreased bowel wall edema or intraluminal fluid (Mercadante, Support Care Cancer, 1996)
Double-Blind, Placebo-Controlled, Randomized Trial of Octreotide in MBO

- Sites: 12 sites across Australia
- Eligibility: Not surgical candidates, diagnosis by two independent practitioners, excluded patients with NG’s *unless vomiting*
- Arms: Octreotide 600 mcg/24 hrs by infusion vs. Placebo
- Both arms received standardized supportive therapy (ranitidine, dexamethasone, IV hydration)
- Primary outcome: *Patient reported* days free of vomiting at 72 hrs
- 45 patients treated with Octreotide; 42 treated with Placebo
- No difference in vomiting at 72 hrs (38% vs. 33%, p=0.67)
- Conclusion: No obvious difference, further study warranted of somatostatin analogues

Currow DC, J Pain Symp Manag, 2016
Is Operative Management Better than Non-operative Management for MBO?

- Retrospective review over 8 years at Univ. Conn (n=48)
- 32 patients treated with operation, 16 treated non-operatively
- Non-OR management - patient too ill for OR/too much disease
- Non-OR patients - fewer days in the hospital (10 vs. 21 mean, p<0.01); fewer days with NG tubes (4 vs. 8 mean, p=0.05)
- In-hospital mortality equivalent (22% vs. 38%, p=0.25)
- No difference in survival based on treatment
- No difference in outcome based on treatment (“good” outcome/2 mo)
- Conclusion: No benefit from surgery if likely due to carcinomatosis

Woolfson RG, Arch Surg, 1997
Is surgery better than “aggressive” palliative management in MBO?

- Palliative care for intestinal obstruction in recurrent ovarian cancer: a multivariate analysis

  - Retrospective review- 27 surgical vs. 20 Octreotide-based tx
  - Age/symptom/sign equivalent; worse PS in Octreotide group
  - OR: 18% exploration only; 22% morbidity, 22% mortality
  - Equal ability to control symptoms
  - Survival predictors: type of treatment, performance status, palpable mass
  - Conclusion: Consider surgery with good performance status

Mangili, Int J Gynecol Cancer, 2005
What is the optimal outcome measure for MBO?

- Alleviate nausea/vomiting
- Recurrence of obstruction
- Ability to have bowel movement/return of bowel function
- Allow to go home/leave hospital
- Enable to eat/drink
- Morbidity and mortality
- Improve survival

Feuer, Gynecol Oncol, 1999
MBO and Surgery - Beliefs and Reality

Belief
- Probable best modality if patient has “reasonable” expected survival
- May spend shorter time in hospital
- May relieve possible ischemia/infarction of bowel
- May improve survival

Reality
- Explorations alone - 3-18%
- 10-50% chance of recurrence
- Morbidity ~42%
- May spend longer time in hospital
- Mortality 5-32%
- QOL improvement variable (42-85%)
Can we test which treatment strategy (surgical vs. non-surgical) is optimal in MBO?
Agency for Healthcare Research and Quality (AHRQ) R01 HS021491/S1316
Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction

PI: Robert S. Krouse, MD (CMC VA Medical Center/University of Pennsylvania, Surgical Oncology)

Co-Investigator:
Garnet Anderson, PhD (Fred Hutchinson, Statistician)

Consultants:
Marcia Grant, PhD, RN, FAAN (City of Hope, Nursing Research)
Jeff Sloan, PhD (Mayo Clinic Rochester, Statistician)
S1316 - Prospective Comparative Effectiveness Trial for Malignant Bowel Obstruction

**Schema**

- Meets all eligibility requirements (N=180)
- Consents to randomization (N=50)
  - Surgery (50%) (Arm 1)
  - Non-surgical management (50%) (Arm 2)*
- Consents to non-randomized treatment (N=130)
  - Surgery (Arm 3)
  - Non-surgical management (Arm 4)*

**Primary Outcome:** “Good days” = days out of the hospital and alive in the first 91 days (13 weeks) after registration

*Recommend a trial of somatostatin analog
Timeline for Initial Patient Care

Up to 3 working days

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<td>Seen by surgical team or completion of treatment for surgical eligibility</td>
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Up to 2 working days

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<tr>
<td>Register to S1316</td>
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Begin Treatment

Treatment may begin on the same day as the surgical consult as long as the order of events is preserved (registration, then treatment).

Treatment must begin after registration. May have 48 hours of somatostatin-analogue.
**Patient Timeline**

- **Hospitalization with MBO**
  - Day 0: Registration
- **Data for primary endpoint reported**
  - Week 13:
    - Report all hospitalizations
    - Site calls patient weekly for assessments
    - Patient has dietary recall every 4 weeks
- **Follow-up Complete**
  - Week 53:
    - Site calls patient every 4 weeks for assessments
    - Patient has dietary recall every 4 weeks
S1316 – MBO Study
Eligibility Criteria

- MBO based on clinical/radiological criteria
- MBO due to intra-abdominal cancer
- Performance status (Zubrod Performance Status of 0 - 2 one week prior to admission)
- Able to complete questionnaires in English or Spanish
- All patients must pass “test” from surgical team:
  - Surgical candidate (indication and would tolerate an operation)
  - Equipoise (reasonable to treat operatively or non-operatively)
S1316

Primary Endpoint

“Good days” = days out of the hospital and alive in the first 91 days (13 weeks) after registration

Secondary Endpoints

• Days with NG
• Days eating (Diet recalls)
• HRQOL (MDASI-GI, EQ-5D-5L)
• Morbidity/Mortality
• Survival
Analysis Plan

Study includes two components: randomized (n=50) and non-randomized (n=130)

Inference will be based on assigned treatment

- Randomized component will use randomized treatment (intent to treat)
- Non-randomized component will use initially chosen treatment (pseudo-intent to treat)
Sites = 32

- Baylor University Medical Center (Dallas)
- Baylor College of Medicine (Houston)
- Brown University/Rhode Island Hospital
- City of Hope Cancer Center**
- Columbia University
- Duke University**
- Essentia Health Care Center (Duluth)
- Hackensack University Medical Center*
- Loma Linda University
- MD Anderson Cancer Center**
- Medical College of Wisconsin
- Medical University of South Carolina
- Moffitt Cancer Center
- National Institute of Colombia
- National Institute of Mexico*
- National Institute of Peru*
- Northwell Health (Long Island)

- University of Toronto/Princess Margaret Cancer Center*
- Rush University Medical Center (Chicago)
- Swedish Hospital (Seattle)*
- Temple University
- University of Arizona**
- University of Arkansas
- University of Kansas
- University of Massachusetts
- University of Michigan**
- University of New Mexico
- University of Oklahoma
- University of Pennsylvania
- University of Tennessee
- University of Texas – San Antonio
- Valley Health (Winchester, VA)

*Not yet open = 7
**Original sites = 5
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<th>N Patient Choice</th>
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S1216 MBO Trial Contacts

1. Giorgos Karakousis, MD – Site-PI, University of Pennsylvania
2. Sean Harbison, MD – Lead, Presbyterian Hospital
3. Donna Pucci – Coordinator (609-790-9672)
4. Abigail Blauch – Study management, regulatory matters, etc.
Objectives – Palliative Surgical Care

1. Define palliation and palliative surgery

2. Appreciate the importance of palliative surgery in the practice of surgery

3. Understand the various roles of the surgeon for patients with advanced cancers

4. Consider optimal surgical care in the palliative care setting
Palliative Care:

An interdisciplinary team approach to care with a focus on comfort and quality of life rather than prolongation or ‘cure’ for a patient and their loved ones.

Palliative Surgery

Surgery … with the sole intent of improving quality of life and symptom burden.

Badgwell BD, Supp Care Cancer, 2009
Palliative Surgery and the American College of Surgeons

- The surgeon’s role in palliative care, Robert A. Milch and Geoffrey P. Dunn, Bulletin of the American College of Surgeons, April 1997
- First meeting as Working Group September 10, 2001
- Elevated to Task Force October 2002
- Statement of Principles of Palliative Care, Bulletin of the American College of Surgeons, 2005
- Surgical Palliative Care: A Resident’s Guide, 2009
- Committee on Surgical Palliative Care, August 2013
“I don’t do palliative surgery.”

Unnamed Surgeon, City of Hope National Medical Center, 1999.
## Retrospective Review of Palliative Surgeries

<table>
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<th>SERVICE</th>
<th>Palliative Surgeries as Primary Surgeon</th>
<th>Total # of Surgeries By Service (% palliative)</th>
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<td>TOTALS</td>
<td>170</td>
<td>70</td>
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</table>

* GOS = General Oncologic Surgery (Skin/Soft Tissue Cancer, GI Cancers, Breast Cancer, Head & Neck and Endocrine)
** LOS = length of hospital stay
*** The 240 surgeries involved 164 patients

Krouse, Arch Surg, 2000
Society of Surgical Oncology Survey: Palliative Surgeries per Year

Krouse RS, et al., ASCO presentation, 2002
Palliative Surgery Consultations

- 40% of surgical consultations at a major cancer center
- Reasons for consults
  - Bowel obstruction (43%)
  - Wound complications/infections (10%)
  - Gastrointestinal bleeding (8%)
  - Other (39%)

Badgwell BD, et al., Supp Care Ca, 2009
Surgery as Palliative Therapy of Advanced Cancers

Benefits

Primary: Quality of Life
  Symptom control (e.g., pain, shortness of breath, emesis)
  Symptom prevention (e.g., neurologic, fractures)

Secondary: Survival

Risks

Morbidity (e.g., pain, immobility, hospitalization, worsening of symptoms)
Mortality (treatment-related)

Markman, Semin Oncol, 1995
The Role of Surgery: Palliation

Hormonal manipulation (eg, orchiectomy: prostate cancer; oophorectomy: premenopausal breast cancer; endocrine tumors)

Malignant fluid reaccumulation
- Pleural (tube drainage/sclerosis; talc)
- Pericardial (catheter drainage, pericardial “window” pericardiectomy)
- Ascites (catheter drainage, Levine/Denver shunt)

Obstruction
- Biliary (percutaneous stent v open surgical bypass)
- Urinary (ureteral stents)
- Large bowel (colostomy)
- Small bowel, esophagus, stomach (bypass v gastostomy tube)

Tumor resection
- Bleeding complications (eg, stomach, colon, kidney)
- Prevention of local complications (eg, toilet mastectomy, node dissection in extremity melanoma, fractures, brain metastasis)

Pain control
- Venous access, nerve blocks (percutaneous, open surgical)
- Neurologic procedures, orthopedic procedures, tumor resection

Markman, Semin Oncol, 1995
What are the goals of palliative surgery?
Survey of SSO members, 2000

- Symptom relief
- Pain relief
- Maintaining patient independence/function
- Symptom avoidance
- Decreased hospitalization
- Improved body image
- Minimizing burden of care
- Increasing patient survival

McCahill LE, et al., Ann Surg Oncol, 2002
Surgical Approaches

- Minimally invasive
- Radical
- Non-surgical
Minimally invasive surgical techniques

- Ablative techniques
- Laparoscopic approaches
- Endoscopic approaches
- Cystoscopic approaches
- Radiosurgery
- Percutaneous drainage
- Shunts
Radical surgical approaches

- Resections
- Debulking
- Reconstruction
- Bypass procedures
“Common” Surgical Problems in Palliative Care for Cancer

- Malignant bowel obstruction
- Biliary obstruction
- Gastric outlet obstruction
- Ascites
- GI endocrine tumors
- Wounds
Peripancreatic biliary obstruction
Biliary obstruction: treatment options

- Transhepatic biliary stent
- Endoscopic biliary stent
- Open bypass
  - Cholecystjejunostomy
  - Choledochoenteric bypass
- Laparoscopic bypass
  - Cholecystjejunostomy
  - Choledochoenteric bypass
## Randomized Controlled Trials Comparing Biliary Stent versus Biliary Surgical Bypass for Obstruction

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<tr>
<th>Author</th>
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### Meta-Analysis of Technical Success after Surgical Bypass versus Biliary Stenting

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<th>Surgery</th>
<th>Stent</th>
<th>Risk Ratio</th>
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<td><strong>Total (95% CI)</strong></td>
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<td><strong>100.0%</strong></td>
<td><strong>0.99 [0.93, 1.05]</strong></td>
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Total events: 171

Heterogeneity: Tau² = 0.00; Chi² = 2.35, df = 4 (P = 0.67); I² = 0%

Test for overall effect: Z = 0.43 (P = 0.67)

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Glazer ES, JPSM, 2014
Meta-Analysis of Major Complications and Mortality after Surgical Bypass versus Biliary Stenting

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<td>Total (95% CI)</td>
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Heterogeneity: Tau² = 0.25; Chi² = 10.37, df = 4 (P = 0.03); τ² = 61%
Test for overall effect: Z = 1.49 (P = 0.14)

Glazer ES, JPSM, 2014
# Meta-Analysis of Recurrent Obstruction after Surgical Bypass versus Biliary Stenting

Glazer ES, JPSM, 2014

<table>
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</tr>
<tr>
<td>Shepherd 1988</td>
<td>0 25</td>
<td>7 23</td>
<td>17.0%</td>
<td>0.06 [0.00, 1.02]</td>
<td></td>
</tr>
<tr>
<td>Smith 1994</td>
<td>2 101</td>
<td>36 100</td>
<td>31.2%</td>
<td>0.06 [0.01, 0.22]</td>
<td></td>
</tr>
<tr>
<td><strong>Total (95% CI)</strong></td>
<td><strong>191</strong></td>
<td><strong>188</strong></td>
<td><strong>100.0%</strong></td>
<td><strong>0.14 [0.03, 0.63]</strong></td>
<td></td>
</tr>
<tr>
<td>Total events</td>
<td>6</td>
<td>54</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Heterogeneity: $\hat{\tau}^2 = 1.33; \hat{\chi}^2 = 8.07, df = 3 (P = 0.04); I^2 = 63$

Test for overall effect: $Z = 2.56 (P = 0.01)$
## Outcomes after Index Procedures for Biliary Obstruction due to Peri-pancreatic Cancer based Meta-analysis as well as Non-randomized Clinical Trials

<table>
<thead>
<tr>
<th>Index Procedure</th>
<th>Biliary Stent</th>
<th>Surgical Bypass</th>
</tr>
</thead>
<tbody>
<tr>
<td>Estimated obstruction rate after index procedure until death</td>
<td>29% (Range 10%-40%)</td>
<td>3% (Range 0%-10%)</td>
</tr>
<tr>
<td>Treatment for re-obstruction</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgical</td>
<td>18%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Endoscopic/percutaneous</td>
<td>82%</td>
<td>75%</td>
</tr>
<tr>
<td>Medical</td>
<td>&lt;1%</td>
<td>25%</td>
</tr>
<tr>
<td>Total hospital days until death from time of index procedure (range)</td>
<td>30-35 days</td>
<td>10-22 days</td>
</tr>
</tbody>
</table>

Late duodenal obstruction for biliary decompression alone

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>Tumor</th>
<th>Procedure</th>
<th>Late GOO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parks, 1997</td>
<td>61</td>
<td>Peripancreatic</td>
<td>Bypass</td>
<td>8%</td>
</tr>
<tr>
<td>Coene, 1994</td>
<td>581</td>
<td>Pancreas</td>
<td>Endoscopic</td>
<td>9%</td>
</tr>
<tr>
<td>Coene, 1994</td>
<td>81</td>
<td>Ampullary</td>
<td>Endoscopic</td>
<td>23%</td>
</tr>
<tr>
<td>Holbrook, 1990</td>
<td>128</td>
<td>Peripancreatic</td>
<td>Bypass</td>
<td>10%</td>
</tr>
<tr>
<td>Huguier, 1993</td>
<td>636</td>
<td>Pancreas</td>
<td>Bypass</td>
<td>16%</td>
</tr>
</tbody>
</table>
Gastric Outlet Obstruction
Treatment options:
Gastric outlet obstruction

- NG
- PEG
- Stent
- Bypass
- Resection
## Outcomes for gastric outlet obstruction

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedure</th>
<th>Morbidity</th>
<th>Positive Results</th>
<th>Recur.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kaw, 2001</td>
<td>Stent</td>
<td>0</td>
<td>29/33 (91%)</td>
<td>14%</td>
</tr>
<tr>
<td>Kim, 2001</td>
<td>Stent</td>
<td>0</td>
<td>26/29 (89.7%)</td>
<td>7%</td>
</tr>
<tr>
<td>Choi, 2002</td>
<td>Open/Lap</td>
<td>21%/10%</td>
<td>68/68 (100%)</td>
<td>6%</td>
</tr>
<tr>
<td>Lucas, 1990</td>
<td>Antrect</td>
<td>?</td>
<td>19/19 (100%)</td>
<td>5%</td>
</tr>
</tbody>
</table>
Should one do a gastrojejunostomy in the setting of pancreatic cancer?

<table>
<thead>
<tr>
<th>Pre-OR Status (n=81)</th>
<th>Poor outcome*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patent duodenum (45)</td>
<td>40%</td>
</tr>
<tr>
<td>Duodenal narrowing (36)</td>
<td>70%</td>
</tr>
<tr>
<td>Emesis (21)</td>
<td>90%</td>
</tr>
<tr>
<td>No emesis (60)</td>
<td>40%</td>
</tr>
</tbody>
</table>

*Inability to retain a “reasonable” amount of food and death within 30 days

Weaver, Surg, 1987
Surgical Palliation for Pancreatic Malignancy: Practice Patterns and Predictors of Morbidity and Mortality

- NSQIP 2005 – 2011 (1,126 patients undergoing bypass)
- Gastrojejunostomy alone 33%, bile duct bypass alone 27%, both 31%, cholecystojejunostomy 9%
- Major complication: 20%; Mortality 6.5%

Unresectable peripancreatic tumors - Recommendations

- If endoscopic expertise available, stenting is usually preferable for both biliary and gastric obstructions.
- If endoscopic stenting fails or is unavailable, open or laparoscopic bypass is warranted.
- If explore through laparoscope and unresectable, reasonable to close.
- If explore open and unresectable, reasonable to bypass (GI, biliary, or both).
Malignant Ascites
Malignant ascites: Treatment options

• Medical management
  – Diuretics - help in 1/3 patients
  – Serial paracentesis - 90% relief (temporary)

• External drains: Dialysis catheter, fenestrated port, Foley catheter, Pleurex catheter, pig-tail catheter

• Intraperitoneal sclerosis

• Peritoneal-venous shunts: Leveen, Denver

• Resection
  – Debulking alone
  – Hyperthermic chemotherapy
CT- Ascites and tumor caking
# Outcomes for ascites

<table>
<thead>
<tr>
<th>Study</th>
<th>Procedure</th>
<th>Functional Until Death (%) (Range-days)</th>
<th>Complication (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>O’Neill, 2001</td>
<td>Pig-tail</td>
<td>23/24 (96%) (7-98)</td>
<td>4/24 (17%)</td>
</tr>
<tr>
<td>Barnett, 2002</td>
<td>Tenckhoff</td>
<td>27/29 (93%) (9-218)</td>
<td>5/29 (17%)</td>
</tr>
<tr>
<td>Smith, 1989</td>
<td>Denver/Leveen</td>
<td>31/50 (62%) (0-104)</td>
<td>16/50 (32%)</td>
</tr>
<tr>
<td>Bieligk, 2000</td>
<td>Denver shunt</td>
<td>Not reported</td>
<td>26/51 (51%)</td>
</tr>
<tr>
<td>Zanon, 2002</td>
<td>Denver</td>
<td>24/25 (96%) (17 A)</td>
<td>6/44 (14%)</td>
</tr>
<tr>
<td>Loggie, 2000</td>
<td>CR/IP Chemo</td>
<td>31/39 (79%) (7.6 mo med) NR</td>
<td></td>
</tr>
</tbody>
</table>
Major surgical complications

- **Drainage procedures**
  - Infection
  - Occlusion
  - Leak

- **Peritoneal-venous shunts**
  - DIC
  - CHF
  - Occlusion (~25%)
  - Infection
Malignant ascites-
Recommendations

- Intermittent drainage and diuretics is reasonable to try first or if nearing death

- External drains are reasonable procedures to treat malignant ascites with minimal major morbidity

- Peritoneal-venous shunts can have excellent long-term results but major complications are possible

- Debulking with/without hyperthermic chemotherapy can have dramatic results but necessitate expertise and may have high morbidity
Conclusions:

- Palliative procedures are an important part of the practice for Surgeons
- It is imperative to focus on Quality of Life outcomes for patients with advanced cancer
- As long as realistic goals of the patient and their family are identified, all treatment modalities should be considered
Reminder:

All MBO patients are potentially eligible for S1316