Surgical Management of Cholangiocarcinoma

9th Annual Symposium on Gastrointestinal Cancers
St. Louis University
Missouri Baptist Medical Center
ASGE
St. Louis, Missouri
September 11, 2010

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Chair, Division of Transplantation Surgery
Mayo Clinic Rochester
Surgical Management of Cholangiocarcinoma

No financial disclosures
No off label drug use discussion
Surgical Management of Cholangiocarcinoma

• Intrahepatic cholangiocarcinoma
  – Resection

• Perihilar cholangiocarcinoma
  – Resection
  – Liver Transplantation

• Diagnostic challenge and malignant masquerades
Surgical Management of Cholangiocarcinoma

Locations
- Intrahepatic
- Hilar
- Extrahepatic

Growth Patterns
- Mass
- Sclerosing
- Papillary

Liver Disease
- None
- PSC
- Cirrhosis
  - HCV
Intrahepatic Cholangiocarcinoma
Intrahepatic Cholangiocarcinoma

- Incidence is rising presumably due to HCV
- Symptoms develop late
- Presents with advanced stage
  - Mass lesion with vascular involvement
  - Lymph node metastases
- Liver resection with or without biliary resection and lymphadenectomy is the standard of care
# Intrahepatic Cholangiocarcinoma Resection

<table>
<thead>
<tr>
<th>Study</th>
<th>N</th>
<th>% Resectable</th>
<th>Overall Survival</th>
<th>Median Survival</th>
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</thead>
<tbody>
<tr>
<td>Jonas ’09</td>
<td>195</td>
<td>71</td>
<td>30%</td>
<td>29 mo</td>
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<td>Lang ’09</td>
<td>158</td>
<td>52</td>
<td>21%</td>
<td>27 mo</td>
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<tr>
<td>Shao-qiang ’09</td>
<td>136</td>
<td>59</td>
<td>21%</td>
<td>20 mo</td>
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<tr>
<td>Shen ’09</td>
<td>429</td>
<td>74</td>
<td>24%</td>
<td>19 mo</td>
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<tr>
<td>Zhou ’09</td>
<td>272</td>
<td>100</td>
<td>26%</td>
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<tr>
<td>Ercolani ‘10</td>
<td>102</td>
<td>71</td>
<td>48%</td>
<td>49 mo</td>
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Intrahepatic Cholangiocarcinoma

• Hepatic resection with or without bile duct resection is treatment of choice
  – Resectability rate ~ 70%
  – Five year survival ~ 30%
  – Survival related to TN status

• No role for liver transplantation except for small tumors arising in cirrhosis (that are usually presumed to be HCC)
Hilar Cholangiocarcinoma
Hilar Cholangiocarcinoma

- Incidence is stable or decreasing
- Symptoms related to biliary obstruction
  - Jaundice, abdominal pain, weight loss
- Often associated with PSC
- Liver resection with biliary resection and lymphadenectomy is the standard of care
- Neoadjuvant therapy and liver transplantation has emerged as effective treatment for selected patients with unresectable CCA and CCA arising in setting of PSC
Resection for Hilar Cholangiocarcinoma

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<thead>
<tr>
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<td>37</td>
<td>&lt;10</td>
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<td>45</td>
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Overall survival: 30 – 45% for R0 resection and <20% for incomplete resection
## Resection for Hilar Cholangiocarcinoma

### Resectability

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**Overall resectability: 779 of 1051 = 74%**
Hilar Cholangiocarcinoma

• Operative resection is the standard of care
  – 30 – 45% five year survival with complete resection
  – No prolongation of survival with incomplete resection
  – Resectability rate is ~ 70% with multimodality imaging
  – Adverse prognostic factors: vascular or perineural invasion, high grade histology, regional lymph node metastases

• Resection often precluded by biliary extension, vascular involvement, underlying liver disease (PSC), and advanced stage disease
Cholangiocarcinoma
Rationale for Liver Transplantation

- Avoid positive margin of resection
- Obviate concerns regarding vasculature and volume of remnant liver
- Achieve radical resection
- Treat underlying liver disease (PSC)
Cholangiocarcinoma
Cincinnati Transplant Tumor Registry
207 patients, 1968 - 1997

Patient Survival, %

Year

Transplantation 2000; 69:1633
Cholangiocarcinoma
Cincinnati Transplant Tumor Registry
207 patients, 1968 - 1997

• PSC in addition to cholangiocarcinoma - 28%
  – No difference in survival
• Tumor recurrence - 51%
  – 84% within 2 years
  – 47% in allograft and 30% in lungs
  – Survival after recurrence less than 1 year
• No survival advantage for incidental tumors
• No advantage of postoperative adjuvant therapy

Transplantation 2000; 69:1633
Cholangiocarcinoma
Spanish Liver Transplant Experience
36 patients, 1988 - 2001

- 36 hilar CCA transplants at 12 of 19 centers
- 13 of 36 with hepatic lymph node involvement
- 4 incidental tumors
- Patient survival:
  - 82% at one year
  - 53% at two years
  - 30% at three years
- 19 (53%) recurrences at mean of 21 months
  - 13 intraabdominal
- 17 of 23 deaths (47%) due to recurrent disease

Annals of Surgery 2004; 239:265
Cholangiocarcinoma
French Experience

- 12 French centers, 1985 – 2008
- 97 transplants: 67 hilar CCA and 26 intrahepatic CCA
- Few associated with cirrhosis (16%) or PSC (6%)
- Incidental finding of CCA in 15 patients (16%)
- 17 patients received neoadjuvant therapy
- 22 patients had concomitant pancreatic or GI resections

HPB 2010; 12(suppl 1) PL-03
Cholangiocarcinoma
French Experience

• 14% 90-day mortality
• Overall survival: 75% at 1 year, 38% at 3 years, 29% at 5 years, and 24% at 10 years
• Disease-free survival: 63% at 1 year, 29% at 3 years, 23% at 5 years, and 20% at 10 years
• 16 recurrences (61%) at a median interval of 17 months
• Adverse prognostic factors: prior cholecystectomy, acute rejection, lymphatic emboli
  – Intrahepatic CCA: microvascular emboli and lymph node metastases
• Neoadjuvant therapy: 81% versus 27% 5-year survival

HPB 2010; 12(suppl 1) PL-03
Cholangiocarcinoma
Extended Bile Duct Resection
Berlin Experience

• 16 patients, 1992 – 1998
• 8 (50%) recurrences
• Overall survival: 63% at 1 year, 38% at 5 and 10 years
• More morbidity and no survival advantage compared to 8 patients without EBDR
• Only 1 recurrence in 6 patients with stage 1 disease
• 56% 10-year survival for node-negative disease (excluding postoperative deaths)
Incidental Cholangiocarcinoma

Canadian Transplant Experience

n=10

Liver Transplantation 2005; 11:1412
Is Liver Transplantation Worthwhile for Cholangiocarcinoma?

The answer: NO

• Overall survival <= 50%
• Recurrence rates are high
• Unresectable intrahepatic CCA associated with poor prognosis
  – Large tumors
  – Regional lymph node involvement
  – Microvascular invasion
Hilar Cholangiocarcinoma

- Results with liver transplantation alone are poor
- Lymph node metastases portend poor prognosis
- Radiation with chemosensitization affords palliation
- University of Nebraska protocol with neoadjuvant brachytherapy and liver transplantation
Mayo Clinic Protocol

External beam radiation therapy

Brachytherapy

IV 5-FU / PO Capecitabine

Abdominal exploration for staging

Liver transplantation
Mayo Clinic Protocol
Rationale

• Radiotherapy with chemosensitization
  – High dose therapy is effective
  – Future liver problems obviated by liver transplantation

• Liver transplantation
  – Removal of residual disease
  – Hepatic margin is irrelevant
  – Treatment of underlying PSC
  – Avoidance of late side-effects of high dose radiotherapy
Mayo Clinic Protocol

Rationale

• **Patient selection**
  – Inclusion/exclusion criteria select for patients most likely to respond to neoadjuvant therapy and survive after transplantation
  – Operative staging to avoid patients destined to develop distant metastases

• **Timing of therapy and transplantation**
  – Avoid dissemination during operative staging and liver transplantation
Hilar Cholangiocarcinoma
Criteria for Unresectability

- Bilateral segmental ductal extension
- Encasement of main portal vein
- Unilateral segmental ductal extension with contralateral vascular encasement
- Unilateral atrophy with either contralateral segmental ductal or vascular (HA, PV) involvement
Hilar Cholangiocarcinoma
Mayo Clinic Approach
1993 to Present

• Appear resectable
  – Resection with excision of extrahepatic bile duct, regional lymphadenectomy, and right or left hepatectomy (+ caudate)

• Appear unresectable
  – Liver transplantation protocol

• Arising in setting of PSC
  – Liver transplantation protocol
Patient Eligibility

• Diagnosis of cholangiocarcinoma requires a malignant appearing stricture on cholangiography and at least one of the following:
  – Pathological confirmation with transcatheater biopsy or brush cytology
  – CA-19.9 >100 mg/ml
  – Mass on cross-sectional imaging
  – *Biliary ploidy by FISH*

• Unresectable tumor above cystic duct
  – *Pancreatoduodenectomy for microscopic involvement of CBD*
  – *Resectable CCA arising in PSC*

• Absence of intra- and extrahepatic metastases

• Candidate for liver transplantation
Exclusion Criteria

• Intrahepatic cholangiocarcinoma
• Uncontrolled infection
• Prior radiation or chemotherapy
• Prior biliary resection or attempted resection
• Intrahepatic metastases
• Evidence of extrahepatic disease
• History of other malignancy within 5 years
• Transperitoneal biopsy (including EUS)
• Radial diameter > 3cm
Endoscopic Ultrasound

- EUS (with regional lymph node aspiration) prior to enrollment added in 2002
- Avoids neoadjuvant therapy for many patients that would otherwise fall-out at operative staging
  - 30 – 40% staged positive prior to EUS
  - 10 – 15% stage positive with EUS
- EUS guided aspiration of the primary tumor causes seeding and should not be done
Radiation Therapy

• **External beam radiotherapy**
  – Primary tumor and regional (porta hepatitis, celiac, and pancreatoduodenal) lymph nodes
  – Window extended 3-5cm intrahepatically beyond ductal involvement
  – 4000 to 4500 cGy

• **Intraluminal brachytherapy**
  – 2-3 weeks after completion of external beam therapy
  – Iridium inserted through endoscopic or percutaneous tubes
  – 2000 to 3000 cGy delivered to a 1cm radius
Chemotherapy

- 5-FU daily bolus for three consecutive days at the beginning and end of external beam radiotherapy
- Protracted IV therapy begun with brachytherapy and continued until staging operation (daily for five weeks with one week off) and resumed afterward
- Oral capecitabine
Radiation and Chemotherapy Toxicity

- Nausea and vomiting
- Leukopenia
- Cholangitis
- Cholecystitis
- Gastroduodenal ulceration
  - Catastrophic bleeding and perforation
- Gastroparesis
- Hepatic abscess
- Liver failure
Explanted Liver After Neoadjuvant Therapy
Explanted Liver After Neoadjuvant Therapy: Duct Necrosis
Surgical Staging

- Completion of brachytherapy
  - as time nears for deceased donor transplantation
  - 1-2 days prior to living donor transplantation
- Thorough intraabdominal examination
- Palpation of liver
- Assess local extent of disease
- Regional hepatic lymph node biopsies
  - common hepatic artery lymph node
  - pericholedochal lymph node
- Assess for caval-sparing hepatectomy
- Hand-assisted laparoscopy for selected patients
Liver Transplantation

- Avoid hilar dissection
- Arterial interposition graft with deceased donor transplantation
- Low division of portal vein
- Portal vein interposition graft with living donor transplantation
- Caval replacement with caudate involvement
- Frozen section of cut common bile duct
  - *pancreatoduodenectomy if positive*
Cholangiocarcinoma Treatment Protocol

Results: 1993 – 2010

- 196 neoadjuvant therapy
  - 16 deaths, debilitation, or disease progression
  - 3 transplant elsewhere
  - 5 receiving neoadjuvant Rx

- 172 staging operation
  - 38 (22%) positive
  - 3 awaiting transplantation
  - 1 death, 1 hepatic metastases
  - 3 transplant elsewhere

- 126 liver transplantation
  - 84 deceased donor
  - 41 living donor
  - 1 domino donor

April 10, 2010
Patient Survival After Start of Therapy

1993 – 2010

n=196

Years after start of therapy

% 40 50 60 70 80 90 100

0 1 2 3 4 5

82 ± 3%

62 ± 4%

56 ± 4%

April 10, 2010
Patient Survival After Start of Therapy
1993 – 2010

Years after start of therapy

PSC (121)
De Novo (75)

% survival over time:
- PSC: 63 ± 5%
- De Novo: 44 ± 7%

Statistical analysis:
- $p = 0.13$ log-rank
- $p = 0.60$ Wilcoxon
Patient Survival After Transplantation

1993 – 2010
n=126

Years after transplantation

%

91 ± 3%
81 ± 4%
74 ± 5%

April 10, 2010

MAYO CLINIC
**Recurrences After Liver Transplantation**

21 of 126 (17%)

<table>
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<tr>
<th>Site</th>
<th>Time (mo)</th>
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<td>Regional</td>
<td>7, 10, 14</td>
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<td>14, 15, 17, 65</td>
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<tr>
<td>Peritoneal</td>
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<td></td>
<td>22, 25, 27</td>
<td>dead at 29, 41, 43</td>
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Mean time to recurrence – 25 months
## Recurrences After Liver Transplantation

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10 of 21 recurrences (48%) – distant metastases
## Predictors of Recurrence

**Clinical Factors**
- Older patient age
- Prior cholecystectomy
- CA-19.9 > 100 at transplant
- Visible mass on imaging
- Prolongation of waiting time

**Pathological Factors**
- Residual CCA > 2 cm
- High grade histology
- Perineural invasion

*Transplantation 2006; 82:1703*
Special Problems

- Medical and neoadjuvant therapy problems
- Hepatic decompensation
- Technical problems
- Late vascular problems
Is Liver Transplantation Worthwhile for Hilar Cholangiocarcinoma?

The answer: YES

- 74% 5-year survival with careful patient selection and neoadjuvant therapy
- Patients with CCA arising in PSC fare better than those with de novo CCA, 80% versus 64% 5-year survival
- Neoadjuvant therapy presents a formidable challenge
Key Points

• Adherence to selection criteria and protocol are key to success

• Patients should not undergo transperitoneal FNA or biopsy which cause peritoneal seeding

• UNOS MELD score exception adjustment requires:
  – CCA within Mayo criteria
  – Neoadjuvant therapy
  – Operative staging

• EUS with FNA of regional hepatic lymph nodes avoids neoadjuvant therapy for patients destined to fall out at staging
Surgical Management of Cholangiocarcinoma

• Resection – when possible – is the treatment of choice for intrahepatic cholangiocarcinoma and de novo hilar cholangiocarcinoma
  – Few tumors are resectable
  – Complete resection achieved in 75% of operative cases
  – Five year survival 30 – 45% with complete resection
  – Little efficacy of incomplete resection

• Liver transplantation alone is fraught with early recurrence and poor patient survival
Surgical Management of Cholangiocarcinoma

• Liver transplantation with neoadjuvant therapy achieves >70% survival for highly selected patients with early stage disease
  – Is the treatment of choice for patients with hilar CCA arising in the setting of PSC
  – Is the only treatment affording prolonged survival for patients with unresectable hilar CCA
The Emergence of Liver Transplantation for Hilar Cholangiocarcinoma
A Success Story of Team Care and Combination Therapy

Greg Gores – Transplant Hepatology
Julie Heimbach – Transplant Surgeon
James Martenson, Mike Haddock – Radiation Oncology
Steve Alberts – Medical Oncology
David Nagorney – Hepatobiliary Surgeon
David Rea – Surgery Resident, Transplant Fellow
Henk-Jen Mantel – Medical Student
Ziad Hassoun – Hepatology Fellow
E Ramos, B Taner, H Pollinger, J Burns – Transplant Fellows

Liver Transplant Team
Medical and Radiation Oncology
Case Presentation

• 62M with 5 month history of fatigue
  – Slight elevation in AST and ALT: attributed to past EtOH by local physician
  – Bili 2.0
  – US shows sludge in biliary ducts
  – Cholecystectomy 10 years earlier

• Studies:
  – ERCP
  – CT
  – CA-19.9 is 24.7
Cholangiography

ERCP with stent placement  PTC R posterior duct

Biopsy and Cytology both negative, FISH – trisomy 7
CT Scan

1.4cm mass, no vascular involvement
Case Presentation

- Malignant appearing stricture with R posterior duct obstruction
  - “1.4cm mass” on CT
  - Trisomy 7 on FISH
  - Negative cytology and histology
  - Liver biopsy: cholestasis with stage 2-3 fibrosis
Case Presentation
Treatment and Outcome

• R posterior hepatectomy and bile duct excision with L hepaticojejunostomy (R anterior duct drains into L duct)
  – Benign fibrosis with inflammation, no cholangiocarcinoma

• 4 years later: secondary biliary cirrhosis vs PSC
  – Evaluation for liver transplantation
  – Low MELD

• 6 years later: multiple co-morbidities, no longer a candidate for liver transplantation
Case Presentation

Discussion

- ERCP often fails to visualize obstructed intrahepatic ducts
- Trisomy 7 – need polysomy on FISH for reasonable certainty (85%) in diagnosis of CCA
- Diagnosis of CCA can be difficult and cytological or histological confirmation may not be possible
  - Avoid percutaneous or EUS FNA/biopsy
  - Wait, observe, and repeat imaging and cholangiography/brushings
- Malignant masquerades
  - Few malignant appearing strictures are benign in absence of PSC
  - Unexpected benign findings after resection: ~ 5 – 10%