Pancreatic Cancer: Chemoembolization Using A Double Balloon Catheter

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Disclosures

• Post Market Registry Investigator
Adenocarcinoma of the Pancreas

- 54,000 cases of pancreatic adenocarcinoma per year in US
- Only potential cure: resection

Pancreatic Cancer Stages:

- Stage 2: Not spread to vessels or lymph nodes
  - 15% - “Resectable”
- Stage 3: Spread to vessels and/or lymph nodes, but not other parts of body
  - 35% LAPC
- Stage 4: Spread to other parts of the body
  - 50% Metastatic

- Primary reason Locally Advanced Pancreatic Cancer (LAPC) not resectable: tumor involvement of celiac axis and SMA; can not get clean margin with resection
- Systemic gemcitabine is only guideline driven treatment with Class 1 evidence benefit; other treatment regimen extrapolated from studies of patients with stage 4 disease
- Therefore, LAPC patients undergo a potpourri of treatment options: systemic gemcitabine, combination chemo, chemo-radiation, research protocol, etc.
Can TACE Benefit these patients?
Several studies, including meta analysis with the use of gemcitabine, have shown promise

Opportunities:
Familiar Anatomy

Challenges: can not identify or engage tumor feeder vessels
Potential Solution:
Adjustable balloon size for vessel diameters from 4 mm to 11 mm

Two-part handle for easy control of balloon distance.

VERSATILITY
Operator controlled adjustable occlusion length.

Length can be adjusted from 25 mm to 120 mm

TARGETED DELIVERY
Dual occlusion balloons for precise infusion. Closed seal system ensures infusate is confined between the balloons.
RenovoCath Balloons

Common Hepatic Artery

Tumor Head

SMA

RenovoCath Balloons

Common Hepatic Artery

SMA

RenovoCath Balloons
66 y/o M 
Pancreatic CA 

Post Systemic Chemo 
Continued growth
4 Treatments: Hepatic, SMA, Hepatic, SMA
Infuse 100-120 cc at 6cc/Min
Technical Considerations when using RenovoCath

• 6 Fr Guiding Sheath must be advanced into Celiac or SMA
• RenovoRx Catheter is compatible with 0.014 wire
• Acute angled SMA may be difficult to access with routine techniques
• Working length 76-86 cm. (RA access is not feasible)
• Morph Catheter can be extremely helpful
Use of a Morph Catheter
Clinical Response with RenovoCath TACE vs. Historical Control
Adenocarcinoma of the Pancreas

- RenovoCath completing 8 treatments – Average 5.75g/m2 of Gemcitabine (n=9)
- RenovoCath greater than 2 treatments – Average 4.4g/m2 of Gemcitabine (n=15)
- Systemic Intravenous Gemcitabine – Average 6.8g/m2 (n=44) *

<table>
<thead>
<tr>
<th>Levels</th>
<th>Grade 3 myelosuppression</th>
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<tbody>
<tr>
<td>Systemic Gemcitabine</td>
<td>20 µg/ml</td>
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<tr>
<td>RenovoCath Gemcitabine</td>
<td>1.9 µg/ml</td>
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</tbody>
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- 65% survival
- 51% survival
- 37% Survival*  

Post-Market Registry

A Multi-Center, Post-Marketing, Prospective, Observational Study Following Treatment with Intra-Arterial Delivery of Chemotherapeutic Agents Using the RenovoCath™ Catheter

• Up to 10 US centers
• Up to 100 patients
• Launched January 2016
• 5 centers recruiting
• Additional centers in process
Conclusions

• Intra-arterial gemcitabine can be given to patients with pancreatic cancer using localized delivery via RenovoCath Catheter with acceptable safety profile

• There is less Systemic side effects of gemcitabine as assessed by hematologic markers, using RenovoCath localized delivery

• There appears to be survival benefits in patients receiving localized gemcitabine especially if they complete a full course of therapy

• Post Market registry data will be extremely important for the adaptation of this mode of therapy