The Pancreas and Pancreatic Cancer

The pancreas is a small vital organ located between the stomach and the duodenum, at the back of the body near the spine.[2] The organ has two main functions: producing digestive enzymes that pass through pancreatic ducts to the small intestine; and secreting glycogen and insulin to regulate blood glucose levels.[2]

Pancreatic cancer is the 12th most common type of cancer in the US. Pancreatic cancer is particularly deadly, with a five year survival rate of 6.7% compared to the national average of 66.1% for all cancer sites.[3]

<table>
<thead>
<tr>
<th>Types of Lesions</th>
<th>IPMN</th>
<th>MCN</th>
<th>SCA</th>
<th>SPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rate of Occurrence</td>
<td>21 - 33</td>
<td>10 - 45</td>
<td>32 - 39</td>
<td>&lt; 10</td>
</tr>
<tr>
<td>Age Affected</td>
<td>70</td>
<td>40 - 60</td>
<td>Unknown</td>
<td>&lt; 40</td>
</tr>
<tr>
<td>Location in Pancreas</td>
<td>Head / Body / Tail</td>
<td>Head / Body / Tail</td>
<td>Head / Body / Tail</td>
<td>Head / Body / Tail</td>
</tr>
<tr>
<td>Malignancy</td>
<td>High</td>
<td>Moderate</td>
<td>Low</td>
<td>Low</td>
</tr>
</tbody>
</table>

Comparison of four different types of pancreatic lesions. The project focuses on IPMNs and MCNs due to their high occurrences and high malignancies.

Stakeholders

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Physicians</th>
<th>Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unwilling to recommend risky treatments without significant, proven benefits</td>
<td>Cost of long-term medical care</td>
<td></td>
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<tr>
<td>Lack of standards for treatment options</td>
<td>Anxiety over personal health when monitoring</td>
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<tr>
<td>Effort required to learn new techniques</td>
<td>Disruption of lifestyle for regular medical visits</td>
<td></td>
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</tbody>
</table>

A successful device has to offer significant health benefits with fewer or equal drawbacks compared to surgical removal.

Treatments

Lesion removal involves the destruction of premalignant cysts. Lesions in the 1-3 cm range could be ablated utilizing a variety of methods. Treating these lesions could prevent progression to malignancy and lower the anxiety of patients that comes with monitoring, as well as remove the stress on the patient, doctor, and hospital that the annual visits cause. There are only a small number of clinical trials to date, so there is an increasing demand to create devices to treat premalignant lesions.[1]

Designing and Testing Our Device

We generated device design requirements with input from physicians and Boston Scientific to guide our device development. Design requirements include both logistical challenges, such as integration with existing endoscopic devices and compatibility with a 19 gauge needle, as well as usability challenges such as the necessity for doctors to be able to operate the device seamlessly.

Criteria:
1. Potential for near 100% removal of the cyst, which minimizes the risk of developing complications such as pancreatitis
2. Fits in a 3.7 mm working channel
3. Fabricated from biologically inert materials
4. Potential for visualization on an ultrasound
5. Similar to current gastroenterology treatment procedures
6. Sufficiently flexible to move through the tortuous path of the endoscope

Unknowns:
1. May not be as effective for irregular cyst shapes and sizes
2. Treatment area is not yet predictable, though will be after more testing
3. The size of the treatment area is not yet measurable

References:

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