Management Algorithms for Pancreatic Cysts and Intraductal Papillary mucinous Neoplasms: The Surgeon’s Perspective

PRESENTED BY
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Disclosure of Relevant Financial Relationships

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Professor Jin-Young Jang reported no relevant financial relationships

Content

• Background (Changing concept)
• Comparison of Guidelines
• Consideration Points in Decision of Treatment
• Optimal Indication for Surgery (Management Algorithm)

Changes in Epidemiology of Pancreatic Cyst

Age & sex-adjusted incidence: 0.31 → 4.35/100,000 (14-fold)

2.2% of normal population

Klibansky DA, et al., Clin Gastroenterol Hepatol 2012
Chang and Jang, Medicine 2016

Patients Number and Types/Size of IPMN

Patients Number and Types/Size of IPMN

Mixed, 14
BD, 64


**Clinical Characteristics**

N=2,622 from 71 multicenters, 23 nations

Three serous cystadenocarcinomas (0.1%)

Tumour size and growth rate

Growth rate:
- <4 cm: 1.25 mm/yr
- ≥4 cm: 2.7 mm/yr


**Malignancy Potential and Survival**

N=351, Korean multi-centers study

Malignant features (28%)
- invasion to adjacent tissues, perineural/lymphovascular invasion,
- metastasis (4%)

International Consensus (15 years ago)

- W. Traverso: The survival curves between invasive IPMN and ductal adenocarcinoma are the same!! We should resect IPMN before they become invasive.
- M. Buchler: We operate all, branch type IPMN except malignancy with nonresectable situation or metastasis....
- C. Yeo: We have been resecting healthy folks with presumed side branch IPMNs. less than 20% are observed.

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Numbers of Publication on IPMN

Description of mucin-producing pancreatic carcinoma: Ohhashi et al. Prog Dig Endo 1982.
Surgical Indication of IPMN

**Expert opinion**

**Treatment Guidelines on IPMN**

<table>
<thead>
<tr>
<th>Authors (Organization)</th>
<th>Year</th>
<th>Titles or Subject</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hruban</td>
<td>2004</td>
<td>Pathologic consensus</td>
</tr>
<tr>
<td>Tanaka (IAP)</td>
<td>2006</td>
<td>Guideline on Diagnosis &amp; Treatment</td>
</tr>
<tr>
<td>SSAT</td>
<td>2007</td>
<td>Guidelines on Cystic neoplasms of the pancreas</td>
</tr>
<tr>
<td>Tanaka (IAP)</td>
<td>2012</td>
<td>2nd Guideline</td>
</tr>
<tr>
<td>Del Chiaro</td>
<td>2013</td>
<td>European experts consensus</td>
</tr>
<tr>
<td>Buscarini</td>
<td>2014</td>
<td>Italian guideline</td>
</tr>
<tr>
<td>Vege (AGA)</td>
<td>2015</td>
<td>American Gastroenterological Association</td>
</tr>
<tr>
<td>Adsay</td>
<td>2016</td>
<td>Revision on pathologic consensus guideline</td>
</tr>
<tr>
<td>Tanaka (IAP)</td>
<td>2017</td>
<td>3rd Guideline</td>
</tr>
<tr>
<td>Del Chiaro</td>
<td>2018</td>
<td>2nd European Guideline</td>
</tr>
</tbody>
</table>

**Comparison of Guidelines on IPMN**

**Guideline** | **Absolute indication for Surgery** | **Relative indication for Surgery** |
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>European 2018</td>
<td>Jaundice</td>
<td></td>
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<td>Enhancing nodule ≥ 5mm</td>
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</tr>
<tr>
<td></td>
<td>MPD ≥ 10mm</td>
<td></td>
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<tr>
<td>IAP 2013/2017</td>
<td>Jaundice</td>
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</tr>
<tr>
<td></td>
<td>Enhancing nodule ≥ 5mm</td>
<td></td>
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<tr>
<td></td>
<td>MPD ≥ 10mm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive Cytology</td>
<td></td>
</tr>
<tr>
<td>AGA 2015</td>
<td>Symptomatic</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Solid component and MPD dilatation</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Positive Cytology</td>
<td></td>
</tr>
</tbody>
</table>

**Cystic Fluid Cytology**

- Specificity 83%
- Sensitivity 35%
- Accuracy 59%

- 33% Inadequate or non-diagnostic

*Data from Mount Sinai (Scapeal et al.)*

Needs Invasive procedures
Long-term risk of malignancy in BD-IPMN

- Jan. 1994 ~ Dec. 2017 (20 years)
- Single institution (Univ. of Tokyo)

**Cumulative Malignancy Rate**

- Annual Malignancy Rate: 0.7%
- Cumulative Malignancy Rate: 3.3%

**Sensitivity and Specificity of Clinical Guidelines on IPMN**

<table>
<thead>
<tr>
<th>Guideline</th>
<th>Sensitivity %</th>
<th>Specificity %</th>
</tr>
</thead>
<tbody>
<tr>
<td>AGA with required cytology</td>
<td>7.3</td>
<td>88.2</td>
</tr>
<tr>
<td>IAP</td>
<td>73.2</td>
<td>45.6</td>
</tr>
</tbody>
</table>

**Examples**

- 76 year, male
  - Tumor size (mm): 16
  - MPD (mm): 4
  - Mural nodule: +
  - CA19-9: 45
  - European Resection
  - AGA Observation

- 73 year, male
  - Tumor size (mm): 42
  - MPD (mm): 9
  - Mural nodule: -
  - CA19-9: 17
  - IAP Resection
  - Observation

- 75 year, male
  - Tumor size (mm): 42
  - MPD (mm): 12
  - Mural nodule: -
  - CA19-9: 12
  - AGA Observation

**Content**

- Background (Changing concept)
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**Observation vs Resection**

- Considering factors
  - **Disease factors**
    - Natural History
    - Malignant potential
    - Symptoms/sign
    - Extent of the disease
    - Location
  - **Host factors**
    - Age
    - Co-morbidity
    - Life expectancy
    - Op. risk
    - Pancreas function
    - Medical accessibility
  - **ETC**
    - Efficacy
    - Morbidity/Mortality
    - Safety
  - Longitudinal risk of at least HGD or IC is time-dependent.

- Optimal Indication for Surgery

**Natural History of IPMN**

- Malignancy rate according to the type
  - Main duct type: 45-92% (60%)
  - The majority are candidates for resection
  - Branch duct type: 5-50% (20%)
  - Operation or Surgery (optimal indication?)

- Annual Malignancy Rate: 2-3%
Annual growth rate:

- 2001-2016
  - Followed up duration over 3 yrs
  - CT MRI or EUS
  - pleomorphc cyst
  - cl0cked, f1nger tip cyst
duct communication (+)
  - S1pervised by Radiologist

FU duration (month):

- Patient with suspicion of IPMN (n=1,083)
- Uncertain diagnosis (n=4,566)
- Eligible patient (n=1,369)
- Main duct type (n=47)
- Follow up <3year (n=3630)
  - Only sono f/u (n=473)
- Diagnosed as IPMN (n=5,519)

Natural History & Surveillance of IPMN

- Median FU: 60m

Malignancy Rate During Surveillance in BD & Mixed IPMN

- Size
  - ≥3cm: 13.1%
  - 2 ≤<3: 12.8%
- Annual growth rate
  - 0.6 ± 0.9 mm/yr

Optimal Surveillance Interval Based on Growth Rate & Cyst Size

- G1 (0-9.9mm): N=667
  - Cyst size (mm): 7.0 ± 1.9
  - Growth rate (mm/yr): Max. growth rate: 95% CI: 0.6 ± 0.9
  - Median doubling time: 11
  - Minimum doubling time: 1
  - Malignancy Rate: 1.8%
- G2 (10-19.9mm): N=608
  - Cyst size (mm): 13.4 ± 2.6
  - Growth rate (mm/yr): Max. growth rate: 95% CI: 0.5 ± 0.9
  - Median doubling time: 26
  - Minimum doubling time: 1.8
  - Malignancy Rate: 2.3%
- G3 (20-29.9mm): N=84
  - Cyst size (mm): 23.3 ± 2.7
  - Growth rate (mm/yr): Max. growth rate: 95% CI: 1.0 ± 1.5
  - Median doubling time: 23
  - Minimum doubling time: 2.5
  - Malignancy Rate: 2.5%
- G4 (over 30mm): N=10
  - Cyst size (mm): 34.1 ± 9.4
  - Growth rate (mm/yr): Max. growth rate: 95% CI: 1.0 ± 1.2
  - Median doubling time: 34
  - Minimum doubling time: 11.2
  - Malignancy Rate: 3.3%

- Size 10Y worrisome feature (+)
  - ≥3cm: 83.1%
  - 2 ≤<3: 69.6%
- Total: 35.2%
  - 1 ≤<2: 20%
  - <1cm: 7.3%

appearance of worrisome features during surveillance in BD & mixed IPMN

- Han & Jang. Gastroenterol. 2019

- Appearance of Worrisome Features During Surveillance in BD & Mixed IPMN

- Han & Jang. Gastroenterol. 2018

- Revised Surveillance Program by IAP 2017

- Tanaka et al. Pancreatology 2017

- Comparative Effectiveness of Resection vs Surveillance for Pancreatic Branch Duct Intraductal Papillary Mucinous Neoplasms With Worrisome Features

- Hu et al. JAMA Surgery 2019
The Clinical and Socio-Economic Relevance of Increased IPMN Detection Rates and Management Choices

- **Surveillance Strategy**
  
  Must spend >$20,000/patient to improve quality adjusted life year (QALY)

- **Surgery Strategy**
  
  $132,436/QALY

  Least deaths from PDAC (5.4%), but 4.7% died due to the surgery

Budde et al. Visceral Medicine 2015

The Clinical and Socio-Economic Relevance of Increased IPMN Detection Rates and Management Choices

- **Surveillance Strategy**
  
  Must spend >$20,000/patient to improve quality adjusted life year (QALY)

- **Surgery Strategy**
  
  $132,436/QALY

  Least deaths from PDAC (5.4%), but 4.7% died due to the surgery

Budde et al. Visceral Medicine 2015

Malignancy Potential and Survival

- AGA systematic review-SYSR of invasive IPMN: 40%

5 year survival rate


National Cancer Center, Korea, 2013

Criteria for Resection in BD-IPMN

1st Consensus Guideline (2006)

- >3cm
- Mural nodule (+)
- Duct dilatation
- Cytology (+)
- Symptomatic

2nd Consensus Guideline (2012)

- worrisome feature

High-risk stigmata

- MPD >10 mm
- Enlarged solid component


Revised Criteria for Malignancy Predicting Factors

2nd Consensus Guideline (2012)

- worrisome feature

High-risk stigmata

- Obstructive jaundice
- MPD >10 mm
- Enlarged mural nodule

Worrisome features

- >3cm
- Mural nodule (+)
- Duct dilatation > 5 mm
- Thickened enhanced cyst walls
- Abrupt change in the MPD caliber with distal pancreatic atrophy
- Lymphadenopathy

Tanaka et al. Pancreatology 2012, 2017

Revised Consensus Guideline (2017)

- worrisome feature

High-risk stigmata

- Obstructive jaundice
- MPD >10 mm
- Enlarged mural nodule >10 mm

Worrisome features

- >3cm
- Mural nodule (+)
- Duct dilatation > 5 mm
- Thickened enhanced cyst walls
- Abrupt change in the MPD caliber with distal pancreatic atrophy
- Lymphadenopathy
- Increased serum CA19-9
- Cyst growth rate >5mm/2 yrs

Tanaka et al. Pancreatology 2013
<table>
<thead>
<tr>
<th>Variable</th>
<th>P-value</th>
<th>Sensitivity(%)</th>
<th>Specificity(%)</th>
<th>PPV(%)</th>
<th>NPV(%)</th>
<th>Accuracy(%)</th>
<th>HR</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cyst size (≥3 cm)</td>
<td>0.057</td>
<td>56.1</td>
<td>53.7</td>
<td>37.4</td>
<td>71.2</td>
<td>54.5</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MPD (&gt;5 mm)</td>
<td>0.001</td>
<td>54.7</td>
<td>78.0</td>
<td>55.1</td>
<td>77.7</td>
<td>70.3</td>
<td>5.32</td>
<td>2.67 – 10.60</td>
<td>0.001</td>
</tr>
<tr>
<td>Mural nodule</td>
<td>0.001</td>
<td>62.8</td>
<td>71.6</td>
<td>60.7</td>
<td>82.7</td>
<td>70.2</td>
<td>6.13</td>
<td>4.68 – 9.00</td>
<td>0.001</td>
</tr>
<tr>
<td>Thicken cystic wall</td>
<td>0.001</td>
<td>56.5</td>
<td>65.0</td>
<td>56.7</td>
<td>76.4</td>
<td>70.4</td>
<td>4.48</td>
<td>1.53 – 13.73</td>
<td>0.004</td>
</tr>
<tr>
<td>Abrupt change in MPD</td>
<td>0.001</td>
<td>19.3</td>
<td>95.9</td>
<td>70.3</td>
<td>70.5</td>
<td>70.4</td>
<td>2.45</td>
<td>0.78 – 7.94</td>
<td>0.124</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>0.002</td>
<td>5.2</td>
<td>99.6</td>
<td>87.5</td>
<td>67.8</td>
<td>68.2</td>
<td>5.79</td>
<td>0.31 – 46.71</td>
<td>0.298</td>
</tr>
<tr>
<td>CEA (&gt;5 ng/mL)</td>
<td>0.046</td>
<td>6.8</td>
<td>97.7</td>
<td>60.7</td>
<td>76.7</td>
<td>67.3</td>
<td>3.58</td>
<td>0.05 – 35.15</td>
<td>0.194</td>
</tr>
<tr>
<td>CA 19-9 (&gt;37 U/mL)</td>
<td>0.001</td>
<td>34.9</td>
<td>92.3</td>
<td>69.9</td>
<td>73.5</td>
<td>72.9</td>
<td>5.25</td>
<td>2.05 – 13.42</td>
<td>0.001</td>
</tr>
<tr>
<td>Cyst growth rate (&gt;5 mm/2 year)†</td>
<td>0.012</td>
<td>60.9</td>
<td>70.3</td>
<td>42.4</td>
<td>83.3</td>
<td>67.8</td>
<td>3.68</td>
<td>0.001</td>
<td></td>
</tr>
</tbody>
</table>

**Comparison of diagnostic performance between 2017 and 2012 ICG**

<table>
<thead>
<tr>
<th>AUC</th>
<th>LR</th>
<th>SVM1</th>
<th>SVM2</th>
<th>SVM3</th>
<th>RF</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012 IAP</td>
<td>0.746</td>
<td>0.650</td>
<td>0.650</td>
<td>0.650</td>
<td>0.758</td>
</tr>
<tr>
<td>2017 IAP</td>
<td>0.784</td>
<td>0.680</td>
<td>0.686</td>
<td>0.684</td>
<td>0.787</td>
</tr>
</tbody>
</table>

**Biomarkers Predicting Malignancy**

**Hazard Ratio of Malignancy Predicting Factors**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Hazard ratio (95% CI)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPD &gt;5mm</td>
<td>4.538 (2.449 – 8.408)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Mural nodule</td>
<td>6.267 (3.271 – 12.009)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Thickened cystic wall</td>
<td>1.549 (1.193 – 2.010)</td>
<td>0.023</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>4.966 (1.033 – 23.374)</td>
<td>0.044</td>
</tr>
<tr>
<td>CA 19-9 (&gt;37 U/mL)</td>
<td>4.032 (1.826 – 8.903)</td>
<td>0.001</td>
</tr>
</tbody>
</table>

**Additive Effect of Malignancy Predicting Factors**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Number of Risk Factors</th>
<th>Benign (n=253)</th>
<th>Malignant (n=97)</th>
<th>Accuracy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumor size</td>
<td>0</td>
<td>71</td>
<td>26 (10%)</td>
<td>84.4</td>
</tr>
<tr>
<td>Duct diameter</td>
<td>1</td>
<td>132</td>
<td>24 (18%)</td>
<td>76.5</td>
</tr>
<tr>
<td>Mural nodule</td>
<td>2</td>
<td>41</td>
<td>22 (54%)</td>
<td>67.8</td>
</tr>
<tr>
<td>Thickened cystic wall</td>
<td>3</td>
<td>11</td>
<td>22 (197%)</td>
<td>38.9</td>
</tr>
<tr>
<td>Lymphadenopathy</td>
<td>≥4</td>
<td>8</td>
<td>21 (72%)</td>
<td>38.3</td>
</tr>
</tbody>
</table>

**Personalized approach for IPMN**

Diagnostic tools (Nomogram) is needed to predict malignancy risk quantitatively in BD-IPMN considering different statistical value of several variables.

- **Malignancy Risk Score**
  - Tumor size
  - Duct diameter
  - Mural nodule
  - Tumor marker
  - Symptoms, etc.

**Korea-Japan 1st International collaboration study**

Initial enrolled patients (n=2,488)

- Main duct diameter >10mm (n=622)
- Insufficient/incorrect data (n=5)

**Proposed Nomogram Predicting the Individual Risk of Malignancy in the Patients With Branch Duct Type Intraductal Papillary mucinous Neoplasms of the Pancreas**

- Conclusion: A nomogram predicting malignancy in patients with BD-IPMN was constructed using a logistic regression model. This nomogram may be useful in identifying patients at risk of malignancy and for selecting optimal treatment methods. The nomogram is freely available at http://diagnosis.pcn.annals.org/article/S1072-7515(17)30203-9.
Model development – Internal validation

Evaluate performance – External validation

- 1,000 times boot-strapped Calibration

Global Validation of Nomogram Predicting Malignancy

- Europe
- Karolinska U
- Academic Medical Center
- Verona U
- USA
- Johns Hopkins
- Columbia U
- China
- Peking U
- Fudan U
- Taiwan
- National Taiwan U
- Taipei Veterans H

External Validation - Malignancy prediction

Survival according to Pathology and Nomogram

- Han and Jang, NEJM (Submitted)
Life Expectancy and Quality Adjusted Life Year according to treatment (Surgery vs Surveillance) Using Nomogram

<table>
<thead>
<tr>
<th>Age</th>
<th>Malignancy risk</th>
<th>Surveillance (Mortality 1%)</th>
<th>Surveillance (Mortality 3%)</th>
<th>Surveillance (Mortality 5%)</th>
<th>Surgery (Mortality 1%)</th>
<th>Surgery (Mortality 3%)</th>
<th>Surgery (Mortality 5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;65</td>
<td>&lt;10%</td>
<td>13.22</td>
<td>12.46</td>
<td>11.81</td>
<td>13.29</td>
<td>12.43</td>
<td>11.81</td>
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<tr>
<td></td>
<td>10~35%</td>
<td>12.48</td>
<td>11.73</td>
<td>11.26</td>
<td>12.41</td>
<td>11.68</td>
<td>11.22</td>
</tr>
<tr>
<td></td>
<td>&gt;35%</td>
<td>11.81</td>
<td>11.24</td>
<td>10.86</td>
<td>12.17</td>
<td>11.66</td>
<td>11.21</td>
</tr>
<tr>
<td>&gt;65</td>
<td>&lt;10%</td>
<td>12.46</td>
<td>11.81</td>
<td>11.24</td>
<td>12.64</td>
<td>12.06</td>
<td>11.73</td>
</tr>
<tr>
<td>65-75</td>
<td>10~35%</td>
<td>11.73</td>
<td>11.18</td>
<td>10.65</td>
<td>12.42</td>
<td>11.84</td>
<td>11.47</td>
</tr>
<tr>
<td></td>
<td>&gt;35%</td>
<td>11.24</td>
<td>10.88</td>
<td>10.46</td>
<td>12.14</td>
<td>11.70</td>
<td>11.31</td>
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<tr>
<td>&gt;75</td>
<td>&lt;10%</td>
<td>13.01</td>
<td>12.38</td>
<td>11.89</td>
<td>13.37</td>
<td>12.69</td>
<td>12.21</td>
</tr>
<tr>
<td></td>
<td>10~35%</td>
<td>12.39</td>
<td>11.85</td>
<td>11.42</td>
<td>12.79</td>
<td>12.11</td>
<td>11.71</td>
</tr>
<tr>
<td></td>
<td>&gt;35%</td>
<td>11.89</td>
<td>11.46</td>
<td>11.04</td>
<td>12.37</td>
<td>11.89</td>
<td>11.49</td>
</tr>
</tbody>
</table>

Examples

<table>
<thead>
<tr>
<th>Age</th>
<th>Malignancy risk</th>
<th>Tumor size (mm)</th>
<th>MPD (mm)</th>
<th>Mural nodule</th>
<th>CA19-9</th>
<th>Malignancy risk</th>
<th>Invasive risk</th>
<th>Final pathology</th>
</tr>
</thead>
<tbody>
<tr>
<td>76</td>
<td>&lt;10%</td>
<td>16</td>
<td>4</td>
<td>-</td>
<td>99</td>
<td>47.5%</td>
<td>21.6%</td>
<td>T1N0 invasive</td>
</tr>
<tr>
<td></td>
<td>10~35%</td>
<td>40</td>
<td>2</td>
<td>-</td>
<td>45</td>
<td>17.9%</td>
<td>6.3%</td>
<td>Low grade dysplasia</td>
</tr>
<tr>
<td></td>
<td>&gt;35%</td>
<td>42</td>
<td>10</td>
<td>-</td>
<td>17</td>
<td>44.4%</td>
<td>15.2%</td>
<td>T2N1 invasive</td>
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<tr>
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Summary & Conclusion

- Detection of small IPMN has been increasing.
  - Most of BD-IPMN are dormant. Annual malignancy conversion rate 0.2-0.6%.
  - But large cyst over 3cm or growing BD-IPMN must be carefully monitored due to the increasing risk of malignancy.
- Three guidelines have controversies on some issues due to lack of evidences.
  - needs more evidences in a future.
- Tailored approach is needed in selection of surgery or surveillance considering malignancy potential and patient’s factors. Nomogram could be a valuable tool in selecting treatment methods as customized approach for IPMN.