**Introduction**

Sensitivity of ERCP brush cytology for diagnosis of malignant biliary strictures has been disappointing, with reported sensitivity of 20-60%.

Recently, a new brush incorporating multiple device improvements has become available (Infinity Brush, US Endoscopy, Mentor, OH).

We wanted to determine if this brush yielded more cytologic specimen and so doing improved sensitivity for diagnosis of malignancy.

**Methods**

Retrospective chart review was done of all ERCPs where cytologic brushing of a biliary stricture was performed and the patient was eventually diagnosed with a malignant stricture.

In accordance to current standards in the literature, cytopathological diagnosis of “malignant” or “suspicious” were considered positive, while “atypical” was considered negative.

**Historical Control:**

- Procedures performed between 1/2008 and 6/2011.
- Cytology brushing done with a standard wire-guided brush with a 6Fr sheath.
- 1 or 2 passes across the stricture were done.
- 2 smears were prepared, and in most cases the brush head was cut off into cytology fluid (RPMI) and a cell block obtained.

**New Standardized Protocol:**

- Instituted after 7/2011.
- All cases were done with the Infinity and 2 passes were always made of the stricture.
- 2 smears were prepared on the first pass (one air dried and one fixed), and the brush agitated in RPMI to dislodge cells. On the second pass, the brush was cut off into the RPMI.
- Salvage cytology was also done by injecting 5mL of RPMI through the brush catheter after brushing was completed. The 2 slides and the tube of RPMI were submitted, and cell block made.
- Smears and cell blocks were reviewed by 2 experienced cytopathologists blinded to final diagnosis.

**Endpoints:**

1) Cellular yield - Quantified by describing the number and size of cell clusters seen. (Large clusters: >50 cells, medium: 6-29 cells, small: 2-5 cells, and single cells).
2) Diagnostic Sensitivity – Ability to make the diagnosis of a malignant stricture by brushing alone.

**Diagnostic Yield – Ability to Make Diagnosis of Malignancy**

<table>
<thead>
<tr>
<th></th>
<th>Standardized Protocol</th>
<th>Historical Control</th>
<th>( p )-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>All cases</td>
<td>25/32 (78.1%)</td>
<td>17/46 (37.0%)</td>
<td>0.0003*</td>
</tr>
<tr>
<td>Pancreatic adenocarcinoma</td>
<td>17/23 (73.9%)</td>
<td>6/20 (30.0%)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Cholangiocarcinoma</td>
<td>7/7 (100%)</td>
<td>8/22 (36.4%)</td>
<td>0.004*</td>
</tr>
<tr>
<td>Other malignancies</td>
<td>1/2 (50.0%)</td>
<td>3/4 (75.0%)</td>
<td>0.6</td>
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</tbody>
</table>

**Results**

32 new brush cases and 46 historical cases were analyzed.

25 of 32 (78.1%) cases in the new device group could be diagnosed with malignancy compared to 17 of 46 (37.0%) in the historical group (\( p = 0.0003 \)).

Significant increase in the average number of cell clusters obtained with the new device (21.1 vs. 9.7, \( p = 0.001 \)).

This improvement in cellular yield held true for clusters of all sizes.

**Conclusions**

A standardized protocol that includes: a) use of an improved ERCP-cytology brush, b) two brush passes in the stricture, and c) preparation of both smears and cell block provides more tissue and higher sensitivity for the diagnosis of malignant biliary strictures.