2. EUS-Guided Core Biopsy with a Novel 19-Gauge Flexible Fine Needle Biopsy (FNB) Device: Multi-Center Experience.

J. Y. Bang, S. H. Magee, J. Ramesh, J. M. Trevino, S. Varadarajulu; University of Alabama at Birmingham, Birmingham, Alabama (USA); Florida Hospital, Orlando, Florida, USA. DDW 2013 abstract #MO1496.

Does Technique Matter?

Liver Biopsy Study

- EUS-guided hepatic biopsy with a novel single step lumen-apposing covered metal stent delivery system can decrease the cost of pancreatic cyst drainage.
- The cost of LA-CMS is lower than that of standard pancreatic duct drainage.

Pancreatic Fluid Collections Drainage

- EUS-guided drainage of pancreatic fluid collections using a novel single-step lumen-apposing metal stent with pre-mounted stent and delivery system is safe, easy to perform, and a highly effective minimally invasive treatment for PFCs.

Procedure Time

- Procedure time and facilitates necrosectomy sessions. The cost of LA-CMS is lower than that of standard pancreatic duct drainage.

FNA vs FNB Study

- Randomized trial comparing the 22-gauge aspiration and 25-gauge FNB needles for EUS-guided sampling of solid pancreatic mass lesions.
- Ninety-three patients with PFCs (80% with complex collections) underwent drainage using the study device.
- Complete resolution of the PFC was obtained in 86% of cases (92.5%), with no recurrence during follow-up. EUS-guided drainage of pancreatic fluid collections is safe, easy to perform, and a highly effective minimally invasive treatment for PFCs.

FNA of the Standard Needle: M005

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19ga (1.10mm)</td>
<td>2.8mm</td>
</tr>
<tr>
<td>19ga Flex (1.14mm)</td>
<td>2.8mm</td>
</tr>
<tr>
<td>22ga (0.72mm)</td>
<td>2.4mm</td>
</tr>
<tr>
<td>25ga (0.52mm)</td>
<td>2.4mm</td>
</tr>
</tbody>
</table>

FNA of the Flex Needle: M005

<table>
<thead>
<tr>
<th>Diameter (mm)</th>
<th>Length (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>19ga Flex (1.14mm)</td>
<td>2.8mm</td>
</tr>
</tbody>
</table>

Conclusion

- EUS-LB was successful in achieving a pathological diagnosis in 94.4% of patients.
- On-site diagnostic sufficiency: 94.4% vs 88.9%.
- Diagnostic Accuracy = 76.9% vs 96.4%.
- Standard Technique = 26 Patients; Fanning Technique = 28 Patients.

Note: Although both cohorts required a median of 1 pass to reach diagnostic adequacy, the fanning technique was superior to the standard technique for establishing the diagnosis between the median number of passes required to establish the diagnosis in both groups.

Liver Biopsy Study

- Multi-Center Randomized Trial Comparing the 19-ga and 25-ga Needle Biopsy Devices: Multi-Center Experience.
- D. L. Diehl et al.; Affiliations: Geisinger Medical Center, Danville, PA, USA; Winthrop University Hospital, Mineola, NY, USA; University of Alabama, Tuscaloosa, AL, USA; Medical Center, Springfield, VA; GEAG; DDW 2013 abstract #MO1496.

- EUS-Guided Core Biopsy with a Novel 19-Gauge Flexible Fine Needle Biopsy (FNB) Device: Multi-Center Experience.
- J. Y. Bang, S. H. Magee, J. Ramesh, J. M. Trevino, S. Varadarajulu; University of Alabama at Birmingham, Birmingham, Alabama (USA); Florida Hospital, Orlando, Florida, USA. DDW 2013 abstract #MO1496.

- Does Technique Matter?

Liver Biopsy Study

- Multi-Center Randomized Trial Comparing the 19-ga and 25-ga Needle Biopsy Devices: Multi-Center Experience.
- D. L. Diehl et al.; Affiliations: Geisinger Medical Center, Danville, PA, USA; Winthrop University Hospital, Mineola, NY, USA; University of Alabama, Tuscaloosa, AL, USA; Medical Center, Springfield, VA; GEAG; DDW 2013 abstract #MO1496.

- Does Technique Matter?

Liver Biopsy Study

- Multi-Center Randomized Trial Comparing the 19-ga and 25-ga Needle Biopsy Devices: Multi-Center Experience.
- D. L. Diehl et al.; Affiliations: Geisinger Medical Center, Danville, PA, USA; Winthrop University Hospital, Mineola, NY, USA; University of Alabama, Tuscaloosa, AL, USA; Medical Center, Springfield, VA; GEAG; DDW 2013 abstract #MO1496.

- Does Technique Matter?
The world’s first stent designed for endoscopic ultrasound guided transluminal therapy

Expect™ Endoscopic Ultrasound Aspiration Needles

Custom Needle Grind for Improved Sampling
- Sharp grind and deep needle bevel help provide precise penetration into the target area and the potential for improved tissue sampling

Cobalt-Chromium Construction
- Provides benefits over some stainless steel alloys, including greater needle hardness and excellent tensile properties to deliver:
  - Superior needle penetration
  - Improved pushability and kink resistance
  - Increased resistance to needle damage or deformation after multiple passes

Echogenic pattern extends onto needle tip
- Provides precise guidance within the target site
- Helps maintain tip visibility at all times

Slimline Handle
- Smaller diameter handle
- Preference around tactile feel may help to:
  - Facilitate control when targeting lesions
  - Reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE™
- Two ergonomically defined areas designed to optimize control during actuation
- Accommodates different hand sizes and techniques

19ga Flex Needle for flexibility and durability

The Nitinol Difference
- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle
- More resistant to needle deformation through tortuous anatomy compared to stainless steel

The world’s first stent designed for endoscopic ultrasound guided transluminal therapy

Hot AXIOS™ Stent and Electrocautery Enhanced Delivery System

Cautery-enabled access and delivery catheter with the preloaded therapeutic AXIOS Stent for an exchange-free procedure
- Proprietary one-step combined diathermic ring and cut-wire provides easy access into target tissue
- Perpendicular flanges secure tissue layers and help to prevent migration
- Stent creates anastomotic conduit between two lumens
- Large diameter fully covered lumen apposition stent enables rapid, effective drainage and passage of the endoscope for additional Peri-procedural procedures

Indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or the biliary tract

Intuitive user-friendly delivery system for easy and efficient stent deployment


Diagnostic Solutions

Therapeutic Solutions

Custom Needle Grind for Improved Sampling
- Sharp grind and deep needle bevel help provide precise penetration into the target area and the potential for improved tissue sampling

Cobalt-Chromium Construction
- Provides benefits over some stainless steel alloys, including greater needle hardness and excellent tensile properties to deliver:
  - Superior needle penetration
  - Improved pushability and kink resistance
  - Increased resistance to needle damage or deformation after multiple passes

Echogenic pattern extends onto needle tip
- Provides precise guidance within the target site
- Helps maintain tip visibility at all times

Slimline Handle
- Smaller diameter handle
- Preference around tactile feel may help to:
  - Facilitate control when targeting lesions
  - Reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE™
- Two ergonomically defined areas designed to optimize control during actuation
- Accommodates different hand sizes and techniques

19ga Flex Needle for flexibility and durability

The Nitinol Difference
- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle
- More resistant to needle deformation through tortuous anatomy compared to stainless steel

The world’s first stent designed for endoscopic ultrasound guided transluminal therapy

Hot AXIOS™ Stent and Electrocautery Enhanced Delivery System

Cautery-enabled access and delivery catheter with the preloaded therapeutic AXIOS Stent for an exchange-free procedure
- Proprietary one-step combined diathermic ring and cut-wire provides easy access into target tissue
- Perpendicular flanges secure tissue layers and help to prevent migration
- Stent creates anastomotic conduit between two lumens
- Large diameter fully covered lumen apposition stent enables rapid, effective drainage and passage of the endoscope for additional Peri-procedural procedures

Indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or the biliary tract

Intuitive user-friendly delivery system for easy and efficient stent deployment


Diagnostic Solutions

Therapeutic Solutions

Custom Needle Grind for Improved Sampling
- Sharp grind and deep needle bevel help provide precise penetration into the target area and the potential for improved tissue sampling

Cobalt-Chromium Construction
- Provides benefits over some stainless steel alloys, including greater needle hardness and excellent tensile properties to deliver:
  - Superior needle penetration
  - Improved pushability and kink resistance
  - Increased resistance to needle damage or deformation after multiple passes

Echogenic pattern extends onto needle tip
- Provides precise guidance within the target site
- Helps maintain tip visibility at all times

Slimline Handle
- Smaller diameter handle
- Preference around tactile feel may help to:
  - Facilitate control when targeting lesions
  - Reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE™
- Two ergonomically defined areas designed to optimize control during actuation
- Accommodates different hand sizes and techniques

19ga Flex Needle for flexibility and durability

The Nitinol Difference
- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle
- More resistant to needle deformation through tortuous anatomy compared to stainless steel

The world’s first stent designed for endoscopic ultrasound guided transluminal therapy

Hot AXIOS™ Stent and Electrocautery Enhanced Delivery System

Cautery-enabled access and delivery catheter with the preloaded therapeutic AXIOS Stent for an exchange-free procedure
- Proprietary one-step combined diathermic ring and cut-wire provides easy access into target tissue
- Perpendicular flanges secure tissue layers and help to prevent migration
- Stent creates anastomotic conduit between two lumens
- Large diameter fully covered lumen apposition stent enables rapid, effective drainage and passage of the endoscope for additional Peri-procedural procedures

Indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or the biliary tract

Intuitive user-friendly delivery system for easy and efficient stent deployment


Diagnostic Solutions

Therapeutic Solutions

Custom Needle Grind for Improved Sampling
- Sharp grind and deep needle bevel help provide precise penetration into the target area and the potential for improved tissue sampling

Cobalt-Chromium Construction
- Provides benefits over some stainless steel alloys, including greater needle hardness and excellent tensile properties to deliver:
  - Superior needle penetration
  - Improved pushability and kink resistance
  - Increased resistance to needle damage or deformation after multiple passes

Echogenic pattern extends onto needle tip
- Provides precise guidance within the target site
- Helps maintain tip visibility at all times

Slimline Handle
- Smaller diameter handle
- Preference around tactile feel may help to:
  - Facilitate control when targeting lesions
  - Reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE™
- Two ergonomically defined areas designed to optimize control during actuation
- Accommodates different hand sizes and techniques

19ga Flex Needle for flexibility and durability

The Nitinol Difference
- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle
- More resistant to needle deformation through tortuous anatomy compared to stainless steel

The world’s first stent designed for endoscopic ultrasound guided transluminal therapy

Hot AXIOS™ Stent and Electrocautery Enhanced Delivery System

Cautery-enabled access and delivery catheter with the preloaded therapeutic AXIOS Stent for an exchange-free procedure
- Proprietary one-step combined diathermic ring and cut-wire provides easy access into target tissue
- Perpendicular flanges secure tissue layers and help to prevent migration
- Stent creates anastomotic conduit between two lumens
- Large diameter fully covered lumen apposition stent enables rapid, effective drainage and passage of the endoscope for additional Peri-procedural procedures

Indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or the biliary tract

Intuitive user-friendly delivery system for easy and efficient stent deployment


Diagnostic Solutions

Therapeutic Solutions

Custom Needle Grind for Improved Sampling
- Sharp grind and deep needle bevel help provide precise penetration into the target area and the potential for improved tissue sampling

Cobalt-Chromium Construction
- Provides benefits over some stainless steel alloys, including greater needle hardness and excellent tensile properties to deliver:
  - Superior needle penetration
  - Improved pushability and kink resistance
  - Increased resistance to needle damage or deformation after multiple passes

Echogenic pattern extends onto needle tip
- Provides precise guidance within the target site
- Helps maintain tip visibility at all times

Slimline Handle
- Smaller diameter handle
- Preference around tactile feel may help to:
  - Facilitate control when targeting lesions
  - Reduce tension and friction during actuation
- Low-profile locking knobs

Control ZONE™
- Two ergonomically defined areas designed to optimize control during actuation
- Accommodates different hand sizes and techniques

19ga Flex Needle for flexibility and durability

The Nitinol Difference
- Provides flexibility, passability and actuation comparable to the 22ga Expect Needle
- More resistant to needle deformation through tortuous anatomy compared to stainless steel

The world’s first stent designed for endoscopic ultrasound guided transluminal therapy

Hot AXIOS™ Stent and Electrocautery Enhanced Delivery System

Cautery-enabled access and delivery catheter with the preloaded therapeutic AXIOS Stent for an exchange-free procedure
- Proprietary one-step combined diathermic ring and cut-wire provides easy access into target tissue
- Perpendicular flanges secure tissue layers and help to prevent migration
- Stent creates anastomotic conduit between two lumens
- Large diameter fully covered lumen apposition stent enables rapid, effective drainage and passage of the endoscope for additional Peri-procedural procedures

Indicated for use to facilitate transgastric or transduodenal endoscopic drainage of a pancreatic pseudocyst or the biliary tract

Intuitive user-friendly delivery system for easy and efficient stent deployment