Visualization of endometriosis: comparative study of 3-dimensional robotic and 2-dimensional laparoscopic endoscopes

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Main objective
Compare the results of using the robotic 3D/HD scope and the 2D/HD laparoscope for visual detection of histologically confirmed endometriosis

Study period
April 2011 to December 2014

Study size
Ninety-eight patients from three surgeons in different practices

Visualization of endometriosis: comparative study of 3-dimensional robotic and 2-dimensional laparoscopic endoscopes

Study overview

- 598 lesions were visualized in 98 patients. Patients were premenopausal women ≥18 years who had elected to undergo robotic-assisted endometriosis resection.

- There were no significant differences in age, BMI, prior endometriosis surgery, clinical stage, and adhesion severity between randomization sequence groups.

- Patients were randomized to 2D/HD lap visualization either before or after 3D/HD visualization. Resections then proceeded robotically.

- Patients who were randomized to undergo 2D visualization first had a greater average number of detected lesions than did patients who were randomized to undergo 3D robotic visualization first (p < 0.05).

- The number of histologically confirmed lesions overall and by abdomino-pelvic location, the appearance, and the size were compared by the scope type used.

Characteristics of lesions visualized with the 2D compared to the 3D scope

<table>
<thead>
<tr>
<th>Lesions visualized</th>
<th>Total No. Lesions</th>
<th>2D Scope</th>
<th>3D Scope</th>
<th>Difference, % (3D–2D)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lesions/person, mean (SD)</td>
<td>598</td>
<td>474 (79.3%)</td>
<td>595 (99.5%)</td>
<td>20.2</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive for endometriosis</td>
<td>349</td>
<td>272 (77.9%)</td>
<td>349 (100%)</td>
<td>22.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Visualized in the cul-de-sac</td>
<td>131</td>
<td>105 (80.2%)</td>
<td>130 (99.2%)</td>
<td>19.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive</td>
<td>81</td>
<td>64 (79.0%)</td>
<td>81 (100%)</td>
<td>21.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Visualized with atypical appearance</td>
<td>473</td>
<td>357 (75.5%)</td>
<td>470 (99.4%)</td>
<td>23.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive</td>
<td>254</td>
<td>181 (71.3%)</td>
<td>254 (100%)</td>
<td>28.7</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Width &lt;5 mm</td>
<td>253</td>
<td>188 (74.3%)</td>
<td>251 (99.2%)</td>
<td>24.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive</td>
<td>121</td>
<td>75 (62.0%)</td>
<td>121 (100%)</td>
<td>38.0</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Width ≥5 mm</td>
<td>345</td>
<td>286 (82.9%)</td>
<td>344 (99.7%)</td>
<td>16.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive</td>
<td>228</td>
<td>197 (86.4%)</td>
<td>228 (100%)</td>
<td>13.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Superficial lesion</td>
<td>474</td>
<td>372 (78.5%)</td>
<td>472 (99.6%)</td>
<td>21.1</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive</td>
<td>254</td>
<td>191 (75.2%)</td>
<td>254 (100%)</td>
<td>24.8</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Deep lesion</td>
<td>124</td>
<td>102 (82.3%)</td>
<td>123 (99.2%)</td>
<td>16.9</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Histology positive</td>
<td>93</td>
<td>79 (84.9%)</td>
<td>93 (100%)</td>
<td>15.1</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>

Results and limitations

Results

- 100% of lesions confirmed as endometriosis were detected using the robotic 3D/HD scope, and 77.9% were detected using the 2D/HD laparoscope (p<0.001)
- Of all lesions detected, the robotic 3D scope enabled visualization of a significantly higher proportion (99.5%) compared to the 2D laparoscope (79.3%) (p<0.001)
- Compared to lap visualization, robotic visualization detected more confirmed lesions in all anatomic locations and for most appearances, including cul-de-sac, atypical appearance, and width <5 mm (p<0.001)
  - The 3D robotic endoscope enabled identification of more positive lesions than the 2D laparoscope for all lesion appearances, except in the cases of ‘stellate’ and ‘ovarian endometrioma’ where both scopes visualized the same small number of lesions
  - Positive lesions with cobblestoning and terrain changes were visible only with the robotic 3D endoscope
  - Almost twice as many positive lesions appearing as peritoneal defects (pockets) were detected with 3D compared to 2D scope
- Logistic regression indicated that the use of 3D/HD robotic scope was independently associated with 2.36 times the likelihood of detecting a confirmed lesion, compared to the 2D/HD laparoscope (95% CI 1.20, 4.66; p=0.014)

Limitations

- Neither method identified the true number of lesions in the pelvic cavity
- Surveys were not blinded to the results from the first scope that, in turn, could have unknowingly influenced the findings noted during the second visualization

Risks associated with endometriosis resection include bowel injury, bladder injury, urinary tract injury.

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The demonstration of safety and effectiveness for the specific procedure(s) discussed in this material was based on evaluation of the device as a surgical tool and did not include evaluation of outcomes related to the treatment of cancer (overall survival, disease-free survival, local recurrence) or treatment of the patient’s underlying disease/condition. Device usage in all surgical procedures should be guided by the clinical judgment of an adequately trained surgeon.

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