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ORIGINAL ARTICLE

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

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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.

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

	Total No. Lesions	2D Scope	3D Scope	Difference, % (3D–2D)	*p* value
Lesions visualized	598	474 (79.3%)	595 (99.5%)	20.2	<0.001
Lesions/person, mean (SD)		4.8 (2.7)	6.1 (3.1)		0.008
Histology positive for endometriosis	349	272 (77.9%)	349 (100%)	22.1	<0.001
Visualized in the cul-de-sac	131	105 (80.2%)	130 (99.2%)	19.1	<0.001
Histology positive	81	64 (79.0%)	81 (100%)	21.0	<0.001
Visualized with atypical appearance	473	357 (75.5%)	470 (99.4%)	23.9	<0.001
Histology positive	254	181 (71.3%)	254 (100%)	28.7	<0.001
Width <5 mm	253	188 (74.3%)	251 (99.2%)	24.9	<0.001
Histology positive	121	75 (62.0%)	121 (100%)	38.0	<0.001
Width ≥5 mm	345	286 (82.9%)	344 (99.7%)	16.8	<0.001
Histology positive	228	197 (86.4%)	228 (100%)	13.6	<0.001
Superficial lesion	474	372 (78.5%)	472 (99.6%)	21.1	<0.001
Histology positive	254	191 (75.2%)	254 (100%)	24.8	<0.001
Deep lesion	124	102 (82.3%)	123 (99.2%)	16.9	<0.001
Histology positive	93	79 (84.9%	93 (100%)	15.1	<0.001

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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
- Surgeons were not blinded to the results from the first scope that, in turn, could have unknowingly influenced the findings noted during the second visualization

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Important safety information

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

Serious complications may occur in any surgery, including *da Vinci*® Surgery, up to and including death. Examples of serious or life-threatening complications, which may require prolonged and/or unexpected hospitalization and/or reoperation, include but are not limited to one or more of the following: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain. Individual surgical results may vary.

Risks specific to minimally invasive surgery, including *da Vinci*® Surgery, include but are not limited to, one or more of the following: temporary pain/nerve injury associated with positioning; a longer operative time, the need to convert to an open approach, or the need for additional or larger incision sites. Converting the procedure could result in a longer operative time, a longer time under anesthesia, and could lead to increased complications. Contraindications applicable to the use of conventional endoscopic instruments also apply to the use of all *da Vinci* instruments. You should discuss your surgical experience and review these and all risks with your patients, including the potential for human error and equipment failure. Physicians should review all available information. Clinical studies are available through the National Library of Medicine at www.ncbi.nlm.nih.gov/pubmed.

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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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