



# Applying STARD Criteria to the Laparoscopic Identification of Endometriosis

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## Abstract

**Study Objective:** This review investigates application of the Standards for Reporting of Diagnostic Accuracy (STARD) criteria to endometriosis research.

**Design:** A literature was performed for criteria used for diagnosis of endometriosis. These were compared with the STARD criteria for research.

**Setting:** Literature review

**Patients or Participants:** None.

**Interventions:** None

**Materials and Methods:** Literature search.

**Measurements and Main Results:** An article by Wykes (2004) suggested use of STARD criteria to avoid methodological deficiencies in research on diagnostic accuracy. She emphasized the features that constitute a normal or abnormal laparoscopy should be explicit and recorded. Possible criteria for STARD analysis include histologic requirements, laparoscopy appearances, the distance of observation, use of clinical palpation, use of exam under anesthesia, use of intra-operative palpation, palpation with instrumentation, and other concerns that may affect recognition.

Batt (1989) suggested 4 grades of histologic certainty:

Grade 1: Possible residua of resorbed endometriosis.

Grade 2: Consistent with endometriosis, i.e. characteristic glands or stroma.

Grade 3: Definite endometriosis, i.e. characteristic glands and stroma with hemosiderin; and

Grade 4: Grade III with structures conveying and organoid pattern.

Preliminary considerations of laparoscopic grades of certainty are:

Grade 1: Vesicles, polyps, hypervascularity, scar, adhesions;

Grade 2: Chocolate cyst with free flow of chocolate fluid;

Grade 3: Dark scarred lesions, red lesion on fibrous scarred background, chocolate cyst with mottled red and dark areas on white background; and

Grade 4: Dark, scarred lesions at first surgery.

Simpler versions can also be suggested.

**Conclusions:** There are many questions and concerns that need to be addressed at a research level before biopsy becomes a generalized clinical standard for the diagnosis of endometriosis. In the meantime, biopsy is useful in clarifying the diagnosis of similar appearing lesions and in ruling out cancer.

## Objectives

A recent article by Wykes pointed out that there is very little good quality literature assessing the value of visual diagnosis of endometriosis at laparoscopy.<sup>1</sup> She suggested use of Standards for Reporting of Diagnostic Accuracy (STARD) criteria to avoid the methodological deficiencies in research on diagnostic accuracy discovered in her systematic review.<sup>2,3</sup> This literature focuses on the Wykes review<sup>1</sup> in order to point out some of the difficulties of endometriosis research.

## Design

The literature was reviewed for criteria used in publications such as Batt's 1989 histologic grades of certainty in the histologic diagnosis of endometriosis. These were expanded and compared to the STARD criteria for research

## Materials and Methods

A computerized literature search was performed using the keywords "diagnostic," "criteria" and "endometriosis." Relevant articles were identified and incorporated into the review.

## Results

Batt studied the histologic criteria and suggested 4 grades of histologic certainty:<sup>3,4</sup> Histologic Grades of Certainty

- Grade 1: Possible residua of resorbed endometriosis, i.e., hemosiderin, nerve, blood vessels and smooth muscle.

- Grade 2: Consistent with endometriosis, i.e. characteristic glands or stroma.

- Grade 3: Definite endometriosis, i.e. characteristic glands and stroma with hemosiderin.

- Grade 4: Grade III with structures conveying and organoid pattern, i.e. glandular-stromal layer overlying well developed smooth muscle layer.

A recent article by Wykes pointed out that there is very little good quality literature assessing the value of visual diagnosis of endometriosis at laparoscopy.<sup>1</sup> She suggested use of Standards for Reporting of Diagnostic Accuracy (STARD) criteria to avoid the methodological deficiencies in research on diagnostic accuracy discovered in her systematic review.<sup>2,3</sup> This included use of an adequately described population spectrum that reflected standard practice. She further emphasized the features that constitute a normal or abnormal laparoscopy should be explicit and the type, site and extent of disease should be recorded to assess their impact on accuracy. Finally, test results must be verified in all cases and potential bias due to variation in interpretation of the histological reference standard should be minimized by standardized reporting and blinding assessment of the laparoscopy findings.<sup>1</sup>

The contrary view was presented by Cerrato.<sup>5</sup> He points out that researchers often fail to prove that their evidenced-based conclusions are actually applicable to everyday practice. Put another way, clinical investigators don't always prove that their findings have external validity so that the results apply outside a carefully controlled experimental environment. In fact, according to a recent report, "lack of consideration of external validity is the most frequent criticism by clinicians of RCTs, systematic reviews, and guidelines."<sup>6</sup>

## Discussion

Applying the STARD criteria requires clarification of the methods used.<sup>1,2</sup> As examples, criteria will be needed for degrees of histologic certainty and degrees of certainty in laparoscopy appearance.<sup>3,4</sup> Degrees of laparoscopic certainty are considered below. Other considerations include the distance of observation, use of loupes, use of operating microscope, use of clinical palpation, use of pre-operative palpation under anesthesia, use of intra-operative palpation, manual palpation, palpation with instrumentation, and other concerns that may affect the observer's recognition.

The next two possibilities are preliminary considerations suggested for thought.

Laparoscopic Grades of Certainty (4 Grades)

- Grade 1: Peritoneal vesicles, red polyps, yellow polyps, hypervascularity, scar, adhesions.

- Grade 2: Chocolate cyst with free flow of chocolate fluid.

- Grade 3: Dark, scarred (or puckered, pigmented) lesions, red lesion on fibrous scarred background, chocolate cyst with mottled red and dark areas on white background.

- Grade 4: Dark, scarred (or puckered, pigmented) lesions at first surgery.

Laparoscopic Grades of Certainty (Simpler version)

- Probable Endometriosis - A peritoneal, retroperitoneal, ovarian, diaphragmatic or other red or dark lesion associated with a white, scarred perimeter seen at first surgery.

- Abnormal Peritoneal Lesion - Any peritoneal, retroperitoneal, ovarian, diaphragmatic, scar or other abnormality not classified as "Probable Endometriosis."

These two versions of "Laparoscopic Grades of Certainty" are not meant to be a new grading system. They are meant to provide a starting point for considerations regarding the criteria to be applied to Items 7 and 9 of the STARD checklist for the reporting of studies of diagnostic accuracy.<sup>2</sup> Items 7 and 9 pertain to selection and use of the research standard, units, cut-offs and categories for observations.

## Discussion (continued)

Since accuracy has been associated with increasing clinical volume and with experience,<sup>8-13</sup> a decision would need to be made about STARD item 10. Item 10 clarifies the need for determining the number, training and expertise of the laparoscopists.<sup>2</sup> In addition, to be clinically useful the result must also be relevant to a definable group of patients in a particular clinical setting.<sup>5</sup> Studies done in chronic pelvic pain patients in a referral practice may not be generalizable to a normal population.

Furthermore, laparoscopic techniques would need to be standardized to consider such concerns as single-puncture technique, double-puncture technique, triple-puncture technique, other puncture technique, 10 mm laparoscope, 5 mm laparoscope, 3 mm laparoscope, turning the ovaries, lysis of adhesions, resection of the body of adhesions, resection of the peritoneal-adhesion junction, etc. To produce STARD quality research is a challenge. That is even a greater challenge when there is no licensing body, such as the Food and Drug Administration, to require evidence that a treatment has a clinically useful effect or that a trial population is representative of routine clinical practice.<sup>6,7</sup>

## Conclusions

There are many questions and concerns that need to be addressed at a research level before biopsy becomes a generalized clinical standard for the diagnosis of endometriosis.<sup>4, 13</sup> In the meantime, biopsy is useful in clarifying the diagnosis of similar appearing lesions and in ruling out cancer

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