

Progress Report: Using the Delphi Method to Develop a Classification System for Uterine Fibroids

Presented at the *Advances in Uterine Leiomyoma Research: 3rd NIH International Congress*
Bethesda, MD
November 21-23, 2010

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Advances in Uterine Leiomyoma Research: 3rd NIH International Congress

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Progress Report: Using Delphi Method to Develop a Classification System for Uterine Fibroids

After attending this session participants will be able to:

- Describe the current status of the development of a new classification system for uterine fibroids
- Identify a consensus classification based system for uterine fibroids

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The second National Institutes of Health International Congress on advances in uterine leiomyoma research: conference summary and future recommendations

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- “...lack of a standardized, clinical system for classification of these tumors.”
- “...a consensus...conference be organized to facilitate the establishment of a scoring system or clinical classification scheme ... “
- “...classifications should be interchangeable between disciplines and useful to clinicians...and clinical researchers.”

SESSION VIII. FUTURE DIRECTIONS: CHARTING THE COURSE

A common problem among investigators conducting clinical or translational leiomyoma research, or testing efficacy of medical, radiological, and/or surgical therapies is the current lack of a standardized, clinical system for classification of these tumors. Uterine leiomyomas by nature are difficult to classify because they can be single or multiple, of different sizes and located within different regions of the uterus. Furthermore, there are clear genetic syndromes that feature leiomyoma development, yet the molecular and clinical features of these rare genetic conditions may or may not resemble those of common leiomyomas. Several attendees suggested that a consensus or state-of-the-art conference be organized to facilitate the establishment of a scoring system or clinical classification scheme for leiomyomas. This suggestion was endorsed by comments from several scientists, clinicians, and other participants, and it was emphasized that the classifications should be interchangeable between disciplines and useful to clinicians, as well as basic and clinical researchers.

Goal: develop a classification system, usable by clinicians and researchers, that eventually can be used to guide treatment and predict response

RAND/UCLA Modified Delphi method

- 9-12 experts representing various stakeholder groups (gynecology, REI, IR, pathology, basic science, FDA) from diverse settings (geographic, practice base)
- 3 cycles of ratings (premeeting written ratings, in person discussion, post meeting written)
- Premeeting ratings help focus discussion
- “Nominal group process”



Round 1: Establish Criteria for New System

Panelists rated 203 items in 15 domains, including:

- Goals
 - Severity (burns, hearing loss)
 - Function (NYHA, Glasgow coma)
 - Predictive (APACHE, Ottawa ankle rules)
 - Prognosis/treatment selection (cancer)
- Characteristics that would increase adoption
 - Reliability, ease of use, cost
- Measurement domains
 - Myoma size, volume, location, % of uterus affected, presence of adenomyosis
 - Signs and symptoms
- Tools needed to collect data

Round 1: Rating Form

1. How difficult would it be to create a uterine fibroid classification system within the next 5 years that achieves the following goals? Please answer about each goal independently.

2. To what extent would achieving this goal affect the likelihood that...

A. the CLINICIAN community would adopt the classification system?

B. the RESEARCH community would adopt the classification system?

| GOAL | Mark one box on each line | | | | | Mark one box on each line | | | | | Mark one box on each line | | | | |
|-------------------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|----------------------------|
| | Not at all difficult | Somewhat difficult | Moderately difficult | Quite difficult | Extremely difficult | No effect | Somewhat increase | Moderately increase | Significantly increase | Is essential | No effect | Somewhat increase | Moderately increase | Significantly increase | Is essential |
| a. Assesses risk/predicts prognosis | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> |
| b. Aids in planning treatment | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> |
| c. Compares outcomes | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> |
| d. Describes condition | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> | 1 <input type="checkbox"/> | 2 <input type="checkbox"/> | 3 <input type="checkbox"/> | 4 <input type="checkbox"/> | 5 <input type="checkbox"/> |

Round 1: Rating Form

4. How valuable is this domain in...

| MEASUREMENT DOMAINS | A. <u>assessing and managing a patient with uterine fibroids?</u> | | | | | B. <u>performing and interpreting research on uterine fibroids?</u> | | | | |
|---|---|--------------------------|--------------------------|--------------------------|--------------------------|---|--------------------------|--------------------------|--------------------------|--------------------------|
| | Not at all | Somewhat | Quite | Extremely | Is essential | Not at all | Somewhat | Quite | Extremely | Is essential |
| | valuable | | | | | valuable | | | | |
| | Mark one box on each line | | | | | Mark one box on each line | | | | |
| ANATOMIC (UTERUS/MYOMAS) | | | | | | | | | | |
| a. Myoma location compared to uterine cavity (either relative [sub-mucosal] or absolute [mm]) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| b. Myoma location compared to body axes (e.g., anterior/posterior) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| c. Myoma location compared to uterine structures (e.g., uterine vessels, tubal cornua) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| d. Myoma diameter | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| e. Myoma volume | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| f. Myoma number | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| g. Dominance of subserous/intracavitary/intramural myomas | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| h. Proportion of uterus affected | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

4. How valuable is this domain in...

| MEASUREMENT DOMAINS | A. <u>assessing and managing a patient with uterine fibroids?</u> | | | | | B. <u>performing and interpreting research on uterine fibroids?</u> | | | | |
|---|---|--------------------------|--------------------------|--------------------------|--------------------------|---|--------------------------|--------------------------|--------------------------|--------------------------|
| | Not at all | Somewhat | Quite | Extremely | Is essential | Not at all | Somewhat | Quite | Extremely | Is essential |
| | valuable | | | | | valuable | | | | |
| | Mark one box on each line | | | | | Mark one box on each line | | | | |
| RADIOLOGIC CHARACTERISTICS | | | | | | | | | | |
| i. Uterine cavity size | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| j. Uterine cavity distortion (e.g., degree) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| k. Uterine size | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| l. Location/description of uterus (e.g., retroverted, anteverted) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| m. Description of other pelvic structures (e.g., bowel between abdominal wall and uterus) | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| n. Adenomyosis present | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| SIGNS/SYMPTOMS (USING VALIDATED SCALE) | | | | | | | | | | |
| s. Bulk | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| t. Pain | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

Round 1 Results: September 2007 Panel

Areas of disagreement discussed at 1 ½ day in person meeting.
Ratings repeated.

High level of agreement that a new system must:

- be useful to compare treatment outcomes
- use widely available technology
- be validated
- give myoma location
- measure myoma diameter
- count number of myomas
- 4-6 categories

Moderate agreement on utility of capturing

- race/ethnicity
- prior interventions for fibroids

Round 2: Develop System

- October 2008, proposed systems distributed
- Rated on extent to which they met previously established goals
- November 2008, 1 day in person discussion
- Goal: developed final proposed system

For each Model, answer questions 1-3.

Round 2: Ratings, November 2008 Panel

- Initial proposed systems rated on extent to which original goals met
- Final system proposed and rated

| | 1. Does the model system provide a count of myomas? | | | | 2. Does the model system give myoma location compared to the uterine cavity? | | | | 3. Does the model system provide a measurement of myoma diameter? | | | |
|---------|---|-----------------------------------|----|----------------------------|--|-----------------------------------|----|----------------------------|---|-----------------------------------|----|----------------------------|
| | Yes, as is | Could be easily modified to do so | No | Unclear or cannot evaluate | Yes, as is | Could be easily modified to do so | No | Unclear or cannot evaluate | Yes, as is | Could be easily modified to do so | No | Unclear or cannot evaluate |
| | Mark one box on each line | | | | | | | | | | | |
| Model A | 1 | 3 | 3 | 5 | 1 | 3 | 3 | 5 | 1 | 3 | 3 | 5 |
| Model B | 1 | 3 | 3 | 5 | 1 | 3 | 3 | 5 | 1 | 3 | 3 | 5 |
| Model C | 1 | 3 | 3 | 5 | 1 | 3 | 3 | 5 | 1 | 3 | 3 | 5 |

| | 1. To what extent is the model system suited for the task of comparing outcomes of treatment for uterine fibroids? | | | | |
|---------|--|------------------|-------------------|-------------|----------------|
| | Not suited | Minimally suited | Moderately suited | Well suited | Ideally suited |
| | Mark one box on each line | | | | |
| Model A | 1 | 3 | 3 | 5 | 5 |
| Model B | 1 | 3 | 3 | 5 | 5 |
| Model C | 1 | 3 | 3 | 5 | 5 |

Final Proposed System

November 2008 Final Proposed Fibroid Classification System

| | Submucous ^a | | Subserous ^b | | Intramural ^c | Other | Summary |
|------------------------------|------------------------|--------|------------------------|--------------|-------------------------|-------|---------------------------------|
| | Type 0/1 | Type 2 | Not pedunculated | Pedunculated | | | |
| Number (0,1,2,3,4,5+) | | | | | | | Total^c |
| Size^d | | | | | | | Largest Fibroid size |
| Location^e | | | | | | | Uterine Size^f |

^a Type 0 (completely in the cavity); Type 1 ($\geq 50\%$ of volume in cavity); Type 2: ($< 50\%$ in cavity)

^b no submucous component

^c no subserous component

^c add numbers from entire row, using “+” to indicate any single category with >5 fibroids

^d of single largest fibroid in that category

^e defined as fundus (upper 2/3 of uterus); isthmus (lower 1/3 of uterus); and cervix (below internal os)

^f in 3 dimensions

November 2008 Final Proposed Fibroid Classification System

| | Submucous ^a | | Subserous ^b | | Intramural ^c | Other | Summary |
|------------------------------|------------------------|--------|------------------------|--------------|-------------------------|-------|---|
| | Type 0/1 | Type 2 | Not pedunculated | Pedunculated | | | |
| Number (0,1,2,3,4,5+) | 1 | | 1 | | 1 | | Total^c 3 |
| Size^d | 1.2 | | 3 | | 2 | | Largest Fibroid size 3 |
| Location^e | F | | F | | F | | Uterine Size^f 2.5 x 4 x 5 |

^a Type 0 (completely in the cavity); Type 1 ($\geq 50\%$ of volume in cavity); Type 2: ($< 50\%$ in cavity)

^b no submucous component

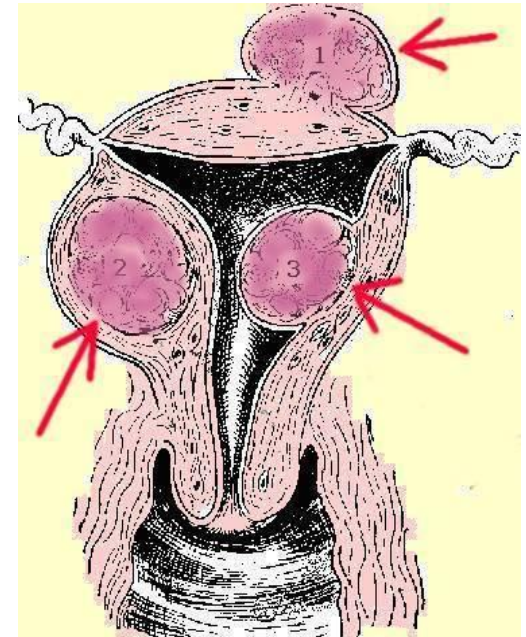
^c no subserous component

^d add numbers from entire row, using “+” to indicate any single category with >5 fibroids

^e of single largest fibroid in that category

^f defined as fundus (upper 2/3 of uterus); isthmus (lower 1/3 of uterus); and cervix (below internal os)

^g in 3 dimensions



November 2008 Final Proposed Fibroid Classification System

| | Submucous ^a | | Subserous ^b | | Intramural ^c | Other | Summary |
|------------------------------|------------------------|-----------|------------------------|--------------|-------------------------|-------|---|
| | Type 0/1 | Type 2 | Not pedunculated | Pedunculated | | | |
| Number (0,1,2,3,4,5+) | 1 | 1 | 1 | | 3 | | Total^c 6 |
| Size^d | .8 | .6 | 1.2 | | 2 | | Largest Fibroid size 2 |
| Location^e | F | | I | | F, I | | Uterine Size^f 2.5 x 3.5 x 5 |

^a Type 0 (completely in the cavity); Type 1 ($\geq 50\%$ of volume in cavity); Type 2: ($< 50\%$ in cavity)

^b no submucous component

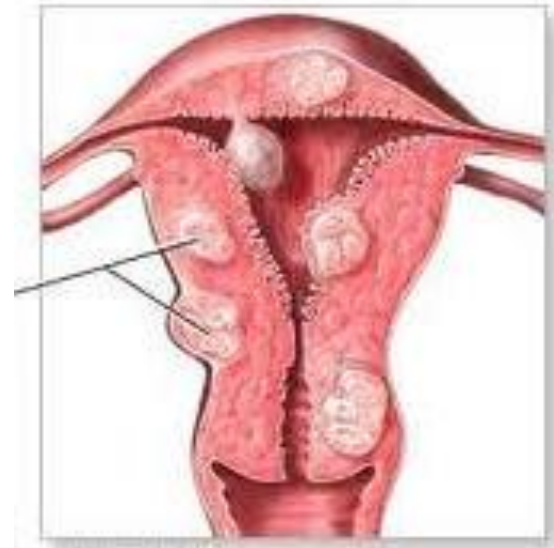
^c no subserous component

^d add numbers from entire row, using “+” to indicate any single category with >5 fibroids

^e of single largest fibroid in that category

^f defined as fundus (upper 2/3 of uterus); isthmus (lower 1/3 of uterus); and cervix (below internal os)

^g in 3 dimensions



Next Steps

- Conduct feasibility study using existing MRI and ultrasound images
- Share system with wider group; solicit structured feedback
- Write joint publication in radiology and gynecology journals

Acknowledgements

The authors would like to acknowledge the participation of the panelists and observers, all of whom were integral to this project

Panelists:

Kristof Chwalisz

Fiona Fennessy

Katherine Hartmann

Lisa Mattson

William Parker

Amal Salama

James Spies

Elizabeth Stewart

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