Multidisciplinary Treatment of Symptomatic Uterine Fibroids

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Disclosures

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Spectranetics
Atrium
CR Bard
Objectives

• Stress the importance imaging has in patient selection and education.
• Update treatment options available for symptomatic fibroids here at DUKE.
• Summarize some of the data available regarding clinical results and potential imaging predictors of failure or potential increase risk of complication.
Leiomyomata

- Prevalence up to 77% women
- Approx 20-40% reproducible age women
- At least 25 – 30% symptomatic
- M/C reason for laparotomy in non-preg

- Over 200,000 hysterectomies/year in U.S.
- 20,000 myomectomies/year in U.S.
- 400,000 new cases dx each year

- Significant morbidity/ economic impact
  - Direct health care and indirect work loss costs
  - Annual $4624/woman, 2.6x controls
Presentation

- Excess bleeding
- Pressure symptoms
- Pelvic pain
- Infertility
- Asymptomatic

- Risk factors:
  - Nulliparity
  - Obesity
  - Age
  - Early menarche
  - Family history
  - Hypertension
  - Race
Classification

- Nomenclature – SM, IM, SS
- European Society of Hysteroscopy Classification
  - Type 0, 1, 2
- Scoring system
- Detection:
  - Pelvic or Trans Vaginal Ultrasound
  - Hysteroscopy
  - Hystersonography
  - MRI
- Significance…
  - Preoperative planning
  - Reproductive outcome
  - Clinical counseling
  - Research
# Symptoms Related to Distribution

<table>
<thead>
<tr>
<th>Distribution</th>
<th>Bleeding</th>
<th>Pain</th>
<th>Infertility</th>
<th>Bulk Symptoms</th>
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<td>Intracavitary</td>
<td>+</td>
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<tr>
<td>Submucosal</td>
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<tr>
<td>Intramural</td>
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<tr>
<td>Subserosal</td>
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<td>Pedunculated</td>
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</tbody>
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Adapted Table from Guarnaccia, Rein. Traditional Surgical Approaches to Uterine Fibroids: Myomectomy and Hysterectomy. Clinical Obstetrics and Gynecology 2001;44:2 385-400
36yo with heavy menses and pain

Submucosal
Intramural
Subserosal
Intracavitary
Pedunculated
Key points to evaluation MRI

- Enhancement of fibroids.
- Fibroid and uterine volume.
- Pedunculated fibroid with stalk diameter less than 50% fibroid diameter.
- Intracavitary fibroid or polyp.
- Adenomyosis.
- Absent uterine artery / ovarian supply
Adenomyosis
Adenomyosis
Treatment Options

• Management depends on size, number, and location of myoma, as well as patient symptoms and preference for fertility and/or uterine sparing interventions

• Medical therapy

• Devascularization - UFE

• Heat/Electrocoagulation/Cryo- Myolysis, MRgFUS

• Surgical – H/S, L/S, Abdom myomectomy vs hysterectomy
Payer cost comparison

- 2836 hysterectomy, 704 myomectomy, 125 UAE patients
- Procedure costs were lower for UAE versus myomectomy and hysterectomy
- No difference in total 12 month payer costs due to greater imaging following UFE

Dembek, et al. JVIR 2006
Surgical Treatments

- Hysteroscopic Myomectomy
- Laparoscopic Myomectomy – Robotic assistance
- Abdominal Myomectomy
- Hysterectomy
Hysteroscopic Myomectomy

- Minimally invasive procedure
  - Same day endoscopic surgery
  - MAC anaesthesia
- Resection of submucosal fibroids
  - 5-8 mm hysteroscope
  - Loop electrode
- Quick recovery, immediate relief of symptoms, fertility enhanced
- Fluid/electrolyte monitoring
- Technology advancing
  - Bipolar resectoscope
  - Saline distension
  - Intrauterine morcellator
Focused Ultrasound

- Prostate
- Breast
- Liver
MRgFUS

- New therapy for leiomyomas:
  - Thermocoagulation \(\rightarrow\) focal coagulative necrosis (vs ischemic)
- Uses real-time MRI mapping and thermal feedback imaging to focus ultrasound energy to ablate tissues

- For symptomatic leiomyomas:
  - Phase III trial, FDA approved 2004
  - Over 3000 women treated
  - US centers
Post-Treatment Care

Recovery

• Patients may experience some degree of abdominal cramping and nausea shortly after the procedure.
• Patients will stay 45-60 minutes to recover from conscious sedation after treatment, and require someone to drive them home.

Follow-up

• Usually, over-the-counter pain relief medication is all that is required.
• Patient may experience some cramping, similar to menstrual period cramping; or shoulder or back pain that lasts a few days after the procedure from lying in the treatment position.
Uterine Artery Embolization

History

• In 1995, Drs. Ravina and Merland performed preoperative embolization of the uterus in 16 patients to prevent blood loss during surgery
  – 100% technical success
  – 11 with complete response
• In 1997, Drs. McLucas and Goodwin (UCLA) published their series of 11 pts
  – 100% technical success
  – Of the nine with f/u, 3 had complete response
The History

- Now, greater than 150,000 women treated worldwide to date
- 13,000 to 15,000 UFE procedures annually in the United States
Contraindications

- Pregnancy
- Active Pelvic Infection
- Vasculitis
- Prior Pelvic Radiation Therapy
- Pelvic Malignancy
- Life Threatening Contrast Allergy
- Coagulopathy
- Renal Insufficiency
- Intracavitary Fibroid > 3 cm
- Pedunculated Fibroid with attachment less than 50% diameter
- Adnexal Pathology
UTERINE ARTERY EMBOLIZATION

Procedure

Selective internal iliac artery catheterization
Roberts Catheter

Selection of the Uterine Artery Microcatheter

Embolization
Embospheres 500-700 & 700-900 μ (Biosphere Medical)

Intravenous conscious sedation
Versed, Dilaudid

Peri-procedural Antibiotics/ Anti-inflammatory Agents
Cefazolin 1 gm IV
Toradol 15 mg IV q 6hrs
Ovarian Arterial Supply =
- Ovarian arteries in 40%
- Uterine and ovarian arteries in 56%
- Uterine arteries alone in 4%

Ovarian artery arises from the abdominal aorta a few cm below the renal arteries in 80-90% of cases.
Pre
Left Uterine Artery
Post
Left Uterine Artery
500-700 Embospheres
Pre
Right Uterine Artery
24 Hour Observation

- Dilaudid PCA - Wt based dosing
  - Mild pelvic pain in 80% post procedure

- Anti-inflammatory medication
  - Toradol 15 mg IV q6 x 24 hrs
  - Ibuprofen 400 mg po qid x 4/7 days

- Fever control (Post Embolization Syndrome)
  - Tylenol 2 tabs po qid

- Anti-Nausea medication
  - Zofran 4mg IV q6hr

**References**

JVIR 1997;8:517-526
Curr Opin Obstet Gynecol 1998;10:315-320
Post-Procedure Follow-up

• Discharge Home:
  – Oxycontin, Oxycodone, Ibuprofen, Colace, Phenergan

• Phone call day after discharge.

• Contact information given to patient. (24 hour access)

• Follow-up office visit at 14 days.

• UFS-QOL: 3 months and 1 year.

• Repeat Imaging only if symptoms recur.
Reduced Bulk Related Symptoms and Bleeding
Complications of UFE

• 90% in a series of 400 had no complications during 3 month minimum interval
• Most common complication
  – Allergic and drug reactions in 2.5%
• Most common reason for hospitalization
  – Leiomyoma tissue passage
• 0.04% of patients required re-hospitalization for SCVIR class C and D complications
• No permanent adverse sequelae or death

Complications

- Non target embolization
  - Amenorrhea – 2 to 15% of cases
- Thromboembolic complications
  - Transient hypercoagulability
  - Prevention = off OCP pre-procedure, early ambulation, venous compression devices
- Rash several days to a week after the procedure
  - Short course of oral diphenhydramine/corticosteroids
- Arterial dissection/perforation = <1%
Infectious Complications

- Retrospective review from 1/2000 to 7/2003 = 410 patients
- Intrauterine infectious complications requiring iv abx or surgery in 5 pts (1.2%)
- Variables analyzed for risk of intrauterine infection
  - Submucosal vs. nonsubmucosal
  - Use or preprocedure antibiotics
  - Type of embolic agent (PVA vs. Embospheres)
  - Vials of embolic used
  - Size of dominant fibroid
  - Location of dominant fibroid
- None achieved statistical significance
  - Rajan, et al, JVIR 2004
Complications Hysterectomy

RARE

- Pyometrium, sepsis
- Off-cycle or severe bleeding
- Severe ischemic uterine injury – persistent severe pain
- Uterine rupture/necrosis
- Vesicouterine fistula
- Adhesion = bowel obstruction
Recurrent Symptoms
FIBROID Registry

- Major research initiative of the Cardiovascular and Interventional Radiology Research and Education Fund (CIRREF)
- Managed by Duke Clinical Research Institute
- 1999-2002
- >85 participating sites (2,112 patients)
- Follow-up data on 1,701 patients at 12 months
FIBROID Registry

• 1 year conclusions:
  – 82% of patients agree or strongly agree that they were satisfied with their outcome
  – Only 5.47% had no improvement in their mean symptom score at 12 months
  – Only 5.0% did not improve in their health related quality of life score
  – 2.9% had hysterectomy
  – Amenorrhea in 7.3% of patients (86% of these were 45 + yo)
FIBROID Registry

• 3 year conclusions: n=1,278 patients (2,112 eligible)
  – 85.3% patients improved 10 or more points on symptom score.
  – 85.7% would recommend therapy to family member
  – Further surgical care
    • 2.82% Myomectomy
    • 9.8% Hysterectomy
    • 1.8% 2\textsuperscript{nd} UFE
  – Prior medication use, heavy bleeding, submucosal fibroid location all correlated with improve score and outcome
  – Amenorrhea 365 patients(28.6%)
    • 78.9% Greater than 45
    • 15.6% Between 40 and 45.
    • 5.5% Under 40.(1.6% of total cohort)

Obstetrics & Gynecology; Jan. 2008
Key points to follow-up MRI

- Enhancement of fibroids.
- Fibroid and uterine volume.
- Submucosal fibroid ulceration or enucleation.
- Reserved for fertility patients and recurrent symptoms.
Adenomyosis
Adenomyosis

• 55 patients
• 3 year period
• 31/54 (57.4%) had long term resolution of symptoms.
• 4 immediate failures (7.4%)
• 19 Relapses (35%)
• 5 Hysterectomies in patients who failed.
  – 21% of failures
  – 9% overall

Kim et al. AJR, January 2007
Failure of Symptomatic Relief.

Patient stated symptoms improved first two months only to return.
Causes of Technical Failure of UAE

• Failure to cannulate the uterine artery
• Ovarian Arterial blood supply
• Spasm leading to poor flow to peri-fibroid plexus - insufficient delivery of embolic material
• Clumping of embolic material leading to ‘false endpoint’
Anomalous Arterial Supply
Incidence 10%
Vasospasm
Objectives

• Stress the importance imaging has in patient selection and education.

• Update treatment options available for symptomatic fibroids her at DUKE.

• Summarize some of the data available regarding clinical results and potential imaging predictors of failure or potential increase risk of complication.
Summary

- MR Imaging provides critical information used in patient selection.
- Patient selection important for successful outcome
- Patient symptoms, long term goals, and expectations individualize approach
- Balance short term and long term benefits vs. potential risks and disadvantages, consider repeat treatments
- Long term data, comparative trials, RCT’s required.