AGL 2022

51st GLOBAL CONGRESS ON MIGS

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SYLLABUS

FIBR-609: Evolving Technologies and Their Role in Patient Care

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FIBR-609: Evolving Technologies and Their Role in Patient Care

Co-Chairs: *Michael L. Moore, MD, Kristen J. Pepin, MD, MPH*

Faculty: *Daniel S. Dias, MD, PHD, James A. Greenberg, MD, David J. Levine, MD, Rooma Sinha, MD*

Course Description

This course will review care options for women with fibroids. The course will compare more established forms of fibroid care to newer FDA approved technologies. The course is a combination of didactic and visual learning modes. A panel of faculty will discuss multiple case scenarios and what procedures might apply along with anticipated outcomes.

Learning Objectives

At the conclusion of this course, the participants will be able to: 1) Cite the histopathology, incidence, natural course and ideal treatment of leiomyosarcoma; 2) Follow the current standard of care for pre-operatively diagnosing leiomyosarcoma and recognize potential future directions for improved detection; 3) Identify the incidence of leiomyosarcoma at the time of surgery for presumed benign leiomyoma (fibroids); 4) Utilize currently available techniques and technologies to minimize the risks of incidentally encountered leiomyosarcoma during surgery for benign leiomyomas; and 5) Explore the potential future technologies to improve care with this clinical challenge.

Course Outline

9:45 am	Welcome, Introduction and Course Overview	M.L. Moore/K.J. Pepin
9:50 am	The FDA has Approved New Medications: What Do They Do? What is the Data on Already Available Options?	K.J. Pepin
10:15 am	Myomectomy: Choosing Route of Myomectomy	R. Sinha
10:40 am	Morcellation Techniques: Scalpel, Bag, No Bag?	D.S. Dias
11:05 am	How Does Leiomyosarcoma Fit into the Management of Fibroids?	J.A. Greenberg
11:30 am	RFA for the Treatment of Fibroids	D.J. Levine
11:55 am	Questions & Answers	All Faculty
12:15 am	Adjourn	

The FDA Has Approved New Medications: What Do They Do? What Is The Data On Already Available Options?

Kristen Pepin MD, MPH
Minimally Invasive Gynecologic Surgery
Weill Cornell Medicine

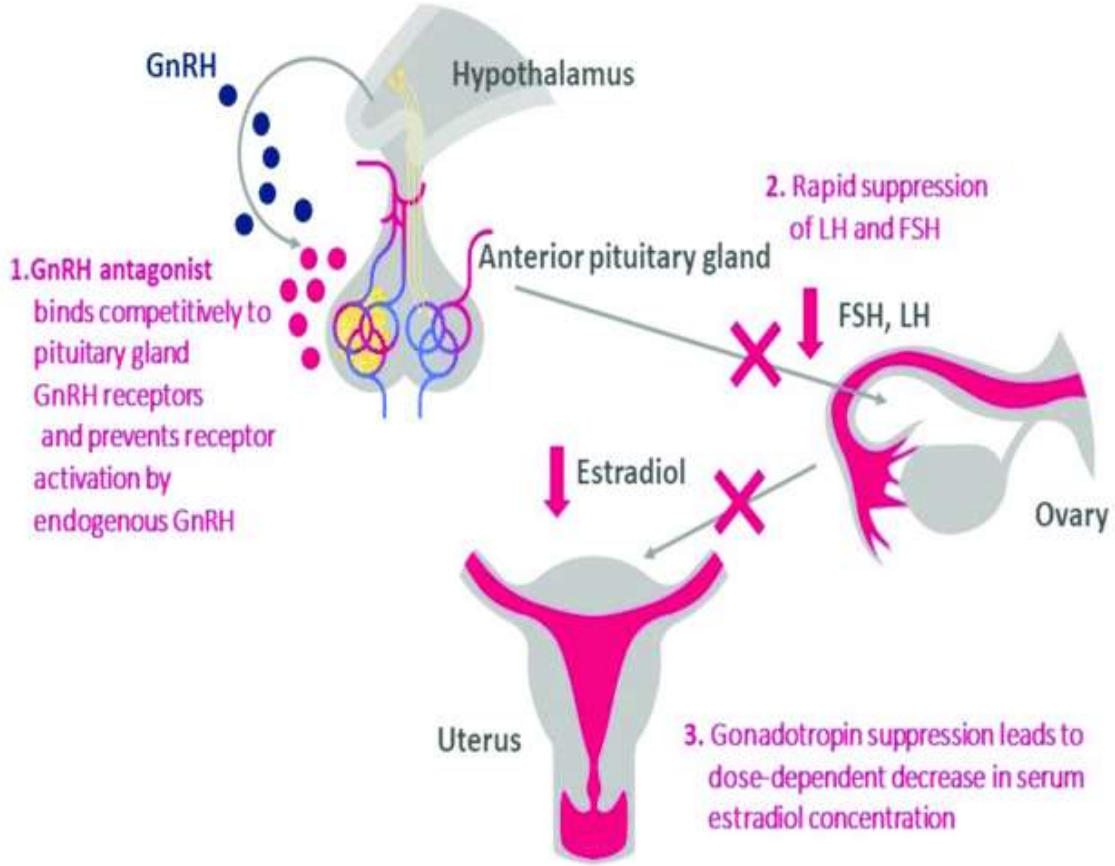
Disclosure

I have no financial relationships to disclose.

Objectives

- Articulate the mechanism of action of GnRH antagonists.
- Distinguish which fibroid symptoms are improved with GnRH antagonist use.
- Compare efficacy of GnRH analogues.
- Recognize patients most likely to benefit from treatment with GnRH analogues.

GnRH Antagonists: Mechanism of Action



https://www.researchgate.net/figure/GnRH-antagonist-mechanism-of-action-The-main-advantages-of-GnRH-antagonists-are_fig1_349855318

Advantages Over GnRH Agonists

- Orally delivered
- Rapidly reversible
- No flare effect
- Dose-dependent suppression

Distinguish which fibroid symptoms are improved with GnRH antagonist use.

Elaglolix Trial

FDA Approved Dose for 24 months of Use

Morning Dose:

- Elagolix 300 mg + estradiol 1 mg + norethindrone 0.5 mg

Evening Dose:

- Elagolix 300 mg

Inclusion criteria

- Nonpregnant
- Premenopausal
- Ages 18 and 51 years old
- Menstrual blood loss of greater than 80 mL
- Regular menstrual cycles less than 38 days
- Uterine leiomyomas: one or more (3 cm +) or multiple small leiomyomas (total uterine volume, 200–2,500 cm^3, inclusive)
- Focal or diffuse nondominant adenomyosis were included

Primary Endpoints

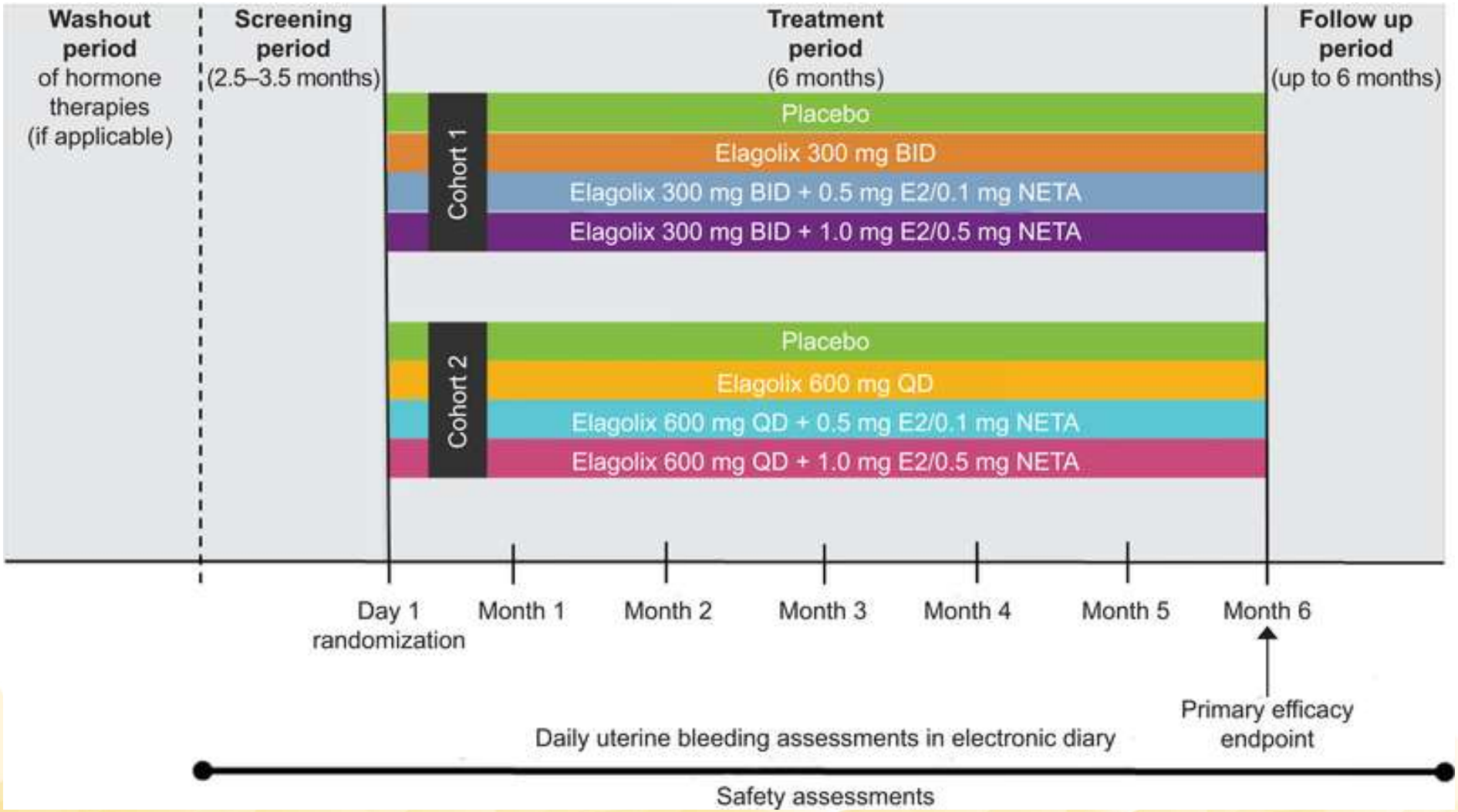
- Percentage of women who had menstrual blood loss volume of less than 80 mL at the final month of the trial.

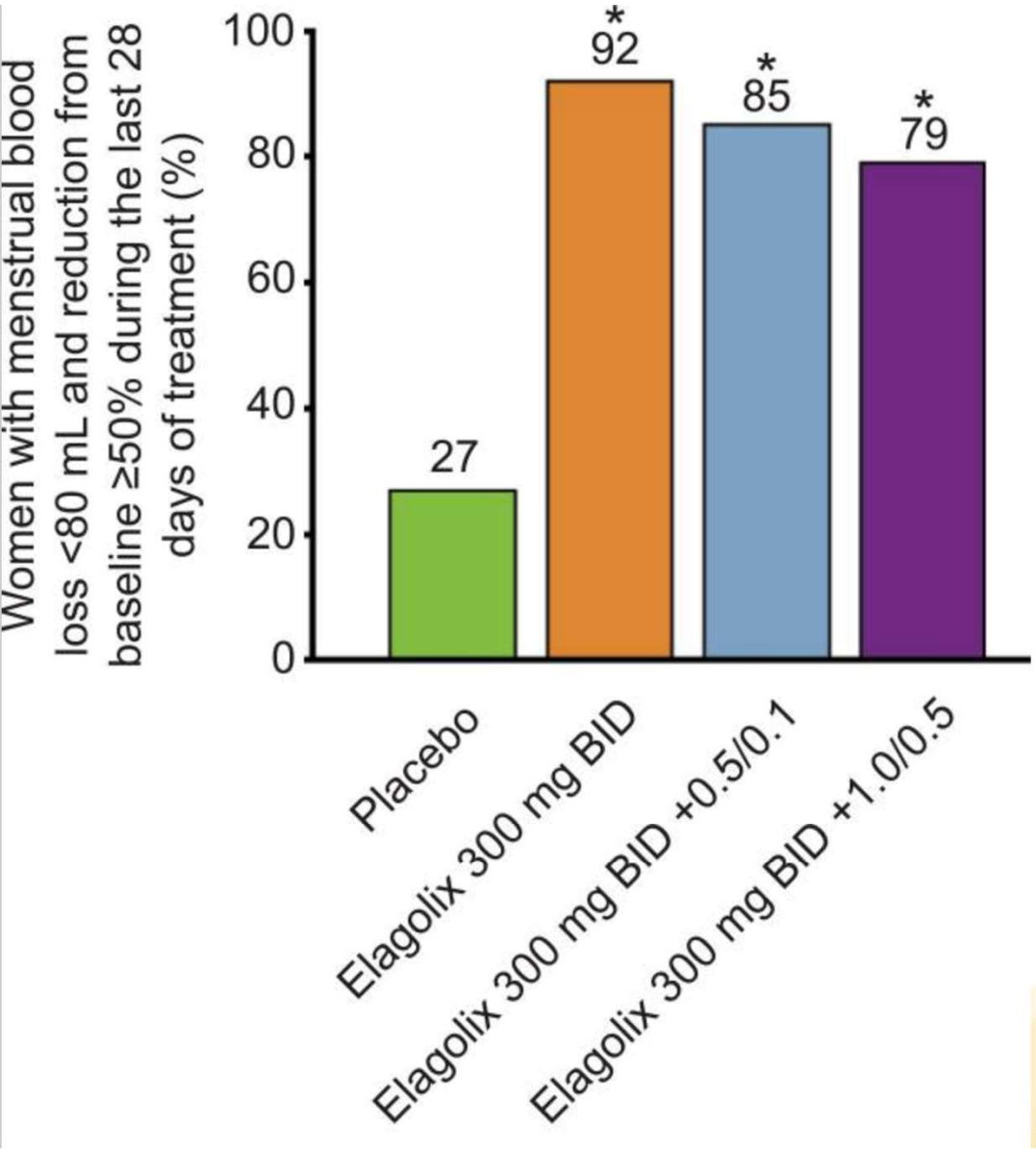
AND

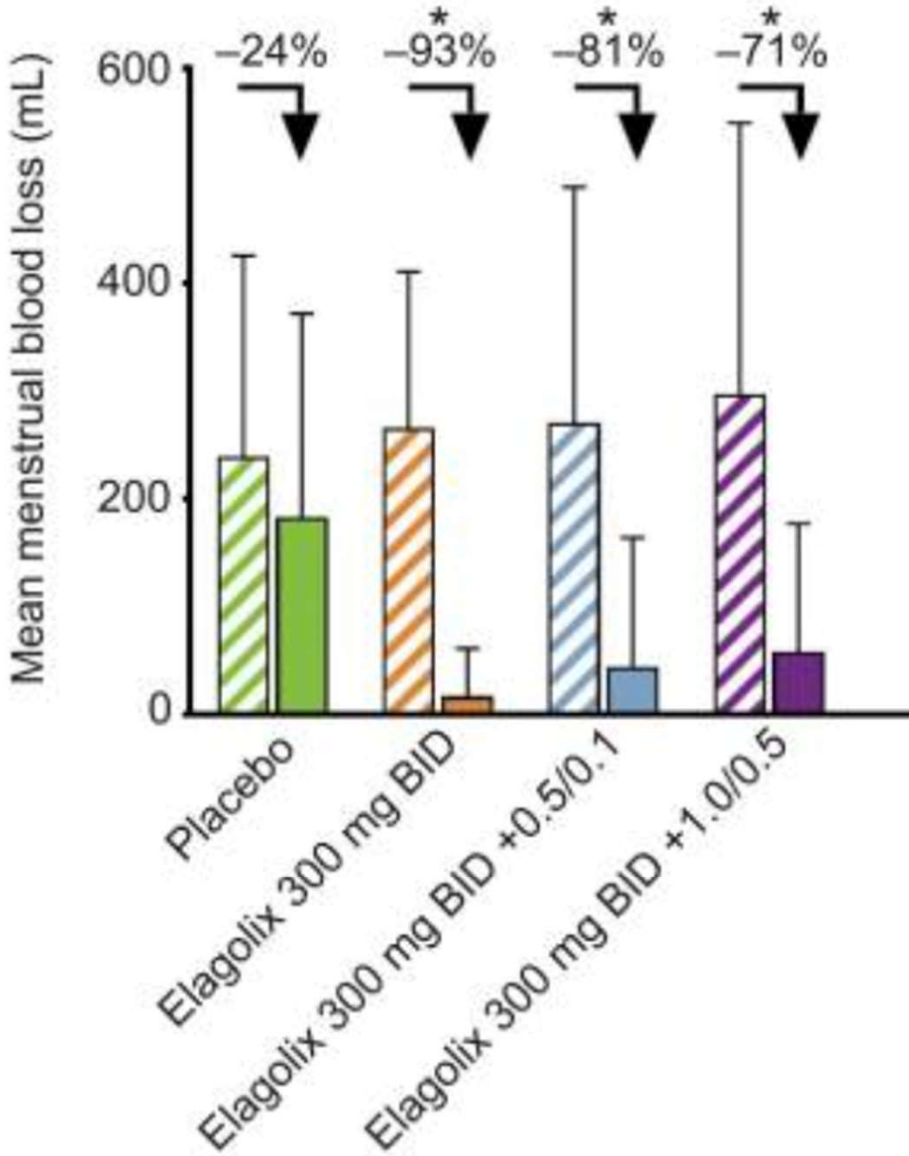
- 50% or greater reduction in menstrual blood loss volume from baseline to the final month.

Secondary Endpoints

- Amenorrhea.
- 1-g/dL or greater increase in hemoglobin concentration
- Mean change in hemoglobin concentration.
- Leiomyoma & uterine volume.
- Uterine Fibroid Symptom and Health Related Quality of Life Questionnaire score.

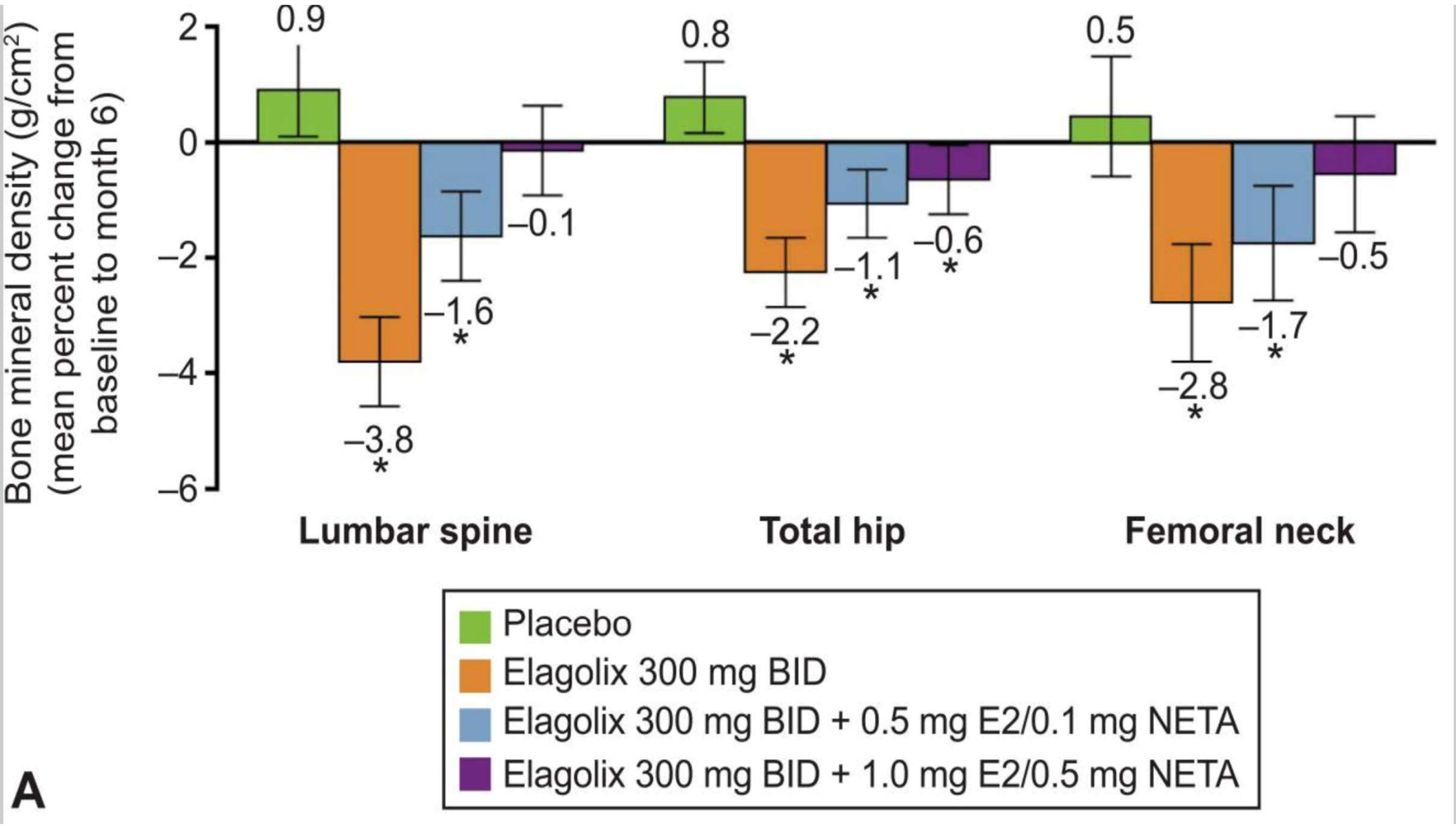

Washout period of hormone therapies (if applicable)
Screening period (2.5–3.5 months)
Treatment period (6 months)
Follow up period (up to 6 months)
Cohort 1
Placebo
Elagolix 300 mg BID
Elagolix 300 mg BID + 0.5 mg E2/0.1 mg NETA
Elagolix 300 mg BID + 1.0 mg E2/0.5 mg NETA
Cohort 2
Placebo
Elagolix 600 mg QD
Elagolix 600 mg QD + 0.5 mg E2/0.1 mg NETA
Elagolix 600 mg QD + 1.0 mg E2/0.5 mg NETA
Day 1 randomization
Month 1
Month 2
Month 3
Month 4
Month 5
Month 6
Primary efficacy endpoint
Daily uterine bleeding assessments in electronic diary
Safety assessments


Women with menstrual blood loss <80 mL and reduction from baseline ≥50% during the last 28 days of treatment (%)
100
80
60
40
20
0
27
92
85
79
*
*
*
Placebo
Elagolix 300 mg BID
Elagolix 300 mg BID +0.5/0.1
Elagolix 300 mg BID +1.0/0.5


Mean menstrual blood loss (mL)
600
400
200
0
−24%
−93%
−81%
−71%
*
*
*
Placebo
Elagolix 300 mg BID
Elagolix 300 mg BID +0.5/0.1
Elagolix 300 mg BID +1.0/0.5

Secondary Outcomes of FDA Approved Dose

Outcome	Placebo	Elagolix + Add Back
Amenorrhea	1.6%	28%
1-g/dL or greater increase in hemoglobin concentration	30%	60%
Mean change in hemoglobin concentration.	+7.6%	+ 15%
Leiomyoma & uterine volume	+4.6% +15.9%	-12.9% -11.8%
Uterine Fibroid Symptom and Health Related Quality of Life Questionnaire	+14.7 points	+ 36 points


Bone mineral density (g/cm²)
(mean percent change from baseline to month 6)
2
0
−2
−4
−6
0.9
−3.8
*
−1.6
*
−0.1
0.8
−2.2
*
−1.1
*
−0.6
*
0.5
−2.8
*
−1.7
*
−0.5
Lumbar spine
Total hip
Femoral neck
Placebo
Elagolix 300 mg BID
Elagolix 300 mg BID + 0.5 mg E2/0.1 mg NETA
Elagolix 300 mg BID + 1.0 mg E2/0.5 mg NETA
A

Relugolix Combination Therapy

FDA Approved Dose for 24 months of Use

- Once Daily:
  - Relugolix 40 mg + estradiol 1 mg + norethindrone acetate 0.5 mg

Inclusion criteria

- Premenopausal women 18 to 50 years of age.
- Diagnosis of fibroids as confirmed on ultrasonography .
- Heavy menstrual bleeding
  - Volume of menstrual blood loss of 80 ml or more per cycle for two cycles or a volume of 160 ml or more during one cycle.

Primary Endpoints

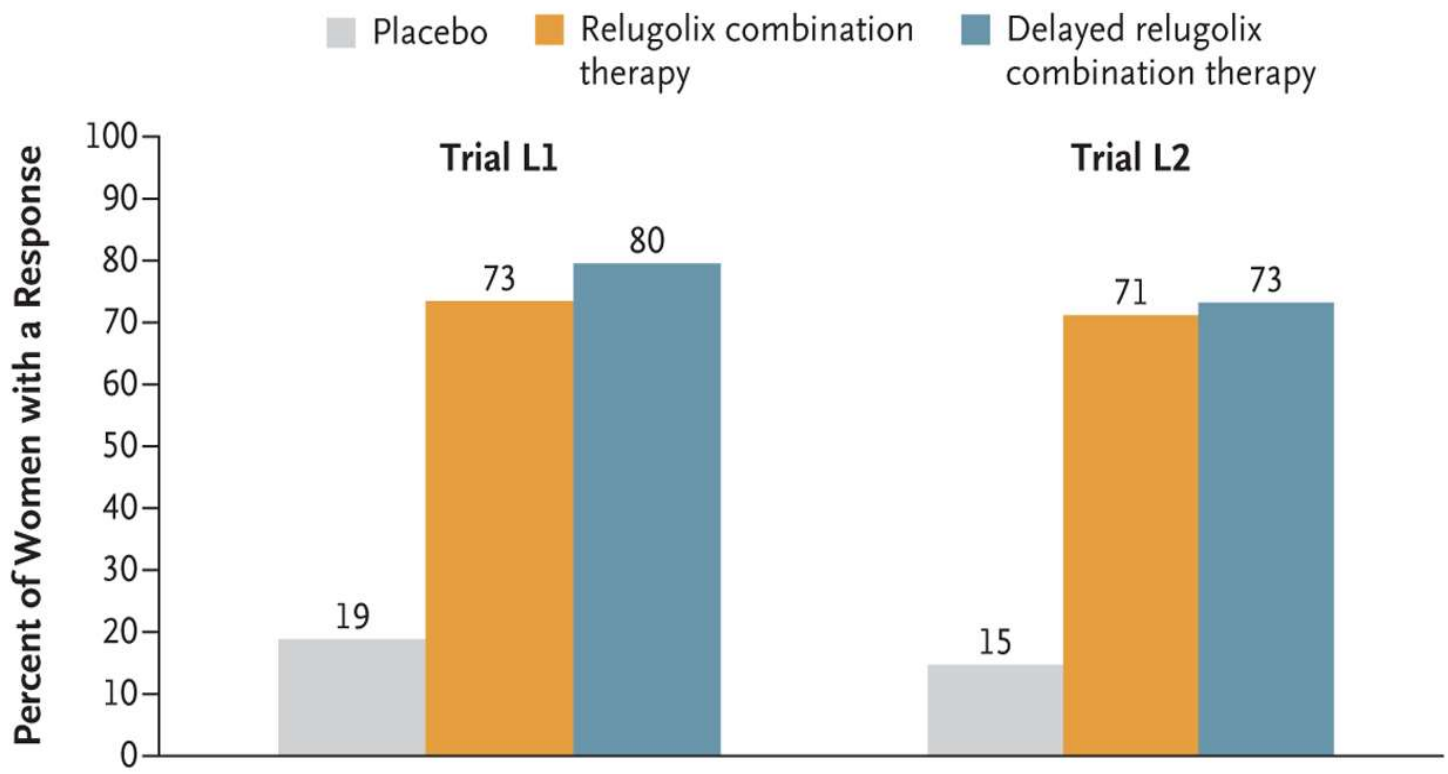
% of women who had menstrual blood loss volume of less than 80 mL at the final month of the trial.

AND

50% or greater reduction in menstrual blood loss volume from baseline to the final month.

Secondary Endpoints

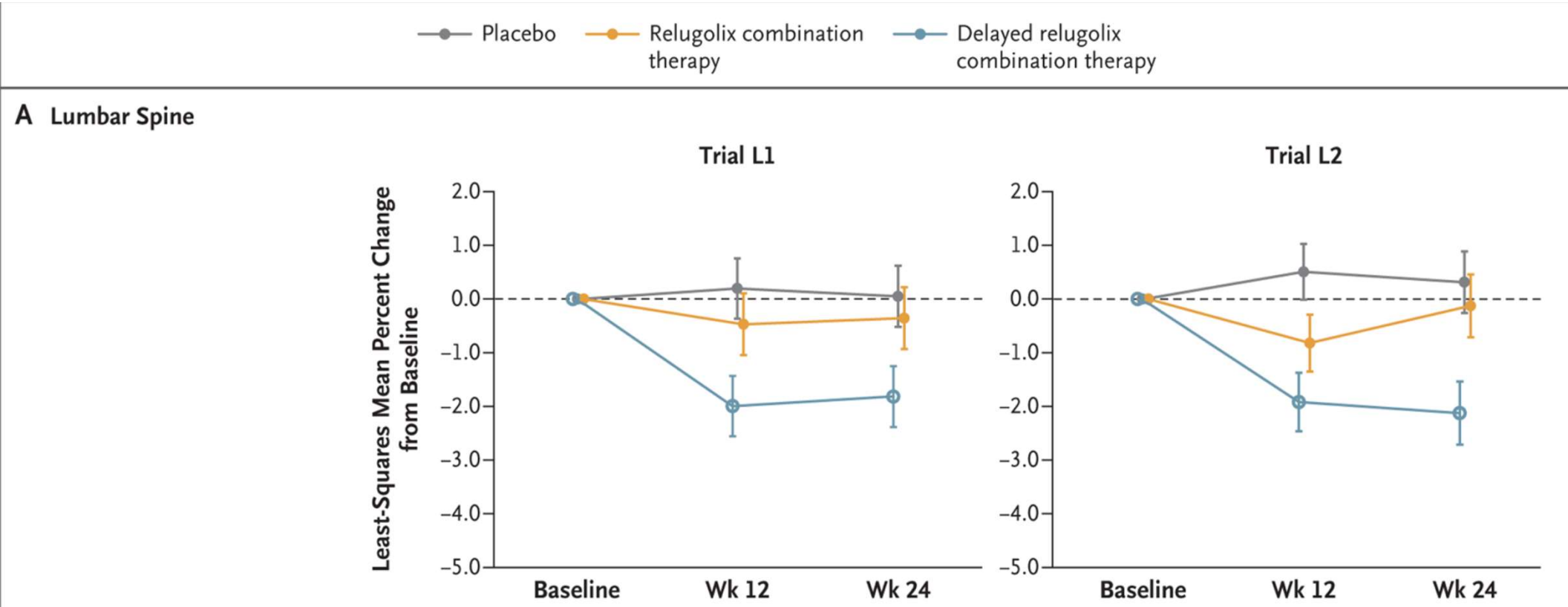
- Amenorrhea.
- % reduction in the volume of menstrual blood loss.
- Reduction in Bleeding and Pelvic Discomfort scale.
- % of women with increase hemoglobin of more than 2 g per deciliter.
- % of women with improvement in fibroids associated pain.
- % change in the volume of the largest fibroid.
- % change in uterine volume.



No. of Patients	127	128	132	129	125	127
Difference vs. Placebo — percentage points (95% CI)		55 (44–65)	61 (51–70)		56 (46–66)	58 (49–68)
P Value vs. Placebo		<0.001			<0.001	

Secondary Outcomes of FDA Approved Dose

Outcome	Placebo	Relugolix + Add Back
Amenorrhea	7%	67%
% reduction in the volume of menstrual blood loss	-23%	-85%
Bleeding and Pelvic Discomfort Scale	- 16 points	-45 points
% of women with increase hemoglobin of more than 2 g per deciliter	22%	50%
% Pain Scale ≤1 over last 35 days of treatment period	10%	43%
Largest Leiomyoma & Uterine Volume	-0.3 % -2.2%	-12.4% -12.9%



	Trial L1			Trial L2		
Placebo — No.	127	103	102	129	104	95
Relugolix Combination Therapy — No.	128	101	100	126	103	95
Difference vs. Placebo — percentage points (95% CI)		−0.7 (−1.4 to 0.1)	−0.4 (−1.2 to 0.3)		−1.3 (−2.0 to −0.6)	−0.4 (−1.2 to 0.3)
Delayed Relugolix Combination Therapy — No.	132	103	100	126	95	94
Difference vs. Placebo — percentage points (95% CI)		−2.2 (−2.9 to −1.5)	−1.9 (−2.6 to −1.1)		−2.4 (−3.1 to −1.7)	−2.4 (−3.2 to −1.7)

Compare efficacy of GnRH analogues

Outcome	Elagolix + Add back	Relugolix + Add back	Leuprolide
Fibroid Size	- 12.9%	- 12.4%	- 5.7 mL to - 155.4 mL
Uterine Size	-11.8%	-12.9%	-175 mL
Hemoglobin increase	60% (increased by 1 g/dL)	50% (increased by 2 g/dL)	0.88 g/dL

Recognize patients most likely to benefit from treatment with GnRH analogues.

Needs surgery, but the time is not now.

- Heavy menstrual bleeding without or without fibroid pain.
- Unable to have surgery in the short term for personal or medical reasons.
- Planning pregnancy in the future, but not immediately.

May be able to avoid surgery all together.

- Perimenopausal
- Heavy menstrual bleeding without or without fibroid pain
- Unlikely to have bulk symptoms after menopause
- Not anticipating using hormone replacement therapy after menopause

References

- Carr BR, Stewart EA, Archer DF, et al. Elagolix Alone or With Add-Back Therapy in Women With Heavy Menstrual Bleeding and Uterine Leiomyomas: A Randomized Controlled Trial. *Obstet Gynecol*. 2018;132(5):1252-1264.
- Al-Hendy A, Lukes AS, Poindexter AN 3rd, Venturella R, Villarroel C, Critchley HOD, Li Y, McKain L, Arjona Ferreira JC, Langenberg AGM, Wagman RB, Stewart EA. Treatment of Uterine Fibroid Symptoms with Relugolix Combination Therapy. N Engl J Med. 2021 Feb 18;384(7):630-642. doi: 10.1056/NEJMoa2008283. PMID: 33596357; PMCID: PMC8262231.

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Choosing the Route for Myomectomy

Dr Rooma Sinha
Hon Professor, Gynecology
Associate Professor, Macquarie University, Sydney
President- Association of Gynecological Robotic Surgeons of India (AGRS)
Board Member Asian Society of Gynecological Robotic Surgeons
Apollo Hospitals, Hyderabad, INDIA

drroomasinha

Hyderabad

drroomasinha

Uterine myomas - most common benign gynecologic tumor
(Significant position in gynecologic practice)

Incidence -70% to 80% of reproductive-age women
Symptomatic in only 20% to 40% of women over 35 years old
Symptoms –
- AUB, associated anemia
- Pelvic pain or pressure, urinary symptoms
- Adverse reproductive outcomes – RPL, preterm delivery, placental abruption, malpresentation, & growth restriction

References
1. Stewart EA. Clinical practice. Uterine fibroids. N Engl J Med. 2015;372:1646–1655.
2. Baird DD, Dunson DB, Hill MC, Cousins D, Schectman JM. High cumulative incidence of uterine leiomyoma in black and white women: ultrasound evidence. Am J Obstet Gynecol. 2003;188:100–107.
3. Spies JB, Bradley LD, Guido R, Maxwell GL, Levine BA, Coyne K. Outcomes from leiomyoma therapies. Obstet Gynecol. 2010;116:641–652.
4. Falcone T, Parker WH. Surgical management of leiomyomas for fertility or uterine preservation. Obstet Gynecol. 2013;121:856–868.

drroomasinha

WHY & When one should one do myomectomy?

- Menometrorrhagia and anemia
- Pelvic pain and pressure
- Enlarging leiomyoma (greater than 12 weeks)
- Possibility of neoplasia
- Associated fetal wastage and infertility
- Obstructed ureter

drroomasinha

MEDICAL HISTORY

The master of myomectomy

Geoffrey Chamberlain MD FRCOG

J R Soc Med 2003;**96**:302–304 SECTION OF OBSTETRICS AND GYNAECOLOGY, 2 DECEMBER 2002

'In my early years as a gynaecological surgeon, a case occurred which profoundly affected my outlook. A lady, recently married, wishing above all things to have a child underwent a subtotal hysterectomy on account of a single submucous fibroid. Being a woman of strong character and reticent fortitude, she accepted the blow without complaint and by assuming a proud indifference to children held her insistent mother instinct at bay and none but those who knew her well perceived the tragedy. I was among this number and the grief of it is still keen in me today.'—Victor Bonney[1]

This was the opening of one of the last papers that Victor Bonney gave on conservation in surgery. He was describing what had happened to his wife. Victor and Annie had met and courted while he was a resident and she a sister at the Chelsea Hospital for Women in London. They married in

doctors and 'our medical students' in the room for the operation. A long mid-line subumbilical incision was made and, to their surprise, an eighteen-inch pedunculated fibroid was found. The pedicle was transfixed with three wax silk sutures and the abdomen was closed with fifteen through-and-through sutures. The woman recovered. This was by our standards a simple operation, but we must admire the courage of both the woman and the surgeon.

Before the days of general anaesthesia with ether or chloroform, which started in the late 1840s and became popular in the early 1850s, there were few abdominal operations. Charles Clay, the great Manchester gynaecological surgeon, recorded that of his 108 abdominal operations, 14 were done before chloroform was discovered and in 9 of these cases the patient recovered. He recorded that he was uncertain that the anaesthetic added to the success of the operation.[3] Soon after the

swabbed with this solution. A sterile waxed blanket was then placed over the abdomen and the woman came to theatre with this blanket still in place; it was only removed after the anaesthetic had been given.

The problem of dead space was solved by use of an old surgical technique—obliteration of the fibroid cavity. He under-sewed the finished bed, and if there was excess superficial uterine muscle, this was excised to leave a hood over the operative field with an overlap of myometrium and overlying peritoneum (Figures 3 and 4).[8]

Bonney performed over 700 myomectomies in his surgical life.[1] There were only 8 deaths (1.1%). Most of these operations were in the pre-blood-transfusion and pre-antibiotic days. By the 1930s Bonney was preaching that any woman with fibroids under the age of 41 and wishing to have further children should be offered a myomectomy rather than hysterectomy.

Not everyone agreed. Some critics felt that, after such traumatic surgery, women would be unlikely to have children. In Bonney's cases, of those who wanted to have children, 38% did. Another concern was that fibroids would return, but in Bonney's records only 4% of those who were re-examined showed recurrence. He himself would not

as follows:

> 'I do most earnestly commend this beneficial operation in the hopes that in the near future removal of a relatively young woman's womb on account of fibroids will, excepting in exceptional circumstances, cease to be perpetrated'.[1]

REFERENCES

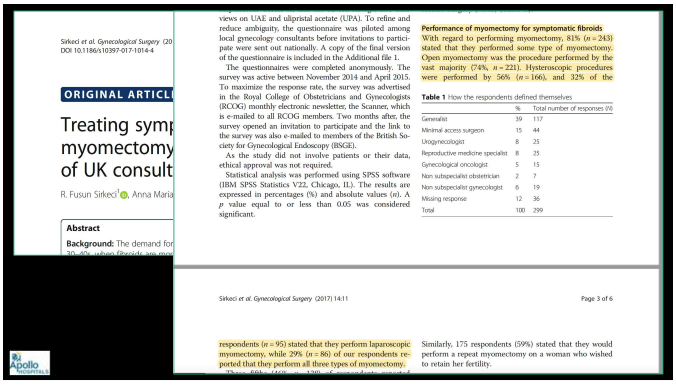
1 Bonney V. The fruits of conservation. *J Obstet Gynaecol Br Emp* 1937;**44**:1–12
2 Atlee WL. Removal of fibrous tumour of the uterus. *Am J Med Sci* 1845;**11**:309–35
3 Clay C. Observations on ovariotomy. *Trans Obstet Soc* 1863;**5**:58–74
4 Alexander WA. Myomectomy. *Med Press & Circular* 1898;**14**:47
5 Bonney V. Conservation of function in gynaecology. *Med J Aust* 1928;**i**: 741–4
6 Bonney V. A clamp forceps for controlling haemorrhage when performing myomectomy. *J Obstet Gynaecol Br Emp* 1923;**30**:447–9
7 Bonney V, Browning C. Sterilisation of the skin by a mixture of crystal violet and brilliant green. *BMJ* 1918;**i**:562–3
8 Bonney V. *Extended Myomectomy and Ovarian Cystectomy*. London: Cassell, 1946

Why discuss the route to perform Myomectomy?

Planned laparoscopic myomectomy is nearly always successful
Analysis of 731 intended laparoscopic myomectomies
Only 7 cases required open conversion- numerous (mean number 9.75 vs 3.48, p = .003) and heavier (mean weight 667.9 vs 259.25 g, p = .015) myomas and entailed significantly more blood loss (1381.25 vs 167.95 mL, p ≤ .001)

Sandberg EM, Cohen SL, Jansen FW, Einarsson JI. Analysis of risk factors for intraoperative conversion of laparoscopic myomectomy. J Minim Invasive Gynecol. 2016;23:352–357.

Is open surgical approach ethical when laparoscopy is considered as gold standard?



Sirkeci et al. Gynecological Surgery (20
DOI 10.1186/s10397-017-1014-4

ORIGINAL ARTICL

Treating symp
myomectomy
of UK consult

R. Fusun Sirkeci[1], Anna Maria

Abstract

Background: The demand for

views on UAE and ulipristal acetate (UPA). To refine and reduce ambiguity, the questionnaire was piloted among local gynecology consultants before invitations to participate were sent out nationally. A copy of the final version of the questionnaire is included in the Additional file 1.

The questionnaires were completed anonymously. The survey was active between November 2014 and April 2015. To maximize the response rate, the survey was advertised in the Royal College of Obstetricians and Gynecologists (RCOG) monthly electronic newsletter, the Scanner, which is e-mailed to all RCOG members. Two months after, the survey opened an invitation to participate and the link to the survey was also e-mailed to members of the British Society for Gynecological Endoscopy (BSGE).

As the study did not involve patients or their data, ethical approval was not required.

Statistical analysis was performed using SPSS software (IBM SPSS Statistics V22, Chicago, IL). The results are expressed in percentages (%) and absolute values (*n*). A *p* value equal to or less than 0.05 was considered significant.

Performance of myomectomy for symptomatic fibroids

With regard to performing myomectomy, 81% ($n = 243$) stated that they performed some type of myomectomy. Open myomectomy was the procedure performed by the vast majority (74%, $n = 221$). Hysteroscopic procedures were performed by 56% ($n = 166$), and 32% of the

Table 1 How the respondents defined themselves

	%	Total number of responses (N)
Generalist	39	117
Minimal access surgeon	15	44
Urogynecologist	8	25
Reproductive medicine specialist	8	25
Gynecological oncologist	5	15
Non subspecialist obstetrician	2	7
Non subspecialist gynecologist	6	19
Missing response	12	36
Total	100	299

Sirkeci et al. Gynecological Surgery (2017) 14:11 Page 3 of 6

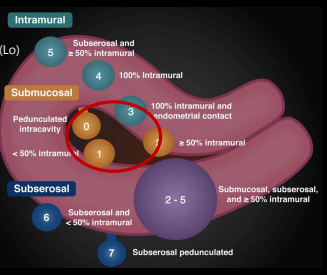
respondents ($n = 95$) stated that they perform laparoscopic myomectomy, while 29% ($n = 86$) of our respondents reported that they perform all three types of myomectomy.

Similarly, 175 respondents (59%) stated that they would perform a repeat myomectomy on a woman who wished to retain her fertility.

MYOMECTOMY- Three concerns

1. Hemorrhage
2. Difficulty in adequate uterine reconstruction
   1. Risk of subsequent rupture
   2. Uteroperitoneal fistula
3. Conversion- Failure to complete the myomectomy

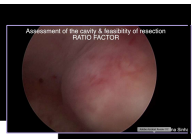
The FIGO Classification- two further subcategories
1. Submucosal myomas (Lsm)
2. Myomas that do not impact the endometrial cavity (Lo)

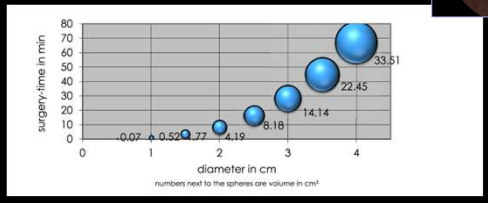


Do we need mathematics in myomectomy?

While performing the surgery- Volume of myoma more important than the weight we record the end of the procedure
Volume calculations- pre-opertaively
RATIO factor- Hysteroscopy & Laparoscopy / Robotics

Relevance of volume in hysteroscopic myomectomy





Emanuel / Best Practice & Research Clinical Obstetrics and Gynaecology 29 (2015) 920-929

Ratio factor in Hysteroscopic Myomectomy

The Ratio factor in Laparoscopy / Robotics

Body habitus

Obesity / Panniculus

Location of Anterior Superior Iliac spine & relation to Umbilicus & Costal margin

drroomasinha

Size & Volume of myoma

Volume of a Sphere

$= \frac{4}{3}\pi r^3$

Diameter of Myoma	Expected Volume that needs to be resected
4cm	33.51cm³
8cm	269.9 cm³
12cm	904.32 cm³
20 cm	4186.6 cm³

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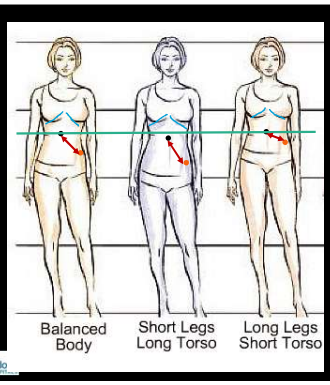

The Surgical Torso

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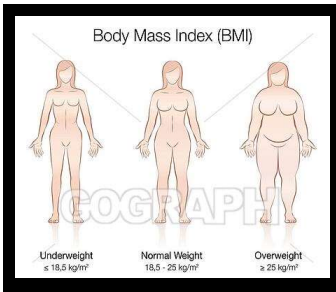

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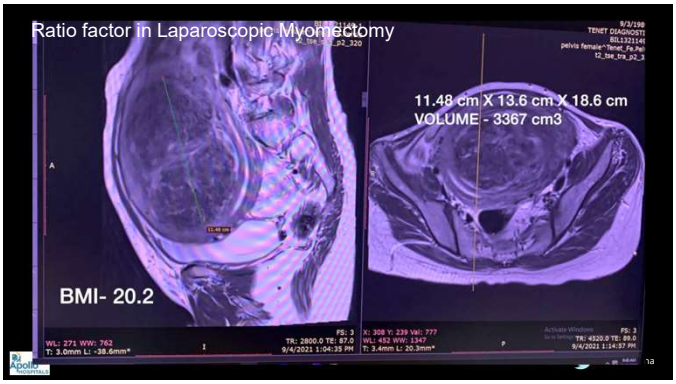

Tip 1

Don't settle on the route of myomectomy prematurely

Do your MATH by detailed preoperative planning

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One size does not fit all!

Best scenario to attempt Laparoscopic Myomectomy
Location- Fundal / Fundo anterior / Fundo posterior
Size < 10 cms
Number < 6

Our Unit @ Apollo Hospitals Hyderabad India
NO SET GUIDELINES- We offer MIS myomectomy to all patients
OPTIONS
1. Hysteroscopic Myomectomy
2. Laparoscopic Myomectomy (LM)
3. Laparoscopic Assisted Myomectomy (Hand Assisted)
4. Robot assisted Laparoscopic Myomectomy (RALM)
5. Hybrid Myomectomy

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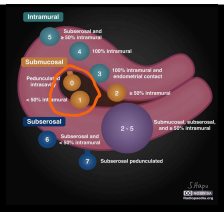
Hysteroscopic Myomectomy

<3 cm



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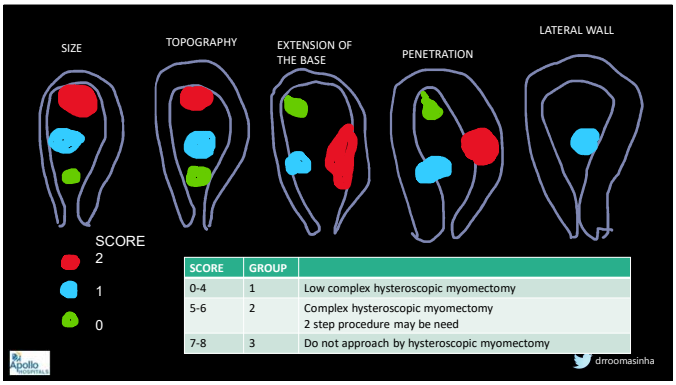

SCORE	GROUP	
0-4	1	Low complex hysteroscopic myomectomy
5-6	2	Complex hysteroscopic myomectomy 2 step procedure may be need
7-8	3	Do not approach by hysteroscopic myomectomy

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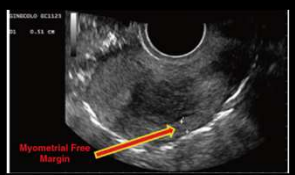
Myometrial free margin

- Minimum thickness between outer edge of fibroid & inner edge of uterine serosa
- STATIC /DYNAMIC



Tinelli, A., Alonso Pacheco, L., & Vaimovich, S. (2018). Hysteroscopy (1st ed. 2018.). Cham: Springer International Publishing. https://doi.org/10.1007/978-3-319-57559-9

Hysteroscopic Myomectomy - Classical technique

STEP-W score -4

Tip 2

Consider

Pre operative MRI

3D – Computer aided model in OT

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1. Mapping of all fibroids its essential as there is no scope of palpating the fibroids Intraoperatively
2. Mapping - feasibility of LM as compared to AM in depending on one's skill and setting
3. Helps plan hysterotomy
4. Reduces the incidence of residual fibroids (reason for recurrence in MIS)[1]
5. Reproducibility of MRI is higher than US regarding the very big size and number of fibroids

[1]*Kotani Y, Tobiume T, Fujishima R, Shigeta M, Takaya H, Nakai H, et al. Recurrence of uterine myoma after myomectomy: Open myomectomy versus laparoscopic myomectomy. J Obstet Gynaecol Res. 2018 Feb;44(2):298–302.*

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Recurrence

512 women - retrospective study ((laparoscopic myomectomy)

Cumulative probability of leiomyoma recurrence

- After 1 year -11.7 %
- After 3 years- 36.1 %
- After 5 years - 52.9 %
- After 8 years - 84.4 %

Yoo EH, Lee PI, Huh CY, Kim DH, Lee BS, Lee JK, Kim D. Predictors of leiomyoma recurrence after laparoscopic myomectomy. J Minim Invasive Gynecol. 2007;690.

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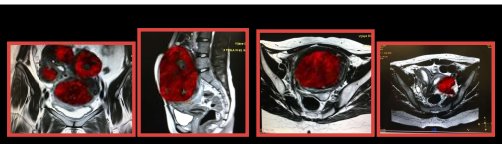
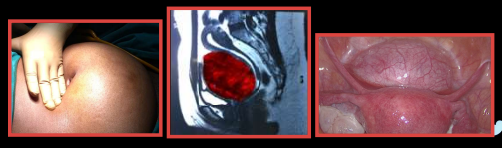


Preoperative MRI (GPS)

Minimal Access Myomectomy-LARGE & MULTIPLE

1. MYOMA MAPPING-Location & Number of myoma (plan incisions; consents)
2. Identify ADENOMYOMA
3. MYOMA Burden (VOLUME)



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3D DIGITAL MODEL

Precise presurgical planning of Robotic Myomectomy

Rooma Sinha, Bana Rupa, Ravi Kanthi Prasad
Apollo Hospitals, Hyderabad India

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Pre operative imaging

Intraoperative aid during myomectomy

1. Planning of hysterotomy
2. Assessment of the depth of myometrial involvement
3. Proximity to the endometrial cavity
4. Intraoperative identification of fibroids which are not palpable during surgery

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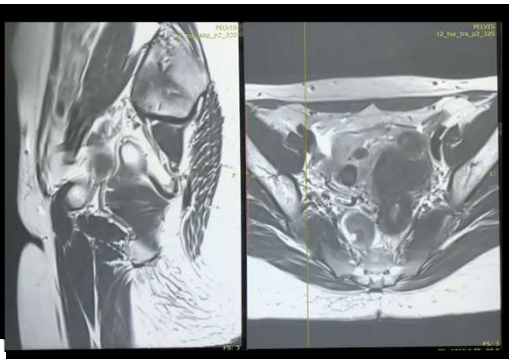

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Decisions for Hysterotomy

Role of pre operative imaging

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38 years, HMB, Dysmenorrhoa, Severe Anaemia (now optimised)
USG- 5.6 cm fibroid arising from anterior wall indenting the endometrial cavity

Surgical Plan- Laproscopic Myomectomy

Complex Myomectomy
Robotic assistance

Priamry Infertility
Pelvic pressure symptoms

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3 steps in myomectomy
- Enucleation
- Reconstruction
- Morcellation

Tip 3

Estimate the duration of surgery
Estimated Blood Loss

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JOURNAL OF GYNECOLOGIC SURGERY
Volume 32, Number 1, 2016
© Mary Ann Liebert, Inc.
DOI: 10.1089/gyn.2015.0012

Longer Operative Time During Laparoscopic Myomectomy Is Associated with Increased 30-Day Complications and Blood Transfusion

Tatiana Catanzarite, MD,[1] Brittany Vieira, BS,[2] Nicholas Hackett, BA,[2] John Y.S. Kim, MD,[2] and Magdy P. Milad, MD[1]

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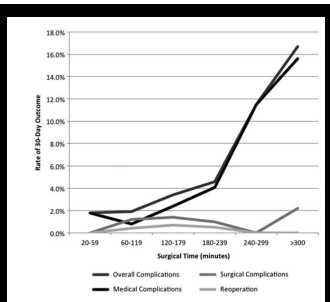

FIG. 1. Rates of overall, medical, and surgical complications and return to operating room by 60-minute intervals of operative time.

Independent association -Longer operative time
& higher rates of 30-day overall complications

1. medical complications
2. Surgical morbidity
3. Need for blood transfusion
4. Post operative recovery

3 hours

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Intra operative hemorrhage

Gynecology and Minimally Invasive Therapy 9 (2020) 6-12

Review Article

The Significant Risk Factors of Intra-Operative Hemorrhage during Laparoscopic Myomectomy: A Systematic Review

Zaki Sleiman[1]*, Rania El Baba[2], Simone Garzon[3], Aline Khazaka[2]
[1]Department of Obstetrics and Gynecology, Lebanese American University, [2]Laboratory of Science and Research, Saint Joseph University, Beirut, Lebanon, [3]Department of Obstetrics and Gynecology, "Filippo Del Ponte" Hospital, University of Insubria, Varese, Italy

Age, body mass index, and phase of the menstrual cycle – No affect in blood loss

Size and number of myomas & operative time- directly related to the increase of blood loss

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3 hours

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Tip 4

Choose the route judiciously!

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LARGE ANTERIOR WALL FIBROID ROBOT ASSISTED MYOMECTOMY

Dr. Rooma Sinha
Hon Professor AHERF
Hon Associate Prof Macquarie University, Australia
Gynecologist, Laparoscopic & Robotic Surgeon
Apollo Hospitals, Hyderabad, INDIA

Dr Rooma Sinha

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Laparoscopic Assisted Myomectomy "LAM" or "HAND" assisted

1. **A very large uterus** (>10cm) **- Concern BLOOD LOSS**
   (operating time-extensive suturing and morcellation)
2. **More than 10 fibroids on MRI-** challenge to locate all of the fibroids; multiple uterine incisions may be necessary (residual fibroid disease)
3. **Medical comorbidity-** unable to tolerate prolonged anaesthesia , Trendelenburg

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Rapid extra-abdominal morcellation of the myomas (FDA statement)
Prevents iatrogenic formation of parasitic myomas
Prevents injury to intra-abdominal structures such as the bowel, bladder or pelvic vessels
Laparoscopic portion of the procedure - diagnosis and treatment of associated endometriosis or adhesions

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LAPAROSCOPIC ASSISTED MYOMECTOMY
A combination of Laparoscopic & Open surgical technique
A Modified Minimal Access Surgery for Large Fibroids

Dr Rooma Sinha
Hon Professor, Gynecology
Associate Professor, Macquarie University, Sydney
Laparoscopic & Robotic Surgeon
Apollo Hospitals, India

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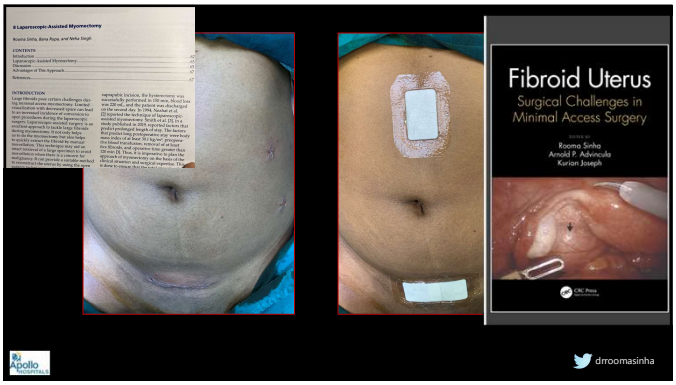

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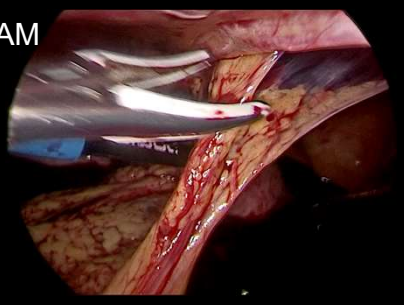
POST LAM



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Myoma Burden !!
Multiple locations-needs combination

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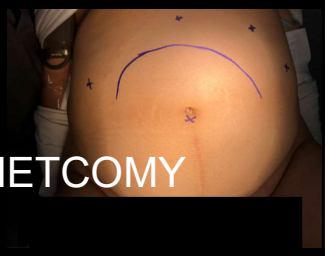
32 years, infertilty, BMI 18
Mass upto epigastrum
Multiple fibroids

Wants to preserve uterus
How to approach?

Dr Rooma Sinha
Apollo Hospitals Hyderabad

DR. Rooma Sinha



HYBRID MYOMETCOMY

"LABOTIC Surgery"

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WHAT are the situations?

1. Single large fibroid beyond the true pelvis > 10 cms
2. Multiple fibroids with one or two large fibroids obscuring the vision and reach to the smaller ones

***Sinha R**, Madhumati S, Rupa B, Shamita Kumari. Robotic Myomectomy- Tips and Tricks, Apollo Medical Journal (AMJ); September 2014, Volume 11, Issue 3, 174-178.*

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HYBRID MYOMECTOMY- Large fibroid

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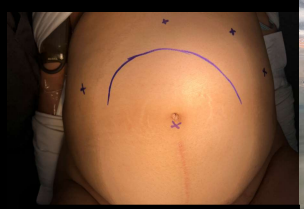

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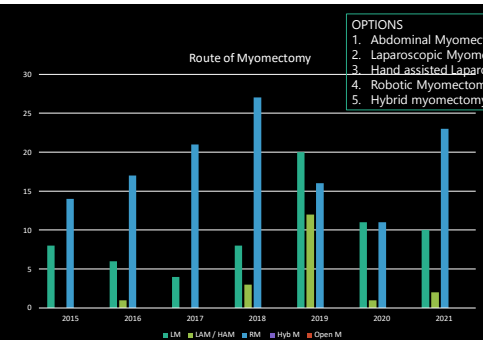

OPTIONS
1. Abdominal Myomectomy
2. Laparoscopic Myomectomy
3. Hand assisted Laparoscopic Myomectomy
4. Robotic Myomectomy
5. Hybrid myomectomy

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Morcellation Techniques: Scalpel, Bag, No Bag?

Daniel Spadoto-Dias
Clinical Assistant Professor
Botucatu Medical School – FMB
São Paulo State University – UNESP

AAGL 2022 51st GLOBAL CONGRESS ON MIGS
December 1-4, 2022 | Aurora, CO | congress.aagl.org

Morcellation Techniques: Scalpel, Bag, No Bag?

Daniel Spadoto-Dias
Clinical Assistant Professor
Botucatu Medical School – FMB
São Paulo State University – UNESP

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Botucatu – SP, Brasil

Disclosure

"I have no financial relationships to disclose"

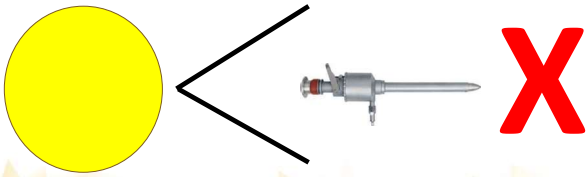
Objectives

After this presentation, participants will be able to:

- describe the strategies proposed for preoperative assessment of the risk of malignancy
- discuss the molecular pathogenesis of uterine smooth muscle tumors
- indicate different morcellation techniques
- discuss the risk of tissue leakage and spread associated with different techniques
- recognize the importance of shared decision making and preoperative informed consent

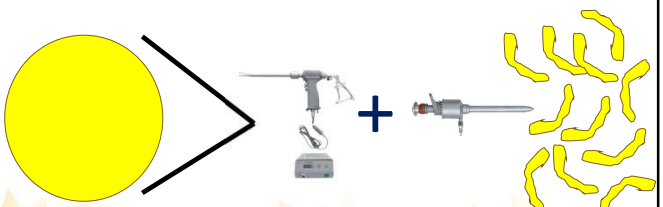
the good side of morcellators

Introduced in 1993, electromechanical devices (power morcellators / shave / cut tissue) allow tissue extraction



the good side of morcellators

procedures remain minimally invasive even with bulky specimens



the good side of morcellators

decreased risk of:

- infection
- dehiscence
- hernia

The problem of Power Morcelation

Open (uncontained) morcellation of the uterus and myomas has been scrutinized → possible spread of an unsuspected leiomyosarcoma

Since 2014 an even greater crackdown on the use of power morcellation → The FDA called morcellation into question following a highly publicised case

The FDA issued a Safety Communication in November 2014 warning "*against the use of laparoscopic power morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids*"

After that warning, use of laparoscopic hysterectomy and myomectomy decreased

Uterine Morcellation for Presumed Leiomyomas: ACOG Committee Opinion, Number 822. Obstet Gynecol. 2021 Mar 1;137(3):e63-e74. doi: 10.1097/AOG.0000000000004291. Erratum in: Obstet Gynecol. 2021 Aug 1;138(2):313. PMID: 33595252.

INTERIM UPDATE

ACOG The American College of Obstetricians and Gynecologists

ACOG COMMITTEE OPINION

Number 822 *(Replaces Committee Opinion No. 770, March 2017)*

Uterine Morcellation for Presumed Leiomyomas

Before considering morcellation of the uterus, take in mind that:

- patients should be **evaluated preoperatively** to determine if there is an increased **risk of malignancy** of the uterine corpus
- **laparoscopic power morcellation** for myomectomy or hysterectomy should only be performed with a **tissue containment system**
- **shared decision making**, including informed consenting, requires explaining the risks and benefits of each approach, the risks and benefits of morcellation, and alternatives to morcellation

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Preoperative evaluation to determine if a woman is at increased risk of malignancy of the uterine corpus

POSTMENOPAUSAL OR OLDER THAN 50 YEARS

Preoperative evaluation includes:

- ❖ risk stratification → **Clinical/Familiar History**

- ➢ Median age at diagnosis of leiomyosarcoma is 54 years [48–63 years]
- ➢ History of tamoxifen use (> than 5 years is associated with increased risk of endometrial carcinoma and also may increase the risk of leiomyosarcoma)
- ➢ History of pelvic irradiation
- ➢ Hereditary cancer syndromes (retinoblastoma; Li Fraumeni syndrome)
- ➢ Uterine size and rapid uterine growth are not associated with increased risk of leiomyosarcoma

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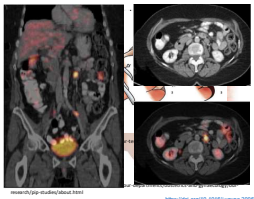
Preoperative evaluation to determine if a woman is at increased risk of malignancy of the uterine corpus

Preoperative evaluation includes:

- ❖ risk stratification
- ❖ cervical cancer screening
- ❖ endometrial tissue sampling
- ❖ appropriate use of imaging



research/jsp-studies/about.html

https://doi.org/10.1016/j.ygyno.2006.10.060

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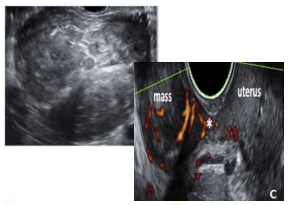
proper use of imaging

consensus on preoperative findings to consider a leiomyoma as 'suspicious' is still lacking

Ultrasound

the presence of a:

- ➢ large, single, growing lesion with
- ➢ cystic degeneration
- ➢ marked peripheral and central vascularity



sonographic features supporting the presence of a suspect myometrial malignancy

Critical Reviews in Oncology/Hematology 98 (2016) 302–308. http://dx.doi.org/10.1016/j.critrevonc.2015.11.015

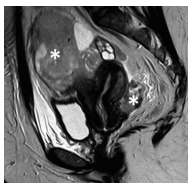
proper use of imaging

consensus on preoperative findings to consider a leiomyoma as 'suspicious' is still lacking

MRI

radiological appearance as:

- ➢ single, large, rapidly growing, infiltrating myometrial mass
  irregular borders
- ➢ heterogeneous hypointensity on T1-weighted images
- ➢ intermediate-to-high signal intensity on T2-weighted images
  (due to necrosis and hemorrhagic foci)



Diffusion-weighted imaging (DWI) and the apparent diffusion coefficient (ADC)

Critical Reviews in Oncology/Hematology 98 (2016) 302–308. http://dx.doi.org/10.1016/j.critrevonc.2015.11.015

Preoperative evaluation to determine if a woman is at increased risk of malignancy of the uterine corpus

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- ❖ endometrial tissue sampling
- ❖ appropriate use of imaging

***although**, leiomyosarcoma cannot be reliably identified preoperatively*

Uterine Morcellation for Presumed Leiomyomas: ACOG Committee Opinion, Number 822. Obstet Gynecol. 2021 Mar 1;137(3):e63-e74. doi: 10.1097/AOG.0000000000004291. Erratum in: Obstet Gynecol. 2021 Aug 1;138(2):313. PMID: 33595252.

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Preoperative evaluation includes:

- ❖ risk stratification
- ❖ cervical cancer screening
- ❖ endometrial tissue sampling
- ❖ appropriate use of imaging

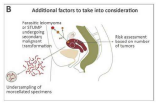
although, leiomyosarcoma cannot be reliably identified preoperatively

the differentiation between myomas and sarcomas can be achieved by histological confirmation only

in vivo 34: 1-9 (2020)
doi:10.21873/invivo.11739
Review

Reasons to Reconsider Risk Associated With Power Morcellation of Uterine Fibroids

CARSTEN HOLZMANN[1], WOLFGANG KUEPKER[2], BIRGIT ROMMEL[3], BURKHARD HELMKE[4*] and JOERN BULLERDIEK[1,3*]



➢ **Implications related to the genetic basis of fibroid development**

Fibroids are of monoclonal origin → nearly every individual nodule have their own independent history and pathogenesis

more appropriately, risk should refer to the number of tumors → *every single nodule arises independently and carries an independent risk of malignancy*

GENETIC CLASSIFICATION diagnostic and predictive relevance

direct biopsy of leiomyomas is not practical

Strategies

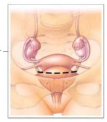
1) **To prevent morcellation**
2) **Scalpel**
3) **Safetybag**
4) **Sarcoma rate is low: "Do nothing"– Proper Selection of Cases**

Strategies

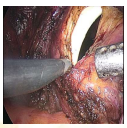
1) **To prevent morcellation**

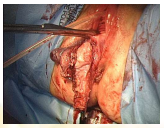
Posterior Colpotomy

Mini-Pfannenstiel



surgical specimen extraction vaginally





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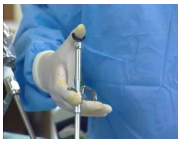
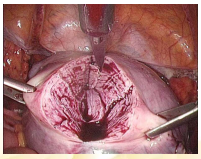
Strategies

2) **Scalpel**

Video Courtesy: Dr. William Kondo, MD – Curitiba, PR-Brazil





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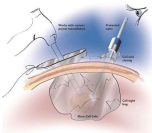
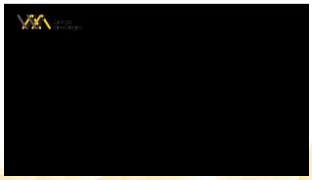
Strategies



3) **Safetybag**



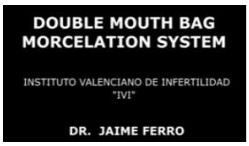
Courtesy videos: Dr. William Kondo, MD – Curitiba, PR-Brazil

Strategies

Safetybag

❖There are different types of bags

❖ Make your own bag



Double Mouth Bag Morcelation System. Instituto Valenciano de Infertilidad "IVI" – Dr. Jaime Ferro

Universidad de Valencia España

JMIG

Original Article

Risk of Leakage and Tissue Dissemination With Various Contained Tissue Extraction (CTE) Techniques: An in Vitro Pilot Study

Two containment bags were studied:

- a 1-piece clear plastic 50x50-cm isolation bag

  (3M Steri-Drape Isolation Bag 1003; 3M Corp., St. Paul, MN)

- a stitch-sealed rip-stop nylon bag

  (TRS200; Anchor Products Co., Inc., Addison, IL).

JMIG

Original Article

Risk of Leakage and Tissue Dissemination With Various Contained Tissue Ext

Two con

- a 1-pi
- a stitc

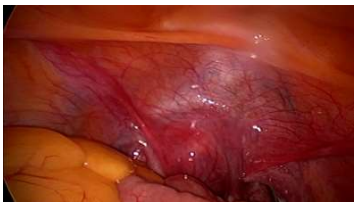
Table 1

Contained tissue extraction

Bag type	Visual inspection of trainer box	Visual inspection of bag	Cytologic findings	Comments
Anchor TRS 200, multi-port				
Trial 1	Clean, no tissue chip	Intact	Negative	
Trial 2	Several drops of blue dye	Intact	Positive for muscle fragments	Leak from seam of bag at high-pressure insufflation
Trial 3	Clean, no tissue chip	Intact	Negative	
Trial 4	Clean, no tissue chips	Intact	Negative	
Isolation bag, multi-port				
Trial 1	Clean, no tissue chips	Intact	Negative	
Trial 2	Clean, no tissue chips	Intact	Negative	
Trial 3	Clean, no tissue chip	Intact	Negative	
Trial 4	Clean, no tissue chips	Intact	Negative	
Isolation bag, single site				
Trial 1	Clean, no tissue chips	Intact	Negative	
Trial 2	Clean, no tissue chips	Intact	Negative	

As a pilot study it is limited by the small number of trials, and results should be interpreted with caution for clinical aplications

contained in bag morcellation



Gynecological Endoscopy Sector – FMB/UNESP

Subsero us Fibroids

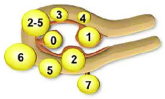
Lo 7

Leiomyoma Subclassification System

Laparoscopic Myomectomy

Lo 2-6

Leiomyoma Subclassification System

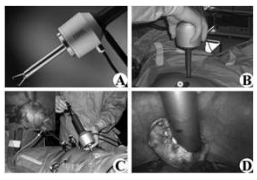


Gynecological Endoscopy Sector – FMB/UNESP

"Even with tissue removal via laparotomy, it is conceivable that there could be disruption of tissue that may result in adverse outcomes such as dissemination of benign or malignant cells".

J Minim Invasive Gynecol. 2014;21(5):935-9. doi: 10.1016/j.jmig.2014.06.004.

Strategies



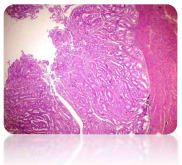
4) Sarcoma rate is low: "Do nothing"– Proper Selection of Cases

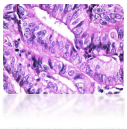
Evidence that morcellation of a leiomyosarcoma worsens a patient's prognosis is limited

Uterine Morcellation for Presumed Leiomyomas: ACOG Committee Opinion, Number 822. Obstet Gynecol. 2021 Mar 1;137(3):e63-e74. doi: 10.1097/AOG.0000000000004291. Erratum in: Obstet Gynecol. 2021 Aug 1;138(2):313. PMID: 33595252.

Risk

Undiagnosed leyomisarcoma





> 2 mitotic figures/10FHM or 5/10FHM

- SARCOMATOUS DEGENERATION - of a malignant character; isolated cellular atypia is not a reliable criterion; 0.04% of cases (< 1%)

Agency for Healthcare Research and Quality (AHRQ) 2017 report

the largest and most comprehensive dataset and rigorous analytic methods

Prevalence of leiomyosarcoma may range from: **1 in 770** to less than **1 in 10,000** surgeries

Uterine Morcellation for Presumed Leiomyomas: ACOG Committee Opinion, Number 822. Obstet Gynecol. 2021 Mar 1;137(3):e63-e74. doi: 10.1097/AOG.0000000000004291. Erratum in: Obstet Gynecol. 2021 Aug 1;138(2):313. PMID: 33595252.

morcellation of fibroids

Risk

Undiagnosed leyor

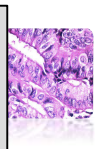
➢ SARCOMATOUS DEGENERATION :

2017 AHRQ – the expected 5-year survival:

- ➢ 30% for power morcellation (95% BCI,13–61%)
- ➢ 59% for scalpel morcellation (95% BCI, 33–84%)
- ➢ 60% for no morcellation (95% BCI, 24–98%)

UNCERTAINTY

the estimates for the three groups overlap



res/10FHM or 5/10FHM

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Agency for Healthca (AHRQ) :

the largest and most c rigorous analytic methods

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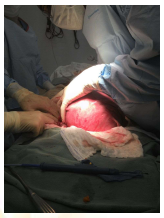
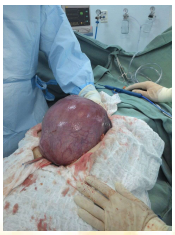
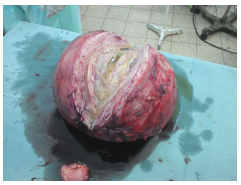
there is still room for laparotomy

Limitations

Fibroids size? X Mobility



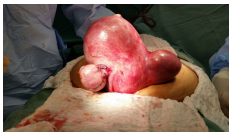


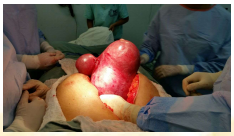


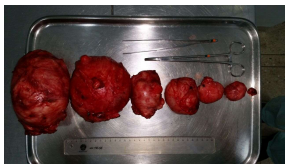
there is still room for laparotomy

Limitations

Fibroids size? X Mobility







Multiplicity

The role of shared decision making

- ❖ **Shared decision making**
- ❖ Informed consent
- ❖ Explaining the risks and benefits of each approach
- ❖ Explaining the risks and benefits of morcellation
- ❖ Alternatives to morcellation

Take Home Messages

Safe In-Bag Morcellation

- ✓ **Undestanding the needs of our patients**
- ✓ **Individualize approach**
- ✓ **Informed couseling**, explaining the risks and benefits of each approach, the risks and benefits of morcellation, and alternatives to morcellation
- ✓ **The obstetrician–gynecologist and patient should engage in shared decision making**

FACULDADE DE MEDICINA DE BOTUCATU – FMB
UNIVERSIDADE ESTADUAL PAULISTA "JÚLIO DE MESQUITA FILHO" – UNESP
PROGRAMA DE PÓS-GRADUAÇÃO EM GINECOLOGIA, OBSTETRÍCIA E MASTOLOGIA
SETOR DE ENDOSCOPIA GINECOLÓGICA E PLANEJAMENTO FAMILIAR
CHEFE DO SETOR PROF. ADJUNTO ROGÉRIO DIAS

Thank you
Obrigado
Merci
Gracias
Grazie
Danke
спасибо
謝謝
ありがとう

Daniel S. Dias
Setores de Endoscopia Ginecológica e Oncoginecologia
Faculdade de Medicina de Botucatu – FMB/UNESP

References

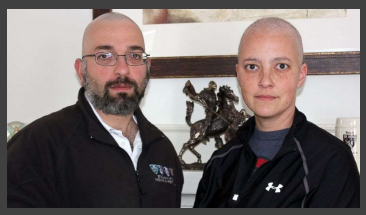
- Cohen SL, Greenberg JA, Wang KC, Srouji SS, Gargiulo AR, Pozner CN, Hoover N, Einarsson JI. Risk of leakage and tissue dissemination with various contained tissue extraction (CTE) techniques: an in vitro pilot study. J Minim Invasive Gynecol. 2014 Sep-Oct;21(5):935-9. doi: 10.1016/j.jmig.2014.06.004. Epub 2014 Jun 11. PMID: 24928740.
- Bogani G, Chiappa V, Ditto A, Martinelli F, Donfrancesco C, Indini A, Lorusso D, Raspagliesi F. Morcellation of undiagnosed uterine sarcoma: A critical review. Crit Rev Oncol Hematol. 2016 Feb;98:302-8. doi: 10.1016/j.critrevonc.2015.11.015. Epub 2015 Nov 23. PMID: 26672915.
- Ricci S, Stone RL, Fader AN. Uterine leiomyosarcoma: Epidemiology, contemporary treatment strategies and the impact of uterine morcellation. Gynecol Oncol. 2017 Apr;145(1):208-216. doi: 10.1016/j.ygyno.2017.02.019. Epub 2017 Feb 13. PMID: 28209496.
- Rousseau M, Morel A, Dechoux S, Bouet PE, Catala L, Lefebvre Lacoeuille C, Descamps P, Legendre G. Can the risks associated with uterine sarcoma morcellation really be prevented? Overview of the role of uterine morcellation in 2018. J Gynecol Obstet Hum Reprod. 2018 Oct;47(8):341-349. doi: 10.1016/j.jogoh.2018.05.015. Epub 2018 Jun 4. PMID: 29879489.
- Juhasz-Böss I, Gabriel L, Bohle RM, Horn LC, Solomayer EF, Breitbach GP. Uterine Leiomyosarcoma. Oncol Res Treat. 2018;41(11):680-686. doi: 10.1159/000494299. Epub 2018 Oct 16. PMID: 30321869.
- Bretthauer M, Goderstad JM, Løberg M, Emilsson L, Ye W, Adami HO, Kalager M. Uterine morcellation and survival in uterine sarcomas. Eur J Cancer. 2018 Sep;101:62-68. doi: 10.1016/j.ejca.2018.06.007. Epub 2018 Jul 17. PMID: 30025231.
- Halaska MJ, Gracia M, Laky R, Zapardiel I. Morcellation of the Uterus: Is There Any Place? Curr Oncol Rep. 2020 Jun 9;22(7):68. doi: 10.1007/s11912-020-00927-6. PMID: 32514869.
- Holzmann C, Kuepker W, Rommel B, Helmke B, Bullerdiek J. Reasons to Reconsider Risk Associated With Power Morcellation of Uterine Fibroids. In Vivo. 2020 Jan-Feb;34(1):1-9. doi: 10.21873/invivo.11739. PMID: 31882457; PMCID: PMC6984091.
- Uterine Morcellation for Presumed Leiomyomas: ACOG Committee Opinion, Number 822. Obstet Gynecol. 2021 Mar 1;137(3):e63-e74. doi: 10.1097/AOG.0000000000004291. Erratum in: Obstet Gynecol. 2021 Aug 1;138(2):313. PMID: 33595252

Financial Disclosures

USPTO – Intellectual Property -Patents on tissue extraction bags
Gynesonics - Consultant
Channel Medsystems - Consultant
Hologic - Contracted Research
Emmy Medical - Stock Ownership
Polygon, Inc - Stock Ownership

Dr. Amy Reed

March 22, 1973 – May 24, 2017
Age 44



Remember why we are here

Goals

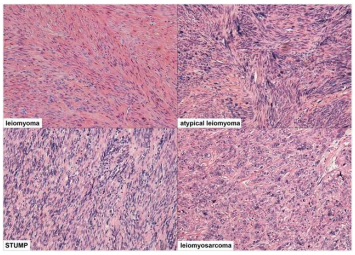
- Define the problem
  - What is leiomyosarcoma?
  - Prevalence of leiomyosarcoma
  - Outcomes with leiomyosarcoma
- Current and future technologies
- Summary and recommendations

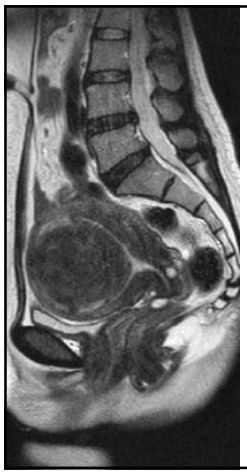
Leiomyosarcoma

- Rare: < 1% of adult malignant tumors
- Uterine corpus malignancy: 3-8%
- Mean age of diagnosis: 60 years old
  - Women under 40: 15%
  - African Americans compared with White: 2-fold increase

Leiomyosarcoma: Pathology

- Mesenchymal origin
- Typically *de novo* rather than malignant transformation
- Complicated karyotype with instability of many genes and mutations; p16, p53 and Ki-67
- Histopathology: > 15 mitosis per 10 HPF and moderate-to-severe cytologic atypia





Leiomyosarcoma: Diagnosis

- Endometrial sampling: only 25-50%
- Ultrasound: poor sensitivity and PPV
  - Large size
  - Degenerative cystic changes
  - Increased vascularity
- MRI: sensitivity/specificity ~ 50%/90%
  - Solitary and heterogeneous
  - Poorly demarcated
  - Hemorrhage and necrosis

Leiomyosarcoma: Presentation

- Stage I – 68%
- Stage II – 3%
- Stage III – 7%
- Stage IV – 22%

Stage	Definition	
I	Tumor limited to uterus	IA: <5 cm IB: >5 cm
II	Tumor extends beyond the uterus, within the pelvis	IIA: adnexal involvement IIB: involvement of other pelvic tissues
III	Tumor invades abdominal tissues (not just protruding into the abdomen)	IIIA: one site IIIB: more than one site IIIC: metastasis to pelvic and/or para-aortic lymph nodes
IV		IVA: tumor invades bladder and/or rectum IVB: distant metastases

Note: Data from *International Journal of Gynecology & Obstetrics*, 2009.
Abbreviations: FIGO, International Federation of Gynecology and Obstetrics; ULMS, uterine leiomyosarcoma.

Lies, damned lies, and statistics

(not Twain, Disraeli, Balfour, Courtney, etc)

Occult Gynecologic Neoplasia

If morcellation is planned - BIOPSY

Table 3. Pathology Among Women Undergoing Laparoscopic Supracervical Hysterectomy With Power Morcellation Comparing the Pre–U.S. Food and Drug Administration Guidance and Post–U.S. Food and Drug Administration Guidance Periods and the Use of Containment Bag by Pathology

Pathology	Pre–FDA Guidance (n=31,664)		Post–FDA Guidance (n=5,546)		*P*
Uterine cancer or sarcoma	54	0.17	7	0.12	.45
Other gynecologic cancers	17	0.05	8	0.14	.02
Uterine neoplasms of uncertain malignant potential	30	0.09	4	0.07	.61
Ovarian neoplasms of uncertain malignant potential	12	0.04	0	0.0	.15
Endometrial hyperplasia	299	0.94	38	0.69	.06

FDA, U.S. Food and Drug Administration.
Data are n (%) unless otherwise specified.

Wright et. al., *Obstetrics & Gynecology* 2022

Occult LMS: The Numbers Debate

2014
FDA - 9 studies
- 1 in 498

2017
AHRQ – 160 studies
- Risk of occult LMS 1-13/10,000 surgeries

2015
Pritts et. al.
- 1 in 2,000 using 134 studies
- 1 in 8,300 using only 64 prospective studies

FDA Methodology

- Targeted search using search terms:
  "uterine cancer"
  AND
  "hysterectomy or myomectomy"
  AND
  "incidental cancer or uterine prolapse, pelvic pain, uterine bleeding, and uterine fibroids"

With "uterine cancer" as a required search term, studies without cancers were excluded

FDA Methodology

- Included only studies with 100 or more subjects
- Included only English articles
- Included 1 non-peer-reviewed abstract and 1 letter to the editor
- Mostly retrospective studies (8/9)

Pritts et. al. Methodology

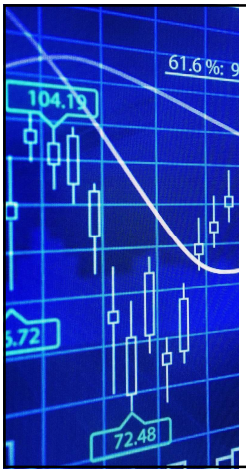
- Search terms alone or in combination:
  - "myoma"
  - "leiomyoma"
  - "fibroid"
  - "hysterectomy"
  - "incidental malignancy"
  - "myomectomy"
  - "neoplasm"
  - "leiomyosarcoma"
  - "incidence"
  - "pathology"
  - "histopathology"
  - "morcellation"
  - "complications"

Pritts et. al. Methodology

- 5 or more subjects
- All languages
- All peer-reviewed
- Included only original data
- Included only post-op histopathology for all patients extracted
- Included only fibroid-related primary indications
- Bayesian binomial random effect specification

Pritts et. al. Results

- 4864 studies identified – 3844 excluded by abstracts
- 1020 studies fully reviewed
- 134 studies included - 64 prospective
- 32 leiomyosarcomas in 30,193
- Of 134 studies, 118 had no LMS and would not have appeared in the FDA's search



Leiomyosarcoma: Prognosis

- Aggressive and poor prognosis
- Recurrence rates: 53-71%
- 5-year survival:
  - Stage I: 51%
  - Stage II: 25%

With Morcellation*

- Recurrence rate: 3-4 fold increase
- Overall survival: 2.5-fold decrease

*Bogani, 2015

Leiomyosarcoma: Prognosis

en bloc vs. any tumor injury* (i.e. myomectomy)

- Recurrence rate: 22-51% vs. 50-74%
- 5-year survival: 43-73% vs. 38-74%

*Tantitamit, 2018

Cytology positive for myoma cells after myomectomy but before morcellation: 15-25.8%

FULL TEXT ARTICLE

Cell Spillage after Contained Electromechanical Morcellation Using a Specially Designed In-Bag System for Laparoscopic Myomectomy: Prospective Cohort Pilot Study

FULL TEXT ARTICLE

Peritoneal Washings After Power Morcellation in Laparoscopic Myomectomy: A Pilot Study

Intermezzo

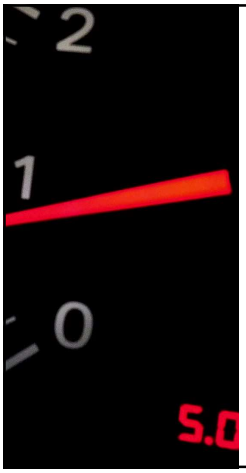
- Leiomyosarcoma
  - Uncommon
  - Difficult to diagnose pre-operatively
  - Poor prognosis
  - Worse prognosis with anything short of *en bloc* resection
  - Myomectomy – open or laparoscopic spreads cells

Options for removal of uterine tissue

- Universal open surgery
- Uncontained morcellation
- Selectively contained morcellation
- Universal contained morcellation

Open vs. Laparoscopic

If you need data for this, you are at the wrong conference



Power vs. Manual Morcellation

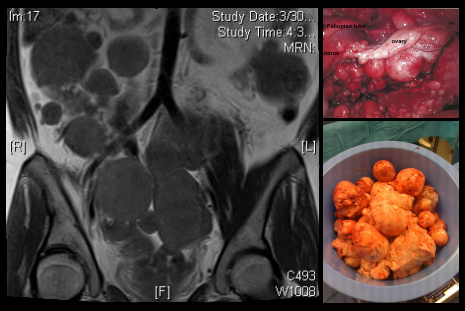
- Speed
- Cost
- Incision size
- Likely no difference in prognosis

Contained vs. Uncontained

Contained
- Harder
- Added time
- Added cost
- Less spillage

Uncontained
- Easier
- Faster
- Less cost
- Lots of spillage

Leiomyomatosis



1976 Karl Semm mechanical morcellator

1993 Steiner power morcellator

1997 Carter 53" save time saving

October 2013 sentinel case

April 2014 FDA Black Box warning

April 2016 FDA approves PneumoLiner™

February 2020 FDA updated recommendation

UPDATE: Perform Only Contained Morcellation When Laparoscopic Power Morcellation Is Appropriate: FDA Safety Communication

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Date issued: December 29, 2020

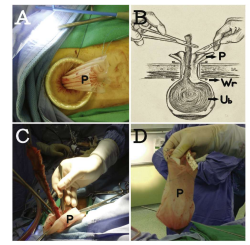
Contained Tissue Extraction Technology

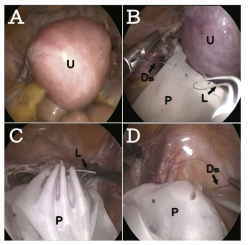
- Manual morcellation vs. power morcellation
- FDA regulates power morcellators
- Challenges
  - ***Barrier Testing – only applies to power morcellation systems***
  - Cost
  - Easy of use
    - Insertion and deployment
    - Visualization
    - Getting specimen into device
    - Getting specimen out of device

Contained Tissue Extraction Manual Technique

- Introduce bag into the abdomen
- Put the tissue in the bag
- Exteriorize the opening of the bag
- Morcellate the tissue
- Don't cut the bag

Contained Tissue Extraction Manual Technique

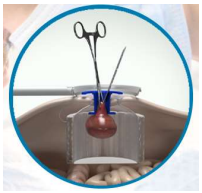




Wu MY, et. al. 2016

Contained Tissue Extraction Manual Technologies and Tips

- Abdominal or vaginal
- Bag orientation
- Hold posterior edge
- Wound retractor helps



Contained Tissue Extraction Power Morcellation Technologies

Barrier Testing

- There is no FDA "recipe" that assures acceptance
- Prove the containment material is impermeable to human cells
- Prove the containment device maintains its integrity after morcellation

Barrier Testing - PneumoLiner

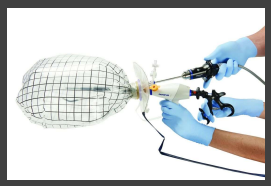
- Filter Tryptone Soya Broth (TSB) inoculated with *B. diminuta* through the Pneumoliner pouch material including the seam and assess filtrate for bacterial growth
- Pouch filled with TBS and inoculated with *B. diminuta.* Morcellations then performed. Pouch then immersed in TBS and assessed for bacterial growth on the outside of the pouch

Contained Tissue Technologies for Power Morcellation

(I could find on the web)

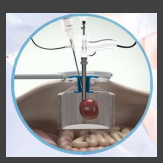
- Bag with single port
  - PneumoLiner™ - FDA approved (US)
  - LapBox (Israel)
- Bag with multiple ports
  - MorSafe® (India)
  - More-Cell-Safe™ (Austria)
  - Safety Isolation Bag® (India)
  - LiNA Xcise Morcellation Bag™ - CE marked (Denmark)
  - Espiner ECO-T Containment Bag - CE marked (UK)

Single Port Systems



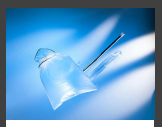
PneumoLiner

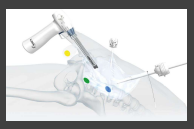
LapBox

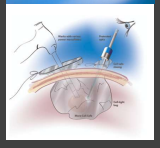


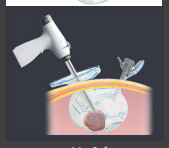
Multiport Systems

Espiner ECO-T









LiNA Xcise Morcellation Bag

More-Cell-Safe

MorSafe

Summary and Recommendations

- Non-LMS malignant neoplasm are not uncommon – if morcellation is planned – BIOPSY
- Parasitic leiomyomas and leiomyomatosis are real
- Occult LMS probably occurs in about 1-13/10,000 cases
- LMS is difficult to consistently identify pre-op
- Worse prognosis with anything short of *en bloc* resection
- I think containment should always be used with morcellation
- Help is on the way

вопросов?

des questions?

Fragen ?

질문?

問題嗎？

Questions?

maswali?

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الأسئلة

spurningar?

คำถาม ?

Transcervical and Transabdominal Treatment of Fibroids Utilizing Ultrasonic Directed RF Energy

David J. Levine M.D.
Director of Minimally Invasive Gynecologic Surgery
Mercy Hospital St.Louis

Disclosures

Speakers Bureau & Consultant to Gynesonics

Why do we need new technology?

- Find a better mouse trap
- Cheaper
- Faster
- Safer
- Procedure looking for an indication
- Generally motivated by poor long term results or limited options post procedure

indications

- Heavy menstrual bleeding
- Pressure symptoms
- Uterine preservation

Radiofrequency Ablation of Uterine Fibroids

Volumetric, image-guided ablation:

- Optimizes ablated volume of targeted fibroid
- Avoids multiple passes of energized needles through the serosa
- Treats the fibroids that are likely to be symptomatic
- Incites thermal fixation and coagulative necrosis
  - Avoids infarction-related postembolization syndrome seen with UAE

Coagulative Necrosis

- Cell Death
  - Function of temperature and time
- Human Cells
  - 42-46 C for 45 minutes
  - 51 C for 2-6 minutes
  - 60 C nearly instantaneous
  - 100 C H2O vaporization, tissue desiccation /charring
- Ablation Volume
  - Temperature and duration of time at given temperature
  - Needle probe characteristics (size, shape, number)
  - Target tissue characteristics (heat sinks, scarring, heterogeneity)
  - No “Post –UAE Syndrome”

RF Ablation vs Myolysis

- Myolysis
  - Bipolar cauterization of fibroid capsule and myometrium/serosa
  - Multiple punctures around the periphery of the tumors
  - No needle guidance with ultrasound
- RF Ablation
  - Limited to the fibroid
  - Ultrasound guided

Contraindications for the laparoscopic and transcervical approach

- Patients who are not candidates for laparoscopic surgery due to intrabdominal adhesions or lack of uterine mobility due to scarring or adjacent pathology
- Uterine size greater than 14 weeks (this may vary with experience)
- Suspected or undiagnosed uterine malignancy
- Active genital infection
- Metal implants near the ablation site or along the RF return path (hip and back implants knee is not in the path)
- Future pregnancy

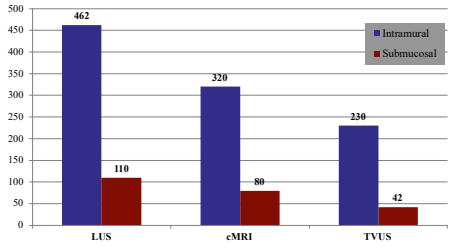
Preop evaluation

Ultrasound or MRI with proper fibroid measurements and mapping

Endometrial sampling

Blood work and LDH 3 isoenzyme panel (if over 40)

Number of IM vs SM Fibroids



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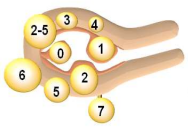
FIGO Fibroid Classification

Leiomyoma Subclassification System



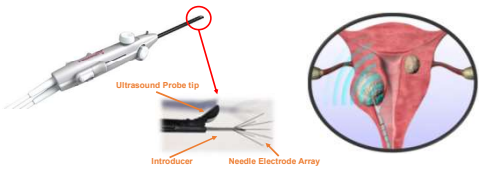
S - Submucosal	0	Pedunculated Intracavitary
	1	<50% Intramural
	2	≥ 50% Intramural
O - Other	3	Contacts endometrium; 100% Intramural
	4	Intramural
	5	Subserosal ≥50% Intramural
	6	Subserosal < 50% Intramural
	7	Subserosal Pedunculated
	8	Other (specify eg. cervical, parasitic)

Hybrid Leiomyomas (impact both endometrium and serosa)	Two numbers are listed separated by a dash. By convention, the first refers to the relationship with the endometrium while the second refers to the relationship to the serosa. One example is below.	
	2-5	Submucosal and subserosal, each with less than half the diameter in the endometrial and peritoneal cavities respectively.

technique

Acessa: 2 transabdominal midline ports one for laparoscopic visualization and one for ultrasound wand and ProVu guidance system

Sonata: transcervical insertion of ultrasound probe with SMART Guide handpiece



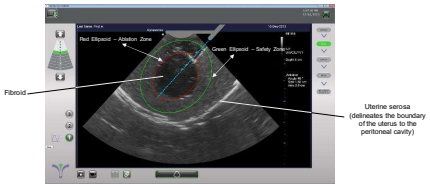
- **The Intrauterine Ultrasound Probe and the RFA Handpiece combine to form a single integrated Treatment Device**
- **Main Procedure Steps:**
  - Access the endometrial cavity through a transcervical approach
  - Locate and target a fibroid
  - Graphically select the ablation size and location
  - Deploy Introducer and then Needle Electrodes into the fibroid
  - Ablate (time at temperature is automatically selected based on the ablation zone)
  - Repeat if needed
- **Depending on size, one ablation will require 2-7 minutes (time at temperature)**

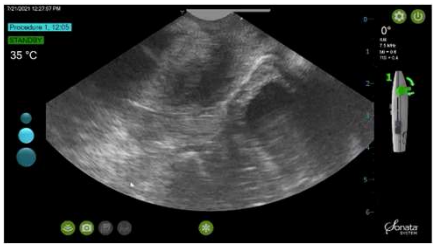
SMART Targeting Guide: **S**etting **M**argins of **A**blation in **R**eal **T**ime

Graphic overlay of live sonographic image set by operator using the control knob on the RFA Handpiece, determining:

- Size and duration of ablation (red ellipse – tissue inside will be ablated)
- Correlating safety border (green ellipse – outside of the ellipse is safe from ablation/heat)
- Mechanical safety stops limit depth for Introducer and Needle Electrode advancement
- Duration of radiofrequency energy delivery

In this example, the ablation is appropriately sized to ablate 100% of the fibroid while the green ellipsoid (Thermal Safety Border) is safely located within the uterine serosa





complications

- Laparoscopic approach
- abdominal wall hematoma
- pelvic abscess
- superficial colonic laceration

- Transcervical
- endometritis

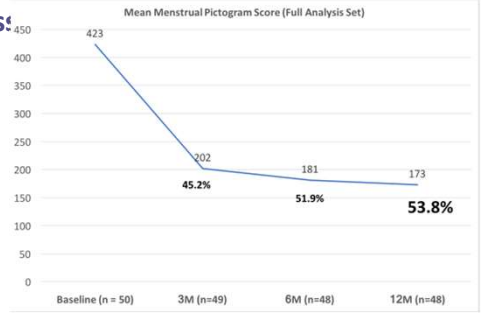
Comparable data at 12 months

- Acessa:
  - 82% reduction in menstrual bleeding of which 40% experienced a 50% reduction
  - 45% mean fibroid volume reduction and 24% decrease on uterine volume
  - 94% patient satisfaction
  - 1 serious adverse event
  - return to normal activity in 4-9 days

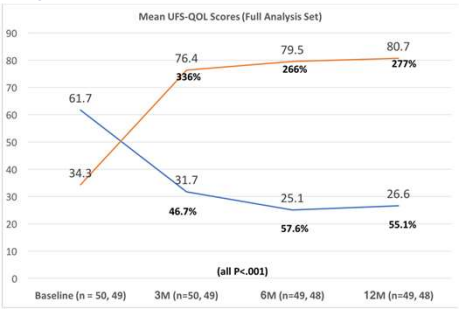
Sonata:

- 95% reduction in menstrual bleeding of which 65% reported at least 50% reduction
- 96% reported symptom relief
- no adverse events
- 50% returned to normal activity the next day

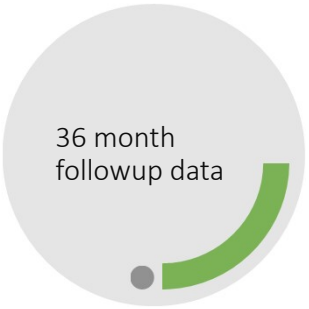
Significant Reduction in Menstrual Blood Loss



Significant Improvements in Patient-Reported Outcomes



- Both techniques showed continued significant reduction and health improvements sustained
- Transabdominal reported 11% cumulative reintervention rate (½ from undiagnosed adenomyosis)
- Transcervical reported 8% surgical reintervention for heavy menstrual bleeding



Conclusion

Management of symptomatic fibroids with both transabdominal and transcervical modalities has demonstrated long term benefit with minimal surgical reintervention

The Transcervical approach is incisionless, 24-48 hr. return to normal activity and is best utilized for severe menorrhagia due to submucosal and intramural fibroids

The Transabdominal approach can treat all fibroids requires general anesthesia is technically more challenging, return to normal activity in 4-9 days

References

- Chudnoff et al Outpatient Procedure for the Treatment and Relief of Symptomatic Uterine Fibroids OBGYN 2013 121(5)1075-82
- Berman et al Three year outcome from the Halt trial A prospective analysis The Journal of Minimally Invasive Gynecology 2014 21 (5) 767
- LukesA, Green MA Three year Results of the Sonata Pivotal Trial of Transcervical Fibroid Ablation for Symptomatic Uterine Myomata J. Gynecol Surg 2020 36:5 228-233

CULTURAL AND LINGUISTIC COMPETENCY & IMPLICIT BIAS

The California Medical Association (CMA) announced new standards for Cultural Linguistic Competency and Implicit Bias in CME. The goal of the standards is to support the role of accredited CME in advancing diversity, health equity, and inclusion in healthcare. These standards are relevant to ACCME-accredited, CMA-accredited, and jointly accredited providers located in California. AAGL is ACCME-accredited and headquartered in California.

CMA developed the standards in response to California legislation (Business and Professions (B&P) Code Section 2190.1), which directs CMA to draft a set of standards for the inclusion of cultural and linguistic competency (CLC) and implicit bias (IB) in accredited CME.

The standards are intended to support CME providers in meeting the expectations of the legislation. CME provider organizations physically located in California and accredited by CMA CME or ACCME, as well as jointly accredited providers whose target audience includes physicians, are expected to meet these expectations beginning January 1, 2022. AAGL has been proactively adopting processes that meet and often exceed the required expectations of the legislation.

CMA CME offers a variety of resources and tools to help providers meet the standards and successfully incorporate CLC & IB into their CME activities, including FAQ, definitions, a planning worksheet, and best practices. These resources are available on the CLC and IB standards page on the CMA website.

Important Definitions:

Cultural and Linguistic Competency (CLC) – The ability and readiness of health care providers and organizations to humbly and respectfully demonstrate, effectively communicate, and tailor delivery of care to patients with diverse values, beliefs, identities and behaviors, in order to meet social, cultural and linguistic needs as they relate to patient health.

Implicit Bias (IB) – The attitudes, stereotypes and feelings, either positive or negative, that affect our understanding, actions and decisions without conscious knowledge or control. Implicit bias is a universal phenomenon. When negative, implicit bias often contributes to unequal treatment and disparities in diagnosis, treatment decisions, levels of care and health care outcomes of people based on race, ethnicity, gender identity, sexual orientation, age, disability and other characteristics.

Diversity – Having many different forms, types or ideas; showing variety. Demographic diversity can mean a group composed of people of different genders, races/ethnicities, cultures, religions, physical abilities, sexual orientations or preferences, ages, etc.

Direct links to AB1195 (CLC), AB241 (IB), and the B&P Code 2190.1:

Bill Text – AB-1195 Continuing education: cultural and linguistic competency.
Bill Text – AB-241 Implicit bias: continuing education: requirements.
Business and Professions (B&P) Code Section 2190.1

CLC & IB Online Resources:

Diversity-Wheel-as-used-at-Johns-Hopkins-University-12.png (850×839) (researchgate.net)
Cultural Competence In Health and Human Services | NPIN (cdc.gov)
Cultural Competency – The Office of Minority Health (hhs.gov)
Implicit Bias, Microaggressions, and Stereotypes Resources | NEA
Unconscious Bias Resources | diversity.ucsf.edu
Act, Communicating, Implicit Bias (racialequitytools.org)
https://kirwaninstitute.osu.edu/implicit-bias-training
https://www.uptodate.com/contents/racial-and-ethnic-disparities-in-obstetric-and-gynecologic-care-and-role-of-implicitbiases
https://www.contemporaryobgyn.net/view/overcoming-racism-and-unconscious-bias-in-ob-gyn
https://pubmed.ncbi.nlm.nih.gov/34016820/