

As enacted by Maryland State Law, the University of Maryland School of Medicine was required to convene a workgroup that includes representatives from the Department of Health and Mental Hygiene, certain experts, and interested stakeholders to study issues related to the incidence of uterine fibroids in the State; required the workgroup to examine certain issues; required, on or before a certain date, the University of Maryland School of Medicine to report certain findings to certain committees of the General Assembly.

The University of Maryland Fibroid Workgroup participants included:

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The specific tasks of the Workgroup were to examine:

- (1) the incidence of uterine fibroids among women in the State, by race, ethnicity, age, and county of residence;***
- (2) the types of treatments and procedures used to treat uterine fibroids;***
- (3) data on the number of women in the State who undergo a hysterectomy (surgical removal of the uterus), myomectomy (surgery to remove a fibroid without removing the uterus), or other type of treatment for uterine fibroids each year;***
- (4) alternative, innovative, and less invasive treatments and procedures that are available to treat uterine fibroids;***
- (5) whether there is a need for more research to study the cause and treatment of uterine fibroids; and***
- (6) whether licensed physicians in the State are willing and able to perform less invasive procedures to treat uterine fibroids.***

BACKGROUND

Uterine leiomyomas (also called fibroids) are the most common solid pelvic tumors in women and the leading indication for hysterectomy. Although many women with uterine leiomyomas are asymptomatic and can be monitored without treatment, some will require more active measures. The two most common symptoms of uterine leiomyomas for which women seek treatment are abnormal uterine bleeding and pelvic pressure. The most common kind of abnormal uterine bleeding associated with leiomyomas is heavy or prolonged menstrual bleeding, which frequently results in iron deficiency anemia (1). This heavy flow may result in significant disruption of a woman's daily activities. The pelvic and abdominal discomfort that women experience with leiomyomas often is described as pressure. In addition to pelvic

pressure, leiomyomas may interfere with adjacent structures, leading to dyspareunia and difficulty with urination or defecation.

Uterine leiomyomas are very common, with some studies reporting leiomyomas in 70% of white women and more than 80% of black women by age 50 years (2). Leiomyomas can vary greatly in size and may be present in subserosal, submucosal, intramural, pedunculated, or combined locations. Symptoms and treatment options are affected by the size, number, and location of the leiomyomas. The lack of a simple, inexpensive, and safe long-term medical treatment means that most symptomatic leiomyomas are still managed surgically.

Hysterectomy remains the most common surgical treatment for leiomyomas because it is the only definitive treatment and eliminates the possibility of recurrence. Many women seek an alternative to hysterectomy because they desire future childbearing or wish to retain their uteri even if they have completed childbearing. As alternatives to hysterectomy become increasingly available, the efficacies and risks of these treatments are important to delineate. (3)

SPECIFIC TASKS

(1) the incidence of uterine fibroids among women in the State, by race, ethnicity, age, and county of residence

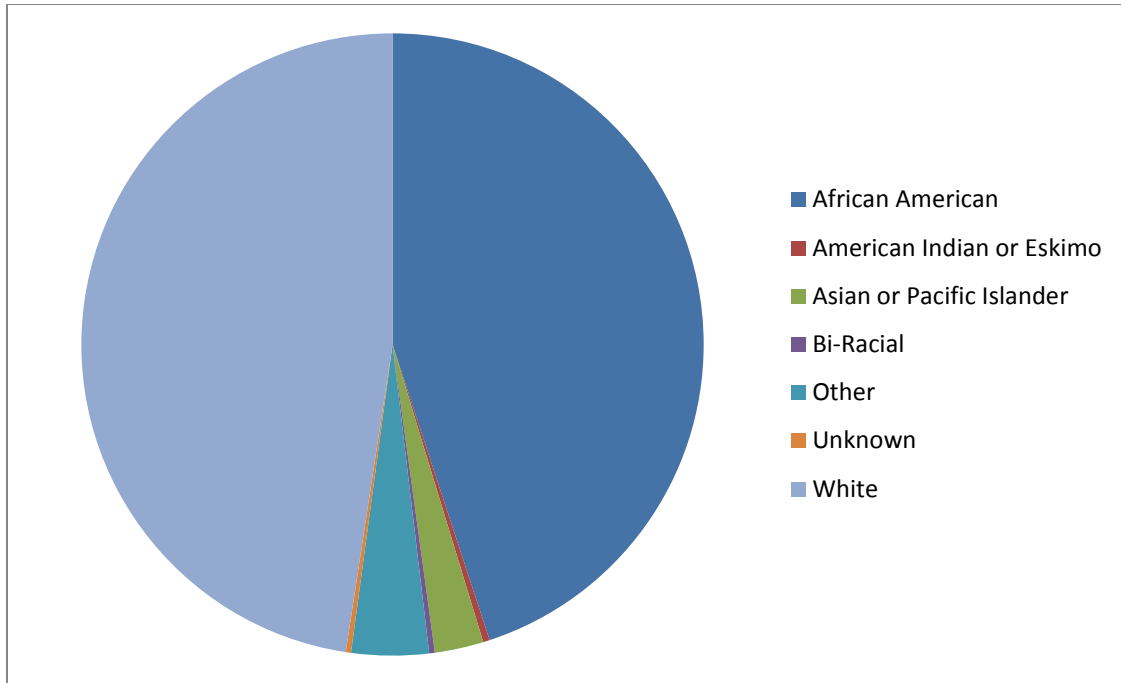
Uterine fibroids are very common, but inconsistently reported. Many women have fibroids and may be completely without symptoms. Thus, the University of Maryland Fibroid Workgroup sought to respond to Task 1 by estimating the prevalence of fibroids among women in the State of Maryland using clinically significant fibroids as a proxy. As such, the major health care providers in the State were approached to participate; ultimately, University of Maryland Medical System (UMMS) and Johns Hopkins Health System (JHHS) contributed. In 2015, of the approximately 3 million women residents of the State, 549,537 women (18.3%) were treated by the UMMS and JHU medical systems (UMMS 264,933; JHHS 284,604).

Ten years of UMMS and JHHS in-patient and out-patient data (July 1, 2005-June 30, 2015) were reviewed, searching for fibroid diagnosis codes and fibroid-related procedural codes. Over these ten years, there were 9850 different encounters for fibroid or fibroid-related diagnoses and procedures. These translated to 9587 individual women, many of whom had multiple office visits, hospital admissions, and procedures to address their fibroid-related symptoms.

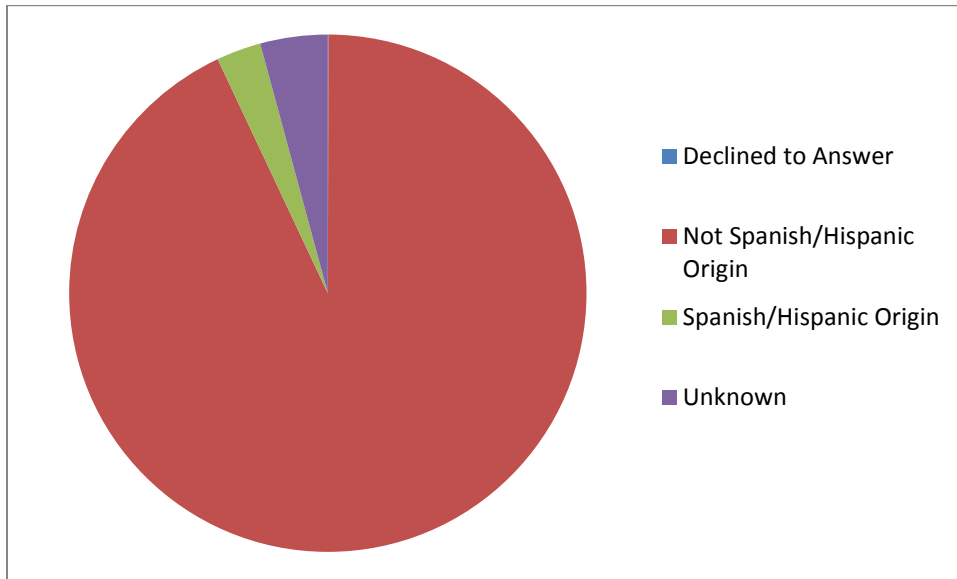
Among all women with fibroid or fibroid-related diagnoses, demographics are as follows:

Race	count	percent
African American	4309	44.9
American Indian or Eskimo	33	0.3

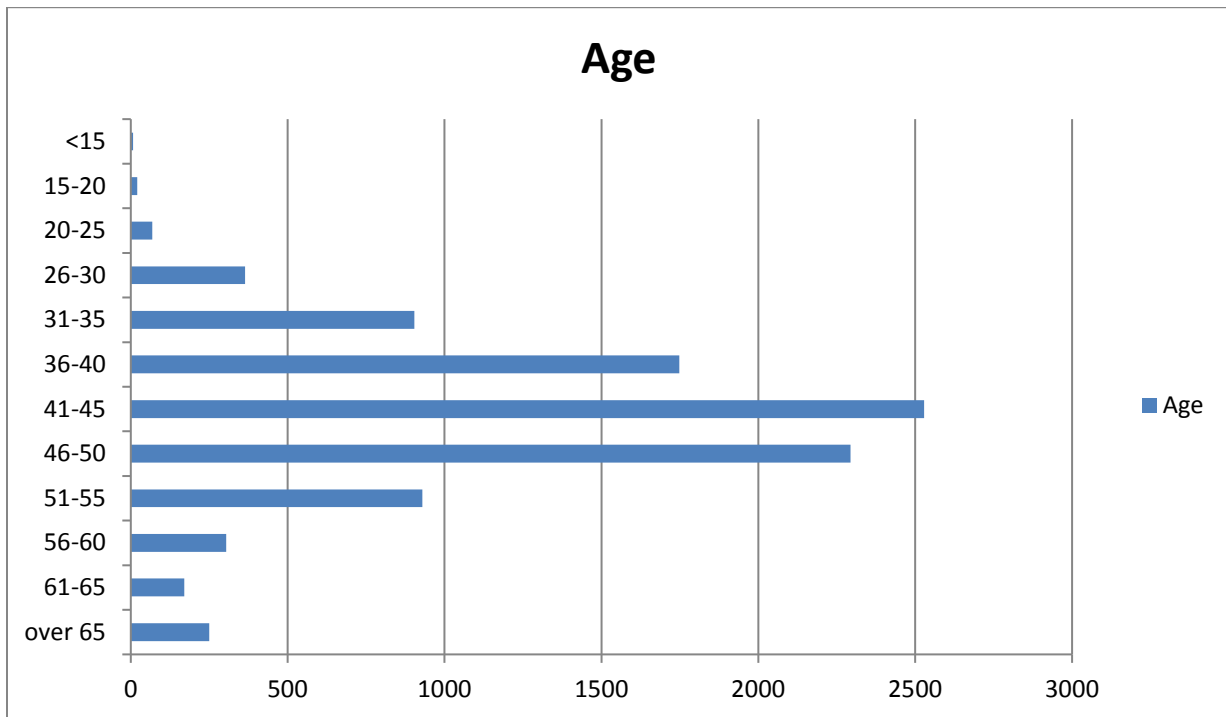
Asian or Pacific Islander	243	2.5
Bi-Racial	28	0.3
Other	385	4
Unknown	26	0.3
White	4563	47.6
Total	9587	



Ethnicity	count	percent
Declined to Answer	4	0.04
Not Spanish/Hispanic Origin	8912	93
Spanish/Hispanic Origin	267	2.8
Unknown	404	4.2
Total	9587	



Age Bracket	count	percent
<15	7	0.07
15-20	21	0.2
20-25	68	0.7
26-30	364	3.8
31-35	904	9.4
36-40	1748	18.2
41-45	2528	26.4
46-50	2294	23.9
51-55	929	9.7
56-60	304	3.2
61-65	170	1.8
over 65	250	2.6
Total	9587	



County of Residence	count
Baltimore County	1790
Baltimore City	1660
Harford	1012
Anne Arundel	917
Howard	676
Charles	452
Montgomery	402
Unidentified	435
Dorchester	282
Talbot	259
Caroline	242
Unidentified Maryland	187
Prince George's	181
Queen Anne's	135
Virginia	112
Cecil	107
Carroll	105
Pennsylvania	104
Kent	98
Other States	83
St. Mary's	63

REPORT OF THE UNIVERSITY OF MARYLAND WORKGROUP
TO STUDY ISSUES RELATED TO UTERINE FIBROIDS

JUNE 30, 2016

Wicomico	54
Delaware	49
Frederick	45
Calvert	29
Washington	29
Foreign	27
West Virginia	15
Somerset	13
Allegany	9
District of Columbia	7
Worcester	6
Garrett	2

Payor	count
BLUE CROSS	232
BLUE CROSS - NATIONAL CAPITAL AREA	378
Blue Cross - NCA	450
Blue Cross - other state	621
Blue Cross of Maryland	1180
Charity	93
COMMERCIAL INSURANCE	362
Commercial Insurance/PPO	1542
HMO	619
INTERNATIONAL	4
Managed care payer	2124
MD Medicaid - Only FFS and Pending	121
MD Medicaid HMO	632
MEDICAID	15
MEDICAID - ONLY FFS	20
MEDICAID HMO	116
MEDICAID MANAGED CARE PAYER	144
MEDICARE	50
Medicare - Only FFS	379
Medicare HMO	17
MEDICARE MANAGED CARE PAYER	1
Other	39
OTHER GOVERNMENT PROGRAM	140
Other government program (incl Non Maryland Medicaid 07/2015+)	130
SELF PAY	25
Self-pay	151

REPORT OF THE UNIVERSITY OF MARYLAND WORKGROUP
TO STUDY ISSUES RELATED TO UTERINE FIBROIDS
JUNE 30, 2016

TITLE V	1
Unknown	1
Total	9587

Health Plan Payor	count
Aetna	206
Aetna (Golden Choice)	1
Aetna (Medicare Advantage)	1
Aetna Health Plans	487
Amerigroup	107
Amerigroup Community Care	14
CareFirst - CFMI (Maryland) (PPO, POS, Blue Preferred, FEP)	232
CareFirst - GHMSI (DC) (PPO, POS, Blue Preferred, FEP)	158
CareFirst - Group Hospitalization and Medical Services Inc. (Non HMO)	451
CareFirst - Group Hospitalization and Medical Services Inc. (Non HMO) (BC/BS Plan #080/580) Federal Employee Program	50
CareFirst - RPN NETWORK (PPO/INDEMNITY)	7
CareFirst (e.g. Blue Choice)	724
CareFirst (i.e., Blue Choice)	134
CareFirst Blue Choice	227
CareFirst CareFirst of Maryland, Inc. (BC/BS Plan #190/690)	47
CareFirst CareFirst of Maryland, Inc.(BC/BS Plan #190/690)	2
CareFirst RPN Network (Pro/Indemnity)	1025
Carefirst-Carefirst of Maryland, Inc. (BC/BS Plan #190/690)	161
Carefirst-CMFI (Maryland)(PPO, POS, BLUE PREF., FEP)	23
Carefirst-GHMSI (DC)(PPO, POS, BLUE PREF., FEP)	47
Carefirst-Group Hospitalization and Medical Services Inc. (NONHMO)(BC/BSPLAN #080/580)(Federal First Employee Progra	174
CCN/First Health	1
Cigna	143
Cigna Healthcare of Mid-Atlantic	237
Cigna HealthSpring (Bravo)	1
Coventry Health Plan of Delaware	154
Coventry Health Plan of Delaware (Diamond Plan)	14
ElderHealth (thru 06/2015)	5
Employer Health Plan (EHP)	398
Great West One Plan	22
InforMed	2
Invalid	1
JAI Medical Group	25

REPORT OF THE UNIVERSITY OF MARYLAND WORKGROUP
TO STUDY ISSUES RELATED TO UTERINE FIBROIDS

JUNE 30, 2016

JAI Medical Systems	8
Kaiser Permanente	43
MAMSI	157
MAMSI (i.e., Alliance PPO and MAMSI Life and Health)	18
Maryland Physicians Care	177
Maryland Physicians Care (Maryland)	1
MD Health Insurance Plan (MHIP) EPO	1
MD Health Insurance Plan (MHIP) PPO	3
MedStar Family Choice, Inc.	1
MedStar Family Choice, Inc.	9
National Capital PPO (NCPPO)	27
Not applicable	1388
Other Commercial, PPO, PPN, TPA	861
Other HMO/POS	106
Other Medicaid MCO/HMO	15
Other Medicare HMO	10
Other miscellaneous government programs	22
Priority Partners	368
Priority Partners (Maryland)	3
Private Health Care Systems	2
Private Health Care Systems (PHCS)	8
Riverside Health	5
Tricare - examples: Health Net	12
Tricare (i.e.: Health Net)	122
Uniformed Services Family Health Plan (USFHP)	138
United Healthcare	286
United Healthcare (Americhoice)	41
United Healthcare (Community Plan)	1
United HealthCare (e.g. One Net PPO, MAMSI Life & Health, Optum)	317
United Healthcare (Evercare)	2
United Healthcare (Evercare) (thru 06/2015)	1
United Healthcare (Evergreen)	2
UNITED HEALTHCARE (I.E., ONE NET PPO, MAMSI LIFE AND HEALTH, OPTUM)	2
UnitedHealthcare	2
UnitedHealthcare Community Plan	144
Value Options	3
Total	9587

(2) the types of treatments and procedures used to treat uterine fibroids; (4) alternative, innovative, and less invasive treatments and procedures that are available to treat uterine fibroids

Management of symptomatic uterine fibroids (SUF) can be broadly divided into 3 categories: medical management, conservative management, and surgical intervention.

MEDICAL MANAGEMENT

Several options exist in the armament of medical management: hormonal preparations (both progestin-only and combined estrogen-progestin forms), gonadotropin-releasing hormone antagonists and agonists, aromatase inhibitors, progestin-releasing intrauterine devices, and selective progesterone receptor modulators.

Although combined estrogen-progestin preparations are controversial in the management of the symptomatic fibroids, their wide availability and relative safety profile, as well as some data demonstrating the reduction in menstrual bleeding associated with fibroids, have made them an option used in clinical management of SUF (4).

Progestin- only preparations, such as injectable medroxyprogesteron acetate (MPA, Depo-Provera™), implants (Nexplanon™), and progestin-only oral pills have been used extensively in the treatment of SUF, although their pharmacological effect is unclear, due to the fact the progestins act as stimulating factors for leiomyoma. Yet their beneficial effect on the endometrium have made them a choice in management of SUF-associated bleeding (5). The same arguments and observations have been made regarding the use of the levonorgestrel-releasing intrauterine device (LNG-IUD) in the management of abnormal uterine bleeding with leiomyoma (AUB-L) (6).

Gonadotropin-releasing hormone (GnRH) antagonists and agonists have been used extensively and with good results in the treatment of SUF, both for control of abnormal uterine bleeding, as well as for the control of bulk symptoms and reduction of pressure symptoms related to fibroids (7). Both types of medications cause long-term suppression of pituitary hormone production and subsequent decrease in estrogen and progestin production by the ovaries, thus reducing the size of fibroids and all effects associated with them, such as bleeding. Although highly effective in their action, these medications have multiple side effects, including medically-induced menopause with all the symptoms of the menopausal state, osteopenia and osteoporosis, and severe arthralgia to name a few. Usually, GnRH agonist/antagonists are administered with add-back therapy to blunt the anti-estrogenic effect and reduce postmenopausal symptoms. Available in three different forms – injections, implants and intranasal spray—they are FDA-approved for pre-surgical treatment of leiomyomas rather than long-term maintenance therapy.

Selective progestin receptor modulators (PRM) represent a novel approach in the management of SUF. Ulipristal Acetate has been approved in Europe and Japan (not approved in the US for

this purpose) and has been shown to be an extremely effective treatment with minimal side effects and long-acting therapeutic benefits (8). Several studies demonstrated superior reduction in bleeding and size of fibroids compared to placebo, and even quicker reduction in bleeding than leuprolide acetate (GnRH agonist). Concerns for premalignant endometrial hyperplasia with the use of PRMs have not been validated so far and it appears that PRMs are safe to use.

Aromatase inhibitors (AI) that have been extensively used in the treatment of hormonally-dependent breast cancers have been shown to be effective in the treatment of SUF (9). These agents have better tolerability profile than GnRH agonist/antagonist preparations and primarily act locally to block the production of estrogens in the peripheral tissue. However, the most recent Cochrane review could not demonstrate enough evidence to unequivocally suggest the use of AI for the treatment of uterine fibroids (10), despite good results demonstrated in studies.

CONSERVATIVE MANAGEMENT

Conservative management comprises uterine fibroid artery embolization (UFAE), magnetic resonance guided focus ultrasound (MRgFUS), and transcervical ultrasound-guided radiofrequency ablation (SONATA™, in clinical trial currently). What distinguishes all these procedures is the outpatient nature of the intervention with minimal post-procedural recovery time.

Uterine fibroid artery embolization (UFAE) is an outpatient procedure usually performed by interventional radiologists. It consists of injection of synthetic particles into the arteries supplying the fibroids and is done under fluoroscopic guidance and moderate sedation. Studies have demonstrated a reduction in fibroid volume by 40% after UFAE, much less postoperative pain, and shorter recovery than conventional open surgical procedures (11). The disadvantages include the need for post-operative pain control, need for an overnight stay, and relatively high re-intervention rate of 20-30% in 5 years. Although successful pregnancies have been reported after UFAE, the current recommendations for women are not to become pregnant after the procedure due to risks of abnormally-developing pregnancy (12).

Magnetic resonance-guided focused ultrasound (MRgFUS) is another non-invasive procedure directed toward treatment of fibroid-associated conditions, such as bleeding and bulk/pressure symptoms. It utilizes focused beam ultrasound under direct MRI guidance to destroy fibroid tumors by thermal energy. There are certain limitations of the procedure, including inability to treat submucosal fibroids, calcified fibroids, and where visualization is obscured by surrounding structures (bladder, bowel). It can be used to treat fibroids of various sizes. Studies have demonstrated reduction in fibroid volume by 40% following treatment at up to 36 months (13, 14). As with UFAE, this procedure is only recommended for premenopausal women who have finished childbearing – pregnancies have been reported after MRgFUS, but the long-term follow up is uncertain.

Transcervical ultrasound-guided radiofrequency ablation (SONATA™) is an investigational device in the clinical trial stage that utilizes radiofrequency to destroy fibroids within the wall of the uterus that are causing heavy abnormal bleeding (AUB-L). The procedure is usually completed in under one hour, does not require general anesthesia or cutting, and the patient is home within two hours. It is not yet available to the general public in the US, but rather in specialized centers participating in the trial (including the University of Maryland Medical Center).

SURGICAL MANAGEMENT

Surgical management of SUF comprises of endometrial ablation, hysteroscopic myomectomy, laparoscopic myolysis, open abdominal myomectomy, laparoscopic myomectomy and laparoscopically-assisted myomectomy, and ultimately hysterectomy (vaginal, laparoscopic, and abdominal hysterectomy).

Endometrial ablation falls somewhere between conservative outpatient procedure and operating room procedure. Utilized exclusively to treat abnormal uterine bleeding, possibly related to fibroids, it uses either direct thermal energy, microwave energy, cryotechnology or radiofrequency to cause the destruction of the endometrium, thus leading to reduction of bleeding. Studies have demonstrated reduction of bleeding in women who underwent selected procedures with fibroids less than 3 cm (15, 16).

Hysteroscopic myomectomy involves surgical resection of submucous fibroids—those confined to and accessible via the endometrial cavity. For fibroids distorting the endometrial cavity, removal of these fibroids may achieve resolution of bleeding symptoms. The benefits of hysteroscopic myomectomy are that the procedure is nearly always an outpatient surgery, preserves the option for future childbearing, and can be performed without the need for any abdominal incision. Surgical risks of the procedure include electrolyte imbalances if there is excessive absorption of hysteroscopic distension medium (more common in prolonged procedures), uterine perforation (particularly if the fibroid extends from the endometrial cavity beyond half the thickness of the uterine wall), and the possible need for repeat procedures if the fibroid(s) cannot be removed safely in one event.

Laparoscopic myolysis is a surgical laparoscopic minimally invasive procedure that uses different types of energy or cryotechnology to destroy fibroids under laparoscopic and ultrasound guidance. Multiple devices have been FDA-approved in this US – the procedure is easier to perform than laparoscopic myomectomy and has good results. The disadvantages include need for general anesthesia and risks associated with surgery, such as bleeding, infection, and damage to major pelvic and abdominal organs. Reduction in sizes of myoma by 50% have been reported with good patient satisfaction related to abnormal uterine bleeding (17, 18).

Laparoscopic myomectomy is a fertility-sparing surgery that has been under fire in recent years due to media-fueled concerns over the risks of leiomyosarcoma (LMS). Performed to remove the fibroids in women desiring to preserve the option of future childbearing, it utilizes a variety of laparoscopic instruments and small abdominal incisions to surgically excise fibroids and reconstruct the uterus, thereby seeking to alleviate the symptoms related to fibroids. It is the most difficult and challenging laparoscopic surgery, requiring high levels of skill in laparoscopic suturing and manipulation. With the FDA- issued warning (erroneously and prematurely) that the risk of LMS could be as high as 1 in 350 fibroids, the procedure became the topic of hot debate, and has been banned by many institutions. Industry and national societies have responded with developing new standards and devices (containment bags) for morcellation protocols, yet the significance of all this is unclear. Most recent studies point to the incidence of LMS to be somewhere between 1 in 1,000 to 1 in 2,500 (19).

Open myomectomy is a procedure reserved for women in whom the laparoscopic approach is not technically possible, due to the size or the position of fibroids, or other surgically related conditions. Major disadvantages include larger abdominal incision, longer post-operative recovery (usually several weeks to months), increased post-operative pain, and often the need for blood transfusion.

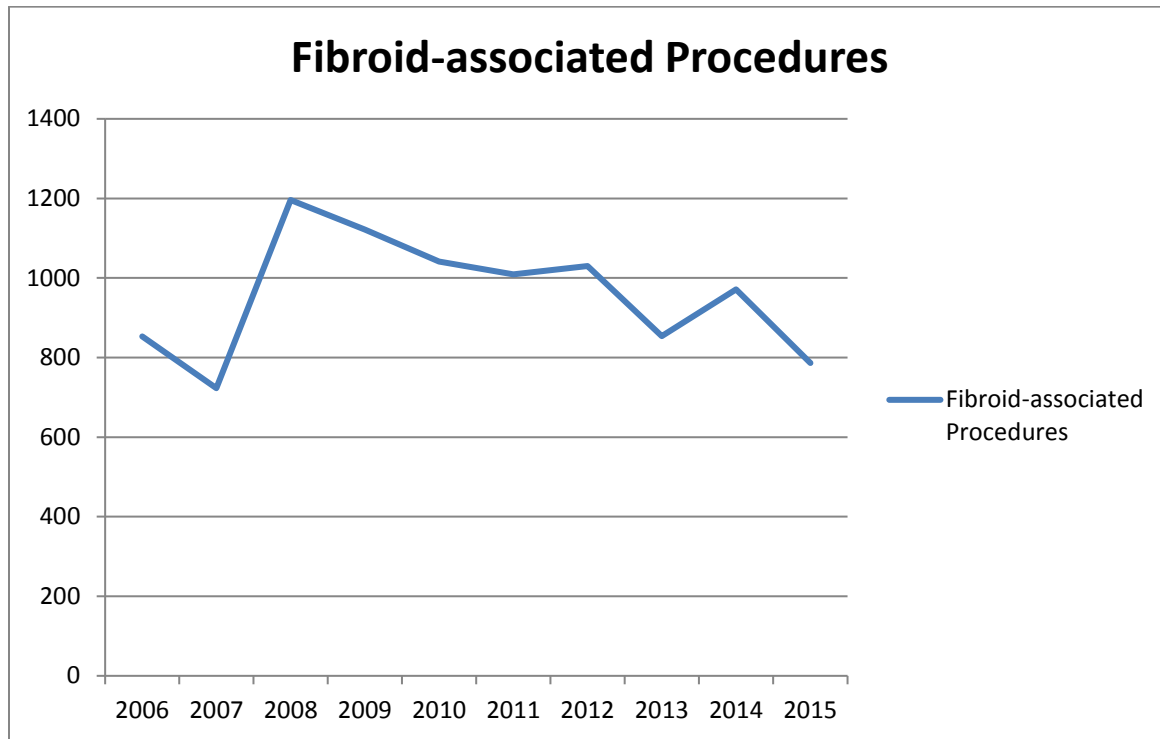
Hysterectomy (all routes) is the ultimate and most aggressive management of SUF, with laparoscopic and vaginal hysterectomy being procedures of choice over open hysterectomy. The discussion of hysterectomy is outside the scope of this discussion.

(3) data on the number of women in the State who undergo a hysterectomy (surgical removal of the uterus), myomectomy (surgery to remove a fibroid without removing the uterus), or other type of treatment for uterine fibroids each year

Among all women undergoing fibroid-related procedures in this data set, there was variability of numbers of procedures performed per year over the ten-year period surveyed, as well as inconsistency in the precision of documentation of types of procedures performed. In general, fibroid-related procedures have shown a steady decline since 2008. This may reflect a limitation of data capture, a move toward procedures being performed in free-standing surgi-centers, or a true trend in utilization of more outpatient and office-based therapies.

Academic Year	count
2006	853
2007	723
2008	1196
2009	1122
2010	1041
2011	1009

2012	1030
2013	854
2014	971
2015	786
Total	9585

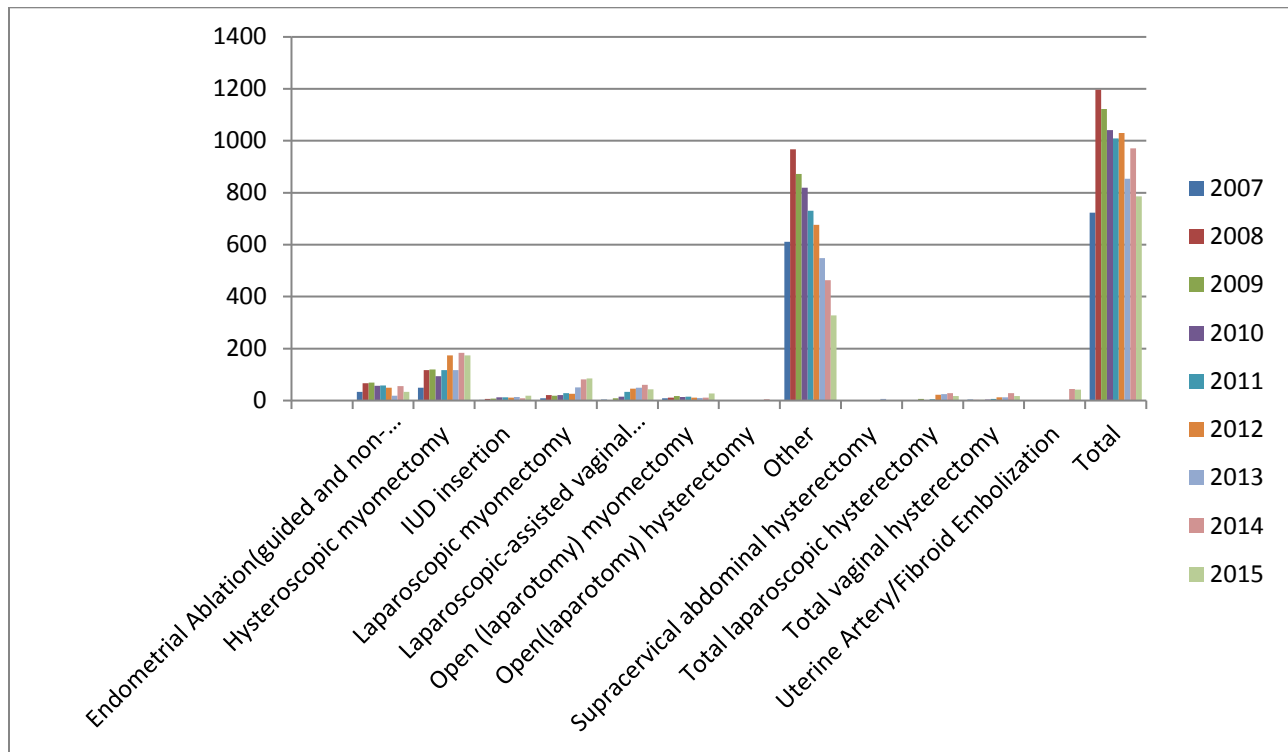


Procedure Category	2007	2008	2009	2010	2011	2012	2013	2014	2015
Endometrial Ablation(guided and non-guided)	33	67	69	57	58	50	19	55	33
Hysteroscopic myomectomy	49	117	120	94	117	174	117	184	174
IUD insertion	3	6	7	12	13	11	14	9	19
Laparoscopic myomectomy	9	21	19	21	28	26	51	82	85
Laparoscopic-assisted vaginal hysterectomy	4	2	9	15	33	46	49	60	43
Open (laparotomy) myomectomy	9	11	17	14	15	11	10	11	27
Open(laparotomy) hysterectomy				2	2	1	1	5	1
Other	611	967	872	820	731	677	549	464	328
Supracervical abdominal hysterectomy					1		6		

REPORT OF THE UNIVERSITY OF MARYLAND WORKGROUP
TO STUDY ISSUES RELATED TO UTERINE FIBROIDS

JUNE 30, 2016

Total laparoscopic hysterectomy	1	2	6	2	5	22	25	28	17
Total vaginal hysterectomy	4	3	3	4	6	12	13	29	17
Uterine Artery/Fibroid Embolization								44	42
Total	723	1196	1122	1041	1009	1030	854	971	786

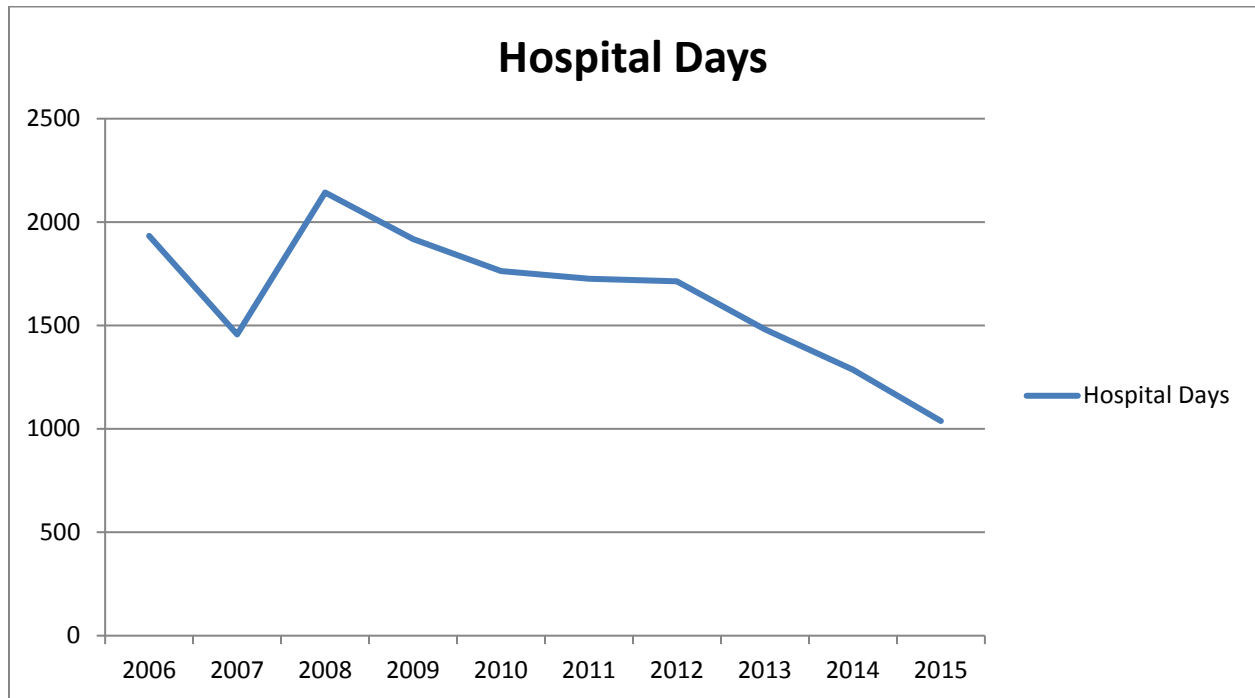


“Other” is listed as the greatest number of type of procedure performed each year, as linked to a diagnosis of fibroids. This reflects a limitation of the data source and variability in categorization, where “other” includes events where there was a procedure done for a diagnosis of fibroids, but did not have any of these identified typical fibroid-related procedures attached, or may have had no procedure code listed at all. Typically, “open (laparotomy) hysterectomy” would be anticipated to have significantly higher numbers than are represented here.

(5) whether there is a need for more research to study the cause and treatment of uterine fibroids

Review of hospital days associated with fibroid-related diagnoses suggests that there continues to be a significant impact on the women of the State.

Academic Year	Hospital Days
2006	1933
2007	1456
2008	2143
2009	1918
2010	1763
2011	1726
2012	1714
2013	1482
2014	1287
2015	1038
Total	16460



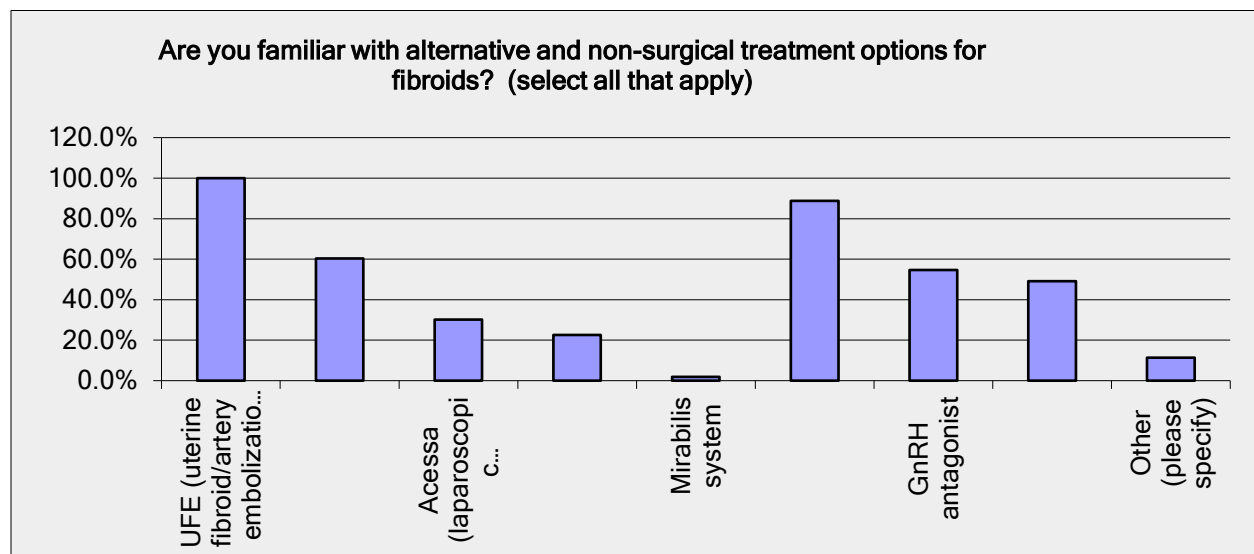
The decrease in annual hospital days related to fibroid-related diagnoses may reflect the increased move toward less invasive approaches to treatment, including shorter-stay laparoscopic or out-patient hysteroscopic procedures. Nevertheless, the total number of hospital days impacting women of the State are still significant from the standpoint of lost days at work (wages), family impact, and effect on quality of life. This report is limited by lack of procedure data from free-standing surgi-centers and office-based procedures. A true understanding of the impact of fibroid pathology on women is hampered by lack of national

and state-specific data. Progress in evaluation, management, and treatment need continued research to identify effective therapies.

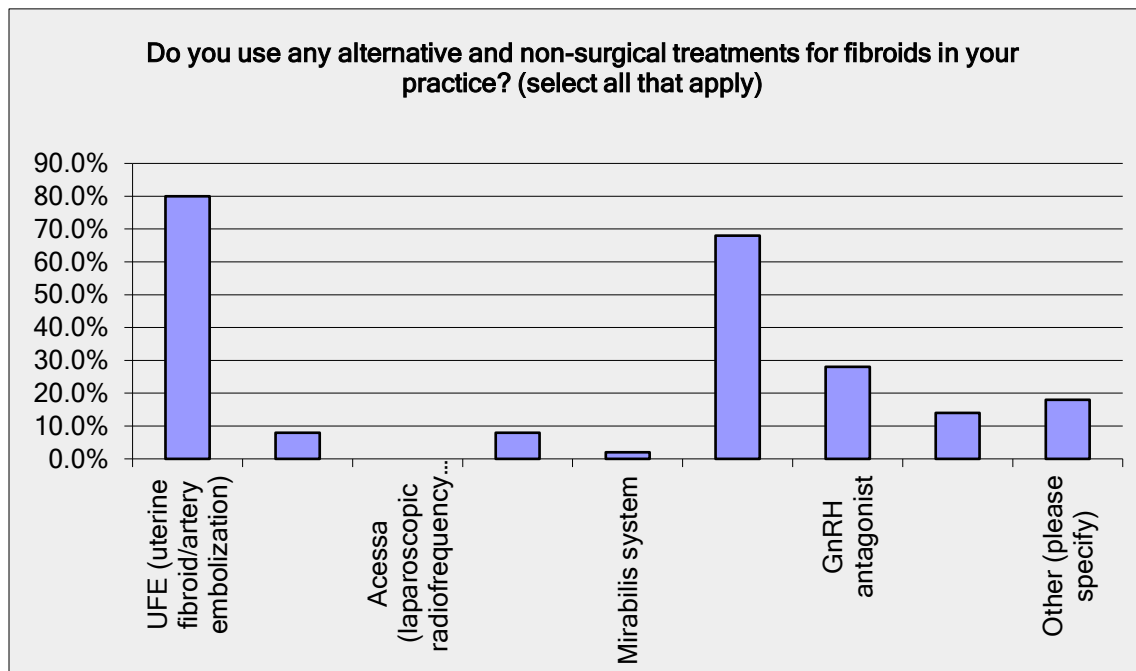
6) whether licensed physicians in the State are willing and able to perform less invasive procedures to treat uterine fibroids

A survey of 626 obstetrician-gynecologists (OBGyn) members of ACOG (American College of Obstetricians and Gynecologists) Maryland Section (53 respondents, 8.5% response rate) indicate awareness of new less-invasive alternative therapies, as well as interest in being able to offer these therapies to patients:

Are you familiar with alternative and non-surgical treatment options for fibroids? (select all that apply)		
Answer Options	Response Percent	Response Count
UFE (uterine fibroid/artery embolization)	100.0%	53
High-intensity focused ultrasound	60.4%	32
Acessa (laparoscopic radiofrequency ablation)	30.2%	16
Sonata (transcervical radiofrequency ablation)	22.6%	12
Mirabilis system	1.9%	1
GnRH agonist	88.7%	47
GnRH antagonist	54.7%	29
Aromatase inhibitor	49.1%	26
Other (please specify)	11.3%	6
answered question		53
skipped question		0

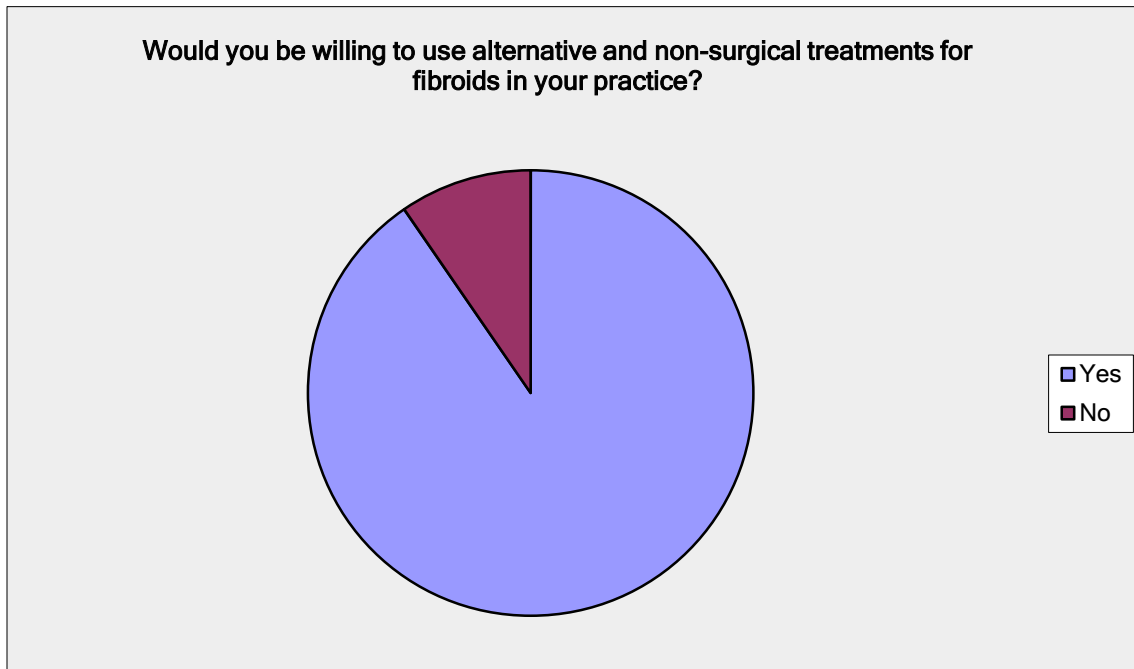


Do you use any alternative and non-surgical treatments for fibroids in your practice? (select all that apply)		
Answer Options	Response Percent	Response Count
UFE (uterine fibroid/artery embolization)	80.0%	40
High-intensity focused ultrasound	8.0%	4
Acessa (laparoscopic radiofrequency ablation)	0.0%	0
Sonata (transcervical radiofrequency ablation)	8.0%	4
Mirabilis system	2.0%	1
GnRH agonist	68.0%	34
GnRH antagonist	28.0%	14
Aromatase inhibitor	14.0%	7
Other (please specify)	18.0%	9
<i>answered question</i>		50
<i>skipped question</i>		3



Would you be willing to use alternative and non-surgical treatments for fibroids in your practice?		
Answer Options	Response Percent	Response Count

Yes	90.4%	47
No	9.6%	5
Comments		6
<i>answered question</i>		52
<i>skipped question</i>		1



OBGyns of the state are not the only physician group who evaluate, treat, and manage patients with fibroids and fibroid-related issues. Further query of those in other specialties such as Internal Medicine, Family Medicine, and Radiology is necessary.

CONCLUSION

The impact of fibroids and fibroid-related disease extends to women of all races and ethnicities of the State, and has greatest influence among women in their most productive decades of life (30-60 years of age). Treatment has historically been invasive and surgical. Recently, there have been many innovative and less invasive options available to physicians and their patients. It is worthy of note that there has been a steady decrease in fibroid-related procedures since 2008, as evidenced by the data gathered here. This further substantiates interest on the part of physicians to offer and provide less invasive therapies. Some limitations of this report include the use of financial rather than clinical data, as well as the willingness of only two medical systems to participate, thus restricting the ability to generalize trends and provide insight into more detailed influences of fibroids on the rural versus urban population, variations based on

race and ethnicity, access to treatment and care, and current locations and venues of therapy. A review of the annual breakdown of procedures for treatment during the ten years studied shows inconsistency in documentation, and consequently unreliable capture of specific modes of management (abdominal hysterectomies are very likely represented in the large number of “other” procedures). Furthermore, the ability to track the outpatient therapies and treatments which may have been provided is limited by the available database. More study is needed, and a more complete data set with broader State-wide representation is recommended.

ACKNOWLEDGEMENTS

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REFERENCES

1. Fraser IS, Critchley HO, Munro MG, Broder M. A process designed to lead to international agreement on terminologies and definitions used to describe abnormalities of menstrual bleeding. Writing Group for this Menstrual Agreement Process. *Fertil Steril* 2007;87:466–76.
2. Day Baird D, 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;188:100–7.
3. ACOG Practice Bulletin Number 96: Alternatives to Hysterectomy in the Management of Leiomyomas, August 2008 [reaffirmed 2014].
4. Marshall LM, Spiegelman D, Goldman MB, Manson JE, Colditz GA, Barbieri RL, Stampfer MJ, Hunter DJ. A prospective study of reproductive factors and oral contraceptive use in relation to the risk of uterine leiomyomata. *Fertil Steril*. 1998;70(3):432.
5. Venkatachalam S, Bagratee JS, Moodley J. Medical management of uterine fibroids with medroxyprogesterone acetate (Depo Provera): a pilot study. *J Obstet Gynaecol*. 2004;24(7):798.
6. Grigorieva V, Chen-Mok M, Tarasova M, Mikhailov A. Use of a levonorgestrel-releasing intrauterine system to treat bleeding related to uterine leiomyomas. *Fertil Steril*. 2003;79(5):1194.
7. Carr BR, Marshburn PB, Weatherall PT, Bradshaw KD, Breslau NA, Byrd W, Roark M, Steinkampf MP. An evaluation of the effect of gonadotropin-releasing hormone analogs and medroxyprogesterone acetate on uterine leiomyomata volume by magnetic

- resonance imaging: a prospective, randomized, double blind, placebo-controlled, crossover trial. *J Clin Endocrinol Metab.* 1993;76(5):1217.
8. Donnez J, Vazquez F, Tomaszewski J, Nouri K, Bouchard P, Fauser B, Barlow DH, et al, for the PEARL III and PEARL III Extension Study Group. Long-term treatment of uterine fibroids with ulipristal acetate. *Fertil Steril*, 101(6);2014:1565.
 9. Parsanezhad ME, Azmoon M, Alborzi S, Rajaeefard A, Zarei A, Kazerooni T, Frank V, Schmidt EH. A randomized, controlled clinical trial comparing the effects of aromatase inhibitor (letrozole) and gonadotropin-releasing hormone agonist (triptorelin) on uterine leiomyoma volume and hormonal status. *Fertil Steril.* 2010 Jan;93(1):192-8
 10. Song H, Lu D, Navaratnam K, Shi G. Aromatase inhibitors for uterine fibroids. *Cochrane Database Syst Rev.* 2013 Oct 23;(10).
 11. Spies JB. Current Role of Uterine Artery Embolization in the Management of Uterine Fibroids. *Clin Obstet Gynecol.* 2016 Mar;59(1):93-102
 12. Torre A, Paillusson B, Fain V, Labauge P, Pelage JP, Fauconnier A Uterine artery embolization for severe symptomatic fibroids: effects on fertility and symptoms. *Hum Reprod.* 2014 Mar;29(3):490-501.
 13. Funaki K, Fukunishi H, Sawada K. Clinical outcomes of magnetic resonance-guided focused ultrasound surgery for uterine myomas: 24-month follow-up. *Ultrasound Obstet Gynecol.* 2009;34(5):584.
 14. Kim HS, Baik JH, Pham LD, Jacobs MA. MR-guided high-intensity focused ultrasound treatment for symptomatic uterine leiomyomata: long-term outcomes. *Acad Radiol.* 2011 Aug;18(8):970-6.
 15. Sabbah R, Desaulniers G. Use of the NovaSure Impedance Controlled Endometrial Ablation System in patients with intracavitary disease: 12-month follow-up results of a prospective, single-arm clinical study. *J Minim Invasive Gynecol.* 2006;13(5):467
 16. Soysal ME, Soysal SK, Vicdan K. Thermal balloon ablation in myoma-induced menorrhagia under local anesthesia. *Gynecol Obstet Invest.* 2001;51(2):128
 17. Zupi E, Marconi D, Sbracia M, Exacoustos C, Piredda A, Sorrenti G, Townsend D. Directed laparoscopic cryomyolysis for symptomatic leiomyomata: one-year follow up. *J Minim Invasive Gynecol.* 2005;12(4):343.
 18. Nisolle M, Smets M, Malvaux V, Anaf V, Donnez J. Laparoscopic myolysis with the Nd:YAG laser. *J Gynecol Surg.* 1993;9(2):95.
 19. Pritts E, Vanness, D, Berek J, Parker W, Feinberg R, Feinberg J, Olive D. The prevalence of occult leiomyosarcoma at surgery for presumed uterine fibroids: a meta-analysis. *Gynecol Surg.* 2015; 12(3)165