

Table. Comparison of uterine length  $\geq 4.5$  cm and uterine length  $< 4.5$  cm among six groups

Variable	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	Total	p value
Uterine length $\geq 4.5$ cm	4 (19.0%)	9 (26.5%)	5 (83.3%)	2 (28.6%)	1 (9.1%)	9 (8.6%)	27 (18.1%)	-
Uterine length $< 4.5$ cm	17 (81.0%)	25 (73.5%)	1 (16.7%)	5 (71.4%)	10 (90.9%)	64 (91.4%)	122 (81.9%)	-
Total	21	34	6	7	11	70	149	.001

Ordinal logistic regression analysis of factors related to reproductive outcomes among six groups

Group	Odds Ratio	Std.err	Sig.	95% CI lower bound	95% CI upper bound
Uterine length	8.035	4.020	0.000	3.014	21.424
Uterine cavity length	0.321	0.129	0.005	0.146	0.707
Endometrial thickness	0.789	0.437	0.669	0.267	2.334
Uterine wall thickness	0.297	0.206	0.081	0.076	1.160
Cervical length	1.042	0.310	0.889	0.583	1.865

Comparison of uterine size measured by pelvic MR between six groups

Variable	Group 1	Group 2	Group 3	Group 4	Group 5	Group 6	p value
Uterine length	4.85 (0.48)	4.78 (0.64)	4.21 (0.48)	4.60 (0.45)	4.89 (0.41)	5.08 (0.49)	.001
Uterine cavity length	3.95 (0.54)	3.65 (0.72)	3.27 (0.35)	3.86 (0.63)	3.85 (0.62)	3.81 (0.58)	.17
Cervical length	3.08 (0.56)	3.02 (0.530)	3.52 (0.97)	2.86 (0.38)	2.85 (0.27)	3.15 (0.53)	.122
Uterine wall thickness	1.33 (0.21)	1.33 (0.26)	1.28 (0.25)	1.35 (0.32)	1.39 (0.39)	1.30 (0.25)	.917
Uterine volume	73.54 (23.74)	68.06 (28.32)	55.71 (25.00)	42.44 (23.70)	64.33 (19.50)	78.71 (27.94)	.122
Uterine cavity volume	6.11 (2.96)	4.61 (3.79)	4.34 (3.07)	4.25 (3.72)	4.10 (2.56)	5.80 (3.82)	.318
The ratio of uterine length and uterine cavity length	1.23 (0.12)	1.34 (0.16)	1.45 (0.15)	1.28 (0.11)	1.34 (0.15)	1.26 (0.15)	.022
The ratio of uterine length and cervical length	1.61 (0.31)	1.62 (0.28)	1.28 (0.37)	1.62 (0.15)	1.73 (0.18)	1.65 (0.27)	.047
Endometrial thickness	1.07 (0.25)	0.89 (0.36)	0.92 (0.33)	0.80 (0.39)	0.85 (0.35)	1.05 (0.36)	.075

occurred in 22 patients (13.2%). 9 patients had Intrauterine Fetal Death (IUFD) and 98 patients had live birth, of which abnormal fetal position at delivery occurred in 37 patients (37/98, 37.6%). Preterm delivery, premature rupture of membrane, Preterm premature rupture of membrane, intrauterine growth restriction (IUGR) and caesarean section delivery rates were 22.4%, 12.2%, 9.2%, 10.2%, 72.4%, respectively. There were no significant differences in the uterine cavity length, cervical length, endometrial thickness and uterine wall thickness between the six groups while the uterine length ( $p = .001$ ), the ratio of uterine length and uterine cavity length ( $p = .022$ ), the ratio of uterine length and cervical length ( $p = .047$ ) was statistically significant respectively. Women with uterine lengths  $\geq 4.5$  cm were more likely to experience full-term delivery compared with the other group ( $p < .000$ ). The odds ratios for uterine length and uterine cavity length were 8.035 (95% CI: 3.014–21.424) and 0.321 (95% CI 0.146–0.707), respectively, according to ordinal logistic regression analysis (Figure).

**Conclusions:** The uterine length is a reliable prognostic factor to the gestational weeks of delivery and an appropriate antenatal surveillance factor of woman with unicornuate uterus.

WEDNESDAY, NOVEMBER 14, 2018

## 166 Open Communications 14 - Pelvic Pain (2:15 PM – 3:15 PM)

### 2:15 PM – GROUP A

#### Efficacy and Safety of Elagolix in a Subgroup of Women with Uterine Fibroids and Adenomyosis:

##### Results from a Phase 2 Trial

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**Objective:** Elagolix, an oral, gonadotropin-releasing hormone receptor antagonist, reduces dysmenorrhea in women with endometriosis and heavy menstrual bleeding (HMB) in women with uterine fibroids (UF). We evaluated the efficacy and safety of elagolix in a subgroup of women with both UF and adenomyosis.

**Design:** 6-month, randomized, double-blind, placebo-controlled, phase 2b trial.

**Settings:** Outpatient in clinic/office.

**Patients:** Premenopausal women with HMB ( $\geq 80$  mL menstrual blood loss [MBL]/cycle) with confirmed UF.

**Interventions:** Elagolix 300 mg twice daily [BID] in Cohort 1 and elagolix 600 mg once daily [QD] in Cohort 2. Each cohort had 4 arms: placebo, elagolix alone, and 2 elagolix with hormonal add-back arms (0.5 mg estradiol [E2]/0.1 mg norethindrone acetate [NETA] and 1.0 mg E2/0.5 mg NETA).

**Measurements/Results:** Patients were evaluated with ultrasound and a subset were also evaluated by MRI (both read centrally). Women were to be excluded if they had evidence of diffuse or segmental adenomyosis as a dominant condition ( $>50\%$  of the myometrium via ultrasound/MRI). Efficacy and safety were evaluated in a post hoc defined subgroup of women who had confirmed adenomyosis (ultrasound/MRI) at baseline (BL). The primary endpoint was the proportion of women who had a  $\geq 50\%$  reduction from BL in menstrual blood loss (MBL) and  $<80$  mL MBL in the last 28 days of treatment (quantified using alkaline hematin method). Of the 567 women treated, 86 (Cohort 1 = 32; Cohort 2 = 54) had confirmed adenomyosis at BL; the

Table. Efficacy &amp; Safety Results in a Subgroup of Women with both Uterine Fibroids &amp; Adenomyosis

	Cohort 1 N=32				Cohort 2 N=54			
	Placebo	Elagolix 300mg BID	Elagolix 300mg BID + 0.5mg E2/0.1mg NETA	Elagolix 300mg BID + 1.0mg E2/0.5mg NETA	Placebo	Elagolix 600mg QD	Elagolix 600mg QD + 0.5mg E2/0.1mg NETA	Elagolix 600mg QD + 1.0mg E2/0.5mg NETA
n/N (%) of women who met the primary endpoint*	4/10 (40%)	4/5 (80%)	10/12 (83%)	5/5 (100%)	2/16 (13%)	12/13 (92%)	13/14 (93%)	8/9 (89%)
n/N (%) of women who experienced $\geq 1$ adverse event	9/10 (90%)	5/5 (100%)	7/12 (58%)	5/5 (100%)	14/16 (88%)	10/14 (71%)	9/15 (60%)	6/9 (67%)

\* % of women who had a  $\geq 50\%$  reduction from baseline in menstrual blood loss and  $<80$  mL menstrual blood loss in the last 28 days of treatment  
BID = twice daily, QD = once daily, E2 = estradiol, NETA = norethindrone acetate

majority (87%) of these women had a BL BMI  $\geq 25$  kg/m<sup>2</sup>. The proportion of women who met the primary endpoint and the proportion of women in each treatment group who reported at least 1 adverse event are presented in Table.

**Conclusions:** A higher proportion of elagolix-treated (with or without add-back) women who had UF with HMB and adenomyosis at BL had a reduction in MBL compared to placebo, suggesting that further studies evaluating elagolix treatment in women with adenomyosis are warranted.

## 167 Open Communications 14 - Pelvic Pain (2:15 PM – 3:15 PM)

### 2:22 PM – GROUP A

#### An Assessment of the Role of Racial Demographics in the Management of Chronic Pelvic Pain

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**Objective:** To determine racial variation in treatment history, treatment willingness, and pain presentation with chronic pelvic pain (CPP).

**Design:** Retrospective cross-sectional study.

**Settings:** Tertiary CPP referral clinic.

**Patients:** Patients with chronic pelvic pain.

**Interventions:** All new CPP patients complete a battery of validated questionnaires prior to initial patient visit. In addition, patients are asked to describe symptoms, past treatments, and willingness to try specific pain treatments. Past treatments included prior surgical interventions, hormonal suppression, neuromodulating medications, physical therapy. Exam findings were abstracted from the chart. The survey results were separated into self-identified African American and Caucasian racial groups for statistical comparison using chi squared tests. Each African American patient was matched (1:2) with Caucasian patients based on age ( $\pm 3$  years) and education level (below bachelor degree or bachelor and above).

**Measurements/Results:** A review of 524 patients identified 46 African American patients with completed questionnaires, who were matched 1:2 with Caucasian patients (n = 92) based on age and education. African American patients reported significantly higher pain severity (6.32 versus 5.31,  $p = .016$ ) and greater pain interference (6.86 versus 5.66,  $p = .033$ ) compared to Caucasian patients. Degree of dysmenorrhea, dyspareunia, dysuria, widespread pain, and myofascial pain on exam did not differ between the groups. There were no significant differences in prior pharmacologic treatments, including hormonal suppression, neuromodulating medications, narcotics, or NSAIDs. Similarly, there were no significant differences in prior non-surgical treatments, including pelvic floor physical therapy, acupuncture, or injections. Both groups had similar rates of prior laparoscopy and hysterectomy for pelvic pain. There were no significant differences between patient willingness to try hormonal suppression, neuromodulating medications, narcotics, nerve blocks, physical therapy, psychiatry and surgery for pelvic pain.

**Conclusions:** African American patients with CPP reported significantly higher pain severity and pain interference than their Caucasian counterparts despite similar utilization of prior treatments and similar interest in future treatment options.

## 168 Open Communications 14 - Pelvic Pain (2:15 PM – 3:15 PM)

### 2:29 PM – GROUP A

#### Superior Gluteal Vein (SGV) Syndrome:

##### An Intrapelvic Cause of Sciatica

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**Objective:** The role of malformed or dilated branches of iliac vessels in causing pelvic pain and sciatica is not well understood. We describe cases of sciatica in which laparoscopy revealed compression of lumbosacral (LS) nerve roots by variant superior gluteal veins (SGVs). In demonstrating an improvement in symptoms after decompression, we identify this neurovascular conflict as a potential intrapelvic cause of sciatica.

**Design:** Retrospective case series, with a mean follow-up duration of  $13.2 \pm 10.6$  months after surgery.

**Settings:** Academic tertiary care hospital.

**Patients:** Thirteen female patients with sciatica were selected for laparoscopic exploration based on clinical neuropelvicological and urodynamic assessment, between 2012 and 2016. All patients previously failed conservative management. Underlying spinal or musculoskeletal lesions were excluded by orthopedic, neurosurgical and radiological evaluation.

**Interventions:** Laparoscopic retroperitoneal dissection identified variant SGV branches, defined as those superior to and therefore compressing LS nerve roots. SGV variants were sealed and transected, thereby detraping the underlying nerves (Figure).

**Measurements/Results:** The primary outcome measure was improvement in symptoms after detrapment, determined by comparison of pre- and post-operative visual analogue scale (VAS) scores. All patients had a variant SGV transected intraoperatively. The average preoperative VAS score was  $9.62 \pm 0.77$ , which decreased significantly to  $2.54 \pm 2.88$  postoperatively ( $p = .000001$ ). The success rate (defined as at least 50% improvement in VAS score) was 92.3%.

**Conclusions:** Our case series demonstrates a high success rate and significant decrease in pain scores after laparoscopic intrapelvic decompression, thereby identifying pelvic nerve entrapment by aberrant SGVs as a potential yet previously unrecognized cause of sciatica. This intrapelvic neurovascular conflict - The SGV Syndrome - should be considered in cases of sciatica with no identifiable spinal or musculoskeletal etiology. Future directions include conducting a cadaver study to determine the prevalence of variants in the general population, and developing and validating diagnostic radiological markers on MRI.

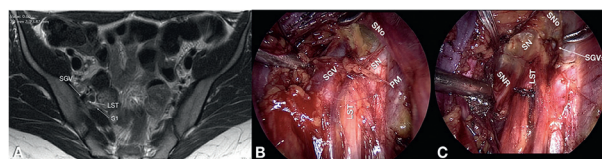


Figure. MRI demonstrating variant SGV (vSGV) compressing the LST (lumbosacral trunk) and S1 nerve root – A. Intraoperative findings before & after decompression; B – Before decompression: Variant SGV compressing LST (lumbosacral trunk) & SN (sciatic nerve); C – After decompression LST, SN and SNR (sciatic nerve roots) visible after vSGV ligation; SNo (sciatic notch); PM (psoas muscle).