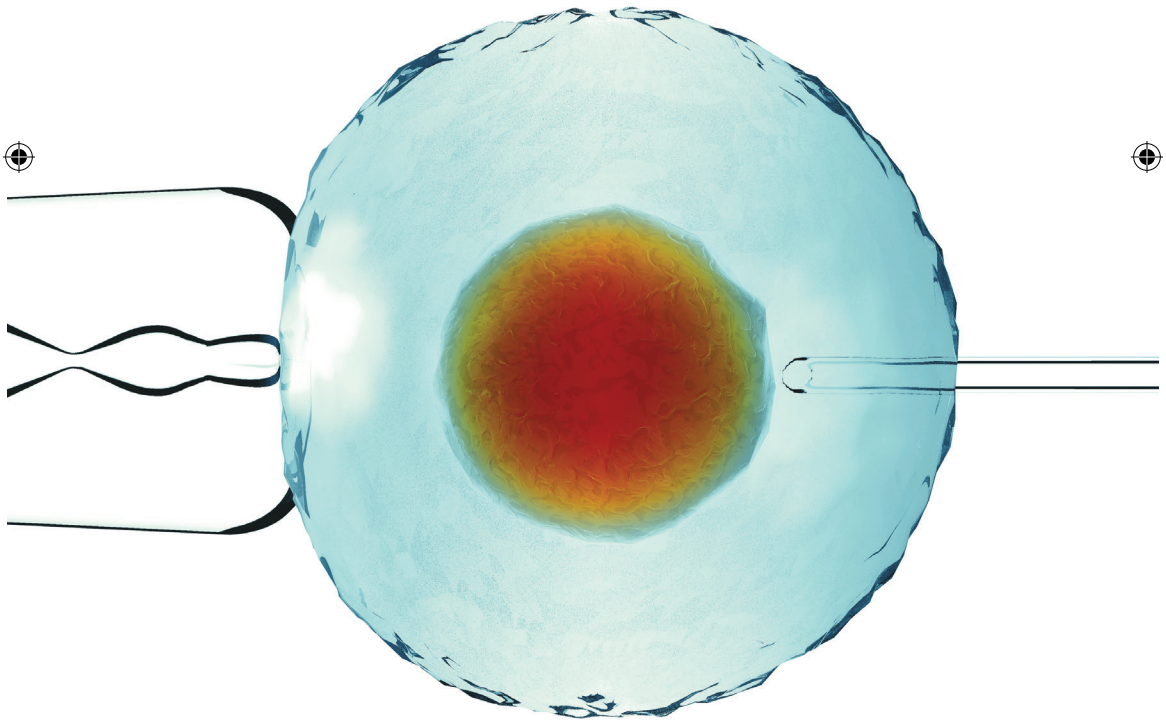
Cleveland Clinic

Obstetrics, Gynecology & Women's Health Institute

7TH ANNUAL

Research Day



May 11, 2022
via Webex

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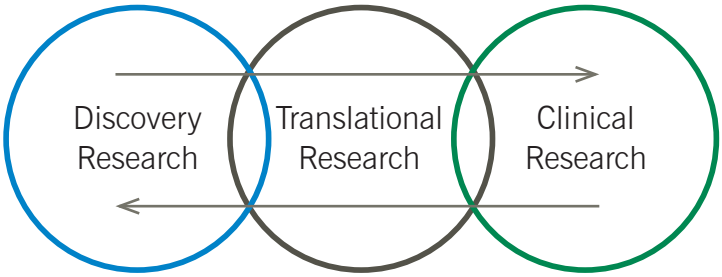


Key Note Address & Lecture

Jeffrey Peipert, MD, MPH, PhD
Clarence E. Ehrlich Professor and Chair
Department of Obstetrics and Gynecology
Indiana University School of Medicine

Judges (Oral Presentations)

Jeffrey Peipert, MD, MPH, PhD
Pelin Batur, MD
Ashley Brant, DO
Miriam Cremer, MD, MPH
Justin Lappen, MD
Elliott Richards, MD
Roberto Vargas, MD

Judges (Poster Presentations)

Jeffrey Peipert, MD, MPH, PhD
Stacey Ehrenberg, MD
Jonathan Emery, MD
Holly Thacker, MD
Miguel Luna Russo, MD

Agenda

7:00 am	**Presenter & Judges Registration**
7:15 am–7:20 am	**Welcome** Tristi Muir, MD Chair, Ob/Gyn & Women's Health Institute
7:20 am–7:25 am	Introduction & Welcome Ruth Farrell, MD, MA Vice Chair, Research, Ob/Gyn & Women's Health Institute
7:25 am–8:10 am	**Key Note Address** ***The Contraceptive CHOICE Project to Path4You: Lessons Learned*** Jeffrey Peipert, MD, MPH, PhD Clarence E. Ehrlich Professor and Chair Department of Obstetrics and Gynecology Indiana University School of Medicine
8:10 am–8:20 am	**Q&A**

8:20–10:30 am	**PGY3 RESIDENT ORAL PRESENTATIONS**
8:20 am	***The Risk of Venous Thromboembolism in Patients With and Without Leiomyomas Undergoing Hysterectomy*** Annika Sinha, MD
8:30 am	Discussant: Cory Messingschlager, MD & Q&A
8:35 am	***Management of Abnormal Urinalysis Results in Urogynecologic Patients Undergoing Preoperative Urodynamic Testing Prior to pelvic Organ Prolapse Surgery*** Rachael Baird, MD
8:45 am	Discussant: Cory Messingschlager, MD & Q&A

8:50 am	***Incidence and Prognostic Significance of Inguinal Lymph Node Metastasis in Women with Newly Diagnosed Epithelial Ovarian Cancer*** Julia Chalif, MD
9:00 am	Discussant: Morgan Gruner, MD & Q&A
9:05 am	***A Retrospective Look at Pre-eclampsia within the Cleveland Clinic Health System: Are There Opportunities for early Diagnosis and Intervention in African-American Women?*** Imani Chatman, MD
9:15 am	Discussant: Kate Lintel, MD & Q&A
9:20 am	***Provider Practice Patterns Pertaining to Malpresentation in Pregnancies Conceived Via Assisted Reproductive Technology*** Catherine Keller, MD
9:30 am	Discussant: Carrie Bennett, MD & Q&A
9:35 am	***Endometrial Abnormalities During Endometrial Maturation for Frozen Embryo Transfer (FET): A Pilot Study*** Kaia Schwartz, MD
9:45 am	Discussant: Molly Morton, MD & Q&A
9:50 am	***An Exploratory Study Comparing the Quality of Contraceptive Counseling Provided Via Telemedicine Versus In-Person Visits*** Rachel Shin, MD
10:00 am	Discussant: Carrie Bennett, MD & Q&A
10:05 am	***Perioperative Adverse Events In Women Undergoing Concurrent Mid-urethral Sling Placement at the Time of Minimally Invasive Benign Gynecologic Surgery*** Nicole Wood, MD
10:15 am	Discussant: Becca Omosigho, MD & Q&A
10:20 am	**Break & PGY 2 Poster Presentations Viewing and Judging Online**

10:40 am–12:45 pm	GRADUATING FELLOWS ORAL PRESENTATION
10:40 am	***Ovarian Senescence: Is There an Explanation for Variability in ovarian Aging?*** Tiffany Cochran, MD Clinical Fellow, Specialized Women's Health
10:50 am	Q&A
10:55 am	***The Symptoms and Timing of Menopause in Women with Polycystic Ovarian Syndrome*** Tara Iyer, MD Clinical Fellow, Specialized Women's Health
11:05 am	Q&A
11:10 am	***The Validation of Novel Methods to Differentiate Radiation Sensitivity in Cervical Cancer Cell Lines Allows for the Development of a Gene Signature Predictive of Radiation Response*** Michelle Kuznicki, MD Fellow, Gynecologic Oncology
11:20 am	Q&A
11:25 am	***Is There an Association Between 6-month Genital Hiatus Size and 24-month Composite Subjective Prolapse Recurrence following Minimally Invasive Sacrocolpopexy?*** Vivana Casas Puig, MD Fellow, Female Pelvic Medicine & Reconstructive Surgery
11:35 am	Q&A
11:40 am	***The Standard versus No Opioid Prescription after Prolapse and Anti-Incontinence Surgery (STOP-PAIN) Trial*** Angela Yuan, MD Fellow, Female Pelvic Medicine & Reconstructive Surgery
11:50 am	Q&A
11:55 am	***Salpingo-Oophorectomy or Surveillance for Ovarian Endometrioma in Asymptomatic Premenopausal Women: A Cost-Effectiveness Analysis*** Megan Orlando, MD Clinical Fellow, Minimally Invasive Gynecologic Surgery

12:05 pm	Q&A
12:10 pm	***Caloric Restriction Increases Ovarian FOXO3A Expression in a Mouse Delayed Aging Model: Implications for Reproductive Longevity*** Natalia Llarena, MD Fellow, Reproductive Endocrinology & Infertility
12:20 pm	Q&A
12:25 pm	***The FLOWER Trial: A Randomized Trial Comparing Perioperative Pelvic Floor Physical Therapy to Current Standard of Care in Transgender Women Undergoing Vaginoplasty For Gender Affirmation*** Frances Grimstad, MD Clinical Fellow, Transgender Medicine & Surgery
12:35 pm	Q&A
12:40–1:05 pm	**Lunch Break & Review posters online**

1:05–2:00 pm	**INNOVATIONS IN OB/GYN & WOMEN'S HEALTH INSTITUTE LECTURE**
1:05 pm	***Ob/Gyn & Women's Health Institute Innovations Lecture Development of Fetal Surgery at Cleveland Clinic: Serendipity, Teamwork and Innovation*** Darrell Cass, MD Director of Fetal Surgery, Director of Fetal Care Center, Cleveland Clinic
1:50 pm	Q&A
2:05 pm	**Announcement of Award Winners & Closing Remarks** Ruth Farrell, MD, MA
2:30 pm	Group picture of all presenters, award winners, speakers & Institute Leadership

2:30–5:00 pm FACULTY DEVELOPMENT/PANEL DISCUSSION RESEARCH TO REDUCE HEALTHCARE DISPARITIES IN WOMEN'S HEALTH

2:30 pm **Panel**

Mariam Cremer, MD, MPH
Cleveland Clinic, Ob/Gyn & Women's Health Institute

Ronald Hickman, RN, PhD
Bolton School of Nursing Case Western Reserve University

Sarah Ronis, MD, MPH
University Hospitals of Cleveland

Kristie Ross, MD
University Hospitals of Cleveland

Darcy Freeman, MPH, PhD
Case Western Reserve University

Jarrod E. Dalton, PhD
Cleveland Clinic, Quantitative Health Sciences

Past Research Day Award Winners

Resident Poster Presentation – 1st Place

2021	Rachel Shin, MD, MPH
2020	Carrie Bennett, MD
2019	Jessica Son, MD
2018	Sarah Hershman, MD
2017	Caitlin Carr, MD
2016	Laura Moulton, DO, MS

Resident Oral Presentation – 1st Place

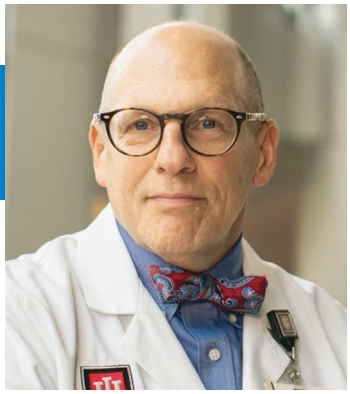
2021	Jonathan Hunt, MD, MBA
2020	Anna Chichura, MD
	Alyssa Herrmann, MD
2019	Emily Holthaus, MD
2018	Caitlin Carr, MD
	Julian Gingold, MD, PhD
2017	Laura Moulton, DO, MS
2016	Jamie Stanhiser, MD
2016	Lisa Caronia Hickman, MD

Fellow Oral Presentation – 1st Place

2021	Laura Chambers, DO, MS
2020	Katie Crean-Tate, MD
2019	Elizabeth Conner, MD
2018	Tonya Nikki Thomas, MD
2017	Kathryn Maurer, MD
2016	Linnea Goodman, MD

Keynote Address & Lecture

Jeffrey Peipert, MD, MPH, PhD



Clarence E. Ehrlich Professor and Chair
Department of Obstetrics and Gynecology
Indiana University School of Medicine

Jeffrey Peipert, MD, MPH, PhD is the Clarence E. Ehrlich Professor and Chair of Obstetrics and Gynecology at Indiana University School of Medicine. He is board-certified in obstetrics and gynecology and has a doctorate in epidemiology. He has conducted numerous studies including: NICHD-funded randomized trial of a computer-based intervention to encourage dual method contraceptive use to prevent unplanned pregnancy and STIs and an NIH-funded randomized trial of therapy for pelvic inflammatory disease (PEACH Study).

Dr. Peipert was also the Principal Investigator of a large prospective study, the Contraceptive CHOICE Project, which recruited 9,256 women and successfully followed them for 2-3 years for contraceptive effectiveness, satisfaction, and continuation rates. Dr. Peipert 's research interests are family planning, STI prevention, women's health and public health.

Judges (Oral Presentations)

Jeffrey Peipert, MD, MPH, PhD
Clarence E. Ehrlich Professor and Chair
Department of Obstetrics and Gynecology
Indiana University School of Medicine

Ashley Brant, DO
Assistant Professor of Surgery
Cleveland Clinic
Obstetrics, Gynecology & Women's
Health Institute
Obstetrics and Gynecology

Pelin Batur, MD
Assistant Professor of Ob/Gyn &
Reproductive Medicine
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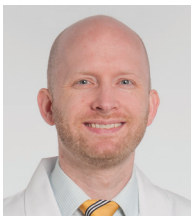
Institute
Subspecialty Care for Women's Health
Specialized Women's Health

Miriam Cremer, MD, MPH
Professor of Ob/Gyn & Reproductive Medicine
Cleveland Clinic
Obstetrics, Gynecology & Women's
Health Institute
Subspecialty Care for Women's Health
Global Health/Family Planning

Justin Lappen, MD
Associate Professor of Ob/Gyn & Reproductive Medicine
Cleveland Clinic
Obstetrics, Gynecology & Women's Health Institute
Subspecialty Care for Women's Health
Section Head, Maternal Fetal Medicine



Elliott Richards, MD
Associate Staff
Cleveland Clinic
Obstetrics, Gynecology & Women's Health Institute
Subspecialty Care for Women's Health
Faculty, Reproductive Endocrinology & Infertility

Roberto Vargas, MD
Clinical Assistant Professor of Ob-Gyn & Reproductive Biology
Cleveland Clinic
Obstetrics, Gynecology & Women's Health Institute
Subspecialty Care for Women's Health
Associate Staff, Gynecologic Oncology

Judges (Poster Presentation)

Jeffrey Peipert, MD, MPH, PhD
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Indiana University School of Medicine

Holly Thacker, MD
Professor of Ob-Gyn & Reproductive Biology
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Health Institute
Subspecialty Care for Women's Health
Section Head, Specialized Women's Health

Stacey Ehrenberg, MD
Staff, Cleveland Clinic
Obstetrics, Gynecology & Women's
Health Institute
Obstetrics and Gynecology

Miguel Luna Russo, MD
Associate Staff, Cleveland Clinic
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Health Institute
Subspecialty Care for Women's Health
Faculty, Minimally Invasive
Gynecologic Surgery

Jonathan Emery, MD
Faculty Council Representative of
Ob-Gyn & Reproductive Biology
Assistant Professor of Ob-Gyn &
Reproductive Biology
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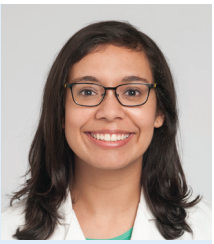
Obstetrics, Gynecology & Women's
Health Institute
Obsetrics & Gynecology
Vice Chair, Obstetrics & Gynecology

Obstetrics, Gynecology & Women's Health Institute

PGY3 Resident Oral Presentations

The Risk of Venous Thromboembolism in Patients With and Without Leiomyomas Undergoing Hysterectomy



Annika Sinha, MD

Objective: Leiomyomas occur in 80% of women and can require hysterectomy for management. The risk for venous thromboembolism (VTE) is 0.7% for any hysterectomy. However, it has been theorized that large uterine size due to fibroids increases VTE risk due to pelvic vasculature compression. The objective of this study is to evaluate if the risk of VTE of women undergoing surgeries for fibroid-related indications is different compared to women undergoing hysterectomy for non-fibroid related indications. We also aimed to determine the preexisting incidence of VTE between the groups and identify risk factors for VTE.

Methods: Patients who underwent hysterectomy by any route at an academic center between January 2019-December 2019 were included. Demographic, pathology, and VTE diagnosis data were assessed. Preoperative VTE occurred prior to surgery. Perioperative VTE occurred within 6 weeks of surgery. Patients with malignancy and known thrombophilias were excluded.

Results: A total of 1,029 patients were included, of which 687 patients had fibroids and 342 had none. Patients with fibroids were likely to be older, have higher BMI, larger uterine size, and greater EBL ($p<0.05$). Of the total cohort, 22 patients (2.0%) had VTE, of which 19 (1.8%) were preexisting, and 3 (0.2%) occurred peri-operatively. Ten of the 22 patients (45%) with preexisting VTE had fibroids; none of whom developed perioperative VTE. The presence of fibroids did not increase odds of perioperative VTE (OR 0.2, CI [0.02-2.7]). Those with preexisting VTE were more likely to have increased BMI, Charleston Comorbidity Index (CCI), postoperative length of stay and ASA risk score ($P<0.05$). In both univariate analysis and logistic model, both fibroids and total uterine size was not associated with preexisting VTE (univariate $p= 0.18$, $p=0.50$; logistic model $p=0.08$, $p=0.17$ respectively). Higher BMI and ASA score of 3-4 are associated with higher odds of preexisting VTE (1 unit increase of BMI OR 1.06, CI [1.0-1.1]; OR 3.6 [1.4-9.3]). However, specifically in patients with fibroids, only ASA score of 3-4 is associated with higher odds of preexisting VTE (OR 4.2, CI 1.2-15.1).

Conclusions: Patients undergoing hysterectomy for fibroid-related indications

are not at increased risk for VTE compared to patients undergoing surgery for non-fibroid-related indications. Preexisting VTE in patients with fibroids did not increase the risk for perioperative VTE. Overall, for patients with fibroids, higher ASA scores are associated with VTE event.

Funding Source: None

Faculty Mentor: Rosanne Kho, MD
Disscussant: Becca Omosigho, MD

Management of Abnormal Urinalysis Results in Urogynecologic Patients Undergoing Preoperative Urodynamic Testing Prior to Surgery for Pelvic Organ Prolapse

Rachel Baird, MD, MS

Objective: To evaluate the management of abnormal urinalysis in women undergoing preoperative urodynamic testing prior to pelvic organ prolapse surgery.

Methods: This is a retrospective study of women age 18 years or older undergoing preoperative urodynamic testing at the Cleveland Clinic Center for Urogynecology & Pelvic Reconstructive Surgery prior to pelvic organ prolapse surgery from January 2016-December 2018. Records were reviewed for presence of pelvic organ prolapse and urinalysis results. Abnormal urinalysis result was defined as the presence of blood, leukocyte esterase, and/or nitrites. These abnormal urinalysis results were divided into two groups. A urinalysis positive for only blood or leukocyte esterase was included in the "broad definition" group. A urinalysis positive for nitrites or blood and leukocyte esterase was included in the "narrow definition" group.

Results: One third of patients undergoing urodynamic testing had an abnormal urinalysis result (303 of 1684 patients, 31%). Of these 303 patients, 243 (80%) were included in the broad definition group and 60 (20%) were included in the narrow definition group. Patients in the narrow definition group were older (69 vs. 61 years, $p<0.001$), more likely to be postmenopausal (93% vs. 75%, $p=0.003$), and more likely to have prior pelvic organ prolapse surgery (30% vs. 14%, $p=0.003$). Seventy-two percent of patients in the narrow definition

group had a urine culture obtained versus 5% in the broad definition group ($p<0.001$) with 63% of those in the narrow definition group ultimately having a positive urine culture. Twenty-three percent of patients in the narrow definition group had their urodynamics cancelled or rescheduled versus only 2% in the broad definition group ($p<0.001$). Two patients had their surgery cancelled or postponed. There were no differences in post-operative urinary retention or urinary tract infection between the broad and narrow groups.

Conclusions: Patients with positive nitrites or positive blood and leukocyte esterase in their pre-operative urinalysis were more likely to have their urodynamic testing cancelled or rescheduled but did not have increased risk of post-operative urinary retention or urinary tract infection. Providers can be reassured that a narrowly defined abnormal urinalysis result at time of urodynamic testing does not affect clinically significant surgical outcomes.

Funding source: None

Faculty Mentor: Cecile Ferrando, MD, MPH
Discussant: Cory Messingschlager, MD

Incidence and Prognostic Significance of Inguinal Lymph Node Metastasis in Women with Newly Diagnosed Epithelial Ovarian Cancer– IRB#18-1339

Julia Chalif, MD

Objective: To assess incidence and oncologic outcomes in women with advanced epithelial ovarian cancer (EOC) with inguinal lymph node metastasis (ILNM) at diagnosis**.**

Methods: An IRB-approved, retrospective single-institution cohort study was performed in women with stage III/IV EOC from 2009-2017. Patients with inguinal lymphadenopathy (defined as >1cm in short axis) clinically or radiographically were identified. The impact of ILNM on progression-free survival (PFS) and overall survival (OS) were assessed.

Results: Of the 562 women with advanced EOC, 18 (3.2%) had ILNM at diagnosis, accounting for 25.7% of all patients with stage IVB disease (n=70). Five patients (27.7%) had a known genetic predisposition for EOC, including BRCA1 (11.1%, n=2), BRCA2 (11.1%, n=2) and BRIP1 (5.6%, n=1). The

majority of patients underwent optimal primary cytoreductive surgery (CRS), including debulking of inguinal nodal metastasis (83.3%, n=15), with 50% (n=9) having no gross residual disease after surgery. There was no difference in PFS (19.9 vs. 19.9 vs. 17.2 months, p=0.84) or OS (137.2 vs. 52.9 vs. 67.6 months, p=0.29) in women with stage III/IV with ILNM, stage III/IV without ILNM, and stage IVB disease without ILNM, respectively. Progression-free survival was improved in women with ILNM who underwent an optimal resection to no macroscopic disease vs. non-optimal resection (27.4 vs. 14.3 months, p=0.019). Median overall survival at the time of analysis did not reach statistical significance (137.2 vs. 57.3 months, p=0.24).

Conclusions: In this retrospective cohort study, 3.2% of women with advanced EOC presented with ILNM at diagnosis. Although ILNM did not portend worse clinical outcomes compared to all Stage III/IV and Stage IVB patients, respectively, resection to no gross residual disease was associated with improved PFS.

Funding source: None

Faculty Mentor: Robert DeBernardo, MD
Discussant: Morgan Gruner, MD

A Retrospective Look at Pre-eclampsia Within the Cleveland Clinic Health System: Are There Opportunities for Early Diagnosis and Intervention in African-American Women?

Alexandra Imani Chatman, MD

Objective: To evaluate the diagnosis and management of all women who delivered within the Cleveland Clinic Cleveland area hospitals in the year 2018 with a diagnosis of pre-eclampsia.

Methods: This was a retrospective chart review of 346 patients who delivered at the Cleveland Clinic Women's Health Institute in the year 2018. Initial search was for patients with ICD 10 diagnosis codes for preeclampsia which had to be present before delivery. The primary outcome measure was whether or not the diagnosis of gestational hypertension or preeclampsia was made when the patient met criteria. Patients were then screened for the following demographics: age, race, pre-pregnancy BMI, last pre-pregnancy blood pressure, pregnancy

episode start date, pregnancy start date, delivery date/location, type 1 or 2 diabetes, obesity, gravidity, parity, tobacco use, initial prenatal visit blood pressure, history of preeclampsia in prior pregnancy, chronic hypertension, and whether or not the patient was started on baby aspirin between 12 & 28 weeks gestational age. Gestational age at time of diagnosis of gestational hypertension were collected in addition to sequalae such as presence of pulmonary edema, eclampsia, and readmission to hospital for postpartum preeclampsia. If patients were not diagnosed when they met criteria, a difference in the number of days between when they met criteria and when they were officially diagnosed was calculated and recorded. Comparisons were made between black, white, and other race patients. Categorial variables are presented as n/N (%) with 95% confidence intervals. These will be compared using Pearson's chi-square or Fisher's exact tests. Continuous variables will be presented as mean +/- SD, median [P25, P75], N (column%).

Results: 346 patients were included in the study. Of those patients, 339 or 98% were diagnosed with gestational hypertension or preeclampsia when they met criteria for the disease. 7 patients or 2% were not diagnosed when they met criteria for the disease. This study was an exploratory study and a power calculation was not performed.

Black patients had a statistically significantly higher pre-pregnancy BMI on average when compared to other races (34.8 ± 9.4 vs 30.7 ± 7.7, $p<0.001$). Black patients were also statistically significantly more likely to have a pre-existing diagnosis of chronic hypertension (44.6% vs 21.2%).

There were 49 patients who had a history of chronic hypertension that were not started on baby aspirin between 12-28 weeks. There were 10 patients with a history of preeclampsia in a prior pregnancy who were not started on baby aspirin between 12-28 weeks.

Conclusions: There were only 2% of patients who experienced a delay in diagnosis of gestational hypertension or preeclampsia. Therefore, the outcome of interest was too rare to detect any significant difference between the black and white populations. However, the study did find that 49 patients with a clear indication for baby aspirin prophylaxis were not started on it and went on to develop chronic hypertension with superimposed preeclampsia. Black patients were statistically more likely to have a higher pre-pregnancy BMI and a pre-existing diagnosis of chronic hypertension when compared to women of all other races.

Funding source: None

Faculty Mentor: Oluwatosin Goje, MD
Discussant: Kate Lintel, MD

Provider Practice Patterns Pertaining to Malpresentation in Pregnancies Conceived Via Assisted Reproductive Technology

Catherine Keller, MD

Objective: To analyze rates of external cephalic version (ECV) attempts in ART pregnancies.

Methods: An IRB-approved, retrospective cohort study was performed in patients who delivered at a single institution from 2014-2020 with diagnosis of malpresentation. Method of conception was defined as ART or spontaneously conceived. Patients undergoing intrauterine insemination were excluded. Primary outcome was the proportion of patients offered ECV in pregnancies conceived by ART compared to pregnancies conceived spontaneously.

Results: The study included 179 patients; 118 spontaneously conceived and 61 conceived with ART. ART patients were older (35.3 ± 3.7) than spontaneously conceived patients (30.1 ± 5.4) ($p<0.001$) and more likely to have private insurance (98.4% versus 76.7%, respectively, [$p<0.001$]). ECV was offered for 61.0% (n=72) of spontaneously conceived patients and 67.2% (n=41) of ART patients (p=0.42). Patients who spontaneously conceived were more likely to accept ECV when offered, with 38.9% (n=28) versus 20.5% (n=9) of ART patients (p=0.039). ECV success rates were similar: 48% (n=12) for non-ART and 40% (n=6) for ART patients (p=0.62).

Conclusions: While ECV was offered at the same rate in spontaneously conceived and ART pregnancies, patients who conceived with ART were less likely to accept ECV at our institution. Further research is needed in this population to understand the decision-making process surrounding ECV.

Funding: None

Faculty Mentor: Jeffrey Goldberg, MD
Discussant: Jonathan Hunt, MD, MBA

Endometrial Abnormalities During Endometrial Maturation for Frozen Embryo Transfer (FET): A Pilot Study

Kaia Schwartz, MD

Objective: We sought to retrospectively analyze the ultrasound characteristics of patients undergoing medicated endometrial maturation for FET to identify characteristics of abnormal endometrial echoes on transvaginal ultrasound performed prior to FET. Secondly, we aimed to identify if any of these abnormal endometrial characteristics were associated with FET pregnancy outcomes. We present preliminary data on the first 22 consecutive patients.

Methods: Abnormal endometria were diagnosed by the presence of polyps, cystic lesions, heterogeneous morphology (coexisting hypo- and hyperechoic areas), homogeneous morphology (as opposed to a normal trilaminar endometrium). All patients had undergone a uterine cavity assessment with an office hysteroscopy or a sonohysterogram prior to starting stimulation. Endometrial characteristics and patient demographics, including FET outcomes, were collected. All endometrial ultrasounds were performed by skilled sonographers leading up to FET, typically occurring between stimulation day 8-15. Evaluation of the endometrial echo morphology was performed by one of seven physicians on duty for IVF that day, and verified by a second physician. Outcome measures were cycle cancellation, failed conception, early pregnancy loss/biochemical pregnancy, and ongoing pregnancy. Fisher's Exact test and correlations were used to analyze the data and a $p<0.05$ determined statistical significance (R statistical program version 4).

Results: Of 22 abnormal endometria, 7 embryo transfers resulted in failed conception (23.3%), 4 resulted in ongoing pregnancy (13.3%), 6 cycle cancellations (20.0%), 2 early pregnancy losses (6.7%), and 2 biochemical pregnancies (6.7%). Of the endometrial characteristics analyzed, cystic lesions seen on the mid-cycle endometrial ultrasound were associated with either a cancelled cycle (22.7%), failed conception (22.7%), biochemical pregnancy (4.5%), or early pregnancy loss (9.1%) versus only 9.1% associated with ongoing pregnancy ($p=0.18$). Homogenous endometria were associated with no conception 9.1%, cancelled cycle in 9.1%, and with biochemical pregnancy in 4.5% of cases. Homogenous endometria were not associated with any ongoing pregnancies ($p=0.65$). When a polyp was present, FET would be cancelled.

Conclusions: The presence of endometrial abnormalities at endometrial ultrasound in preparation for FET was correlated with poor cycle outcomes (cancelled cycle, no conception, or early pregnancy loss/biochemical pregnancy) in the majority of the cases. Furthermore, there appears to be a possible association between poor FET outcome and endometrial cystic lesions. The association was not statistically significant, but the overall detrimental impact of endometrial abnormalities on FET cycles warrants further investigation in larger cohorts, which the authors intend to accomplish with expansion of the present study.

Funding: None

Faculty Mentor: Laura Detti, M
Discussant: Molly Morton, MD

An Exploratory Study Comparing the Quality of Contraceptive Counseling Provided Via Telemedicine Versus In-Person Visits

Rachel Shin, MD, MPH

Objective: To assess the quality of contraceptive counseling during telemedicine and office visits.

Methods: We conducted a cross-sectional study at Cleveland Clinic Women's Health Institute to compare contraceptive counseling quality between telemedicine (synchronous video) and office visits. We identified eligible patients through ambulatory encounters with primary contraceptive management or counseling ICD-10 codes. Respondents completed a survey assessing demographics, quality of contraceptive counseling, contraceptive method choice, affinity for technology, and attitudes toward telemedicine. We used the validated Interpersonal Quality of Family Planning (IQFP) scale to assess counseling quality. We used the Wilcoxon rank sum test, Pearson's chi-square test and Fisher's exact test to compare baseline characteristics.

Results: Of all eligible patients, 110/380 (29%) completed the survey. Of those who were successfully contacted by phone or mail, 110/201 (55%) completed the survey. The IQFP scores were 'high quality' for 28/52 (54%) of telemedicine-visit respondents versus 37/58 (64%) of office-visit respondents ($p = 0.29$). The birth control pill was the most popular method, chosen by

27/52 (52%) of telemedicine-visit respondents and 24/58 (41%) of office-visit respondents (p = 0.27). Telemedicine respondents identified ease of communication and less scheduling difficulty as factors that promote telemedicine use. Office-visit respondents identified privacy and communication concerns as factors that deter telemedicine use.

Conclusions: When patients self-select the encounter type, their assessment of the quality of contraceptive counseling among telemedicine and office visits is similar, with no statistically significant differences in contraceptive method chosen. Results from this single-center study support the integration of telemedicine in contraceptive service provision.

Funding: Falcone Grant

Faculty Mentor: Ashley Brant, DO, MPH
Discussant: Molly Morton, MD

Perioperative Adverse Events In Women Undergoing Concurrent Mid-urethral Sling Placement at the Time of Minimally Invasive Benign Gynecologic Surgery

Nicole Wood, MD

Objective: To compare perioperative complication rates between women undergoing mid-urethral sling (MUS) placement at the time of benign gynecologic surgery and those undergoing MUS procedures alone.

Methods: This is a retrospective matched cohort study of women undergoing MUS placement with or without concurrent minimally-invasive benign gynecologic surgery from January 2010 through December 2020. Women who had undergone concurrent minimally invasive gynecologic surgery and MUS placement for stress urinary incontinence were identified by their Current Procedural Terminology (CPT) codes. Once identified, they were matched to a cohort of women who had undergone MUS placement alone. Subjects were matched by age, surgeon, and date of surgery. Once identified, the electronic medical record was queried for demographic and perioperative data. Definitions for adverse events were determined a priori and captured at defined time points up to 12 months following surgery.

Results: A total of 38 patients met inclusion criteria for the concurrent surgery group, and 152 patients were matched accordingly. Mean age and BMI were 51 years and 22-173 kg/m^2. Patient characteristics were similar between the groups with the following exceptions: the concurrent surgery group had fewer previous vaginal surgeries ($p=0.005$), and a more frequent history of fibroids ($p=0.01$), benign adnexal disease ($p<0.001$), and endometriosis ($p<0.001$). The majority of the slings placed in the MUS-only group were retropubic (69%). Clavien-Dindo Grade 1 and Grade 2 adverse events were more frequent in the concurrent surgery group (5% vs 0%, $p=0.04$, 16% vs 6%, $p=0.04$). Similarly, composite post-operative resource utilization was greater in the concurrent surgery group (76% vs 49%, $p=0.003$). The rate of mesh extrusion/erosion ($p=0.03$) and sling lysis/excision rates ($p=0.02$) were found to be higher in the concurrent surgery group. On logistic regression, concurrent surgery cases were no longer associated with Clavien-Dindo Grade 2 events (adj OR 3.95, 95% CI 0.61-25.4), but remained significantly associated with sling mesh erosion (adj OR 12.6, 95% CI 1.4- 116.4).

Conclusions: Midurethral sling placement at the time of minimally invasive benign gynecologic surgery is safe, but is associated with a higher rate of postoperative resource utilization and sling mesh erosion and revision rates.

Funding: None

Faculty Mentor: Cecile Ferrando, MD, MPH
Discussant: Becca Omosigho, MD

PGY2 Obstetrics & Gynecology Residents

Poster Presentations

Fetal Echocardiography Outcomes in Mothers at Increased Risk of Fetal Congential Heart Disease

Faculty Mentor: Maeve Hopkins, MD

Lauren Buckley, MD

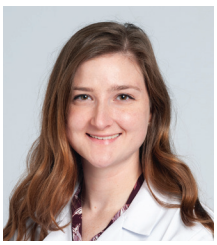
Evaluation of Oxytocin Dysfunction as a Predictor of Developing Autism-Like Behavior in a *Pten* Mutant Mouse Model

Faculty Mentor: Charis Eng, MD, PhD

Parker Bussies, MD

Necrotizing Soft Tissue Infections in Obstetric and Gynecologic Patients

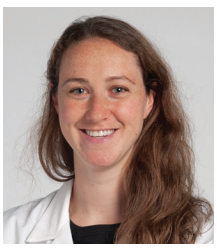
Faculty Mentor: Roberto Vargas, MD



Katie Klammer, MD

Efficacy and Toxicity of Carboplatin and Gemcitabine dosed on Day 1/Day 8 versus Day 1 alone for Platinum-sensitive Recurrent Epithelial Ovarian Cancer

Faculty Mentor: Robert DeBernardo, MD



Erika Lampert, MD

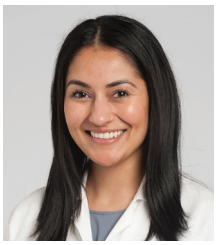
Umbilical Cord Blood Collection during Cesarean Section: Impact on Maternal Blood Loss

Faculty Mentor: Maeve Hopkins, MD

Madeline Lederer, MD

Prevalence of Polycystic Ovarian Syndrome in Young and Adolescent Transmasculine Patients Presenting for Gender Affirmation Care

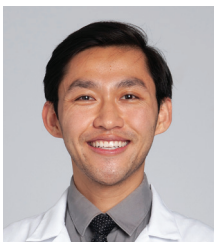
Faculty Mentor: Cecile Ferrando, MD, MPH



Sabrina Rangi, MD

Foley Balloon for Cervical Preparation Prior to Surgical Abortion

Faculty Mentor: Mitchell Reider, MD



Johnathan Zhao, MD

Graduating Fellow

Oral Presentations

Reported Case Numbers and Variability in Delivery Route and Volume by Obstetrician-Gynecologist Residents from 2003 to 2019

Tiffany Cochran, MD

Objective: Ovarian aging is an intricate physiologic process resulting in the age-specific, irreversible decline in the number and quality of the primordial follicle pool (PFP) to the point of infecundity and cessation of hormonal production resulting in menopause. The 12 months following the last menstrual cycle signals menopause after losing ovarian function, and its timing is affected by genetics. It is well studied that ovarian reserve decreases chronologically with age. Ovarian aging happens faster than other bodily organs, causing infertility and leading to harmful health diseases such as cardiovascular and ischemic heart disease, osteoporosis and loss of bone density, Alzheimer's disease, and weight gain and changes in the adipose deposition. Maintaining ovarian function also has a caveat associated with increased risk for breast, ovarian, and endometrial cancer. The rate of decline for ovarian reserve varies widely even among females of similar age. Within our Center for Specialized Women's health menopause clinic, we have witnessed several women who spontaneously had a return of ovarian function with the return of menstrual bleeding from the active uterine lining with a benign investigation for bleeding. These specific cases of return of ovarian function sparked curiosity in questioning the mechanism. Since age at menopause has been identified as a critical marker of a woman's health, research efforts to investigate the physiology of ovarian aging and factors that influence ovarian reserve are imperative. We know ovarian aging is influenced by multiple factors such as environment, nutrition, and genetics. Here we will conduct a retrospective study observing the effect of multiple factors (melatonin, metformin, parity, ethnicity, body mass index, age of menarche, age at first and last birth, smoking history, and diet) on ovarian aging. This study aims to increase research efforts to investigate the impact of multiple factors on ovarian function.

Methods: The EMR will be searched to obtain information about demographics, relevant clinical information, and menopause diagnosis. Baseline characteristics of interest will include age, BMI, ethnicity, gravidity/parity, age of menarche, age at first and last birth, smoking history, A1c, blood glucose, TSH, free T4 and T3, use of specific medications (melatonin, metformin, or hormonal contraceptives), FSH and AMH testing, menstrual cycles, history of malignancy (chemotherapy,

malignancy, and surgery), symptoms of menopause (severity and duration).

Results: IRB recently approved. Epic Chart received on 03/28/2022 for data collection

Conclusions: IRB recently approved. Epic Chart received on 03/28/2022 for data collection

Funding: None

Faculty Mentor: Holly L Thacker, MD and Ula Abed Alwahab, MD

The Symptoms and Timing of Menopause in Women with Polycystic Ovarian Syndrome

Tara Iyer, MD

Objective: This study aims to increase research efforts to investigate the implications of menopause for women diagnosed with PCOS. Specifically, this study aims to evaluate the effect of PCOS on the timing of menopause and severity of menopausal symptoms, when controlling for influential clinical factors and co-morbidities.

Methods: The study will be an observational, retrospective cohort study with random selection for the cohort control. The data for this study will be collected via chart review. Our study population will include postmenopausal women with PCOS as diagnosed by the clinical definition of menopause and the Rotterdam criteria for PCOS. The EMR will be searched to obtain information about demographics, relevant clinical information, PCOS and menopause diagnosis. Baseline characteristics of interest will include age, BMI, gravidity/parity, insulin resistance (HgbA1c), smoking, CAD, hormonal contraception, FSH and AMH testing, menstrual cycles, history of infertility treatment, history of depression, history of malignancy (chemotherapy, malignancy, surgery), symptoms of menopause (prevalence, severity, duration)

Analysis:
Aim 1: Between study cohort and control cohort, approximately normally-distributed continuous measures will be summarized using means and standard deviations and will be compared using two-sample t-tests. Continuous measures

that show departure from normality and ordinal measures will be summarized using medians and quartiles and will be compared using Wilcoxon rank sum tests. Categorical factors will be summarized using frequencies and percentages and will be compared using Pearson's chi-square tests or Fisher's Exact tests. Linear regressions adjusting for factors of clinical importance will be performed for menopause age.

Aim 2, 3: Depending on the distribution of final data, Pearson or Spearman correlation will be calculated between the menopause age and other continuous variables. For each level of categorical factors, the X will be summarized using mean and standard deviation or median and quartiles, and will be compared using ANOVA or Kruskal-Wallis tests.

All analyses will be done using SAS (version 9.4, The SAS Institute, Cary, NC) and a $p < 0.05$ will be considered statistically significant.

Results: In progress

Conclusions: In progress

Funding: None

Faculty Mentor: Holly L. Thacker, MD

The Validation of Novel Methods to Differentiate Radiation Sensitivity in Cervical Cancer Cell Lines Allows for the Development of a Gene Signature Predictive of Radiation Response

Michelle Kuznicki, MD

Objective: In cervical cancer cell lines (CCCL) we aimed to 1) Validate a high throughput (HTP) assay as a reliable method for determining radiation sensitivity. 2) Validate area under the radiation response curve (AUC) as an accurate measure of radiation sensitivity. 3) Use RNA sequencing to explore differential gene expression based on AUC.

Methods: The HTP assay utilized 96-well plates and a multidrop liquid handler for high replicate plating. Plates were exposed to radiation and cell survival was determined at 9 days using luminescence signal measurement after application of Cell-Titer-Glo. Colony Forming Assay (CFAs) were performed using 6 well

plates, cells were exposed to radiation, and cell survival at 9 days was determined by manually counting colonies. Surviving fraction at 2Gy (SF2) and AUC were measured. CFAs were completed for 6 CCCL and HTP was completed for 16 CC cell lines. Pearson correlation coefficients were used for linear correlations and one-way ANOVA was used to determine differences in HTP AUC between cell lines. Illumina hiseq double end paired RNA sequencing of each cell line was completed. Differential gene expression between CCCL was calculated using edgeR and DESeq2 packages in R. Partial least squares (PLS) model was used to determine relative impact of gene expression on AUC. A gene signature that correlated with AUC was then developed using PLS and differential expression data.

Results: In 6 CCCL CFA SF2 correlated with CFA AUC (Pearson r=0.987, p=<0.0002) and CFA AUC correlated with HTP AUC (Pearson r= 0.932, p=0.0068), Figure 1.1-1.2. HTP SF2 correlated with HTP AUC (Pearson =0.868, p=0.068). Differential radiation sensitivity in 16 CCCL was found using both HTP SF2 (F=7.201, p=<0.0001), and HTP AUC (F=17.44, p=< 0.0001), Figure 1.3 and 1.4. RNAseq analysis demonstrated significantly differentially expressed genes based on AUC and using this data a predictive gene signature was created (Figure 2)

Conclusions: We have demonstrated the HTP correlates with gold standard CFA in cervical cancer cell lines and that AUC correlates with SF2. Using RNA seq and AUC we were able to detect differential gene expression and develop a gene signature that is predictive of radiation phenotype.

Funding: 2020 Cleveland Clinic Research Program Committees Grant

Faculty Mentor: Roberto Vargas, MD

Is There an Association Between 6-month Genital Hiatus Size and 24-month Composite Subjective Prolapse Recurrence following Minimally Invasive Sacrocolpopexy?

Viviana Casas Puig, MD

Objective: To describe 24-month composite subjective prolapse recurrence following MI-SCP between patients with a 6-month post-operative GH<3cm compared to those ≥3cm; and, to explore the impact of concurrent level 3 support procedures on subjective prolapse recurrence, bowel, and sexual function.

Methods: This was a secondary analysis of two randomized, single-blinded controlled trials of women who underwent MI-SCP for uterovaginal or vaginal vault prolapse from June 2014 through January 2020. Women who had a documented preoperative and 6-month postoperative POP-Q examination, and those who had completed the PFDI-20 questionnaire preoperatively and at 6- and 24 months postoperatively were included. Our primary outcome was composite subjective prolapse recurrence defined as retreatment with either a pessary or surgery, and/or a positive response to question 3 of the PFDI-20 questionnaire. A ROC curve was generated to identify a 6-month GH cut point associated with 24-month composite prolapse recurrence. Based on this threshold, patients were categorized as having a GH<3cm or GH≥3cm.

Results: A total of 108 women met inclusion criteria. 35 patients (32%) underwent robotic-assisted SCP and 73 (68%) laparoscopic SCP. The majority of women were white (94%), postmenopausal (94%), and had stage 3 POP (56%). 23 (21%) patients had a GH<3cm and 85 (79%) patients a GH≥3cm. Women with a 6-month GH<3cm were older (65±7 vs 60±8, p=0.002); otherwise, patient characteristics were similar between the groups. A total of 13 patients (12%) had a composite prolapse recurrence at 24-months: 12 patients (11.1%) reported bothersome vaginal bulge symptoms, and 3 patients (2.8%) underwent retreatment with surgery. A ROC curve demonstrated that a 6-month postoperative GH size of 3cm had 84.6% sensitivity (CI, 65-100%) to predict bothersome vaginal bulge and/or retreatment at 24 months (AUC=0.52). Composite subjective prolapse recurrence did not differ between the groups, however, only patients with a 6-month GH>3cm underwent retreatment. Of the patients, 45% (49) underwent a concurrent level 3 support procedure at the time of MI-SCP.

Conclusions: 24-month composite subjective failure following MI-SCP did not differ based on 6-month GH size; however, surgical failure was only seen in patients with a GH size ≥3cm. Concurrent level 3 support procedures were not associated with subjective prolapse recurrence, bowel symptoms, or de novo dyspareunia.

Funding source: None

Faculty Mentor: Cecile Ferrando, MD, MPH

The Standard versus No Opioid Prescription after Prolapse and Anti-Incontinence Surgery (STOP-PAIN) Trial

Angela S. Yuan, MD

Objective: To determine if a restrictive opioid prescription protocol is acceptable to patients after minor and major urogynecologic surgery, compared to standard opioid prescribing practices.

Methods: This was a pragmatic, non-inferiority, randomized trial of patients who underwent minor (e.g. colporrhaphy or mid-urethral sling) and major (e.g. vaginal or minimally-invasive abdominal prolapse repair) urogynecologic surgery. Subjects were randomized to receive a standard opioid prescription (3-10 tablets of oxycodone 5 mg) or no opioid prescription upon discharge. All patients received multimodal pain medications. Exclusion criteria included a history of preoperative opioid use, allergy to study medications, and a score of ³30 on the Pain Catastrophizing Scale. Subjects were asked to record their pain medication use and pain levels for 7 days. The primary outcome was satisfaction with pain control reported at the 6 week postoperative visit. The non-inferiority margin was 15 percentage points. A sample size of 128 subjects (64 per arm) was planned.

Results: To date, a total of 113 patients have been randomized, with 55 patients assigned to the Standard Opioid Prescription arm, and 58 assigned to the Restricted Opioid Prescription arm. The following are results from a preliminary analysis of the available data. Mean age of subjects was 56 ± 12.4 years, and subjects were predominantly white (106 [91.4%]), non-Hispanic (111 [95.7%]) and postmenopausal (74 [63.8%]). At 6 weeks, satisfaction with pain control was reported in 90.7% and 92.7% of subjects in the Standard and Restricted arms, respectively (p=.706). Sample size has not yet been achieved to demonstrate non-inferiority. Median prescribed number of opioid tablets at discharge was 5 (interquartile range [IQR] 5-10) for Standard arm subjects and 0 (IQR 0-5) for Restricted arm subjects (p<.001). Opioid use was significantly lower in the Restricted arm (median [IQR] 0 [0-1]) compared to Standard arm (1 [0-2.8]), p=.023. There were also fewer unused opioid tablets in the Restricted arm (median [IQR] 1 [0-9]) compared to Standard (5 [3-8]), p<.001. No postoperative opioid use was seen in 71.9% of Restricted arm patients compared to only 48.9% of Standard arm patients (p=.016). These

findings were sustained in planned sub-analyses of subjects who underwent minor vs. major surgeries.

Conclusions: In this preliminary analysis of patients randomized to standard versus restricted opioid quantities prescribed after urogynecologic surgery, significantly less opioid use was seen with the restrictive protocol without impact on satisfaction rates.

Funding: Supported by a grant from the Lerner Research Institute Research Program Committees (RPC 1785).

Faculty Mentor: Cecile Ferrando, MD, MPH

Salpingo-Oophorectomy or Surveillance for Ovarian Endometrioma in Asymptomatic Premenopausal Women: a Cost-Effectiveness Analysis

Megan Orlando, MD

Objective: To determine if performing unilateral salpingo-oophorectomy (USO) is cost-effective for prevention of death compared to surveillance for asymptomatic endometriomas.

Methods: We created a cost-effectiveness model using TreeAge Pro with a lifetime horizon. Our hypothetical cohort included premenopausal patients with two ovaries who do not desire fertility. Those diagnosed with asymptomatic endometrioma underwent USO or surveillance (ultrasound 6-12 weeks after diagnosis, then annually). Our primary effectiveness outcome was mortality, including death from ovarian cancer or surgery and all-cause mortality related to surgical menopause (+/- hormone replacement therapy). We modeled the probabilities of surgical complications, occult malignancy, development of contralateral adnexal pathology, surgical menopause, use of hormone replacement therapy, and development of ovarian cancer. Costs included surgical procedures, complications, ultrasound surveillance, hormone therapy, and treatment of ovarian cancer, with information gathered from Medicare reimbursement data and published literature. Cost-effectiveness was determined using the incremental cost-effectiveness ratio (ICER) of Δ costs / Δ deaths with a willingness-to-pay (WTP) threshold of $11.6 million as the value of a statistical life. Multiple one-way sensitivity analyses were performed to evaluate model robustness..

Results: Our model demonstrated that USO is associated with improved outcomes compared to surveillance, with fewer deaths (0.28% vs.1.50%) and fewer cases of ovarian cancer (0.42% vs. 2.96%). However, USO costs more than surveillance at $6,403.43 vs. $5,381.39 per case of incidental endometrioma. The ICER showed that USO costs $83,773.77 per death prevented and $40,237.80 per case of ovarian cancer prevented compared to surveillance. As both values were well below the WTP threshold, USO is cost-effective and the preferred strategy. If USO were chosen over surveillance for premenopausal patients with incidental endometriomas, one diagnosis of ovarian cancer would be prevented in every 40 patients and one death averted in every 82 patients. We performed one-way sensitivity analyses for all input variables, and determined that there were no reasonable inputs that would alter our conclusions.

Conclusions: USO is cost-effective and the preferred strategy compared to surveillance for the management of incidental endometrioma in a premenopausal patient not desiring fertility. USO incurs fewer deaths and fewer cases of ovarian cancer with costs below national willingness-to-pay thresholds.

Funding: None

Faculty Mentor: Rosanne Kho, MD

Caloric Restriction Increases Ovarian FOXO3A Expression in a Mouse Delayed Aging Model: Implications for Reproductive Longevity

Natalia Llarena, MD

Objective: To evaluate the nutritional triggers, specifically the contribution of amino acid composition during CR, as well as the molecular mechanisms, by which CR impacts ovarian reserve during physiologic aging in mice.

Methods: Twenty-six 9-month-old female C57BL/6 mice were divided into 4 groups: (1) ad libitum feeding, (2) 40% caloric restriction (CR), (3) 40% CR + non-essential glycine amino acid supplementation (CR + Gly), and (4) 40% CR + sulfur amino acid supplementation (CR + SAA). CR was continued for 12 weeks. Following CR, the ovarian reserve was quantified. Formalin-fixed ovaries were sectioned and stained with hematoxylin and eosin for primordial follicle counts. Quantitative polymerase chain reaction (qPCR) was used to

quantify levels of ovarian expression of forkhead box protein O3A (FOXO3A), an important suppressor of follicular activation, growth hormone receptor (GHR), and insulin-like growth factor-1 (IGF-1).

Results: Primordial follicle counts increased in the 40% CR (53 vs 41, p = 0.7) and CR + Gly supplementation groups (82 vs 41, p = 0.029) compared to the ad-lib fed group. There was no increase in primordial follicles in the CR + SAA group (44 vs 41, p = 0.99). The relative expression of FOXO3A was increased by 10-fold in the CR group (p = 0.3) and 20-fold in the CR + Gly group compared to the ad lib group (p = 0.016). There was no increase in FOXO3A expression in the CR + SAA group. Relative GHR expression was decreased 4-fold in the CR + Gly compared to the ad-lib¬-fed animals (p = 0.07). There was no difference in IGF-1 levels between the CR + Gly group and controls; however, levels of IGF-1 in the CR + SAA group increased dramatically by 100-fold (p = 0.001).

Conclusions: CR (40%) with Gly supplementation significantly increases ovarian reserve in a mouse model of physiologic aging. The improvement in ovarian reserve appears to be mediated by an increase in the expression of FOXO3A, an important suppressor of follicular activation. This study provides insight into pathways that regulate the ovarian reserve. These pathways can be leveraged to design interventions that prolong the reproductive lifespan.

Funding source: NIH/NIA

Requirement of Hydrogen Sulfide for the Benefits of Dietary Sulfur Amino Acid Restriction

This project seeks to identify a central factor driving aging in order to develop targeted interventions to delay the onset or even reverse aging-related pathologies. I will test age related declines of endogenous hydrogen sulfide production and if it is delayed by DR, and the requirement for increased H2S to deliver the longevity benefit of DR.

K99 Phase: 08/15/2015 - 10/31/2016

R00 Phase: 04/01/2017- 03/31/2020

Faculty Mentor: Christopher Hine, PhD

The FLOWER Trial: A Randomized Trial Comparing Perioperative Pelvic Floor Physical Therapy to Current Standard of Care in Transgender Women Undergoing Vaginoplasty for Gender Affirmation

Frances Grimstad, MD

Objective: To compare the effectiveness of postoperative pelvic floor physical therapy (PFPT) compared to no PFPT in transgender women undergoing vaginoplasty surgery for gender affirmation.

Methods: This is a randomized double-blind study of transgender adult women undergoing full-depth vaginoplasty. Patients were randomized to one of two groups: PFPT or no PFPT following vaginoplasty. Those who were randomized to PFPT were additionally randomized to receiving or not receiving additional preoperative PFPT. We determined that 17 subjects in each arm were needed to detect a difference of 2 (+/-1) points between the two groups (PFPT versus no PFPT) with 80% power and a significance level of 0.05. Accounting for potential drop out as well as unforeseen factors in recruiting we are plaining to recruit 20 subjects to each arm, for a total of 40 subjects. Primary outcome was patient reported ease of dilation 12 weeks following surgery. Secondary outcome was severity of pelvic floor dysfunction at 12 weeks, assessed by the Colorectal-Anal Distress Inventory (CRAD-8), Urogenital Distress Inventory (UDI-6), Pelvic Floor Impact Questionnaire (PFIQ-7), and Patient Impression of Improvement (PGI-I).

Results To date, 36 patients have qualified for the study, 31 enrolled. Of those, four were lost to follow up at the 12-week postoperative visit, 22 completed the study, and four are actively enrolled. One had their surgery postponed following the initial enrollment. Mean age and BMI of those enrolled thus far (n=31) were 33.1±14.5 years and 24.6±4.1 kg/m2., respectively. The majority (n=29, 93.5%) were white with two African American patients. Patients had been on estrogen hormone therapy for a mean of 53.9±49.3 months. Four participants had a history of chronic pain. Analysis of outcomes data is pending completion of study enrollment. This will include comparing ease of dilation and pelvic floor symptoms between arms. We will also perform subgroup analyses, between those who underwent both preoperative and postoperative PFPT, and postoperative PFPT alone. Binary logistic regression will be used to assess the influence of various patient factors on the patient reported ease of dilation as

well as pelvic floor symptoms.

Conclusions This is the first randomized study to interrogate the utility of PFPT following full-depth vaginoplasty in transgender women.

Funding source: none

Faculty Mentor: Cecile Ferrando, MD, MPH

2021

Resident, Fellow and Faculty Publications

Ob/Gyn

1. Fishel Bartal M, Premkumar A, Rice MM, Reddy UM, Tita ATN, Silver RM, El-Sayed YY, Wapner RJ, Rouse DJ, Saade GR, Thorp JM Jr, Costantine MM, Chien EK, Casey BM, Srinivas SK, Swamy GK, Simhan HN; Eunice Kennedy Shriver National Institute of Child Health, Human Development (NICHD) Maternal-Fetal Medicine Units (MFMU) Network. Hypertension in pregnancy and adverse outcomes among low-risk nulliparous people expectantly managed at or after 39 weeks: a secondary analysis of a randomized controlled trial. *BJOG*. 2021 Dec 20. doi: 10.1111/1471-0528.17059. [Epub ahead of print] PubMed [citation] PMID: 34927787

2. Pippen J, Stetson B, Doherty L, Varner MW, Casey BM, Reddy UM, Wapner RJ, Rouse DJ, Tita ATN, Thorp JM Jr, Chien EK, Saade GR, Blackwell SC; Eunice Kennedy Shriver National Institute of Child Health Human Development Maternal-Fetal Medicine Units Network. Neonatal Birthweight, Infant Feeding, and Childhood Metabolic Markers. *Am J Perinatol.* 2021 Dec 16. doi: 10.1055/s-0041-1740056. [Epub ahead of print] PubMed [citation] PMID: 34918330

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8. Braginsky L, Weiner SJ, Saade GR, Varner MW, Blackwell SC, Reddy UM, Thorp JM Jr, Tita ATN, Miller RS, McKenna DS, Chien EKS, Rouse DJ, El-Sayed YY, Sorokin Y, Caritis SN; Eunice Kennedy Shriver National Institute of Child Health Human

Development Maternal-Fetal Medicine Units (MFMU) Network. Intrapartum Fetal Electrocardiogram in Small- and Large-for-Gestational Age Fetuses. *Am J Perinatol*. 2021 Dec;38(14):1465-1471. doi: 10.1055/s-0041-1735285. Epub 2021 Aug 31. PubMed [citation] PMID: 34464982, PMCID: PMC8608729

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