SYLLABUS

PANEL SESSION 4:
Debate: “There Will Be an Answer, Let It Be” – Expert Debate on Treatments for Endometriosis Associated Pain
Professional Education Information

Target Audience
This educational activity is developed to meet the needs of surgical gynecologists in practice and in training, as well as other healthcare professionals in the field of gynecology.

Accreditation
AAGL is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians.

The AAGL designates this live activity for a maximum of 1.75 AMA PRA Category 1 Credit(s)™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Disclosure of Relevant Financial Relationships
As a provider accredited by the Accreditation Council for Continuing Medical Education, AAGL must ensure balance, independence, and objectivity in all CME activities to promote improvements in health care and not proprietary interests of a commercial interest. The provider controls all decisions related to identification of CME needs, determination of educational objectives, selection and presentation of content, selection of all persons and organizations that will be in a position to control the content, selection of educational methods, and evaluation of the activity. Course chairs, planning committee members, presenters, authors, moderators, panel members, and others in a position to control the content of this activity are required to disclose relevant financial relationships with commercial interests related to the subject matter of this educational activity. Learners are able to assess the potential for commercial bias in information when complete disclosure, resolution of conflicts of interest, and acknowledgment of commercial support are provided prior to the activity. Informed learners are the final safeguards in assuring that a CME activity is independent from commercial support. We believe this mechanism contributes to the transparency and accountability of CME.

Anti-Harassment Statement
AAGL encourages its members to interact with each other for the purposes of professional development and scholarly interchange so that all members may learn, network, and enjoy the company of colleagues in a professional atmosphere. Consequently, it is the policy of the AAGL to provide an environment free from all forms of discrimination, harassment, and retaliation to its members and guests at all regional educational meetings or courses, the annual global congress (i.e. annual meeting), and AAGL-hosted social events (AAGL sponsored activities). Every individual associated with the AAGL has a duty to maintain this environment free of harassment and intimidation.

AAGL encourages reporting all perceived incidents of harassment, discrimination, or retaliation. Any individual covered by this policy who believes that he or she has been subjected to such an inappropriate incident has two (2) options for reporting:

1. By toll free phone to AAGL's confidential 3rd party hotline: (833) 995-AAGL (2245) during the AAGL Annual or Regional Meetings.
2. By email or phone to: The Executive Director, Linda Michels, at lmichels@aagl.org or (714) 503-6200.

All persons who witness potential harassment, discrimination, or other harmful behavior during AAGL sponsored activities may report the incident and be proactive in helping to mitigate or avoid that harm and to alert appropriate authorities if someone is in imminent physical danger.

For more information or to view the policy please go to:
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Panel Session 4: Debate: “There Will Be an Answer, Let It Be” – Expert Debate on Treatments for Endometriosis Associated Pain

Moderator: Frank F. Tu
Faculty: Megan Billow, Susan Pierce-Richards, David B. Redwine

Course Description
This session provides a forum to critically, holistically, and “combatively” address treatment of Endometriosis, an enigmatic condition that can significantly impact an individual’s quality of life. Its varied clinical presentation, pain symptoms, and confounding medical conditions lead to not only diagnostic challenges but also controversial treatment considerations. This session will host a lively debate regarding the optimal treatment for endometriosis. Panelists will discuss evidence-based strategies for medical management, surgical management, and interdisciplinary care coordination to support patient-centered goals. Challenging clinical scenarios will be discussed to discern best approaches to the treatments for endometriosis associated pain.

Course Objectives
At the conclusion of this activity, the participant will be able to:
1) Formulate valid, specific, patient-affirming multidisciplinary treatment plans for endometriosis-associated pelvic pain.

Course Outline

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<tr>
<th>Time</th>
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<td>11:00</td>
<td>Welcome, Introductions, and Course Overview</td>
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<td>The Down and Dirty Clinical Realities: EAPP Management in the Real World</td>
<td>All Faculty</td>
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PLANNER DISCLOSURE
The following members of AAGL have been involved in the educational planning of this workshop (listed in alphabetical order by last name).
Art Arellano, Professional Education Director, AAGL*
Linda D. Bradley, Medical Director, AAGL*
Erin T. Carey
Consultant: MedIQ
Mark W. Dassel
Contracted Research: Myovant Sciences
Erica Dun*
Adi Katz*
Linda Michels, Executive Director, AAGL*
Erinn M. Myers
Speakers Bureau: Laborie Medical Technologies, Teleflex Medical
Other: Unrestricted educational grant to support NC FPMRS Fellow Cadaver Lab: Boston Scientific Corp. Inc.
Amy Park*
Grace Phan, Professional Education Specialist, AAGL*  
Harold Y. Wu*
Linda C. Yang
Other: Ownership Interest: KLAAS LLC
Frank F. Tu
Consultant: AbbVie, Uroshape
Speakers Bureau: AbbVie

FACULTY DISCLOSURE
The following have agreed to provide verbal disclosure of their relationships prior to their presentations. They have also agreed to support their presentations and clinical recommendations with the “best available evidence” from medical literature (in alphabetical order by last name).
Megan Billow
Consultant: AbbVie
Susan Pierce-Richards*
David B. Redwine*
Frank F. Tu
Consultant: AbbVie, Uroshape
Speakers Bureau: AbbVie

Content Reviewer has nothing to disclose.

Asterisk (*) denotes no financial relationships to disclose.

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Patient-Centered Management of Endometriosis

Susan Pierce-Richards, DNP, ARNP, FNP-BC, ANP-BC, RN-BC
CAPT, US Public Health Service
Nurse Practitioner/Clinical Informaticist/Senior Health Insurance Specialist

Disclosure

- I have no financial relationships to disclose
- Disclaimer: The views presented herein do not represent the views of the Federal Government

Objectives

- Describe the impact of endometriosis on patients and the health care system
- Recognize biases and limitations in the literature that impact the application of evidence in an evidence-informed, person-centered approach to care
- Identify areas of your practice where you can better engage with and empower patients

Brokengirl: the secret shame of pelvic pain

Urgency
Frequency
Obstipation
Dysmenorrhea
Dyschezia
Menorrhagia
Fixed uterus
Dyspareunia
Pelvic fullness
“Hemorrhagic” cysts
Infertility
Flank pain
Hematochezia

Dysmenorrhea
Dyschezia
Menorrhagia
Fixed uterus
Dyspareunia

Time to dx: 30+ year
Time on hormones pre dx: 19+ years

What is person-centered care?

The ideal
- Dignity, compassion, respect
- Coordinated care
- Personalized care
- Collaborative and empowering

The reality
- Struggle for credibility
- Castration
- Invalidation
- Shame
- Misinformation
- Dx & Tx delay
- Repeated ablation surgery
- Incomplete surgery
- Disease progression
- Limited treatment options
- Hopelessness
- Limited options
- Disease progression
- Medicalization
- Disempowerment
- Loss of dignity
- Self doubt

What evidence do we need to support PCC?

- Is our evidence base patient-centered?
- Are meta-analyses of RCTs the best evidence?
- Do we really engage in shared decision making?
- Do we appreciate the power imbalances?
- What happens outside of the exam room?
- What about the people we don’t see?

Understand limitations and biases ... appraise carefully
What can I do differently to meet patients needs?

Dimensions of patient centered endometriosis care:
- Respect for patient’s values, preferences, and needs
- Information, communication, and education
- Continuity and transition
- Access to care
- Technical skills

"Evidence-based, patient-focused" ideology

"Evidence-informed, person-centered" health and social care

Summary

"I will remember that there is an art to medicine as well as a science, and that the warmth, sympathy, and understanding may outweigh the surgeon’s knife or the chemist's drug." Dr. Louis Lasagna

Your words, silence, and actions are powerful

Choose them wisely

Ask, listen, hear, validate, ACT

References

Medical Management of Endometriosis: Can it solve the painful problem?

Megan Billow, DO
Director, Division of Minimally Invasive Gynecologic Surgery
Assistant Professor
University Hospitals Cleveland Medical Center
Case Western Reserve University

Disclosure
Consultant: Abbvie

Objective

- Discuss the medical management of endometriosis.

Principles

- Reduce symptoms
- Improve quality of life
- Increase interval time between surgical intervention
  - Prevent disease recurrence
- Post-operative hormonal suppression
  - Without, recurrence 21.5% at 2 years, 40-50% at 5 years

Factors to consider:
- Patient age
- Patient preference
- Treatment goals—pain, fertility
- Extent of disease—presence of DIE?

Pathophysiology of Pain

- Estrogen dependent sloughing of implants
- Implants secrete E2 and PGE2
- Chronic inflammatory reaction
• ACOG and ASRM: empiric medical therapy prior to definitive surgical diagnosis
• COCPs: cyclic vs continuous
  – Muzzi et al. AJOG 2016. Systematic review and metaanalysis
  – continuous is more effective in improving dysmenorrhea
• Progestin monotherapy:
  – Casper et al. Fert Steril 2017. POP may be more effective than COCPs
  – Levonorgestrel IUS decreases endometriosis related pain
  – Crosignani et al. Hum Reprod 2006. DMPA as effective as GnRH agonist
• GnRH agonist: higher cost, side effects
  – Brown et al. Cochrane review, 41 studies
    • GnRH agonist superior to placebo
    • GnRH agonist as effective as COCPs and progestin methods
• GnRH antagonist
  – Significant improvement in dysmenorrhea
  – Less hypoestrogenic side effects

Algorithm

• Clinical suspicion of endometriosis
  – Empiric therapy for 3 months (COCPs, Progestin only method, GnRH agonist or antagonist)
  – Assess for improvement in pain – switch to another method?
• Surgical intervention – patient goals
  – Conservative – post operative suppression (duration?)
  – Hysterectomy with ovarian conservation – post-operative suppression? Duration?
  – Hysterectomy + BSO – suppression?

References
• Casper et al. Progestin only pills may be a better first-line treatment for endometriosis than combined estrogen-progestin contraceptive pills. Fert Steril 2017; 107: 53-64.
Surgery the Only Answer

David B. Redwine, M.D.
Retired general ob/gyn

I have no financial disclosure

Objective
Apply a critical review of Lupron and Orilissa to surgical practice

Lupron:
Klein vs Abbott
United States District Court, Las Vegas
Case 2:08-CV-00681

Orilissa:

Lupron effects on estradiol

Age 18 - 35
M84-042: Lupron SC x 7 d then nasal spray x 6 months
By one year after stopping Lupron:
average estradiol 95.5 pg/mL (baseline: 121.8)
75% of patients had not returned to baseline E2
12% had menopausal estradiol
M92-878: Lupron + NET x 52 weeks - Post-Rx E2 below baseline in >50%

Lupron x 6 months for pain relief
M86-031: 50% of patients required narcotics during RX
59% still had dyspareunia at end of 6 mo RX
75% still had pain at end of 6 months RX
M86-039: no change in analgesic usage during RX
M90-471: pain returned to baseline in majority by 6 months after RX
M91-601: 40% used narcotics during RX
M92-878: > 33% of patients stopped RX before 1 year
Lupron: BMD loss, adverse events higher than reported
Abbott interference in medical education

Of 22 authors, 8 (36%) were employees or ex-employees of AbbVie with stock or stock options; an increase from Lupron era (0% – 33% of authors)
The first draft of the manuscript was written by an AbbVie employee.

Elagolix is not indicated for:
- Tenderness on pelvic exam
- Pelvic nodularity (deep endometriosis)
- Severe or deep endometriosis
- Ovarian endometriomas > 3cm
- GI, GU endometriosis
- Diaphragmatic endometriosis

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Informed consent

1960’s BCP
1970’s danazol
1980’s progesterone
1990’s Lupron
2000’s Mirena
2018 Orilissa

What’s wrong with this picture?

It is simply no longer possible to believe much of the clinical research that is published... Marcia Angell, former Editor-in-chief NEJM

Most patients will not respond to Orilissa. Not a cure, like all hormonal medical Rx.
Genetic basis of the embryonic origin of endometriosis

Genome-Wide Association Study of SNPs

GREB1
WNT4
FN1
KDR
ID4
7p15.2
CDKN2A
-EN
BS

Hidden seeding in:
Colon
Ovary
Lymph nodes

From: Redwine, Hopton editorial re:


Cochrane reviews for pain:
medroxyprogesterone better than placebo but no better than low dose BCP or Lupron;  Lupron better than gestrinone.

Gestrinone no better than danazol, worse than Lupron for dysmenorrhea but better than Lupron for dyspareunia.

Combined oral contraceptives better than placebo for dysmenorrhea but low quality evidence. BCP equal to goserelin

THE END
CULTURAL AND LINGUISTIC COMPETENCY

Governor Arnold Schwarzenegger signed into law **AB 1195** (eff. 7/1/06) requiring local CME providers, such as the AAGL, to assist in enhancing the cultural and linguistic competency of California’s physicians (researchers and doctors without patient contact are exempt). This mandate follows the federal Civil Rights Act of 1964, Executive Order 13166 (2000) and the Dymally-Alatorre Bilingual Services Act (1973), all of which recognize, as confirmed by the US Census Bureau, that substantial numbers of patients possess limited English proficiency (LEP).

**California Business & Professions Code §2190.1(c)(3)** requires a review and explanation of the laws identified above so as to fulfill AAGL’s obligations pursuant to California law. Additional guidance is provided by the Institute for Medical Quality at [http://www.imq.org](http://www.imq.org).

**Title VI of the Civil Rights Act of 1964** prohibits recipients of federal financial assistance from discriminating against or otherwise excluding individuals on the basis of race, color, or national origin in any of their activities. In 1974, the US Supreme Court recognized LEP individuals as potential victims of national origin discrimination. In all situations, federal agencies are required to assess the number or proportion of LEP individuals in the eligible service population, the frequency with which they come into contact with the program, the importance of the services, and the resources available to the recipient, including the mix of oral and written language services. Additional details may be found in the Department of Justice Policy Guidance Document: Enforcement of Title VI of the Civil Rights Act of 1964 [http://www.usdoj.gov/crt/cor/pubs.htm](http://www.usdoj.gov/crt/cor/pubs.htm).

**Executive Order 13166, “Improving Access to Services for Persons with Limited English Proficiency”,** signed by the President on August 11, 2000 [http://www.usdoj.gov/crt/cor/13166.htm](http://www.usdoj.gov/crt/cor/13166.htm) was the genesis of the Guidance Document mentioned above. The Executive Order requires all federal agencies, including those which provide federal financial assistance, to examine the services they provide, identify any need for services to LEP individuals, and develop and implement a system to provide those services so LEP persons can have meaningful access.

**Dymally-Alatorre Bilingual Services Act** (California Government Code §7290 et seq.) requires every California state agency which either provides information to, or has contact with, the public to provide bilingual interpreters as well as translated materials explaining those services whenever the local agency serves LEP members of a group whose numbers exceed 5% of the general population.

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