Title: The sepsis in obstetrics score (SOS): A model for predicting morbidity from sepsis in pregnancy

Authors: Catherine M. Albright, MD
Preceptor: Brenna Anderson, MD
Other authors: T. N. Ali, MD, Dwight Rouse, MD, Vrishali Lopes, MS

Objective: To establish an emergency department (ED) scoring system that takes into account the physiologic changes of pregnancy in order to better predict clinical deterioration in pregnant and post-partum women with signs or symptoms suggestive of sepsis.

Methods: Retrospective cohort of pregnant and postpartum patients who presented to the ED and underwent blood culture or influenza swabbing. The Sepsis in Obstetrics Score (SOS) was developed by modifying validated scoring systems which are based on easily obtained parameters in a pre-hospital setting (temperature, heart rate, blood pressure, respiratory rate, oxygen saturation, white blood cell count, band count, and lactic acid concentration). The SOS modifications were specific to the metabolic and physiologic changes of pregnancy.

The primary outcome was intensive care unit (ICU) admission within 48 hours of presentation. Secondary outcomes were admission to a telemetry unit, length of stay, positive blood cultures, positive flu swabs, antibiotic use, fetal outcome, and maternal mortality. Assuming a 2% ICU admission rate, to detect an area under the curve (AUC) of $\geq 0.7$ with a power of 80%, 17 ICU admissions, or 850 total patients were needed.

Results: Between February 2009 and May 2011, 964 charts were identified. 850 were found to be eligible and were abstracted. There were 9 ICU (1.1%), 32 telemetry admissions (3.8%), and no maternal deaths. The SOS score had an overall AUC of 0.97 for ICU admission. A score $\geq 6$ had an AUC of 0.92 with a sensitivity of 88.9%, a specificity of 95.2%, a positive predictive value of 16.7%, and a negative predictive value of 99.9% for ICU admission, with an adjusted odds ratio of 109 (18 – 661). An SOS score $\geq 6$ was associated with ICU admission, telemetry unit admission, positive blood cultures, and fetal tachycardia.

Conclusion: By using a scoring system modified for physiologic changes specific to pregnancy, we were able to predict those patients at high risk for transfer to the ICU within 48 hours of presentation to the ED. Prospective validation of SOS is warranted.

Title: Reproductive coercion: A prevalence study

Authors: Lindsay E. Clark, MD
Preceptors: Rebecca H. Allen, MD, MPH, Amy S. Gottlieb, MD, Vinita Goyal, MD, MPH
Other Authors: Christina A. Raker, ScD

Objective: Reproductive coercion (RC) is male behavior to control pregnancy and pregnancy outcomes of female partners. RC includes males pressuring partners to become pregnant (pregnancy coercion) and damaging or preventing access to contraception (birth control sabotage). RC is estimated to occur in 19% of women seeking reproductive health services. Experiencing RC is strongly associated with intimate partner violence (IPV) victimization. To date, RC has been studied only in select populations. This investigation aims to estimate the prevalence of RC in a large obstetrics and gynecology clinic at an academic health center. Additionally, the study will estimate the prevalence of IPV in relationships with RC.

Methods: The study involves a cross sectional anonymous survey which utilizes a 28-item, self-administered questionnaire. All women ages 18-44 presenting to the Women’s Primary Care Clinic at Women and Infants Hospital of Rhode Island for general obstetrics and gynecology visits are eligible for participation. The questionnaire includes 14 RC questions derived from prior studies. Women who answer “yes” to any of these questions are considered positive for RC and are then assessed for IPV with a previously validated screening tool.
**Results:** 595 women (83.8% of those approached) have completed the survey to date. This sample had a mean age of 26.2 (±6.3) years, 58.3% were currently pregnant, 46.9% had some college education or more, and the majority (68.7%) relied on Medicaid. Ninety-four (15.8%) reported reproductive coercion (95% CI 13.0-19.0%), 67 (11.3%) pregnancy coercion (95% CI 8.7-13.8%), and 55 (9.2%) birth control sabotage (95% CI 6.9-11.6%). Of the women who experienced RC, 31.9% also reported IPV in that relationship (95% CI 22.7-42.3%).

**Conclusion:** Reproductive coercion is common in women seeking routine care in a large obstetrics and gynecology clinic. Approximately one third of women reporting RC also reported IPV in the same relationship. These findings have tremendous implications for family planning counseling as well as prevention of unintended pregnancy. At a minimum, all reproductive-aged women presenting for routine obstetric and gynecologic care should be screened for reproductive coercion.

**Title:** The effect of immediate postpartum compared to interval etonogestrel contraceptive implant insertion on removal rates for bleeding

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**Objective:** To compare the discontinuation rate of the etonogestrel contraceptive implant due to irregular vaginal bleeding among women with immediate postpartum and interval placement.

**Methods:** We performed a retrospective cohort study comparing women who underwent immediate postpartum (within 96 hours of delivery) insertion of the etonogestrel contraceptive implant at Women and Infants Hospital to those who underwent interval (more than 6 weeks postpartum) insertion at the Women’s Primary Care Center between January 2008 and December 2010. Charts were reviewed for implant removal, reasons for removal, and number of clinic visits prior to removal as well as sociodemographic and clinical characteristics. A chi-squared test was used to compare the primary outcome between cohorts.

**Results:** To date, 203 records have been reviewed; 110 in the immediate postpartum insertion group and 93 in the interval insertion group. The average age at insertion was 22.7 (± 5.4) years. Women in the postpartum group were more likely to be non-Hispanic white and on Medicaid compared to the interval group. Overall 35% of women in the postpartum group and 39% of women in the interval group requested implant removal due to side effects prior to the 3-year duration of efficacy (p=0.6, OR 0.84, 95% CI 0.47-1.48). Removals for irregular bleeding occurred in 22% of the postpartum group compared to 24% in the interval group (p=0.9, OR 0.90, 95% CI 0.47-1.74). There were no characteristics predictive of premature implant removal in general or for bleeding in either group.

**Conclusion:** Approximately one-fifth of etonogestrel contraceptive implant users requested premature removal due to irregular bleeding. Delaying implant insertion after the postpartum period does not reduce premature removal. Other mechanisms to help women manage irregular bleeding due to the implant are needed.

**Title:** Adherence patterns to National Comprehensive Cancer Network (NCCN) guidelines for referral to cancer genetic professionals

**Authors:** Terri Febbraro, MD, MPH

**Preceptor:** Ashley Stuckey, MD

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**Objective:** Genetic predisposition is responsible for 5-10% of breast cancer, 10% of ovarian cancer and 2-5% of uterine cancer. The National Comprehensive Cancer Network (NCCN) established guidelines delineating appropriate candidates for genetic counseling and testing. This study aims to determine referral patterns for genetic counseling and testing among women who met NCCN referral guidelines.

**Methods:** Utilizing an institutional tumor registry database, patients from Women’s oncology were identified who met a subset of NCCN guidelines for genetic evaluation referral between 2004-2010. Patients diagnosed with ovarian cancer, breast cancer < 50 years of age, or uterine cancer < 50 years of age were included. A retrospective electronic chart review was conducted. Statistics were analyzed using SAS version 9.2 (SAS Institute, Cary, NC); categorical variables were compared by chi-square or Fisher's exact test and
continuous variables were compared by ANOVA. Logistic regression was used to calculate odds ratios and 95% confidence intervals.

**Results:** 601 women were included (215 uterine cancer, 182 breast cancer and 204 ovarian cancer). Overall genetics referral rate was 18.1%. 30.8% of eligible breast cancer patients, 13.5% of uterine cancer patients, and 11.8% of ovarian cancer patients were referred (p<0.0001). Younger age, breast cancer diagnosis, and family history of cancer were all significant predictors for referral. The odds of being referred increased with the number of affected family members. Among patients referred, 67% consulted with a genetics counselor and 94.5% underwent genetic testing. 50% of uterine cancer, 26.3% of breast cancer and 50% of ovarian cancer were found to harbor a genetic mutation. Once referred, none of the variables studied impacted patients' choices to proceed with testing. 57% of women opting for a prophylactic contralateral mastectomy were referred to counseling.

**Conclusions:** Genetic counseling and testing is being underutilized in women who meet NCCN referral guidelines. Age, breast cancer diagnosis, and family history appear to be predictive of referral for genetic evaluation. While referral rates appear to be increasing over time, further research is needed to determine additional factors that may impact not only referral rates but also subsequent care for women with possible genetic predispositions to cancer.

**Title:** Clinical use of antenatal magnesium sulfate for fetal neuroprotection: Evaluation of practice change over time

**Authors:** Karen J. Gibbins, MD

**Preceptor:** Dwight J. Rouse, MD

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**Objective:** Recent randomized trials show that antenatal magnesium sulfate (MgSO4) reduces the risk of cerebral palsy among children who survive early preterm birth. However, there are no reports characterizing the actual clinical use of MgSO4 for this purpose. In 2008, our center implemented use of MgSO4 for neuroprotection for threatened delivery prior to 32 wks, and herein we review our experience with magnesium utilization before and after this policy change.

**Methods:** We used a computerized database to identify a random sample of gravidas admitted because of threatened delivery prior to 32 wks, and systematically reviewed the maternal and corresponding neonatal records. The primary study outcome was the % annual use of MgSO4 among sampled patients. Secondary outcomes were total MgSO4 dose, retreatment, and associated complications. A sample size of 75 gravidas/yr was calculated to provide 80% power to detect a 15% increase in use from 2007-2011.

**Results:** A total of 373 charts have been reviewed. The percent of sampled patients who received MgSO4 was 20% (95% CI 9.1-35.6) in 2007, 51% (95% CI 40.8-61.1) in 2008, 76% (95% CI 66.4-84.0) in 2009, 81% (95% CI 71.9 – 88.2) in 2010 and 93.9% (95% CI 79.8 – 99.3) in 2011 (P<0.0001). These differential rates are accounted for by the utilization of MgSO4 for neuroprotection. Among mothers who delivered prior to 32 wks, % MgSO4 receipt was 28% (95% CI 12.1 – 49.4) in 2007, 55.6% (95% CI 43.4-67.3) in 2008, 77.5% (95% CI 66.8-86.1) in 2009, 89.7% (95% CI 79.9 – 95.8) in 2010 93.1% (95% CI 77.2 – 99.2) in 2011 (P<0.0001). Mean dose of MgSO4 among deliveries prior to 32 wks was 57.4 g (SD 50.6) and similar across diagnoses. Dosing patterns were stable over time. Patients received a median of 1 MgSO4 course (range 1-5). No serious maternal treatment associated complications were noted (e.g., respiratory or cardiac compromise, dangerously elevated serum magnesium concentration).

**Conclusion:** From 2007-2011 use of antenatal MgSO4 has increased substantially in our institution. Retreatment was infrequent and maternal harm not evident. MgSO4 for neuroprotection can be safely administered outside of clinical trials, with rapid scale-up to eligible candidates.

**Title:** Impact of age on prevalence of pelvic floor disorders in a community-dwelling, professional group of African American women

**Authors:** Kavita Mishra, MD

**Preceptor:** Vivian W. Sung, MD, MPH

**Other Authors:** Blair B. Washington, MD, Christina A. Raker, ScD
**Objective:** To estimate the association between age and pelvic floor disorder (PFD) symptom prevalence among community-dwelling, professional African American (AA) women. A secondary objective was to estimate the association between age and life impact in symptomatic women.

**Methods:** A secondary analysis was performed of a cross-sectional study evaluating barriers to help-seeking in AA women. All women attending the 37th National Assembly of The Links Inc., a volunteer service organization of professional Black women, were eligible. Women were excluded if they could not read English, were not U.S. citizens or <20 years old. The questionnaire included: demographics, history of PFD symptoms, diagnoses, the Pelvic Floor Distress Inventory (PFDI-20) and Pelvic Floor Impact Questionnaire (PFIQ-7). Women were categorized into three age groups: ≤ 50, 51-65, and >65 years.

**Results:** Of 568 questionnaires distributed, 372 (66%) were completed and 355 (95%) met inclusion criteria. The mean age was 57 ± 11 years; 28% were ≤ 50 years, 50% were 51-65 years, and 22% were >65 years. 76% of women had private insurance, 78% held a graduate level degree and 71% reported a household income ≥ $100,000/year. The prevalence of any PFD symptom was 31% and did not differ by age group (24%, 35%, and 33%, for women ≤ 50, 51-65, and >65 years, respectively, p>0.05). In the subset of women reporting PFD symptoms (N=110), increasing age was associated with increased urinary incontinence (UI) symptoms (65%, 75% and 96% for women ≤50, 51-65, and >65 years, respectively, p=0.02), but was not associated with pelvic organ prolapse or fecal incontinence symptoms. Controlling for BMI, parity and vaginal deliveries, women 51-65 years had higher odds of PFDs than women ≤50 years (OR 1.94, CI 1.05-3.58, p=0.03). Increasing age was also associated with worse mean Urinary Distress Inventory (UDI-6) scores [9 vs. 15 vs. 17, p=.01] and worse mean Urinary Impact Questionnaire (UIQ-7) scores [2 vs. 5 vs. 5, P=.03].

**Conclusion:** Among community-dwelling, professional AA women, women 51-65 years were more likely to have PFD symptoms when compared to women ≤50 years. Among women with PFD symptoms, advanced age was associated with increased prevalence of UI symptoms, symptom bother and life impact.

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**Title:** The effects of age on treatment and outcomes in women with stage IB-IIB cervical cancer.

**Authors:** Dario R. Roque, MD

**Preceptors:** Don S. Dizon, MD, Katina Robison, MD

**Other Authors:** Beth Cronin, MD, Gary Frishman, MD, Tina Rizack, MD, Vrishali Lopes, MS

**Objective:** Advanced age may affect the treatment choice and subsequent outcome in elderly patients with cervical cancer. Given the potential for cure with either surgery or chemoradiation in early stage disease, we aimed to determine whether a patient’s age influenced the treatment received and the outcome.

**Methods:** Our retrospective cohort identified a total of 303 patients diagnosed with Stage IB1 through IIB cervical carcinoma who were treated at our institution between 2000 and 2010. The eligible patients were divided into two groups based on age at the time of diagnosis: <65 and ≥ 65 years. Adjusted odd ratios were calculated to determine variables associated with treatment received (chemoradiation or surgery). Single and multivariate Cox proportional hazards modeling were used to estimate hazard ratios for variables associated with disease specific survival.

**Results:** Of the patients meeting inclusion criteria, 253 were <65 years and 50 were ≥ 65 years. The distribution of tumor histology, stage and grade was not different between the two groups. After adjusting for histology, stage and a validated comorbidity score, the odds ratio of receiving chemoradiation vs. surgery for the cohort ≥ 65 years was 1.69 (OR 95% CI: 0.68-4.17). There was no significant difference in the type of primary treatment received between the two groups (P = 0.16). Persistent disease was seen in 46 (18%) of the younger patients and in 19 (38%) of the older patients (P = 0.02). In the elderly cohort the treatment received did not influence disease-specific or all-cause mortality. However, compared to women under 65, older women treated surgically had increased disease specific (HR 3.18, 95% CI: 0.98-10.3) and all-cause mortality (HR 6.53, 95% CI: 2.57-16.6).

**Conclusions:** Age does not appear to be a factor influencing the treatment received by patients with Stage IB-IIB cervical cancer. The type of treatment received does not seem to affect disease-specific mortality among older versus younger women. However, surgery was associated with a 6.5-fold increased risk of all cause mortality among older women when compared to women under 65 (HR 3.18, 95% CI: 0.98-10.3) and all-cause mortality (HR 6.53, 95% CI: 2.57-16.6).
Presenting Fellows

Title: Does every patient with breast cancer need a sentinel lymph biopsy?
Author: Heather M. King MD
Preceptor: Jennifer Gass MD
Other authors: Susan Koelliker, MD, Christina A. Raker, ScD, David Edmonson, MD, Don Dizon, MD

Objective: SLNB does have its own comorbidities: 7% risk of lymphedema, injection cost and tissue processing. Could the use of AXUSFNA safely eliminate the need for SLNB in a select group of breast cancer patients? We aim to identify the AXUSFNA false negative cohort and describe their characteristics in comparison to the AXUSFNA true positive cohort.

Methods: Breast Cancer patients who had an AXUSFNA in radiology registry from 1/1/2006-8/1/2009. These patients were cross-referenced with the tumor registry patients who were node positive. Study population consists of 134 patients. We reviewed the AXUSFNA and SLNB/ALND final pathology reports. Variables collected on each patient: age, BMI, type of surgery, tumor histology, grade, lymphovascular invasion (LVI) on final pathology and core biopsy, Bloom Richardson’s score (BRS), size of tumor, DCIS, grade of DCIS, DCIS% and receptor status. The date collected from AXUSFNA included number of nodes seen, size of node, and description of node. The data was then analyzed using statistical software: STAT 10.

Results: AxUSFNA Sensitivity 64.9%, AxUSFNA False Negative Rate (FNR) 35.1%. Comparison of demographic and tumor characteristics between true positives and false negatives revealed smaller tumor size, greater DCIS, absence of extracapsular extension, and smaller size of metastatic focus were statically significant in predicting a false negative AxUSFNA. Multivariable logistic regression revealed extracapsular extension was no longer statistically significant.

Conclusion: Axillary US/FNA has a FNR of 35%, too high to omit a sentinel node biopsy in patients with a negative Axillary US FNA. Removing suspicious nodes on US and LVI on core from the false negative cohort drops False Negative Rate to 15% for AXUSFNA. This approaches 11% FNR seen in SLNB following neoadjuvant chemotherapy and the FNR of 10% in B-32. Correlation between the presence of LVI on final pathology and core biopsy is poor. Sensitivity of the core biopsy to predict LVI on final pathology was 24%. 65% of the false negative cohort had benign appearing lymph nodes on ultrasound, of these 50% contained macro metastasis. Therefore, until genomic analysis supplants nodal assessment in determining adjuvant recommendation SLNB remains the most accurate tool for axillary staging.

Title: 7 Methyl Indole Ethyl Isothiocyanate- A Novel Cytotoxic Agent for Endometrial Cancer
Authors: Katrin Kristjansdottir, MD
Preceptor: Rakesh Singh, PhD
Other authors: Kyu Kwang Kim, PhD, Joong Sub Choi, PhD, Thilo S Lange PhD, Laurent Brard, MD, PhD, Richard G Moore, MD

Objective: Chemotherapy options for advanced endometrial cancer are limited and newer therapeutic agents are urgently needed. 7Methyl Indole Ethyl Isothiocyanate (7Me-IEITC) is a novel agent with antitumor activity in ovarian cancer cell lines and neuroblastoma cell lines. The objective of this study is to evaluate 7Me-IEITC antitumor effect in endometrial cancer cell lines.

Methods: Cell viability of endometrial cancer cell lines (KLE, ECC-1) in conjunction with an ovarian cancer cell line (IGROV-1) after treatment with 7Me-IEITC was determined using MTS assay. Morphological and apoptotic responses of KLE cells were studied by fluorescence microscopy (DAPI staining, TUNEL assay). Changes of the mitochondrial transmembrane-potential, the effect of reactive oxygen species (ROS) production and cell-cycle progression were studied by FACS analysis. To determine the molecular mechanism and role of ROS activation in 7Me-IEITC induced cytotoxicity, cells were pretreated with ascorbic acid in the presence or absence of drug. Expression profiles of MAP-Kinases, pro-survival factors, cell-cycle regulators and the activation of PARP-1 and caspases were studied by western blotting.
Results: 7Me-IEITC reduced the cell viability of KLE cells, ECC-1 cells (IC\textsubscript{50} values~20\textmu M). At sub-cytotoxic concentration (8\textmu M), 7Me-IEITC caused rapid loss of the mitochondrial transmembrane-potential and strong apoptosis in KLE cells. There was down-regulation of pro-survival kinases and, up-regulation of pro-apoptotic BCL2 family members along with activation of caspases. 7Me-IEITC acted as an anti-proliferative agent and arrested cell cycle progression of KLE cells in S-phase. Pretreatment with ascorbic acid abrogated caspase 3/7, SAPK/JNK activation and cleavage of PARP-1 suggesting that 7Me-IEITC mediated its cytotoxicity in these endometrial cancer cell lines primarily by ROS production.  
Conclusion: 7Me-IEITC has antitumor effects in endometrial cancer cell lines and may be developed as a potential therapeutic drug for endometrial cancer.

Title: Does Hemoglobin A1c value determine risk of congenital heart disease in pregestational diabetes?
Authors: Roman Starikov, MD
Preceptor: Donald Coustan, MD
Other Authors: Edward Chien, MD, Michael Paglia, MD, Vrishali Lopes, MS
Objective: To identify a critical hemoglobin A1c (HbA1c) level associated with an increased risk of congenital heart disease (CHD) in women with pre-existing diabetes.
Methods: Retrospective review of diabetic gravidas, whose HbA1c value was recorded during pregnancy. The incidence of prenatally diagnosed CHD was calculated and stratified by HbA1c level. Neonatal charts were reviewed for confirmation of the diagnosis.
Results: Total 347 patients were identified. Eight fetuses were identified prenatally with CHD. Neonatal echocardiography confirmed CHD in four infants and excluded CHD in two infants. Autopsy confirmed CHD in one patient. One infant did not have neonatal echocardiogram but newborn physical exam was consistent with CHD. Neonatal echocardiography identified additional five infants with CHD.
Conclusions: On case of congenital heart disease was identified in patients with Hgb A1c level <6.5\%, whereas ten cases were identified in patients with HgA1C level \geq 6.5\%. However, our study failed to identify critical HbA1c level.

Title: Anti-mullerian hormone upregulates androgen synthesis in human theca cells
Authors: Wendy Vitek, MD
Preceptor: Jared Robins, MD
Other authors: Sandra Carson, MD, Lori Underhill, PhD, Jeffrey Morgan, PhD
Objective: While AMH has been identified as an autocrine and paracrine regulator of steroidiogenesis in granulosa and leydig cells, little is known regarding the effect of AMH on theca cells. The objective of this research is to determine the effect of anti-mullerian hormone (AMH) on human theca cell androgen synthesis in vitro.
Method: Primary cultured human theca cells were evaluated for the presence of anti-mullerian hormone type II receptor (AMHR2) by immunocytochemistry. After treating monolayer theca cells and 3D co-cultured theca and granulosa cells with recombinant human AMH, CYP17 transcript levels were analyzed by RT-PCR. Testosterone levels in the culture media were quantified by ELISA. The effect of AMH on theca cell proliferation was evaluated by MTT assay and cell counts.
Results: AMHR2 was present in the perinuclear cytoplasm of human theca cells. AMH significantly upregulated expression of CYP17 by 1.9 fold (P=0.02) in monolayer cell culture and in 3D co-cultured theca and granulosa cells when compared to control. AMH significantly increased testosterone production (P<0.001) in cultured human theca cells when compared to control. Anti-mullerian hormone did not alter theca cell proliferation.
Conclusions: Human theca cells express AMHR2 and AMH upregulates androgen synthesis by inducing CYP17 expression. These findings demonstrate that AMH stimulates theca cell steroidogenesis in contrast to its suppressive effect on leydig cell androgen synthesis. This data suggests a dimorphic role of AMH in the ovary and testis and a new paracrine relationship between granulosa and theca cells.
Objectives: To develop an educational video (EV) aimed at addressing the needs of patients with overactive bladder (OAB) considering sacral nerve stimulation (SNS). This was accomplished through three aims: 1) Identifying patient information needs through focus groups; 2) video developing an innovative video based on focus group findings domains; 3) pilot-testing our educational video (EV) and comparing patient knowledge and attitudes after watching our EV versus the standard manufacturer video (MV).

Methods: Aim 1: 5 semi-structured focus groups were conducted to identify patient knowledge gaps, information needs, patient-acceptable terminology, and video content preferences. Each session was transcribed, coded, and examined using an iterative method to ensure identification of all important domains.
Aim 2: We created an EV based on domains identified in focus groups combining patient footage, 3-dimensional animation, and medical literature.
Aim 3: Women eligible for SNS were randomly assigned to watch the EV versus the MV and completed pre-and post-test knowledge and attitude questionnaires. We compared within and between group changes in knowledge.

Results: In aim 1, 31 women participated in our focus groups and we identified the following knowledge gaps: SNS device efficacy, expectations, recovery, complications, side-effects, anatomy, surgery, device maintenance, post-operative restrictions, and general knowledge. In Aim 2, a 16-minute EV was developed targeting these domains.
For Aim 3, 20/40 women thus far have been randomized to watch the EV versus MV. Within groups, knowledge scores improved significantly in both groups (P<.05). Between groups, the EV group had higher improvement in knowledge scores than the MV group (delta = 76.6 vs 24.2 percent, P<0.0001). Women who watched the EV video reported higher satisfaction (P<.05).

Conclusions: Women with OAB considering SNS therapy have specific information and decision-making needs. We developed a video that addresses these needs and is associated with improvements in knowledge.