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OB/GYN Clinical [ALERT]

Evidence-based commentaries on women's reproductive health

ABSTRACT & COMMENTARY

# Are There Risks With Early-term Birth?

*By John C. Hobbins, MD*

*Professor, Department of Obstetrics and Gynecology, University of Colorado School of Medicine, Aurora*

**Dr. Hobbins reports no financial relationships relevant to this field of study.**

SYNOPSIS: The authors of a multicenter study suggest that composite neonatal outcome is worse when pregnancy is interrupted in uncomplicated pregnancies at 37 to 38 weeks, even with documented fetal lung maturity, compared to pregnancies delivered at full term (39 to 40 weeks).

SOURCE: Tita ATN, Jablonski K, Bailit JL, et al. Neonatal outcomes of elective early-term births after demonstrated fetal lung maturity. *Am J Obstet Gynecol* 2018;219:296.e1-296.e8.

In a blockbuster study that was covered in the April 2018 issue of *OB/GYN Clinical Alert*, Grobman et al suggested that intervention at 39 weeks in well-dated, seemingly normal pregnancies improves perinatal outcome.[1] So, why not push back the envelope further to 37-38 weeks?

These researchers at the Eunice Kennedy Shriver National Institute of Child Health and Human Development Maternal-Fetal Medicine Units Network evaluated data from 11,502 patients in 25 hospitals from 2008 to 2011, where, on occasion, patients were induced between 37 and 38 weeks for no obvious indications other than having a positive amniotic fluid test for fetal lung maturity. Tita et al compared neonatal outcomes with 47,957 full-term births in the overall patient population of uncomplicated pregnancies. Fetal pulmonic maturity testing was conducted on 180 of the early-term "normal" patients and they were delivered. The authors studied a variety of adverse outcome measures, including continuous positive airway pressure (CPAP), transient tachypnea of the newborn (TTN), sepsis, hypoglycemia, hyperbilirubinemia, and five-minute Apgar scores < 7. Other variables included newborn intensive care unit (NICU) admission and the need to stay there longer than two days.

For the early-term deliveries, the investigators noted significant increases in the need for CPAP (odds ratio [OR], 3.0; 95% confidence interval [CI], 1.91-8.0), hyperbilirubinemia (OR, 3.0; 95% CI, 1.8-5.0), TTN (OR, 5.5; 95% CI, 3.3-9.1), NICU

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admissions (OR, 2.8; 95% CI, 1.8-4.5), and > 2-day length of stay (OR, 4.3; 95% CI, 2.4-7.7). The composite adverse neonatal outcome was significantly worse in the early-term delivery group (OR, 3.2; 95% CI, 2.1-4.8) and remained significant (OR, 3.5; 95% CI, 1.8-6.5) when propensity score matching was applied (early-term deliveries were more common in non-Hispanic whites, smokers, and those given steroids).

## ■ COMMENTARY

Term has been defined as a pregnancy lasting more than 36 weeks. This has been divided into early-term (37 to 38 weeks) and late-term (39 to 40 weeks) segments. The data from Grobman et al dealing with late-term pregnancies unexpectedly showed that delivery at 39 weeks not only was safe, but also was associated with better outcomes compared to expectant management in late-term normal pregnancies.[1]

However, the study by Tita et al regarding early-term deliveries should give pause to anyone wishing to stray into the land of uncomplicated early-term pregnancies with this approach — even if there is documentation of pulmonary maturity.

It was surprising that during the study period, as many as 259 uncomplicated early-term patients had amniotic fluid testing for pulmonary maturity and that the 180 who tested positive delivered early. Some of these patients even took steroids for good measure (again, with a positive test). Despite the loaded hand, infants of these patients trended toward having more respiratory distress syndrome and a significantly enhanced chance of having TTN, along with other non-pulmonic adverse neonatal events. One must wonder if there really was something different about these overtly "normal" fetuses and infants who were targeted for early delivery. Nevertheless, the results of this study strongly imply that tinkering too much with the length of pregnancy does not seem to pan out. ■

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## ABSTRACT & COMMENTARY

# Opportunistic Salpingectomy at the Time of Cesarean Delivery for Postpartum Permanent Contraception

***By Rebecca H. Allen, MD, MPH***

*Associate Professor, Department of Obstetrics and Gynecology, Warren Alpert Medical School of Brown University, Women and Infants Hospital, Providence, RI*

**Dr. Allen reports she is a Nexplanon trainer for Merck.**

SYNOPSIS: In this retrospective cohort study, almost 20% of women who desired bilateral complete salpingectomy for permanent contraception at the time of cesarean delivery could not undergo the procedure because of adhesions or engorged vasculature.

SOURCE: Lehn K, Gu L, Creinin MD, Chen MJ. Successful completion of total and partial salpingectomy at the time of cesarean delivery. *Contraception* 2018;98:232-236.

Lehn et al conducted a retrospective study of all 122 women who underwent permanent contraception procedures during cesarean delivery at the University of California Davis Medical Center between November 2015 and April 2017. This time period was the first 18 months after an education program was presented to increase physician awareness of complete salpingectomy as an option for permanent contraception after cesarean delivery.

The authors collected data from the operative report, as well as demographic data, obstetric data, body mass index (BMI), medical comorbidities, previous abdominal surgeries, and smoking status. Surgical complications, blood transfusion, prolonged hospitalization (more than four days), hospital readmission, and reoperation also were evaluated. Procedure type could include complete salpingectomy, partial salpingectomy, or a mixed procedure (complete on one side and partial on the other).

The proportion of planned complete salpingectomy procedures increased from 50% in the first three months of the study to 94.1% in the last three months ($P < 0.01$). Among the 32 (26.2%) women who desired partial salpingectomy, all underwent successful procedures. For the 90 (73.8%) women who desired complete salpingectomy, 17 (18.9%) could not undergo the procedure. Surgeons performed a mixed procedure in nine women because of adhesive disease (n = 4), proximity to large vessels in the mesosalpinx (n = 3), or both (n = 2). They performed bilateral partial salpingectomy in seven women because of adhesive disease (n = 4), engorged vasculature (n = 1), or unspecified reasons (n = 2). One woman was not able to undergo any procedure because of adhesions. A history of three or more cesarean deliveries was associated with failure to perform bilateral complete salpingectomy compared to women with fewer cesarean deliveries ($P = 0.04$). There was no statistically significant difference between the two groups in operative time, estimated blood loss, need for blood transfusion, or hospital readmission.

## ■ COMMENTARY

In a U.S. study conducted between 2008 and 2013, Moniz et al estimated postpartum permanent contraception rates to be 683 to 711 per 10,000 deliveries.[1] The procedure was more common in women 35 years of age and older and during cesarean compared to vaginal delivery. Traditionally, surgeons performed a partial salpingectomy technique for postpartum procedures. This technique removes a mid-isthmic segment of fallopian tube bilaterally. Complete bilateral salpingectomy in the immediate postpartum period for permanent contraception also has been described, as interest in salpingectomy increases because of its potential to decrease the risk of ovarian cancer.[2,3] Bilateral salpingectomy for permanent contraception is safe and presumably more effective than partial salpingectomy, with a lower risk for ectopic pregnancy.[4]

Complete salpingectomy at the time of cesarean delivery has been described in several studies.[5-8] Some surgeons elect to use an electrothermal bipolar tissue-sealing instrument and others opt for traditional suture ligation. In a randomized, controlled noninferiority trial, Garcia et al compared complete and partial salpingectomy using the electrothermal bipolar tissue-sealing device at the time of cesarean delivery in 37 women.[7] Bilateral complete salpingectomy was successful in 19 of 20 women. One procedure was converted to partial salpingectomy because of adhesions. Estimated blood loss was not different between the groups. There was a a mean procedure time of 5.6 minutes in the complete salpingectomy group and 6.1 minutes in the partial salpingectomy group. In another small randomized trial, Subramaniam et al compared complete salpingectomy to partial salpingectomy in 80 women at the time of cesarean delivery, this time using suture ligation rather than the device.[8] The procedure was performed successfully in 27 of 40 (68%) women randomized to complete salpingectomy and 38 of 40 (95%) women in the partial salpingectomy group. Total operative time using the suture ligation technique was 15 minutes longer for the complete salpingectomy group compared to partial salpingectomy. There was no difference between the groups in terms of estimated blood loss or complications. Women with higher BMIs and a longer time from skin incision to tubal operation start had an increased risk of a failed procedure. The authors did not report details as to why complete salpingectomy could not be performed.

[Bilateral salpingectomy for permanent contraception is safe and presumably more effective than partial salpingectomy, with a lower risk for ectopic pregnancy.]

Lehn et al reported that 81% of women who desired complete salpingectomy had successful procedures compared to 95% in the first randomized, controlled trial and 68% in the second randomized, controlled trial described earlier. Therefore, there is a wide range of success, which likely reflects the small sample sizes in these studies. Nevertheless, the Lehn et al study added reasons why complete salpingectomy was unsuccessful in some women, mainly because of adhesions and concerns of engorged postpartum vasculature near the fallopian tubes. Studies also reflect that the electrothermal bipolar tissue-sealing device offers a faster procedure but presumably at a higher financial cost to the hospital compared to suture ligation. Women should be counseled up front that there is a possibility that surgeons may not be able to perform complete salpingectomy and that partial salpingectomy

can be offered as a backup. Of course, in some women, severe adhesions may not allow access to the fallopian tubes at all, and an alternative contraception plan should be offered. This will be true especially among women with a history of multiple cesarean deliveries. As opportunistic salpingectomy for permanent contraception becomes a more popular and accepted option for patients, surgeons will gain more experience. The data show that the procedure is safe and adds minimal operative time, but that some women may not be appropriate candidates. ■


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## ABSTRACT & COMMENTARY

# Help-seeking Behavior for Pelvic Floor Dysfunction


***By Chiara Ghetti, MD***

*Associate Professor, Obstetrics and Gynecology, Division of Female Pelvic Medicine and Reconstructive Surgery, Washington University School of Medicine, St. Louis*



**Dr. Ghetti reports no financial relationships relevant to this field of study.**



SYNOPSIS: Women are more likely to seek help for pelvic floor symptoms if they have increased bother and are less likely to seek help if they perceive their symptoms as normal.


SOURCE: Tinetti A, Weir N, Tangyotkajohn U, et al. Help-seeking behaviour for pelvic floor dysfunction in women over 55: Drivers and barriers. *Int Urogynecol J* 2018;29:1645-1653.

The objective of this study was to identify drivers and barriers to help-seeking behavior for pelvic floor disorders in older women. The study included women ≥ 55 years of age living independently in Australia. This was a cross-sectional survey of women at two retirement communities, at two family practice offices, and on Facebook using a combination of electronic and paper questionnaires.

The main outcomes were general pelvic floor symptoms, measured by Australian Pelvic Floor Questionnaire (APFQ) scores, and help-seeking behavior, measured using the Barriers to Incontinence Care Seeking Questionnaire with author modifications. The APFQ includes four subscales: bladder dysfunction, bowel dysfunction, sexual dysfunction, and prolapse. Subscale scores range from 0-10, where higher scores represent greater bother. The total score is a sum of the subscale scores. A total of 4,980 participants were invited (808 paper; 4,172 social media) to participate in the study. Of these, 427 (8.5%) agreed to participate; response rates were 27% from paper survey and 5% from Facebook. Responses were excluded for subjects who did not sign consent, who were out of the age range, and who submitted incomplete questionnaires. A total of 376 responses were included. Responders were a mean age of 68.6 years, and 98.7% of respondents scored greater than 0, indicating some pelvic floor bother.

All subscale scores were near 2.2 or less, suggesting most respondents had some pelvic floor symptoms. Fifty percent of women with symptoms measured by APFQ sought help. A large number of patients who sought help did so through a general practitioner or gynecologist, and the most common treatments employed were advice-giving and physical therapy, followed by medication and surgery. Respondents identified the following barriers to help seeking: perception of PFD as a normal part of aging (29%), self-managing their condition (21%), the condition was not serious enough to warrant treatment (18%), embarrassed to seek help (13%), and symptoms

did not bother them (13%). The higher the APFQ score, the more likely a respondent was to seek help. The highest drivers to seeking help were increased bother (51.4%), worsening symptoms (49.1%), and discovery of available treatment (30.6%).

## ■ COMMENTARY

I was particularly drawn to the subject of help-seeking in women with pelvic floor disorders. As a female pelvic medicine subspecialist, I always have been curious about what drives bother, help-seeking, and decision-making in women with pelvic floor disorders. Pelvic floor disorders have a long history as silent diseases; too frequently, women are embarrassed to discuss the subject, even with their closest female friends and family. Pelvic floor disorders have been shown to affect not only activities of daily living but also mental health.[1-3] This study suggests that both bother and symptoms drive help-seeking in women with pelvic floor disorders, and that is counteracted by barriers, such as the perception that their experience is a normal part of aging. This is a barrier that providers can overcome through patient education.

This study had several limitations, including the use of a small population in one country, an overall low response rate with the electronic portion of the survey, and a poor description of the measures used to assess primary outcomes. Tinetti et al used the APFQ, which, despite other existing pelvic floor questionnaires, was developed to assess broader pelvic floor symptoms, including bladder, bowel, and sexual function and prolapse symptoms; symptom severity; and the effect on quality of life. However, its scoring is difficult to uncover.[4-5] The authors also used the Barriers to Incontinence Care Seeking Questionnaire, which was validated in an incontinence population and not in women with other pelvic floor disorders or community-dwelling women. In addition, they did not describe their own modifications or scoring methodology.[6]

Despite these limitations, their key findings are important. First, many women believe or are told that pelvic floor disorders are a normal part of aging. Second, women are embarrassed to discuss their problem. Third, women often are unaware that treatment options exist. Providers need to recognize these barriers that prevent women from seeking help for their pelvic floor disorders. These findings reinforce results from other authors. Dunivan et al reported focus group results in which women described feeling ashamed of their pelvic organ prolapse and expressed discomfort speaking with anyone, including physicians, about their symptoms.[7] Themes from focus groups conducted by our group highlighted the lack of information available to women regarding pelvic prolapse and indicated that women would like to be asked about prolapse at regular gynecologic visits.[8] McKay et al recently found that peripartum women lack knowledge about urinary incontinence and prolapse.[9]

[Pelvic floor disorders are not just the consequence of aging, and women should not "just have to live" with the pelvic floor symptoms that bother them.]

In a survey of general gynecologists, Yune et al found the comfort level with treating pelvic floor disorders differed widely among gynecologists. Although most are comfortable offering treatment for stress incontinence and prolapse, younger gynecologists tended to be comfortable with fewer treatment options. Since full discussion of treatment options for pelvic floor options increasingly may fall within the realm of urogynecologists, obstetrician-gynecologists are perfectly poised to ask patients about their pelvic floor symptoms regularly and educate them about appropriate treatment choices. In September 2018, the Women's Preventive Services Initiative (WPSI) published its screening recommendations for urinary incontinence in women.[11] Following a systematic literature review, the WPSI recommended screening women for urinary incontinence annually. The WPSI based its recommendation on the high prevalence of urinary incontinence and the significant effect of incontinence on women's health, quality of life, and function. Ideally, this annual screening would assess not only whether women experience symptoms of urinary incontinence but also whether incontinence affects their activities and quality of life using validated measures. In addition, the WPSI recommended referring women for additional evaluation and management if needed.

By adopting these screening recommendations, providers easily could broaden screening to include other pelvic floor disorders including prolapse, fecal incontinence, and pelvic pain. Although more common as women age, pelvic floor disorders are not just the consequence of aging, and women should not "just have to live" with the pelvic floor symptoms that bother them. ■

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ABSTRACT & COMMENTARY

# Venous Thromboembolism Risk After Abortion

***By Jeffrey T. Jensen, MD, MPH, Editor***

*Leon Speroff Professor and Vice Chair for Research, Department of Obstetrics and Gynecology, Oregon Health & Science University, Portland*

**Dr. Jensen reports that he is a consultant for and receives grant/research support from Bayer, Merck, ContraMed, and FHI360; he receives grant/research support from Abbvie, HRA Pharma, Medicines 360, and Conrad; and he is a consultant for the Population Council.**

SYNOPSIS: Women experience a two-fold increase in risk of venous thrombosis (relative to nonpregnant women) following induced abortion, but a more than six-fold overall reduction in risk of thrombosis compared to women who continue the pregnancy to term.

SOURCE: Liu N, Vigod SN, Farrugia MM, et al. Venous thromboembolism after induced abortion: A population-based, propensity-score-matched cohort study in Canada. *Lancet Haematol* 2018;5:e279-e288.

We know that pregnancy increases the risk of thromboembolic disorders, but few researchers have evaluated the risks associated with abortion specifically. To close this knowledge gap, Liu et al used data available from the universal healthcare system of Ontario, Canada, where all healthcare, including access to abortion and obstetrics services, receives public funding. Health outcomes recorded in several databases were linked by unique patient identifiers. For this analysis, the authors identified all primigravid women aged 15-49 years who had an induced abortion (< 20 weeks' gestation) between Jan. 1, 2003, and Dec. 31, 2015. They then used a propensity score to match patients to primigravid women who had a live birth (1:1 match) or nulligravid women who were not pregnant on the procedure date of the matched counterpart and who did not conceive within one year afterward (5:1 match). Liu et al defined the index date as the induced abortion procedure date for the induced abortion group and the matched nonpregnant group, and the delivery date for the live birth group. The authors generated hazard ratios (HRs) of the 42-day risk of venous thromboembolism (VTE) after the index date using Cox proportional hazard models. They confined the analysis to primigravid women to avoid the inclusion of more than one pregnancy per woman during the study period and to minimize the influence of previous pregnancy events (e.g., VTE) on the therapeutic decision-making (e.g., prophylactic anticoagulation or the decision to terminate the pregnancy) in the index pregnancy.

The authors identified 176,001 cases of induced abortion during the study interval, and propensity-matched these to 880,005 nonpregnant women and 176,001 primigravid women in the live birth group. Propensity matching was effective, with standardized differences of < 0.1 for all covariates.

Compared to the matched nonpregnant group (incidence rate, 14 per 100,000 women), women in the induced abortion group experienced a more than two-fold increase in VTE (30 per 100,000; HR, 2.23; 95% confidence interval [CI], 1.61-3.08). Not surprisingly, women who underwent abortion at early gestational ages (< 15 weeks) had a lower incidence of VTE (27 per 100,000) than women at ≥ 15 weeks (136 per 100,000). The highest risk of VTE was seen among the live birth group (185 per 100,000). In comparison to this live birth group, women undergoing induced abortion had a six-fold reduction in VTE (HR, 0.16; 95% CI, 0.12-0.22). In a separate analysis, the authors compared the incidence of

VTE in the 42 days following the index date among an induced abortion subgroup with known exact gestational age to the incidence of VTE observed in the 42 days from the same index gestational age among the matched live birth group counterparts and found no significant difference (HR, 1.29; 95% CI, 0.64-2.59). All of these effects are consistent with prior research that supports an increasing risk of VTE with advancing gestational age.

The authors concluded that the risk of VTE increases during pregnancy, regardless of how the pregnancy ends, and suggested that testing for VTE and the provision of VTE prophylaxis should apply both to women who undergo termination of pregnancy or continue to term.

## ■ COMMENTARY

I sometimes fantasize that data demonstrating the safety of abortion somehow will influence the political debate. While this paper may not move the needle of public opinion, it should influence the way clinicians evaluate the risks and benefits associated with contraception care and pregnancy.

First, consider the known risks associated with VTE. The overall risk of VTE for women without a positive family history, other identifiable risk factors, or known thrombophilia is low. It is well-established that both pregnancy and estrogen-containing contraceptives increase the risk of VTE.[1] The risk appears to be related to circulating estrogen levels and likely evolved as a life-saving adaptive strategy for female mammals in response to pregnancy. Potent synthetic estrogens like ethinyl estradiol and the first-pass effects after oral administration of any estrogens mimic the hepatic stimulation seen during pregnancy. In contrast, transdermal administration of estradiol in postmenopausal women does not increase VTE risk.[2]

Inherited thrombophilias increase the baseline risk of VTE and also interact with other known risk factors, such as pregnancy and combined hormonal contraception (CHC).[3] For this reason, both the Centers for Disease Control and Prevention and the World Health Organization provide a Category 4 (unacceptable risk) rating for CHC in women carrying a known mutation. Although a personal history of VTE also carries a Category 4 recommendation, a family history of VTE in a first-degree relative is only a Category 2 (advantages generally outweigh risks). Routine testing for known thrombophilias in women with a positive family history is not recommended because of cost and low yield.[4] There is no Medical Eligibility Criteria for pregnancy, but providers should consider applying similar recommendations against pregnancy for women with Category 3 or 4 recommendations for estrogen-containing contraceptives.

Liu et al provided important new data demonstrating the risk of VTE associated with abortion care before 20 weeks. The bottom line: an overall two-fold increase in risk relative to nonpregnant woman, and a six-fold reduction in risk compared to women who continue pregnancy to live birth. The two-fold increase in risk was similar to the risk associated with the use of combined oral contraceptives.[5,6] In other words, if non-use of a combined method because of concern over VTE risk resulted in an unintended pregnancy and abortion, the overall increase in VTE risk was about the same. Should the woman decide to continue the pregnancy to term, the risk of VTE increases dramatically, comparing rates from the Canadian study, in which there was a 13-fold (RR, 13.2) increase over the nonpregnant cohort.

[The takeaway point is that clinicians should strongly consider risk factors for VTE in abortion patients and consider prophylaxis and treatment as indicated.]

The takeaway point is that clinicians should strongly consider risk factors for VTE in abortion patients and consider prophylaxis and treatment as indicated. However, the subgroup analysis finding no difference in the risk of VTE in the 42 days following the index abortion date to the same gestational time interval in women continuing their pregnancy strongly supports that the abortion itself is not an independent risk factor for VTE. These data demonstrated that the VTE risk increased with gestational age. ■

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## CME/CE QUESTIONS

1. **Although composite neonatal adverse events were more common in early-term deliveries in the study by Tita et al, a positive amniotic fluid test of pulmonic maturity enabled the neonates to avoid respiratory difficulties.**
   a. True
   b. False
2. **In the study by Lehn et al, complete salpingectomy was not possible in what percent of patients?**
   a. 10%
   b. 20%
   c. 30%
   d. 40%
3. **Which of the following statements is true based on results from the study on help-seeking in women with pelvic floor disorders?**
   a. Most women immediately seek help for pelvic floor disorders.
   b. Many women are hindered from seeking help because they perceive pelvic floor disorders as normal.
   c. Most women speak openly and are not embarrassed to talk about their symptoms; therefore, they do not need to be asked about pelvic floor symptoms.
   d. Pelvic floor disorders are a normal part of aging.
4. **Compared to non-pregnant women, what is the risk of venous thromboembolism following abortion?**
   a. Higher than that seen in women carrying a pregnancy to term
   b. About the same magnitude as that seen with use of combined oral contraceptives
   c. Not increased or decreased
   d. Six-fold higher than in women using combined oral contraceptives



## CME/CE OBJECTIVES

Upon completion of this educational activity, participants should be able to:

- Explain the latest data regarding diagnosis and treatment of various diseases affecting women;
- Discuss new data concerning prenatal care, neonatal health, and complications arising in pregnancy and the perinatal period; and
- Discuss the advantages, disadvantages, and cost-effectiveness of new testing procedures in women's health.

## [IN FUTURE ISSUES]

Hormonal Contraceptives and Ovarian Cancer