:

Article Type: Mini commentary

Corresponding author mail id: methodiustuuli@yahoo.com

Mini-commentary on 2018-RCT-21679R2 and 2018-OG-21731R1

Prophylactic negative pressure wound therapy at cesarean: Are we there yet?

Methodius Tuuli

Indiana University School of Medicine
Obstetrics & Gynecology
340 West 10th Street
Fairbanks Hall, Suite 6200
Indianapolis, IN 46202-3082
USA

Prophylactic negative pressure wound therapy (NPWT) has emerged as a promising intervention in patients at high risk for surgical site infection (SSI). One such group is obese gravidae, a growing population worldwide who are at high risk for both cesarean delivery and SSI. Although the precise mechanism by which NPWT aids incisional wound healing is unclear, experimental evidence suggests that it reduces bacterial contamination, edema, and exudate, increases microvascular blood flow, promotes formation of granulation tissue and reduces lateral tensile and shear stress. Data on NPWT after cesarean have hitherto been limited to retrospective cohort and small pilot randomized trials (RCT). Whereas some studies demonstrated benefit in reducing SSI and other wound complications, they were limited by small sample sizes, selection bias and confounding.

Hyldig et al. conducted a multicenter RCT comparing NPWT with the PICO™ device (n=432) to standard dressing (n=444) in obese (BMI≥ 30Kg/m2) women after cesarean delivery in five hospitals in Denmark (Hyldig et al. BJOG. 2018 (2018-RCT-21679)). The primary outcome, SSI within the first 30 days, was reduced by 50% from 9.2% with standard dressing to 4.6% with NPWT. NPWT also reduced wound exudates, with no impact on endometritis and wound dehiscence. In an accompanying trial-based economic evaluation, NPWT appeared to possibly be cost saving particularly for women with a BMI ≥35 kg/m2 (Hyldig et al. BJOG. 2018 (2018-OG-21731)).

These data are an important contribution to the evidence-base for the use of NPWT after cesarean delivery. The multicenter randomized design and sample size of over 800 patients are strengths of the study. Given that the current FDA-cleared prophylactic single-use NPWT devices cost between $200 (PICO™) and $500 (Prevena™) on average per unit, cost is an important consideration. The economic analysis presented here is a significant improvement upon the model based cost effectiveness analyses that were conducted prior to the

This is the author's manuscript of the article published in final edited form as:
Tuuli, M. (2018). Prophylactic negative pressure wound therapy at cesarean: Are we there yet? BJOG: An International Journal of Obstetrics & Gynaecology, 0(ja). https://doi.org/10.1111/1471-0528.15572

availability of RCT data on the efficacy of NPWT after cesarean delivery (Echebiri et al, Obstet Gynecol. 125(2):299–307; Tuffaha et al. J Surg Res 2015;195:612-2). However, while the sample size of over 800 is the largest to date, it remains modest. Moreover, the patient population of largely young obese Caucasian women without co-morbidities limits generalizability of the findings to other settings.

So are we there yet? A meta-analysis of four small RCTs with sample sizes ranging from 87 to 535) suggested that use of NPWT after cesarean delivery in high-risk patients significantly reduced the risk of SSI (pooled relative risk 0.55; 95% confidence interval 0.35, 0.87) (Yu et al. Am J Obstet Gynecol. 2018 Feb; 218 (2):200-210.e1). Together with data from the RCT by Hyldig et al., the evidence in support of NPWT after cesarean is increasing. However, the studies are clinically heterogeneous with small to moderate sample sizes and limited generalizability. Results of ongoing large multicenter RCTs in the United States and Australia enrolling more diverse patients will help clarify the role of NPWT after cesarean delivery (NCT03009110; ACTRN12615000286549).

Disclosure of interests

Dr. Tuuli is supported by a National Institutes of Health grant R01HD086007 and supplemental funding from Acelity for an ongoing multicenter trial testing the effectiveness of prophylactic negative pressure wound therapy after cesarean delivery in obese women. A completed disclosure of interest form is available to view online as supporting information.