A multicenter RCT makes a case for transabdominal cerclage

According to results of a recent trial, transabdominal cerclage should be considered the treatment of choice for women with a prior failed transvaginal cerclage, but the risks also must be weighed

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Since the 1950s, when Shirodkar (1955) and McDonald (1957) published their seminal works detailing a transvaginal method to suture a "weak" cervix, clinicians and researchers have debated the indications for and utility of cerclage for preventing pregnancy loss and preterm birth.[1,2]

Originally based on a history of recurrent mid-trimester loss (that is, a clinical diagnosis of cervical insufficiency), cerclage has been expanded to capture both ultrasonography and physical-exam indications. While cerclage has proven useful in select patient populations, an infrequent but vexing problem is what to do when a woman has experienced 1 or more (transvaginal) cerclage "failures."

With a dearth of well-controlled, randomized data to support the use of cerclage for either history- or physical-exam indications, it is not surprising that we still debate whether the Shirodkar method is superior to the McDonald technique as well as how to best manage a patient when either or both methods previously resulted in an unsatisfactory outcome.

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First randomized study to directly compare cerclage techniques

Fortunately, Shennan and colleagues in the United Kingdom have greatly enlarged our knowledge in this area by performing the first well-powered, 3-arm, randomized trial of transabdominal cerclage (TAC) compared with both high and low vaginal cerclage (HVC, LVC).[3] They analyzed data for 111 women who were randomly assigned to TAC (n = 39), HVC (n = 39), or LVC (n = 33).

Interestingly, the investigators chose to not attach conventional eponymous labels to their transvaginal methods, and they do not even provide a reference or detailed description of the surgical methods, telling us instead that, "Techniques used were left to the local clinician's discretion." Writing also that HVC cases, like the transabdominal surgeries, were carried out in specialty centers, they implied that additional training was required for the HVC. I inferred that indeed they actually were performing the McDonald and Shirodkar transvaginal methods and with possible by-physician, local modifications.

I am certain that the authors' results did not surprise proponents of transabdominal cerclage for transvaginal cerclage failures, defined in this trial as prior birth from 14 to 28 weeks' gestation. Since some clinicians use a more generous definition of cerclage failure (such as birth at less than 34 weeks), this study population was clearly at high risk for poor outcomes; in fact, more than 90% of each group had experienced at least 2 prior mid-trimester losses. As anticipated with randomization, other characteristics were well distributed across the 3 groups.

Transabdominal cerclage significantly reduced preterm birth rates

Using a primary outcome of preterm birth less than 32 weeks,

which concentrates neonatal morbidities, the investigators observed an overall 4.5-fold higher rate of preterm birth in the transvaginal cohorts compared with the transabdominal patients (33% and 38% versus 8%, respectively). Comparing the TAC group individually with both LVC and HVC groups, the relative risk of preterm birth was 0.20 compared with the HVC group and 0.23 compared with the LVC group, reflecting an approximate 80% reduction.

Not surprising to me, the investigators observed nearly identical outcomes between the HVC and LVC cohorts, substantiating *my* bias that the 2 transvaginal methods are similarly effective. Opponents will quickly remind me that the study was not well-powered to detect a clinically significant difference between these 2 groups; touché!

Risks of TAC. We all know that, despite its now-proven benefits, the transabdominal approach is associated with a risk of special complications, including the surgical risks of placement (and removal) of the cerclage, the management of fetal death beyond approximately 14 weeks, and the absolute requisite for hysterotomy/cesarean birth. While serious complications are rare, in the trial by Shennan and colleagues none were recorded in the 39 TAC cases. Nevertheless, for women with no children or only prior early births, the risks seem to be justified; the number needed to treat was less than 4 to prevent 1 birth at less than 32 weeks and was 5.3 to prevent a fetal loss.

TAC is an option for select patients

Given that TAC now can be successfully placed using minimally invasive surgery, either prior to or following conception, this study provides unique level I evidence that should not be discounted and should further be considered in the context of confirming prior cohort studies that suggested a significant benefit. Although specialized training is required and the procedure may involve travel to a specialty center, the weight of clinical data clearly supports the use of TAC.

In summary, based largely on the trial by Shennan and colleagues, women with prior failed vaginal cerclage can and should be counseled regarding the availability of TAC and given the opportunity to weigh the reported risks and benefits. ●

References

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