

Q Is routine episiotomy justified?

A The answer is a resounding “No.” Episiotomy can worsen outcomes when women who would have had no incision are subjected to the procedure.

EXPERT COMMENTARY

Consider this observation, now more than 100 years old:

Episiotomy . . . is practiced in the belief that the vulvar opening, if sufficiently enlarged by the incisions, will not tear farther, or that in any case the laceration will occur in the continuation of the incisions, whose clean-cut edges will heal more readily than the irregular spontaneous tears. Personally, I see no advantage in the procedure, as my experience is that ordinary perineal tears will heal almost uniformly if properly sutured and cared for.

—J. Whitridge Williams¹

Since that opinion was published, many would claim, medicine has evolved from an anecdotal discipline to a more evidence-based science. Ironically, it has taken a systematic, evidence-based review of articles from a 54-year period to determine what Williams discerned anecdotally at the turn of the 20th century.

Details of the study

Hartmann et al reviewed 26 trials from 1950 to 2004, each of which included at least 40 participants. For short-term maternal outcomes, they restricted their

review to randomized clinical trials. When long-term outcomes were assessed, they included nonrandomized trials and prospective cohorts.

Short-term outcomes included third- and fourth-degree lacerations, pain, wound healing, and blood loss. Long-term outcomes included incontinence, pelvic floor defects, and sexual function.

The findings: Immediate maternal outcomes were not improved with routine episiotomy. Though we lack long-term follow-up into the age range most likely to have pelvic floor sequelae, episiotomy does not appear to prevent fecal and urinary incontinence or pelvic floor relaxation, or to preserve sexual function.

A resounding chorus

These findings exactly mirror those of a Cochrane review by Carroli and Belizan.² Both reviews make it clear that routine episiotomy is outdated.

While some uses for episiotomy remain—such as hastening delivery in the setting of a nonreassuring fetal tracing or shoulder dystocia—the procedure of incising the perineum prior to delivery of the baby’s head should be limited to indicated instances only and should never be performed routinely.

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Hartmann K, Viswanathan M, Palmieri R, Gartlehner G, Thorp J, Lohr KN. Outcomes of routine episiotomy: a systematic review. *JAMA*. 2005;293:2141–2148.

FAST TRACK

Never perform episiotomy routinely—it is for special circumstances only

Palomba S, Orio F Jr, Falbo A, et al. Prospective parallel randomized double-blind double-dummy controlled clinical trial comparing clomiphene citrate and metformin as the first-line treatment for ovulation induction in non-obese anovulatory women with polycystic ovary syndrome. *J Clin Endocrinol Metab.* 2005;90:4068.

FAST TRACK

Until now, whether metformin helps achieve and maintain pregnancy has been explored only in small trials

Q Which drug is best for infertile PCOS patients—clomiphene or metformin?

A Metformin wins hands-down in non-obese women. Although the 2 drugs induced ovulation at roughly the same rate, metformin was associated with a higher pregnancy rate, a lower abortion rate, and a higher positive trend for live births.

EXPERT COMMENTARY

While metaanalysis suggests metformin improves ovulatory frequency in women with PCOS, until now the question of whether it helps achieve and maintain pregnancy has been explored only in small trials. The superiority of metformin for primary treatment of PCOS-related anovulatory infertility over standard-of-care clomiphene citrate was a matter of speculation (partly because metformin therapy was often reserved for “clomiphene failure”).

Palomba et al are to be commended for their study design (double-dummy, double-blind, randomized controlled trial) and choice of pregnancy as the primary outcome—a quantum leap forward for clinical trials involving PCOS. They studied 100 nonobese (BMI <30) women with PCOS and primary infertility (male and tubal factor excluded) and randomized them in equal groups to metformin (850 mg bid) or clomiphene citrate (150 mg/day for 5 days per treatment cycle). Both groups were monitored with ultrasound for follicular development, ovulation, and pregnancy during 6 months of treatment. Ovulation occurred without human chorionic gonadotropin trigger, with no inseminations.

Twice the pregnancy rate

The pregnancy rate after 6 months was significantly higher in the metformin group (69%) than in the clomiphene group (34%), and the abortion rate was significantly lower

with metformin (10% versus 38% for clomiphene). There also was a trend toward a better live birth rate with metformin (84% versus 56% with clomiphene).

Intriguingly, ovulation and fecundity rates improved progressively with metformin and were highest during the sixth month of treatment, whereas an opposite trend was noted with clomiphene.

Flaws may limit credibility

Several imperfections mark this trial. Although it was billed as double-dummy, the dummy used for both clomiphene and metformin was described as “polyvitamin tablets similar in appearance to metformin and/or CC.” A true dummy is *identical* in appearance to the medication; any suggestion that a medication is inactive will lead to unblinding, potentially biasing the results.

Another problem: 10% of metformin patients and 6% of clomiphene patients were excluded from the analyses, in some cases for vague reasons (eg, significant weight loss). An intention-to-treat analysis including *all* randomized patients would have been more appropriate, although pregnancy rates would have been lower.

Finally, this comparatively large sample size is not nearly large enough to detect a significant difference in the ultimate pregnancy goal: a live birth.

Metformin best in nonobese women

This study reinforces the use of metformin as first-line therapy for PCOS in nonobese women with anovulatory infertility. It is too soon to extrapolate results to an obese PCOS population, which is more characteristic of the United States.

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Q Does treating gestational diabetes improve outcomes?

A Yes, in this study, but the findings may not apply to the entire US population. Treatment reduced serious perinatal morbidity and improved the mother's quality of life.

EXPERT COMMENTARY

Gestational diabetes mellitus has occasionally seemed like a name looking for a disease. Screening recommendations and diagnostic criteria have been debated and changed, and it has appeared that, regardless of intervention, outcomes are the same.

This randomized trial sheds new light on the effectiveness of diagnosis and intervention, but some issues remain unclear—a fact pointed out in an editorial accompanying the study.¹ My interpretation is similar to the one outlined in that editorial.

Nonstandard diagnostic criterion

Though the results are compelling and the randomized clinical trial model lends credence to the conclusions, the diagnostic test and criterion for diagnosing gestational diabetes (75-g glucose load with a 2-hour value >140 mg/dL) are not the standard in the United States, so the results may not be applicable in the US.

A real difference, or coincidence?

More adverse perinatal outcomes were reported among the “routine care” group than the intervention group. The authors did not clarify, however, whether the 5 perinatal deaths in the routine care group could be attributed to gestational diabetes or were coincidental. Also, although the difference in birth weight was statistically significant (mean weight of 3,335 g in the intervention group versus 3,482 g for routine care; $P < .001$), I am unsure of the clinical importance of this difference.

Other variables listed under adverse outcomes included 5-minute Apgar scores

of less than 7 and admission to the NICU, both of which can be based on highly subjective criteria. No information was offered about whether—and how—such decision-making was standardized.

Was it ethical to ignore screening?

US practitioners would not ignore the results of a gestational diabetes screening test, as in this study (neither practitioners nor patients were made aware of the diagnosis). Thus, the findings shed little light on real-world practices of US ObGyns.

We also lack information on the cost (in dollar terms and morbidity) of any false-positive results.

Stick to ACOG guidelines

Gestational diabetes is an increasing problem, compounded by the obesity epidemic. Failing to screen patients, or ignoring a positive screen, would seem ill-advised, and glucose control would seem to be a prudent way to minimize maternal and perinatal morbidity. We need to determine the appropriate screening tools and diagnostic criteria, glucose values that should prompt intervention, and the optimal form of intervention, be it through diet alone or in combination with oral hypoglycemics or insulin.

Until these questions are resolved (probably not within this decade), I suggest we continue to follow ACOG guidelines for diagnosis and management.² ■

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FAST TRACK

Until further data are available, continue to follow ACOG guidelines on diagnosis and management: Practice Bulletin #30, from 2001