Zhang J, Gilles JM, Barnhart K, et al. A comparison of medical management with misoprostol and surgical management for early pregnancy failure. N Engl J Med. 2005;353:761–769.

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Women favored misoprostol despite side effects

Q Is misoprostol as effective as surgery for early pregnancy failure?

A Misoprostol is slightly less effective than vacuum aspiration, but is well tolerated by patients.

EXPERT COMMENTARY

About 1 in 5 women experience "early pregnancy failure," a term that includes incomplete abortion, inevitable abortion, anembryonic gestation, and embryonic or fetal death. Since misoprostol was first described in 1997 as a single agent for evacuating the uterus in early pregnancy failure,[1] many cohort studies have evaluated it for this purpose. Zhang et al provide level I evidence that intravaginal misoprostol is effective for uterine evacuation in early pregnancy failure.

"Noninferior," technically

This study involved 652 women at 10 weeks' gestation or less (crown-rump length of ≤40 mm or an average gestational sac diameter of ≤45 mm) who were randomized in a 3:1 ratio to misoprostol 800 µg vaginally (repeated in 2 days if necessary) or vacuum aspiration. Complete expulsion of the products of conception in the misoprostol group occurred in 71% of women by the second day after the initial dose and in 84% of women within 1 week.

Although the 1-week failure rate (16%) was higher than that for vacuum aspiration (3%), this was a "noninferiority trial." That is, Zhang et al recognized that medical treatment was unlikely to surpass the success rate of surgery, so they calculated an absolute difference of 18% as the maximum difference that would demonstrate noninferiority of misoprostol.

Treatment tips

This treatment is not for every patient. However, for women at gestational ages of less than 10 to 11 weeks who prefer to avoid a trip to the operating room, misoprostol is an attractive option.

Follow this protocol:

- provide oral analgesia (eg, ibuprofen and codeine)
- advise patients when to seek emergency care (heavy bleeding for more than 1 to 2 hours or pain unrelieved by medication)
- order a follow-up ultrasound exam.

More cost-effective than surgery

Although expense was not addressed in this study, misoprostol is more cost-effective than uterine curettage. Because only 1 in 7 women treated with misoprostol ultimately require surgery and at least one third of women choosing expectant management do not have a spontaneous abortion in a reasonable amount of time, misoprostol may be more cost-effective than expectant management.

Side effects had little impact

Of the patients treated with misoprostol, three quarters said they would opt to use it again, and four fifths said they would recommend it to others. These proportions were similar for the subgroup who had undergone surgical management for failure of an earlier pregnancy.

This finding is noteworthy because misoprostol caused more side effects. Women taking it had more bleeding (measured by the change in hemoglobin concen-

trations), gastrointestinal side effects (nausea, vomiting, and diarrhea), and pain.

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The author reports no financial relationships relevant to this article.

Q Does vacuum extraction increase the risk of brachial plexus palsy?

Mollberg M, Hagberg H, Bager B, Lilja H, Ladfors L. Risk factors for obstetric brachial plexus palsy among neonates delivered by vacuum extraction. Obstet Gynecol. 2005;106:913–918.

A No, unless the vacuum extraction involves shoulder dystocia, high fetal birth weight, or application of fundal pressure. Shoulder dystocia is by far the most significant risk factor for brachial plexus palsy in this context.

EXPERT COMMENTARY

This excellent study provides indirect scientific evidence that shoulder dystocia is the prominent risk factor for brachial plexus palsy in the setting of vacuum extraction, with an odds ratio (OR) of 16.0 (95% confidence interval [CI] 8.9–28.7). Other independent factors include fetal birth weight of 3,999 g or more (OR 7.1; 95% CI 4.8–10.5) and application of fundal pressure (OR 1.6; 95% CI 1.1–2.3). However, 81% of the infants with brachial plexus palsy did not experience shoulder dystocia during vacuum extraction. This finding is in accord with recent studies of obstetric brachial plexus palsy.[1]

Duration of vacuum extraction plays a role. The authors determined that 5 minutes of vacuum extraction carries an estimated risk of brachial plexus palsy of 0.8%, whereas 25 minutes carries a risk close to 4%.

Longstanding enigma

Ever since the 1978 landmark study by Benedetti and Gabbe,[2] the association between operative vaginal delivery and shoulder dystocia has aroused interest. Even today, clinical questions persist when an infant experiences brachial plexus palsy in the setting of operative vaginal delivery. Did the application of the vacuum or forceps cause the neonatal injury? Was the shoulder dystocia a direct consequence of the vacuum or forceps? Given the marked decrease in forceps usage and increasing reliance on vacuum extraction, this research article is timely and clinically relevant.

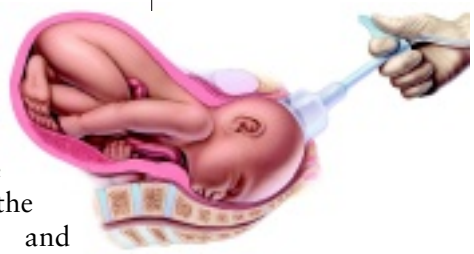

IMAGE: TODD BUCK

Strength in numbers: 13,716 vacuum deliveries

In Sweden since 1973, all deliveries have been recorded in the Medical Birth Registry of the National Board of Health and Welfare. Using this registry, Mollberg and colleagues were able to study 13,716 deliveries involving vacuum extraction, 153 of which resulted in brachial plexus palsy. The strength of this study lies in its immense power, which yielded insight into the approximate incidence (1.1%) of brachial plexus palsy in the setting of vacuum extraction.

Some medical records were incomplete

This study had a relatively high exclusion rate of 32%, since charts were analyzed only if they possessed a completed instrumental delivery protocol. As a result, Mollberg and colleagues were able to evaluate only a limited number of factors that could potentially be tied to brachial plexus palsy: shoulder dystocia, fetal birth weight, fundal pressure, number of tractions, duration of vacuum application, parity, vacuum silicone cup, epidural anesthesia, and fetal station.

No details on fundal pressure. A surprising

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Shoulder dystocia is the most prominent risk factor for brachial plexus palsy in the setting of vacuum extraction

percentage (58%) of infants with brachial plexus palsy had fundal pressure applied. Unfortunately, no indication was given as to whether this fundal pressure was used to assist with maternal expulsive efforts, to aid with placement of the vacuum extractor, or as a maneuver to alleviate shoulder dystocia.

Prolonged second stage defined differently from ACOG standard. This study defined a prolonged second stage as longer than 60 minutes in parous women and longer than 120 minutes in nulliparous women, whereas the American College of Obstetricians and Gynecologists defines it in multiparous women as longer than 2 hours with or 1 hour without regional anesthesia, and in nulliparous women as longer than 3 hours with or 2 hours without regional anesthesia.

Another weakness: Some vacuum extractions may have been midpelvic, given that cases with the fetal vertex at the level of the ischial spine were allowed.

Take-home message: Don't retire the vacuum extractor

There is no reason obstetricians should stop using the vacuum extractor for fear of brachial plexus palsy. However, they should continue to:

- minimize the duration of application,
- monitor the rate of fetal descent and,
- as always, employ sound clinical judgment.[3]

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Macones GA, Peipert J, Nelson DB, et al. Maternal complications with vaginal birth after cesarean delivery: a multicenter study. Am J Obstet Gynecol. 2005;193:1656–1662.

Q How likely is uterine rupture in VBAC attempts?

A The incidence was less than 1% in this study. Uterine rupture occurred in 9.8 of 1,000 attempts at vaginal birth after cesarean delivery (VBAC). Previous vaginal delivery decreased the risk of uterine rupture by 60%. Although use of prostaglandins did not increase the risk of rupture, sequential use of a prostaglandin and oxytocin did.

EXPERT COMMENTARY

The popularity of VBAC is waning in the United States, due mainly to concerns about complications after uterine rupture. The most recent national data show that the VBAC rate, which was 28.3% in 1996, declined to a mere 9.2% in 2004.[1] In this context, Macones and colleagues undertook their multicenter case-control trial to determine the incidence of and risk factors for uterine rupture in a variety of hospital settings.

Study involved both community and tertiary-care hospitals

This is the largest trial to date to analyze VBAC success rates in university/tertiary care centers and community hospitals (with or without residency programs) to verify whether the typically quoted uterine rupture rate of less than 1% can be generalized to most settings.[2] Macones et al used International Classification of Diseases, 9th revision (ICD-9) codes to perform this retrospective cohort review, identifying 13,706 patients who attempted VBAC in a 5-year period. Within this cohort, after reviewing all the charts, they performed a nested case-control comparison of uterine ruptures and nonruptures in a 5 to 1 ratio.

Women most likely to succeed had prior vaginal delivery

Recent studies have also sought to identify women less likely to experience uterine

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rupture with VBAC.[3–5] In the Macones study, among historical risk factors for uterine rupture, only prior vaginal delivery affected rupture rates, decreasing the incidence by 60% (odds ratio [OR] 0.40; 95% confidence interval [CI] 0.20–0.81).

Hendler and Bujold[6] also found that a history of vaginal delivery lowered the VBAC uterine rupture rate—to 0.5%, versus 1.4% in women without that history (*P*=.02). But they cautioned that this finding may be incidental. Other studies that explored effects of previous vaginal delivery focused on VBAC success rather than uterine rupture. The finding that a previous vaginal delivery increases the likelihood of VBAC success has remained consistent.[6–10]

How this study differs from others

Macones et al found that neither labor induction with prostaglandins, induction with oxytocin, nor augmentation with oxytocin affected rupture rates. However, sequential use of prostaglandins and oxytocin did increase these rates (OR 4.54; 95% CI 1.66–12.42; *P*=.003). These findings contrast those of a cohort study by Lydon-Rochelle et al,[11] who used ICD-9 codes without chart review to estimate the incidence of uterine rupture in the Washington State Birth Events Database. Using elective repeat cesarean as their reference group, Lydon-Rochelle et al found a 15-fold increase in rupture rates when labor was induced with prostaglandins (relative risk 15.6; 95% CI 8.1–30.0).

Don't switch to prostaglandins just yet. In response primarily to the Lydon-Rochelle study, the American College of Obstetricians and Gynecologists published a Committee Opinion[12] in April 2002, discouraging the use of prostaglandins to induce labor in women attempting VBAC. In the current study by Macones and colleagues, the authors pointed out that prostaglandin E_2 (and not misoprostol or prostaglandin E_1) was the only type of prostaglandin used in all centers evaluated. Thus, although the study by Macones et al is well designed, it is retrospective and should not encourage the use of prostaglandins for VBAC until the question has been answered prospectively.

Encourage VBAC in women who have delivered vaginally

Overall, the study by Macones et al adds important information to the literature. The uterine rupture rate (<1%) seen with VBAC attempts is generalizable to the community setting, and VBAC attempts are appropriate provided a physician capable of performing emergent cesarean is immediately available, as well as anesthesia and OR personnel.[2]

In women who have delivered vaginally, VBAC should be encouraged. However, the use of prostaglandins to induce labor in these cases warrants further investigation.

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Previous vaginal delivery lowered the uterine rupture rate 60%