additional attempts at fine-tuning of these processes are not likely to yield information of significant clinical utility. Rather, we believe a refocus of research efforts on alternative or adjunctive techniques of assessment not based on heart rate and blood gas analysis will be necessary to make further significant impacts upon the prevention of perinatal neurologic impairment. ■

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REFERENCES

1. Clark SL, Hamilton EH, Garite TJ, et al. The limits of electronic fetal heart rate monitoring in the prevention of neonatal metabolic acidemia. Am J Obstet Gynecol 2016:163.e1-6.
2. Racinet C, Ouellet P, Charles F, Daboval T. Neonatal metabolic acidosis at birth: in search of a reliable marker. Gynecol Obstet Fertil 2016;44:357-62.
3. Rosen KG, Murphy KW. How to assess fetal metabolic acidosis from cord samples. J Perinat Med 1991;19:221-6.
4. Kellum JA. Clinical review: reunification of acid-base physiology. Crit Care 2005;9:500-7.
5. Corey HE. Stewart and beyond: new models of acid-base balance. Kidney Int 2003;64:777-87.
6. Siggaard Andersen O, Engle K. A new acid base nomogram. Scand J Clin Lab Invest 1960;12:177-86.
7. American Academy of Pediatrics. Committee on fetus and newborn. Hypothermia and neonatal encephalopathy. Pediatrics 2014;133:1146-50.

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Intrauterine hemostatic balloon placement: is <12 hours really better?

TO THE EDITORS: We commend Einerson et al[1] for answering a very important unsolved question: whether the Bakri balloon can be removed <12 hours after placement. Their retrospective observational study showed that Bakri balloon removal before or after 12 hours does not affect outcomes, and thus concluded "if ongoing hemorrhage has abated, it is reasonable to consider removal of an intrauterine balloon by 12 hours after its initial placement." We have a concern and an addition.

Our concern regards selection bias. Who decided early (<12 hours) vs late (>12 hours) removal? They stated, "the duration of balloon was at the discretion of the clinical provider and was not dictated by protocol." They also stated, "the study was performed at a single academic institution with a high obstetric volume, a postpartum hemorrhage protocol, and experience with balloon." It is therefore likely that experienced obstetricians ("experts") decided. Although the background characteristics did not differ between the early and late groups (their Table 1), this does not eliminate selection bias. For example, uterine contraction usually affects decision-making by an expert. If uterine contraction becomes better after balloon placement, there is no need for prolonged placement, but if the uterus contracts but occasionally becomes floppy (repeatedly floppy contraction), it may be better to place it longer. There may be no difference demonstrable in Table 1 to differentiate these 2 situations. In addition to uterine contraction, experienced obstetricians evaluate early vs late removal by intuition, which may involve, for example, bleeding pattern, placental location, and placental separation pattern. The basis of this intuition should be analyzed and determined, so that less experienced obstetricians can utilize this experience. The data of Einerson et al[1] should be interpreted as, "it is reasonable to consider removal of an intrauterine balloon by 12 hours based on the judgment of an experienced obstetrician to the extent that they can judge the merits of early vs late removal in this patient."

Our addition regards balloon prolapse. While the balloon remained intrauterine in 274 patients (study population), it was prolapsed in 33. Balloon prolapse should be prevented, and is preventable. We devised "holding the cervix" (closing the cervical ostium with forceps, preventing balloon prolapse),[2] "abdominal traction stitch" (balloon shaft being pulled cephalad through the abdominal wall),[3] and their combination[4] to achieve this goal. Depending on the situation, we use either procedure, preventing balloon prolapse. The outcome of these 33 patients with balloon prolapse is of interest. ■

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REFERENCES

1. Einerson BD, Son M, Schneider P, Fields I, Miller ES. The association between intrauterine balloon tamponade duration and postpartum hemorrhage outcomes. Am J Obstet Gynecol 2017;216:300.e1-5.
2. Matsubara S, Kuwata T, Usui R, Ohkuchi A. "Holding the cervix" technique for post-partum hemorrhage for achieving hemostasis as well as preventing prolapse of an intrauterine balloon. J Obstet Gynaecol Res 2013;39:1116-7.
3. Matsubara S, Baba Y, Morisawa H, Takahashi H, Lefor AK. Maintaining the position of a Bakri balloon after cesarean section for placenta previa using an abdominal traction stitch. Eur J Obstet Gynecol Reprod Biol 2016;198:177-8.
4. Matsubara S, Baba Y, Takahashi H. Preventing a Bakri balloon from sliding out during "holding the cervix": "fishing for the balloon shaft" technique (Matsubara). Acta Obstet Gynecol Scand 2015;94:910-1.

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REPLY

We thank Dr Matsubara and colleagues for their thoughtful comments. We appreciate the important work that they are doing to prevent expulsion of intrauterine balloon tamponade (IUBT) devices. These patients were excluded from our study since cases of failed IUBT placement or expulsion did not address the central research question of IUBT duration and postpartum hemorrhage outcomes, however we look forward to reading more results of the impact of their techniques.

We also welcome the opportunity to address their concerns. We agree that selection bias cannot fully be discounted given our study design. Regarding the expertise of providers determining duration of IUBT, we want to clarify that the study site is an academic institution where 48 residents, supervised by >140 private and academic generalist obstetrician-gynecologists, fellows, and maternal-fetal medicine specialists, manage cases of postpartum hemorrhage with IUBT. Thus, the decision to remove the balloon was not dictated by a few experts or by protocol, but rather was left to the discretion of a wide spectrum of providers.

They also raise concern of unmeasured confounding, particularly regarding differences in uterine tone after IUBT. While sustained atony was not a variable we could measure, we suspect that ongoing atony would have prompted additional uterotonic use, use of additional procedural interventions, or contributed to additional postplacement blood loss, none of which differed between the groups. Other unmeasured clinical characteristics may have informed the "intuition" of the clinician guiding decisions about IUBT removal, however the absence of measurable differences provides some reassurance.

Despite attempts to address these issues in our study design, we have acknowledged the potential for bias in our study, and do not believe that our study definitively answers the question of how long IUBT should be used. A prospective randomized trial of IUBT duration would more definitively answer this question and we hope our observational study provides the preliminary data needed to inform such a trial. ■

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