Guidelines for Labor Assessment: Failure to Progress?

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Condensation: Most studies so far suggest that adopting the ACOG/SMFM labor management guidelines results in a small decrease in the cesarean delivery rate at the expense of enhanced maternal, fetal and neonatal morbidity.

Short title: Critical assessment of proposed guidelines for labor assessment

Abstract

The ongoing debate about what models of cervical dilatation and fetal descent should guide clinical decision-making has sown uncertainty among obstetric practitioners. We previously argued that the adoption of recently published labor assessment guidelines promoted by the American College of Obstetricians and Gynecologists and the Society for Maternal-Fetal Medicine may have been premature. Before accepting any new clinical approaches as the standard of care, their underlying hypotheses should be thoroughly tested to ensure they are at least equivalent (or, preferably, superior) to existing management paradigms. Some of the apparent urgency to subscribe to new clinical tactics has been fueled by legitimate concerns about the rise in the cesarean delivery rate over the past several decades. A major contributor to this change in practice patterns is that more cesarean deliveries are being done for diagnoses that fall under the rubric of dystocia than ever before. As a consequence, traditional labor curves--fundamental for assessing labor progress—and the practice paradigms associated with them have received intense scrutiny as a possible contributor to this delivery trend. Moreover, the recent proposal of new labor curves and accompanying management guidelines has, understandably, fed the appetite to correct a perceived problem. However, the cesarean delivery rate rose most rapidly during decades when there was no major change in traditional labor curves or in the guidelines for their interpretation. Also, during the years since the new guidelines were first published, there has been no major fall in cesarean delivery frequency. This raises the question of whether there was truly a fundamental flaw in the traditional labor management paradigms or whether their proper interpretation and use had been somehow forgotten, ignored, or corrupted. More important, existing studies have shown that application of the new guidelines often (but not always) results in a modest fall in the cesarean delivery rate, but that this change may be accompanied by

significant increases in maternal and neonatal morbidity. These results strongly suggest more caution in the adoption of the ACOG/SMFM labor assessment recommendations. They are based on a hypothesis that has yet to undergo thorough evaluation of its risks and benefits.

Key words: cervical dilatation, cesarean delivery, clinical practice guidelines, fetal station, labor, labor curves, partogram

The ongoing debate about what graphic models of cervical dilatation and fetal descent during labor should guide obstetricians' clinical decision-making has sown uncertainty among practitioners and trainees. It has also provided a meaningful lesson in how any specialty should vet and adopt new clinical care guidelines.

In a 2015 editorial in this journal[1] and in several further publications[2-4] we expressed concerns about the rapid adoption of recently developed guidelines for the assessment of labor progress promulgated by the American College of Obstetricians and Gynecologists (ACOG) and the Society for Maternal-Fetal Medicine (SMFM).[5,6] We objected on several bases to the widespread acceptance of these guidelines. We opined that: 1) Lowering the cesarean delivery (CD) rate is important, but should not be the principal objective of obstetric practice; 2) The new recommendations were based heavily on recently published revisions to traditional labor curves and their associated management paradigms.[7,8] The new curves are considered by some to be flawed because they were distorted by exclusion of women delivered by CD, by failure to account for various confounding factors, and by the use of an error-prone curve-fitting approach; 3) The guidelines do not mention the need for customary clinical methods of physical examination used to evaluate labor with no evidence whatsoever that this is safe or sensible; 4) the recommendations take no account of what the effects of their adoption might be on fetal and maternal welfare; and, most important, 5) they were adopted without evidence that they were superior or even equivalent to existing approaches.

The crescendo in the frequency of CD over recent decades in the industrialized world has occurred for a complex labyrinth of reasons.[9,10] Social, cultural and economic forces have played as large a role as medical ones. Increased patient autonomy, including patient-request CD, has

altered physicians' attitudes. The current state of the tort system in most of the US has made many physicians and hospitals increasingly risk-intolerant. Changes in reimbursement and physician scheduling have influenced practice patterns, and there have been relevant demographic changes in the pregnant population. To what extent these, or other factors have actually influenced practice is difficult to determine. There is, nevertheless, general agreement that a substantial contributor to the CD trend is that more cesareans are being done for diagnoses that fall under the rubric of dystocia than ever before.[11-13]

As a consequence, the fundamental tool for assessing labor progress—labor curves—has received intense scrutiny as the potential villain in this unfortunate diagnostic trend. And the fortuitous appearance of the "new" labor curves as the CD rate was rising rapidly has fed the exigent need to identify and correct a perceived problem. Any sapient witness to obstetric practice patterns will, however, have made a telling observation in this regard. No major change in traditional labor curves or in the guidelines for their interpretation occurred between 1970 and 2000, during which the national CD rate quadrupled from 5.5 to 22.9%. This raises the question of whether there was truly a fundamental flaw in the traditional Friedman curves or whether their proper interpretation and use had been somehow forgotten, ignored, or corrupted. Also, during the years since the new guidelines were first published, the CD rate has remained stable at about 32-33%, suggesting the new recommendations have thus far not had a major effect on practice patterns.

With regard to whether the original curves per se were spurious, do not apply to today's parturients, or have simply been misused and misinterpreted, we think the latter is most likely. We have in fact observed a widespread indifference to understanding and practicing according to extant guidelines. Moreover, determining fetal station and position, assessing feto-pelvic

relationships thoroughly, or interpreting labor curves accurately and meaningfully are basic clinical skills that, based on our observations, have atrophied drastically in today's learning environments and degraded the acute situational awareness required to work in a labor and delivery environment. This lamentable trend coexists comfortably with the ACOG/SMFM recommendations, which do not require any clinical skills beyond measuring cervical dilatation and counting the passage of time. To follow the guidelines requires no knowledge of fetal position, attitude, station, molding, or any other aspect of fetopelvic relations.

Concerns expressed about the new guidelines, [1-4,14,15] have so far gone unheeded. The guidelines were adopted in whole or in part in the US and internationally without any objective proof of either their value or safety.[16-20] Fortunately, in the intervening half-decade there have been several reported studies that tested whether the implementation of the new recommendations resulted in measurable benefit.[21-27] Admittedly, these studies do not provide a definitive answer to the question because they have used different populations and various experimental designs, often with historical controls. In some studies, changes in practice other than those in the new guidelines were introduced at the same time. Outcome variables differed among studies, and there is still no applicable randomized clinical trial to help guide our decision-making. Moreover, thus far most studies have been powered to detect changes in the CD rate, and not to identify much less frequent events like severe neonatal acidosis or abnormal neurologic outcome.

These caveats notwithstanding, we feel there is sufficiently worrisome information in many of the results of these studies to once again urge the new guidelines not be accepted as the standard for practice before there is compelling evidence of their effectiveness and safety. Most, but not all, studies have shown a fall in the overall cesarean rate with implementation of the

ACOG/SMFM guidelines. Some, however, have found a concomitant increase in the incidence of poor neonatal outcome.

Wilson-Leedy et al. did a before-after retrospective cohort study with about 200 patients who were receiving oxytocin per group[21] The cesarean rate fell significantly from 35.5% to 24.5% after implementation of the guidelines. Neonates had higher (but not significantly so) [22] published thus far only as an abstract, the CD rate among nulliparas with term singleton pregnancies fell modestly from 33.1 to 29.5% after implementation of the guidelines. The concomitant frequency of very low 5-min Apgar scores, however, more than doubled. Similar adverse effects on indices of maternal and neonatal morbidity were found in the US.[23] A study over 2010-2014 of nearly 8000 patients showed no fall in the CD rate despite implementation of the guidelines. In fact it increased slightly (but not significantly)

In a study by Thullier et al. in France two groups of about 3000 women were evaluated before and after introduction of the guidelines. The overall CD rate fell significantly from 9.4% to 6.9% when the new guidelines were introduced. No major changes in associated maternal or immediate neonatal outcome were observed. In Norway, Bernitz et al. studied almost 7300 women included in a cluster-randomized trial.[25] Control institutions practiced according to existing World Health Organization partograph standards (which are based largely on Friedman's precepts); the intervention units used Zhang's guidelines. The intrapartum CD rate in active phase labor did not differ significantly between the two clusters; in fact, the rate was slightly higher in the intervention group (5.9% vs. 6.8%). There was no difference in the frequencies of low Apgar scores or low cord pH between the groups.

The Maternal Quality Care Collaborative in California undertook a large-scale (56 hospital) quality improvement project designed to reduce CDs among nulliparous women.[26] Hospitals were

helped to implement the ACOG/SMFM guidelines for management of the first stage. In addition, new protocols for nursing support during labor were implemented. Data were obtained primarily from birth certificate and discharge diagnosis data. When compared to a historical control year, the overall CD rate dropped by 4.5 % among term nulliparas, but ranged from a fall of 17.1% to a rise of 4.7% among participating hospitals. Overall, there was no increase in perinatal morbidity noted.

Concerns about the potential negative impact of the guidelines relate in part to the very long second stages they espouse (regardless of progress in descentLeveno and colleagues.[14,15 f] They raised many of the same concerns as have been discussed above for the first stage. As but one example, Zipori et al. studied two groups, each of about 10,000 women, in Israel[27] The study, focused on the impact of new guidelines for the second stage, documented a considerable fall in CDs among nulliparas from 23.3% in historical controls to 15.7% after implementation of the guidelines. This decrease was, however, accompanied by significant increases in the occurrence of severe perineal lacerations (1 vs. 1.3%, P=.024) , postpartum hemorrhage (1.4 vs. 2.3%, P<.001), operative vaginal delivery in nulliparas (17.7 vs. 19.2%, P,.001), cord blood arterial pH <7.0 (.04 vs. .48% P<.0001), and NICU admission (1 vs. 1.5%,<.001) and a doubling of the frequency of shoulder dystocia (.2 vs .4%, P=.016).

What have we learned thus far from the extant research on the new guidelines? Obviously, if one redefines the fundamental understanding of what is normal labor progress one can certainly reduce the CD rate. If the considerably longer labors suggested by the guidelines are followed, more women will deliver vaginally, and that is for the most part what the studies have shown. That generalization aside, one must ask why there has been such a large range in the effect size,

from a halving in one case to small or absent fall in others, to more than a 4% rise in one study hospital.nonasphyxial (probably traumatic) intrapartum injury is being exposed.[28-30]

This saga should stand as an object lesson for our specialty, which, like many institutions, sometimes has difficulty absorbing the lessons of history. For example, in the 1970s electronic fetal monitoringmultimillion dollar industry it spawned, we still argue and wonder about its worth. The same could be said for many other medical interventions in our specialty and others.[31] A recent example is the wavering certainty about the value of hydroxyprogesterone caproate for prevention of preterm labor.

We applaud and encourage the reassessment of traditional methods for the assessment and management of labor. But we also urge that new studies and their consequences are evaluated thoroughly and judiciously before being accepted as models of best practices. The ACOG/SMFM guidelines are based on a hypothesis that requires extensive testing before adoption. The results so far are not encouraging to us and more data are needed. If they reveal no advantage or, worse, a disadvantage over traditionally accepted methods, a mistake has been made. But it is correctable, and a specialty entrusted with the care of a nation of pregnant women should be courageous enough to do so. There are, after all, other ways to reduce the CD rate.[32-35] Moreover, if we practice obstetrics in a manner consistent with the best health and safety interests of fetus and mother, the optimal cesarean rate will reveal itself pari passu.

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