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Spring 2003 Newsletter

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I N M E M O R I U M

Gerald A. Burger

1953-2003

Gerry Burger, MD, SOAP member and former SOAP Newsletter editor, died tragically in a plane crash on January 30, 2003. Gerry was flying his Beechcraft Bonanza from Casper, Wyoming to San Diego when he was caught in a snowstorm that iced his airplane's wings. Gerry had reported icing problems to air traffic control. He was advised to land at a nearby airport in Wyoming but contact with him was lost shortly thereafter.

Gerry was raised in Kansas City, Missouri, the son of a funeral home director. It may have been this environment that gave him his wonderful wit and sense of humor. He entered the Naval Academy in 1971 and graduated 16th in his class in 1975. Rumor has it that Gerry helped steal the Army mascot (a mule) prior to the annual Army-Navy football game. Following graduation, Gerry attended medical school at Washington University in St. Louis, followed by a residency at Bethesda Naval Hospital.



After his residency, Gerry completed an obstetric anesthesia fellowship at the Brigham and Women's Hospital. It was here that he met Vicki, his wife to be, who was a Labor and Delivery nurse. From Gerry's endless stories about the Brigham, this training was one of the high points of his life. When recounting his year at the Brigham, he would frequently tell the story of how he acquired the nickname, "Sheethead". It was one of his favorite tales.

Following his education, Gerry began his naval career. He and Vicki headed to Okinawa, where Gerry eventually assumed the chairmanship of the Naval hospital anesthesia department. From there, Gerry became chairman of the Navy's largest teaching hospital, Naval Medical Center, San Diego where he served from 1990 to 1995. During his time in San Diego, not only did Gerry manage the anesthesia needs of a large hospital and the Navy's largest anesthesia training program, but he also had the added responsibility of deciding which of his staff were going to be sent into combat zones. This was a task in which he never delighted.

At the end of Gerry's naval career, he was recruited to supervise the development of a new Labor and Delivery suite at the Cleveland Clinic Foundation. During his time at the Cleveland Clinic, Gerry became actively involved in SOAP, taking on the reins of newsletter editor in 1997. During his tenure as editor, Gerry was instrumental in moving SOAP into the computer age by directing the development of SOAP's web page. As is typical of the career Navy man, Gerry couldn't stay in one place for very long. In 1998, he moved on to develop an outpatient surgery center in one of the Cleveland Clinic's regional hospitals. This was quickly followed by a move to Casper, Wyoming where he joined a private practice group at Wyoming Medical Center.

Following his move into private practice, those of you who knew Gerry will remember how he liked to flaunt his rustic home by showing up at meetings looking like a cowboy. He especially took pride in his collection of boots and belt buckles. The opportunities for civic involvement in Casper also appealed to Gerry. He was very fond of regaling folks about his wife's election to the city's board of education.

This move to private practice and the end of academic responsibilities allowed Gerry time to renew a passion for flying. Gerry had been flying periodically since his days in Okinawa, but it wasn't until arriving in Casper that he was able to devote significant amounts of time to this hobby. At last year's SOAP meeting in Hilton Head, Gerry had flown all the way from Casper in his new Beechcraft Bonanza. At the time of his death, Gerry was an instrument rated pilot who had logged well over 1000 hours of flight time.

Jon Waters, MD

35th Annual Meeting Forecast



While the ides of March will have passed by the time you read this, the ides of May are now close upon us, and that means it's time for the 35th Annual Meeting. In the last newsletter, I updated you on some of the highlights and developments of the Scientific Program. The abstracts have now been collected, reviewed and scored, and I'm very pleased to announce that we have accepted a record number of abstracts for presentation, 149 in all! The record number of submissions indicates that despite the travails of academic anesthesiology in recent years, interest in Obstetric Anesthesia continues to surge. Just as in the past, you can be assured that several of the advances that you'll first encounter at the Meeting will be everyday practice in the very near future.

In fact, we had so many excellent submissions that we had to deviate from the practice of having posters up for viewing for the whole meeting. This year they will be on display for only one day of the meeting, in order that we have enough space to present them all. While this may seem to put more pressure on each of us to be sure to "make the rounds", the three poster review sessions will highlight and summarize some of the most interesting and outrageous presentations.

But enough about all the scientific stuff, everyone knows the Meeting Host sinks or swims on the strength of the Social Program! Here's what we've been working on: Following tense, twelfth hour negotiations by Stewart "Don't take no for an answer" Hinckley, we have secured the services of "Dark Horse", one of the Valley's hottest dance bands for the Saturday night banquet. They perform a full variety of classic rock from the 60s to the present, blended with driving contemporary country, blues, and adult contemporary sounds. I'm sure what adult contemporary sounds are, but I have heard this group, and with their excellent harmonies, and audience rapport, they'll have everyone out of their seats and making a beeline for the dance floor. Finishing touches are being put on the menu for the "Western Cookout" banquet, which will of course be held outdoors - don't worry, the chance of rain is nil in Phoenix in May.

Speaking of rain, or the lack thereof, for daytime activities, I would recommend packing a good sunscreen. This will be essential for any of the outdoor activities on Friday afternoon. Pack light - the daytime highs will likely be in the 90's, but remember, with the lack of humidity (it often drops below 10%), it feels a good deal cooler, unless you're standing in the direct sun. A hat you're not embarrassed to be seen in can also come in handy. At night, the temperature drops rapidly to lows sometimes 30 or even 40 degrees below the daytime high, so a light jacket, sweater, or sweatshirt is a good idea.

Be sure to sign up early if you are interested in the golf outing - at this price, it may sell out fast. The Golf Club at Lookout Mountain is one of the premier courses in the Valley, and the number of tee times is limited. If you are an avid golfer, you might want to consider coming a few days early or staying a couple days after the meeting. The greater Phoenix area has one of the most outstanding arrays of public

and semi-private courses anywhere in the world, and even discounting the physical beauty of the layouts, desert golf is uniquely challenging.

While we were all disappointed by the early departure of the defending World Series Champion Arizona Diamondbacks from the National League playoffs last year (well, O.K., maybe I was the only one disappointed.), they are back at full strength again this year, still with the strongest pitching at least this side of the Mississippi. On Friday night, May 16th, we have reserved a block of seats for their game against the Pittsburgh Pirates at Bank One Ballpark. The "BOB" is one of the newest parks in major league baseball, and is actually fully air-conditioned, though I expect the retractable roof will be open that night. If you'd like to join the fun, tickets (at \$30 each), are available on a first-come, first-served basis. Send an e-mail to Stewart Hinckley at soap@societyhq.com, or call the office at 1-(804)-282-5051.

Well, that's probably enough for now. You might want to check the website on occasion for any updates between now and the start of the meeting. Get your registrations and reservations in, and we'll see you by the pool in May!

Craig M. Palmer, MD

Government Affairs

The OB Malpractice Crisis: What Can We Do?

I was hitting the snooze button for the third time when something on National Public Radio (NPR) caught my attention. A news release from the American College of Obstetricians and Gynecologists (ACOG) announced that most newborn brain injuries do not occur during childbirth. This may not be breaking news if you keep track of such things, but what brought this to public attention now? The news release was based upon a joint ACOG and American Academy of Pediatrics publication titled "Neonatal Encephalopathy and Cerebral Palsy". This 94-page report is the synthesis of two years of work by an ACOG task force composed of experts in the field. It is highly recommended reading.¹ For instance, the Executive Summary states:

"The criteria to define an acute intrapartum event sufficient to cause cerebral palsy, as modified by this Task Force from the template provided by the International Cerebral Palsy Task Force, are listed as follows:²

Essential criteria (must meet all four)

1. Evidence of a metabolic acidosis in fetal umbilical cord arterial blood obtained at delivery (pH <7 and base deficit =12 mmol/L)
2. Early onset of severe or moderate neonatal encephalopathy in infants born at 34 or more weeks of gestation
3. Cerebral palsy of the spastic quadriplegic or dyskinetic type³
4. Exclusion of other identifiable etiologies such as trauma, coagulation disorders, infectious conditions, or genetic disorders

Criteria that collectively suggest an intrapartum timing (within close proximity to labor and delivery, e.g., 0-48 hours) but are nonspecific to asphyxial insults

1. A sentinel (signal) hypoxic event occurring immediately before or during labor
2. A sudden and sustained fetal bradycardia or the absence of fetal heart rate variability in the presence of persistent, late, or variable decelerations, usually after a hypoxic sentinel event when the pattern was previously normal
3. Apgar scores of 0-3 beyond 5 minutes
4. Onset of multisystem involvement within 72 hours of birth
5. Early imaging study showing evidence of acute non-focal cerebral abnormality."

Why was this press release sufficient to jar me from sleep? As anyone practicing obstetrics or obstetric anesthesia knows, the threat of malpractice litigation is a major fear. Coupled with this is the soaring cost of malpractice insurance. In many states including my own, this cost has led to the loss of insurance coverage for obstetricians and massive dropouts in obstetrical care. We have heard the stories of pregnant women delivering by the side of the road while driving long distances to find an obstetric provider. If we are to reverse these trends we must understand the complexities of the problem. Rising malpractice insurance costs themselves are at least partially linked to the recent stock market decline and attempts by insurance carriers to maintain profits. Unless there is a legislative solution, it is likely that these costs will remain high until the economy improves. Innovative strategies are being examined to limit the impact on physicians. One such scheme has physicians asking patients to sign documents agreeing to binding arbitration rather than legal recourse in the event of an adverse outcome.

Separate, albeit related, to the cost of malpractice insurance is the pervasive increase in defensive medicine being practiced over the last few decades. This returns me to the ACOG report. The marked increase in Cesarean deliveries and electronic fetal heart rate monitoring has largely been driven by the false promise that we would reduce the incidence of cerebral palsy if we detected intra-partum abnormalities early and intervened. It has not worked. Unfortunately it has had an unintended and detrimental effect. Now, when there is a bad neonatal outcome, there are often lawsuits alleging that monitoring was not employed soon enough, not interpreted correctly, or that a Cesarean section was not done soon enough or at all. What is missing in most cases is evidence that it matters.

If we are to break the cycle of defensive practice patterns and introduce more rational guidelines, where are we to turn? Surely not to the courts. Political pressure and special interest groups will make serious tort reform difficult. Indeed, there has already been a predictable and swift backlash against the ACOG report. In the Jan. 31st Boston Globe we have comments from various malpractice lawyers such as "This is not a medical research paper." Another called the report "dangerous, intellectually indefensible, and morally irresponsible." One may perhaps appreciate the irony here. Some states have introduced caps on pain and suffering awards in an attempt to attenuate some of the extreme settlements. Just how big is the problem? In the same Boston Globe article it is stated that, on average, obstetricians are sued in excess of 2 times over their career and that over 30% of the suits are for neurologically impaired infants. In addition, the average jury award is over one million dollars.

If legal reforms are not forthcoming what else is possible? I believe we must turn to educating ourselves about the true relationship of cerebral palsy and intra-partum events. If we as physicians have limited knowledge of the antecedent causes of newborn brain injury we can hardly be surprised if the general public brings forth unjustified lawsuits. Unfortunately we have a long way to go. The lead author of the ACOG Task Force surveyed both ACOG members of the Collaborative Ambulatory Research Network and randomly selected ACOG fellows.⁴ The questionnaire was composed of 15 knowledge questions and 3 clinical scenarios regarding OB management and neonatal neurologic outcome. The Network and at-large ACOG fellows did equally poorly on the survey. The most common answer to knowledge questions was "I don't know." There was however, significant correlation between their self-assessment and their actual scores, meaning they at least knew they didn't know! If we are to be part of the solution to this

crisis we must do our part. Reading the ACOG report would be a good start.

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Donald H. Penning MD, MS, FRCP(C)
Associate Professor Anesthesiology/CCM & Obstetrics & Gynecology
Johns Hopkins Hospital
SOAP Government Affairs committee

You may contact the Government Affairs committee at soap-govaffairs@soap.org.

Clinical Forum Revisited: The "P" Value

In the Fall 2002 SOAP newsletter, I argued that a healthy pregnant woman should be classified as ASA I. This debate was sparked by an abstract presented by Barbeito et al that stated only 39% of anesthesiologists would classify a healthy parturient in labor an ASA I, and that if she presented for an urgent cesarean section, 4% classified her an ASA III and 2% stated she should be an ASA IV¹!! My argument focused on two main points. First, pregnancy is a normal physiologic condition and thus should not increase the ASA class. Second, those who argue for ASA II often do so because of an increase in operative or anesthesia risk. The ASA class was never designed as a risk assessment and to use it as one is inappropriate. I firmly believe that healthy pregnant women should be an ASA I within the current ASA classification system. However, I am not unsympathetic to those who would argue otherwise. It does seem odd that a woman can go through the dramatic physiologic and anatomic changes of pregnancy, changes that clearly influence how we anesthetize her, and yet she is assigned to the same class as she would have been 9 months earlier. Perhaps the problem is that the current ASA classification system does not fit the pregnant patient well.

Saklad first proposed the ASA physical status class in 1941². The system was modified and reintroduced to the ASA House of Delegates by Dripps in 1961³, and except for small changes in language, the system has remained in its current form for more that 40 years. The original intent of this classification system was to improve communication. Clinicians would be able to describe their patients, researchers could compare populations, and outcomes could be analyzed with reference to baseline health characteristics of the patient population. Based on the findings by Barbeito, it appears that the current system may actually *increase* confusion rather than decrease it when applied to the parturient. Apparently, if a colleague tells me she administered anesthesia to an ASA IV for a cesarean section, I can't tell if she means that the woman has unstable angina or is healthy but presenting for an emergent procedure.

This type of inconsistency in ASA rating is not unique to obstetrics. Several authors have demonstrated poor inter-rater correlations^{4,5,6,7}. Conditions that frequently increase this inconsistency include: obesity, patient age, the extent of proposed surgery, anemia, and previous myocardial infarction^{6,7}. In an eloquent editorial accompanying the paper by Owen et al, Keats described the ASA classification and highlighted the concerns related to inconsistencies in ratings⁸. He conceded that except for the original paper by Saklad et al, the ASA has never described each class using examples. Thus, practitioners have had to decide for themselves how specific disease processes fit into the vague definition of each ASA class. Keats went on to state that we should agree by convention how to classify those disease processes that lead to wide variation in class assignment. Keats made his comments in 1978, and yet no changes were made to the ASA classification. Thus, to no surprise, Haynes and Lawlor found similar inconsistencies 17 years later⁵. Since pregnancy appears to be another condition that leads to variability in ASA assignment, I propose that we in SOAP, as the experts in the anesthesia care of the pregnant patient, decide by consensus on how we should assign ASA class to the parturient.

As I have stated above, I believe that the healthy parturient should be ASA I. Pregnancy is not a disease

and SOAP should not imply that it is. However, I do understand the cognitive dissonance that this creates. The pregnant woman is not the same patient she was 9 months earlier. I believe that the way to overcome this is to apply a modifier to the ASA score, much as we do for emergency procedures. Adding the letter "p" to the ASA class could be used to indicate that the patient is pregnant, with all of the changes that this implies. Thus a healthy parturient would be ASA Ip, one with mild asthma would be IIp and so on. We would thus be able to clearly communicate the fact the patient is pregnant (a huge anesthetic consideration) *and* the fact that she has co-morbid disease(s). I would be able to tell with certainty that an ASA IVp is a very sick parturient, not simply a healthy woman presenting for an emergency c-section.

There are those who might argue that simplicity is one of the strengths of the current system, that this simplicity is what has facilitated its widespread usage. Further, they might argue that to add a modifier might open create a slippery slope that could lead to endless modifiers. Why not add "ob" for the obese patient or "pmi" for those with a previous myocardial infarction? To these objections I would make three comments. First a system that is simple but does not work is not useful. The current system does not work, does not facilitate accurate communication, in the pregnant population. The addition of this modifier does little to complicate the current system and would do much to increase its applicability to the pregnant patient. Second, we are already on the slippery slope with regards to ASA class modifiers, we have just been there so long we have become accustomed to it. We add "E" for emergent procedures to communicate important information that the ASA class itself does not. Once on such a slope, any decision to add an additional modifier might seem both drastic and arbitrary. However, the decision *not* to add an important modifier is just as arbitrary. I see no inherent problem with creating one additional modifier and not allowing others unless compelling reasons could be demonstrated. Finally, the reason that we need a modifier for pregnancy is the same that we needed one for emergency procedures. The ASA class was not designed to describe either situation within the numbering system. As a community, we could decide that anyone with a previous MI should be an ASA III and that would be appropriate because the system was designed precisely to incorporate this kind of information. We need only decide to which class it should be assigned. However, the system was not designed to incorporate information about a normal, albeit altered, physiologic state such as pregnancy any more than it was designed to incorporate information about the emergent nature of a surgical procedure.

The ASA Physical Status Classification system is a powerful tool. It allows clinicians to transfer a large amount of information in a rapid and simple fashion, and works very well across a wide range of clinical scenarios. It is not perfect, however. There are several disease states about which clinicians frequently disagree and thus the information transfer may be imprecise or misunderstood. In addition, some information is not, and should not be, included in the ASA class (e.g. emergency surgery). I believe that pregnancy is another such piece of information. The addition of a simple modifier, "p," could improve the quality and consistency of information transferred between Obstetric anesthesiologists.

Stephen D. Pratt, MD

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Review: Crystalloid Prehydration Time to Change our Practice?

The concept of prehydration (PH):

Hypotension is the most common side effect of neuraxial blocks in the obstetric patient. Over the last decades several interventions, such as pelvic tilt and the prophylactic administration of fluids or ephedrine, have been proposed to reduce the incidence of maternal hypotension. This article discusses the effectiveness of a prophylactic intravenous fluid bolus, often referred to as "prehydration", to prevent hypotension after spinal anesthesia.

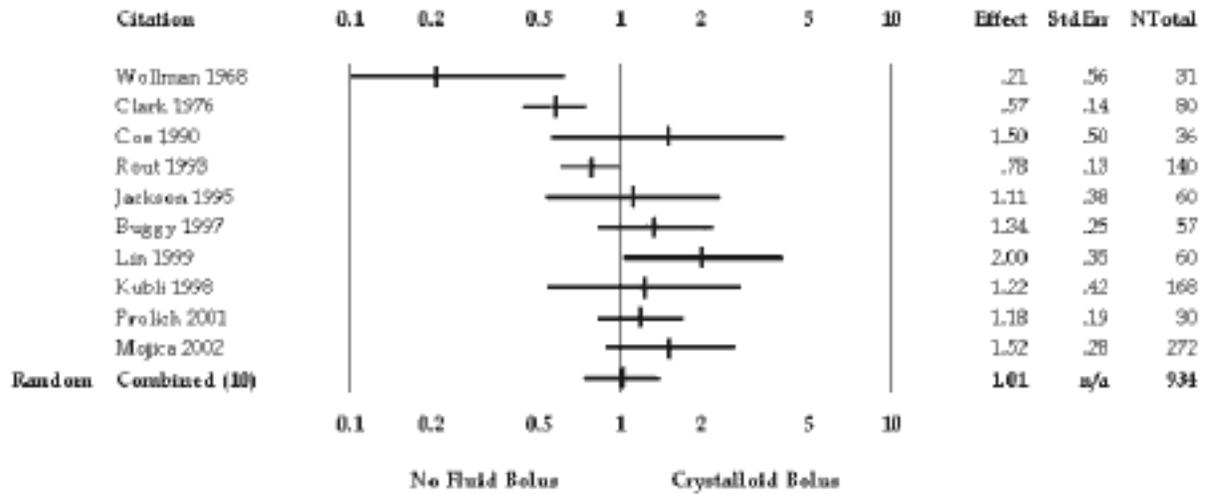
The cause of hypotension after spinal anesthesia is the preganglionic sympathetic blockade resulting in vasodilatation. Arterial and venous vasodilatation reduces cardiac preload. Decreased cardiac preload in turn limits cardiac output, the main compensatory mechanism to counteract spinal vasodilatation. In the pregnant patient, compression of the vena cava by the gravid uterus further impedes venous return to the heart. If untreated, this process may lead to maternal hypotension and uterine hypoperfusion.

Prehydration (PH) unfolds:

In 1968, Wollman and Marx (1) introduced a concept subsequently known as "prehydration" (PH). The authors proposed that intravenous volume expansion should be instituted as a prophylactic rather than therapeutic measure in response to hypotension. They reported PH to be successful in all 14 patients receiving prophylactic volume expansion after spinal anesthesia and a complete failure to prevent hypotension in five non-PH women. Although Clark et al (2) reported similar results in 1976, the remarkable success (100% prevention of hypotension) was never reproduced. Many investigators tested different PH regimens by modifying fluid characteristics (crystalloid versus colloid), volume or timing with mixed results. Repeated discussions and reports about PH led many anesthesiologists to routinely administer a fluid bolus prior to spinal anesthesia despite the lack of solid and reproducible evidence.

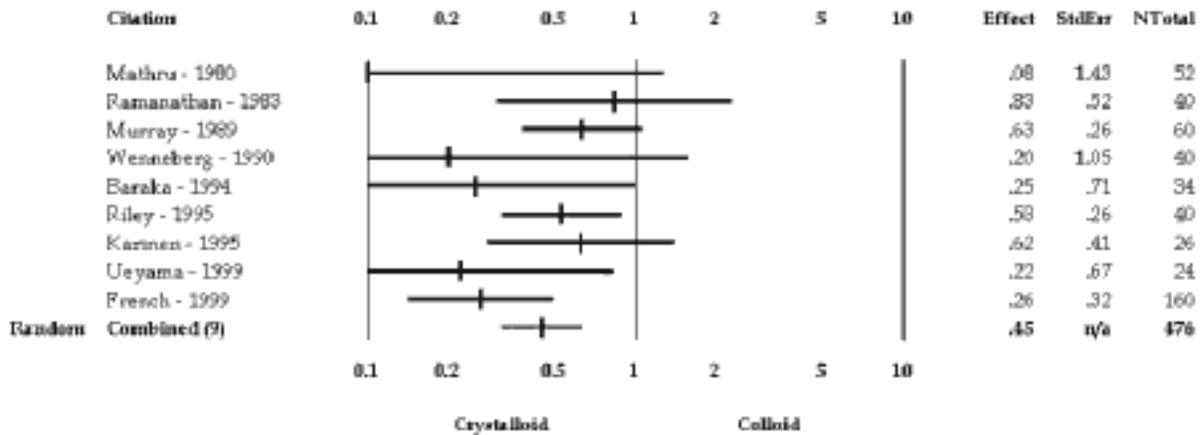
Meta Analysis of Studies on Prehydration
Graphical Representation of the Relative Risk of Hypotension
(Click graphs for larger images)

Crystalloid Prehydration versus Control



Point Estimate: 1.06 , Standard Error 1.17, p=0.73

Crystalloid versus Colloid Prehydration



Point Estimate: 0.47 , Standard Error 1.15, p<001.

Legend to Figure:

Statistics: Effect size (relative risk) is based on the incidence of hypotension provided by the articles. The homogeneity assumption was rejected in the crystalloid versus control study set because of outliers. Therefore, a random effect size model was chosen.

Interpretation: The relative risk (RR) of a study refers to the hypotension risk. For example, Riley et al found the RR to be 0.5. The risk for hypotension in that study group was therefore twice as high if a subject was randomized to crystalloid versus colloid prehydration.

A growing body of evidence challenges PH:

In recent years, policy makers in medicine have called for a more scientific decision-making process. Many researchers started to critically review current practice parameters. Rout took on the concept of PH when he discovered that even large volume crystalloid PH would not decrease the incidence of postspinal hypotension (3). In a large prospective randomized trial, Rout discovered that crystalloid PH provided only a marginal benefit (4). As in many other studies, ephedrine requirements did not differ among groups. Two years later, in 1995, Jackson et al once again took on the topic of PH (5). This time crystalloid PH did not appear to offer even a small advantage.

As the body of literature on PH grew, researchers started to compare articles. The Cochran Pregnancy and Childbirth Group started a database on the evidence about prophylactic measures to prevent post-spinal hypotension (6). In their 2002 review the group concluded that no intervention reliably prevented hypotension during spinal anesthesia for cesarean section. A recent review by Frigo (7) focused on crystalloid and colloid PH and concluded that crystalloid PH was not effective.

Understanding apparently contradictory study results:

The practicing anesthesiologist is now faced with the task of implementing the results of apparently opposite findings into clinical practice. Frustrated by the lack of consistent recommendations, many physicians choose not to disregard new evidence completely. Instead, with a little insight one might understand why research findings can vary.

With respect to post-spinal hypotension, several factors need to be considered: One can begin with the definition of the primary outcome measure, hypotension. Most articles define hypotension as a 20% decline of baseline blood pressure but many variations of this designation are used. Some use mean blood pressure, others are more generous with respect to the degree of hypotension (25% or 30% of baseline) and some do not define a baseline value at all. Another important issue is the amount of ephedrine used; obviously the severity of hypotension can be camouflaged if patients are aggressively treated with ephedrine. Other differences can be explained by variations in study design (e.g. was there a control group not receiving PH?) and statistical analysis. However, a complete discussion of the latter would go beyond the scope of this review.

Reviewing the evidence with a meta-analysis:

A formal approach to summarizing and evaluating a multitude of randomized clinical trials was proposed in the mid-1970s when hundreds of studies of psychotherapy had produced a dizzying array of positive, null and negative results, and reviews of those studies had failed to resolve the debate. Gene Glass statistically standardized 375 psychotherapy studies, calling this method "meta-analysis" (8).

The key concept of such an analysis is based on the idea of being able to summarize and compare the results of different tests. Introducing the parameter "effect size" does this. The effect size can be based on a wide array of statistical tests used to compare outcomes in studies. Using the example of hypotension, this approach allows us to compare studies even if one reports only the incidence of hypotension using a chi-square test and another the total ephedrine requirements using the t-test.

Results are usually presented graphically displaying effect sizes of studies with their respective 95% confidence intervals. Effect sizes of included studies are then treated as dependent variables. The selection of studies should be unbiased and representative of the whole population of studies. The overall analysis of studies is based on a preliminary test, like the homogeneity test, similar to the choice of analysis in an individual study, which will be affected by items such as the normality test of the equal variance test.

Figure 1 presents the comparison of a representative sample of studies comparing (a) crystalloid preloading to control (no volume challenge) and (b) crystalloid preloading to colloid preloading (albumin, dextran or hetastarch). The analysis indicates that (a) the risk of hypotension when receiving PH is almost identical to the risk of hypotension without PH and (b) the risk of hypotension is halved when prophylactic colloid fluid expansion is compared to prophylactic crystalloid fluid expansion.

The take home message:

I have been interested in the concept of PH for several years and was fascinated by the results of a British survey (9). According to the authors of that survey, anesthesiologists routinely practice PH, despite a growing body of evidence challenging the concept. Today the more relevant question to be asked appears to be: How do we effect change in the practice of medicine? The necessary ingredients for a change in medical practice based on evidence appear to be: continuing education of health care providers at all levels, addressing ethical concerns and drawing modest conclusions that do not overstate the facts.

I have summarized the evidence above. Now, let me try to draw a sensible conclusion: Undisputed by most clinicians is the notion that neither crystalloid nor colloid PH reliably prevents hypotension. There appears to be little to no benefit of crystalloid PH and a distinct but small benefit of colloid PH. Based on this information, we have eliminated the nursing policy on routine crystalloid fluid administration prior to neuraxial blockade at the University of Florida. In addition we do not believe that the small benefit of colloid PH outweighs the potential risk of volume overloading and the overall substantial cost.

Michael A. Frölich, MD, DEAA

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Research Column

The Research Committee of SOAP, in an effort to assist members in conducting and evaluating research in obstetric anesthesia, presents this column. If you have ideas, suggestions, or questions for future topics, please write, phone, fax, or E-mail me:

Philip Hess, MD

Dept. of Anesthesiology

Beth Israel Deaconess Medical Center

330 Brookline Ave. East/St-308

Boston, MA 02215

Coordinator, SOAP Research Column

Phone: (617) 667-3112

Fax: (617) 667-7849

E-mail: phess@bidmc.harvard.edu

Measuring Motor Block

Edward T. Riley, MD

Department of Anesthesia

Stanford University School of Medicine

Stanford, CA

The perfect labor analgesic technique would provide complete pain relief with no motor block. Why is maintenance of motor function important? Adequate muscle strength will enable the parturient to push effectively to facilitate spontaneous vaginal delivery. Several studies have shown that epidural techniques utilizing higher concentrations of local anesthetic are associated with an increased incidence of instrumented vaginal delivery and a longer second stage of labor.[1, 2] It is commonly assumed that decreased motor function associated with higher concentrations of local anesthetics causes these adverse outcomes. In addition, patients prefer less motor block; many parturients complain if they cannot move their legs and some find it quite distressing. Some patients want to ambulate during labor or get up to use the bathroom without assistance. Those who do so may succeed in voiding, thus avoiding placement of a urinary catheter. For these reasons, obstetric anesthesiologists have developed and continue to refine analgesic techniques that minimize motor block.

One of the difficulties facing the researcher studying labor analgesic techniques is how to measure motor block. Obviously, if one is interested in a specific outcome, that outcome should be measured. For instance, mode of delivery is the ultimate outcome of interest relative to the effects of motor block. If we

wanted to determine which of two techniques had the higher rate of spontaneous vaginal deliveries, we could randomize a series of patients and measure the outcome of labor. The problem with this type of study is that it requires a prohibitively large sample size. For example, if the expected vaginal delivery rates in the two groups were 70% and 80% and one wanted the study to have a power of 0.80 with a significance level of 0.05, 293 subjects would need to be enrolled in each group (586 subjects total)(GB-STAT™ v.6.5, Dynamic Microsystems, Inc, Silver Springs, MD).

The reality of enrolling hundreds of spontaneously laboring, nulliparous women makes such a study difficult, both in cost and in labor for the researchers. However, these types of studies are invaluable in demonstrating important clinical outcomes. Recently the Comparative Obstetric Mobile Epidural Trial study group in the UK reported an investigation in which they randomized 1054 nulliparous women to 3 treatment groups. They demonstrated that women who received labor analgesia that caused less motor block had a significantly higher rate of spontaneous vaginal delivery.[3] Given adequate time and resources, a study like this is the best way to evaluate the effects of motor block in laboring women.

Because it is difficult to generate the resources to conduct such large clinical trials, we often measure surrogate outcomes. One surrogate outcome for the mode of delivery is the length of the second stage of labor. Lesser degrees of motor block have been associated with a shorter second stage of labor. By measuring a continuous variable (time), instead of the proportional variable (mode of delivery), the sample size can be reduced significantly. For example, if the expected durations of the second stage of labor in a two-sample study are 90 min and 120 min with a standard deviation of 60 min, a sample size of only 31 per group (total 62) would have a power of 0.80 at a significance level of 0.05.

Of course motor block can be measured directly. The most frequently used measure of motor block is the Bromage scale.[4] In this scale the intensity of motor block is assessed by the patient's ability to move their lower extremities (Table 1). The most significant shortcoming of the Bromage score in studies of labor analgesia is that it was designed to measure differences in surgical blocks, and is somewhat irrelevant to measuring motor block due to dilute local anesthetic solutions for labor analgesia.

When using the Bromage scale for research in labor analgesia, it is important to measure motor block intermittently throughout labor, as the degree of block will change. For most analyses I document the greatest degree of motor block measured during the period of the study. It is also important to measure motor block in both legs since the block may be asymmetrical.

Several modification of the Bromage scale have been described, including the use of more gradations of motor block. For example, Breen et al. used a six-point scale to assess motor block (Table 2). The value is to differentiate patients in the Bromage score IV.

Table 1. Description of the Bromage score.[4]

Grade	Criteria	Degree of Block
I	Free movement of legs and feet	Nil (0%)

II	Just able to flex knees with free movement of feet	Partial (33%)
III	Unable to flex knees, but with free movement of feet	Almost Complete (66%)
IV	Unable to move legs or feet	Complete (100%)

Table 2. Modified Bromage score as used by Breen et al. [5].

Score	Criteria
1	Complete block (unable to move feet or knees)
2	Almost complete block (able to move feet only)
3	Partial block (just able to move knees)
4	Detectable weakness of hip flexion while supine (full flexion of knees)
5	No detectable weakness of hip flexion while supine
6	Able to perform partial knee bend

Several investigators have measured motor block on a scaled score by quantifying the force of isometric muscle contraction or by using average rectified electromyography.[6-8] Most of these methods are not easy to perform on the labor ward. However, an adaptation of these methods by Graham and McClure may be a viable and useful measure of motor in laboring women.[9] A force transducer in the shape of a dumbbell was placed between the subject's legs with the ends of the dumbbells resting on the medial epicondyles. The subject then squeezed her legs together and this maximal force was recorded. When compared with a modified Bromage score, the correlation coefficient was -0.58, whereas the correlation coefficient between the modified Bromage score and the original Bromage score in these same subjects was only 0.4. Therefore, this methodology is as consistent a measure as the Bromage score, and it is a scaled measure, and therefore should have increased power over the categorical type scores.

Recently, several studies have used the ability of women to walk after the induction of labor analgesia as an outcome variable. Walking is an important outcome variable since many women desire to ambulate during labor. However, there is no proven association between walking and an improved outcome of labor.[2] In addition, the ability to walk is again proportional data. Therefore, large sample sizes will be needed to assess differences among techniques.

The fundamental problem with the Bromage scale, walking studies, and other measures of lower extremity strength for assessing a woman's ability to push in labor, is that a woman does not push a baby through her pelvis with her legs! A better surrogate measure of a woman's ability to push would be to measure intra-uterine or intra-abdominal pressure generated during a contraction.[10] I have not seen any published studies in which intra-uterine or intra-abdominal pressure were used to assess the ability to push as affected by labor analgesic techniques. The reason for this may be the difficulty involved with enrolling laboring women in a study in which they are required to have an intra-uterine or rectal catheter placed. However, I believe this methodology could be useful in labor analgesia studies.

In summary, motor block is assessed in labor analgesia studies because of the assumption that the outcome of labor and maternal satisfaction is affected. The best measure is to assess the outcome of interest. Other measures such as the Bromage scale and isometric muscle contraction strength are easy, non-invasive measures of motor block that may be predictive of the effect a labor analgesic technique has on the outcome of labor. Intra-uterine and intra-abdominal measures of motor strength could be useful ways to assess the effect of labor analgesia.

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