

“FAREWELL TO INDIGO CARMINE”

ROBERT L. BARBIERI, MD
(EDITORIAL; SEPTEMBER 2014)

Use baby formula to check for bladder integrity

There is an additional method that can be used to check for bladder injury that some of us “older” gynecologists have employed. Baby formula is packaged in sterile bottles. I have had the rare occasion to need to check for bladder integrity and have had the circulating nurse inject diluted formula through the indwelling urinary catheter. I have yet to encounter (or read about) an allergic response from this technique.

Martin E. Kanoff, DO
Sewell, New Jersey

I found Dr. Barbieri’s editorial on the indigo carmine shortage very appropriate and timely.

When intraoperatively testing a bladder repair or looking for a possible bladder injury, administration of phenazopyridine or instillation of dilute methylene blue as noted are reasonable approaches. Due to tissue staining, which can make repeat bladder assessment more difficult, I have found that instilling sterile formula, usually easily available on the obstetric unit, will allow detection of “leaks” and easily can be rinsed out of the pelvis with saline, allowing repeat instillation if necessary.

Also, if the bladder is distended with fluid when looking for defects, it pays to wait a few minutes before decompressing, as small leaks may gradually deflate the bladder and alert the surgeon to the need for further investigation.

William J. Mann, Jr, MD
Executive Medical Director
Olde Towne Medical and Dental Center
Clinical Professor, ObGyn
Virginia Commonwealth School of Medicine
Richmond, Virginia



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What about using sterile milk?

Dr. Barbieri, what is your opinion and do you have any ideas on sourcing sterile milk for use in diagnostic cystoscopy and tubal patency in gynecology?

Donna G. Ivery, MD
Titusville, Florida

Is there a methylene blue shortage too?

I commonly perform chromotubation for my infertility patients and for tubal reversals. I have been substituting methylene blue for indigo carmine. Recently, I was told by my surgical center that methylene blue is on back order. Have you noticed the methylene blue shortage? Do you have suggestions for a replacement for my indications of chromotubation and tubal reversal surgeries?

Online I have seen mention of isosulfan blue being injected into lymphatic tissue to identify sentinel nodes—although it is more expensive. I will be searching now for a supplier of isosulfan blue. Sterile milk has been used to identify

bladder fistulas. Can it be used for chromotubation?

Peter G. Van Deerlin, MD
South Jersey Fertility Center
Marlton, New Jersey

Can we brainstorm a solution to the shortage?

Dr. Barbieri, once again you have demonstrated your clear thinking and reasoned approach to what is a clinical problem.

I would add the following thought: Perhaps a group of physicians from major specialty/sub-specialty organizations could meet with the present manufacturers and brainstorm for a solution. Self-interest is clearly the practical path and patient safety/customer satisfaction can come into play also.

Stephen S. Schuster, MD
Queens, New York

Another way to diagnose PROM

I read with interest the editorial covering the shortage of indigo carmine. In the section “Options to diagnose PROM ...”, you stated NONE as the option for diagnosing premature rupture of membranes (PROM) when standard clinical testing is equivocal.

A recent article in *Journal of Perinatal Medicine* suggests that placental alpha microglobulin-1 (PAMG-1) testing is as reliable as dye studies.¹ This was a 140-patient prospective study and is certainly encouraging.

I don’t use PAMG-1 as a first-line agent for diagnosing rupture of membranes (ROM). Speculum examination with pooling of amniotic fluid, nitrozine testing, and microscopic examination for ferning confirm or rule out ROM in most cases. This article points toward avoiding the more invasive dye

study. The data are timely in light of the indigo carmine shortage.

John R. Hannig, MD
Salem, Oregon

Reference

1. Sosa CG, Herrera E, Restrepo JC, Strauss A, Alonso J. Comparison of placental alpha macroglobulin-1 in vaginal fluid with intra-amniotic injection of indigo carmine for the diagnosis of rupture of membranes. *J Perinat Med.* 2014;42(5):611-616.

» Dr. Barbieri responds

I appreciate the great suggestion by Drs. Kanoff, Mann, and Ivery to use sterile baby formula to test bladder integrity. Sterile baby formula is usually available on an obstetric unit, and less available in a main operating room environment. One small caveat about the use of the word "sterile." Baby formula is "sterile" using criteria for a commercial food product. Injectable agents typically need to be both sterile, using criteria for a pharmaceutical agent, and pyrogen free. These criteria are more stringent than for a food product. Some surgical nursing and pharmacy administrators may focus on this technical difference and resist the use of sterile baby formula to test bladder integrity.

First it was indigo carmine, now methylene blue is on back order. As Dr. Van Deerlin suspects, isosulfan blue is expensive. A 5-mL vial of isosulfan blue has a list price of \$714. If no dye were available to test tubal patency, I would consider using saline or lactated Ringer's solution. I would hesitate to use sterile baby formula because I would be concerned about peritoneal and tubal epithelial inflammation.

Dr. Schuster has a great suggestion to better coordinate the capabilities of manufacturers with the needs of clinicians and patients. We will forward your suggestion to the ACOG leadership.

I agree with Dr. Hannig's suggestion that measurement of placental alpha macroglobulin-1 in vaginal fluid is an excellent option for replacing intra-amniotic injection of indigo carmine. Some obstetric units have not yet deployed this test because, in many centers, only a few cases per year needed this test. With the loss of access to indigo carmine, it is a good option to consider measurement of placental alpha macroglobulin-1 in vaginal fluid in cases where it is unclear if the membranes have ruptured.

"PREVENTING POSTOPERATIVE NEUROPATHIES: PATIENT POSITIONING FOR MINIMALLY INVASIVE PROCEDURES"

TIFFANY JACKSON, MD; BICH-VAN TRAN, MD; ARNOLD ADVINCULA, MD; KAREN WIERCINSKI, RN, BSN; JULIO LOPEZ (VIDEO; SEPTEMBER 2014)

May I share the video?

The video on patient positioning to prevent postoperative neuropathies is a great resource for physicians and nurses! May I share this video with our gynecologic operative room staff as a teaching tool?

Christinne D. Canela, MD
Roanoke, Virginia

» The Editors respond

This, and all of the videos at obgmanagement.com are meant to be shared with your colleagues.

"TISSUE EXTRACTION DURING MINIMALLY INVASIVE GYN SURGERY. SECOND OF 2 PARTS: COUNSELING THE PATIENT"

(ROUNDTABLE; OCTOBER 2014)

May I morcellate your uterus please?

The laparoscopic approach to the fibroid uterus is currently a puzzle. After the FDA released a statement

in April postulating that the use of power morcellation to remove uterine fibroids should be "discouraged," a great controversy developed in the minimally invasive surgical community.

Subsequently in July, the Obstetrics and Gynecology Devices Advisory Panel of the FDA held a 2-day meeting to analyze risks, benefits, and the overall clinical role of laparoscopic power morcellation in gynecology. One recommendation was to include in the informed consent a disclosure of the risks of disseminating an occult uterine malignancy. I salute the efforts of the panel and agree on the necessity for a comprehensive consent process that discloses risks that could worsen the patient's prognosis.

Soon after that FDA panel met in July, Ethicon, a division of Johnson and Johnson, made a business decision to initiate a worldwide withdrawal of the company's morcellation devices.

Now, on November 24, the FDA issued an updated Safety Communication recommending that the use of power morcellators is contraindicated for removal of uterine tissue containing suspected fibroids in patients who are peri- or postmenopausal, or are candidates for en bloc tissue removal. They also said that laparoscopic power morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy. The FDA is issuing a boxed warning, and recommends that surgeons thoroughly discuss the benefits and risks of all treatment to patients, including younger women who want to maintain their fertility or women not yet perimenopausal who wish to keep their uterus.

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How will having a patient sign a consent form change the risk of unfortunate dispersion? How will it protect the surgeon from the subsequent liability? Who will be responsible for worsening the patient's survival?

Month after month in the Medical Verdicts column, we see cases of unfortunate patients who suffer well-known surgical complications that are litigated, with different outcomes and compensations. I am certain that in most of these cases, the patients had signed at least a standard consent form that lists the most commonly known complications. Having a patient sign a consent form does not reduce the incidence of complications nor protect the physician from liability.

In my opinion, effort should be concentrated on finding a way to better preoperatively identify the patient at risk of occult uterine malignancy so that the surgical approach can be modified accordingly.

The controversy regarding morcellation is far from over. Perhaps the last tissue extractor remaining in the market should be used to morcellate the tort system and finally build a system that will protect patients and physicians.

Jose Carugno, MD
Miami, Florida

» Dr. Iglesia responds

Dr. Carugno is correct. A "consent form" does not protect the surgeon from potential liability nor the patient from potential harm. Informed decision-making is a process wherein providers and patients discuss the diagnoses and conditions; the treatment options and alternatives ranging from expectant management, medical management or surgical intervention; and the potential risks and benefits of each of those



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options. Physicians should perform an adequate preoperative evaluation, and patients should be given the opportunity to ask questions with the understanding that no treatment is without risks (including the option for watchful waiting). Physicians should describe the steps that will be taken during the preoperative, intraoperative, and postoperative periods to mitigate those risks.

"TOTAL ABDOMINAL HYSTERECTOMY THE MAYO CLINIC WAY"

JOHN B. GEBHART, MD, MS
(SURGICAL TECHNIQUE; OCTOBER 2014)

We need to focus on improving vaginal hysterectomy

I found Dr. Gebhart's article on abdominal hysterectomy technically very accurate and well written. It is with the greatest respect that I write to express my concern with the author's response that because of the restriction of power morcellation devices, the rate of abdominal hysterectomy will increase.

Rather than focus on the

improvement of the most common gynecologic surgical procedure, we should be focusing on improving techniques of vaginal hysterectomy, a route that unfortunately is under-taught in the United States.

I have been a practicing ObGyn for more than 20 years, and exclusively as a gynecologist for the last 4 years. I perform vaginal hysterectomies more than 90% of the time. My total abdominal hysterectomy and laparoscopic-assisted vaginal hysterectomy rates remain less than 5%; laparoscopic supracervical hysterectomy and total laparoscopic hysterectomy rates: 0%; and power morcellation rate: 0%.

In conclusion, why abdominal hysterectomy?

Robert C. Raymond, MD, MBA
Fort Payne, Alabama

» Dr. Gebhart responds:

Dr. Raymond, I thank you for your comments and question. I applaud your surgical skill set and approach to hysterectomy. My preferred route of hysterectomy for benign disease is the vaginal route. A few years ago we published an article in OBG MANAGEMENT on keys to success in vaginal hysterectomy.¹ Indeed, the vaginal approach remains the least expensive and least morbid approach to hysterectomy, yet the least common. I continue to publish and lecture on the benefits of a vaginal approach and societies, such as the Society of Gynecologic Surgeons (SGS), remain committed to teaching and advocating this well-established, evidence-based yet under-utilized approach.

Given the interest and controversy in the use of power morcellation after the FDA's Safety Communication last April,² it was felt that a good technical review of abdominal hysterectomy was cogent. If surgeons have a concern about using power

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morcellation or their institution has banned use of a power morcellator, then the abdominal route is the most likely alternative for removing the enlarged uterus intact. As you state, the abdominal approach remains the most common route of hysterectomy. My sense is that most providers faced

with an enlarged uterus that cannot be removed via laparoscopic morcellation (for reasons stated previously) are likely to turn to abdominal hysterectomy. Hopefully, the article gives readers a chance to assess and develop their technical approach to abdominal hysterectomy.

References

1. Occhino JA, Gebhart JB. The difficult vaginal hysterectomy: 5 keys to success. *OBG Manag.* 2010;22(11):32-47.
2. US Food and Drug Administration. Laparoscopic uterine power morcellation in hysterectomy and myomectomy: FDA Safety Communication. <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm393576.htm>. Published April 17, 2014. Accessed December 8, 2014.

Quick Poll results suggest that many gynecologists agree with the main points of AAGL's recent privileging and credentialing guidelines for robotic surgery, although some feel the approach is too restrictive.

A recent OBG MANAGEMENT Quick Poll took as its subject Dr. John Lenihan's article, "Flight plan for robotic surgery: New AAGL guidelines." In it, Dr. Lenihan described the rationale for the guidelines, and how the recommended requirements of credentialing emulate the aviation industry.

Our poll asked how many responders agreed that the following points are essential components of the robotic gynecologic surgery credentialing and privileging process:

1. Surgeons should be selected for training who are most likely to be successful in performing robotic surgeries safely and efficiently.
2. There should be a minimum number of procedures performed on a regular basis to ensure that the surgeon maintains his or her psychomotor (hand-eye coordination) skills.
3. Surgeons, like pilots, should be required to demonstrate their competency in operating the robot on a regular basis.

More than 150 readers responded:

- **90 readers (59.2%)** reported agreeing with the guidelines
- **59 readers (38.8%)** reported believing the approach is too restrictive
- **3 readers (2%)** reported believing the approach is not restrictive enough

To participate in the latest poll, see the Quick Poll at obgmanagement.com

