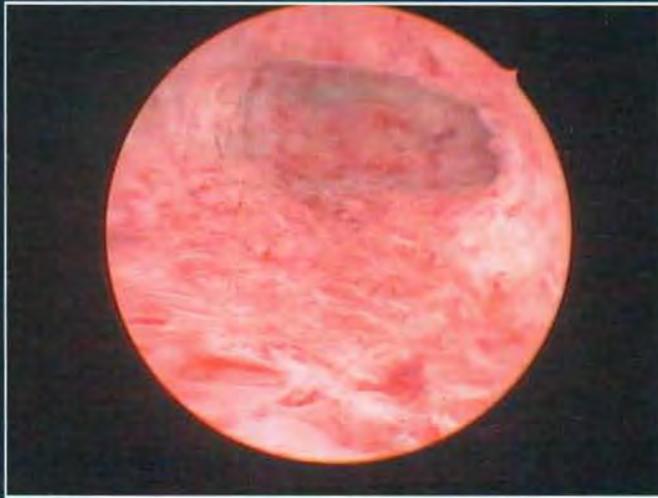




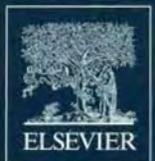
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MORRIS MORTMAN, M.D.
2020 CLINTON AVE S
ROCHESTER NY 14618-5703
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Editorial

Pain Management for Office-Based Surgery: Expanding Our Flight Envelope

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The proliferation of technologies that enable office-based surgical procedures accompanied by strong economic incentives creates both opportunities and hazards for gynecologists and their patients. Diagnostic hysteroscopy, tubal occlusion, and endometrial ablation are just a sample of commonly performed procedures that have already migrated to the office-based setting, and others will no doubt follow. The gynecologist, however, must be mindful that although these procedures are minimally invasive and relatively safe, they can be associated with substantial anxiety and pain, occasionally to a degree that precludes their completion. In the hospital or ambulatory setting, the task of administering anxiolytic and analgesic agents is left to our anesthesia colleagues. However, by relocating these procedures to the office, we are obliged to prepare for and manage unanticipated pain, apprehension, and their sequelae. This task mandates a thoughtful understanding of the physiology of pain and anxiety, the limits of local anesthesia, and the role of other possible pharmacologic interventions. In addition, practitioners must have a clear understanding of state and federal laws, and the pertinent policies of the American College of Obstetricians and Gynecologists (ACOG) and the American Society of Anesthesiologists.

Diagnostic hysteroscopy is among the simplest office-based gynecologic procedures. With the introduction of small-diameter and flexible fiberoptic hysteroscopes, excellent results, as judged by procedure completion, have been achieved. Yet Bradley and Widrich [1] have reported that even in the most experienced hands, 48 of 417 patients (12.4%) considered performance of a vaginoscopic technique without paracervical block (PCB) anesthesia and a small-diameter (3.6 mm) flexible hysteroscope "barely tolerable," and another 14 (3.6%) considered the procedure "intolerable," precluding its completion. One could reasonably assume that less experienced physicians who perform

even more complex procedures would report higher rates of patient discontent.

One might wonder whether PCB anesthesia would improve these results. Many physicians who perform office-based gynecologic procedures in the uterine cavity, such as endometrial biopsy, insertion of an intrauterine device, diagnostic hysteroscopy, tubal occlusion, polypectomy, and endometrial ablation, rely on the use of PCB or intracervical block (ICB) anesthesia. Often these local anesthetic blocks are used as the sole analgesic regimen or as part of a pain management protocol that includes orally administered medications to improve patient comfort. Given the widespread use of PCB anesthesia, it is worth noting that there has been considerable controversy over its value. A randomized controlled trial (RCT) by Lau et al [2] concluded that the use of PCB anesthesia fails to attenuate the pain associated with hysteroscopy and noted that the injection itself is also painful and not without risk. In a comprehensive review, Readman et al [3] reviewed 40 articles involving more than 10,000 women undergoing diagnostic hysteroscopy, and concluded that patient acceptability using a variety of analgesic protocols was not substantially affected by PCB, ICB, or transcervical block. Indeed, their analysis revealed that in many instances, women perceived the injections to be as painful as the procedure. Similar results have been demonstrated in women undergoing hysteroscopic tubal occlusion. In an RCT, Chudnoff et al [4] demonstrated that "paracervical block does not afford significant pain relief in upper uterine manipulations." They concluded that "additional methods for pain reduction in procedures performed higher in the uterus at the time of hysteroscopy should be sought, because paracervical block offers little improvement in these symptoms" [4]. It is not surprising that even when PCB anesthesia is supplemented with orally, intramuscularly, or rectally administered sedatives and analgesics, patients often find pain management for endometrial ablation procedures

in an office setting suboptimal. Clark et al [5] conducted an RCT that compared bipolar radiofrequency with thermal balloon endometrial ablation in an office setting. In addition to PCB anesthesia, subjects were pre-medicated with a 100-mg diclofenac rectal suppository as well as 10 mg dihydrocodeine tartrate, 100 mg acetaminophen, and 50 mg cyclizine, all administered orally. The authors noted that 41% of women undergoing thermal balloon ablation and 34% of women undergoing radiofrequency impedance-controlled endometrial ablation "would have preferred a general anesthesia with hindsight" [5]. Indeed, 5% of women undergoing thermal balloon ablation did not complete the 8-minute treatment cycle.

One can only conclude that while many gynecologic procedures have been successfully completed with use of PCB anesthesia, often supplemented with orally, intramuscularly, and rectally administered agents, these successes do not reflect patient comfort and adequate pain control as a measure of success.

So that we can fulfill the ethical requirement for adequate pain control and anxiolysis in an office setting [6], we must first accept that the relentless belief that PCB and ICB block anesthesia offers reliable pain mitigation must be challenged; in short, we must evolve beyond denial. Charles Tremper, noted author and former Associate Dean of the University of Nebraska School of Law, noted that "Denial is a common tactic that substitutes deliberate ignorance for thoughtful planning" [7]. Once we accept that the use of PCB and ICB anesthesia is of dubious value in office-based procedures and that unanticipated pain and anxiety do occur, our task becomes unclouded and manageable, that is, to produce scientifically valid procedure-specific protocols for analgesia and anxiolysis.

Our ethical responsibilities for providing patient safety and comfort in an office setting are affirmed in the ACOG Executive Summary for the Presidential Task Force on Patient Safety in the Office Setting [6], which states that "the type and level of anesthesia should be dictated by the procedure with input based on patient preference. The decision regarding type of anesthesia should not be altered based on limitation of equipment or personnel in the office setting; rather, it should be based on patient needs in relation to the planned procedure" [6]. Despite this exhortation, many of us continue to perform office-based surgery hoping that our patients fit our protocols rather than the other way around. Although the ACOG provides laudatory goals, we must acknowledge 2 facts: that there are few peer-reviewed procedure-specific protocols for the management of pain and anxiety in an office setting and that residency training programs have yet to require teaching this combination of art and science [8,9].

In this knowledge vacuum, most gynecologists have erred on the side of caution, opting to provide minimal (level 1) sedation in an office-based surgical setting. This approach seems reasonable given that level 1 sedation requires limited training and capital equipment investment and does not entail

accreditation by any of the state health departments [10,11]. Although most procedures that have been advocated for the office setting can be performed in properly selected women with use of minimal sedation, most physicians lack an understanding of the legal and pharmacologic boundaries that govern their office use. This has caused many physicians to operate within a narrow set of self-imposed guidelines that hinder the use of the full range of options available to us and our patients even under the category of minimal sedation.

The fact remains, however, that level 1 anesthesia, which the ACOG defines as "mild sedation/anxiolysis," defines neither the agents nor the route of administration. The Executive Summary specifically states that "The level of anesthesia achieved, not the agents used, is the primary concern regarding patient safety. Whether given orally or parenterally, narcotics and sedatives pose similar risks" [6]. Although intravenously administered agents are easier to titrate and control, most physicians rely on longer acting orally or intramuscularly administered agents, which often provide suboptimal levels of sedation and analgesia and are difficult to adjust in the short time frame required for office-based surgical procedures.

During a recent postgraduate course at our 40th Annual Meeting, I asked the presenter what she would offer her patient who experienced unanticipated pain during a hysteroscopic tubal occlusion. After the presenter stumbled, I asked whether she would consider establishing intravenous access and administering small incremental doses of a non-steroidal anti-inflammatory drug, an opiate, or a sedative. Without hesitation, the presenter pointed out that providing intravenous access and administration of medications by this route was *illegal* in her state. I was both surprised and discouraged by this factually incorrect statement. As the late Senator Daniel Patrick Moynihan reputedly said, "While we are each entitled to our own opinions, we are not entitled to our own facts." In truth, parenteral administration of analgesic and sedative agents for the purpose of achieving the target of minimal sedation is legal and allowable in *every* state [10,11]. The use of moderate sedation is restricted in many states, however, and if one is intent on providing this level of analgesia and sedation, it is wisest to check with the appropriate state's Department of Health or Medical Board. Similarly, the use of opioids and benzodiazepines is also allowable in every state, but requires that one carefully adhere to state and federal Drug Enforcement Administration requirements for the dispensing and storage of these medications. On the other hand, many pharmacologic agents are available today that offer excellent sedation and analgesia and are not categorized as controlled substances.

The future will no doubt provide us with additional innovations that allow us to perform an increasing array of office-based procedures. Once we accept that even well-selected patients experience unforeseen pain in an office setting, we can begin to develop an array of protocols that are both

safe and acceptable to our patients. In the meantime, the art and science of pain management and anxiolysis in the office setting has not kept pace with the great technologic strides of the last few decades. While we await RCTs and improved training to guide us, there is much that we can do so that we do not sacrifice patient comfort for expediency.

First, define your target level of sedation and follow the guidelines established by the ACOG [6], the American Society of Anesthesiologists [12], and state regulatory agencies [10]. If your target is minimal sedation, know that it is allowable in every state by any route of administration as long as one complies with federal and state Drug Enforcement Administration regulations for distribution and storage of controlled substances.

Second, understand the pharmacokinetics of the agents you rely on. Office-based surgical procedures generally last only a few minutes and are best served with short-acting intravenously administered medications that provide therapeutic serum concentrations that are quickly metabolized and excreted.

Third, control over the targeted level of sedation is best achieved by using small incremental doses of medication with a sufficient period of time to allow them to act.

Fourth, be mindful that individual patient requirements for specific agents vary widely and that pain management protocols should reflect an individual's response to a given agent and dosage.

Fifth, avoid "polypharmacology." When physicians have had a poor experience with a particular pharmacologic regimen, there is often a tendency to use a pharmacologic stew rather than rely on the least number of agents necessary to safely and comfortably complete a procedure. Most office procedures can be performed with the use of 1 or 2 agents, an analgesic alone or an analgesic in combination with a sedative. The use of 3 or more agents to achieve patient comfort in an office setting should be questioned.

The use of a disciplined approach and good judgment should enable most physicians to expand what pilots refer to as their "flight envelope," that is, the range of possible behaviors that allow safe flight under a variety of atmospheric, weight, and load conditions. This same approach to pain control, exploring the range of possibilities by making small incremental and thoughtful adjustments to medications and dosages, can enable us to define the flight envelope for

a given patient undergoing a particular procedure within a given targeted level of sedation. With discipline and planning, we can provide surgical comfort in the office setting and eradicate "intolerable" or "barely tolerable" experiences for our patients.

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Morris Wortman, MD
Clinical Associate Professor of Gynecology
University of Rochester Medical Center
Rochester, New York

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