

Are low-volume ERCPists a problem in the United States? A plea to examine and improve ERCP practice—NOW

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In this issue of the *Journal*, Cote et al report their assessment of current ERCP practice and attitudes toward it from an online survey of U.S. gastroenterologists.¹ More than 1000 American Society for Gastrointestinal Endoscopy (ASGE) members responded. An important feature is that they asked practitioners to categorize themselves by annual volume, defining low volume as fewer than 50 ERCPs per year, moderate at 50 to 200, and high as more than 200. Their most striking and worrying data are that 40% of the respondents were in the low-volume category. They had less training (77% had not performed 180 ERCPs in fellowship); only 58% “enjoyed” and only 60% were “very comfortable” with ERCP. Because only 18% responded to the survey, it seems likely that the overall situation is even worse than stated. This raises fundamental and sensitive questions. Should low-volume ERCPists (and hospitals) be doing it? Are we comfortable with the state of ERCP practice in the United States?

ERCP has changed substantially over its 40-year history. It is difficult to overstate the impact and excitement when it was introduced widely in the 1970s. There were no scans at that time, and biliary and pancreatic diseases were usually diagnosed at a late stage by laparotomy, with poor outcomes. Surgery for bile duct stones carried a mortality rate of 5% to 10% in the best of hands. To be able to image the ducts accurately and then to remove stones and drain obstructions noninvasively was truly a remarkable revolution in medicine. No wonder it was embraced enthusiastically by many gastroenterologists. Most advertisements

for practice positions requested ERCP expertise, and trainees lined up to gain the necessary skills, without which they would feel somewhat marginalized.

The pancreaticobiliary world has changed substantially, and progressively, in the past 2 decades. Sophisticated imaging procedures (multislice CT, MRCP, and EUS) have challenged and should have largely eliminated the need for ERCP as a diagnostic procedure.² Our goal as therapeutic endoscopists used to be to avoid sending patients to surgery if at all possible, but times have changed. Surgery has become very much safer, at least potentially (because volumes are also important in the surgical field) with advances in minimally invasive techniques and excellent perioperative anesthesia and care. Endoscopy remains the obvious primary choice of treatment for common biliary problems (duct stones, leaks, and low tumors), but some procedures that we assumed were helpful, such as preoperative stenting for malignant obstructive jaundice and urgent sphincterotomy for acute gallstone pancreatitis, are looking less convincing under the spotlight of serious scientific evaluation.^{3,4} Large numbers of patients are being treated by ERCP (often many times) for all types of pancreatitis, with little validation. Some may do well, but data are scarce. Two randomized trials showed that surgery is more effective than ERCP for treating obstructive chronic pancreatitis.^{5,6} Even more controversial and worrying is “suspected sphincter of Oddi dysfunction,” where the benefits of sphincterotomy are unproven, and the risks are very substantial.⁷ This is a clinical minefield and the most common scenario in the more than 100 ERCP-related lawsuits with which I am familiar.⁸ These issues point strongly to the need for more evaluation research.

It is important to appreciate that ERCP is not actually a procedure, but merely a method of access to ductal systems that may harbor diseases and require treatment (analogous to laparoscopy being simply a way into the abdomen). There are many different contexts in which ERCP may be applied, of varying complexity and risk. Schutz and Abbott⁹ first introduced the concept by suggesting 5 levels of difficulty, later modified to 3.¹⁰ This concept was updated recently by a working party of the ASGE (and extended to other endoscopic procedures).¹¹ Four levels of complexity are proposed. The primary goal of the

Abbreviations: ACG, American College of Gastroenterology; ASGE, American Society for Gastrointestinal Endoscopy.

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fellowship programs that offer ERCP training is to get fellows to competence in level 1 and 2 contexts (mainly standard biliary work). Postfellowship programs are needed to master more complex challenges at levels 3 and 4 and related career development needs.

How much training is needed to reach competence at each level remains an ongoing debate, depending on the case load, the skills, the patience and teaching skills of the teacher, and the dexterity and dedication of the trainee. The early “threshold number” of 100 ERCPs suggested by ASGE in 1988 was shown to be grossly inadequate by the seminal study from Duke University that found that their fellows (presumably pretty smart) were only approaching 80% competence after performing 180 to 200 ERCPs.¹² At the Medical University of South Carolina, our fellows are involved in more than 300 procedures in the regular third-year program. Our fourth-year advanced trainees from “outside” get about 350 cases, but their eventual level of competence depends greatly on their previous experience. Sadly there is as yet no mechanism for assessing the competence of finishing trainees in an objective manner. Although most seem to have achieved adequate cognitive and technical skills, and recognition of risky areas, their performance after leaving the mother ship may be different, with unfamiliar equipment and staff, no one at the shoulder, and some peer pressure to succeed.

How many ERCPs is it necessary to perform each year to maintain skills and to enhance them is the crucial and perhaps most controversial issue. One can imagine that a very experienced ERCP practitioner could remain competent for a while, performing only about 50 ERCPs per year, but those recently out of training are unlikely to perform adequately, let alone to improve, without substantially more.

Competence implies that the practitioner can do the procedure unassisted and perform adequately.¹³ What is an acceptable level and who defines that? Determining how to make the necessary assessments is challenging.

One key quality metric for ERCP is achieving deep biliary cannulation because it is a prerequisite for success in most common procedures.^{14,15} Experts achieve less than 95%.¹⁶ Not all patients can be managed by experts, so how much less is acceptable? Early training documents suggested figures as low as 80%,^{12,17} but I suspect that an informed patient would not knowingly accept a procedure from someone shooting less than 90%, unless there was no alternative, in an emergency. But most patients currently have no way of knowing. They may assume that their local gastroenterologist, who did their upper and colon examination, is equally competent at ERCP.

The situation bears some comparison with colonoscopy a decade ago. Experts published very high cecal intubation rates, and everyone assumed that colonoscopy was usually successful and accurate (even by occasional practitioners like me). The blinders came off with some shocking data from Britain, and less impressive results from U.S.

practice.^{18,19} Many subsequent seminal studies, including back-to-back colonoscopies, adenoma detection rates, results from national cancer statistics, and comparisons with CT colonography have stripped the thin gold veneer from the supposed criterion standard and revealed huge variations in performance.^{20,21}

I suspect that most ERCP experts believe that huge variations also exist in their world. An unsuccessful ERCP is disappointing and expensive in itself, but also adds the significant burden of the additional risks and costs of other procedures needed to take care of the problem. ERCP is about 20 times more likely than colonoscopy to result in a serious complication. About 1% of relatively healthy patients who walk in for ERCP spend months in the hospital with pancreatitis or perforation, and some die.¹⁶

The crucial issue, of course, is the quality of the procedures that are being done, especially by the less experienced. Where is the evidence that volume and outcomes are positively associated? It is not necessarily the case in some areas of human endeavor (like my golf), but has been shown repeatedly in many surgical contexts, including cardiovascular, cancer, and orthopedic procedures.^{22,23} Many of these surgical studies have shown also that institution volume is as important as the experience of individual practitioners, and indeed that some low-volume surgeons may do well in high-volume centers. Similar conclusions come from interventional radiology and hospital management of acute GI bleeding.²⁴ The importance of center volume must have resonance in the world of ERCP, which also requires a full team approach. Because of the need for X-ray equipment, ERCP differs from other endoscopic procedures in being almost entirely confined to hospitals. Significant ongoing activity is needed to develop and to maintain the skills of the nurses and radiology support (and anesthesia where used) and to keep the necessary inventory of accessories.

Technical outcomes such as cannulation and stone extraction rates are not the only aspects of ERCP practice that may be affected by low volumes by individuals and hospitals. It is more difficult to keep up-to-date with the literature on the role of ERCP in the modern world, specific safety issues (antiplatelet agents, antibiotics, contrast alternatives), prophylactic pancreatic stenting, the roles of EUS and especially of MRCP (with secretin stimulation), advances in surgery and interventional radiology, and other treatments (eg, extracorporeal shock wave lithotripsy for pancreatic stones). Complex pancreatic and biliary diseases require a multidisciplinary team approach involving gastroenterologists, specialized surgeons, and imaging and interventional radiologists. Lack of such a team will lead to errors in the selection of tests and treatments and also in the recognition and effective management of post-ERCP complications. A common reason for lawsuits is failure to recognize retroduodenal perforation after sphincterotomy. These are all bad for patients—and expensive.

All this sounds logical, at least to me, but we have to admit that there are rather few data on the performance of low-volume ERCPists (or hospitals). For obvious reasons they rarely publish (or perhaps even collect) their data, but what we do have consistently supports the idea that more is better.²⁵ A recent large prospective, multicenter study from Austria showed greater technical success and fewer complications by endoscopists performing more than 50 ERCPs per year.²⁶ Studies in Sweden²⁷ and Italy²⁸ both showed better outcomes in centers doing more than 200 ERCPs per year. In North America, Freeman et al²⁹ showed that ERCPists doing more than 50 sphincterotomies per year were more successful and had fewer complications, especially less severe ones. Similarly, a single-center study in Germany showed that ERCPists doing fewer than 40 sphincterotomies per year had more complications.³⁰ Many years ago we showed better outcomes in the management of duct stones in the community by ERCPists with experience of more than 200 ERCPs.³¹ Looking only at inpatient ERCPs, Varadarajulu et al³² found lower failure rates in hospitals with more than 200 ERCPs per year compared with those with fewer than 100.

Audits in Britain have shown some worrying data on ERCP performance,³³ as they did years ago for colonoscopy. That has focused the authorities (which do have some authority over there) to clean house. The last recommendation was that ERCPists should do at least 75 procedures per year in units doing more than 200.³⁴

To test practitioners' interest in knowing how their performance compares with others, I set up a benchmarking project in 2007. The ERCP quality network is Web based, voluntary, and free.³⁵ Practitioners can see their own data and compare it with everyone else's (anonymously). A total of 193 ERCPists have registered, and 142 have entered data on more than 22,000 ERCPs. There is understandable criticism about self-reported, nonaudited data, but it is somewhat reassuring (for the project) that some individuals are reporting low success rates (eg, biliary cannulation rates <85%). The biliary cannulation rates for those with less experience (defined as <1000 lifetime or <100 in the past year) is slightly lower than the remainder, but we do not have contributors with fewer than 50 cases per year. This is not an academic/community issue. Not surprisingly, the spectrum of indications is different in the community, but we did not find any large differences in technical success of basic procedures, and 2 U.S. community practice groups recently reported very acceptable results from careful prospective audits.^{36,37} Benchmarking will become much easier (and less subject to gaming) when the data can be extracted directly from reporting systems, which is being achieved (with difficulty) for the joint ACG/ASGE benchmarking tool GIQuIC.³⁸ This is currently restricted to colonoscopy, but we hope that it will be able to take over benchmarking of ERCP.

I am not arguing for all ERCPs to be done in specialized centers, as recently apparently proposed by a well-known

ERCPist.³⁹ Clearly we need an adequate cohort of well-trained basic-level ERCPists to deal with the standard biliary work (and their emergencies) in all communities, and some "experts" in regional referral centers to handle more complex cases, to teach the procedures, and, perhaps, to do the research needed to clarify the role.

One might ask why low-volume ERCPists persist in doing procedures. No doubt many choose their cases carefully and have good results, and some have the data to prove it.^{36,37} Some may think that they are doing an adequate job, but have not kept up with the progressive and often subtle changes that have occurred in the field in recent years. Some may feel obligated to continue, to make sure that ERCP is covered by their practice, especially for emergencies. Some have, in fact, stopped, with relief (before or after a lawsuit), feeling that their time can be better spent doing other procedures.

All professional societies, authoritative organizations, and spokespersons for community ERCP practice speak bravely about the need for ERCP to be done by endoscopists with appropriate training and ongoing experience.^{2,13,36,40} My experience in a referral center and my medicolegal work convince me that this is not the current situation in the United States. Of course, my vision may be distorted by the fact that I tend to see many unsuccessful cases and disasters, but I believe there to be a problem that we need to address. I am certainly not the first to publish these misgivings. One wise editorial by Sivak⁴¹ in 2003 reflected on the embarrassing results of a survey of U.S. fellows completing their training.⁴² Almost two thirds had not completed (or been involved in) 200 ERCP procedures, one third rated their training as inadequate, yet 91% planned to perform ERCP in practice. Is this acceptable? Do we believe that these fellows can reach acceptable performance when learning on the job, even if well proctored by colleagues? Are patients paying the tuition for this haphazard postgraduate training?

Has anything changed in 8 years? At a center known for ERCP work and training, we have seen some reduction in enthusiasm for ERCP training by our fellows who are now opting more often for EUS. Many centers do not offer hands-on ERCP training in fellowship, and the number of fourth-year programs has increased. These are good trends, but we do not know the full spectrum of performance of those entering ERCP practice today. What needs to be done?

Countries with national health systems are in a position to mandate changes at central and regional levels. Britain has a Joint Advisory Group with representatives from all stakeholders that has spearheaded huge (needed) improvements in endoscopy services.³⁴ Australia has tough control of ERCP through its multidisciplinary conjoint committee.⁴³ This decreed very strict rules for ERCP training, demanding 200 completed ERCPs, unassisted, before a formal certification process.

In some such countries, it may be possible to plan a national ERCP service, and attempts have been made. Because there is a finite number of ERCPs to be done each year, one might argue that the number of ERCP practitioners should be somehow limited to a number sufficient to give each the necessary volume to maintain and enhance their skills. Data from the United States,⁴⁴ Britain,⁴⁵ Canada,⁴⁶ and Sweden²⁷ suggest that somewhat less than 1:1000 of the adult population undergo ERCP each year. All of the studies show progressive increases in the percentage of procedures done for therapeutic purposes. Taking a figure of 1:1000 and assuming a desirable number of at least 75 ERCPs per endoscopist per year (and perhaps an average of 150 to include referral centers) suggest that we need about 2000 active ERCPists in the United States, performing a total of about 300,000 procedures. Looked at from another perspective, an average town with a commuting population of 500,000 would generate about 500 cases each year, which could be handled by 3 to 4 ERCPists.

The United States is completely different, with no national or regional controls or planning mechanism. Practice is based on competition rather than collaboration. There are multiple interested organizations, but no coordinated response, and nothing close to a mandate. Note that Varadarajulu et al³² found that ERCPs were being performed in 2659 hospitals in the United States, with half performing fewer than 49 per year.

What needs to be done? Cote et al¹ make some wise suggestions for consolidation of ERCP practice and for more data on the outcomes of low-volume practitioners. In the absence of an "ERCP Czar," we can and should all contribute to documenting and improving the current situation. Even if my concerns are overblown, there is always room for improvement.

ACTION PLAN FOR IMPROVING THE QUALITY OF ERCP SERVICES IN THE UNITED STATES

1. All gastroenterologists should be mindful of the substantial risks and costs of poor-quality ERCP and should realize their concerns by appropriate referrals and advice to privileging bodies.
2. Low-volume ERCPists. Anyone performing fewer than 50 procedures per year should consider carefully their reasons for continuing. Some will decide to stop. Those who wish to continue should justify their decision by collecting performance data prospectively.
3. All endoscopists should keep track of their practice and outcomes. This is really not difficult to do for ERCP because the numbers are small (at least compared with colonoscopy). There are many potential metrics,^{14,15} but this can start small, to include only raw annual numbers and, for each case, spectrum by complexity (using new ASGE metrics^{11,47}), in- or outpatient, suc-

cess of deep biliary cannulation (when relevant), removal of bile duct stones (<10 mm), success in relieving low biliary obstruction in patients with jaundice, immediate adverse events, unplanned admissions, and a call at 3 to 4 weeks to capture delayed events. This data collection could be focused in each practice and perhaps best in collaboration with the local hospital(s) where the procedures are done. More complex data can be collected (and compared) by joining the ERCP quality network, and through the ASGE/ACG benchmarking initiative (GIQUiC) when it is open for ERCP cases.

4. Practices should collaborate to provide emergency ERCP services by a relatively small number of experienced doctors.
5. Fellows and fellowship training programs. Fellows should appreciate that training in ERCP is a major undertaking⁴⁸ in both the short and long term. Training programs have a huge responsibility in this context. Getting properly trained in ERCP (during a 3-year fellowship) significantly cuts into time available for other important topics. Directors should encourage fellows to explore all of the other parts of the broad gastroenterology church, where there many exciting pews, and certainly more to come. All fellows should be exposed to some ERCP procedures as part of their training in pancreatic and biliary medicine to understand the potential benefits and risks of the various interventions and to learn how to use a side-viewing instrument. However, hands-on training should not be given unless there is a plausible plan to reach competence in basic level 2 procedures, which means at least 200 ERCPs and preferably more. Directors who allow fellows to dabble in ERCP with insufficient training should be embarrassed and anticipate a lawsuit. Fellows should keep a detailed record of their experience, with progressive documentation of the established key quality metrics. Although training centers concentrate their time and efforts on fellows and advanced trainees, they should consider offering mini-sabbaticals for those in practice who wish to get up-to-date. There are financial and political challenges, but the concept is likely to become more pressing as our profession evolves and our armamentarium expands.
6. Hospitals. The process for credentialing, privileging, and reprivileging should be tightened and data driven.^{17,49} Allowing incompetent practitioners to perform dangerous procedures carries medicolegal risk.¹³ In communities with multiple smaller hospitals, it would be preferable if ERCP procedures were concentrated on 1 or 2 so as to ensure a good team environment for each case. In the following, I propose that the ASGE should set standards for ERCP units and methods for recognizing them.
7. Professional societies. I recommend that the ASGE establish some form of official recognition of competence

in ERCP (which would be greatly facilitated by extending GIQuIC to include ERCP). Formal certification by the American Board of Internal Medicine of fourth-year training in general or ERCP in particular may be a dream too far away at present. Perhaps equally important, I also recommend that the ASGE should expand its Endoscopy Unit Recognition Program to include recognition of ERCP units. This would be based on their annual volumes, credentialing practices, facilities, and outcomes. These projects might alienate significant parts of the Society membership, but that is the burden of leadership. Our organizations are designed to support their members, but protecting patients should take precedence

8. Research agencies. It is a major responsibility of the leaders in this field and their organizations to promote and support the sophisticated research needed to refine the role of ERCP in controversial areas. The ASGE and ACG should identify key areas for research focus and issue requests for applications. These will need to come from groups because most studies will need multicenter input. Costs are significant and clinical research has not been a high priority at the National Institutes of Health. However, there is increasing interest in studies of comparative effectiveness, and the American Recovery and Reinvestment Act includes substantial funding. I cannot understand why some of the payers are not motivated to fund similar research. The track record of the new Chief of the Centers for Medicare and Medicaid Services might suggest a move in that direction. Not all clinical research has to involve randomization, as I have argued elsewhere. We could learn a great deal from stringent but relatively simple prospective registries in areas such as the ERCP management of hilar tumors and recurrent pancreatitis.

9. Patients. Potential ERCP patients need to understand that ERCP is not just another endoscopy (“like the one we did last week, but going a bit further”); it is now essentially a surgical intervention, with all that implies. Proper informed consent is of course mandatory, and there are now some sophisticated online interactive educational tools that can help in this process (and which hospitals might well consider adopting). But we could all do a better job of education in the broader community, especially about the risks involved in cases with iffy indications. I still believe that patients should have access to data about the performance of their proposed endoscopists (report cards).⁵⁰

My opinions are heartfelt, and not self-serving, because I have just stopped performing ERCP after 40 years. I hope that these comments will stimulate vigorous debate and serious remedial action. Together we can prevent much distress and cost—and a few lives. The time is now.

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