EDITORIAL

ERCP: Time to take the lead off?

Multiple studies have shown ERCP to generate significant doses of ionizing radiation. Yet, with the exception of the pregnant patient, most endoscopists performing ERCP are not precisely aware of, much less concerned about, the ionizing radiation generated. It's just another day in the ERCP suite, and what counts is the procedural outcome: Was cannulation of the targeted duct accomplished, and was the therapeutic intervention successfully executed? Historically, the radiation exposure from ERCP to the patient has been perceived as trivial and—even when longer fluoroscopy times are needed—as a necessary tradeoff to reap the advantages of ERCP over more invasive and risky radiologic and surgical alternatives. Of note, a metric of radiation exposure such as fluoroscopy time was not included as a quality indicator in the 2015 ASGE standards of practice guidelines for ERCP.[1]

This attitude of relative complacency regarding radiation exposure is changing across all specialties that use radiation in medical imaging. Although the effects of any single radiation-generating procedure are indeed likely to be trivial, the cumulative effects of multiple radiologic procedures, including ERCP, over a lifetime can be significant and detrimental. Nearly a decade ago, a lead article in *JAMA* entitled "Computed tomography—an increasing source of radiation exposure" reported an increase in the number of annual CT scans in the United States from 3 million in 1980 to 62 million in 2007.[2] A *New York Times* article in 2010 highlighted a dramatic sevenfold rise in in the patient's average lifetime dose of diagnostic radiation since 1980.[3] In the same year, the Center for Devices and Radiological Health of the U.S. Food and Drug Administration published a white paper entitled "Initiative to reduce unnecessary radiation exposure from medical imaging," which placed particular emphasis on increasing patients' awareness to manage their exposure to radiation from medical imaging.[4]

Limiting radiation exposure is a patient safety goal according to the ALARA principle (As Low As Reasonably Achievable). Concerns are driving efforts to stem the overuse of radiation. In 2012, the California legislature passed Senate Bill 1237 requiring that CT scanner dose metrics be included in the radiology report for all patients. Documentation of radiation dose metrics is currently not required for procedures that use fluoroscopy, but this practice has been recommended by the American College of Radiology.[5] However, the Centers for Medicare and Medicaid Services does identify reporting of exposure time or other radiation exposure indicators as a quality metric (measure no. 145) for the previous Physician Quality Reporting System and the current Merit-Based Incentive Payment System.

MINIMIZING RADIATION EXPOSURE IN ERCP

What is the radiation exposure from ERCP? Radiation doses in medical imaging are expressed as millisieverts (mSv). These units of "equivalent dose" take into account the biologic effect of radiation, which varies with the type of radiation and the vulnerability of the affected body tissue. For reference, an abdominal CT scan results in an effective average dose of 10 mSv.[2] Larkin et al[6] reported an average of 12.4 mSv for therapeutic ERCP. The dose for a complex ERCP, such as one involving multiple stent placement for a Klatskin tumor, will of course be higher. Twenty minutes of fluoroscopy time has been roughly correlated to 30 mSv, which is 10 mSv above the 20 mSv/year annual dose limit recommended by the International Commission on Radiological Protection.[7] Epidemiologic research has shown that there is a 10% increase in cancer risk with a lifetime exposure of 1 Sv or 1000 mSv. BEIR (Biological Effects of Ionizing Radiation) VII reconfirmed that low-dose radiation risks are linear, time sensitive, and cumulative and that the risk is stochastic, meaning that there is increased risk even with the lowest dose.[8]

> Ultrasonography and endoscopy should be the preferred ductal imaging modalities, fluoroscopy being reserved for indications that require additional definition of ductal anatomy, such as cholangiographic filling of the intrahepatic ducts in primary sclerosing cholangitis.

Minimizing radiation exposure from ERCP begins with appropriate justification for subjecting a patient to ERCP.[1] For potential therapeutic ERCP cases, EUS can help determine the actual necessity of intervention. For

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2017.07.019

example, an EUS-guided strategy eliminates unnecessary ERCP in the setting of suspected choledocholithiasis. Using a strategy of EUS-based ERCP in patients referred to our center for stone extraction, we found that EUS showed no biliary stones in 38% of patients, thus negating the indication for ERCP.[9] Others have reported a similar benefit of same-session EUS-based ERCP.[10]

During ERCP, we can minimize radiation exposure by appropriate dose optimization, using techniques that fulfill the ALARA principle. These include reducing the frame rate, using collimation, and keeping the image intensifier as close to the patient as possible while keeping the x-ray tube as far away as possible. Magnification should be used only when needed; demagnification is something the endoscopist should be routinely reminded of, because it is easy to stay in magnification while one is preoccupied with other facets of ERCP. Previous studies have shown that the amount of radiation exposure during ERCP is directly proportional to the fluoroscopy time. In turn, it has also been shown that radiation exposure to patients during ERCP is significantly higher with low-volume endoscopists who perform fewer than 200 ERCPs per year. In a study by Liao et al,[11] the differences in median radiation exposure to patients essentially doubled when a low-volume endoscopist performed the procedure. Therefore, ERCPs should be performed in high-volume referral centers with the use of dose-minimizing techniques.

ERCP WITHOUT FLUOROSCOPY

Can ERCP be performed safely and effectively while avoiding the use of radiation altogether? Numerous other gastroenterologic procedures that were once dependent on fluoroscopic assistance are now performed without radiation. Bougie dilation was once routinely performed under fluoroscopic guidance. In the initial 1980 description of a technique for esophageal stricture dilation with the use of polyvinyl chloride bougies, Savary[12] used fluoroscopic guidance for monitoring of guidewire positioning and bougie passage across the stricture. Subsequent publications emphasized the use of fluoroscopy during dilation.[13] Similarly, endoluminal stent placement with self-expandable metal stents, once routinely performed under fluoroscopic guidance, is increasingly being performed without fluoroscopy with good outcomes.[14-16]

Binmoeller and Katon[17] first reported ERCP without fluoroscopy (ERCP-WF) in a pregnant patient with an impacted common bile duct stone in 1990. Multiple case reports of ERCP-WF have followed.[18,19] The technique uses confirmation of selective bile duct cannulation by bile aspiration through the sphincterotome. This is followed by sphincterotomy and stone extraction by the use of a balloon or basket. An obvious limitation is the lack of confirmation of complete stone clearance. EUS, intraductal ultrasonography (IDUS), and cholangioscopy are imaging modalities that can be applied in the same session as ERCP to provide this confirmation. EUS before ERCP has the advantage that it provides confirmation of a stone before ERCP is undertaken, thus avoiding a potentially unnecessary ERCP, and it provides a "road map" for ERCP-WF by diagramming and characterizing stone size and location within the bile duct. The number and size of stones extracted can be matched to those seen on the immediate preprocedural EUS image, eliminating the need for imaging confirmation of stone clearance. We applied this approach of EUS-based ERCP in a case series of 10 pregnant patients with suspected choledocholithiasis, 6 of whom were confirmed to have common bile duct stones on pre-ERCP EUS and then underwent successful ERCP-WF stone clearance.[20] We subsequently applied the same approach in a cohort of 61 nonpregnant patients; we avoided unnecessary ERCP in 38% of patients with suspected choledocholithiasis, achieved successful cannulation without fluoroscopy within 10 minutes in 84% of patients, and cleared stones without adverse events in all.[9]

ERCP-WF VERSUS STANDARD ERCP

In this issue of *Gastrointestinal Endoscopy*, Nisa et al[21] report on a prospective randomized trial of 114 patients comparing EUS-based ERCP-WF versus standard ERCP with fluoroscopy in patients with common bile duct stones. The cannulation success rates, adverse event rates, and total procedure times were similar in both groups, but the stone clearance rate in the ERCP-WF group (85.5%) was inferior to that in the ERCP group (100%) ($P = .002$). In 2 of the patients in the ERCP-WF group, stone extraction was unsuccessful because of failed cannulation. The stone count at the time of stone extraction matched the number by EUS in 50 of 53 patients (94%), with successful cannulation in the ERCP-WF group. The authors did not perform EUS after ERCP, nor did they use any ancillary techniques, such as intraductal catheter probe ultrasonography or cholangioscopy, to verify complete stone clearance.

Several technical aspects of the approach used by the authors for ERCP-WF deserve comment. A guidewire was used to cannulate the bile duct, then removed for bile aspiration after the sphincterotome entered the duct. This technique of blind advancement of a guidewire warrants caution. The wire may create a false tract or may enter a side branch of the pancreatic duct. Because fluoroscopy is not being used, these mistakes may be unrecognized and compounded by proceeding with intervention inappropriately. Additionally, the authors used a balloon inserted over a guidewire for stone extraction, inflated to a maximal diameter of 15 mm. As a rule, we prefer to avoid the use of a guidewire during ERCP-WF, whether for cannulation or for coaxial advancement of a device such as a balloon catheter. If a wire is used, a tap on the fluoroscopy pedal is justified to confirm proper placement. We prefer to use a basket for stone extraction, which eliminates the