



# Q & A

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## Why ERCP Is So Critical to Effective GI Care

The risk of infection from inadequate endoscope reprocessing is relatively low, but there is a risk nonetheless – which has sparked much discussion around endoscopic retrograde cholangiopancreatography and patient safety. Dr. Mark Gromski says research needs to drive future attention to cross-contamination.

Dr. Mark Gromski is a gastroenterologist, advanced endoscopist, and assistant professor of medicine at IUHealth/Indiana University School of Medicine in Indianapolis, Indiana, where he personally performs about 400 endoscopic retrograde cholangiopancreatography procedures per year. He's also an expert on the patient safety issues surrounding ERCP.

More than **500,000 ERCP procedures are performed in the U.S. annually**. ERCP combines upper gastrointestinal (GI) endoscopy with fluoroscopic imaging to evaluate – as well as to treat – conditions involving the biliary tree and pancreas.

Gromski and his team have done extensive research into ERCP technology, and he has a personal interest in the duodenoscope reprocessing issue as well. The unique and complex design of duodenoscopes is what makes ERCP effective, but their difficult-to-clean components can put patients at risk if the instrument is not reprocessed properly – a risk that is perhaps overstated in media coverage.



"The fact is that we simply don't know yet how much of a risk cross-contamination poses," Gromski says. "The data isn't there yet. However, that shouldn't suggest that cross-contamination isn't an important issue."

In this Q&A, he weighs in on the ERCP cross-contamination issue that has become so prevalent in the press, and on the steps that practitioners and manufacturers can take to ensure patient safety.

## GI ENDOSCOPY: What's the role of ERCP in gastroenterological care?

**DR. GROMSKI:** ERCP is an extremely important diagnostic and treatment tool for us. It's the least invasive way we have of accessing the bile ducts and the pancreas ducts — where serious and sometimes life-threatening diseases can develop.

With ERCP, we have a means to detect these diseases and to treat them. Stones of the gallbladder which have lodged in the bile duct are one common example. With ERCP, it's relatively straightforward to go in and remove a stone, whereas many years ago we could only remove it with surgery.

We can also use ERCP to diagnose cancers of the bile ducts and the pancreas. Though we can't perform any curative cancer treatment with ERCP, we can diagnose cancers, and relieve cancer-related obstructions from bile ducts, which can improve patients' quality of life and allow them to have more definitive therapy such as chemotherapy or surgery.

These by no means exhaust the value of the procedure. There are many, many conditions that can be ameliorated by use of ERCP.

## What is ERCP and how does it work?

The pancreas and bile duct systems together form an important part of the digestive system. The pancreas and liver produce juices that help in the process of breaking down foods into parts easily absorbed and used by the body.

Bile ducts carry bile — the fluid made by your liver to transport toxins and waste products out of your body — from your liver to your gallbladder and duodenum.

If there's a kink in this process, problems arise -- and that's where endoscopic retrograde cholangiopancreatography, or ERCP, can save lives. A gastroenterologist maneuvers an instrument called a duodenoscope through the lumens of the esophagus, stomach, and the first part of the small intestine known as the duodenum and injects contrast material

directly into the biliary tree or pancreatic duct for radiographic visualization of the biliary and pancreatic duct anatomy. The physician is then able to assess for obstruction or narrowing of the ducts that may be caused by cancer, gallstones, inflammation, infection, and other conditions.

The ERCP procedure also enables immediate treatment, which can be life-saving by decompressing the obstructed duct. While there is debate about how best to tackle infection risks from reprocessing endoscopes, all agree that patients should not cancel or delay a planned ERCP procedure without first discussing the benefits and risks with a doctor. After all, ERCP yields important information that can't be obtained by other diagnostic examinations such as abdominal ultrasound, a CT scan or MRI.

## GI ENDOSCOPY: ERCP does entail some risk. Can you explain some of the adverse outcomes patients may encounter?

**DR. GROMSKI:** By far the biggest risk of ERCP is pancreatitis. The manipulation of the pancreas or bile duct, which drains in very close relation to the pancreatic duct, can lead to edema and a local inflammatory cascade — which can manifest as acute pancreatitis. Patients who have this often will experience pain and nausea and may need hospitalization. Post-ERCP pancreatitis happens in 3 to 10 percent of cases. But that rate does vary depending on the patient's other risk factors and factors that have to do with the procedure, with some patients carrying a risk likely of 10 to 15 percent.

Less frequently, we also encounter bleeding from the procedure, significant enough to require an intervention like a transfusion or repeat endoscopy. This happens in 1 percent or so of patients.

Then there are less likely events, like unintentional perforation, or an infection resulting from an incomplete drainage of the contrast material. Those both happen less than 1 percent of the time. There is a very small risk of death from the ERCP procedure itself, with a mortality rate associated with the procedure well less than 1 percent.

Finally, there's the outcome that's been covered substantially in the media in the last five or six years: cross-contamination, or transmission of organisms from one patient to another. This has happened by organisms staying on the specialized ERCP endoscope between procedures, despite the scopes having been cleaned. The rates of this outcome are very difficult to quantify, because reports are so few and far between. But we know the risk is not zero.

## GI ENDOSCOPY: Even with all the other risks involved, it seems there's a lot of focus on cross-contamination right now. Is that justified?

**DR. GROMSKI:** Personally — and I will admit to some bias here — I think the exposure of this problem is perhaps over-stated and may not be accurate. The fact is that we simply don't know yet how much of a risk cross-contamination poses, particularly with implementation of supplemental cleaning measures. The data isn't there yet.

However, that shouldn't suggest that cross-contamination isn't an important issue. Preventing those infections is something that's likely within our control. Even if it's only 10 people who have ever been infected from cross-contamination, that's 10 too many, and if we can prevent that by cleaning our scopes better or by re-designing them, we absolutely should.

“Cleaning a scope is a complex process with **50 to 100 steps** – very difficult for the average GI provider to keep up with, given the rapid pace of changes in the field.”

**GI ENDOSCOPY: Are patients concerned about the cross-contamination issue?**

**DR. GROMSKI:** In truth, it has not been a large issue in my practice. I've personally had very few patients bring it up, and other professionals say the same. That's a little surprising, given the coverage we've had on the issue from major outlets like the New York Times.

What we've found is that patients' concerns are a very localized phenomenon. If a given facility has had an infection issue, local media picks up on the story, and that sticks to patients' minds more than a national trends story does.

So, since we fortunately haven't had any outbreaks at our institution, our patients haven't been raising the concern. I imagine it's much the same for other practitioners.

**GI ENDOSCOPY: How about your colleagues, in gastroenterology or elsewhere? Do they talk about the cross-contamination issue? Has there been any pushback on ERCP since all this coverage has come out?**

**DR. GROMSKI:** In gastroenterology it's on our minds from a prevention point of view. We talk to each other about how to make ERCP safer, and infection prevention is certainly part of the conversation.

Outside of gastroenterology, we haven't really seen a pushback from any of our referring specialties or general practitioners. Although it's entirely possible that they have those thoughts, they haven't been vocalized as a concern in our locale.

One thing I will say is that the level of concern probably varies with the type of institution. Here at IU, for example, we do a high volume of ERCP procedures, we have specialized nurses and post-procedure sterilization workers. That means we have some confidence that we're able to keep up with the latest infection prevention protocols.

Smaller facilities, which aren't doing thousands of ERCPs per year, probably aren't as confident. These issues can be very confusing. Cleaning a scope is a complex process with 50 to 100 steps. Very difficult for the average GI provider to keep up with, given the rapid pace of changes in this field.

**GI ENDOSCOPY: What's your take on the FDA's recent guidance? Are we moving in the right direction?**

**DR. GROMSKI:** I think the FDA's right to call for a re-assessment of our approach to infection prevention for ERCP. But, I think all developments need to be measured very carefully, and we should not have any mandatory decrees from the FDA until we know data on the developing technologies.

The FDA first started calling attention to the cross-contamination issue five or six years ago. Since then, providers and manufacturers have stepped up their approaches to reprocessing the duodenoscopes. In some cases, they majorly overhauled infection control. And we don't know yet how effective these new approaches have been on the large scale. There isn't enough data to confirm what changes have had the most impact.

That makes it hard to tell where we should focus our efforts. Where would we see the most incremental gains? Is it more important to re-design the scopes themselves, or to reconfigure reprocessing procedures? We just don't know.

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Disposable scopes are another issue. I think it's premature to discuss single-use scopes replacing existing reusable fleets entirely. We don't know the effect that disposable scopes will have on those other risk factors — pancreatitis, perforation, bleeding — involved in ERCP.

If cross-contamination risk goes down as a result of disposables, but the risk of pancreatitis goes up, is that a net benefit to patients? Or are we causing more harm than we're preventing? Furthermore, we have no data on the technical success rate of community providers using disposable scopes. That will be an important piece of data.

That said, I'm certain that disposable scopes will find a place within the practice of ERCP. For certain sub-populations, high-risk individuals with a history of drug-resistant infections or recurrent cholangitis, disposables make a lot of sense.

We just can't say right now how widely disposables will be, or should be, adopted.

**In a high-profile move**, the Food and Drug Administration issued a safety communication in August 2019 recommending that hospitals and endoscopy facilities transition away from fixed endcap duodenoscopes to those with newer design features that facilitate or eliminate the need for reprocessing.

"Please note, we recognize that a full transition away from conventional duodenoscopes to the newer, innovative models will take time," the FDA said. "We continue to work with manufacturers to increase the supply of disposable cap duodenoscopes and the development of other new and innovative device designs that will further minimize or eliminate the risk of patient infection. We continue to address challenges with current reprocessing methods and support expanding the types of validated methods available to reprocess duodenoscopes."

### GI ENDOSCOPY: What if patients opt out of the procedure? What are the risks of foregoing ERCP?

**DR. GROMSKI:** There are two ways to look at the risks of passing on ERCP procedures.

The first is what happens when these disease processes go undetected or untreated. Often, they can put patients at serious risk. Cholangitis — infection of the bile duct system — can be life-threatening. A patient can die within days. If a bile-duct stone completely occludes the bile duct, that's also very dangerous as it can lead to cholangitis or pancreatitis.

It's unlikely that patients would seek no treatment for these conditions. But the other risk to consider is what comes with the alternatives to ERCP.

The only other way to access these structures is through options like percutaneous interventional radiology or traditional surgery. Surgery is much more invasive than ERCP. It can delay care because it's more complex and demanding. It also comes with more complications: more time under anesthesia, bleeding, surgical site infections, longer lengths of stay in the hospital, and higher perioperative mortality.

ERCP is a well-established modality, with many comparative studies showing improved outcomes over the alternative surgical or interventional radiology approaches for many disease processes.

### GI ENDOSCOPY: How should we move forward, in ensuring patient safety in ERCP?

**DR. GROMSKI:** I'd say first that we should let the research dictate our approach. Like in everything else, ERCP research lags ERCP technological development, and we're not going to innovate in the right direction without data in hand.

Second, I think we need a comprehensive approach to improve patient safety. That means that no one issue should occupy 100 percent of our energy or our attention. Preventing cross-contamination is important, certainly, but so is preventing procedure-related pancreatitis or perforations or bleeding, or any of the other potential ERCP complications.

A measured approach that looks to curb every adverse outcome is what will do the most good for patients — and that's the approach I think we should pursue.

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