

Research design can be improved to support double-guidewire technique



To the Editor:

We have read with great interest the article by Eminler et al¹ concerning how the method of wire-guided cannulation over a pancreatic stent (WGC-PS) increases the need for needle-knife precutting (NKP) in comparison with the double-guidewire technique (DGW) in patients with difficult biliary cannulation. This is an interesting prospective randomized study; however, we believe that the research design can still be improved.

First, in terms of the randomization of the study, “The first patient was randomized by pitch-and-toss technique, and subsequent patients were alternately randomized.” Actually, this is a method called “quasirandomized,” which is not truly random. This method could not randomize all the patients because once the first patient is grouped, the subsequent patient’s assignment would be determined, leading to selection bias and weaker evidence. This deficiency in randomization would make it harder to rule out confounding variables and to effect internal validity.²

Second, there might be a study design limitation about the ERCP procedure in this study. Considering that the time of grouping is unintentional passage of a guidewire to the pancreatic duct, it might be less appropriate to perform NKP as an alternative when WGC-PS or DGW failed. Because it is a high-risk procedure,³⁻⁶ NKP should be considered cautiously for the patient’s safety. A guideline from the European Society of Gastrointestinal Endoscopy recommended that transpancreatic precut sphincterotomy (TPS) should take precedence over NKP if precutting is needed, especially when unintentional insertion of a guidewire into the pancreatic duct occurs in patients with difficult biliary cannulation.⁴ NKP could be a rescue method only when pancreatic duct cannulation or TPS cannot be achieved.⁷

In addition, it is reported that sole use of the DGW appears to increase the risk of post-ERCP pancreatitis and need for precut sphincterotomy.^{8,9} Considering the optimal strategy for difficult biliary cannulation, especially in patients with unintentional passage of the guidewire into the main pancreatic duct, we suggest a stepwise algorithm using DGW followed by WGC-PS or TPS.

In general, this is valuable research about 2 difficult biliary cannulation techniques. Nevertheless, a better research design could increase the reliability of the conclusion.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Di Zhang, MD
Department of Gastroenterology
Gongli Hospital

Department of Gastroenterology
Changhai Hospital
Jia-su Li, MD

Department of Gastroenterology
Changhai Hospital
Zhao-shen Li, MD

Department of Gastroenterology
Gongli Hospital

Department of Gastroenterology
Changhai Hospital
Feng Liu, MD

Department of Gastroenterology
Changhai Hospital
Dan Wang, MD

Department of Gastroenterology
Gongli Hospital

Department of Gastroenterology
Changhai Hospital
The Second Military Medical University
Shanghai, China

REFERENCES

- Eminler AT, Parlak E, Koksall AS, et al. Wire-guided cannulation over a pancreatic stent method increases the need for needle-knife precutting in patients with difficult biliary cannulation. *Gastrointest Endosc* 2019;89:301-8.
- Dinardo J. Natural experiments and quasi-natural experiments. In: Durlauf SN, Blume LE, eds. *Microeconometrics*. London: Palgrave Macmillan UK; 2010. p. 139-53.
- Cotton PB, Lehman G, Vennes J, et al. Endoscopic sphincterotomy complications and their management: an attempt at consensus. *Gastrointest Endosc* 1991;37:383-93.
- Testoni PA, Mariani A, Aabakken L, et al. Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) Clinical Guideline. *Endoscopy* 2016;48:657-83.
- Kubota K, Sato T, Kato S, et al. Needle-knife precut papillotomy with a small incision over a pancreatic stent improves the success rate and reduces the complication rate in difficult biliary cannulations. *J Hepatobiliary Pancreat Sci* 2013;20:382-8.
- Catalano MF, Linder JD, Geenen JE. Endoscopic transpancreatic papillary septotomy for inaccessible obstructed bile ducts: comparison with standard pre-cut papillotomy. *Gastrointest Endosc* 2004;60:557-61.
- Sugiyama H, Tsuyuguchi T, Sakai Y, et al. Transpancreatic precut papillotomy versus double-guidewire technique in difficult biliary cannulation: prospective randomized study. *Endoscopy* 2018;50:33-9.
- Tse F, Yuan Y, Moayyedi P, et al. Double-guidewire technique in difficult biliary cannulation for the prevention of post-ERCP pancreatitis: a systematic review and meta-analysis. *Endoscopy* 2017;49:15-26.
- Hakuta R, Hamada T, Nakai Y, et al. Early pancreatic stent placement in wire-guided biliary cannulation: a multicenter retrospective study. *J Gastroenterol Hepatol*. Epub 2018 August 27.
<https://doi.org/10.1016/j.gie.2018.10.032>

Response:



We would like to thank Zhang et al¹ for their interest in and comments on our study.² Randomization based on a single sequence of random assignments is defined as a simple randomization. This technique maintains complete

randomness of the assignment of a subject to a particular group. It is simple and easy to implement in clinical research. Simple randomization works well for large trials ($n > 100$) and small to moderate clinical trials ($n < 100$) without covariates.³ In our study, we simply aimed to compare the 2 most common methods that have been used to improve the success rate of biliary cannulation, without any covariates; therefore, we preferred to use the simple randomization method.

Second, it is well known that endoscopists face a dilemma when making a choice about the cannulation technique if the guidewire inadvertently enters the pancreatic duct during attempts at biliary cannulation. In this study, we compared only the 2 most common methods: double-guidewire technique and wire-guided cannulation over a pancreatic stent. Transpancreatic precut sphincterotomy (TPS) is another technique that can be performed in such a case. We agree with Zhang et al¹ that needle-knife precutting (NKP) is a somewhat high-risk procedure, as we mentioned in our study. However, the incidence of adverse events after TPS ranges from 3.5% to 20.5% (median, 13.1%) and the European Society of Gastrointestinal Endoscopy recommends this technique to be performed by only experts.⁴ Recently, we observed 2 patients who experienced perforation or dissection after TPS, and we hypothesized that the septum separating the common bile duct and pancreatic duct was overablated by transpancreatic septotomy, and as a result of loss of tissue integrity, the guidewire was passed through the soft tissue or the common bile duct, causing perforation or dissection.⁵ There are not enough data to guide endoscopists to make a choice between TPS and NKP. However, the anatomy of the papilla (eg, small, protuberant) and the experience of the endoscopist with the technique may play a role.⁴

Finally, we mentioned the increased risk of adverse events (especially post-ERCP pancreatitis) with the double-guidewire technique, and we think that one of the most important factors determining the development of post-ERCP pancreatitis is the successful replacement of a pancreatic stent. We agree with Zhang et al¹ that endoscopists should consider a stepwise algorithm in patients with unintentional passage of the guidewire into the main pancreatic duct. Further prospective randomized studies, including all of the above-mentioned techniques (double-guidewire, wire-guided cannulation over a pancreatic stent, NKP, TPS), and taking into consideration the anatomy of the papilla and experience of the endoscopists, are needed to clarify the issue.

Ahmet Tarik Eminler, MD, Assoc Prof
*Department of Gastroenterology
 Faculty of Medicine
 Sakarya University
 Sakarya, Turkey*

Erkan Parlak, Prof

*Department of Gastroenterology
 Faculty of Medicine
 Hacettepe University
 Ankara, Turkey*

Aydın Seref Koksal, Prof

*Department of Gastroenterology
 Faculty of Medicine
 Sakarya University
 Sakarya, Turkey*

REFERENCES

1. Zhang D, Li J, Li Z, et al. Research design can be improved to support double-guidewire technique. *Gastrointest Endosc* 2019;89:654.
2. Eminler AT, Parlak E, Koksal AS, et al. Wire-guided cannulation over a pancreatic stent method increases the need for needle-knife precutting in patients with difficult biliary cannulation. *Gastrointest Endosc* 2019;89:301-8.
3. KP Suresh. An overview of randomization techniques: an unbiased assessment of outcome in clinical research. *J Hum Reprod Sci* 2011;4:8-11.
4. Testoni PA, Mariani A, Aabakken L, et al. Papillary cannulation and sphincterotomy techniques at ERCP: European Society of Gastrointestinal Endoscopy (ESGE) clinical guideline. *Endoscopy* 2016;48:657-83.
5. Eminler AT, Koksal AS, Parlak E. Modified transprepancreatic septotomy reduces postoperative complications: Is it always innocent? Available at: <https://journals.lww.com/md-journal/Blog/MedicineCorrespondenceBlog/pages/post.aspx?PostID=82>. Accessed June 1, 2018.

<https://doi.org/10.1016/j.gie.2018.11.004>

Endoscopic diagnosis of colorectal polyps with the use of blue-light imaging: For experts only?



To the Editor:

We read with great interest the work of Rondonotti et al¹ in which they conclude that blue-light imaging (BLI) outperforms high-definition white-light endoscopy (HDWL) for the prediction of subcentimetric colorectal polyp histologic features. The overall diagnostic accuracy was 84% and 92% with HDWL or BLI, respectively ($P = .011$). The negative predictive value (to exclude an adenoma) for diminutive rectosigmoid polyps was significantly increased by the use of BLI and reached 88%, close to the performance threshold of 90% recommended by the American Society for Gastrointestinal Endoscopy.²

The study was conducted by 4 gastrointestinal endoscopists highly experienced in the endoscopic diagnosis of colorectal polyps. Even among these experts, a significant heterogeneity in the diagnostic performances appears, with negative predictive values ranging from 67% to 100%. Nevertheless, several publications, based on the analysis of still endoscopic pictures or videos of colorectal polyps, have reported excellent diagnostic performances of nonexperts after short teaching programs on virtual chromoendoscopy.^{3,4}