

index procedure is associated with an earlier resolution of complex WON as compared with late DEN.⁵

In the study by Bang et al,¹ the authors performed single tract transmural cystogastrostomy/duodenostomy for unilocular collections (≥ 60 mm but < 80 mm), whereas for collections ≥ 80 mm in size or extending to the flanks, creation of multiple transmural tracts (the multigate technique that has never gained popularity) was used.⁶ In 16 patients (47.1%) in the endoscopic treatment arm, one of the ports was created by placing a LAMS (the AXIOS Stent, Boston Scientific, Marlborough, MA) to facilitate drainage of the necrotic material and eventual performance of DEN. The mean amount of necrotic tissue in the cohort was 42.2%. No difference in the outcome between plastic stents and LAMSs was observed. Fifteen patients (44.1%) did not respond to the treatment within 72 hours and were managed by DEN in 11, multigate technique in 3, and/or percutaneous catheter placement in 6. One interesting observation is the lack of major procedure-related complications in the LAMS group despite the stent remaining in place for ≥ 6 weeks. This finding differs completely from what was reported by the same group in another recent randomized study of WON, where bleeding requiring embolization, buried stent syndrome, and biliary duct compression were reported to occur in 50% of the patients in whom the same type of LAMS was placed.^{7,8} These complications led the group to change the follow-up protocol with removal of the LAMS after 3 weeks from the index procedure.

Now that endoscopic therapy has been established as the treatment of choice for patients with infected necrotizing pancreatitis or WON, it is time for the endoscopic world to make a big effort to develop common protocols based on all these observations. Many questions remain to be answered, and it is plausible to hypothesize that different treatment approaches will be needed depending on patients' condition and morphologic characteristics of the pancreatic collection. The studies need to be prospective, randomized, and multicenter to verify the hypothesis(es) on a meaningful number of patients and guarantee reproducibility. It is time for endoscopists to apply known methodologies, overcome the embryonic stage, and finally grow up.

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References

1. Bang JY, et al. *Gastroenterology* 2019;156:1027–1040.e3.
2. van Brunschot S, et al. *Lancet* 2018;391:51–58.
3. Bazerbachi F, et al. *Gastrointest Endosc* 2018;87:30–42.
4. Boxhoorn L, et al. *Curr Treat Options Gastroenterol* 2018;16:333–344.
5. Yan L, et al. *Endosc Ultrasound* 2019;8:172–179.
6. Varadarajulu S, et al. *Gastrointest Endosc* 2011;74:74–80.
7. Bang JY, et al. *Gut* 2017;66:2054–2056.
8. Bang JY, et al. *Gut* 2018;31:735–741.

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Surgery Versus Endoscopy for Infected Necrotizing Pancreatitis: A Fair Comparison?



Dear Editors:

We congratulate Bang et al¹ on completing a randomized, controlled, single-center trial on patients with infected necrotizing pancreatitis, comparing minimally invasive surgery with the endoscopic step-up approach. The authors report a significant decrease in major complications, lower costs, and increased quality of life in patients who were treated endoscopically. We, however, feel that the results of this study must be interpreted with caution.

The authors recognize, in accordance with the latest evidence-based guidelines, that minimally invasive techniques within a step-up approach are superior to primary open necrosectomy.^{2,3} This approach consists of catheter drainage followed by necrosectomy only when clinically indicated. Previous research showed that approximately 40%–50% of patients with infected necrotizing pancreatitis can be treated by catheter drainage alone and do not require a necrosectomy.^{4,5} By starting with percutaneous drainage, the risk of new onset systemic inflammatory response syndrome is also decreased as compared with surgery as a first approach. Bang et al, however, did not include a step-up approach in the surgically treated patients: only 28% of patients had a percutaneous drain in situ before surgical necrosectomy. In the remaining patients, minimally invasive necrosectomy, either laparoscopic cystogastrostomy with necrosectomy or video-assisted retroperitoneal debridement, was directly performed. Moreover, patients who were randomized but those who improved clinically within 72 hours after percutaneous drain placement were excluded from further analysis. In contrast, almost all patients assigned to endoscopy (97%) did receive endoscopic drainage first and only endoscopic necrosectomy in case of lack of clinical improvement. In addition, 41.2% of these patients were drained percutaneously before endoscopic intervention. The

comparison of endoscopic step-up treatment to direct surgical necrosectomy could have resulted in a bias in favor of the endoscopic approach.

Moreover, management after the first surgical necrosectomy was not performed in a standardized manner. Surgical necrosectomy failed to result in clinical improvement in 37.5% of patients. Subsequently, several interventions were performed: some patients underwent additional percutaneous drainage (16%) and/or video-assisted retroperitoneal debridement (16%), but others were managed by endoscopic necrosectomy (3%) or endoscopic multiple gateway drainage (6%).

Furthermore, it needs to be underlined that there was no significant difference in mortality (endoscopy 8.8% vs surgery 6.3%; $P = .99$) and new-onset organ failure (endoscopy 5.9% vs 9.4%; $P = .67$). The difference in the composite primary end point was primarily caused by the occurrence of enteral and pancreatic-cutaneous fistulae in the surgical cohort. Although enteral and pancreatic-cutaneous fistulae can lead to significant morbidity, they are not life-threatening complications.

Finally, a second randomized trial on plastic pigtailed stents versus lumen-apposing metal stents for endoscopic treatment of necrotizing pancreatitis was simultaneously completed in the same hospital (overlap period of 13 months; from February 2016 to March 2017).⁶ It is unclear how selection and enrolment for both studies was performed. How was decided in which study patients could participate and how was selection avoided?

In summary, we agree that the endoscopic step-up approach should be preferred over the surgical step-up approach if both techniques are technically feasible, as was shown in the TENSION trial.⁵ But the difference in outcome is in our opinion not as large as stated, because the comparison of endoscopic step-up treatment with direct surgical necrosectomy could have led to a bias in favor of the endoscopic approach. Patients with infected necrotizing pancreatitis require tailor-made therapy by a multidisciplinary team. We would therefore like to emphasize that the surgical step-up approach, starting with percutaneous catheter drainage, still plays an important role in selected patients.

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References

1. Bang JY, et al. *Gastroenterology* 2019;156:1027–1040.e3.
2. IAP/APA evidence-based guidelines for the management of acute pancreatitis. *Pancreatology* 2013;13:1–15.
3. Arvanitakis M, et al. *Endoscopy* 2018;50:524–546.
4. Van Santvoort HC, et al. *Gastroenterology* 2011;141:1254–1263.
5. Van Brunschot S, et al. *Lancet* 2018;391:51–58.
6. Bang JY, et al. *Gut* 2018;1–10.

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Reply. We thank Drs Rizzatti and Boxhoorn for their interest in our randomized trial comparing minimally invasive surgery and endoscopy for the treatment of infected necrotizing pancreatitis.^{1,2}

Eligible patients or their caregivers who presented with suspected or infected necrotizing pancreatitis were informed regarding the multidisciplinary and the endoprosthesis comparative studies and if they expressed preference for either trial, were included for participation in either study.^{3,4} Only 16 of 34 patients underwent placement of lumen-apposing metal stents (LAMS) in the present study (others were treated with plastic stents) and no adverse events were encountered in this cohort at 6-week follow-up.³

In the endoprosthesis study, the overall stent-related adverse event rate was 32% and not 50% as pointed out by Rizzatti et al.^{1,4} These adverse events occurred during the initial period of the study and when the protocol was changed to stent retrieval at 3 weeks (rather than 6), we did not encounter any major adverse events. Additionally, 2 adverse events were not related to stent indwell time: one was related to external migration of the LAMS and the other was bleeding induced by the cautery system during stent placement. These investigations were undertaken at the time of LAMS introduction in the United States. Consequent to the experience from these studies, our treatment protocol has evolved leading to fewer adverse events. Not all patients with an indwelling LAMS (beyond 3 weeks) develop an adverse event. In our experience with 159 patients undergoing LAMS placement, the overall rate of stent-induced adverse events (delayed bleeding, buried bumper or biliary stricture) is 7.5%.

Our study cohort was composed of very sick patients and when the initial surgical intervention was unsuccessful, 9.4% required endoscopic rescue as determined by multidisciplinary consensus.³ A methodologic limitation of randomized trials conducted in this area is that about one-third of the patients do not require the intervention to which they were randomized: decompression by percutaneous drains (in step-up surgery) or by transluminal stents (in endoscopy) preclude the need for any further treatment (necrosectomy). We agree that our attempts to minimize this methodologic limitation in the surgical arm may have created a bias in favor of endoscopy. Although it is exceedingly difficult to execute a perfect study with perfect methodology in necrotizing pancreatitis, when it comes to clinical management, a patient-centered, pragmatic approach is critical for delivering optimal