

PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 37285

Title: Endoscopic ultrasound-guided drainage of pancreatic walled-off necrosis by self-expanding metal stents without fluoroscopy

Reviewer's code: 00504150

Reviewer's country: Canada

Science editor: Ya-Juan Ma

Date sent for review: 2018-01-04

Date reviewed: 2018-01-08

Review time: 4 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> No	<input type="checkbox"/> Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

COMMENTS TO AUTHORS

With great interest, I have read the manuscript entitled, "Endoscopic ultrasound-guided drainage of pancreatic walled-off necrosis using self-expanding metal stents without fluoroscopy" by Braden et al. The study is somewhat interesting and in general goes along well with what has been shown by other groups concerning the benefits of fully covered self-expanding metal stents to treat necrotizing pancreatitis. The following are points that need to be addressed by the authors. (1) The authors state that this study was conducted in two centers on page 5. One can assume that one in England and another in Germany. However, it is not clearly stated anywhere in the text. Moreover, the authors should mention ethical approval of the study from two different centers. (2) The authors state that WOPN content was aspirated and sent for bacterial culture and biochemistry analysis if clinically required in Materials and Methods section on page 6.

However, the results are not shown. (3) On page 7 “5. Slow withdrawal until contact of distal flange to cavity wall”. Withdraw what? (4) Please do not start sentences with a number. Abstract on page 3 and Results on page 9 (27 consecutive...). (5) Clinical outcome was selected as one of the secondary outcomes by the authors. However, the authors’ description of clinical outcome is too brief in Results section. The main indications for drainage was gastric outlet obstruction in 15 cases, biliary obstruction in 3, and infection/fever in 9. Are they fully recovered? If so when? What about the length of hospital stay? More detailed information regarding clinical outcome should be described. (6) “Walled-off pancreatic necrosis” (page 5, line 11 from bottom) and “walled-off necrosis” (page 7) should be “WOPN”. (7) The statement on page 15 that all procedural steps during EUS-guided insertion of FCSEMS are well visualized somewhat contradicts the fact that visibility of the entire coiling of the wire was limited in 6 patients (on page 11). (8) The authors say “some potential limitations” on page 14. They are actual limitations, so simply saying “some limitations” makes more sense.

Dear reviewer,
Thank you for your comments.

- 1. We have added the location of the participating centers and clarified the ethics procedures on both sites.**
- 2. We have deleted the sentence on aspirating fluid for further analysis as not relevant for the paper and not consistently performed.**
- 3. We have added “of the entire delivery system”.**
- 4. We have avoided starting a sentence with a number.**
- 5. We have given more information on the clinical outcome and added the results of imaging follow-up as available.**
- 6. All changed to “WOPN” as suggested.**
- 7. The introduction of the wire could be visualized in all cases.**
- 8. However, due to echogenic debris the visibility of the entire coiling was limited but this is not essential for the stent placement.**
- 9. We have deleted “potential” as suggested.**

PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 37285

Title: Endoscopic ultrasound-guided drainage of pancreatic walled-off necrosis by self-expanding metal stents without fluoroscopy

Reviewer's code: 01558248

Reviewer's country: Taiwan

Science editor: Ya-Juan Ma

Date sent for review: 2018-01-04

Date reviewed: 2018-01-09

Review time: 4 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> [Y] Accept
<input type="checkbox"/> Grade B: Very good	<input type="checkbox"/> [Y] Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> [] High priority for publication
<input type="checkbox"/> [Y] Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> [] Rejection
<input type="checkbox"/> Grade D: Fair	<input type="checkbox"/> Grade D: Rejected	<input type="checkbox"/> Plagiarism	<input type="checkbox"/> [] Minor revision
<input type="checkbox"/> Grade E: Poor		<input type="checkbox"/> No	<input type="checkbox"/> [] Major revision
		BPG Search:	
		<input type="checkbox"/> The same title	
		<input type="checkbox"/> Duplicate publication	
		<input type="checkbox"/> Plagiarism	
		<input type="checkbox"/> No	

COMMENTS TO AUTHORS

1. Please add the indications based on the clinical findings or imaging study. 2. How to manage your patients with pancreatitis due to biliary diseases? 3. Please tell us the days needed for a satisfied improvement after drainage. 4. Please make more simple in the section of methods where possible.

Dear reviewer,

Thank you for your comments.

1. We have described the clinical indication based on clinical symptoms and

imaging findings in table 1.

2. Patients with WOPN caused by acute biliary pancreatitis were first treated by EUS-guided drainage of the collection. ERCP was performed when imaging demonstrated stones within the common bile duct; patients underwent cholecystectomy after they had clinically improved.
3. Clinical improvement is a question of definition. Most patient could feel decreased pressure directly after transmural stenting. Imaging was repeated according to clinical needs and after 5-6 weeks to decide on stent removal. We have added more information to the clinical outcome including imaging follow up and time of intervention.
4. We have deleted sentences from the methods part which were not crucial within the context of this study (e.g. aspiration of fluids)

PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 37285

Title: Endoscopic ultrasound-guided drainage of pancreatic walled-off necrosis by self-expanding metal stents without fluoroscopy

Reviewer's code: 00070310

Reviewer's country: Japan

Science editor: Ya-Juan Ma

Date sent for review: 2018-01-04

Date reviewed: 2018-01-10

Review time: 6 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
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		<input type="checkbox"/> No	

COMMENTS TO AUTHORS

This paper showed the effect of EUS-guided drainage of pancreatic walled-off necrosis using self-expanding metal stents. This manuscript is well written. However it will require some revision before publication. 1, EUS-guided drainage without fluoroscopy is often used for pancreatic walled-off necrosis. Please impact your findings in this paper. 2, Are self-expanding metal stents really useful for necrosis tissue of the pancreas compared with endoscopic nasal drainage?

Dear reviewer,

Thank you for your comments.



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1. In our experience and in the literature, WOPN drainage with metal stents is mainly carried out under EUS-guidance but with fluoroscopic control and standby. This is the first study investigating the feasibility of a purely EUS-guided approach assessing the endosonographic visibility of all procedural steps. We have stronger pointed this out, especially in the study highlights.
2. WOPN drainage with large diameter metal stents has improved the outcome of necrotizing pancreatitis with collections. We have cited the evidence (Ref 1-7). Endoscopic nasal drainage is an additional helpful tool; we have not used it in this study.

PEER-REVIEW REPORT

Name of journal: World Journal of Gastroenterology

Manuscript NO: 37285

Title: Endoscopic ultrasound-guided drainage of pancreatic walled-off necrosis by self-expanding metal stents without fluoroscopy

Reviewer's code: 00045989

Reviewer's country: United States

Science editor: Ya-Juan Ma

Date sent for review: 2018-01-04

Date reviewed: 2018-01-12

Review time: 8 Days

CLASSIFICATION	LANGUAGE EVALUATION	SCIENTIFIC MISCONDUCT	CONCLUSION
<input type="checkbox"/> Grade A: Excellent	<input type="checkbox"/> Grade A: Priority publishing	Google Search:	<input type="checkbox"/> Accept
<input type="checkbox"/> Grade B: Very good	<input checked="" type="checkbox"/> Grade B: Minor language polishing	<input type="checkbox"/> The same title	<input type="checkbox"/> High priority for publication
<input checked="" type="checkbox"/> Grade C: Good	<input type="checkbox"/> Grade C: A great deal of language polishing	<input type="checkbox"/> Duplicate publication	<input type="checkbox"/> Rejection
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		<input type="checkbox"/> No	

COMMENTS TO AUTHORS

1. Please provide more details on your patients. Was drainage done in an ICU setting? Were the patients intubated? Did you use anesthesia assistance? Technically, unless there is significant solid debris, the reviewer agrees that EUS imaging is the primary delivery system for lumen-apposing stents. It does not mean, however, that it should be used in patients with 20 cm collections, necrosis going into the pelvis, patients with major infections and septated WON, or those with concomitant biliary tract disease.
2. Comment is required on your patients, re: the timing of intervention, the clinical success relative to the extent of necrosis, the length of follow-up, the need for pigtail stents to treat disconnected pancreatic ducts at time of SEMS removal (>50% in most series), and the presence or absence of concomitant enteric/colonic or biliary fistulae.
3. Did any of these patients

have either an MRCP or ERCP to define active PD leak? Many endoscopists will consider concomitant ERCP if an active PD leak is likely. 4. The issue of follow-up here is crucial. Removal of SEMS when WON is ≤ 4 cm does not mean resolution, particularly in a patient with disconnected PD. Comment is required in the Discussion section.

Dear reviewer,
Thank you for your comments.

1. We have described the patients and the procedure in more detail, added "monitoring by an anaesthetic team". We have reported that patients were under endotracheal intubation.
2. The timing of intervention was selected at least 4 weeks after the beginning of the necrotizing pancreatitis to allow for demarcation; this has been added. We have also added that we did not use pigtail stents to prevent metal stent migration or after metal stent extraction. We did not encounter biliary or colonic fistulae in this series.
3. All patients had MRCP, none ERCP of the pancreatic duct. We consider the clinical response after drainage of the collection more important than the additional risk of a pancreatic ERCP. MRCP can often not definitely confirm disconnection of the pancreatic duct.
We treat patients with disconnected pancreatic tail syndrome by insertion of a plastic stent as required but this has not become necessary in this study. We have added our data to the long-term follow-up as they were available.
4. We do not think that management of the disconnected pancreatic tail syndrome is within the scope of this study on technical feasibility but we have mentioned the problem in Results and in the discussion. 20 patients had follow-up of at least 6 months time; we did not see reoccurrence of the collection but this might also be due to the fact that the created pancreaticogastric fistula persists after stent extraction in cases of disconnected ducts because of the large diameter orifice. We have discussed this.

COMMENTS TO AUTHORS

It was very interesting in reading the present paper. Indeed, after 8 weeks, the WOPN had resolved in all but one patient (96.0%) to a diameter of less than 4 cm. Therefore, the reviewer has only small comments on this article as below. Reviewer's comments. 1. The authors described that the avoidance of radiation exposure and fluoroscopy would improve the availability of the outcome for these critically ill patients as it could be performed at the bedside. In some patients FCSEMS had to be performed at the intensive care unit. However, X-ray and fistography after FCSEMS may offer significant information for physicians in some non-critical patients. Were the patients in the present study all so septic and critical? 2. There were a few adverse events at the time of FCSEMS as the authors resented. However, the authors did not show adverse events at the time of removal. Were there any difficulties during and after removal of the stent? 3. The authors should show the days from FCSEMS to discharge from the hospital in the 25 successful patients.

**Dear reviewer,
Thank you for your comments.**

- 1. We have described the patients and the procedure in more detail. EUS-guided drainage procedures were performed in the endoscopy unit. The purpose of the study was to prove that it can be performed without fluoroscopy making it available for critically ill patients. Some of the patients were critically ill and septic.**
- 2. There were no adverse events at the time of stent removal. We have added this information.**
- 3. We do not think that these data are necessary to demonstrate that FCSEMS stents can be inserted without fluoroscopy.**

COMMENTS TO AUTHORS

This is an interesting study demonstrating the feasibility of WOPN drainage by self-expanding metal stent under EUS, without the need of fluoroscopic control. Although this is not the first report of this procedure, the results are useful for operative endoscopists. I have some questions: 1- Why the procedure was performed under endotracheal intubation? 2- How could the operator verify that the guidewire coiled at least twice into the cyst cavity? 3- Regarding the migrated stent, was it necessary any treatment for stent removal?



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Dear reviewer,
Thank you for your comments.

This is the first report on evaluating the need for fluoroscopy for the insertion of FCSEMS in WOPN in a systematic fashion.

1. We have chosen endotracheal intubation to reduce the risk of aspiration. When the stents are successfully inserted large amounts of liquids with pancreatic enzymes fill the stomach within seconds.
2. In most cases we could observe the coiling of the wire. In the two cases with large amount of debris we just ensured that a sufficient length of wire had been advanced into the cyst to improve stabilization of the position.
3. X-ray confirmed complete passage of the stent out of the body.