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Endoscopic ultrasonography for preoperative local assessment and endoscopic ultrasonography-guided marking before gastro-jejunostomy for duodenal obstruction using magnetic compression anastomosis

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Dear Dr. Kawabata,

Reviewers have now commented on your paper. You will see that they are advising that you revise your manuscript. If you are prepared to undertake the work required, I would be pleased to reconsider my decision.

For your guidance, reviewers' comments are appended below.

If you decide to revise the work, please submit a list of changes or a rebuttal against each point which is being raised when you submit the revised manuscript. Also, please ensure that the track changes function is switched on when implementing the revisions. This enables the reviewers to rapidly verify all changes made.

Your revision is due by Jul 14, 2021.

To submit a revision, go to https://www.editorialmanager.com/jctres/ and log in as an Author. You will see a menu item call Submission Needing Revision. You will find your submission record there.

Yours sincerely

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Reviewers' comments:

Reviewer #1: This manuscript describes the efficacy and safety of magnetic compression anastomosis for gastrojejunostomy in the duodenal obstruction. Although the manuscript is well-written, there is a need to discuss some aspects for publishing.

1. In the case of duodenal obstruction due to malignancy, a metal stent is usually inserted. What are the advantages of MCA compared to metal stent insertion? A sufficient discussion is needed on this point.
2. In this case, scope passing was possible at the stricture site so that the magnet could be placed in the jejunum. What should you do if the magnet cannot be positioned due to complete GI obstruction by endoscopy?
3. If there is an intervening vessel between two magnets during the MCA procedure, is there a way to avoid it?
4. It is important to position of magnet before the magnet approximation. Is it possible to measure the distance between approximated magnets with EUS before the procedure? Do you expect the distance to be narrowed by magnetic power?
5. What is the follow-up period after new fistula formation, and is there any late complications including leakage?
6. Does 'no non-target tissue' in the abstract mean blood vessels? It would be good to clarify the meaning.

Reviewer #2: Dear Editors,
Thank you for giving me the opportunity to review this paper.
This article is a case report of endoscopic gastrojejunal anastomosis with magnet anastomosis for duodenal stricture caused by malignant lymphoma.
Very interesting read. However, we have a lot of concerns, hoping the authors revise it in a major. The progress of this patient and the details of this procedure should be described and discussed.

Clarify the following points.

1. Apart from the essential point of this report, but we have a serious concern. Was the magnet you used made specifically for this treatment? Had it been approved by the government as a medical device? approved by the ethics committee of our institute. The authors stated that the treatment was done after obtaining approval from the ethics committee, but there is no mention of the name or approval number of the ethics committee. Please

clarify. Furthermore, any medical device or medical procedure that is not approved by the government is subject to free medical treatment forcing patients to bear high medical costs, as well as approval by a proper ethics committee, but is it being followed?
If not, it is a serious violation of the law.

2. With the advent of lumen apposing metal stent (LAMS) and the development of the technique, there are some reports on the safety and usefulness of EUS-guided gastrojejunostomy (EUS-GJ) using LAMS, and that technique is more mainstream. EUS-GJ itself and advantages of MCA compared to EUS-GJ should also be mentioned in the discussion.

3. Describe the patient's progress, including the status of oral intake before and after treatment. Was the patient fasting for the duration of the treatment?

4. In the MCA, we think the most difficult point is to attract the two magnets at the target site, could you tell us more about this technique?
According to figures, it seems that the magnet is placed first on the jejunum side. What is the method of fixing the magnet on the jejunum side to prevent migrate into anorectal intestine during this procedure.

Authors' response

RESPONSE TO REVIEWER 1:
We wish to express our appreciation to the Reviewer 1 for his or her insightful comments, which have helped us significantly improve the paper.

1. In the case of duodenal obstruction due to malignancy, a metal stent is usually inserted. What are the advantages of MCA compared to metal stent insertion? A sufficient discussion is needed on this point.

(Response)
As the Reviewer 1 mentioned, metallic stenting is usually performed for stricture due to malignancy. However, stent dislocation was concerned in this case as the duodenal stricture was made due to compression from tumor but not tumor itself as we mentioned in the main text.

2. In this case, scope passing was possible at the stricture site so that the magnet could be placed in the jejunum. What should you do if the magnet cannot be positioned due to complete GI obstruction by endoscopy?

(Response)
Thank you for the Reviewer 1's comment. Indeed, we cannot avoid giving up this procedure in case of complete GI obstruction that a guidewire is not able to pass through. However, we can perform this procedure using balloon dilation if a guidewire is able to pass through the stricture site. We have previously reported a case of MCA procedure using balloon dilation.

Kawabata H, Sone D, Yamaguchi K, et al. Endoscopic gastro-jejunostomy for superior mesenteric artery syndrome using magnetic compression anastomosis. Gastroenterology Res. 2019;12(6):320-323.

We inserted a sentence in the discussion as below:

However, endoscopic MCA involves passing a magnet with an endoscope through the stricture site, with balloon dilatation able to be used if a guidewire is passed through the stricture site [6].

3. If there is an intervening vessel between two magnets during the MCA procedure, is there a way to avoid it?

(Response)
We can easily avoid intervening vessels by slightly changing the position based on the image of EUS with color Doppler.

We modified a sentence in the discussion as below:

EUS with color Doppler from the stomach can easily visualize the real-time, local condition, including that of vessels and intestine at the anastomosis site, calculate the distance between the magnets, and be adjusted to determine the optimal position.

4. It is important to position of magnet before the magnet approximation. Is it possible to measure the distance between approximated magnets with EUS before the procedure? Do you expect the distance to be narrowed by magnetic power?

(Response)
Thank you for the Reviewer 1's comment.
We can estimate the distance between approximated magnets with EUS before the procedure. Indeed, the distance is narrowed by magnetic power after magnets approximation once they can be attracted each other.

5. What is the follow-up period after new fistula formation, and is there any late complications including leakage?

(Response)
We don't perform follow-up endoscopy regularly if the patients are asymptomatic after eating as the patients usually have a risk for invasive procedures including EGD.
Therefore, we inserted a sentence as below:
Follow-up esophagogastroduodenoscopy was not performed in our present patient as she remained asymptomatic after starting meal intake and had risk factors associated with invasive procedures, including EGD.

6. Does 'no non-target tissue' in the abstract mean blood vessels? It would be good to clarify the meaning.

(Response)
According to the Reviewer 1's comment, we modified a sentence in the abstract as below:

We then confirmed the absence of no non-target tissue, including large vessels and intestine adjacent to the anastomosis where the magnets were to be placed using endoscopic ultrasonography (EUS) from the stomach.

RESPONSE TO REVIEWER 2:
We wish to express our appreciation to the Referee 2 for his or her insightful comments, which have helped us significantly improve the paper.

1. *Apart from the essential point of this report, but we have a serious concern. Was the magnet you used made specifically for this treatment? Had it been approved by the government as a medical device? approved by the ethics committee of our institute. The authors stated that the treatment was done after obtaining approval from the ethics committee, but there is no mention of the name or approval number of the ethics committee. Please clarify. Furthermore, any medical device or medical procedure that is not approved by the government is subject to free medical treatment forcing patients to bear high medical costs, as well as approval by a proper ethics committee, but is it being followed? If not, it is a serious violation of the law.*

(Response)
Thank you for the Reviewer 2's comment. This procedure was performed as a medical treatment but not a study. Therefore, we went on the process according to a guideline in our institute. This procedure was approved by the ethics committee in our institute. Furthermore, we obtained written informed consent from the patient's family as described in the text. We added the approval number in the text.

2. With the advent of lumen apposing metal stent (LAMS) and the development of the technique, there are some reports on the safety and usefulness of EUS-guided gastrojejunostomy (EUS-GJ) using LAMS, and that technique is more mainstream. EUS-GJ itself and advantages of MCA compared to EUS-GJ should also be mentioned in the discussion.

(Response)
According to the Reviewer 2's comment, we introduced EUS-guided gastroenterostomy using lumen-apposing metal stents, and discussed its challenges compared to MCA as below:

Recently, the concept of EUS-guided gastroenterostomy using lumen-apposing metal stents for the management of gastric outlet obstruction has been proposed, and favorable outcomes have been reported [17,18]. A systematic review and meta-analysis [18] demonstrated a pooled technical success rate of 92% (95% CI: 88%–95%) and clinical success rate of 90% (95% CI: 85%–94%) with fewer adverse events and lower recurrence rate than surgical gastrojejunostomy or enteral stenting. However, this technique requires technical expertise and costly devices, and stenting-associated adverse events, including stent misdeployment, gastric leak and peritonitis can occur, leading to life-threating serious conditions requiring surgical salvation.

3. Describe the patient's progress, including the status of oral intake before and after treatment. Was the patient fasting for the duration of the treatment?

(Response)
As we have described in the text, her situation was not improved despite conservative therapy, including liquid food and postural change of one-week duration.
And, we modified the last sentence in the Case report section as below:

The patient subsequently started eating a normal diet, and remained asymptomatic until being transferred from the hospital one month after the procedure.

4. In the MCA, we think the most difficult point is to attract the two magnets at the target site, could you tell us more about this technique?
According to figures, it seems that the magnet is placed first on the jejunum side. What is the method of fixing the magnet on the jejunum side to prevent migrate into anorectal intestine during this procedure?

(Response)
Thank you for the Reviewer 2's comment. We have never experienced the magnet migration into anal intestine. We consider this is because a spasmolytic is premedicated and the magnet is too heavy to easily move. Indeed, we used a premedication of spasmolytic, glucagon (Glucagon G Novo; Novo Nordisk Pharma Ltd, Tokyo, Japan) 0.5 mg intravenously to prevent magnet migration, and added this in the text.

2nd Editorial decision
28-Jul-2021

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Dear authors,

I am pleased to inform you that your manuscript has been accepted for publication in the Journal of Clinical and Translational Research.

You will receive the proofs of your article shortly, which we kindly ask you to thoroughly review for any errors.

Thank you for submitting your work to JCTR.

Kindest regards,

Journal of Clinical and Translational Research
Peer review process file 07.202105.001

Michal Heger
Editor-in-Chief
Journal of Clinical and Translational Research

Comments from the editors and reviewers: