ANSWERING REVIEWERS

May 16, 2013

Dear Editor,

Please find enclosed the edited manuscript in Word format (file name: ESPS_No_3146 (R1).doc).

Title: Can trans-anal reinforcing sutures after double stapling in lower anterior resection reduce the need for a temporary diverting ostomy?

Author: Se-Jin Baek, Jin Kim, Jungmyun Kwak, Seon-Hahn Kim

Name of Journal: *World Journal of Gastroenterology*

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The manuscript has been improved according to the suggestions of reviewers:
1 Format has been updated

2 Revision has been made according to the suggestions of the reviewer

(1) Reviewer 00227446

This paper addresses an important issue which is of interest to most surgeons. Anastomotic breakdown carries a major morbidity and mortality. Any procedure that attempts to reduce this is welcome. The authors suggested that trans-anal reinforcing sutures after double stapling following low anterior resection may reduce the need for a temporary diverting stoma which is the standard option for the majority of surgeons. To demonstrate this they compared a group of patient where a selective policy of stoma formation(30%). The second group all patients underwent this new technique, 12.8% had a covering stoma. Anastomotic breakdown was similar in both groups. This is a well written paper and the authors should be commended for this work. However I have few concerns and points that they need to clarify

Q1. The described technique is not easy. Any learning curve? Any complications? Any risks or pitfalls that should be avoided? How easy to place these sutures particularly anteriorly particularly in a male patient?

A1. As we stated in our manuscript, this technique is very easy. It involves only simple suture through the anus. The performance of transanal suture is very common at the time of transanal excision for early rectal cancer, conventional hemorrhoid, or a procedure for prolapse and hemorrhoids (PPH) using a circular stapler, but we don't say that transanal suture is difficult. We assure you that this procedure is easier than other procedures as above, and we think that a specific learning curve is not necessary for it, even if the patients are male. As female patients have a risk of developing vaginal fistula when their anterior part is sutured, extra efforts should be made to avoid deep sutures at that time. We added sentences reflecting this in the Discussion section (7th paragraph), and we highlighted them in red colored text.

Q2. The authors mention in general terms their selective policy of forming a covering

stoma. However, It is not clear from the paper those patients who had a covering stoma why they had it?

A2. We guess that the patients underwent diverting stoma, including not only the cases where diverting stoma are needed due to the definite risk of anastomotic leakage but also the many cases with unnecessary diverting stoma made due to the surgeon's excessive anxiety, although we cannot present the absolute numbers of these cases. This may be a fundamental problem of a retrospective study. The expected positive effect of transanal sutures is that the sutures can reduce the number of unnecessary stoma. We included an explanation of this in the Discussion section (5th paragraph).

(2) Reviewer 00041589

This paper raises an important issue regarding rectal surgery and suggests a technique that I find very interesting. However, I remain convinced that trans-anal reinforcing sutures can't replace the routine defunctioning stoma. The benefits conferred by a protective stoma have been already demonstrated. It reduces the rate of clinically relevant anastomotic leakages and has been thus recommended in low anterior resection for rectal cancer.

Q3. In my opinion, the selective use of a diverting stoma based on the subjective assessment at the time of surgery is inaccurate. The authors should better explain and justify the choice they make. It would have been relevant to study the number of anastomotic leaks (clinical or not) regarding patients with ileostomy.

A3. Stoma placement usually depends on the subjectivity of the surgeon and others, including us. Apart from the cases where stoma need to be made definitely, numerous diverting stoma are made due only to the surgeon's insecurity. It is expected that the transanal sutures can reduce their anxiety and can decrease the formation of unnecessary stoma. We agree to the opinion that definite anastomotic leakage cannot be preventable using only transanal sutures.

Q4. Considering that eight patients have presented a fistula, the authors should have indicated if these patients had had an ileostomy or not.

A4. We're sorry, but we don't know the eight patients with fistula that you mentioned. There was no case in which fistula occurred postoperatively in our study, and we didn't include sentences about it in our manuscript. If we're missing something, please let us know.

Q5. It's true that temporary loop ileostomy leads to an adverse effect on quality of life, but early stoma closure after proctectomy is possible for certain selected patients and might reduce both stoma-related morbidity and patient discomfort. The authors should have envisaged this option in the discussion.

A5. We also agree that the patients' inconveniences and complications are not serious if these can be addressed early. The fact, however, that another operation is needed still existed, and there is also a definite risk of complications related to stoma, even if with a short duration. Thus, the suggestion that stoma be made routinely and excessively without careful consideration cannot be accepted. We have already included sentences about this in the Discussion section (6th paragraph).

(3) Reviewer 00041581

The reasons I reject this paper for publication in WJG are the same that the authors mentioned as the limitations of their study at the end of their manuscript. First there is a great selection bias in choosing patients to do a covering stoma and second the study is non-randomized. Both reasons greatly jeopardize the results.

Q6. I think the design of this study should have been as follows: First, all patients who would have a covering stoma for any indication that is agreed upon in the surgical community, such as ischemic edges, anastomosis under tension and incomplete doughnuts, should be excluded. Then you randomize the remaining patients, in whom there is no indication for a stoma, into two groups: one with and the other without the reinforcing stitches and compare the results in both groups.

A6. We agree to your opinion that the study design should be performed as per your suggestion if the study is a prospective one. As you well know, this is a retrospective study and thus has some limitations. Many prospective studies can be designed, however, based on retrospective studies, and it is a very impetuous conclusion that retrospective studies are valueless. We agree that the prevention of definite anastomotic leakage using only transanal sutures is not feasible, and we might also replace diverting stoma regardless of the transanal sutures in these cases, although we cannot present their absolute number.

What is important is that many diverting stoma, besides integral cases, are still made based only on the surgeons' subjective judgments and unnecessary anxieties. We believe that the transanal sutures seemed not only to have reduced the chances of microleakage but also to have decreased the number of unnecessary stoma by enhancing the surgeons' emotional stability. We added some sentences about this in the Discussion section (5th paragraph), and we highlighted them in red colored text.

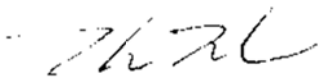
Q7. Moreover, I believe that the stitch that the authors described will not be securing the dog ear which is the most vulnerable point in the anastomosis.

A7. Based on our many related experiences, we determined that transanal sutures are feasible and effective for the re-enforcement of vulnerable points made by crossing stapling lines.

3 References and typesetting were corrected.

Thank you again for publishing our manuscript in the *World Journal of Gastroenterology*.

Sincerely yours,



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