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Isoperistaltic *versus* antiperistaltic stapled side-to-side anastomosis for colon cancer surgery: a randomized controlled trial

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ABSTRACT

Background: Isoperistaltic stapled side-to-side anastomosis (SSSA), which is a modified technique from conventional antiperistaltic SSSA, has the benefits of antiperistaltic SSSA but requires less intestinal mobility. The aim of this randomized controlled trial was to evaluate short-term outcomes of isoperistaltic SSSA comparing them with antiperistaltic SSSA during colon cancer surgery.

Materials and methods: We conducted a randomized controlled trial of patients with colon cancer who underwent elective curative resection and had enough intestinal mobility at anastomosis. The primary outcome was the presence of anastomotic failure, including leakage, hemorrhage, and stenosis.

Results: Between July 2012 and January 2014, forty patients were enrolled (20 patients in each group). The study was suspended on detecting excess morbidity in the isoperistaltic SSSA group. No significant differences were observed in all preoperative backgrounds between the two groups. Anastomotic leakage was seen in two patients in the isoperistaltic SSSA group, compared with none in the antiperistaltic SSSA group, although the difference was not statistically significant ($P = 0.487$). One patient in the antiperistaltic SSSA group had anastomotic stenosis, which improved conservatively, compared with none in the isoperistaltic SSSA group ($P = 1.000$). No anastomotic hemorrhage was seen in either group. There was no significant difference in the median postoperative hospital stay ($P = 0.313$).

Conclusions: This study did not show any short-term advantage or disadvantage of isoperistaltic SSSA compared with that of antiperistaltic SSSA. However, considering that anastomotic leakage occurred only in the isoperistaltic SSSA group, additional modifications are recommended to perform safe isoperistaltic SSSA for colon surgery.

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1. Introduction

Anatomic antiperistaltic stapled side-to-side anastomosis (SSSA), called as functional end-to-end anastomosis, using a linear stapling device after intestinal resection was introduced in 1968 [1]. The convenience, shorter requiring time, and less dependence on surgical skill compared with hand-sewn anastomosis have resulted in the former becoming widespread. Although evidence for the short- and long-term superiority of stapling over hand-sewn anastomosis is sparse, a recent meta-analysis demonstrated that stapled functional end-to-end ileocolic anastomosis is associated with fewer leakages than hand-sewn anastomosis is [2]. However, the disadvantage of antiperistaltic SSSA is that it requires greater mobilization of the intestine to overlap and anastomose than hand-sewn end-to-end anastomosis does.

Laparoscopic surgery for colon cancer has become a common practice worldwide because it is less invasive and has greater cosmetic benefit than conventional open surgery [3,4]. However, the approach occasionally requires more mobilization of the intestine, which should be elevated extracorporeally, to perform safe anastomosis than open surgery, in case intestinal ends and specimen extraction site were distant.

Isoperistaltic SSSA, which anastomoses oral- and anal-sided intestine side-to-sideways in the opposite direction using a linear stapling device (Fig. 1) [5,6], has the benefits of antiperistaltic SSSA but requires less intestinal mobility (schematic representation is shown in Fig. 2). In cases with insufficient intestinal mobility at anastomosis, isoperistaltic SSSA might be a good alternative to antiperistaltic SSSA. Therefore, the aim of this randomized controlled trial was to evaluate whether isoperistaltic SSSA is comparable with antiperistaltic SSSA for colon cancer surgery in terms of short-term outcomes.

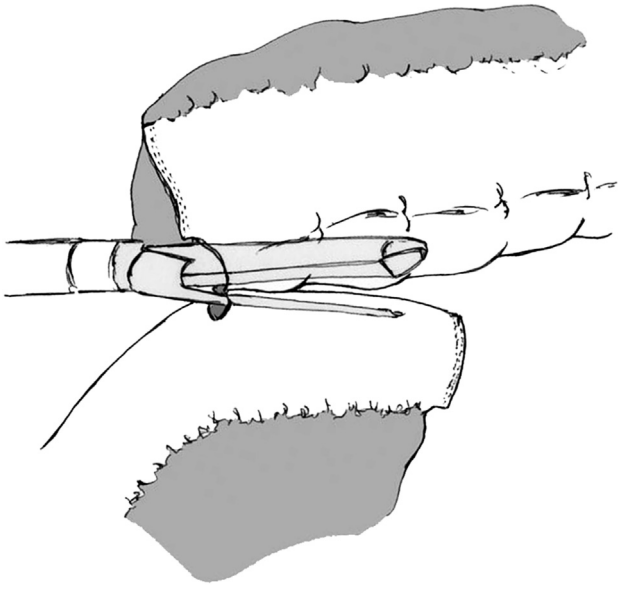

Fig. 1 – Diagrammatic representation of isoperistaltic SSSA. The entry hole for the linear stapler, created at the oral-site of anastomosis, was closed with 1-layer running suture.

2. Materials and methods

2.1. Study population

Patients with histologically proven colon cancer who were candidates for elective curative resection at the Department of Surgery, Nippon Medical School Chiba Hokusoh Hospital were eligible for inclusion. Patients were excluded if they were aged <20 or >85 y, had gastrointestinal obstruction, preoperative chemotherapy, or radiation, ongoing infection, and required defunctioning stoma, multiple anastomosis, or anastomosis by double stapling technique using a circular stapling device. We explained the details of the protocol to candidates and obtained written informed consent from the patients. During surgery, if the patient had enough intestinal mobility to perform whichever antiperistaltic SSSA or isoperistaltic SSSA without overtension, the actual enrollment was decided. Included patients were enrolled in this study and randomly divided into antiperistaltic SSSA and isoperistaltic SSSA groups, by use of numbered, sealed envelopes, which were stratified by the surgeon. This study was conducted in accordance with the Declaration of Helsinki. The ethical committee of our institution approved the study protocol. This study was registered with the clinical trials registry of the University Hospital Medical Information Network (UMIN-CTR, UMIN 000008485) in Japan. Given the nature of the intervention, it was not possible to blind the intervention group of each patient to the surgical team. Patients were not informed of the type of anastomosis performed during the observational period.

Demographic baseline and surgical variables of the patients were collected prospectively. All surgeries were performed by two colorectal surgeons with equivalent experiences in the surgical treatment of colorectal cancer. Surgical approach, open or laparoscopically, was determined by patient factors and surgeon's decision.

2.2. Surgical procedure

Mechanical bowel preparation with 2 L polyethylene glycol was performed at 12–16 h preoperatively. The patients received intravenous antibiotic prophylaxis of 1 g flomoxef sodium before incision, and an additional dose was administered if the operation time exceeded 3 h. Administration was twice daily and continued for 2 d postoperatively.

A 60-mm linear stapling device (Echelon Endopath; Ethicon, Somerville, NJ) with a blue cartridge was applied for all resection and anastomosis procedures. After resecting colonic specimens using a linear stapling device, both ends of the intestines were overlapped for 5 cm in the same direction in the antiperistaltic SSSA group and in the opposite direction in the isoperistaltic SSSA group. In the antiperistaltic SSSA group, 10-mm transverse enterotomies were created at the antimesenteric edges of the stapling line of both intestines. Each jaw of the linear stapling device was inserted into each hole and fired to create a side-to-side anastomosis. The entry hole for the linear stapler was closed with one application of the stapler perpendicular to the first suture line. In the isoperistaltic SSSA group, 10-mm enterotomies were created at

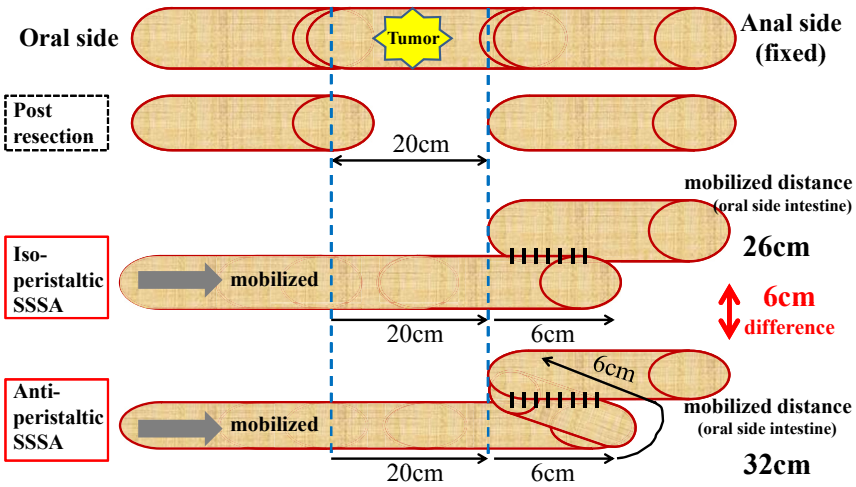

Fig. 2 – Schematic representation of required less intestinal mobilization in isoperistaltic SSSA. A 20-cm intestine was removed to resect tumor and 60-mm linear stapling devices were used for anastomosis. Isoperistaltic SSSA theoretically requires totally 26 cm mobilization distance of oral side end (20-cm defect and 6-cm stapler length). In contrast, antiperistaltic SSSA requires 32 cm mobilization distance of oral side end (20-cm defect and 6 + 6-cm stapler length). This means that isoperistaltic SSSA can shorten the intestinal mobilization for 6 cm compared with that of antiperistaltic SSSA. The edge of the anal side intestine was fixed and only the oral side end was mobilized for either anastomosis to illuminate understanding. (Color version of the figure is available online.)

the antimesenteric site of the oral-sided intestine 5 cm from the first stapling line and the antimesenteric edge of the stapling line of the anal-sided intestine. Each jaw of the linear stapler was inserted into each hole and fired to create a side-to-side anastomosis. The entry hole for the linear stapler, created at the oral-site of anastomosis, was closed with a 1-layer running suture (4-0 PDS II; Ethicon; Fig. 1). Additional hand sutures for reinforcement of anastomosis were applied in both groups. The antiperistaltic SSSA group had three additional hand sutures on a staple line created by the tip of anastomosing stapler and on two rectangular staple line-crossing points created by the entry hole-closing stapler. In contrast, the isoperistaltic SSSA group had one additional hand suture on a staple line created by the tip of anastomosing stapler. The colonic mesenteric defect was closed with interrupted sutures with 4-0 PDS II in open surgery but not laparoscopic surgery.

2.3. *Outcome measures and follow-up*

The primary outcome of this study was the presence of anastomotic failure, including leakage, hemorrhage, and stenosis. The secondary outcomes were the presence of wound infection, prolonged ileus, intra-abdominal abscess, first defecation after surgery, reoperation, and length of postoperative hospital stay. Patients were surveyed in the hospital daily until discharge and at the outpatient department until 28 d after surgery.

2.4. *Statistical analysis*

We calculated that a sample size of 25 patients in each group would give a power of 80% to establish whether isoperistaltic SSSA was not inferior to antiperistaltic SSSA in relation to the incidence of anastomotic failure. This sample size took into account an expected incidence of stapled anastomotic failure after colon cancer surgery of 2% [2], a noninferiority margin of 10%, and a one-sided α risk of 0.05. Data were expressed as median ± standard deviation of the mean. The two-tailed Student *t*-test and Mann–Whitney *U*-test were used to compare continuous variables, and the χ^2 test and Fisher exact test were used to compare discrete variables. A value of $P < 0.05$ was considered statistically significant.

3. Results

Between July 2012 and January 2014, forty-one patients were enrolled in this study. After the initial enrollment, one patient was excluded because of the lack of intestinal mobility. The study was suspended on detecting excess morbidity in the isoperistaltic SSSA group. Finally, forty patients were enrolled in this study and randomly divided into antiperistaltic SSSA and isoperistaltic SSSA groups (20 patients in each group). The preoperative demographic and clinical characteristics of the 40 patients are shown in Table 1. The patient characteristics in the antiperistaltic SSSA and isoperistaltic SSSA groups were well balanced. No significant differences were observed in any of the preoperative variables between the two groups.

Surgical variables and predefined outcomes are shown in Table 2. The operation time was similar in the two groups (203 ± 53 min in the antiperistaltic SSSA group *versus* 215 ± 68 min in the isoperistaltic SSSA group; $P = 0.286$). The required time for anastomosis was also comparable in the two groups (870 ± 240 s in the antiperistaltic SSSA group *versus* 920 ± 248 s in the isoperistaltic SSSA group; $P = 0.372$). Anastomosis time was defined as the period soon after intestinal resection to completion of the anastomosis. There was no

Table 1 – Preoperative demographic and clinical characteristics of the included patients.

Variables	Antiperistaltic SSSA ($n = 20$)	Isoperistaltic SSSA ($n = 20$)	P value
Age	68 ± 10	66 ± 12	0.791
Gender (male/female)	11/9	11/9	0.751
Body mass index (kg/m^2)	23.3 ± 3.5	22.6 ± 2.8	0.973
Tumor location			0.993
Cecum	3	2	
Ascending	9	10	
Transverse	4	3	
Descending	2	3	
Sigmoid	2	2	
Concomitant medical problems (yes/no)	16/4	13/7	0.479
ASA score			0.801
1	2	6	
2	18	13	
3	0	1	
4	0	0	
5	0	0	
Preoperative			
White blood cells (counts/mm^3)	5735 ± 1671	4956 ± 1731	0.111
Hemoglobin (g/dL)	12.6 ± 1.7	12.9 ± 2.0	0.681
C-reactive protein (mg/dL)	0.1 ± 1.3	0.2 ± 1.1	0.730
Total protein (g/dL)	7.0 ± 0.4	6.7 ± 0.5	0.213
Albumin (g/dL)	4.1 ± 0.5	3.9 ± 0.4	0.692

SSSA = stapled side-to-side anastomosis; ASA = American Society of Anesthesiologists.
Values are expressed as median ± standard deviation.

Table 2 – Surgical variables and predefined outcomes of the included patients.

Variables	Antiperistaltic SSSA ($n = 20$)	Isoperistaltic SSSA ($n = 20$)	P value
Operation time (min)	203 ± 53	215 ± 68	0.286
Blood loss (mL)	45 ± 46	80 ± 257	0.154
Transfusion (yes/no)	0/20	1/19	1.000
Anastomosis time (s)	870 ± 240	920 ± 248	0.372
Surgical approach (laparoscopic/open)	20/0	18/2	0.487
Anastomosis type			0.740
Ileocolic	12	14	
Colocolic	8	6	
Pathologic stage (AJCC)			0.671
0	2	6	
I	2	3	
IIA/IIB/IIC	7/0/0	4/0/0	
IIIA/IIIB/IIIC	0/5/4	0/5/2	
IV	0	0	
First defecation after surgery days	3.5 ± 1.6	2.7 ± 2.0	0.428
Surgical complications			
Wound infection	1	1	1.000
Prolonged ileus	1	2	1.000
Intra-abdominal abscess	1	2	1.000
Anastomotic leakage	0	2	0.487
Anastomotic stenosis	1	0	1.000
Other	1	1	1.000
Reoperation	0	3	0.231
Postoperative hospital stay	10 ± 8	12 ± 12	0.313

AJCC = American Joint Committee on Cancer; SSSA = stapled side-to-side anastomosis.
Values are expressed as median ± standard deviation.

significant difference in the ratio between ileocolic and colocolic anastomosis in the two groups (12 : 8 in the antiperistaltic SSSA group *versus* 14 : 6 in the isoperistaltic SSSA group; $P = 0.740$). With respect to the primary outcome, although the difference was not statistically significant, anastomotic leakages were seen only in the isoperistaltic SSSA group (two in the isoperistaltic SSSA group *versus* 0 in the antiperistaltic SSSA group; $P = 0.487$). One patient in the antiperistaltic SSSA group had anastomotic stenosis, which improved conservatively, compared with none in the isoperistaltic SSSA group ($P = 1.000$). No anastomotic hemorrhage was seen in either group. Reoperations was performed only in three patients in the isoperistaltic SSSA group compared with none in the antiperistaltic SSSA group ($P = 0.231$), which comprised two with intra-abdominal abscess due to anastomotic leakage, and one with prolonged ileus. There was no significant difference in the length of postoperative hospital stay (10 ± 8 d in the antiperistaltic SSSA group *versus* 12 ± 12 d in the isoperistaltic SSSA group; $P = 0.313$).

4. Discussion

The factors for ideal intestinal anastomosis after colonic resections are physiological, convenience, less dependence on surgical skill, and fewer complications. We would have to say that no anastomotic method theoretically satisfies all these factors. Although hand-sewn end-to-end anastomosis was a standard procedure after intestinal resection for reestablishing bowel continuity, mechanical anastomosis was rapidly replaced after the introduction of stapling devices [7]. Among the mechanical anastomotic techniques, antiperistaltic SSSA using linear stapling devices, first reported by Steichen [1], has spread worldwide owing to its convenience, stability, independence of bowel diameter discrepancy, and large anastomotic caliber. The superiority of antiperistaltic SSSA in terms of anastomotic failures compared with hand-sewn anastomosis has been reported in several clinical studies [7–12]. It should also be noted that, despite the technique used (hand-sewn or stapled), anastomotic configuration could affect the incidence of anastomotic failures, especially for leakage. Side-to-side anastomosis is proposed to have better blood flow and wider diameter, thus reducing intraluminal pressure and proximal ischemia than that of end-to-end anastomosis [8,13]. However, antiperistaltic SSSA requires sufficient mobilization of the intestine before anastomosis to make oral- and anal-sided intestines overlap. If antiperistaltic SSSA was performed with insufficient intestinal mobilization, increased tension of the anastomotic site could lead to leakage. Additional mobilization of the intestine for safe antiperistaltic SSSA

could prolong the operating time and increase the risks of more hemorrhage and other organ injury. Several case reports have demonstrated that the anastomotic site of antiperistaltic SSSA does not occasionally become straight shaped and the diverticulum resembling anastomosis could be a cause of fecal accumulation-induced ileus [14,15].

Isoperistaltic SSSA applied for ileocolic anastomosis was first reported in 2005 by Tewari *et al.* [6], which anastomoses oral- and anal-sided intestines side-to-sideways in the opposite direction using linear stapling devices. Then, Kawahara *et al.* [5,16] called this anastomosis "sliding functional end-to-end anastomosis" and applied this technique modified from antiperistaltic SSSA for patients undergoing high-anterior resection to abrogate the need for transanal anastomosis using circular stapling devices, which have the potential for local recurrence by implantation of exfoliated cancer cells to the anastomotic site. Tewari *et al.* [6] closed the anal-sided-stapler entry hole with silk 2/0 interrupted sutures. In contrast, Kawahara *et al.* [5,16] used a linear stapler to close the oral-sided-entry hole without any concern for stenosis of the oral-sided-intestine because they applied this technique only to colocolic anastomosis. In the present study, we did not limit enrollment by colonic tumor location, which involved both ileocolic and colocolic anastomosis; therefore, we unified the procedure in which the oral-sided entry hole was closed with a 1-layer running suture. If the oral-sided entry hole was closed with a stapling device, stenosis of the oral-sided ileum would be a major concern in cases of ileocolic anastomosis.

Based on recent developments of surgical devices and a lot of preferable evidence, laparoscopic surgery for colon cancer has become a common practice worldwide [3,4]. However, several technical difficulties of laparoscopic surgery compared with open surgery are still not completely resolved. To resect and anastomose, mobilized intestine should be elevated and drawn from the small wound extracorporeally. This procedure limits the mobility of the intestine, which can sometimes make it difficult to perform antiperistaltic SSSA. Therefore, we investigated whether isoperistaltic SSSA, which requires less intestinal mobility from the configuration than antiperistaltic SSSA, could be a good alternative for patients with insufficient intestinal mobilization undergoing colon cancer surgery. We showed a schematic representation regarding the significant advantage of isoperistaltic SSSA in terms of required intestinal mobility (Fig. 2). If 60-mm linear stapling devices are used for anastomosis, isoperistaltic SSSA can shorten the intestinal mobilization for 6 cm compared with antiperistaltic SSSA, theoretically.

The present study demonstrated that although the difference was not statistically significant, anastomotic leakage occurred only in the isoperistaltic SSSA group. The incidence (2/20; 10%) of leakage was higher than those reported incidences of antiperistaltic SSSA in the literature (2%–9%) [8,9,11,12,17]. Intraoperative findings demonstrated that rupture of the hand-sewn stapler entry hole was the site of the anastomotic leakage in both cases in the isoperistaltic SSSA group (Fig. 3). Marked macroscopic and microscopic ischemic or necrotic changes in the hand-sewn sites were not observed. The reason why the hand-sewn entry hole was ruptured is unclear. Our hand-sewn anastomoses could not be denied as technically inadequate. Other plausible reasons are as follows: (1) increased local septic contamination with hand-sewn method [9]; (2) local inflammation induced by manipulation during hand-sewing [11,18]; and (3) imbalance of withstanding pressure between the different maneuvers, stapled and hand-sewn.

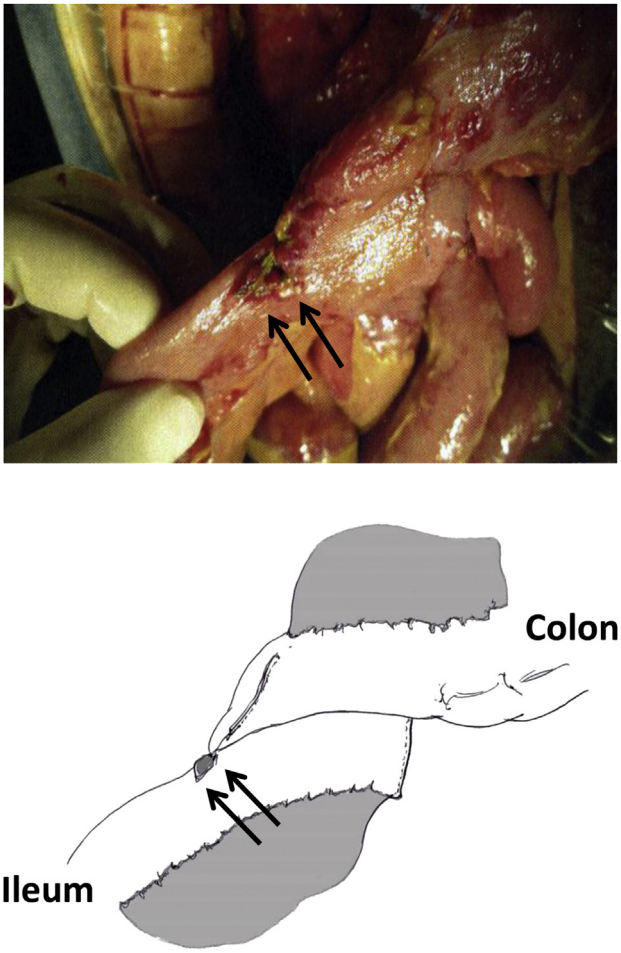

Fig. 3 – Intraoperative findings of the case with anastomotic leakage. Rupture at the hand-sewn stapler entry hole was detected (arrows) without obvious necrosis and ischemic change. (Color version of the figure is available online.)

This study had several limitations that must be taken into account. Even though the present study was a randomized trial, only 40 samples were finally included because of the suspension of enrollment with unexpected high morbidity in the isoperistaltic SSSA group. This number is statistically underpowered to draw a conclusion based on our sample size calculation. Although it is not statistically significant, the isoperistaltic SSSA group had slightly worse nutritional status, longer operation time, and more blood loss than the antiperistaltic SSSA group (Tables 1 and 2). These unfavorable differences of background and surgical variables in the isoperistaltic SSSA group could affect the incidence of anastomotic leakages. Different types of anastomosis (ileocolic and colocolic) were included, and the mixture could have been a confounding factor. Furthermore, the different number of additional hand sutures applied for reinforcement of anastomosis between the groups also could have influenced. The

length of postoperative hospital stay in this study is comparatively longer than reports from the United States [19]. A recent multicenter randomized controlled trial in Japan also reported that the median length of postoperative hospital stay after colectomy is 10–11 d [20]. Social factors, such as medical fees and medical insurance between Japan and the United States, are quite different. In Japan, public health insurance covers 70%–90% of the total medical costs. The length of hospital stay could be affected by these factors.

5. Conclusions

In conclusion, this study did not show any advantage or disadvantage of isoperistaltic SSSA compared with antiperistaltic SSSA in short-term outcomes. However, considering that anastomotic leakage occurred only in the isoperistaltic SSSA group, additional modifications, such as applying not a single but two-layer suture to close the entry hole for the linear stapler, are recommended to perform safe isoperistaltic SSSA for colon surgery.

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Authors' contributions: A.M. and S.M. contributed to the study conception and design. A.M., N.S., G.T., and M.Y. performed the data collection. A.M., M.M., and S.M. did the analysis and interpretation of data. A.M. wrote the article. M.M. and E.U. supervised this study.

Conflict of interest and grant support: none.

Disclosure

The authors report no proprietary or commercial interest in any product mentioned or concept discussed in the article.

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