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Original Article

Primary laparoscopic fundoplication in selected patients with gastroesophageal reflux disease

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SUMMARY. ***Background:*** **Despite proton pump inhibitors being a powerful therapeutic tool, laparoscopic fundoplication (LF) has proven successful in the treatment of gastroesophageal reflux disease (GERD), through mechanical augmentation of a weak antireflux barrier and the advantages of minimally invasive access. A critical patient selection for LF, based on thorough preoperative assessment, is important for the management of GERD-patients. The purpose of this study is to provide an overview on the management of GERD-patients treated by primary LF in a specialized center and to illustrate the possible outcome after several years.** ***Methods:*** **Patients were selected after going through diagnostic workup consisting of patient's history and physical examination, upper gastrointestinal endoscopy, assessment of gastrointestinal Quality of Life Index, screening for somatoform disorders, functional assessment by esophageal manometry, (impedance)-24-hour-pH-monitoring, and selective radiographic studies. The indication for LF was based on EAES-guidelines. Either a floppy and short Nissen fundoplication was performed or a posterior Toupet-hemifundoplication was chosen. A long-term follow-up assessment was attempted after surgery.** ***Results:*** **In total, *n* = 1131 patients were evaluated (603 males; 528 females; mean age; 48.3 years; and mean body mass index: 27). The mean duration between onset of symptoms and surgery was 8 years. Nissen: *n* = 873, Toupet: *n* = 258; conversion rateerativ: 0.5%; morbidity 4%, mortality: 1 (1131). Mean follow-up (*n* = 898; 79%): 5.6 years; pre/post-op results: esophagitis: 66%/12.1%; Gastrointestinal Quality of Life Index: median: 92/119; daily proton pump inhibitors-intake after surgery: 8%; and operative revisions 4.3%.** ***Conclusions:*** **In conclusion, our data show that careful patient selection for laparoscopic fundoplication and well-established technical concepts of mechanical sphincter augmentation can provide satisfying results in the majority of patients with severe GERD.**

KEY WORDS: **Gastroesophageal reflux disease, GERD, laparoscopic antireflux surgery, laparoscopic fundoplication, Nissen fundoplication, Toupet fundoplication.**

INTRODUCTION

Laparoscopic fundoplication (LF) was first performed by Dallemagne in 1991.[1] Competing with proton pump inhibitors (PPI), presenting a powerful therapeutic tool in the treatment of gastroesophageal reflux disease (GERD), LF was very successful based on the mechanical augmentation of a weak antireflux barrier at the esophago-gastric junction (EGJ) and the advantages of minimally invasive access.[2,3] Many trials and meta-analyses have been performed to evaluate the effectivity of the procedure regarding the treatment of GERD as well as the variety of technical modifications of LF.[3–9] Over the years, several alternative techniques have emerged challenging the role of LF as the standard surgical treatment of GERD, such as endoscopic procedures or dedicated devices.[10–14] The ongoing quest for alternatives to LF reflect the fact that LF cannot always be performed with satisfying results.[10–18] Reasons for a limited success may be found in an insufficient patient selection or poor technical execution. Thirty years ago, antireflux surgery was mainly performed by nonspecialized surgeons.[19,20] High volume centers developed only gradually, mainly to patient's preference, and provided a qualitatively improved outcome.[3–5,8] In this study, we used established principles of fundoplication as published earlier.[2,3,7,8] An important factor for the management of GERD-patients was careful patient

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selection for LF, based on a thorough preoperative assessment.[2,5,15,21,22]

The purpose of this study is to provide an overview on the management of a large cohort of GERD-patients treated by primary LF in a specialized center and to illustrate their outcome after several years.

MATERIAL AND METHODS

The study was performed at the AGAPLESION Markus-Krankenhaus in Frankfurt, Germany between 2004 and 2017. The diagnostic and therapeutic concept for the management of GERD had been established earlier.[2,3,22] Patients were selected for primary LF after undergoing diagnostic workup consisting of acerting patient history and physical examination, upper gastrointestinal endoscopy, assessment of quality of life by the Gastrointestinal Quality of Life Index (GIQLI), screening for somatoform disorders, functional assessment by esophageal manometry, (impedance)-24-hour-pH-monitoring and selective radiographic studies such as Barium-sandwich for esophageal passage and gastric emptying evaluation.[22–27] It must be emphasized that a substantial amount of work was invested in evaluation of the patient's functional defects and in sharing this information with the patients to help them understand their chronic disease, the available therapeutic options and their perspective. Patients with GERD, who obtained conservative or endoscopic therapy as well as patients with other esophageal and gastric benign disorders were excluded.

The study was approved by the hospital institutional review board. All patients gave informed consent for study evaluation and diagnostic work-up, and investigations followed a defined study protocol. All procedures were performed in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions.

The patient's symptoms indicative of GERD such as heartburn, regurgitation, epigastric burning/pain, and belching were evaluated with a standardized questionnaire.[27] Quality of life was assessed by GIQL-Index using 36 items with five dimensions (gastrointestinal symptoms, emotional dimension, physical dimension, social dimension, and therapeutic influence).[23] In addition, a screening test for somatoform disorders was applied using a Somatoform Symptom Index (SSI).[26]

All patients underwent upper-gastrointestinal-endoscopy to assess esophagitis. Barrett's esophagus was evaluated endoscopically and histologically. Hiatal hernia size was evaluated endoscopically by measuring vertical length from the top of the gastric folds to the waist of the crura during inspiration at the beginning of endoscopy, thus preventing excessive air insufflation to avoid incorrect measurements. Patients underwent functional evaluation using validated assessment methods.[2,3,22,25] The criteria for an impaired esophageal motility (IEM) were based on earlier studies, defining IEM as presenting $<70\%$ intact peristalsis at the swallowing tests during esophageal manometry.[22,23] Pathologic esophageal acid exposure (EAE; DeMeester pH-score >14.7) was evaluated by 24-hour-pH-monitoring, after pausing all medications affecting motility and acid suppression 7 days prior to the examination.

The indication for antireflux surgery was based on the EAES-guidelines.[15] Patients with troublesome symptoms of GERD, reduced quality of life, functional defects and/or esophageal mucosal damage and/or presence of complications were selected. The technique of LF was based on principles of lower esophageal sphincter (LES) augmentation.[2,3,28,29] The dissection of the hiatus and EGJ, as well as sufficient mobilization of the posterior part of the gastric fundus and the esophagus, were important for anatomical EGJ-reconstruction and presented a prerequisite for an effective functional result. A length of at least 2–3 cm of tension-free LES was positioned within the abdominal pressure-environment below the diaphragm. A sufficient narrowing of hiatal crurae around the LES was achieved without causing esophageal stenosis or kinking. When necessary, a combined posterior and anterior suture-hiatoplasty with non-absorbable 0-size-suture material was performed. Mesh was only used in case of rigid tissue preventing sufficient narrowing of the hiatus. A floppy and short fundoplication was performed as a standard technique applying the Nissen fundoplication in the DeMeester-Sandwich-technique, using pledgets with one U-stitch and a fundoplication-length of 1–2 cm.[2] In the case of IEM, or severe preoperative dysphagia, a partial posterior Toupet-hemifundoplication was performed. The patients underwent general anesthesia and were positioned in anti-Trendelenburg-position. After mobilization, the focus lay on creating a floppy and symmetric fundoplication around a 54 French bougie to allow for sufficient postoperative fundic accommodation. No drains or nasogastric tubes remained in situ after the procedure. All operations were performed by three senior surgeons (KHF, WB, and GV).

Postoperative patient management consisted of parenteral fluid administration for 2–3 days depending on the recovery of gastrointestinal function. Limited oral fluid-intake was permitted from the first evening after the procedure onwards, and providing good tolerance, was increased on postop day1, followed on postop Day 2 by semisolid food. Usually, pain medication was applied only during the first 3 postop days.

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Table 1 Characteristics of GERD-patients prior to primary antireflux surgery

$n = 1131$	Results	
Presence of chief/overall complaints: (%)	Chief:	Overall:
Heartburn	60	90
Regurgitation	17	55
Pain (thoracic and epigastric)	11	73
Dysphagia	3	31
Respiratory symptoms (cough and hoarseness)	1	25
Nausea and vomiting	5	39
Gas-related (belch, bloating, and flatulence)	3	73
Quality of life assessment ($n = 1047$)	Mean 91.7	Range (59–129)
GIQLI: normal (>117; max 144)	Median 92	
Screening with Somatoform Symptom Index	13	Range (0–34)
(SSI): normal < 17	174 (874)	20.4%
Number of patients with SSI > 17		
Esophagitis	*n*	%
Grade 0/no esophagitis	385	34
Grade 1/LA A	294	26
Grade 2/LA B	305	27
Grade 3/LA C	68	6
Grade 4/LA D	79	7
(Barrett's esophagus)	(109)	(9.6)
Hiatal Hernia size; $n = 1131$	*n*	%
0–1 cm	226	20
2–5 cm	837	74
>5 cm	68	6
Delayed gastric emptying	35 positive:	7.9%
($n = 441$ nausea and/or vomiting)	18 mild; 17 marginal	
57 chief-complaint tested		
Esophageal acid exposure (EAE)	Mean 45.8	
pathologic DeMeester score > 14.7	807 (1056)	76.4%

Prior to surgery, all patients were informed about possible dysphagia with regular food within the first days up to a few weeks after LF. Patients were encouraged to adapt their eating habits for 4–6 weeks, with a focus on consuming smaller, more frequent portions rather than risking overly extensive gastric fillings through large meals. Patients were also encouraged to eat in an upright position, extending abdomen and chest, and remain in this upright position for at least 1-hour postprandially, preferably even longer to prevent exceeding pressure on the wrap and the EGJ, thus avoiding early migration of the fundoplication.

Follow-up investigations were recommended to the patients 1-year postoperatively, unless the patient experienced severe problems with nutrition and/or pain meanwhile. Further follow-ups were recommended after 3 and 5 years. Some patients came in for more detailed follow-up investigations. For the purpose of this study, all patients received a letter with standardized questions regarding their symptoms, GIQLI, documentations of investigations during the follow-up time. If there was no response, a telephone interview was attempted. If more than one follow-up dataset was acquired, the data from the longest follow-up were used.

All available data were entered into a prospectively maintained database. For statistical comparisons either an unpaired *t*-test was performed or for group-comparison a Fisher-exact test was applied.

RESULTS

The characteristics of all patients with primary LF are summarized in Table 1. The mean age of these 1131 patients (603 males; 528 females) was 48.3 years (range 18–93). The mean duration between onset of symptoms and surgery was 8 years. The mean BMI of these GERD-patients was 27.[21–33] Table 1 shows that the majority of patients suffered from heartburn and regurgitation as chief-complaints, whereas other symptoms such as thoracic and epigastric pain as well as gas-related symptoms such as belching, bloating, and flatulence were additionally present in up to 73% of patients, but in a lesser severity. Fifty-seven patients suffered from nausea/vomiting as chief-complaints and were tested with gastric emptying studies, out of which 35 patients (3%) were tested positive for delayed gastric emptying (DGE). Preoperative quality of life showed a GIQLI of 92 (59–129) and 20.4% out of the evaluated GERD-patients presented with an abnormal SSI (screening for somatoform disorder: SSI normal < 17). Almost 90% of patients had an incompetent LES, 15.9% had an IEM and 66%

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Table 2 Intraoperative data during primary antireflux surgery

Procedure: technical details	*n*	%
Nissen fundoplication	871	77
Collis–Nissen	2	0.2
Partial fundoplication	258	22.8
Total	1131	
18 additional EPPD for mild DGE		
Laparoscopic access	1128	99.7
Primary open access (prev. surgery)	3	
Conversions	6	0.5
	2 Spleen bleedings	
	4 Massive adhesions	
Intraoperative change to resection	0	
Intraoperative perforation	1	
Intraoperative spleen injury	12	1.0
Intraoperative vagal injury	2	
Postoperative proven gastroparesis	1	
Morbidity	45	4%
Necessary revisional surgery within 4 weeks postoperatively:	6	0.5
Trocar site bleeding	1	
Abscess	3	
Early intrathoracic herniation	2	

had esophagitis. The majority of these patients (76%) suffered from a pathologic EAE.

Table 2 demonstrates the intraoperative data of primary LF. Two patients required an esophageal lengthening by laparoscopic Collis-Nissen fundoplication, while 77% of patients underwent the standard Nissen-fundoplication and 23% underwent a partial fundoplication. Eighteen patients received an additional endoscopic pyloric dilation (EPPD), because of demonstrating DGE in radiographic gastric emptying studies. Six conversions (0.5%) were necessary because of intraoperative complications (spleen hemorrhage and massive adhesions). In addition, another 10 bleedings from splenic lesions could be stopped laparoscopically. Within 4 weeks after primary surgery, 6 (0.5%) revisions were necessary. Unfortunately, 1 patient passed away 6 weeks postoperatively due to persistent pneumonia.

After a mean follow-up of 5.6 years (1–12 years), we received information from 898 patients (79%; Table 3). Four patients died of other causes in the follow-up time, 36 patients had received redo-surgery in our department, while we know of another three revisions elsewhere (4.3%). In total, 793 patients (89%) reported significant improvement in their preoperative reflux-symptoms 5 years after LF. Their GIQLI had a median of 119 (78–142), which represents a significant enhancement in their quality of life compared with the preoperative situation in 88% of patients ($P < 0.0001$). Many patients complained about non-reflux symptoms such as backpain, whereas 60% were completely free of symptoms. The median SSI was 8 (0–34) with 98 out of 534 patients with a SSI above 17 (18.4%). Figure 1 shows the relationship between SSI and GIQLI indicating the substantial influence of somatoform symptoms on GIQLI. Table 3 provides an overview of the relationship between the patient's GIQLI and their common chief-complaints as well as incidence, supporting a major role of non-reflux symptoms in patient's quality of life.

Endoscopy showed a substantial reduction in the presence of esophagitis of the 470 patients, who underwent endoscopy (52.3%). Table 3 shows absence of esophagitis in 88% of the investigated patients with only 1.5% of patients presenting severe esophagitis. In 78% of patients, hiatal hernia recurrence could be ruled out endoscopically. Out of 202 patients, who underwent functional testing, LES-competence could be demonstrated in 80% of measured individuals ($P < 0.001$). IEM could be reduced to 12% after fundoplication (preoperative value 16%; $P < 0.0426$). In 23 out of 202 investigated patients (11%), a pathologic EAE (mean DeMeester score: 9.9) could be detected. Patients with DGE and combined EPPD showed satisfying results in that only one patient needed later on a second EPPD. Patients with preoperative marginal DGE, who received a LF without EPPD, also developed a good postoperative quality of life with one exception, since the latter patient developed a severe emptying problem with subsequent necessity to have a distal gastrectomy.

In sub-analyses, we determined preoperative parameters for possible prediction for an unfavorable outcome (abnormal low GIQLI < 105). As mentioned, the presence of a somatoform tendency (SSI > 17) is a strong predictor for a limited postoperative improvement in GIQLI (Fig. 1). Furthermore, patients with preoperative esophagitis grade 0–1 or LA A have shown in the follow-up assessment a significantly lower GIQLI (mean 112 vs. 117; $P < 0.025$) compared with patients with more severe esophagitis

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Table 3 Results of patient's follow-up (5,6 years) assessment after antireflux surgery

Investigated items ($n = 898$) 79.4%	Results	Results
Chief-complaints/GIQLI	Chief%/GIQLI	Presence%
Heartburn	5/109	12
Pain (thoracic/epigastric)	6/93	20
Dysphagia	4/105	6
Respiratory symptoms	6/98	7
Nausea/vomiting	2/96	3
Gas-related symptoms	5/97	14
Fatigue	3/104	6
Backpain + Joint-pain	10/110	23
Gastrointestinal Quality of Life Index	Mean 115.2	
(GIQLI): (normal: >117)	Median 119 (78–132)	
Esophagitis:470 (898); 52.3%	413 (22)	%
Grade 0/no esophagitis	39 (9)	88
Grade 1/LA A	11 (4)	8.3
Grade 2/LA B	3 (2)	2.3
Grade 3/LA C	4 (4)	0.6
Grade 4/LA D	(41)	0.9
(Barrett's esophagus)		(8.7%)
Hiatal hernia size:		
0–1 cm	0 = 366; 1 = 56	89.8%
2–5 cm	43	9.1%
>5 cm	5	1.1%

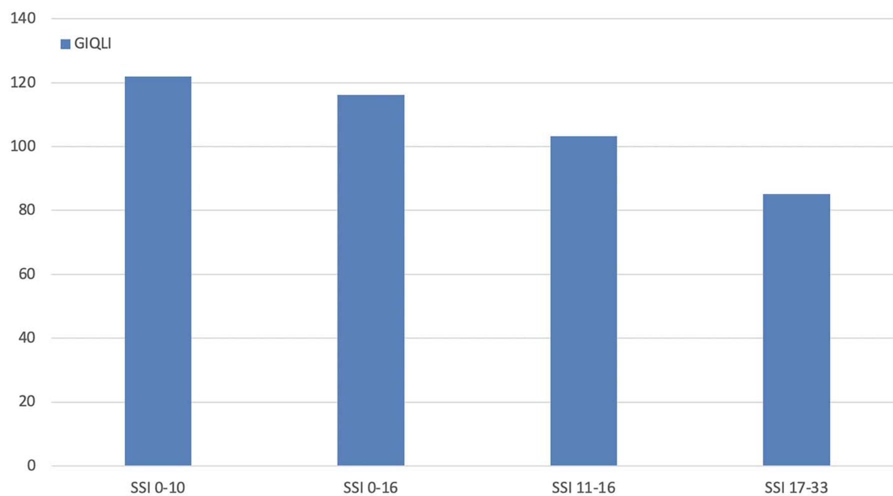

Fig. 1. The relationship between GIQLI and somatoform symptom Index SSI is demonstrated indicating the more somatoform symptoms a patient suffers from, the lower the level of quality of life on follow-up investigations.

and Barrett's esophagus. In contrast, follow-up level of GIQLI is independent form preoperative hiatal hernia size (GIQLI:118–126). The shape of the wrap, full or partial fundoplication showed no difference in the follow-up in GIQLI (120 vs. 117, $P = 0.3$), however there was a difference in EAE after 5 years (mean DeMeester score 9.1 vs. 13.5; $P = 0.0315$).

In 17% of the responding patients, occasional PPI-intake was reported, while 8% of patients required a daily PPI-intake. Long-term GIQLI was lower in the group of patients with regular PPI-intake (mean GIQLI:95), compared with occasional intake (Mean GIQLI:100.4; $P < 0.01$) and no PPI-intake (120; $P < 0.0001$).

In summary, primary LF proved highly successful, providing careful patient selection, since significant reduction in symptoms and esophagitis, in addition to a significant increase in GIQLI and improvement of EGJ functional status could be demonstrated in this study.

DISCUSSION

Although details of the fundoplication-technique have undergone a fine-tuning of the original 'Nissen' over the years, the fundamental principles of action have nevertheless remained consistent.[2,3,5] A 360-degree-fundoplication around the LES can be the most effective 'reflux-stopper', however the technical concept applied can lead to unpleasant side-effects such as dysphagia, bloating and other dysfunction of the GI-tract, which can limit the outcome.[2–9] As a consequence, modifications of the 'Nissen' were

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launched by reducing the mechanical augmentation and creating partial fundoplications.[4–9] The progress of minimally invasive techniques and alongside the application of physiologic understanding to improved details of the procedure such as shaping the wrap, allowed for better functional outcome in esophageal centers.[2–5,28–31] Furthermore, the fundoplication-concept is challenged by new ideas such as endoscopic interventional techniques with even less access trauma and potentially less postoperative side-effects.[10–12] Recently, new operative concepts like the magnetic-device or neurostimulation have emerged.[13,14]

GERD is a chronic disease with a multifactorial pathophysiologic background.[32] It is a common impression that this complex disease cannot exclusively be managed by a single therapeutic procedure. Most likely, a differentiated therapeutic management based on comprehensive diagnostic information about anatomical, mechanical-functional, psychological, and clinical data, is needed.[15,21–27,29,32] This study provides an overview on a large cohort of patients with GERD, selected for LF, responding well to this differentiated approach.

A very important aspect is the optimal selection of patients in order to minimize the number of individuals, not suitable for antireflux surgery in the first place.[5,15,25–29,32–35] We, as well as others, have experienced that symptoms are not the most reliable guide in selecting patients for surgery.[27,33,34] Our approach was to apply objective testing prior to surgery.[15,25] In our cohort, the vast majority of patients had typical reflux-symptoms alongside a lengthy history of GERD and PPI-therapy (100%), and the majority presented with esophagitis despite PPI-therapy, LES-incompetence, hiatal hernia, and/or pathologic EAE. We have previously demonstrated that patients with a combination of GERD and somatoform disorders should be identified, since their potential of good to excellent outcome is limited, although they can still benefit from LF.[26,34] Furthermore, it seems important to verify preoperatively a possible DGE, since postoperatively our DGE-rate was as low as 3%. This kind of patient selection eliminates flaws that have been reported with a frequency of 2–4% in other series.[35,36]

Since our team was experienced with LF, our conversion rate could be limited to 0.5%.[22,29] Furthermore, the complication rate in the primary operation requiring revisional surgery was 0.5% and postoperative morbidity was 4%. Similar good results were reported from other experienced esophageal centers with morbidity and complication rate of only 0.5–4%.[5,28,30,31] In multicenter series and overviews these problems are usually reported in a higher frequency of 5–15%.[19,35,37,38] This underlines the importance of specialization and emphasizes the advantage for patients managed in an esophageal center.

The most important factor in LF-failure is migration causing anatomical alteration and subsequent functional failure.[35] After a follow-up of 5,6 years, our series shows a large variety of chief-complaints among 40% of the observed patients, while 60% have no symptoms. Only a small fraction of these patients have shown reflux-recurrence, since 12% show evidence of esophageal mucosal damage and 11.4% demonstrate objectively measured pathologic reflux. In literature, the hiatal hernia recurrence is frequently described as a recurrence of the disease, however a minor sliding of the wrap into the hiatal opening after the destruction of the phreno-esophageal ligaments is not synonymous with failure of the procedure.[28,31,39] Shaping the fundoplication is a very important element of a successful procedure, since creating a real short, floppy and symmetric full or partial fundoplication has influence on the functional result.[2,8,16,28,35]

Quality-of-Life as a measure of patient satisfaction with the postoperative result, could be reported at normal levels.[5,28–31] Symptom-analysis within this study demonstrates the large variety of complaints that can occur and may not be directly linked to reflux recurrence.[40] The substantial influence of somatoform symptoms on GIQLI was affirmed yet again.[26,34] It is noteworthy that the portion of patients with Barrett's esophagus remained constant between the preoperative (8.7%) and the follow-up assessment (9.3%) 5 years later. Furthermore, the relationship between preoperative grade of esophagitis and follow-up GIQLI indicates that patients with severe GERD and esophagitis have a higher chance of benefiting from an operation. Patients with none or minor esophagitis may not develop a similar GIQLI-improvement, which indicates that additional factors may be involved not related to surgical augmentation.

New operative techniques such as the LINX™ magnetic device have emerged, initially intended for less severe GERD with minor anatomical changes.[13] Meanwhile, growing experience indicates that they may present an alternative to LF, but for verification long-term studies have yet to be performed.[13]

In conclusion, our data show that careful patient selection for LF and a well-established technical concept of mechanical LES-augmentation can provide satisfying results in the majority of patients with severe GERD. Symptomatic burden, reduction in quality of life and anatomical and functional defects can be corrected and will be maintained over > 5 years in most of the patients.

AUTHORS' CONTRIBUTIONS

KHF, WB, and GV provided substantial contributions to the study concept and design. KHF, WB, GV, BB, and TS contributed substantially to the acquisition of data over the years. KHF and AM made substantial contributions to the analysis and interpretation of the data. All authors made substantial contributions to the drafting of the manuscript and

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revising of the manuscript and the final approval of the manuscript to be published. All authors agree to be accountable for all aspects of the work and ensure its accuracy and its integrity.

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CONFLICTS OF INTEREST

All authors declare that they do not have any conflicts of interest.

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