

Preoperative and postoperative evaluation of patients undergone appendectomies either in spinal or general anesthesia

Spinal anesthesia for appendectomy during COVID-19

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Abstract

Aim: The Coronavirus 2019 (COVID-19) pandemic has changed healthcare practices, leading to heightened protective measures and conservative management strategies. In acute appendicitis (AA) cases, conservative surgical and anesthetic approaches, such as spinal anesthesia, were increasingly adopted. However, studies focusing specifically on conventional appendectomy during the pandemic remain limited.

Material and Methods: 126 patients underwent open appendectomy in a single center retrospectively analyzed. Patients are categorized based on COVID status and anesthesia administrations. Cox regression tests were utilized for analyzing factors affecting longer hospitalization.

Results: Major complications (9.8% vs. 25.0%, $p=0.044$) and ileus development (0.0% vs. 4.1%, $p=0.038$), CRP levels (23.64 ± 23.54 vs. 64.42 ± 69.41 ; $p<0.001$), time to initiate oral feeding (1.24 ± 0.91 vs. 1.54 ± 1.74 ; $p=0.018$), length of hospital stay (1.74 ± 1.30 vs. 2.17 ± 3.48 ; $p=0.021$), and surgical durations (35.39 ± 6.74 vs. 37.08 ± 12.93 ; $p=0.016$) were frequent in COVID-19 positive patients. CRP levels (39.98 ± 54.20 vs. 26.13 ± 26.80 ; $p=0.003$), time to initiate oral feeding (1.50 ± 1.60 vs. 1.17 ± 0.65 ; $p=0.002$) and length of hospital stay (2.00 ± 2.87 vs. 1.71 ± 0.93 ; $p=0.002$) were more frequent in general anesthesia. General anesthesia (OR: 32.337; $p<0.001$), advanced age (OR: 1.089; $p<0.001$), perforation (OR: 15.906; $p=0.005$), and the development of major complications (OR: 33.056; $p=0.005$) were independent risk factors for prolonged hospital stay in multivariate analysis.

Discussion: Open Appendectomy under spinal anesthesia was found to be a safe option in patients with AA which also protects both patients and healthcare professionals and lowers hospitalization stays.

Keywords

COVID-19, Acute Appendicitis, Appendectomy, Anesthesia

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This study was approved by the Ethics Committee of Zonguldak Bülent Ecevit University, Faculty of Medicine (Date: 2024-12-19, No: 2024/22/10)

Introduction

The Coronavirus Disease 2019 (COVID-19) pandemic, since its onset in 2020, has caused significant changes in the behaviors and attitudes of both patients and healthcare professionals. During the pandemic, many outpatient services were temporarily suspended to reduce contact and limit the number of visits, while protective measures were heightened. Patients, on the other hand, developed an instinct to avoid seeking hospital care unless their symptoms were unbearable [1-3].

In cases of acute appendicitis (AA), which represents the highest emergency surgical workload in general surgery, more conservative approaches were adopted by both surgical and anesthesia teams [4, 5]. Surgical teams prioritized conservative management strategies, such as close monitoring and antibiotic therapy, while anesthesia teams increasingly preferred sedation or spinal anesthesia instead of general anesthesia [6-8].

During the pandemic, numerous studies were published on appendicitis cases in which these approaches were adopted. While these studies have evaluated laparoscopic appendectomy, literature focusing on conventional appendectomy remains limited. This study aims to determine the impact of anesthesia method selection on perioperative and postoperative outcomes in acute appendicitis cases treated at a public hospital designated as a “pandemic hospital” during the pandemic period.

Material and Methods

Study Design

The study was designed based on patients who presented with acute appendicitis and underwent conventional appendectomy during the pandemic period between 2020 and 2021. Monocentric data collection began after obtaining ethical approval. Since this was a retrospective study, the requirement for informed consent was waived by the ethics committee.

Inclusion Criteria

The study included patients aged 18 years or older who underwent emergency surgery for AA using conventional methods. Only patients whose surgeries were completed via McBurney modified McBurney (Lanz or Langer incision), or Rockey-Davis incisions were included. Additionally, patients who were directly scheduled for surgery without clinical follow-up after admission were also included.

Exclusion Criteria

Patients initially managed with medical follow-up despite suspicion of AA and later operated on, those younger than 18 years, patients who underwent exploratory laparotomy or conversion to median laparotomy after the initial incision, and patients diagnosed with phlegmonous appendicitis who only had a drain placed with interval appendectomy planned were excluded from the study. Additionally, patients with incomplete data required for the study were also excluded.

Preoperative Variables

Appendectomy records were extracted from operating room logs throughout the pandemic. Preoperative data collected for these patients included COVID-19 antigen positivity, COVID-19 Reporting and Data System (CO-RADS) scores from computed tomography scans, C-reactive protein (CRP) levels, and oxygen saturation at the time of admission [9-11].

Additionally history of diabetes, were recorded. Preoperative anesthesia evaluations included American Society of Anesthesiology (ASA) scores and body mass index (BMI) values [12, 13].

Surgery Data

Anesthesia was administered using previously described techniques for both spinal and general anesthesia. During the COVID-19 pandemic, spinal anesthesia was preferred whenever possible. General anesthesia was performed in patients with failed spinal anesthesia, a history of lumbar surgery, or those using anticoagulants [14]. All surgeries were initiated using McBurney, modified McBurney (Lanz or Langer incision), or Rockey-Davis incisions. Depending on the patients’ adhesions and presentation, mesocolic or retrocolic dissection was performed to access the appendix base. The base of the appendix was ligated with double-layer silk sutures and subsequently resected. In patients with abscesses, the cavity was irrigated and aspirated. All patients received 2 grams of cefazolin 60 minutes before the surgical incision. Postoperatively, the peritoneal and muscular layers were closed with polyglactin 910 sutures, the fascial layer was repaired with polydioxanone sutures, and the skin was closed with sharp, non-absorbable monofilament sutures.

Oral feeding was initiated after the return of bowel gas passage in the postoperative period. Postoperative management included only analgesics, antiemetics, and fluid replacement. In patients with perforations and significantly elevated CRP levels, metronidazole therapy was started at a dose of 500 mg twice daily. For COVID-19-positive patients, additional treatments were administered according to the Ministry of Health’s suggested guidelines at the time [15].

Surgical duration, intraoperative bleeding or abscess presence, and perforated cases were extracted from the surgical records. Additionally, postoperative data, including ileus development, time to oral feeding, fistula formation, superficial incisional surgical site infections, intra-abdominal abscess formation, readmissions, length of hospital stay, and major morbidity were recorded. Major morbidities were defined as complications classified as grade 3 or higher according to the Clavien-Dindo classification [16].

Statistics

IBM® SPSS® (Statistical Package for the Social Sciences) version 27 (IBM Corp. Armonk, NY, USA) used for statistical analysis. The distribution of numerical data was performed using the Kolmogorov–Smirnov test with the normal distribution results. Qualitative data were presented as frequency and percentage. Continuous measurements were presented as mean and standard deviation (sd). The chi-square test is used for comparisons involving categorical variables. The relationship between continuous parameters with COVID status or anesthesia type was analyzed through the application of the independent t-test. For the analysis of factors influencing longer hospitalization; multivariate Cox regression tests were conducted. A significance level of 0.05 was considered for all tests.

Ethical Approval

This study was approved by the Ethics Committee of Zonguldak Bülent Ecevit University, Faculty of Medicine (Date: 2024-12-

19, No: 2024/22/10).

Results

The study was conducted by compiling data from patients who underwent emergency appendectomy at the Ministry of Health Besni State Hospital between March 2020 and June 2021. Two surgeons and one anesthesiologist were involved in the surgical

procedures in this single-center study. Data from a total of 126 surgical patients were collected.

When patients were evaluated based on their COVID-19 status, the majority of COVID-19-positive patients were classified as ASA 3E, while most COVID-19-negative patients were categorized as ASA 1E (p=0.022). In CO-RADS assessments, the frequencies of CO-RADS 4 and 5 were significantly higher

Table 1. Patient characteristics based on COVID-19 status

		COVID-19 - (n=102)	COVID-19 + (n=24)	p †
Gender	Female	40 (39.2%)	7 (29.1%)	0.360
	Male	62 (60.7%)	17 (70.8%)	
ASA Score	ASA1E	44 (43.1%)	8 (33.3%)	0.022*
	ASA2E	37 (36.2%)	5 (20.8%)	
	ASA3E	21 (20.5%)	10 (41.6%)	
	ASA4E	0 (0.0%)	1 (4.1%)	
BMI	Underweight	6 (5.8%)	2 (8.3%)	0.901
	Normal	60 (58.8%)	12 (50.0%)	
	Overweight	26 (25.4%)	7 (29.1%)	
	Obese	9 (8.8%)	3 (12.5%)	
DM	No	87 (85.2%)	21 (87.5%)	0.781
	Yes	15 (14.7%)	3 (12.5%)	
CO-RADS	CO-RADS 1	50 (49.0%)	3 (12.5%)	<0.001***
	CO-RADS 2	28 (27.4%)	6 (25.0%)	
	CO-RADS 3	18 (27.6%)	6 (25.0%)	
	CO-RADS 4	6 (5.8%)	8 (33.3%)	
	CO-RADS 5	0 (0.0%)	1 (4.1%)	
Admission SO2	<92	17 (16.6%)	9 (37.5%)	0.011*
	≥92	85 (83.3%)	15 (62.5%)	
Anesthesia	General	35 (34.3%)	13 (54.1%)	0.072
	Spinal	67 (65.6%)	11 (45.8%)	
Perforation	No	83 (81.3%)	19 (79.1%)	0.804
	Yes	19 (18.6%)	5 (20.8%)	
Bleeding	No	99 (97.0%)	23 (95.8%)	0.758
	Yes	3 (2.9%)	1 (4.1%)	
Abscess	No	94 (92.1%)	22 (91.6%)	0.936
	Yes	8 (7.8%)	2 (8.3%)	
Complications	Minor	92 (90.1%)	24 (75.0%)	0.044*
	Major	10 (9.8%)	6 (25.0%)	
Ileus	No	102 (100.0%)	23 (95.8%)	0.038*
	Yes	0 (0.0%)	1 (4.1%)	
Radix Fistula	No	98 (96.0%)	24 (100.0%)	0.324
	Yes	4 (3.9%)	0 (0.0%)	
SI-SSI	No	85 (83.3%)	21 (87.5%)	0.615
	Yes	17 (16.6%)	3 (12.5%)	
Intraabdominal Abscess	No	94 (92.1%)	22 (91.6%)	0.936
	Yes	8 (7.8%)	2 (8.3%)	
Readmission	No	92 (90.1%)	22 (91.6%)	0.825
	Yes	10 (9.8%)	2 (8.3%)	
		Mean ± sd		p ‡
Age		39.72 ± 13.21	38.88 ± 14.30	0.998
Oral Feeding (days)		1.24 ± 0.91	1.54 ± 1.74	0.018*
CRP		23.64 ± 23.54	64.42 ± 69.41	<0.001***
Surgery Duration (minutes)		35.39 ± 6.74	37.08 ± 12.93	0.016*
Length of Stay (days)		1.74 ± 1.30	2.17 ± 3.48	0.021*

COVID-19: Coronavirus Disease 2019, ASA: American Society of Anesthesiologists, BMI: Body Mass Index, DM: Diabetes, HT: Hypertension, CAD: Coronary Artery Disease, COPD: Chronic Obstructive Pulmonary Disease, CO-RADS: COVID-19 Reporting and Data System, SO2: Arterial Blood Oxygen Saturation, SI-SSI: Superficial Incisional Surgical Site Infection, CRP: C-Reactive Protein, †: Chi-Square Test, ‡ Independent t Test, *: p ≤0.05, **: p ≤0.01, ***: p ≤0.001

in COVID-19-positive patients compared to COVID-19 negative patients (5.8% vs. 33.3% and 0.0% vs. 4.1%, respectively; $p < 0.001$). In admission parameter evaluations, arterial oxygen saturation (SO₂) levels were lower in COVID-19-positive patients (16.6% vs. 37.5%; $p = 0.011$). Major complications (9.8% vs. 25.0%, $p = 0.044$) and ileus development (0.0% vs.

4.1%, $p = 0.038$) were also more frequent in COVID-19-positive patients. CRP levels were significantly higher in COVID-19-positive patients (23.64 ± 23.54 vs. 64.42 ± 69.41 ; $p < 0.001$). Additionally, the time to initiate oral feeding (1.24 ± 0.91 vs. 1.54 ± 1.74 ; $p = 0.018$), length of hospital stay (1.74 ± 1.30 vs. 2.17 ± 3.48 ; $p = 0.021$), and surgical durations (35.39 ± 6.74

Table 2. Patient characteristics based on Anesthesia Type

		General Anesthesia (n=48)	Spinal Anesthesia (n=78)	p †
Gender	Female	22 (45.8%)	25 (32.0%)	0.120
	Male	26 (54.1%)	53 (67.9%)	
ASA Score	ASA1E	14 (29.1%)	38 (48.7%)	
	ASA2E	19 (39.5%)	23 (29.4%)	
	ASA3E	14 (29.1%)	17 (21.7%)	
	ASA4E	1 (2.0%)	0 (0.0%)	
BMI	Underweight	1 (2.0%)	7 (8.9%)	0.037*
	Normal	22 (45.8%)	50 (64.1%)	
	Overweight	17 (35.4%)	16 (20.5%)	
	Obese	7 (14.5%)	5 (6.4%)	
DM	No	40 (83.3%)	68 (87.1%)	0.549
	Yes	8 (16.6%)	10 (12.8%)	
CO-RADS	CO-RADS 1	19 (39.5%)	34 (43.5%)	0.565
	CO-RADS 2	11 (22.9%)	23 (29.4%)	
	CO-RADS 3	11 (22.9%)	13 (16.6%)	
	CO-RADS 4	6 (12.5%)	8 (10.2%)	
	CO-RADS 5	1 (2.0%)	0 (0.0%)	
Admission Fever	<38.5°	39 (81.2%)	65 (83.3%)	0.765
	≥38.5°	9 (18.7%)	13 (16.6%)	
Admission SO ₂	<92	12 (25.0%)	12 (15.3%)	0.182
	≥92	36 (75.0%)	66 (84.6%)	
Perforation	No	33 (68.7%)	69 (88.4%)	0.006**
	Yes	15 (31.2%)	9 (11.5%)	
Bleeding	No	44 (81.6%)	78 (100.0%)	0.010**
	Yes	4 (8.3%)	0 (0.0%)	
Abscess	No	42 (87.5%)	74 (94.8%)	0.137
	Yes	6 (12.5%)	4 (5.1%)	
Complications	Minor	39 (81.2%)	71 (91.0%)	0.109
	Major	9 (18.7%)	7 (8.9%)	
Ileus	No	47 (97.9%)	78 (100.0%)	0.201
	Yes	1 (2.0%)	0 (0.0%)	
Radix Fistula	No	46 (45.8%)	76 (97.4%)	0.618
	Yes	2 (4.1%)	2 (2.5%)	
SI-SSI	No	40 (83.3%)	66 (84.6%)	0.848
	Yes	8 (16.6%)	12 (15.3%)	
Intraabdominal Abscess	No	43 (89.5%)	73 (93.5%)	0.419
	Yes	5 (10.4%)	5 (6.4%)	
Readmission	No	43 (89.5%)	71 (91.0%)	0.789
	Yes	5 (10.4%)	7 (8.9%)	
		Mean ± sd		p ‡
Age		42.81 ± 13.65	37.55 ± 12.87	0.579
CRP		39.98 ± 54.20	26.13 ± 26.80	0.003**
Oral Feeding (days)		1.50 ± 1.60	1.17 ± 0.65	0.002**
Surgery Duration (minutes)		36.87 ± 10.03	35.00 ± 6.88	0.099
Length of Stay (days)		2.00 ± 2.87	1.71 ± 0.93	0.002**

COVID-19: Coronavirus Disease 2019, ASA: American Society of Anesthesiologists, BMI: Body Mass Index, DM: Diabetes, HT: Hypertension, CAD: Coronary Artery Disease, COPD: Chronic Obstructive Pulmonary Disease, CO-RADS: COVID-19 Reporting and Data System, SO₂: Arterial Blood Oxygen Saturation, SI-SSI: Superficial Incisional Surgical Site Infection, CRP: C-Reactive Protein, †: Chi-Square Test, ‡: Independent t Test, *: $p \leq 0.05$, **: $p \leq 0.01$, ***: $p \leq 0.001$

Table 3. Regression Analysis of Factors Affecting Discharge After Postoperative 24 Hours

Variables	OR	95% CI	p	OR	95% CI	p
Anesthesia Type	4.211	1.843-9.621	<0.001***	32.337	5.121-204.193	<0.001***
Age	1.038	1.007-1.069	0.015*	1.089	1.036-1.145	<0.001***
BMI	Normal		0.453			
	Underweight	2.000	0.460-8.698	0.355		
	Overweight	1.200	0.256-5.631	0.817		
	Obese	0.714	0.118-4.319	0.714		
	Morbid Obese	0.000	0.000	1.000		
DM	1.080	0.389-3.003	0.882			
CRP	0.989	0.978-0.999	0.031*	0.995	0.980-1.010	0.995
Surgery Duration	0.947	0.901-0.995	0.031*	0.951	0.853-1.024	0.187
Perforation	4.857	1.838-12.835	0.001***	15.906	2.344-107.924	0.005**
Bleeding	4.625	0.467-45.190	0.190			
ASA Score	ASA 1E		0.944			
	ASA 2E	1.078	0.472-2.463	0.858		
	ASA 3E	1.333	0.532-3.341	0.539		
	ASA 4E	0.000	0.000	1.000		
CO-RADS	CO-RADS 1		0.965			
	CO-RADS 2	0.866	0.359-2.088	0.748		
	CO-RADS 3	0.716	0.270-1.901	0.503		
	CO-RADS 4	1.091	0.320-3.718	0.889		
	CO-RADS 5	0.000	0.000	1.000		
Radix Fistula	1.490	0.203-10.933	0.695			
Ileus	0.000	0.000	1.000			
Postoperative Abscess	1.522	0.417-5.551	0.525			
Admission SO2	1.063	0.431-2.621	0.895			
COVID-19 Status	1.842	0.703-4.828	0.214			
Major Complication	8.211	2.203-30.596	0.002**	33.056	2.957-369.526	0.005**
SI-SSI	2.017	0.769-5.291	0.154			
Surgery Duration	0.973	0.931-1.017	0.224			

OR: Odds Ratio, CI: Confidence Interval, BMI: Body Mass Index, DM: Diabetes Mellitus, CRP: C-Reactive Protein, ASA: American Society of Anesthesiologists, CO-RADS: COVID-19 Reporting and Data System, SO2: Arterial Blood Oxygen Saturation, COVID-19: Coronavirus Disease 2019, SI-SSI: Superficial Incisional Surgical Site Infection, *: p ≤0.05, **: p ≤0.01, ***: p ≤0.001

vs. 37.08 ± 12.93; p=0.016) were longer in COVID-19 positive patients. Other parameters showed similar distributions (Table 1).

When patients were evaluated based on the chosen anesthesia method, overweight (35.4% vs. 20.5%) and obese patients (14.5% vs. 6.4%) were more frequently observed in the general anesthesia group (p=0.037). Among perioperative findings, perforated appendicitis (31.2% vs. 11.5%; p=0.006) and bleeding cases (8.3% vs. 0.0%; p=0.010) were more common in the general anesthesia group. CRP levels were higher in the general anesthesia group (39.98 ± 54.20 vs. 26.13 ± 26.80; p=0.003), and both the time to initiate oral feeding (1.50 ± 1.60 vs. 1.17 ± 0.65; p=0.002) and length of hospital stay (2.00 ± 2.87 vs. 1.71 ± 0.93; p=0.002) were longer. However, surgical durations were similar between the two groups (36.87 ± 10.03 vs. 35.00 ± 6.88; p=0.099). Other variables were evenly distributed between the groups (Table 2).

To evaluate length of hospital stay, regression analysis was conducted using both the parameters found to be significant in each group and other known influencing factors from the literature, such as fistula at the appendix base, surgical duration, and surgical site incisions [17-21]Univariate analysis identified general anesthesia use (OR: 4.211; p<0.001), age (OR: 1.038; p=0.015), elevated CRP levels (OR: 0.989; p=0.031), surgical

duration (OR: 0.947; p=0.031), the presence of perforation (OR: 4.857; p=0.001), and the development of major complications (OR: 8.211; p=0.002) as significant risk factors. Variables found to be significant were included in a multivariate analysis, which demonstrated that general anesthesia use (OR: 32.337; p<0.001), advanced age (OR: 1.089; p<0.001), perforation (OR: 15.906; p=0.005), and the development of major complications (OR: 33.056; p=0.005) were independent risk factors for prolonged hospital stay (Table 3).

Discussion

Our study shows similar perioperative findings and postoperative follow-up data were observed compared to patients who underwent general anesthesia in cases where appendectomy was performed under spinal anesthesia, While morbidity rates were comparable between the two groups, patients receiving spinal anesthesia had shorter hospital stays. Our study demonstrated that, during the COVID-19 pandemic, the preference for spinal anesthesia in appendectomies contributed to reduced hospital stays, thereby lowering the workload and potentially reducing morbidity for both patients and healthcare workers. This suggests that spinal anesthesia can be a suitable option for appendectomy in appropriate patients.

The COVID-19 pandemic has left striking impacts not only on medical history but also on modern world history. Throughout the pandemic, many physicians and healthcare professionals worked selflessly to manage the crisis. In our country, physicians took on the care of COVID-19 patients outside their specialties during the crisis management process. Beyond this increased workload, the global effects of the pandemic disrupted international trade, causing delays in the supply of medications and medical devices [22, 23].

Conventional appendectomy is increasingly being replaced by laparoscopic appendectomy in modern surgical practice. However, during global crises like the COVID-19 pandemic, where the availability and supply of medical equipment may be disrupted, conventional appendectomy remains a reliable alternative. It can be easily performed with a single surgical set and basic sutures, ensuring its continued relevance in resource-limited situations [2, 4].

When evaluating other studies in the literature, one study comparing the pre-pandemic and post-pandemic periods reported an increase in complicated appendicitis cases from 8.0% to 33.9% after the pandemic. Although this shift aimed to prioritize the safety of both patients and healthcare professionals by managing cases more conservatively, the study found that the incidence of perforated and phlegmonous appendicitis was higher post-pandemic. Additionally, hospital stays for appendectomy patients were shown to be longer after the pandemic [2].

During the pandemic, studies on appendectomy primarily focused on patients operated on under spinal anesthesia, often evaluating laparoscopic surgeries or combining two surgical techniques. A multicenter analysis from Italy reported that the conversion rate to open surgery in patients with complications was 2.4 times higher, and open surgery was performed 2.24 times more frequently [24]. In a single-center study conducted in Turkey, 588 patients presenting with acute appendicitis were included, and an increase in conversion from laparoscopy to open surgery was observed in cases of perforated appendicitis. Both studies demonstrated that hospital stays were prolonged in cases of perforated appendicitis [25]. Similarly, our study also showed that perforated appendicitis significantly prolonged the length of hospital stay.

Studies comparing only open appendectomy cases are limited. There is only one case series that specifically evaluates these patients. In that series, no major complications were reported among the 11 operated cases, and hospital stays were described as short. Similarly, our study demonstrated that general anesthesia does not increase major complications or prolong hospital stays, consistent with the findings of this series. However, unlike the previous study, our research included a larger patient population. Additionally, by including patients with positive COVID-19 antigen tests or CO-RADS imaging findings, our study uniquely evaluated outcomes specific to the pandemic context [4].

Limitation

Our study has several limiting factors. First, it was designed as a retrospective study. Due to the restricted availability of medical equipment during the pandemic, laparoscopic surgery cases were excluded because of technical limitations at the center where the study was conducted. Lastly, the exact onset

times of patients' symptoms were unknown and therefore could not be included in the analysis. As a strength, the study exclusively focused on a single surgical method, evaluated in a single center by the same surgical team, ensuring consistency in the findings. Also as a technique comparison; interval appendectomy or medical approach patients weren't included which contributes to a more homogenous patient cohort.

Conclusion

Open appendectomy performed under spinal anesthesia demonstrates similar morbidity rates to those under general anesthesia while resulting in shorter hospital stays. Although open appendectomy has largely been replaced by laparoscopy in modern practice, it remains a safe and reliable option under spinal anesthesia during crisis periods, such as the COVID-19 pandemic, when access to minimally invasive techniques may be limited or delayed.

Scientific Responsibility Statement

The authors declare that they are responsible for the article's scientific content including study design, data collection, analysis and interpretation, writing, some of the main line, or all of the preparation and scientific review of the contents and approval of the final version of the article.

Animal and Human Rights Statement

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

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Conflict of Interest

The authors declare that there is no conflict of interest.

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