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ORIGINAL SCIENTIFIC REPORT

The Predictive Value of Pulse Wave Velocity for Anastomotic Leakage After Colorectal Surgery

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Abstract

Background Arterial perfusion defects are a risk factor for anastomotic leakage (AL) following colorectal surgery. Measuring arterial stiffness using pulse wave velocity (PWV) is known to reflect the performance of the arterial network. The objective of this study was to assess the predictive value of PWV for AL after colorectal surgery.

Methods A prospective monocentric study was conducted on all consecutive patients who underwent colorectal surgery scheduled between March 1, 2016 and May 1, 2017. Patients were divided into two groups according to the PWV which was measured preoperatively using the pOpmètre® device: PWV+ (PWV > 10 m/s) and PWV− (PWV ≤ 10 m/s). We then compared the PWV+ and PWV− groups. The primary endpoint was the AL rate.

Results A total of 96 patients were studied, including 60 in the PWV− group and 36 in the PWV+ group. Patients in the PWV+ group were more at risk of presenting with AL than those in the PWV− group (6.25 vs 0%) ($p = 0.002$). There was no difference in immediate postoperative complications between the two groups apart from the length of hospital stay. PWV predicted the appearance of AL with a sensitivity of and a negative predictive value of 100%.

Conclusion Measuring PWV could be a used as a predictive examination in the early detection of AL after colorectal surgery.

Introduction

Colorectal surgery has a morbidity rate between 17 and 35% [1, 2]. Although most complications do not usually have serious consequences for the patient, anastomotic leakage (AL) is the most-feared complication for this type of surgery. Its incidence rate was initially estimated at 1–26% depending on the type of surgery [3] but has decreased thanks to enhanced recovery [4] which has seen this rate reduced to 2.9%, according to some authors [5].

In the USA, AL leads to overspending in healthcare which is estimated at approx. 20,000 dollars per patient [6]. The consequences are relative to the individual patient as they may range from simple antibiotic treatment to repeat surgery with dismantling of the anastomosis and intestinal diversion, depending on the severity of the leakage. More serious consequences are not rare given that the treatment

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of AL is associated with a mortality rate of 6.8% [7]. Considering that the treatment has a higher success rate the earlier the leakage is treated [8], it is absolutely necessary to preoperatively identify at-risk patients in order to offer them close postoperative monitoring.

Several studies have examined independent risk factors for ALs, such as diverticular disease [9], subperitoneal rectal surgery [9, 10], an American Society of Anesthesiology (ASA) score >2 [11], emergency surgery [11], and male gender [10]. Moreover, the success of an intestinal anastomosis is correlated with the efficiency of the arterial vascularization, and without sufficient blood perfusion, the patient is at risk of ischemic AL [12]. Cardiovascular risk factors such as a body mass index >30 kg/m^2 [13], smoking [14, 15], high blood pressure [16], or a history of cardiovascular disease [15] are also individual risk factors for AL. An assessment of the performance of the peripheral arterial network could therefore be of interest in this context.

To this end, measuring arterial stiffness is a relevant indicator recommended by the European Society of Hypertension and the European Society of Cardiology. Arterial stiffness is easy to measure, reproducible, and non-invasive when evaluated using the pOpmètre® (*Axelife SAS, Saint Nicolas de Redon, France*). This measuring device measures carotid-femoral pulse wave velocity and therefore arterial stiffness through a sensor placed on the patient's thumb and big toe. The sensor is connected to a computer [17] and gives a result in m/s. Given that PWV is correlated with cardiovascular morbidity [18] and that altered arterial perfusion of the anastomosis is a risk factor for leakage, an altered measurement of preoperative PWV could help predict the occurrence of ALs.

The aim of this study was to assess the predictive value of measuring arterial stiffness for AL. The secondary objective was to evaluate extent to which measuring arterial stiffness can predict postoperative complications after scheduled colorectal surgery.

Materials and methods

Patients

This was a prospective observational study that included all consecutive patients who underwent scheduled surgery for a colectomy or upper proctectomy by laparoscopy or laparotomy, including anastomosis, between March 1, 2016 and May 1, 2017 in one hospital.

Primary exclusion criteria were emergency surgery, neoadjuvant chemotherapy or radiotherapy, subperitoneal rectal surgery and the need for defunctioning stoma, and chronic inflammatory bowel disease (CIBD).

Secondary exclusion criteria were: (1) no measurement using the pOpmètre® device (due to lack of device availability or contraindication including amputation of a limb, amputation of the right big toe and right thumb or large wounds on fingers or toes, cardiac arrhythmia during the measurement, or stage IV arteriopathy of the lower limbs) and (2) failure of measurement.

Eighteen patients from this study cohort were included in the pre-TAPIOCA randomized controlled study (*ClinicalTrial.gov NCT02815956*).

Our local ethics committee approved the study design.

Pulse wave velocity measurement [19]

To assess the performance of the patients' arterial network, pulse wave velocity was measured using the pOpmètre® device. This is a reference method used to determine arterial stiffness in a non-invasive manner [20]. Pulse wave velocity was measured prior to surgery (the day before or on the day of the surgery) using three successive measures in the patient's room having placed two sensors on the patient's thumb and big toe. The measurement was taken while the patient was in the dorsal decubitus position. After a few seconds, the value of the carotid-femoral pulse wave velocity appeared on the screen of the computer connected to these sensors. The pulse wave velocity value was considered pathological if it was higher than 10 m/s [21]. Two groups were defined based on this value: the PWV+ group (>10 m/s) and the PWV− group (<10 m/s).

Endpoints/definitions

The primary endpoint was the occurrence of AL.

The leak was clinically suspected with the appearance of sepsis (fever, abdominal pain, fecal discharge from the drainage device or the scar) and biologically suspected with the appearance of inflammation. Leakage was systematically confirmed by CT-scan that showed a pneumoperitoneum and/or an intra-abdominal collection and/or peritoneal effusion adjacent to the anastomotic zone [22].

The secondary endpoints were related to postoperative complications. The postoperative complications examined were:

- The appearance of a surgical site infection (SSI) defined according to the definition set by the Centre for Disease Control [23]. Consequently, we took three types of SSI into account: superficial incisional SSIs, deep incisional SSIs, and deep SSIs (infection of organ/area affected by the surgery). ALs were included in the analysis of deep SSIs.

- The occurrence of a postoperative complication linked to the surgery, apart from postoperative ileus, classified according to the Clavien–Dindo classification [24].
- The length of hospital stay, defined as the duration between the patient's admittance and discharge.

Statistical analyses

For the qualitative variables, results were reported in numbers and percentages, then compared using Pearson's Chi squared test (or Fisher's exact test). For quantitative variables, results were reported in mean and standard deviation (or as a median with the 25th and 75th centile) and then compared using Student's t-test (or the nonparametric Mann–Whitney U test). A p value <0.5 was considered statistically significant.

Youden's index was used to assess the test's effectiveness.

Results

General population

Of the 164 patients who underwent surgery for colectomy or intraperitoneal proctectomy during the inclusion period, 96 patients were included in the study (Fig. 1). Eighteen patients were also included in the TAPIOCA study protocol: 7 from the PWV+ group (30%) and 11 from the PWV− group (30.6%) ($p = 0.95$).

Fifty-six patients were male (58.3%), and the mean age was 68 years (32–89). Average body mass index (BMI) was 25.5 ± 0.48 kg/m^2. The ASA score was >2 in 38 (39.6%) patients. Thirty-six patients had a PWV > 10 m/s (PWV+ group) (37.5%), and 60 patients had a PWV < 10 m/s (PWV− group) (62.5%). The demographic characteristics of our general population are reported in Table 1.

Postoperative complications were marked by the appearance of an AL in 6 patients from the PWV+ group. Moreover, 11 patients (11.5%) had an SSI (Table 2). Among them, 3 (27.3%) had a superficial incisional SSI, 1 (1.04%) had a deep incisional SSI, and 7 (7.3%) had a deep SSI (6 ALs and one deep abscess).

One postoperative complication was reported in 36 patients (37.5%), and postoperative ileus was reported in 33% of patients. The average length of hospital stay was 9.8 days.

Comparison of the PWV− and PWV+ groups

Usual cardiovascular risk factors such as high blood pressure (30 vs 64%), dyslipidemia (15 vs 41.7%), and diabetes (5 vs 22%) were more prevalent in the PWV+ group compared to the PWV− group ($p < 0.001$, $p = 0.02$ and $p = 0.01$, respectively). However, the ASA score and the prevalence of obesity did not differ between the two groups ($p = 0.28$ and $p = 0.29$) (Table 1).

Operative indications, the type of surgery, and the surgical approach ($p = 0.24$) did not differ between the two groups (Table 3).

ALs occurred in six cases, exclusively in the PWV+ group (16.7%). None of the patients in the PWV− group presented an AL ($p = 0.002$). No leaks were diagnosed within 72 h. ALs appeared between the 6th day and the 12th day.

Postoperative complications did not differ significantly when considering overall mortality ($p = 0.52$). However, an SSI occurred more frequently in the PWV+ group (25%) than in the PWV− group (3.3%) ($p = 0.002$). In the PWV− group, one patient had a superficial wall abscess and one patient had a deep wall abscess. In the PWV+ group, two patients had a superficial wall abscess, one patient had a deep abscess, and six patients had an AL.

The rates of grade 1–2 and grade 3–4 complications according to the Clavien–Dindo classification were similar in both groups (Table 2). Each patient could present several associated complications. Clavien–Dindo grade 1 and 2 complications included postoperative ileus ($n = 32$), superficial ($n = 3$) and deep ($n = 1$) wall abscesses, AL ($n = 3$), anemia requiring transfusion ($n = 5$), rectal bleeding ($n = 3$), splenic contusion ($n = 1$), acute urine retention requiring urinary catheterization ($n = 3$), pneumopathy ($n = 5$), biloma ($n = 1$) due to metastasectomy associated with colorectal surgery, intestinal obstruction on the adhesions ($n = 1$), cardiac rhythm disorder ($n = 1$), and nosocomial urinary tract infection ($n = 1$). Clavien–Dindo grade 3 and 4 complications included x-ray drainage due to pleural effusion ($n = 1$), epilepsy seizure requiring monitoring in the ICU ($n = 1$), deep abscess on the small intestine wound ($n = 1$), and three ALs.

No deaths were reported in this study.

The length of hospital stay was 11.6 days in the PWV+ group and 8.7 days in the PWV− group ($p = 0.04$).

Predictive value of PWV for the occurrence of AL

Pulse wave velocity gave a sensitivity of 100% and a specificity of 67% for predicting the occurrence of anastomotic leakage. The negative predictive value and the positive predictive value were 100 and 17%, respectively. Youden's index value was 0.67.

Also, the median of the PWV was significantly lower in the group no AL (8.5; 6.7–10.5) as compared to the group AL (13.7; 12.2–17.2) ($p = 0.002$; Fig. 2).

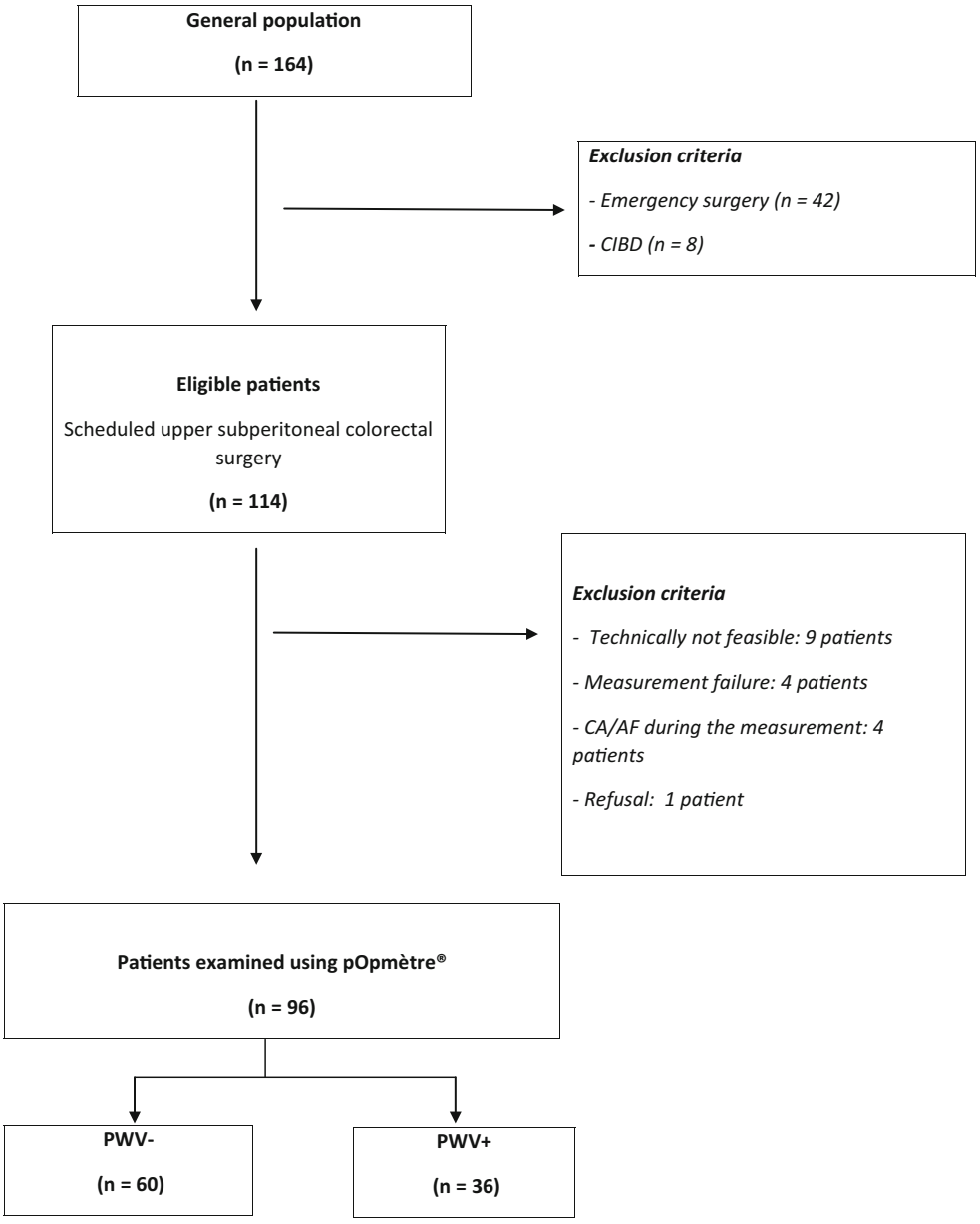

Fig. 1 Flowchart of the study population. *CIBD* chronic inflammatory bowel disease, *CA/AF* cardiac arrhythmia/atrial fibrillation

Discussion

In this study which examined the data of 96 patients who underwent a colectomy or proctectomy, 38% of patients had a pathological PWV. A pathological PWV was significantly associated with the postoperative occurrence of AL ($p = 0.02$). The study's most important finding was that PWV gave a sensitivity of 100% for predicting the occurrence of an AL. The AL rate in the literature is comparable to our results, given that it was reported to be 7.2% by Sammour et al. [25]. It is also interesting to note that there was a significant link between the occurrence of AL and pathological pulse wave velocity ($p = 0.002$).

Given that PWV is developed to screen patients presenting a high cardiovascular risk [26], there was a significant difference between the groups regarding the prevalence of comorbidities such as diabetes ($p = 0.02$), high blood pressure ($p < 0.001$), and dyslipidemia ($p = 0.007$), which were predominant in the PWV+ group. Some of these comorbidities are also known to be risk factors for AL. Diabetes has recently been reported as a risk factor for AL [27], as has high blood pressure [26]. Nevertheless, these patients with added cardiovascular risk factors are not being screened effectively, which is why measuring PWV prior to surgery helps target patients at risk of AL.

Table 1 Comparison of the demographic characteristics of the PWV− and PWV+ groups

	PWV− (n = 60)	PWV+ (n = 36)	General population (n = 96)	p
Age	63 (±1.5)	71 (±1.6)	65.7 (±1.2)	**0.001**
Male sex	34 (56.7%)	22 (61.1%)	56 (58.3%)	0.83
BMI	25.1 (±0.6)	26.2 (±0.8)	25.5 (±0.48)	0.27
ASA score				0.28
<2	39 (65%)	19 (52.8%)	58 (60.4%)	
>2	21 (35%)	17 (47.2%)	38 (39.6%)	
Diabetes	3 (5%)	8 (22.2%)	11 (11.5%)	**0.02**
Dyslipidemia	9 (15%)	15 (41.7%)	24 (25%)	**0.007**
HBP	18 (30%)	25 (69.4%)	43 (44.8%)	**<0.001**
Obesity	7 (11.7%)	7 (19.4%)	14 (14.6%)	0.29
Smoking	20 (33.3%)	9 (25%)	29 (30.2%)	0.49
Alcohol	9 (15%)	11 (30.6%)	20 (20.8%)	0.12

PWV pulse wave velocity, *BMI* body mass index, *ASA* American Society of Anesthesiology, *HBP* high blood pressure

Significant results are given in bold

Table 2 Comparison of postoperative complications between the patients in the PWV− group and the PWV+ group

	PWV− (n = 60)	PWV+ (n = 36)	Total (n = 96)	p
Overall morbidity	27 (45%)	18 (50%)	45 (46.9%)	0.67
Anastomotic leakage	0	6 (100%)	6 (6.25%)	**0.002**
Surgical site infection	2 (3.3%)	9 (25%)	11 (11.5%)	**0.002**
Clavien–Dindo complications (n = 45)				
Grade 1 and 2	24 (88%)	15 (83.3%)	39 (86.7%)	0.67
Grade 3 and 4	3 (12%)	3 (16.7%)	6 (13.3%)	0.67

PWV pulse wave velocity, *NGT* nasogastric tube

Significant results are given in bold

ALs are often diagnosed late, usually on the 8th postoperative day [23], i.e., usually after the patient has already been discharged. Determining which patients are very high-risk prior to the surgery could help ensure that this patient population is closely monitored and potentially anticipate monitoring thanks to systematic biological examinations, even after the patient has been discharged. An abnormality of a biological marker such as C-reactive protein could lead to re-admitting the patient in order to confirm or refute the presence of leakage using imaging so as to ensure optimal and early treatment. Given that early treatment of AL is a prognostic factor for survival [8], this could help reduce the consequences associated with the leak.

The link between the performance of the arterial network and the occurrence of AL has already been suggested in several studies. Eveno et al. [28] studied calcifications in the abdominal aorta on a preoperative scan as a predictor of AL. By establishing an aortic calcification score in 3 grades, their pilot study suggested that a high aortic calcification score was correlated with a high rate of postoperative complications, particularly ALs. The study by Vignali et al. [29] published in 2000 examined colorectal vascularization identified intraoperatively by Mini Doppler in cases of rectal cancer and was able to determine a link between a reduction in arterial flow and the presence of an AL. A linear correlation was found between reduced blood flow and the rate of ALs with a significant difference between the group with a leakage and the group without a leakage ($p < 0.01$). These last two examinations are rather technically challenging and operator-dependent compared to PWV measurement, which is simple and reproducible.

With regard to postoperative complications, PWV was not significantly associated with overall morbidity, but the prevalence of SSIs was higher in the PWV+ group ($p = 0.002$). This could partly be explained by a higher prevalence of risk factors for SSI in this group, such as diabetes and old age [30]. Moreover, the length of hospital

Table 3 Comparison of surgical characteristics between the PWV− and PWV+ groups

	PWV− (n = 60)	PWV+ (n = 36)	General population (n = 96)	p
Indication				
Cancer	36 (60%)	23 (63.8%)	59 (61.5%)	0.829
Polyp	8 (13.3%)	8 (22.2%)	16 (16.7%)	0.272
Diverticulitis	12 (20%)	5 (13.9%)	17 (17.7%)	0.584
Other	4 (6.7%)	0 (0%)	4 (4.2%)	0.293
Surgical procedure				
Right colectomy[a]	17 (28.3%)	13 (36.1%)	30 (31.3%)	0.49
Transverse colectomy	2 (3.3%)	1 (2.8%)	3 (3.1%)	1
Left colectomy[a]	4 (6.7%)	3 (8.3%)	7 (7.3%)	1
Sigmoidectomy	30 (50%)	16 (44.4)	46 (47.9%)	0.59
Subtotal colectomy	2 (3.3%)	2 (5.6%)	4 (4.2%)	0.63
Upper proctectomy	5 (8.3%)	2 (5.6%)	7 (7.3%)	0.71
Stapled anastomosis	36 (60%)	21 (58.3%)	57 (58.7%)	0.87
Surgical approach				0.24
Laparotomy	12 (20%)	11 (30.6%)	23 (24%)	
Laparoscopy	48 (80%)	25 (69.4%)	73 (76%)	
Converted laparoscopy	11 (21.2%)	9 (32.1%)	20 (25%)	0.28
Drainage	24 (40%)	14 (38.9%)	38 (39.6%)	1
Duration of surgery (min)	178 (±6.9)	194 (±11.8)	184 (±6.2)	0.21

PWV pulse wave velocity

[a]One patient had a left colectomy + a right colectomy with 2 anastomosis

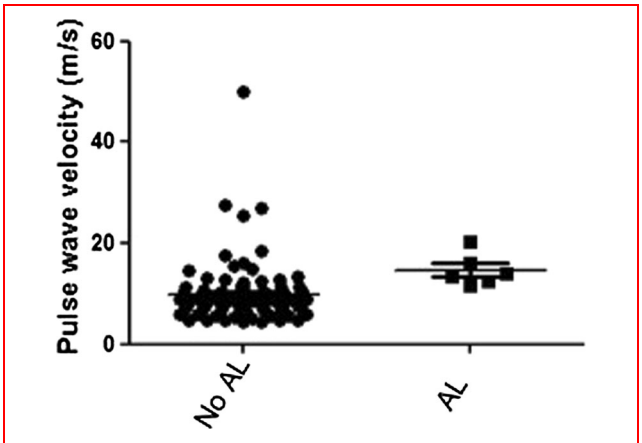

Fig. 2 Mean values of pulse wave velocity in the presence of a leakage or not (p = 0.002). *AL* anastomotic leakage

stay was higher in the PWV+ group (p = 0.04). This result was expected considering that the prevalence of ALs was higher in this group. The length of hospital stays found in our study was shorter than those reported in older multicenter French studies (14–17 days on average). Patients were not treated with an intraoperative enhanced recovery program [31, 32].

Nevertheless, this study contains limitations that are inherent to its observational nature. Some patients were included in the pre-TAPIOCA study (*ClinicalTrial.gov NCT02815956*). The distribution was homogenous and the difference between the groups was not significant, and however, the effects of transcutaneous tibial nerve stimulation on tissue wound healing are unknown and could partially modify our conclusions. Moreover, the low number of events makes it impossible to propose a multivariate analysis to adjust the results to confounding factors, and particularly other cardiovascular risk factors. On the other hand, our study reported 100% sensitivity with a negative predictive value of 100%, which means that PWV is an excellent test for screening patients at risk of SSIs and ALs. The limited number of patients certainly overestimates the results, but it nevertheless points to the benefits of measuring PWV for current clinical practices. A multicenter study with a larger cohort is required to confirm these results.

Our pilot study suggests that measuring pathological pulse wave velocity is correlated with an increased rate of ALs and an increased length of hospital stay. If its effectiveness can be confirmed, this new tool could be a major asset for the practitioner to target patients at risk of anastomotic leakage prior to surgery and to adapt their

postoperative monitoring to ensure a tailored therapeutic approach. Furthermore, PWV could also be used, in association with cardiovascular risk factors, in a composite score to allow a more sensitive and specific targeting of patients at risk of AL.

Author's contribution VA: conception, design, analysis and interpretation of data, manuscript author, provided feedback on the manuscript, drafted the article, and revised it critically with regard to important intellectual content. Final approval of the version to be published. JR: conception, design, analysis and interpretation of data, manuscript author, provided feedback on the manuscript, drafted the article, and revised it critically with regard to important intellectual content. Final approval of the version to be published. LE: provided care for study patients, provided feedback on the manuscript, drafted the article, and revised it critically regarding important intellectual content. Final approval of the version to be published. LNP: provided care for study patients, provided feedback on the manuscript, drafted the article, and revised it critically regarding important intellectual content. Final approval of the version to be published. CC: provided care for study patients, provided feedback on the manuscript, drafted the article, and revised it critically with regard to important intellectual content. Final approval of the version to be published. ME: methodology, statistical analysis and interpretation, provided feedback on the manuscript. Final approval of the version to be published. DE: provided care for study patients, provided feedback on the manuscript, drafted the article, and revised it critically regarding important intellectual content. Final approval of the version to be published. HA: conception, design, analysis and interpretation of data, manuscript author, provided feedback on the manuscript, drafted the article, and revised it critically with regard to important intellectual content. Final approval of the version to be published.

Compliance with ethical standards

Conflict of interest The authors declare no conflicts of interest associated with this study.

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