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ORIGINAL RESEARCH

The Frozen Elephant Technique Using a Novel Hybrid Prosthesis for Extensive Aortic Arch Disease: A Multicentre Study

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ABSTRACT

Introduction: The frozen elephant trunk technique (FET) has become routine for aortic arch and descending aortic repair. New hybrid prosthesis models are constantly being developed to increase effectiveness and durability of aortic repair. Recently, concerns were raised regarding increased post-operative bleeding using a new-generation hybrid prosthesis (E-vita® OPEN NEO, CryoLife Inc. JOTEC GmbH, Hechingen, Germany). We report the outcomes of a multicentre experience of using the E-vita OPEN NEO.

Methods: All patients undergoing aortic surgery at five European centres using the E-vita OPEN NEO from 2020 to 2022 were included

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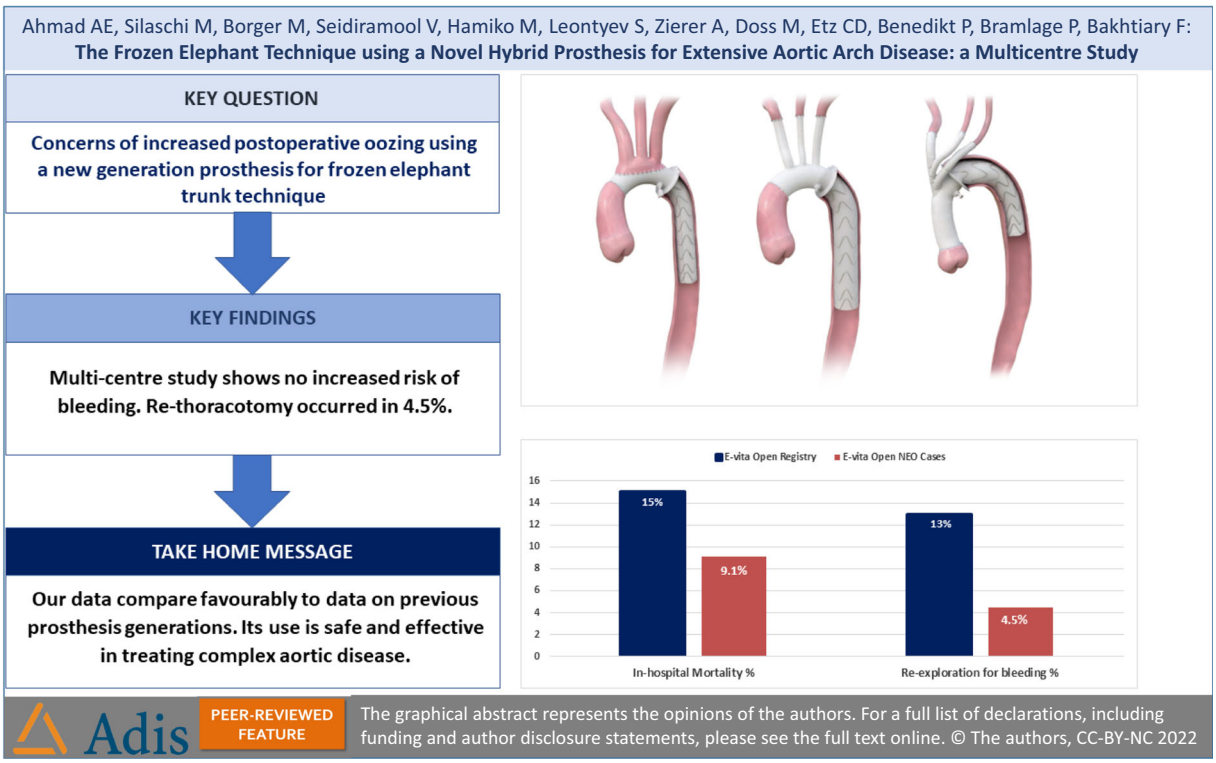
(*n* = 22). The primary endpoint was the amount of chest drain fluid after 24 h and re-thoracotomy rate for bleeding.

Results: Median patient age was 62.5 ± 12.6 years, 50.0% (11/22 patients) were female and 27.3% (6/22) of procedures were re-operative cardiac surgeries. Aortic dissection was present in 54.5% (12/22). The median cardiopulmonary bypass time was 148 min and ischaemia time was 84 min. Mortality at 30 days was 4.5% (1/22) and the stroke rate was 18.2% (4/22). The rate of re-thoracotomy for bleeding was 4.5% (1/22) with a median amount of chest drain fluid within 24 h of 569 (IQR 338–910) ml. There were no device-associated adverse events.

Conclusions: Use of this new-generation hybrid prosthesis for FET was safe and effective. Patient follow-up was largely uneventful given the extent of the procedures performed. In particular, bleeding events were uncommon in this cohort of patients comprising many aortic dissections and re-operative procedures. No increase in oozing was observed.

Graphical Abstract:



Keywords: Frozen elephant trunk; Aortic prosthesis; Aortic surgery; Hybrid aortic repair

Key Summary Points
A new hybrid prosthesis for thoracic aortic repair was introduced into clinical practice in 2020 but there have been reports of increased oozing of the prosthesis leading to increased rates of postoperative bleeding.
We report multi-centre outcomes of routine use with this new hybrid prosthesis with special regard to postoperative bleeding complications.
Outcomes in 22 patients showed no elevated rates of rethoracotomy for bleeding and no elevated amounts of chest drain output during 24 h, while transfusion requirements were average.
All other clinical outcomes seemed comparable to previous generations of the prosthesis as reported by registry data.
As relatively short operative times in this study show, this new hybrid prosthesis for aortic repair enables ease of operation and is not associated with increased bleeding risk compared to its previous generation.

DIGITAL FEATURES

This article is published with digital features, including an infographic to facilitate understanding of the article. To view digital features for this article go to https://doi.org/10.6084/m9.figshare.21757094.

INTRODUCTION

Since the introduction of frozen elephant trunk technique (FET) in 2001, modern surgery of thoracic aortic pathologies has evolved towards a more extensive repair of the aortic arch and descending aorta [1]. The FET technique allows for combined surgical and endovascular treatment of pathologies involving both the aortic arch and descending aorta using a hybrid prosthesis [1]. Since its first application using a prototype hybrid prosthesis, different prosthesis models have been under constant development. The newest of these prostheses is the E-vita® Open NEO hybrid prosthesis (CryoLife Inc. JOTEC GmbH, Hechingen, Germany), which is available in three stent graft configurations (Fig. 1). It is used in patients with aneurysms of the aorta extending into the aortic arch and the descending aorta as well as patients with acute or chronic Stanford type A and B dissections or those with a non-A-non-B type configuration.

A first report was published outlining the successful use in a minimally invasive approach through a partial upper sternotomy in a 47-year-old male patient with prior stent-graft implantation after traumatic aortic rupture in 2021 [2]. The postoperative course was uneventful and the outcome was excellent. Later on, however, some researchers raised concerns about this prosthesis type because of the occurrence of oozing observed by the authors in three cases [3]. They stated that excessive oozing persisted despite protamine

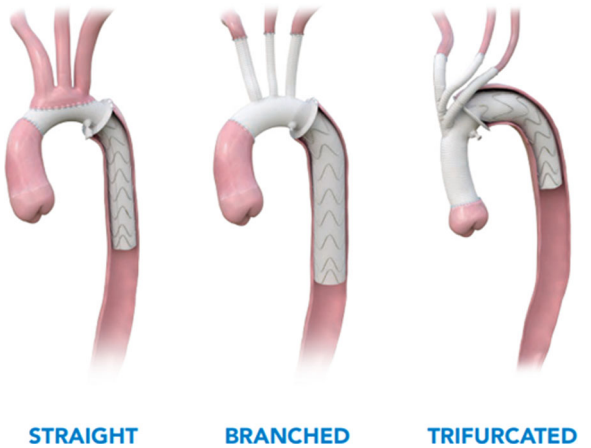


Fig. 1 Prosthesis configurations. Source: https://www.jotec.com/files/media/pdf/EN/E-vita%20OPEN%20NEO%20Brochure%20V02%2002_2021%20Web_klein-komprimiert.pdf. Used with permission from CryoLife Inc. JOTEC GmbH

administration as well as standard substitution of plasmatic and cellular coagulation adjusted to thrombelastometry after weaning from cardiopulmonary bypass, which ultimately led to mass transfusion and increased chest drainage output during the early post-operative course.

This prompted us to review our experience and assess results at six centres (Leipzig, Bonn, Siegburg and Wuppertal in Germany and Linz and Wels in Austria), where the branched E-vita Open NEO hybrid prosthesis has been implanted. To our knowledge, this is the first multicentric assessment of this newly developed prosthesis in a real-world patient cohort. We hypothesized that there is no increased risk of oozing associated with the use of this new prosthesis.

METHODS

This is a multi-centre, observational, retrospective study of 22 consecutive patients undergoing E-vita Open NEO hybrid prosthesis implantation (Fig. 1) for various aortic arch pathologies between October 2020 and May 2022. Six centres participated in data collection (Siegburg, Bonn, Wuppertal and Leipzig in Germany and Linz and Wels in Austria). All patients underwent a pre-operative electrocardiogram (ECG)-gated computed tomography (CT) assessment, combined with magnetic resonance tomography (MRT) in two patients and combined with angiography in one patient.

Ethical Statement

Ethics committee approval was not required because of the observational and retrospective nature of the study without further follow-up. The study was conducted in accordance with the Declaration of Helsinki of 1964 and its later amendments.

Surgical Techniques

Our standard surgical approach to FET has been described previously [4]. Usually, axillary artery cannulation is the preferred route of cannulation at the participating centres. Axillary artery cannulation is performed prior to sternotomy either directly or through an 8-mm graft, according to preference of the operating surgeon. If cannulation of the right axillary artery is not possible, the carotid arteries may be cannulated unilaterally. In some cases, two cannulation sites are used to reduce the risk of false lumen perfusion through one of the cannulation sites, whenever risk for this was increased. After median sternotomy, right atrial venous cannulation establishes cardio-pulmonary bypass. The routine target temperature during the procedure is set to 24–34 °C, depending on the complexity of the procedure. Unilateral selective cerebral perfusion (SACP) is performed via the arterial cannulation site under continuous near-infrared spectroscopy (NIRS) monitoring.

Pathological parts of the aorta are resected, and resection may be performed up to zone 3. Sizing of the stent graft is according to the dimension of the native non-diseased aorta or true aortic lumen in patients with acute or chronic aortic dissection, with 5–10% oversizing to minimize risk of type Ib endoleak [4]. The E-vita OPEN NEO is guided downstream over the wire and deployed. The graft is fixed by a circumferential suture with the collar inside and a Teflon strip outside the aorta. Selective distal perfusion via the side branch is started after retrograde de-airing and clamping of the arch graft. The 10- and 8-mm proximal side branches are used for supra-aortic vessels, respectively. The ascending aorta may also be replaced using an additional graft.

Endpoints

The primary endpoint was the amount of chest drain fluid/bleeding after 24 h post-surgery and the re-thoracotomy rate for bleeding. Secondary endpoints included the rate of in-hospital mortality, post-operative morbidity and prosthesis-related adverse events.

Table 1 Patient characteristics

	***n* = 22**
Age (years), median (IQR)	63 (53; 73)
Female gender, %	11 (50.0)
Body mass index (kg/m^2), median (IQR)	25.9 (23.2; 27.9)
Hypertension (treated), *n* (%)	13 (59.1)
Prior cardiothoracic surgery, *n* (%)	6 (27.3)
Neurological impairment, *n* (%)	2 (9.1)
Previous stroke, *n* (%)	4 (18.2)
Pulmonary hypertension, *n* (%)	0 (0.0)
Peripheral arterial disease, *n* (%)	2 (9.1)
Chronic obstructive pulmonary disease, *n* (%)	2 (9.1)
New York Heart Association class III/IV	6 (27.3)
Left ventricular ejection fraction, median (IQR)	58.5 (55; 64)
Coronary artery disease, *n* (%)	6 (27.3)
Prior percutaneous coronary intervention, *n* (%)	1 (4.5)
Aortic dissection, *n* (%)	
Acute ($\leq$ 14 days), *n* (%)	8 (36.4)
Chronic ($>$ 90 days), *n* (%)	4 (18.2)
Dissection of supra-aortic vessels, *n* (%)	5 (22.7)
Chronic aneurysm, *n* (%)	10 (45.5)

IQR interquartile range

Statistics

Patient data were retrospectively collected into a single database and SPSS (IBM, Amonk, New York, USA) was used to perform basic descriptive statistics. Continuous variables are presented as medians and interquartile ranges (IQRs), dichotomous variables as percentages and absolute numbers with the denominator given in brackets. No statistical testing was performed to compare subgroups of patients.

RESULTS

Patient Characteristics

Between October 2020 and May 2022, 22 patients were treated. They had a median age of 63 (IQR 53–73) years and half (50.0% [1/22]) were female (Table 1). Overall, one-third (27.3% [6/22]) of patients had previously undergone cardiothoracic surgery; of these, five had had a prior surgery on the ascending aorta (5/22). None of the patients had undergone prior mitral valve surgery or coronary artery bypass grafting.

In addition, one patient had had a recent ischemic stroke. In total, history of stroke was observed in 18.2% (4/22) patients. One had pulmonary hypertension. Six patients were in New York Heart Association (NYHA) class III (n = 2) or IV (n = 4); left ventricular (LV) function was normal in most patients (median 58.5%). Detailed patient baseline characteristics are presented in Table 1.

Acute aortic dissection was present in 36.4% (8/22), chronic dissection in 18.2% (4/22) and chronic aortic aneurysms in 45.5% (10/22) of patients. One-third (27.3% [6/22]) patients had pre-operative pericardial effusion on imaging.

Procedural Characteristics

The median cardiopulmonary bypass time was 148 (IQR 97–207) min and ischaemia time was 84 (IQR 59–120) min. The median lowest rectal temperature achieved was 28.6 °C, with a range of 24–36 °C (Table 2). Replacement of the ascending aorta was performed in addition to arch replacement/descending aortic repair in one-third (31.8% [7/22]) of patients. Supra-aortic vessels were anastomosed en bloc in 27.3% (6/22) and separately in 72.7% (16/22) of patients. One patient had concomitant coronary artery bypass grafting and another one had extra-anatomic re-implantation of a coronary ostium. Two (9.1%) patients received endovascular stent graft extension via the femoral arteries during the procedure. No BioGlue was used during the procedures. All patients survived the procedure and no patient needed

Table 2 Procedural details

	n = 22
Arterial cannulation site	
Axillary artery (AA), *n* (%)	17 (77.3)
Left carotid artery + brachiocephalic trunk, *n* (%)	4 (18.2)
Left carotid artery + AA, *n* (%)	1 (4.5)
Selective cerebral perfusion	
Bilateral, *n* (%)	7 (31.8)
Unilateral, *n* (%)	15 (68.2)
Additional ascending aortic replacement	7 (31.8)
Root replacement/re-insertion coronary ostia	2 (9.1)
Valve replacement, *n* (%)	2 (9.1)
Aorto-coronary bypass because of CAD, *n* (%)	1 (4.5)
Arch artery reimplantation	
En block, *n* (%)	6 (27.3)
Separately, *n* (%)	16 (72.7)
Cardiopulmonary bypass time, min, median (IQR)	151 (97; 207)
Myocardial ischaemia time, min, median (IQR)	84 (59; 120)
Lower body circulatory arrest time, median (IQR)	53 (41; 70)
Lowest rectal temperature, °C, median (IQR)	28.6 (28; 24)
Prosthesis diameter vascular graft part	
26 mm	5 (22.7)
28 mm	5 (22.7)
30 mm	12 (54.6)

AA axillary artery, *CAD* coronary artery disease, *IQR* interquartile range

Table 3 Postoperative outcomes

	n = 22
Primary endpoints	
Re-thoracotomy[a], *n* (%)	1 (4.5)
Median chest drain output/24 h, ml, median (IQR)	569 (338–910)
Secondary endpoints	
30-day mortality, *n* (%)	1 (4.5)
Low cardiac output, *n* (%)	4 (18.2)
Myocardial infarction, *n* (%)	0 (0.0)
Mechanical circulatory support, *n* (%)	0 (0.0)
Acute renal failure requiring dialysis[b], *n* (%)	2 (9.1)
Ventilatory support	
Reintubation, *n* (%)	5 (22.7)
Tracheotomy, *n* (%)	2 (9.1)
Long-term ventilation ≥ 7 days, *n* (%)	4 (18.2)
Transfusion requirements within 24 h	
Packed red blood cells, mean no. (SD)	7.5 (6.5)
Packed platelet concentrates, mean no. (SD)	2.5 (2.1)
Fresh frozen plasma, no., mean (SD)	6.1 (5.4)
Fibrinogen, g, mean (SD)	2.9 (1.9)
Prothrombin complex concentrate, international units	2484 (2104)
Neurological complications	
Stroke[c], *n* (%)	4 (18.2)
Delirium, *n* (%)	2 (9.1)
Recurrent nerve injury, *n* (%)	1 (4.5)
Discharge[d], *n* (%)	
Home, *n* (%)	9 (40.9)
Rehabilitation unit, *n* (%)	8 (35.4)

Table 3 continued

	n = 22
Other hospital, *n* (%)	3 (13.6)

[a]Due to bleeding
[b]One temporary, one permanent
[c]Two of these patients already had malperfusion of supraaortic vessels and neurological symptoms at baseline
[d]One patient had died within 30 days and one patient died during hospital stay after 3 months

mechanical circulatory support upon leaving operating theatres.

Primary Endpoint

Re-thoracotomy for bleeding was necessary in 4.5% (1/22) patients. The median overall amount of chest drain fluid within 24 h was 569 (IQR 338–910) ml. The amount of blood transfusions used is detailed in Table 3.

Procedural and In-hospital Outcomes

Post-procedural events and outcomes are detailed in Table 3. In 18.2% (4/22) patients, low cardiac output—defined as the use of at least two inotropic agents—occurred but was ultimately treated without the need for mechanical circulatory support. Acute renal failure with need for dialysis occurred in 9.1% (2/22) patients, which became permanent in 4.5% (1/22).

During hospitalization, 22.7% (5/22) patients were re-intubated and 18.2% (4/22) were on long-term ventilation ($\geq$ 7 days); of these, 9.1% (2/22) patients underwent tracheostomy. Over one-third (40.9% [9/22]) of patients were discharged home, 36.4% (8/22) were discharged into rehabilitation and 13.6% (3/22) to another hospital. One patient died within 30 days and another died in hospital after 3 months. The stroke rate was 18.2% (4/22 patients). Of note, two of these patients had acute cerebral malperfusion with neurological impairment pre-operatively. No cases of paraplegia or spinal cord ischaemia were observed. Delirium was observed in 9.1% (2/22) patients and dysfunction of recurrent nerve in 4.5% (1/22) patients.

DISCUSSION

In this series of 22 patients receiving a new-generation hybrid aortic prosthesis for FET technique (see Fig. 1), the procedural outcomes were excellent and the rate of complications as expected in a patient cohort undergoing complex aortic surgeries. Contrary to previous reports, we observed no cases of increased 'oozing' from the prosthesis, as the amount of chest drain fluid appeared within the expected normal range and the rate of re-thoracotomy for bleeding did not appear elevated. There were no adverse events associated with the prosthesis itself. The use of the E-vita OPEN NEO FET facilitated less complex procedures with reproducibly short operative times.

Comparison with Previous Generations of the Prosthesis

Compared to the international E-vita OPEN registry [5], which documented the outcomes of 1165 patients using predecessor devices (E-vita OPEN prosthesis) starting in 2005, our series of 22 patients included patients of similar age (mean age 60 [median 62] vs. 63 years), while female patients were slightly overrepresented (50.0% in our report, 32% in the registry [5]). Slightly more patients in our report had prior cardiothoracic surgery (27.3%) vs. 24% with previous sternotomy in the registry [5]. On the other hand, approximately equal proportions of patients had peripheral arterial disease, chronic renal failure and a history of stroke; 36.4% of the patients experienced acute dissection, 18.2% had chronic dissection and another 45.5% had chronic true aneurysms compared with 38%, 28% and 34% of patients in the registry, respectively, [5], making our case series comparable regarding baseline characteristics.

We used the axillary artery as an access route in the majority of cases (77.3% vs. 70% in the registry [5]). Contrary to patients in the registry where 94% patients had bilateral selective cerebral perfusion (SCP), most of our patients

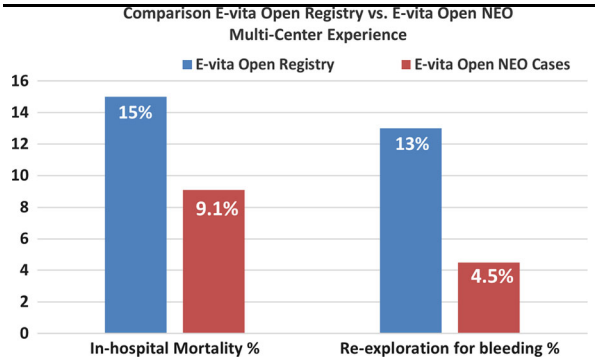


Fig. 2 Results of this study compared to the E-vita Open Registry using a previous generation of the E-vita prosthesis

received unilateral SACP. Furthermore, 72.7% of our patients had their supra-aortic vessels re-implanted separately into the prosthesis, while this rate was only 35% in the registry [5]. Consequently, we mainly used the trifurcated and branched prostheses.

From an outcomes perspective, we experienced 9.1% in-hospital mortality (15% in the registry [5]), and the rate of stroke appeared higher (18.2%) compared to 7% in the registry. Of note, two of the patients with a stroke had cerebral malperfusion at baseline with pre-operative neuological symptoms. The rate of re-thoracotomy for bleeding was lower (4.5% in our cohort, 13% in the registry). A comparison of outcomes between our cohort and the registry is shown in Fig. 2. Further differences between these studies included the rates of renal replacement therapy (9.1% vs. 22%) and low cardiac output syndrome (18.2 vs. 11%). Only one patient (4.5%) underwent re-thoracotomy due to bleeding, which seems low in a patient cohort consisting of mainly surgeries for aortic dissection (compared with 13% in the registry dataset [5]). Our patient cohort, however, was not matched to the patients presented in the registry; therefore, any comparison to their results may be biased. There were no cases of prosthetic "oozing" in our analysis. In contrast, this has been reported previously in three cases [3]. The median overall amount of bleeding within the 24-h post-operative period was 569 ml in our patients with an interquartile range of 338–910 ml. While we found no data to judge the amount of bleeding in the registry, there is no discernible reason why oozing should be an abundant problem with the new prosthesis. A randomized controlled trial is already under way at our centres comparing different types of hybrid prosthesis for thoracic aortic repair.

Implications for Clinical Practice

The E-vita OPEN NEO FET prosthesis was developed based on prior experience with previous generations of the prosthesis and enables transfer of the procedure from aortic zones 2 or 3 into aortic zones 0 or 1 [6]. As also pointed out by Holubec et al., it facilitates surgery through minimally invasive access as the collar anastomoses can be moved up to zones 0 or 1 [2]. A minimally invasive access route, however, was not the routine approach in our cohort of patients. It also appears that the new side branch of the E-vita OPEN NEO prosthesis simplifies the procedure as the use of a Foley catheter to perfuse the lower body is no longer required [6]. Taken together, these features may allow reduced hypothermic circulatory arrest and a decreased risk of paraplegia, which were not observed in our patient cohort.

Limitations

The main limitation of our dataset to fully judge the E-vita Open NEO is the small number of patients. However, a previous report with only three patients concluded there was an increased risked of oozing from this prosthesis [3]; the data presented in this manuscript refute this observation. Our experience is based on our prior extensive experience with previous generations of the prosthesis. Furthermore, as the surgeries were performed between October 2020 and May 2022, the collection of long-term outcome data was not possible. This will be reported and compared to other data at a later stage.

CONCLUSIONS

Outcomes of the latest generation of a hybrid prosthesis for FET technique during aortic surgery were excellent, considering the magnitude of the procedures. The risk of post-operative bleeding did not increase compared to previous generations of the prosthesis. Furthermore, this prosthesis allows for anastomosis in zone 0 or 1, thus facilitating easier and faster procedures and even surgery through minimally invasive access routes. Data with more patients and a longer follow-up are warranted.

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Author Contributions. AELSA, MB, SL, PBe and FB performed the surgeries and documented the cases. AELSA collected all the information and submitted it for statistical analysis. PB and MS performed statistical analysis and wrote the first draft of the manuscript and all authors revised for important intellectual content. All authors approved the final version and the decision to submit and are accountable for all aspects of the work.

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Compliance with Ethics Guidelines. Ethics committee approval was not required due to the observational and retrospective nature of the study without further follow-up. The study was conducted in accordance with the Declaration of Helsinki of 1964 and its later amendments.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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