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Is the flow-safe disposable continuous positive airway pressure (CPAP) system as effective as non-invasive mechanical ventilation (NIMV) in the treatment of acute cardiogenic pulmonary Oedema?

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Background

Acute cardiogenic pulmonary oedema (ACPO) is one of the common causes of acute respiratory failure, constituting 10%–20% of acute heart failure syndromes and potentially causing death [1]. Acute cardiogenic pulmonary oedema usually presents with sudden dyspnoea at rest, impaired exertion capacity, tachypnoea, tachycardia and hypoxia. Increased endogenous catecholamine levels and hypertension due to stress are common in cases with good left ventricular function. Cough is a frequent finding in these cases. In the presence of severe oedema, patients may produce foamy or pink sputum. In these patients, the primary goal is to ensure adequate tissue oxygenation in order to prevent organ dysfunction and multiple organ failure [2].

Treatment options for the management of ACPO in patients with severe respiratory failure include loop diuretics, vasodilating agents, oxygen, non-invasive positive pressure ventilation (NPPV) and endotracheal intubation [3,4]. Several studies report that using NPPV in the early period of ACPO treatment rapidly improves physiological parameters and reduces endotracheal intubation rates as well as the associated complications and mortality [5].

Two main modes of NPPV are applied in the treatment of ACPO: continuous positive airway pressure (CPAP) and bilevel positive airway pressure (BiPAP). It has been shown that both CPAP and BiPAP are well tolerated and do not cause any serious side effects [6,7].

Various CPAP systems have been developed for use in the hospital and, more often, in the pre-hospital period, wherein technological advance processes tend to vary [8]. In recent years, the flow-safe disposable CPAP system (FSD-CPAP-S) has also been used in both pre-emergency and emergency services as an alternative to NIMV for the treatment of respiratory failure in ACPO. However, although there are few studies on FSD-CPAP-S-like CPAP systems, we have not found any study that compares the effectiveness and cost analysis of FSD-CPAP-S with NIMV in ACPO. The aim of this study was to investigate and compare effectiveness and cost analysis between NIMV and FSD-CPAP-S in the early treatment of patients with ACPO admitted to the emergency service.

Methods

This prospective study was conducted between 01 January and 31 December 2018, at a centre receiving approximately 200,000 emergency visits a year.

Patients presenting with sudden-onset severe respiratory distress with tachypnea, tachycardia, hypoxia and acute heart failure findings (paroxysmal nocturnal dyspnoea or orthopnoea, foamy pink or white sputum, moist rales, S3 heart sounds, peripheral oedema, among others) or acute exacerbation of chronic heart failure were evaluated by the emergency physician. After the evaluation of history and physical examination, patients diagnosed with ACPO were treated by the same physician.The diagnosis of ACPO was confirmed by both of the cardiologists and emergency physicians as a result of laboratory and radiological tests (chest x-ray, lung ultrasonography, measurement of plasma natriuretic peptide level and bedside echocardiography).

The study included patients aged over 18 years who were admitted for acute respiratory distress, started on conventional treatment (diuretic, vasopressor, oxygen) following the diagnosis of cardiogenic pulmonary oedema, had a respiratory rate of >25 breaths/min and $SatO_2$ < 90%, lacked any condition that would prevent non-invasive positive pressure support and were planned to receive NPPV support.

The study excluded patients presenting with cardiac and respiratory arrest, those with acute life-threatening multi-organ failure, those with encephalopathy, those who were unconscious, those with inadequate respiratory effort, those who were intubated before or immediately after admission, those with severe upper gastrointestinal bleeding, those who were hypotensive and receiving inotropic support, those with fatal cardiac arrhythmias, aspiration risk and pneumothorax and those with facial trauma, deformity or serious infections.

According to the physician decision, the patients whose respiratory rate and saturation were within the limit values (respiratory rate > 25 breaths/min and $SatO_2$ < 90%) and who were treated isolated oxygen supplementation not NIPPV treatment as respiratory support were not included in the study.

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In terms of respiratory support choice, patients diagnosed with ACPO and receiving conventional treatment were randomised into two groups by assigning odd or even numbers based on their order of admission. Patients with even numbers were treated with Flow-Safe II Disposable Continuous Positive Airway Pressure System (FSD-CPAPII-S; MercuryMed, Florida, USA) (10–15-cm H_2O positive end-expiratory pressure treatment with 10–25 l/min oxygen velocity), while patients with odd numbers were treated with Philips Trilogy 202 portable ventilator (Amsterdam, The Netherlands) device and NPPV (spontaneous ventilation with timed back-up), along with supportive treatment with average volume-assured pressure support and bilevel non-invasive ventilation (inspiratory 15 cm H_2O and expiratory 5 cm H_2O positive air pressures) (Fig. 1).

To ensure that objective numerical data were used in the comparison of both methods, the Ege Acute Cardiogenic Pulmonary Oedema Severity Scoring system (Ege-ACPOSS), which was prepared in accordance with various classifications, such as the Killip classification and the modified Borg classification used to define heart failure and respiratory severity, was used in the present study (Table 1) [9,10].This scoring system was designed by emergency physicians and cardiologists who manage a large number of ACPO patients in our hospital.

Blood pressure, pulse, respiratory rate, saturation, blood gas parameters and severity values calculated by the Ege-ACPOSS were recorded on the patient follow-up form at the time of admission and the 30th and 60th min after admission.The study time began with the initial evaluation of ACPO patients at the time of admission (zero minutes). Physiological and laboratory assessments made at this time were recorded as zero-minute data for the study.

Table 1
Ege Acute Cardiogenic Pulmonary Oedema Severity Scoring (Ege-ACPOSS)

Point	0	1	2	3
Respiratory rate (/minute)	<20	20–25	25–30	>30
Saturation	> % 90	%85–89	%70–84	<%70
Modified Borg scale	0–4	5–6	7–8	9–10
Orthopnoea	None	Moderate	–	Hard + Agitation
Rales	None	<%50	–	>%50
Bronchospasm	None	Moderate	Quiet lung	–
Accessory muscles of respiration	None	Effective	–	Effective + Agitation
Skin pallor- poor perfusion	None	–	Lower extremities	Whole body

Modified Borg scale: *0 = None; 0–4 = Something hard;5–6 = Hard;7–8 = Very hard; 9–10 = Very very hard (maximum).*

Statistical analysis

IBM SPSS Statistics 25.0 Software was used in all analyses. Kolmogorov–Smirnov ($n \geq 50$) test was used to check the normality of numerical variables. Numerical variables were presented as mean and standard deviation or as median (min–max). Categorical variables were presented as numbers and percentages. Independent samples *t*-test was used for variables that were normally distributed, while the Mann–Whitney *U* test was used for variables that were non-normally

Fig. 1. Flow-Safe II Disposable Continuous Positive Airway Pressure System (FSD-CPAPII-S; MercuryMed, Florida, USA).

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distributed. Chi-square test was used for categorical variables. Repeated measures variance analysis was performed for variables checked at different time points. In case of significance, binary comparisons were made with the Bonferroni test. For all hypotheses, a value of $p < .05$ was considered statistically significant. Time dependent changes of the variables in the study were analyzed by means of repeated measurement ANOVA. Repeated measurement ANOVA results were not similar in the time-dependent change in groups(interaction <0.1) so time analysis was repeated with ANOVA for each group.As a result of this analysis if time was statistically significant, binary time comparisons applied with Bonferroni correction and dependent *t*-test. After that, the groups were compared with zero minute independent group t-test.The groups 30 min and 60 min were compared with covariance analysis in which the pretest was taken as covariate. In the results where the interaction was not significant and time was significant, binary time comparisons were given by appliying Bonferroni correction with *t*-test.

Results

Of the 252 patients diagnosed with ACPO, 46 patients recieved isolated oxygen support and 16 patients were intubated (at the site of incident, during transportation or immediately after admission) so these patients were consequently excluded from the study. 190 patients receiving NIMV and FSD-CPAP-S support were included in the study. But 9 of these patients were not included in the analysis because they were intubated within the first 1 h after the start of treatment (five patients in the FSD-CPAP-S group, four patients in the NIMV group) Eventually the study completed with 181 patients. (Fig. 2).

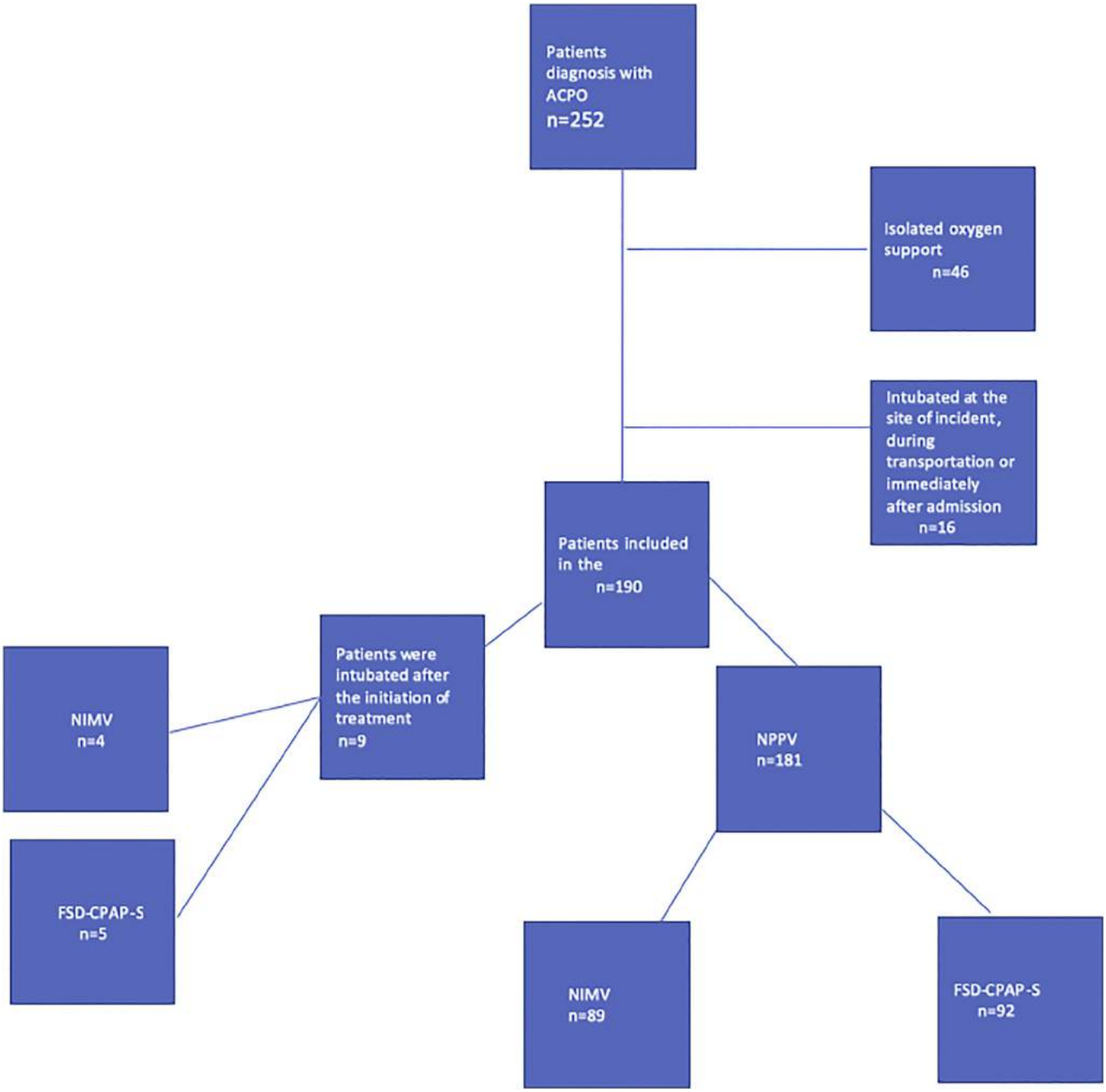

Fig. 2. Distribution of patients diagnosed with ACPO.

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Table 2
The demographic data of two groups

	Total	FSD-CPAP-S	NIMV	*p*
n (%)	181(100)	92(50.8)	89 (49.2)	
Age (year)	71.5(±11.1)	73.8(±9.6)	69.1(±12)	0.004*
Male (n;%)	87(48.1)	37(40.2)	50 (56.2)	0.032*
Female (n;%)	94(51.9)	55(59.8)	39 (43.8)	
ACPO history (n;%)	65(35.9)	32(49.2)	33 (50.8)	0.748
HT (n;%)	136(75.1)	71(52.2)	65 (47.8)	0.519
CHF (n;%)	119(65.7)	62(52.1)	57 (47.9)	0.635
CAD (n;%)	97(53.6)	51(52.6)	46 (47.4)	0.613
DM (n;%)	72(39.8)	39(54.2)	33 (45.8)	0.465
COPD (n;%)	47(26)	17(36.2)	30 (63.8)	0.019*
Valvulopaty (n;%)	35(19.3)	10(28.6)	25 (71.4)	0.003*
AF (n;%)	20(11)	10(50)	10 (50)	0.937
CRF (n;%)	14(7.7)	8(57.1)	6 (6.9)	0.623
CVD (n;%)	12(6.6)	6(50)	6 (50)	0.953

ACPO: Acute Cardiogenic Pulmonary Oedema; HT:Hypertension; CHF: Congestive Heart Failure: CAD: Coronary Artery disease; DM: diabetes mellitus; COPD: Chronic Obstructive Pulmonary Disease; AF: atrial fibrillation; CRF: Chronic Renal Failure; CVD:Cerebrovascular Disease.

The demographic data, vital signs, blood gas analysis and Ege-ACPOSS of the patients and the cost analysis (this includes laboratory, radiological tests, medicines and equipments in the emergency department) results are given in Tables 2 and 3.

In 181 patients analyzed in the study, no mortality was reported within the first 24 h and first 7 days. Six patients died within 30 days, four of whom belonged to the FSD-CPAP-S group and two to the NIMV group.In the first 7 days, seven out of nine patients who were intubated after the initiation of noninvasive positive pressure respiratory support therapy died.

Discussion

NPPV is one of the most important steps in the treatment of respiratory failure in ACPO. In the present study, we found that FSD-CPAP-S is as effective as NIMV in improving blood pressure, pulse, respiration rate and blood gas parameters in patients with ACPO. In addition to the factors that increase the utility of FSD-CPAP-S in emergency practice, such as the fact that FSD-CPAP-S is not an electronic system, its portability, and its individual and disposable use, we believe that FSD-CPAP-S can be used as an effective alternative to NIMV in the treatment of ACPO, especially in emergency services with little to no mechanical ventilation available and large number of incoming patients.

Nowadays, many centres apply NPPV as a standard treatment for ACPO in addition to conventional treatments. The European Society of Cardiology states that the respiratory rates and saturation values at the time of admission of patients with acute heart failure also serve as a guide for NPPV treatment, and that in patients with a respiratory rate > 25 breaths/min and an SpO_2 < 90%, NPPV should be administered as early as possible (recommendation class IIa, level of evidence B) [3]. The guideline also recommends saturation monitoring (recommendation class 1, level of evidence C) as well as monitoring for blood pH, pCO_2 and, if possible, lactate (recommendation class IIa, level of evidence C) during acute heart failure. In the present study, we compared the effectiveness of FSD-CPAP-S and NIMV in ACPO treatment by using the parameters suggested by the guideline and a scoring system (Ege-ACPOSS) that has been planned and developed to be used in the emergency service, and which we believe will provide the means for a more objective evaluation. We found that the patients for both group, blood pressure, pulse respiratory rate, saturation values, pH, pCO_2 and lactate parameters, base excess (BE) and HCO_3 values approached normal values in parallel with their clinical improvement. At the same time,

Table 3
Comparison of parameters for two groups at 0, 30 and 60 min

	Time(minute)	Total	FSD-CPAP-S	NIMV	*P (interaction - group)*
SBP (mm/Hg)	0	197.3 (±26.3)	196.2 (±25.2)	198.3 (±27.5)	
	30	156.2 (±26.1)	158.7 (±24.8)	153.6 (±27.2)	0.095–0.352
	60	138.7 (±21.4)	141.2 (±20.9)	136.0 (±21.6)	
DBP (mm/Hg)	0	108.4 (±20.2)	106.1 (±19.6)	110.9 (±20.7)	
	30	85.2 (±18.4)	84.5 (±16.5)	85.9 (±20.2)	0.430–0.228
	60	75.2 (±16.4)	74.4 (±14.4)	76.0 (±18.3)	
HR (/minute)	0	117.5 (±22.6)	116.5 (±20.2)	118.4 (±24.9)	
	30	100.2 (±21.3)	99.3 (±21.2)	101.2 (±21.4)	0.940–0.553
	60	92.0 (±19.3)	91.4 (±20.1)	92.6 (±18.5)	
BR (/minute)	0	29.1 (±5.3)	28.3 (±4.9)	30.0 (±5.5)	
	30	22.1 (±4.4)	22.2 (±4.1)	22.0 (±74.7)	0.003*-0.497
	60	20.3 (±2.9)	20.5 (±2.8)	20.0 (±3.0)	
SO2 (%)	0	79.4 (±9.0)	79.6 (±8.3)	79.2 (±9.6)	
	30	93.7 (±4.5)	93.1 (±4.5)	94.4 (±4.5)	0.360–0.626
	60	96.2 (±2.4)	96.2 (±2.4)	96.2 (±2.3)	
pH	0	7.23 (±0.09)	7.24 (±0.08)	7.21 (±0.10)	
	30	7.34 (±0.06)	7.34 (±0.05)	7.34 (±0.06)	0.009*-0.096
	60	7.39 (±0.04)	7.40 (±0.04)	7.39 (±0.04)	
pCO2 (kPa)	0	53.1 (±14.8)	48.7 (±10.1)	57.6 (±17.3)	
	30	41.8 (±9.2)	41.1 (±8.4)	42.4 (±10.1)	0.274–0.005*
	60	39.9 (±9.0)	40.0 (±10.5)	39.8 (±7.2)	
HCO3 (mmol/L)	0	20.8 (±4.2)	20.3 (±4.2)	21.3 (±4.2)	
	30	22.2 (±4.2)	22.2 (±4.5)	22.3 (±3.9)	0.203–0.404
	60	23.8 (±3.7)	23.6 (±3.7)	23.9 (±3.7)	
BE (mmol/L)	0	−5.5 (±4.4)	−5.7 (±4.5)	−5.3 (±4.2)	
	30	−2.6 (±4.1)	−2.7 (±4.5)	−2.5 (±3.7)	0.924–0.657
	60	−0.4 (±3.7)	−0.4 (±3.8)	−0.3 (±3.6)	
Lactate (mmol/L)	0	4.2 (±2.2)	4.0 (±2.1)	4.3 (±2.3)	
	30	2.1 (±1.3)	2.1 (±1.5)	2.1 (±1.0)	0.291–0.485
	60	1.6 (±0.8)	1.5 (±0.8)	1.7 (±0.8)	
Ege-ACPOSS	0	13.9 (±3.6)	13.8 (±4.1)	13.9 (±3.0)	
	30	3.8 (±2.0)	4.1 (±2.0)	3.5 (±1.9)	0.191–0.541
	60	1.5 (±1.0)	1.5 (±1.0)	1.5 (±1.1)	
Cost analysis (TL)	–	–	802.5 ± 222.6	701.4 ± 284.4	0.001

SBP:Systolic Blood Presure; DBP:Dyastolic Blood Presure; HR:Heart Rate; BR:Breath Rate; SO2; Haemoglobin Oxygen Saturation; pH: power of Hydrogen; pCO2: Carbon Dioxide Partial Pressure, HCO3: Bicarbonate. BE: Base Excess TL:Turkish Lira.

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we found that normalization of carbon dioxide levels between 0 and 60 min was more effective in the NIMV group.

While NIMV is one of the most preferred modalities in the initial treatment of ACPO, the number of devices that can administer NIMV in the emergency services is limited. For this reason, there may be a need for alternative devices that can be as effective as NIMV in units with large numbers of patients and with limited number of devices that can administer NIMV, especially during the pre-hospital period. Nowadays, there are various CPAP devices with no electronic components, which were developed for the pre-hospital period rather than the hospital period when they were first produced, that could serve as an alternative to NIMV (Orofacial mask devices [Ventumask (StarMed, Mirandola, Italy), EasyVent (Dimar, Mirandola, Italy), Boussignac CPAP system (Vygon, E'couen, France)] and helmet-type devices [Ventukit (StarMed Mirandola, Italy) and EVE Coulisse (Dimar Mirandola, Italy)]). Of these devices, EasyVent and EVE Coulisse systems have been reported to have the best overall performance in terms of effectiveness and efficiency, while the use of the Boussignac CPAP system in coronary care units is reported to be both beneficial and cost-effective [11-13].

While the average cost of FSD-CPAP-S treatment is higher than NIMV, the difference is small. Considering that the device cost is not included in this calculation because the NIMV device is a fixed asset and that the treatment cost is calculated only for equipment such as masks and hoses, the difference between the two treatment methods is very small.

There were certain limitations in this study. Patients could not be equally distributed into the two treatment groups. In the FSD-CPAP-S group, mean age was higher, female patients were predominant and the number of patients with chronic obstructive pulmonary disease and heart valve disease was lower. The Ege-ACPOS system we designed for the study is a nonvalidated scoring system. Isolated oxygen supplementation depends on physician decision and may be preferred for patients with respiratory rate and saturation at the limit level. Although the respiratory rate, pCO_2 and pH values were similar in both groups at the time of admission, there was a statistically significant difference between the two groups. In addition, among the blood gas data, pO_2 data were not included in the evaluations because higher than normal pO_2 results would have been obtained and led to misinterpretation.

Conclusion

The flow-safe disposable CPAP system can be as effective as NIMV in patients with ACPO. Considering the overall improvement observed in the physiological blood gas and other parameters as well as the mortality and cost-related considerations, FSD-CPAP-S can be preferred in emergency services if there are insufficient NIMV devices.

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Conflict of interest

The authors have no commercial associations or sources of support that might pose a conflict of interest.

Ethical approval and consent to participate.

The study was approved by the local ethics committee and the medical device ethics committee of the Ministry of Health. Written and verbal informed consents were obtained from the patients who agreed to participate in the study.

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