

Vascular complications after peripheral veno-arterial extracorporeal life support cannulation in cardiogenic shock

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ABSTRACT

Background: Extra Corporeal Life Support (ECLS) is an evolving therapy in therapy-resistant cardiogenic shock (CS). Vascular cannulation in emergency situations can be accomplished through puncture of the femoral vessels by specialised teams. Since lower limb ischemia constitutes one of the major complications following cannulation, a distal perfusion cannula (DPC) has emerged as standard of care. We here aimed to analyse the impact of the DPC on limb perfusion and 6-month survival rate.

Methods: In a retrospective study from January 2012 to December 2018, 98 patients with cardiogenic shock and peripheral (v-a) ECLS implantation with documented limb perfusion status were identified and analysed. Demographic data, laboratory parameters, cause of CS, comorbidities, limb perfusion complications and complication management were analysed.

Results: 53 patients (54%) received ECLS therapy in referral centers by our mobile ECLS team, while in 45 patients (46%) the cannulation occurred in our center. 71 patients (72%) received a DPC (group A) at the time of ECLS implantation, whereas 27 (28%) (group B) did not or received later (14 patients owing to limb ischemia). 44 patients (45%) developed limb ischemia as a complication of ECLS therapy (31% in group A and 81% in group B- $p < 0.001$). The 6-month survival rate was 28% in our study cohort (30% in group A and 22% in group B- $p = 0.469$).

Conclusion: Lower limb ischemia remains a serious complication after peripheral ECLS cannulation in CS, especially when a DPC is absent. Standardised DPC implementation may reduce the rate of severe limb complications in peripheral ECLS.

1. Introduction

Extracorporeal life support (ECLS) is an evolving treatment for acute cardiac or cardiopulmonary failure in therapy-refractory cardiogenic shock (CS) [1,2]. Criteria for a refractory cardiogenic shock are a CPO (cardiac power output) < 0.6 W, a CI (cardiac index) < 2.2 l/min/m² with vasopressors/inotropes and a lactic acidosis (lactate > 2 mmol/l) [3]. In case of emergency, femoral access is preferred for veno-arterial

(v-a) ECLS cannulation [4,5]. In cases when a cardiac catheterisation laboratory is not available, this may be performed at bedside in the intensive care unit or emergency department. In many cases ECLS is performed during cardiopulmonary resuscitation (CPR) by the rapid response team (RRT) [6]. However, peripheral ECLS therapy is associated with complications. Among these, limb ischemia in various grades has been reported in up to 52–70% of cases [6,7,8,9,10]. To maintain limb perfusion a distal perfusion cannula (DPC) has emerged as standard

Abbreviations: ACT, activated clotting time; aPTT, activated partial thromboplastin time; BSA, body surface area; CFA, common femoral artery; CI, cardiac index; CPO, cardiac power output; CPR, cardiopulmonary resuscitation; CS, cardiogenic shock; DPC, distal perfusion cannula; ECLS, extracorporeal life support; Fr, French; NIRS, near-infrared reflectance spectroscopy; PAD, peripheral arterial disease; RRT, rapid response team; rSO₂, regional oxygen saturation; SFA, superficial femoral artery; v-a, veno-arterial.

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of care in tertiary heart failure centers. The aim of this study was to evaluate 1) the ECLS results focusing on limb perfusion as well as 2) the impact of the prophylactic DPC placement on lower limb ischemia prevention.

2. Methods

2.1. Patients and data retrieval

In this retrospective single center study between January 2012 and December 2018, 98 patients who were treated with peripheral ECLS in CS and had a documented limb perfusion status were included and analysed. Altogether 155 patients were treated from January 2012 to December 2018 with peripheral ECLS in our center. 57 patients were excluded from the study due to elective cannulation by non-cardiogenic shock and/or incomplete documentation of the lower limb perfusion status. All clinical data were collected from our institutional database and anonymised through generalisation. The study protocol was approved by the local committee for ethics (protocol number: 19-9068-BO, University Hospital Essen, Essen, Germany).

2.2. ECLS protocol

Femoral cannulation was performed either percutaneously using Seldinger technique or surgically. For the implantation of the ECLS, arterial cannulas between 15 and 19 French (Fr) and venous cannulas between 21 and 25 Fr were used. Cannulation for ECLS is always performed by an experienced cardiothoracic surgeon. The members of the team do at least one cannulation per week. Our institution has introduced since 2016 a cannulation strategy using small-lumen (15 Fr) arterial cannulas as a preventive measure against lower limb ischemia. In addition, a specially designed 7 Fr catheter-distal perfusion cannula (DPC-CruraSave® femoral perfusion set, Free-life Medical) has been placed distally through the superficial femoral artery (SFA) to ensure perfusion of the dependent extremity.

All patients undergoing femoral ECLS cannulation were considered for primary DPC insertion. However the ultimate decision was left to the discretion of the implanting surgeon, bearing in mind that DPC placement is a technically demanding and not always feasible procedure, especially in patients presenting with a known history of peripheral arterial disease (PAD) or severely deranged haemodynamics with global hypoperfusion, thus making them unlikely to receive a DPC during primary cannulation.

As long as the ECLS was established, an effective anticoagulation through intravenous administration of unfractionated heparin was carried out to avoid thromboembolic complications. The heparin effect was evaluated with measurement of the activated clotting time (ACT), with an ACT target range at 160 to 180 s. As an alternative or parallel to the ACT measurement, the anticoagulation was monitored through calculation of the activated partial thromboplastin time (aPTT), with a target range at 1.5 times the reference range (45 to 60 s).

All patients with peripheral ECLS were monitored in the cardiac surgery intensive care unit. A consistent control of the limb perfusion in terms of clinical examination and Doppler sonography was carried out, focusing on the examination of peripheral pulses. At our center we have introduced a thorough hourly observation protocol by nursing and medical staff since 2016. This protocol includes bilateral clinical evaluation (skin temperature, appearance, capillary refill time), Doppler pulse control, ECLS and DPC flow assessment. Acute limb ischemia was defined consistently over time as a sudden decrease in limb perfusion that causes a potential threat to limb viability. The early detection of limb ischemia was based on the above mentioned clinical signs and diagnostic tools, paying attention to the absence of peripheral pulses, as well as the presence of a pale and cold lower extremity.

Furthermore, in patients presenting with profound hypoperfusion, bilateral clinical examination and comparison with the not cannulated

extremity was helpful to determine the degree of limb ischemia, which was attributed to the cannulation itself.

Regarding the ECLS explantation, the majority of peripheral ECLS were explanted surgically after successful weaning of the system. Occasionally, following punctures below the inguinal ligament, the cannulas were removed using a femoral compression system (Femostop™ femoral compression system, Abbott Laboratories).

2.3. Statistical analysis

All statistical analyses were performed using IBM SPSS Statistic 27 software (SPSS Inc., Chicago, Illinois, United States). The mean value and standard deviation were determined for the results of the quantitative measurements. Comparisons between groups were made using the Mann-Whitney *U* test and the Kruskal-Wallis *H* test in independent samples. To quantify the test results in a comparable manner, asymptotic significance was displayed and exact *p* values were calculated. The level of significance was set at 0.05 ($p < 0.05$).

3. Results

3.1. Patient characteristics and ECLS parameters

Patients were divided into two groups: Group A consisted of 71 patients who had a DPC primarily placed at the time of cannulation (prophylactic placement), whereas group B consisted of 27 patients without a DPC placed at the time of cannulation. Table 1 provides an overview of patient demographics, comorbidities, etiology and characteristics of ECLS therapy.

3.2. Limb ischemia and treatment

44 patients (45%) showed lower limb ischemia as a complication of ECLS therapy (31% in group A and 81% in group B- $p < 0.001$). A compartment syndrome with a subsequent fasciotomy was present in 9 patients (9%- 6% in group A and 19% in group B- $p = 0.05$).

Table 1

Patient demographics, comorbidities, etiology and characteristics of ECLS therapy. Group A: patients with preemptive DPC placement, group B: patients without preemptive DPC placement.

	Patients (N = 98)	Group A: with DPC (N = 71)	Group B: without DPC (N = 27)	p value
Male gender	69 (70%)	50 (70%)	19 (70%)	0.996
Mean age, years (range)	55.8 (18–86)	55.1 (18–86)	57.8 (23–82)	0.538
Arterial hypertension	51 (52%)	37 (52%)	14 (52%)	0.982
Renal insufficiency	64 (65%)	42 (59%)	22 (81%)	0.039
Diabetes mellitus	19 (19%)	12 (17%)	7 (26%)	0.709
Peripheral arterial disease	19 (19%)	13 (18%)	6 (22%)	0.663
Hypercholesterolemia	10 (10%)	5 (7%)	5 (19%)	0.095
Ischemic cardiomyopathy	72 (73%)	51 (72%)	21 (78%)	0.553
Dilated cardiomyopathy	9 (9%)	7 (10%)	2 (7%)	0.709
Implantation during cardiopulmonary resuscitation	60 (61%)	44 (62%)	16 (59%)	0.806
Heart failure - cardiogenic shock	50 (51%)	36 (51%)	14 (52%)	0.920
Acute myocardial infarction - cardiogenic shock	48 (49%)	35 (49%)	13 (48%)	0.920
Percutaneous cannulation	83 (85%)	66 (93%)	17 (63%)	<0.001
Bilateral cannulation	24 (24%)	17 (24%)	7 (26%)	0.839
Implantation by mobile ECLS team	53 (54%)	38 (54%)	15 (56%)	0.857
Mean duration of ECLS therapy (hours)	100	107	81	0.023

Note: Statistically significant values are written in bold ($p < 0.05$).

Furthermore, for 3 patients (3%) an amputation was necessary (3% in group A and 4% in group B- $p = 0.821$) (Fig. 1, Fig. 2).

Regarding the later management of lower limb ischemia, 14 of the 27 patients in group B (52%) received a distal limb perfusion cannula at a later timepoint. Additionally, a conversion to central ECLS through cannulation of the ascending aorta with simultaneous thromboendarterectomy and reconstruction of the femoral vessels was applied to 20 patients (20%- 14% in group A and 37% in group B), following consultation and cooperation with the vascular surgery department of our institution. A surgical revision of the ECLS therapy owing to vascular complications was applied to 33 patients (34%- 21% in group A and 67% in group B- $p < 0.001$). Moreover, a vascular surgical consultation was necessary for 44 of our patients (45%- 37% in group A and 67% in group B- $p = 0.008$). Table 2 provides an overview of the incidence of the complications regarding lower limb perfusion and their treatment.

3.3. Factors associated to lower limb ischemia and evolution of the ECLS therapy over time

Regarding the factors associated to lower limb ischemia, peripheral arterial disease (PAD) was the only predictor in our study (79% of patients with PAD showed limb ischemia- $p = 0.001$; Supplemental Table 1). Other factors and comorbidities, such as diabetes mellitus ($p = 0.810$; Supplemental Table 2), female gender ($p = 0.381$; Supplemental Table 3) and younger age ($p = 0.716$; Supplemental Table 4) were not proven to be significant in our study. The presence of cardiopulmonary resuscitation (CPR) did not contribute to manifest lower limb ischemia ($p = 0.980$; Supplemental Table 5).

With reference to the evolution of the ECLS therapy over time, we have introduced in our institution since 2016 a cannulation strategy using small size arterial cannulas (15 Fr) combined with standardized DPC placement to establish peripheral ECLS. Prior to 2016 predominantly 19 Fr and 17 Fr arterial cannulas were used (period I), whereas since 2016 15 Fr cannulas were used (period II). Comparing the results of the two periods (period I: 2012–2015 and period II: 2016–2018) we point out a lower incidence of lower limb ischemia in period II (38%) compared to period I (62%- $p = 0.028$, Fig. 3; Supplemental Table 6).

3.4. Other vascular complications and 6-month survival

Bleeding complications with formation of groin hematoma and consequent surgical treatment, following cannulation for peripheral ECLS were present in 7 patients of our study (7%), equally distributed in both groups (7% in group A and 7% in group B). 4 patients (4%- 3% in group A and 7% in group B) presented with a thrombosis of the distal perfusion cannula (DPC) and a subsequent DPC replacement was necessary. Furthermore, 1 patient in group A (1%) presented with a dissection of the common femoral artery (CFA) and similarly wound healing complications owing to ECLS therapy occurred to 1 patient of group A (1%).

In addition, the 6-month survival rate was examined. This was 28% in both groups (27 patients). Although there was a higher 6-month survival rate in group A (30%) compared to group B (22%), there was no statistical significance ($p = 0.469$; Supplemental Table 7).

4. Discussion

Our study results demonstrated 1) a difference between the two groups regarding lower limb ischemia incidence. 2) The preemptive DPC placement may have a beneficial effect. Furthermore, 3) the incidence of compartment syndrome with fasciotomy was lower in group A, whereas 4) the amputation rate was not different between the two groups.

Lower limb ischemia in patients with peripheral ECLS has a multifactorial genesis. The principal mechanism is a reduced blood flow and consequent oxygen supply, which arises from a deficit of arterial perfusion to distal tissues [11]. The typical symptoms of acute limb ischemia were described by Pratt in 1954 as follows (“6P’s”): i) Pain, ii) pallor, iii) pulselessness, iv) paresthesia, v) paralysis, vi) prostration (shock) [12]. Furthermore, reperfusion of the ischemic limb by re-establishing distal flow may represent an additional threat resulting in acute compartment syndrome owing to inflammatory mediators released into the systemic circulation, causing rhabdomyolysis, systemic inflammatory response syndrome (SIRS) and multi-organ dysfunction [11,13,14].

The benefit of prophylactic DPC placement regarding lower limb ischemia prevention is highly significant ($p < 0.001$; Fig. 1, Fig. 2). In our institution a 7 Fr catheter was inserted using Seldinger technique through the superficial femoral artery (SFA) mainly percutaneously

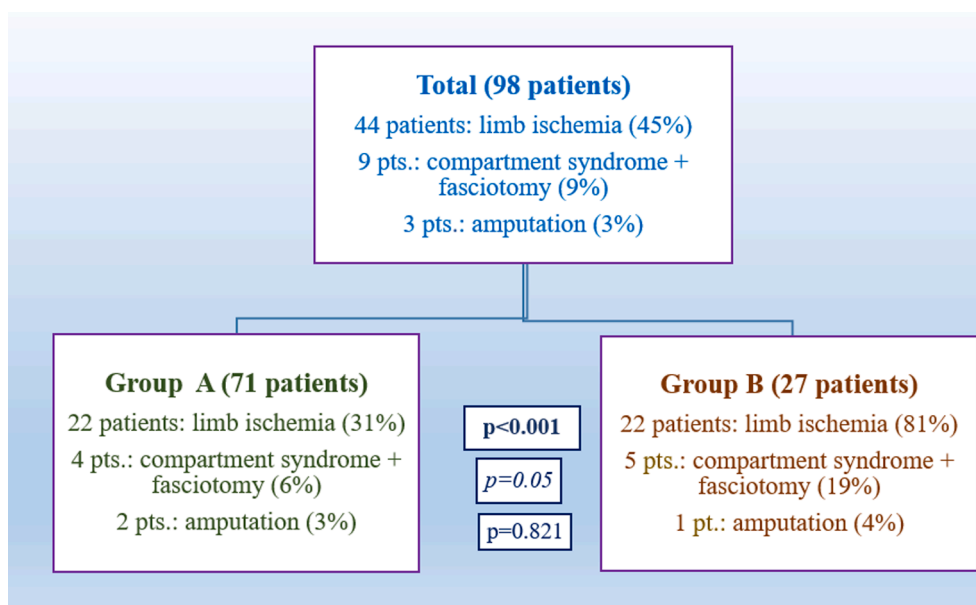


Fig. 1. Incidence of lower limb ischemia, compartment syndrome with fasciotomy and amputation as complications of peripheral ECLS therapy. Group A: patients with preemptive DPC placement, group B: patients without preemptive DPC placement.

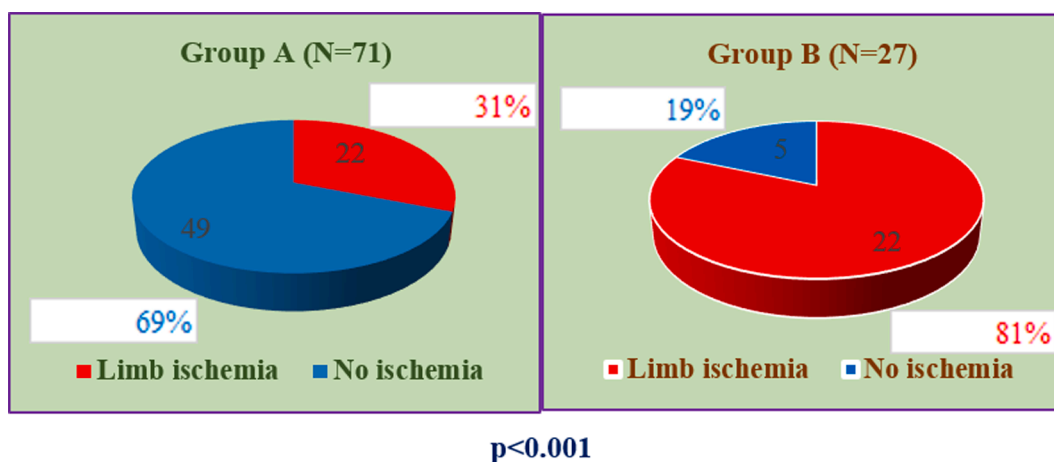


Fig. 2. Comparison of lower limb ischemia incidence between group A and group B as a complication of peripheral ECLS therapy. Group A: patients with preemptive DPC placement, group B: patients without preemptive DPC placement.

Table 2

Incidence of the complications regarding lower limb perfusion and their treatment. Group A: patients with preemptive DPC placement, group B: patients without preemptive DPC placement.

	Group A: with DPC (N = 71)	Group B: without DPC (N = 27)	p value
Ischemia (45%)	22 (31%)	22 (81%)	<0.001
Revision (34%)	15 (21%)	18 (67%)	<0.001
Vascular surgical consultation (45%)	26 (37%)	18 (67%)	0.008
Compartment/ fasciotomy (9%)	4 (6%)	5 (19%)	0.05
Amputation (3%)	2 (3%)	1 (4%)	0.821

Note: Statistically significant values are written in bold ($p < 0.05$).

(93%) to establish antegrade lower limb perfusion. Concerning the timing of the insertion, we insert the distal arterial wire first, as the placement is much more difficult if the femoral artery is already cannulated. To our best knowledge the 7 Fr catheter is a commercially available product with the biggest diameter for this purpose. Additionally this cannula provides significant flow via the femoral vessels. Better outcomes have been observed when the distal perfusion was initiated as early as possible [6]. Furthermore, a delayed distal cannulation failed to prevent ischemia which developed during peripheral ECLS [15,16].

Comparing the results of our investigation with previous studies we could consider the following: The study group of Ranney *et al.* [16] demonstrated the preventive role of the DPC placement, however without statistical significance ($p = 0.483$). The study group of Yeo *et al.* [15] demonstrated the utility of the DPC placement in preventing limb ischemia with statistical significance ($p = 0.036$). Nevertheless the proportion of the patients who were treated primarily with a DPC was distinctly lower (29%- 44 of total 151 patients).

The primary aim is to use the smallest available arterial cannula

according to patient size. A protocol of using a small size arterial cannula (15 Fr) has been documented with promising results of clinical support and lower rate of vascular complications [17]. As far as the cannulation site selection is concerned, bilateral groin cannulation (one cannula in one groin, the other in the contralateral one) should be preferred, due to the reduction of vessel compression and the avoidance of the associated venous congestion in the same limb [11,18].

Monitoring distal perfusion in peripheral ECLS is of paramount importance in order to timely detect and treat lower limb ischemia. Any suspicion of limb ischemia should lead to an increase in monitoring to reach a complete diagnosis. Diagnostic tools include clinical examination followed by Doppler sonography with eventual angiography and further involvement of a multi-disciplinary team [8]. At our center we have introduced a thorough hourly observation protocol by nursing and medical staff since 2016, with positive effect on limb and patient outcomes (Fig. 3). A further diagnostic tool for early detection of limb ischemia comprises the use of near-infrared reflectance spectroscopy (NIRS) which includes measurements of regional oxygen saturation (rSO_2), helping to differentiate between cannula-related obstruction and other causes of hypoperfusion [11,19].

With regard to the treatment of lower limb ischemia, one key to decision is to distinguish a threatened from a nonviable extremity, bearing in mind that limb ischemia is largely transient and the possibility of limb salvage is less likely, the longer the symptoms are present [11]. An early involvement of a vascular surgeon, particularly in patients presenting with peripheral arterial disease (PAD), should be considered regarding ECLS decannulation and vascular reconstruction [6,9,20]. Common invasive strategies, after the conservative management has failed, include removal and reposition of the arterial cannula (contralateral limb, subclavian/axillary artery or aortic cannulation), repair of the femoral artery with suture or bovine pericardial patch angioplasty, Fogarty-catheter based embolectomy, lower limb fasciotomy for acute compartment syndrome and amputation [11,21,22]. In our study a vascular surgical consultation owing to vascular complications was needed in 44 of our patients (45%- 37% in group A and 67% in group B- $p = 0.008$) and is now implemented as a clinical routine. To avoid vascular complications we would suggest the following recommendation: 1) Bilateral groin cannulation. 2) Early use of DPC. 3) Optimisation of the size of DPC and arterial cannula according to BSA (body surface area). 4) Targeted pump output. 5) Monitoring of distal perfusion (rSO_2 , NIRS). 6) Early involvement of a vascular surgeon.

5. Limitations

The limitations of this single-center study arise from its retrospective

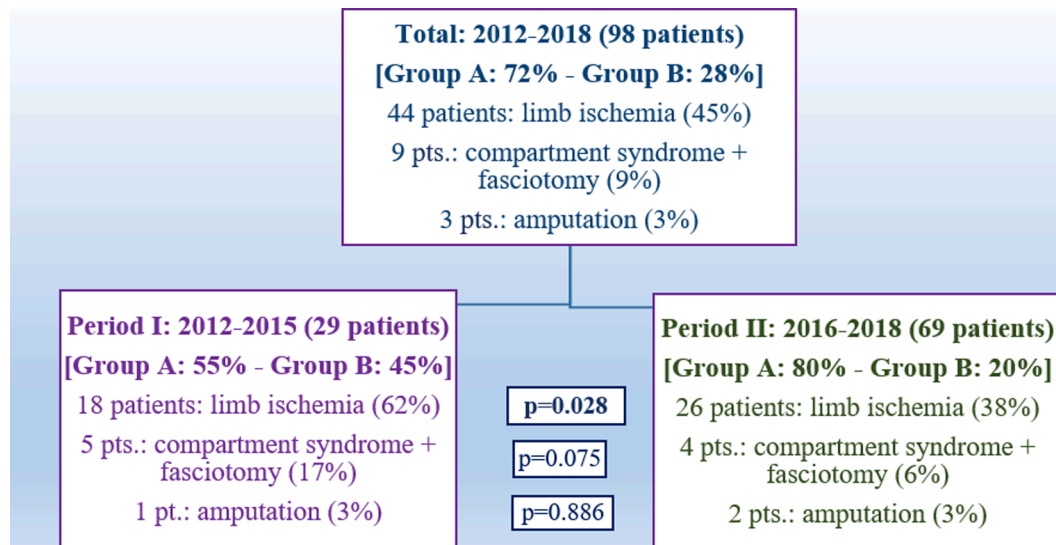


Fig. 3. Comparison of vascular complications incidence between period I (2012–2015) and period II (2016–2018). Group A: patients with preemptive DPC placement, group B: patients without preemptive DPC placement.

nature with potential bias regarding patient selection for primary DPC placement and results. Furthermore, our institution has changed over time to a cannulation strategy using smaller arterial cannulas combined with DPC, whereas post implantation monitoring protocols have been improved over time, thus making comparison of different time intervals prone to bias.

6. Conclusion

Lower limb ischemia remains a frequent complication after peripheral ECLS cannulation in cardiogenic shock, particularly if preventive strategies are not adopted. Standardised preemptive use of an antegrade distal limb perfusion cannula (DPC) and a small size arterial cannula (15 Fr) as well as an intensive hourly observation protocol may be beneficial. Continuous surveillance regarding lower limb perfusion, combined with a rapid reaction to clinical symptoms of ischemia and a punctual interdisciplinary cooperation contribute to avoid long-term serious problems.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Author Contributions

Christos Ilias MD participated in the design, collection, analysis and interpretation of the data, as well as drafting, revision and submission of the article. Professor Achim Koch MD participated in the design, collection, analysis and interpretation of the data, as well as drafting and revision of the article. Maria Papathanasiou MD participated in the design, collection, analysis and interpretation of the data, as well as drafting and revision of the article. Professor Peter Ludike MD

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Registration number of clinical study

19-9068-BO

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ijcha.2023.101230>.

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