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Mobile Cardiac Catheterization for Critical Cardiovascular Disease: A Feasibility and Applicability Study

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Keywords

Mobile cardiac catheterization laboratory · Critical cardiovascular disease · Coronary artery disease · ST-elevation myocardial infarction

Abstract

Introduction: Coronary angiography and percutaneous coronary intervention are essential for managing coronary artery disease, particularly in acute settings such as ST-elevation myocardial infarction. Mobile cardiac catheterization laboratories provide a potential solution for maintaining interventional cardiology services during hospital renovations, disasters, or in resource-limited settings. This study aimed to evaluate feasibility, safety, and quality of care of a mobile cardiac catheterization laboratory compared to a stationary facility. ***Methods:*** A retrospective analysis was conducted, comparing 1,454 patients treated between 2016 and 2019 at either an interim mobile cardiac catheterization laboratory or a stationary facility. Key endpoints included door-to-balloon time, radiation dose, fluoroscopy time, contrast medium usage, and major adverse cardiac events. ***Results:*** The door-to-balloon time was comparable between mobile and stationary facility (29 vs. 33 min, $p = 0.143$). Although fluoroscopy time and radiation dose were significantly higher in the mobile unit ($p < 0.001$), no differences in major adverse cardiac events were observed. The mobile unit demonstrated feasibility and safety for both routine and emergency interventions. ***Conclusion:*** Mobile cardiac catheterization laboratories are a viable alternative for providing interventional cardiology services in various scenarios, including renovations, crises, and underserved regions. Optimizing equipment and workflows could further enhance their performance.

Introduction

Coronary angiography and percutaneous coronary intervention (PCI) are well established diagnostic and therapeutic procedures for coronary artery disease (CAD) [1]. In addition to diagnostic evaluations and treatment for

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stable CAD, these procedures are particularly important in the urgent management of acute coronary syndrome (ACS) patient care. ST-elevation myocardial infarction (STEMI) represents the most critical scenario. Of note, CAD and acute myocardial infarction are the most common causes of death in Germany [2].

To minimize or prevent damage to the myocardium caused by hypoperfusion, reperfusion treatment as early as possible is necessary. Early reperfusion (<2 h) is associated with lower 30-day mortality and longer survival [3].

Studies on STEMI treatment over the last 3 decades have shown a steady decline in mortality. In 1986, the mortality rate was 13% in the control group in the Gruppo Italiano per lo Studio della Streptochinasi nell'Infarto Miocardio (GISSI-1) study using conventional heart attack treatment without reperfusion attempt compared to systemic thrombolysis using streptokinase infusion [4]. In 2014, mortality among young STEMI patients was only 4.1% [5].

Door-to-balloon time (DTB) is an established parameter for the evaluation of STEMI care marking the time from arrival of a patient with STEMI to the clinic until reperfusion of the blocked, symptom-causing coronary vessel by means of balloon dilatation is achieved [6]. DTB is used as quality and performance marker during emergency interventions in STEMI [6].

Further parameters in the evaluation of coronary angiography and intervention are dose-area product as well as amount of intraprocedural contrast medium consumption. Additionally, PTCA reperfusion success can be measured by thrombolysis in myocardial infarction (TIMI) flow, graduating from grade 0 with no perfusion to a grade 3 with prompt and complete perfusion.

Limited access to medical facilities equipped for coronary angiography leads to delayed diagnosis and treatment of CAD not least during hospital renovations or restructuring as well as during periods of overwhelming demand such as during disaster or in a pandemic. We experienced a scenario that occurs frequently after the decision to establish a new coronary angiography unit is made: there is demand for coronary interventions long before the new unit is fully functional.

Moreover, cardiac intervention facilities are lacking in many resource-limited areas. Hence, we hypothesized, that mobile facilities might be an efficient tool in the treatment of CAD, including in developing countries. Mobile cardiac catheterization laboratories may facilitate diagnosis and treatment of CAD in situations when in-hospital cardiac interventions are not readily available. We hypothesized that an interim mobile cardiac catheterization laboratory (ICL) staffed with personal trained in interventional cardiology will provide comparable interventional cardiac care to a stationary cardiac catheterization laboratory (SCL). We therefore investigated an ICL at Caritas St. Josef Hospital Regensburg in Germany. This ICL was comprised of a functional unit on a truck trailer and was installed in 2016 as a bridging strategy prior to completion of a new permanent cardiac catheterization laboratory at this hospital.

Of course, the use of a catheterization laboratory is not limited to the treatment of STEMI patients. A large number of investigations are purely diagnostic. We will also focus on this patient cohort in our manuscript.

Here, we report on procedural outcomes and quality parameters in a ICL in comparison to a SCL in the hospital. Statistical testing should continue to be carried out using retrospectively obtained data. In a search in MEDLINE/PubMed, studies and reports on the use of mobile cardiac catheter units can be found. But these reports consistently describe the use of the mobile cardiac catheter laboratory as "actually mobile" use in the sense of traveling from place to place investigation unit [7]. However, to our knowledge, we describe the first comparison of outcomes and safety of interventional angiography conducted over a prolonged time period in an ICL compared to a SCL that was subsequently in service in the same location and staffed by the same team.

Methods

Structure of the Work and Data Research

This work is a retrospective study. It was designed to compare two observation periods of emergency intervention treatments and routine investigations in ICL and in the newly built SCL in terms of quality and security. All data were routinely collected and documented within the framework of routine diagnostic and treatment of the patients. Thus, an ethics vote and informed consent was waived.

Cardiac Catheterization and PCI

Cardiac catheterization was performed via transfemoral or transradial access. Stents implanted during the PCI were Coroflex Isar (B. Braun Melsungen, Berlin, Germany) and XIENCE V (Abbott Vascular, Abbott Park, IL, USA). All PCIs were performed under unfractionated heparin with a target ACT of 250 s. All patients were on ASA in general. Dual antiplatelet therapy with Clopidogrel as second agent was recommended for 6 months after DES implantation in stable coronary artery disease, patients with ACS received dual antiplatelet therapy (Clopidogrel, Prasugrel, Ticagrelor)

Table 1. Baseline patient characteristics in STEMI patients

	Treatment in the ICL (n = 23)	Treatment in the SCL (n = 40)
Age, mean±SD, years	62.8±14	63.9±14.1
Female, n (%)	5 (21.7)	14 (35)
Smoking history, n (%)	13 (56.5)	21 (52.5)
Diabetes, n (%)	5 (21.7)	11 (27.5)
Hypertension, n (%)	13 (56.5)	29 (72.5)
Hyperlipidemia, n (%)	9 (39.1)	22 (55)
Family History, n (%)	7 (30.4)	8 (20)
Known CAD, n (%)	3 (13)	5 (12.5)
Prior CABG, n (%)	1 (4.3)	2 (5)
Access site radial, n (%)	13 (56.5)	25 (62.5)
Access site femoral, n (%)	10 (43.5)	15 (37.5)

ICL, interim catheterization laboratory; SCL, stationary catheterization laboratory; SD, standard deviation; CAD, coronary arterial disease; CABG, coronary artery bypass graft.

for 12 months. The same four operators with at least 3 years of experience as an interventional cardiologists performed the procedures in the ICL and in the SCL.

Interim Catheterization Laboratory

The commercially available Alliance “Mobile Cathlab” product (Alliance Medical GmbH, Castrop-Rauxel, Germany) was used. This is a movable cardiac catheterization laboratory mounted on a truck trailer. Until a new cardiac catheter building in the Caritas Hospital St. Josef was fully functional, the ICL was placed in the ambulance driving way with direct access to the hospital’s central emergency room. The ICL contained the following equipment: X-ray fluoroscopy system Philips Integris Allura (CATH 1203) (Philips, Amsterdam, Netherlands) – the system has no biplan option; contrast medium injector from ACIST Medical Systems (ACIST, Eden Prairie, MN, USA); and a hemodynamic measuring station from Schwarzer Cardiotek GmbH (Schwarzer Cardiotek GmbH, Heilbronn, Germany). For intravascular diagnostics, a Vulcano system from Philips was available; intravascular ultrasound (IVUS) and pressure wire measurement (FFR and iFR, St. Jude Medical) (St. Jude Medical, Saint Paul, MN, USA) could be used here through.

Stationary Catheter Laboratory

The X-ray fluoroscopy system was Philips Allura. The system has also no biplane option. In the Philips AlluraClarity system with ClarityIQ technology, Philips has achieved a significant reduction in X-ray dose, while maintaining a high image quality compared to previously available models. This technology is based on three pillars: powerful image processing technology, flexible digital imaging pipeline, clinically fine-tuned parameters across the entire imaging chain.

The hemodynamic measuring station was from Schwarzer Cardiotek GmbH. An ACIST Medical Systems contrast medium pump was used. Equipment for intravascular diagnostics has already been used in the interim solution and adopted for further use: volcano system from Philips for IVUS and pressure wire measurement (FFR and iFR). Also, the FFR measuring system from St. Jude Medical was installed.

Study Endpoints

Study endpoints were TIMI flow, DTB time, area dose product for fluoroscopy use and contrast medium use (primary endpoints). Secondary endpoint was incidence of major advance cardiac events (MACEs). Moreover, the results were compared with the German quality report, performed by the IQTIQ (German Institute for Quality and Transparency in Health Care).

Statistical Analysis

Continuous variables are presented as mean ± standard deviation. Continuous variables were not normally distributed. Thus, Wilcoxon-Mann-Whitney-U test was used to compare continuous variables between the two groups. Chi-square test or Fisher’s exact test was performed to compare categorical variables (presented as number and percentage) where appropriate. Groups were compared by the log-rank test. p value <0.05 was considered to indicate a statistically significant difference. All statistical analyses were performed with the use of SPSS 29 (IBM, Armonk, NY, USA).

Results

Patient Cohort

Between October 2016 and April 2019, 1,454 consecutive patients were investigated. Table 1 provides further details on patient characteristics. A total of 576 (39.6%) patients were examined in the ICL (October 2016 – November 2017), and, subsequently, 878 patients (60.4%) in the SCL (November 2017 – April 2019). Twenty-three (36.5%) patients with STEMI were treated in the ICL and 40 (63.5%) in the SCL. A total of 407 patients underwent a coronary intervention in the same procedure, with 147 being examined in the ICL and 260 in the SCL. Of the 147 patients examined in the ICL, 23 (16%) had a STEMI. Of the 260 patients examined in the SCL 40 (15%) had a STEMI. Table 2 provides a detailed comparison of patients with single-stage coronary intervention in ICL vs. SCL. A total of 1,047 patients underwent diagnostic cardiac catheter examination only, 429 (41%) in the ICL and 618 (59%) in the SCL (Fig. 1). Table 3 provides further details on these patients.

The present study aimed to evaluate the clinical safety and feasibility of a mobile cardiac catheterization unit for coronary interventional diagnosis and treatment by comparison to a stationary in-hospital catheter lab. Quality of treatment and treatment performance can be determined using the DTB time (for STEMI treatment), area dose product for fluoroscopy use, contrast medium consumption (primary endpoints), and MACE (secondary endpoint).

In STEMI patients there was no statistically significant difference when evaluating and comparing DTB time, the mean time was 30 min (ICL: 29 min, SCL: 33 min; p = 0.143). In all patients who underwent a single-stage coronary intervention including those with STEMI and with NSTEMI (patients with elevated cardiac marker enzymes without ischemic ECG changes meeting STEMI criteria), there was no difference in contrast medium use between ICL (median 196 mL) and SCL (median 201 mL) (p = 0.41). DAP was statistically significantly higher in patients who underwent the intervention in the ICL (median 2,715 cGy × cm^2) compared to SCL (median 1,008 cGy × cm^2) (both p < 0.001). Unusually high DAP levels >5,500 cGy × cm^2 were more often noted in patients who underwent intervention in the ICL compared to the SCL (p < 0.001) (Table 2).

In those patients who underwent stent placement, the median number of implanted stents was 2.0 with a minimum of 1 and a maximum of 5 in the ICL group and 1.0 with a minimum of 1 and a maximum of 5 in the SCL group. Overall, there was no statistically significant difference in the incidence of MACE: 1 patient in the ICL group developed a stent thrombosis, and 3 patients in the SCL group experienced a MACE (i.e., stent thrombosis, cardiogenic shock, no reflow phenomenon, respectively).

Table 2. Comparison of patients with single-stage coronary intervention in ICL vs. SCL (n = 407)

	ICL, n (%)	SCL, n (%)	p value
All patients (n = 407)	147 (36.1)	260 (63.9)	
Successful intervention			
Yes	147 (100)	260 (100)	
No	0 (0)	0 (0)	
TIMI			
0	0	0	0.658[b]
1	0	0	
2	1 (0.7)	4 (1.5)	
3	146 (99.3)	256 (98.5)	
DAP >5,500 cGy × cm^2			
Yes	21 (14.3)	9 (3.5)	<0.001[a]
No	126 (85.7)	251 (96.5)	
Contrast medium use >250 mL			
Yes	29 (19.7)	57 (21.9)	0.602[a]
No	118 (80.3)	203 (78.1)	
Intravascular imaging			
Yes	2 (1.4)	1 (0.4)	0.297[b]
No	145 (98.6)	259 (99.6)	
Complications			
Yes	2 (1.4)	2 (0.8)	0.622[b]
No	145 (98.6)	258 (99.2)	
Conversion (radial to femoral access site)			
Yes	13 (8.8)	27 (10.4)	0.616[a]
No	134 (91.2)	233 (89.6)	
FFR			
Yes	11 (7.5)	1 (0.4)	**<0.001**[b]
No	136 (92.5)	259 (99.6)	
iFR			
Yes	3 (2.0)	20 (7.7)	**0.023**[b]
No	144 (98.0)	240 (92.3)	

TIMI, thrombolysis in myocardial infarction; DAP, dose-area product; FFR, fractional flow reserve; iFR, instantaneous wave-free ratio. [a]Chi-Squared test. [b]Fisher's exact test. Statistically significant values indicated in bold.

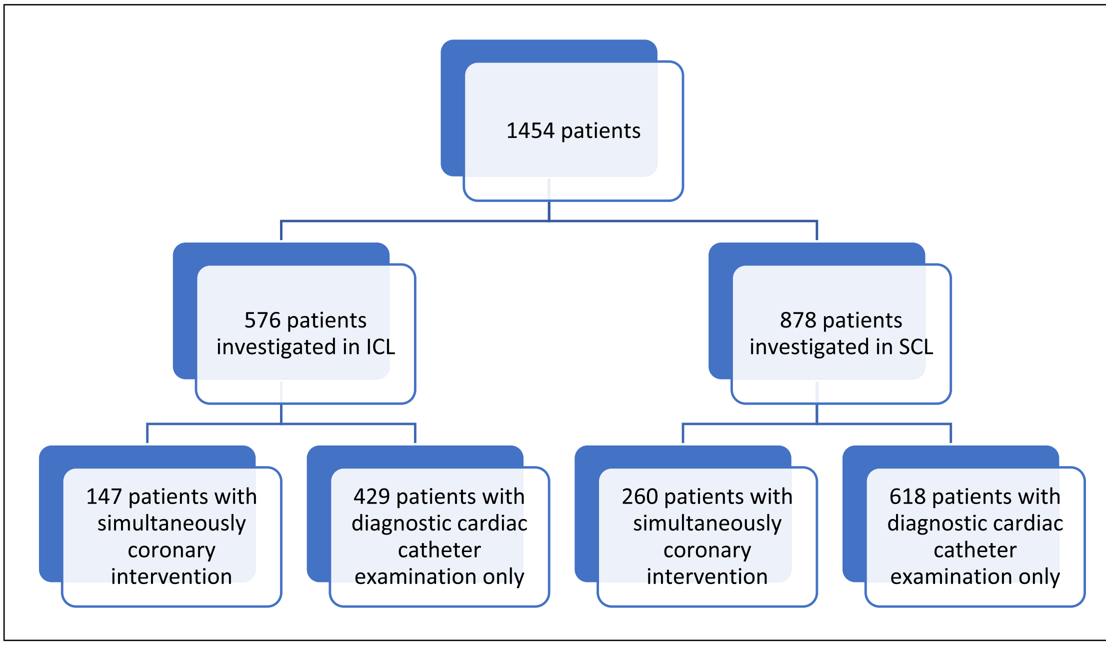

Fig. 1. Flowchart patients.

In diagnostic only cardiac catheter examinations (n = 1,047), there was no significant difference in the percentage of patients with NSTEMI between the ICL and SCL group (45 [10.5%] patients vs. 52 [8.4%] patients, $p = 0.252$). The contrast usage >150 mL differs between both groups (22 [5.1%] patients vs. 56 [9.1%] patients, $p = 0.016$). Overall, contrast medium use was significantly higher in patients who were examined in the SCL ($p = 0.018$) with a median of 74 mL in the ICL and a median of 78 mL in the SCL group. DAP was significantly higher in patients who were examined in the ICL ($p < 0.001$) with a median of 958 cGy × cm^2 in the ICL group and median of 373 cGy × cm^2 in the SCL group. Furthermore DAP >2,800 cGy × cm^2 was found more often in the ICL group compared to the SCL group (33 [7.7%] patients vs. 16 [2.2%] patients, $p < 0.001$).

Discussion

We demonstrated for the first time, that coronary angiography and interventions can be safely performed in standard procedures as well as in rescue and emergency procedures like in an ACS using a mobile cardiac catheterization unit when used long term to replace a stationary cardiac catheterization laboratory. Performance data in both facilities, including DAP and DTB time, were in full accordance with demands by the IQTIQ (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen) institute (Table 4) [8].

Our data strongly suggest that a mobile catheter laboratory is a practical and safe replacement of a stationary in-hospital catheter unit during renovation work. Based on our experience, we believe that an ICL could also serve as an adequate alternative of a SCL in resource-limited areas where there is no access to permanently installed facilities. Additionally, an ICL may facilitate access to state-of-the-art cardiac angiography and interventional cardiac care in areas affected by disaster as long as there is access to electricity and water.

Our cohort consisted of all-comer patients and represents a relevant patient group with coronary artery disease. We believe that the comparable DTB time in our study is certainly also due to the location of the mobile catheter laboratory in the immediate vicinity of the access area to the emergency room, where the patient collective could be transferred very quickly from the mobile rescue vehicle to the catheter facility.

We provide evidence that a mobile cardiac catheterization unit is capable of efficiently and safely performing coronary angiography and PCIs in both routine and emergency cases. Comparable DTB time between the mobile unit and stationary facility underscore the value of an ICL as a transient or long-term alternative to a traditional SCLs. Our findings are particularly noteworthy given the logistical and spatial limitations inherent to mobile

Table 3. Patients with examination only in ICL vs. SCL (*n* = 1,047)

	ICL, *n* (%)	SCL, *n* (%)	*p* value
All patients (*n* = 1,047)	429 (41.0)	618 (59.0)	
NSTEMI			
Yes[a]	45 (10.5)	52 (8.4)	0.252[b]
No	384 (89.5)	566 (91.6)	
DAP >2,800 cGy × cm^2 (*n* = 1,045)			
Yes	33 (7.7)	16 (2.6)	**<0.001**[b]
No	396 (92.3)	600 (97.4)	
Contrast medium use >150 mL (*n* = 1,045)			
Yes	22 (5.1)	56 (9.1)	**0.016**[b]
No	407 (94.9)	560 (90.9)	
FFR			
Yes	14 (3.3)	3 (0.5)	**<0.001**[c]
No	415 (96.7)	615 (99.5)	
iFR			
Yes	9 (2.1)	33 (5.3)	**0.009**[b]
No	420 (97.9)	585 (94.7)	
Intravascular imaging			
Yes	3 (0.7)	4 (0.6)	1.000[c]
No	426 (99.3)	614 (99.4)	
Conversion (radial to femoral)			
Yes	24 (5.6)	50 (8.1)	0.121[b]
No	405 (94.4)	568 (91.9)	
Complications			
Yes	2 (0.5)	2 (0.3)	1.000[c]
No	427 (99.5)	616 (99.7)	

DAP, dose-area product; FFR, fractional flow reserve; iFR, instantaneous wave-free ratio. Statistically significant values indicated in bold. [a]NSTEMI here refers to patients with elevated cardiac enzymes but without obstructive coronary arteries. [b]Chi-Squared test. [c]Fischer's exact test.

setups, suggesting that proper planning and resource allocation can mitigate potential disadvantages.

We noted significantly higher radiation doses in the mobile unit. However, the new SCL was at that time according to the newest standards of radiation reduction; hence, this may be an area where the two modalities are not entirely comparable. That said, radiation doses were already markedly below the German average for the performed interventions both in the ICL and the new SCL likely due to modern radiation sparing technology in both facilities. Possible reasons for higher radiation doses in the ICL include equipment limitations, lower operator familiarity with the mobile setup, or constraints in the physical environment. Hence the most important aspect regarding the observed difference in radiation doses may be due to technical specifications between the two used X-ray systems and improved radiation protection in the new, permanent facility. Even with that, radiation doses were considered safe in both settings. Training programs specifically tailored to the unique conditions of mobile units could further enhance operator efficiency and reduce fluoroscopy times.

Applications of mobile cardiac catheterization laboratories may extend beyond their use as temporary solutions during hospital renovations. These units are particularly well-suited for deployment in disaster scenarios, where conventional healthcare infrastructure may be compromised. In such cases, the mobility and self-sufficiency of these units enable rapid employment and continuity of care. Furthermore, mobile laboratories could play a transformative role in resource-limited settings, such as rural or underserved regions in developing countries. By providing access to advanced diagnostic and interventional cardiology services, these units could significantly improve health outcomes in populations with limited access to care.

Another key consideration is the adaptability of mobile units to different environmental and logistical conditions. The ability to position these facilities near emergency departments, as demonstrated in this study, ensures efficient patient transfer and minimizes delays in critical care. Future designs could incorporate modular configurations that allow rapid assembly and disassembly, further enhancing their utility in diverse settings. Additionally, partnerships with local healthcare providers and government agencies could facilitate the integration of mobile units into broader public health strategies, particularly during pandemics or other large-scale health crises.

The very low incidence of major adverse cardiac events supports the safety of mobile units. Continuous monitoring and date collection are essential to ensure that these outcomes remain consistent across different operational contexts. Further research could explore the cost-effectiveness of mobile laboratories compared to traditional facilities, considering factors such as initial investment, maintenance, and operational costs.

Our study is above all limited by a single center experience and retrospective design, which restricts generalizability. However, it should certainly be noted that the availability of trained staff is the main limitation in resource-limited areas, and costs for equipment and maintenance may further impede deployment of these units. Limitations in infrastructure such as access to electricity, clean water, and transportation, in many areas of the world must be additionally taken into account.

Table 4. Comparison of our data with the average of all catheter laboratories in Germany [8]

Indicator	ICL, %	SCL, %	Average of all catheter laboratories in Germany, %
Coronary angiography, use of contrast medium >150 mL	5.1	9.1	6.11
PCI, consumption of contrast medium >250 mL	19.7	21.9	14.29
Coronary angiography, dose-area product >2,800 cGy × cm^2	7.7	2.6	19.73
PCI, dose-area product >5,500 cGy × cm^2	14.3	3.5	26.29
Achievement of the main intervention goal (TIMI III) performing a PCI in patients with a STEMI	99.3	98.5	90.72
Achievement of the main intervention goal performing a PCI	100	100	93.89
"Door-to balloon" time of 60 min performing a first PCI in patients with a STEMI	86.96	92.50	67.43

TIMI, thrombolysis in myocardial infarction; DFP, dose-area product; PCI, percutaneous coronary intervention; ICL, interim catheterization laboratory; SCL, stationary catheter laboratory.

Conclusion

In conclusion, mobile cardiac catheterization laboratories are capable of providing similar levels of efficient and safe care in patients in need for coronary angiography, including interventions for both, routine and emergency studies. While radiation levels in our study were higher in the mobile unit, overall radiation exposure was safe in both settings. Radiation exposure can likely further limited by using more advanced equipment and specific operator training. Mobile cardiac catheterization units could support state-of-the-art cardiac care in scenarios, such as hospital renovations, disaster response, and global health initiatives in rural medicine.

Statement of Ethics

Ethical approval is not required for this study in accordance with local guidelines. Patient consent was waived since all data were routinely collected and documented within the framework of routine diagnostic and treatment of the patients, in accordance with local ethical guidelines.

Conflict of Interest Statement

The authors declare no conflict of interest.

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Author Contributions

Conceptualization and writing – original draft preparation: M.R. and S.S.; methodology: M.R. and D.E.; validation and data curation: M.R., L.M., and J.B.; formal analysis: J.B.; investigation: M.R., M.D., D.E., and S.S.; resources: D.E.; writing – review and editing: M.R., J.B., L.M., M.D., D.E., and S.S.; visualization: M.R.; supervision: S.S.; project administration: S.S. and D.E.

Data Availability Statement

The data that support the findings of this study are not publicly available due to ensure patient confidentiality and data protection but are available from Markus Resch upon reasonable request.

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