

Retrospective evaluation of interventional radiological treatments for chronic mesenteric ischemia in Germany based on a four-year period of the DeGIR Registry: comparison of outcomes with international quality standards

Bewertung interventioneller radiologischer Behandlungen bei chronischer mesenterialer Ischämie in Deutschland basierend auf einem vierjährigen Zeitraum des DeGIR-Registers: Vergleich der Ergebnisse mit internationalen Qualitätsstandards

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ABSTRACT

Purpose Endovascular treatment has emerged as the gold standard for managing chronic mesenteric ischemia (CMI) resulting from arterial stenosis or occlusion. This study aimed to assess the efficacy and complication rates of continuous interventional radiology treatment for CMI in Germany between

2018 and 2021, comparing these findings with international quality standards.

Materials and Methods Data for CMI therapy with stenting and percutaneous transluminal angioplasty (PTA) was obtained from the quality management system of the German Interventional Radiological Society (DeGIR). A total of 3752 endovascular procedures for CMI performed from 2018 to 2021 were documented (PTA: n = 675; stenting: n = 3077). Data was analyzed for technical and clinical success rates, as well as major complication rates.

Results Overall technical and clinical success rates for PTA and stenting procedures were 92.03 %/85.9 % and 98.76 %/96.62 %, respectively. The most common major complications were: arterial occlusion (PTA: 0.73 %; stenting: 0.63 %), major bleeding (PTA: 1.05 %; stenting: 0.68 %), aneurysm formation (PTA: 0.29 %; stenting: 0.72 %), stent dislodgment (PTA: 0 %; stenting: 0.06 %), and organ failure (PTA: 0.43 %; stenting: 0.96 %). Technical and clinical success rates were higher, while complication rates were lower than the corresponding threshold recommended by the Society of Interventional Radiology for the percutaneous management of chronic mesenteric ischemia.

Conclusion Treatment of CMI performed by interventional radiologists in Germany is safe and effective during daily and on-call shifts with results exceeding internationally accepted standards.

Key Points

- Treatment of CMI by interventional radiologists in Germany is effective and safe.
- The interventions are safe and effective regardless of whether they are performed during on-call shifts or the daily routine.
- The clinical and technical success rates favorably surpass the thresholds presented by SIR.
- Different major complications occurred in under 1.1 % of CMI interventions.

ZUSAMMENFASSUNG

Einleitung Die endovaskuläre Intervention hat sich als Goldstandard zur Behandlung der chronischen mesenterialen Ischämie (CMI) infolge arterieller Stenosen oder Okklusionen etabliert. Diese Studie zielte darauf ab, die Wirksamkeit und Komplikationsraten der täglichen und im Dienst durchgeführten Behandlungen der interventionellen Radiologie für CMI in Deutschland zwischen 2018 und 2021 zu bewerten und diese Ergebnisse mit internationalen Qualitätsstandards zu vergleichen.

Material und Methoden Daten zur CMI-Therapie mittels perkutaner Stentung und transluminaler Angioplastie (PTA) wurden aus dem Qualitätsmanagementsystem der Deutschen Gesellschaft für Interventionelle Radiologie (DeGIR) entnommen. Insgesamt wurden 3752 endovaskuläre Eingriffe zur CMI zwischen 2018 und 2021 dokumentiert (PTA: n = 675; Stenting: n = 3077). Die Daten wurden hinsichtlich technischer und klinischer Erfolgsraten sowie der Majorkomplikationsraten analysiert.

Ergebnisse Die technischen und klinischen Erfolgsraten für PTA- und Stenting-Verfahren betrugen 92,03 %/85,9 %; 98,76 %/96,62 %. Die häufigsten Majorkomplikationen betrugen: arterielle Okklusion (PTA: 0,73 %; Stenting: 0,63 %), schwere Blutungen (PTA: 1,05 %; Stenting: 0,68 %), Aneurysmabildung (PTA: 0,29 %; Stenting: 0,72 %), Stent-Verlagerung (PTA: 0 %; Stenting: 0,06 %) und Organversagen (PTA: 0,43 %; Stenting: 0,96 %). Technische und klinische Erfolgsra-

ten waren höher, während die Komplikationsraten niedriger waren als die von der Society of Interventional Radiology empfohlene Schwellenwerte für die perkutane Behandlung der CMI.

Schlussfolgerung Die Behandlung von CMI durch interventionelle Radiologen in Deutschland ist sowohl während der regulären Arbeitszeit als auch im Bereitschaftsdienst sicher und effektiv, wobei die Ergebnisse international anerkannte Standards übertreffen.

Kernaussagen

- Die Behandlung der CMI durch interventionelle Radiologen in Deutschland ist sicher und wirksam.
- Die Interventionen sind sicher und effektiv, unabhängig davon, ob sie während des Bereitschaftsdienstes oder im täglichen Routinebetrieb durchgeführt werden.
- Die klinischen und technischen Erfolgsraten übertreffen die von der SIR präsentierten Schwellenwerte.
- Verschiedene schwerwiegende Komplikationen traten bei weniger als 1,1 % der CMI-Interventionen auf.

Zitierweise

- Bastian M, Wessendorf J, Scheschenja M et al. Retrospective evaluation of interventional radiological treatments for chronic mesenteric ischemia in Germany based on a four-year period of the DeGIR Registry: comparison of outcomes with international quality standards. *Fortschr Röntgenstr* 2024; DOI 10.1055/a-2258-3437

Introduction

Chronic mesenteric ischemia (CMI) is a severe vascular condition affecting the abdominal arteries, namely the celiac artery, superior mesenteric artery, and the inferior mesenteric artery. Often associated with peripheral artery disease (PAD), CMI manifests through a progression of symptom stages, from postprandial pain and weight loss in its early stages to severe abdominal discomfort and acute intestinal ischemia potentially leading to death in advanced stages [1]. This progression underscores CMI's status as a critical healthcare condition, not just in Germany but on a global scale [2]. Current treatment modalities for CMI encompass a range of options, with endovascular interventions being of paramount importance in addition to open surgical procedures, due to their lower in-hospital mortality rate and lower complication profiles [3–5]. These interventions include percutaneous transluminal angioplasty (PTA) and stenting.

While these endovascular interventions have shown generally high rates of success [1], it is imperative to acknowledge the potential occurrence of complications. Major complications can result in protracted hospitalization and adverse patient outcomes. Hospitals across Germany that engage in interventional radiological procedures certified by the German interventional radiological society (DeGIR) are obligated to report detailed data to DeGIR's quality management system. This system comprehensively evaluates pre-operative, intra-operative, and post-operative informa-

tion, including the nature and severity of complications. A previous investigation, examining data from DeGIR's quality management system, revealed a noteworthy nationwide commitment to maintaining high-quality standards in interventional radiological revascularization procedures [6]. Furthermore, there is a need to benchmark the success and complication rates reported to DeGIR against international quality standards, such as those established by the Society of Interventional Radiology (SIR) [7].

Therefore, the primary objective of this study is to conduct a comprehensive evaluation of the efficacy and safety of interventional radiological treatments employed for the management of chronic mesenteric ischemia in Germany over the four-year period from 2018 to 2021. This investigation aims to juxtapose these outcomes against established international quality standards. The hypothesis guiding this study postulates that interventional radiological treatments for chronic mesenteric ischemia in Germany have sufficient rates of success and correspondingly low major complication rates, regardless of whether the intervention time is during the daily clinical routine or on-call shifts. These outcomes are anticipated to be on par with the international quality standards published by SIR. Consequently, this study seeks to provide an assessment of the safety and efficacy of managing chronic mesenteric ischemia in Germany while concurrently building a foundation for the establishment of national and international thresholds pertaining to complications and success rates.

Material and Methods

Data acquisition

Patient selection for this study involved the extraction of data from the quality management system of the German Interventional Radiology Society (DeGIR). Inclusion criteria included individuals who had undergone stenting or percutaneous transluminal angioplasty (PTA) procedures for the management of chronic mesenteric ischemia within Germany during the period spanning from 2018 to 2021. The dataset comprised 675 PTA procedures and 3077 stenting procedures conducted during this timeframe.

Study Design

The objective of this investigation is to evaluate the safety and efficacy of interventional treatments carried out for chronic mesenteric ischemia in Germany over the specified four-year duration (2018–2021). The focus was on the assessment of both technical and clinical success rates, as well as the incidence of major complications. Interventions were performed either during the daily routine schedule or during on-call shifts. Clinical success was defined as post-therapy relief of presenting symptoms, while technical success was characterized by the angiographically confirmed recanalization of previously stenosed or occluded arteries. Major complications, as per SIR, encompass conditions that necessitate therapy with brief hospitalization (<48 h), demand significant intervention leading to an unplanned escalation in the level of care and prolonged hospitalization (>48 h), result in permanent adverse sequelae, or ultimately lead to death [7]. The findings were subsequently juxtaposed against internationally recognized thresholds, mainly SIR thresholds.

Statistical Analysis

Treatment efficacy and major complication rates were evaluated with Microsoft Excel (Version 16.34, Microsoft, Redmond, WA, USA) and SPSS (Version 29, IBM Corp., Armonk, NY, USA). A comprehensive descriptive statistical analysis was conducted by frequency analysis, focusing on the clinical and technical success rates as integral components of the efficacy assessment. Additionally, tests for normal distribution via Shapiro-Wilk test and t-test were performed to assess whether there was any significant difference between the procedures.

Results

A total of 3752 procedures were documented in the timeframe 2018–2021 for mesenteric interventions on the basis of CMI in the DeGIR quality management system. 675 PTA from 153 hospitals and 3077 stenting procedures from 210 hospitals were reported, respectively. The overall technical success rate was 97.55 %, with a 97.86 % success rate for the daily routine and a 95.4 % success rate for on-call shifts. The overall clinical success rate was 94.77 %, with a 95.34 % success rate for the daily routine and an 89.04 % success rate for on-call shifts. The overall major complication rate was 3.74 %.

PTA

Chronic mesenteric ischemia was treated by PTA in 675 Patients. There were 610 daily routine and 65 on-call emergency interventions. The overall technical success rate of PTA was 92.03 %, while the clinical success rate was 85.9 %. During the daily routine the technical success rate was 92.88 %, with a respective clinical success rate of 86.75 %. The on-call technical success was 82.2 %, whilst the clinical success rate was 76.25 %. The most frequent major complication was major bleeding (1.05 %), followed by arterial occlusion (0.73 %), organ-failure (0.43 %), and aneurysm formation (0.29 %). Further complications were cardiac decompensation (0.16 %), parenchyma ischemia (0.15 %), and others (0.14 %). The technical success rate was higher than the SIR threshold for CMI interventions and the complication rates were lower (► Table 1).

Stenting

Stenting was performed in 3077 patients, with 2685 daily routine interventions and 392 on-call emergency interventions. The overall technical success rate of stenting interventions was 98.76 %, while the clinical success rate was 96.62 %. During the daily routine, the technical success rate was 98.95 %, with a respective clinical success rate of 97.22 %. The on-call technical success rate was 98.22 %, whilst the clinical success rate was 81.84 %. The most frequent major complication was organ failure (0.96 %), followed by aneurysm formation (0.72 %), major bleeding (0.68 %), and arterial occlusion (0.63 %). Further complications were parenchyma ischemia (0.24 %), cardiac decompensation (0.22 %), stent dislodgement (0.06 %), pulmonary dysfunction (0.06 %), and others (0.45 %). The technical success rate was higher than the SIR threshold for CMI interventions while complication rates were lower (► Table 2).

The data from both stenting and PTA demonstrated normal distribution as confirmed by the Shapiro-Wilk test. A t-test comparison revealed a statistically significant difference between the groups ($p < 0.001$), with stenting exhibiting significantly better results than PTA alone.

Discussion

The study assessed the efficacy and safety of interventional radiological treatments utilized for chronic mesenteric ischemia (CMI) in Germany between 2018 and 2021. The results confirmed our hypothesis, with notable overall high rates of technical and clinical success for stenting and PTA procedures. Comparing the subgroups, sole PTA to stenting, there were significantly better results for stenting. The data confirms that endovascular interventions performed by interventional radiologists, specifically in Germany, are effective and generally safe, with success rates that surpass the standards set by SIR. The SIR thresholds were surpassed where there were overlaps with the study, namely in the following cases: arterial occlusion: 3 %; stent dislodgement: 5 %; technical success rate PTA alone: 65 %; technical success rate stenting: 85 %. Remarkably, both during daily routine interventions and on-call duties, the technical and clinical success rates re-

► **Table 1** PTA success rates and major complications.

Intervention:	Technical success			Clinical success			Major complication	
PTA	Total [%]	Daytime [%]	On-call [%]	Total [%]	Daytime [%]	On-call [%]	Type	Total [%]
Total: 675 Daily: 610 On-call: 65	92.03*	92.88*	82.2*	85.9	86.75	76.25	Arterial occlusion	0.73**
							Major bleeding	1.05
							Aneurysm formation	0.29
							Organ failure	0.43
							Cardiac decompensation	0.16
							Parenchyma ischemia	0.15
							Other	0.14

Technical and clinical success rates as well as the frequent major complication rates of percutaneous transluminal angioplasty (PTA) in chronic mesenteric ischemia during the daily clinical routine and during on-call shifts, in Germany from 2018 to 2021 (in % and absolute number of cases).

* higher than SIR technical success threshold of 65 % [7].

** lower than SIR threshold for arterial occlusion as major complication of 3 % [7].

mained higher than the SIR threshold, highlighting the high quality of care irrespective of the operational timeframe.

Comparing our data with the existing literature reveals the high quality of interventional radiology treatment for CMI in Germany. The overall technical and clinical success rates, especially for stenting procedures, are consistently high and are in line with existing literature [8–10]. Previous investigations, highlighting the availability of interventional-radiological revascularization procedures in Germany, underscored a commitment to high-quality standards [6]. Our findings further support this statement. This suggests that the structured quality management and standards set by DeGIR have fostered an environment to realize optimal patient outcomes. Moreover, the incidence of complications, while present, remains relatively low and manageable, as previously shown in a comparable study for lower limb interventions [11].

Notably not all major complications had a respective SIR threshold such as organ failure, cardiac decompensation, aneurysm, major bleeding, parenchyma ischemia, and pulmonary dysfunction. However, even when there was no corresponding threshold, our reported results can be interpreted as safe due to their low occurrence. A notable observation from our findings is the incidence of organ failure as one of the most frequent major complications following CMI interventions. It's worth noting that organ failure is not a typical direct complication attributable to interventional radiological treatments for CMI, as usually other complications are reported [9, 12]. Possibly, these patients experienced decompensated acute ischemia occurring in the context of CMI, but unfortunately, this data was not collected in the database. However, patients with a severe grade of CMI present with a severe clinical profile. Patients in such a condition already have compromised health. Their multifaceted health challenges can trigger a series of negative physiological events, especially considering their multimorbid status. It's important to note that

arteriosclerosis is a systemic issue and is not just confined to the abdominal arteries [13, 14]. As a result, the precarious health of these patients with advanced CMI makes them more susceptible. Furthermore, it is worth noting that revascularization of necrotic intestines may have potentially led to organ failure. The organ failure complication, thus, emphasizes not just the technical nuances of the procedure but more broadly, the complex interplay of patient health, disease severity, and intervention outcomes. Nevertheless, this study provides invaluable insight by showcasing the full complication profiles of CMI interventions, further enriching our understanding of potential risks and areas of improvement. The comparison to international benchmarks, although suggestive of Germany's high standards, would benefit from a more direct head-to-head comparative study with other nations.

While our findings provide valuable insight, several limitations of this study warrant mention. Primarily, its retrospective design means we cannot account for all potential confounders nor directly infer causality. Additionally, the data sourced from the DeGIR quality management system might be prone to reporting biases or inaccuracies, thus affecting the veracity of our results. Since reporting to the DeGIR system is voluntary, there are regional discrepancies, with city-states showing reduced input [15]. A noteworthy number of unrecorded interventions can be presumed, and data reporting is influenced by individual motivation and active participation [16]. Thirdly, while the dataset is expansive, it is restricted to Germany, which may limit the generalizability of the results on a global scale. Finally, the database itself presents certain constraints. Beyond just success rates and major complications, metrics like re-intervention rates and outcomes after the interventions are pivotal. To maintain high data quality, additions to the assessment sheet, such as details on re-interventions and outcomes at follow-up, should be considered.

► **Table 2** Stenting success rates and major complications.

Intervention:	Technical success			Clinical success			Major complication	
Stenting	Total [%]	Daytime [%]	On-call [%]	Total [%]	Daytime [%]	On-call [%]	Type	Total [%]
Total: 3077 Daily: 2685 On-call: 392	98.76*	98.95*	98.22*	96.62	97.22	81.84	Arterial occlusion	0.63**
							Major bleeding	0.68
							Aneurysm formation	0.72
							Organ failure	0.96
							Cardiac decompensation	0.22
							Parenchyma ischemia	0.24
							Others	0.45
							Stent dislodgement	0.06***
							Pulmonary dysfunction	0.06

Technical and clinical success rates as well as the frequent major complication rates of stenting in chronic mesenteric ischemia during the daily clinical routine and during on-call shifts, in Germany from 2018 to 2021 (in % and absolute number of cases).

* higher than SIR technical success threshold of 85 % [7].

** lower than SIR threshold for arterial occlusion as major complication of 3 % [7].

*** lower than SIR threshold for stent dislodgement as major complication of 5 % [7].

Conclusion

In conclusion, our study offers significant insight into the safety and efficacy of interventional radiological treatments for CMI in Germany and shows commendable safety and efficacy profiles of interventional radiological treatments for CMI in Germany. Considering the significantly better results with stenting, a possible trend could be the preference for stenting over sole PTA. Furthermore, clinicians can be reassured about the robustness and safety of endovascular interventions for CMI, especially when guided by the protocols and quality standards set by institutions like DeGIR. Moreover, this study's findings may help the future formulation of evidence-based guidelines for CMI management, potentially reducing major complication rates of interventional radiology treatments.

CLINICAL RELEVANCE

- Treatments for CMI during daily clinical routines and on-call duties are both safe and effective.
- Stenting can possibly be favored over PTA alone for treating CMI.

Conflict of Interest

The authors declare that they have no conflict of interest.

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