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An Empirical Study on the Operative Treatment of Symptomatic Urolithiasis in Germany

Alina Reicherz Rüveyde Sahin Lorine Häuser Joachim Noldus Peter Bach

Department of Urology, Ruhr-University of Bochum, Marien Hospital Herne, Herne, Germany

Keywords
Urolithiasis · Ureteroscopy · Stent · Ureteral stent · Diagnosis-related group-system

Abstract
Purpose: The guidelines of the German, European, and American Urological Associations on urolithiasis advise against general ureteral stenting before and after an uncomplicated ureterorenoscopy (URS). However, German and European guidelines state that stenting prior to URS facilitates stone extraction and reduces intraoperative complications. According to the published literature, German practice seems to deviate from recommendations. This nationwide survey aimed to evaluate the treatment modalities of urolithiasis. ***Methods:*** In November 2018 and March 2019, a total of 199 urological hospital departments in Germany were anonymously surveyed about operative care of symptomatic urolithiasis. The response rate was 72.9%. The survey consisted of 25 questions about diagnostics, surgical technique, and aftercare of the URS. This questionnaire is available in the appendix. ***Results:*** A primary URS is performed in ≤10% in 49.6% of the hospitals. In every second urological department (49.7%), the German Diagnosis Related Group (G-DRG) system influences the period of pre-stenting before a secondary URS. After a secondary URS, which is performed in 53.8% of the departments in over 80% of the patients, 14% of the departments omit stenting. The standard for stenting seems to be a 28-cm-long 7 Charrière double-J stent in Germany. ***Conclusion:*** In Germany, the percentage of primary URS is low, and a ureter stenting is performed in most of the urological departments after URS. Delaying therapy due to economic aspects is the standard in almost half of all urological departments.
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Introduction

About 12% of the world's population suffers from urolithiasis during the course of their lives [1]. In the past, there has been an increasing incidence and prevalence [2]. Therefore, urolithiasis is already compared with other common diseases and takes up a large part of the patient population in Germany's departments of urology. The German Society of Urology first issued a guideline on urolithiasis in 2008. It was last updated in 2018 [3].

In particular, the diagnosis and therapy of urolithiasis have changed over the years with the advancement in technology: ureterorenoscopic (URS) stone extraction is the most common form of therapy with a share of 70% [4]. The need for a stent placement before and after URS

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Alina Reicherz
Department of Urology, Marien Hospital Herne
Hölkeskampring 40
DE–44625 Herne (Germany)
alina.reicherz@rub.de

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is the subject of many considerations. The guidelines of the German, European, and American Urological Associations on urolithiasis advise against general ureteral stenting before and after an uncomplicated URS. However, German and European guidelines state that stenting prior to URS facilitates stone extraction and reduces intraoperative complications. Current studies show that German practices often deviate from recommendations in the guidelines. For example, data from the German BUSTER study show that "pre-stenting" (ureteral stent placement before URS) is performed in 70% of patients before stone extraction in Germany [3, 5–7]. Pre-stenting immediately solves urinary transport disorder in the event of an emergency. Subsequently, secondary URS reduces the risk of iatrogenic injury to the small lumen and fragile ureter and increases the stone freedom rate. On the other hand, there is an increased risk of infections and a significantly reduced quality of life for patients due to so-called stent-related symptoms. In a study by Joshi et al., 78% of the patients reported micturition symptoms and 80% reported pain that affected activities of everyday life. Also, a reduced ability to work with an inserted ureteral stent was reported [8, 9]. Explanations for why Germany, as a highly developed country with a good health system, has a low percentage of primary URS need to be evaluated. Evidence-based recommendations are in contrast with the pressure in the healthcare system for cost efficiency. The two-stage procedure with pre-stenting before URS increases the revenue in the DRG if the interval between these two surgical interventions is at least 30 days. There is a risk that urologists artificially stretch the distance between the two procedures so that one lump sum per case can be charged. The widespread practice of "routine" ureteral stent placement after URS is not in line with German, European, and American guidelines, which do not generally recommend stenting after uncomplicated URS [3, 5, 6]. However, according to a recently published Cochrane analysis, the recommendations are based on a low level of evidence [10]. The present work aims to research and analyse the nationwide care of patients with symptomatic urolithiasis with a focus on URS.

Methods

The FaST 4 study is a Germany-wide empirical analysis for the diagnosis, therapy, and aftercare of urolithiasis with a focus on URS. For this purpose, a non-validated, self-written questionnaire was sent to 199 German departments of urology. The doctors in charge of the endourology department of the hospitals were asked to answer the questions. Participation in the survey was anonymous and voluntary. The questionnaires were sent for the first time in November 2018 and again in March 2019.

A total of 25 questions deal with diagnostics and therapy as well as the follow-up care of urolithiasis. The German questionnaire can be found in the appendix.

Results

With a 72.9% response rate for the questionnaire, a total of 145 out of 199 questionnaire responses were included in the analysis.

Case Numbers

The majority (44.8%) of the departments of urology stated that between 500 and 2001 patients with symptomatic urolithiasis were treated endourological. The number of cases was estimated to be ≤100 by 0.7% of the departments, 14.5%, within 101–200; 20.7%, within 501–750; 8.3%, within 751–1,000; and 7.6%, over 1,000. Hence, urolithiasis is numerically one of the most frequent patient contacts in a urological department.

Diagnosis and Treatment Modalities

Stone CT (computer tomography) is routinely performed by 90.3% of the departments for imaging. In over 50% of symptomatic urolithiasis cases, patients were reportedly treated by URS by 85.6% of the departments; 42.8% estimated the share to be over 70%; 50.3% of departments perform extracorporeal shock wave lithotripsy in less than 10%; and 9% do not offer extracorporeal shock wave lithotripsy. Percutaneous nephrolithotomy was used in 10–30% of cases by 61.4% of urological departments (see Fig. 1).

In 49.6% of the urological departments, a primary URS is performed by ≤10%. The share of secondary URS is over 80% in 53.8% of the departments (see Fig. 2).

In 80% of the urological departments, antibiotic therapy is routinely administered preoperatively. For the remaining 20%, the "single shot" is not routine.

The majority of the departments have 3 to 5 flexible URS devices (58.6%) and 6 to 10 semi-rigid URS devices (50.3%). Disposable devices are used by 41.4%. During on-call duty, 44.8% of the departments carry out a URS.

In 62.2%, the ureteral ostium is not routinely dilated with a bougie in a primary URS. In 13.3%, bougienage is standard. Access sheaths are used by 79.3% of urological departments.

The lumen of the standard URS devices was recorded. Flexible URS devices with 8 Ch were preferred by 31.1%; 19.3%, with ≥9 Ch; and 13.1%, with 7 Ch. During semi-

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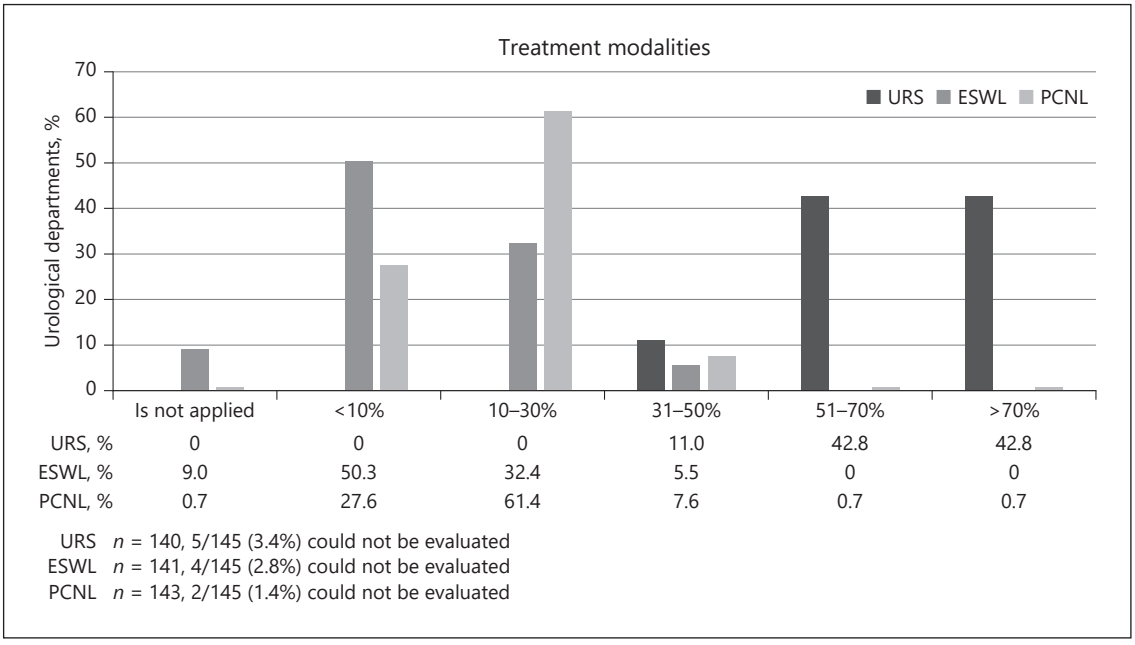

Fig. 1. Estimated percentage of PCNL, URS and ESWL in treating urolithiasis.

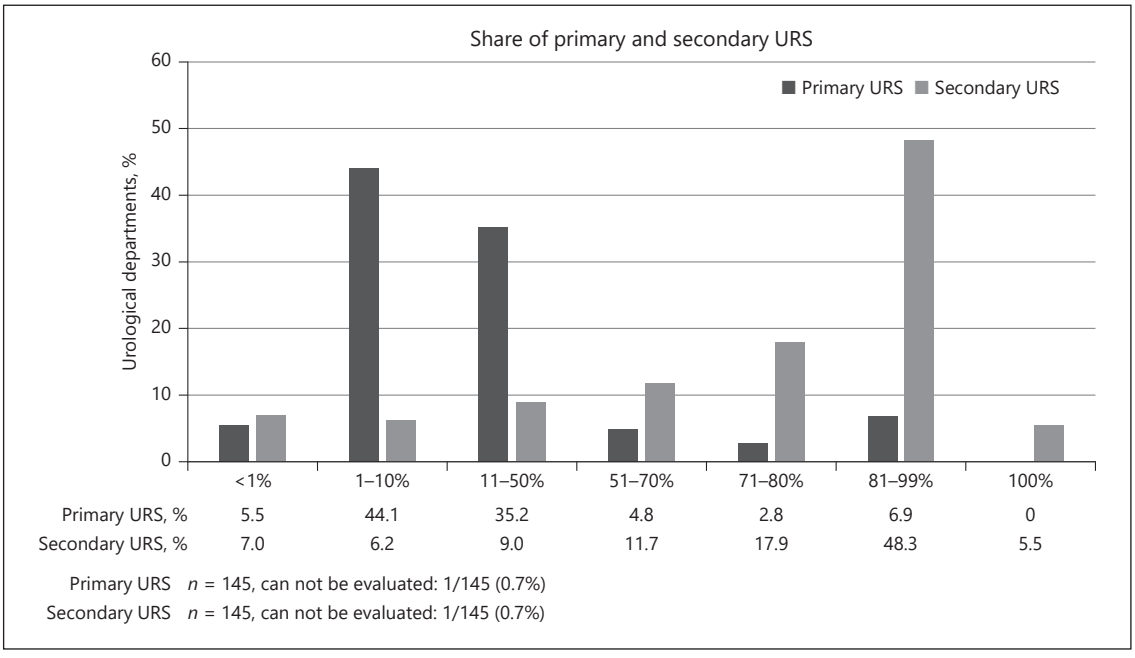

Fig. 2. Estimated percentage of primary and secondary URS.

rigid URS, 25.0% work with 8 Ch URS devices; 19.4%, with ≥9 Ch; and 14.6%, with 7 Ch.

Regarding the experience with URS devices, it was stated that flexible devices need to be repaired more often. In contrast, out of 72.9% of users, only less than a fifth of semi-rigid devices were defective in 2017.

The gold standard for intracorporeal lithotripsy is the laser with 98.6%. Stone fragments are mainly removed

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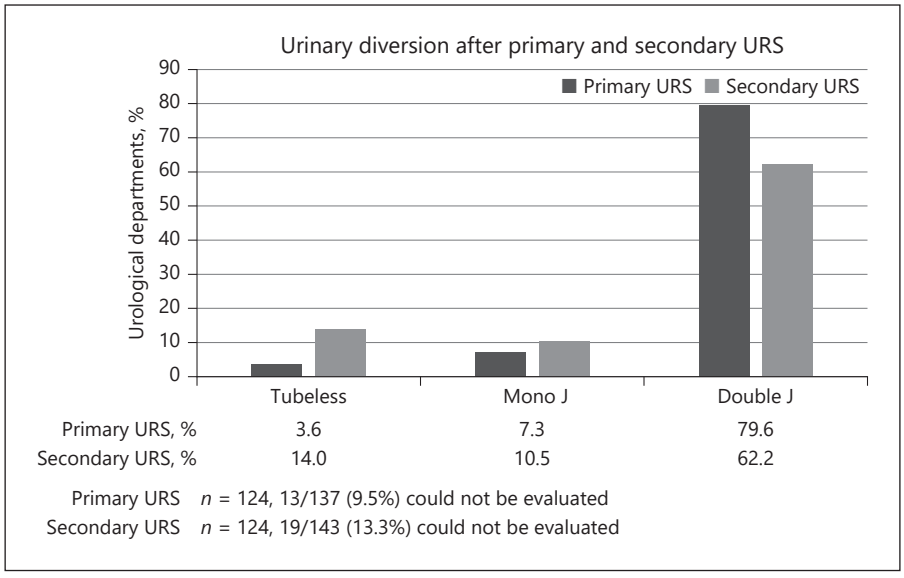

Fig. 3. Estimated percentage of ureteral stenting modalities after primary and secondary URS.

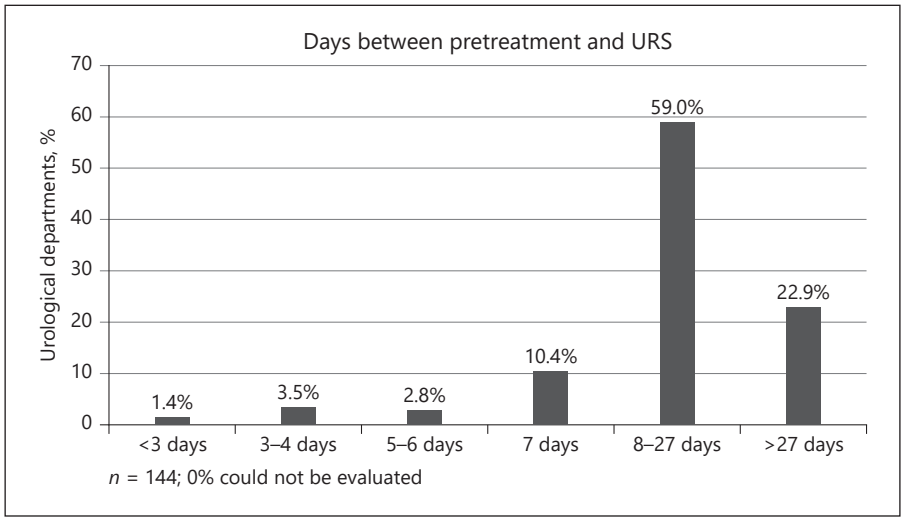

Fig. 4. Estimated days between pre-stenting and ureterorenoscopic stone removal.

with a retrieval basket during semi-rigid and flexible URS. However, forceps are also used. During flexible URS, 84.2% of departments prefer to use a basket; for semi-rigid URS, 48.9% of urological departments do.

The modalities of urinary diversion were also recorded using the questionnaire. After a primary URS, 79.6% of the departments insert a double-J (DJ) catheter, 7.3% chose a mono-J catheter, and 3.6%, a tubeless procedure. After a secondary URS, 14% omit stenting, 10.5% insert a mono-J catheter, and 62.2% insert a DJ catheter (see Fig. 3, 4). In both primary and secondary URS, catheters with 7 Ch and a length of 28 cm were mostly used.

At 59% of departments, the pre-stenting interval before a secondary URS is 8–27 days. In 22.9%, the DJ catheter was left in for over 27 days; 18.1% remove the catheter within 7 days (see Fig. 4). After URS, 32.4% of the departments inserted a foley. In this anonymous survey, 49.7% of urological departments answered the question, "Does the DRG coding system influence the period of the pre-stenting?" with a "yes."

The maximum tolerable operating time differs within the 145 departments surveyed: 25.5% consider ≤60 min, 35.2% 61–90 min, 29.0% 91–120 min, and 9.0% > 120 min tolerable. Metaphylaxis advice is offered by 62.1% of the urologists.

Complications

According to 61% of urological departments, the estimated rate of general complications after URS is less than 5%; 26.2% estimate the complication rate at 6–10%. Urol-

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ogists mostly observe fever (74.5%) but also ureter perforations (55.5%), fornix ruptures (13.8%), and strictures requiring therapy (13.8%); 57.3% of the urological departments estimate that more than 21% of their patients experience stent-associated symptoms. However, 13.8% estimate that less than 10% of their patients show these symptoms and 22.1% of them only administer analgesics. In almost half of the departments of urology, alpha blockers (49.7%) and anticholinergics (48.3%) are administered in addition to analgesics. The revision rate for the primary URS is estimated to be less than 5% by 38.5% of the respondents; 24.4% indicate a rate of 5–10%; and 66.4% estimate the revision rate for the secondary URS to be less than 5%.

Discussion

The German health care system has been trimmed for cost efficiency since the introduction of the G-DRG system in 2003. This trend can also be observed in the therapy of urolithiasis. The revenues for stone treatment add up to the lump sum per case for the diagnosis "urolithiasis" and the coded therapy.

In Germany, the worldwide trend towards URS can be observed; 85.6% of those questioned stated that they perform URS in over 50% of cases with symptomatic urolithiasis (Fig. 1). A review from 2017 by Geraghty et al. [11] confirms the trend and shows a significant preference for URS over EWSL and percutaneous nephrolithotomy ($p < 0.0001$). If pre-stenting before URS and stone removal is performed within 30 days, these 2 cases are combined. This results in monetary loss. The modalities of the DRG system provide an incentive to delay secondary URS. A URS costs around EUR 2,321.68 (DRG L 20C); a DJ catheter insertion, EUR 1,999.73 (DRG L64B). If the URS is carried out within 30 days of the DJ catheter insertion, the cases will be merged, and the revenues will be reduced by EUR 1999,73 to EUR 2,321.68. Almost half of the urologists surveyed stated that they treat 500 stone patients per year. Five hundred therapies per year per hospital reduce their revenue by EUR 999.865.

Based on the FaST 4 survey, it can be shown that for half of all German urological departments, financial incentives play a role in the therapy; 49.7% of the respondents stated that the DRG coding system influences the period of the pre-stenting. Although an optimal duration for pre-stenting is not known, it is known that up to 80% of patients suffer from stent-related symptoms such as pain or micturition problems. Moreover, stent insertion is associated with a reduced quality of life and, for 58% of patients, a limited ability to work [9]. Nevertheless, only 18.1% remove the DJ catheter during the pre-stenting within 7 days.

German, European, and American guidelines currently do not recommend routine ureteral stent placement before and after a URS [3, 5, 6]. However, German and European guidelines specify that stenting before URS can facilitate URS, improve stone-free rates, and reduce intraoperative complications. Although, according to the S2k guidelines, ureter stenting before planned URS is not required [3], only ≤10% of the departments perform primary URS in 49.6% of patients; 53.8% of the departments perform a secondary URS in more than 80% of patients (Fig. 2). While worldwide, the vast majority of patients with ureteric stones are treated without a stent, the percentage of primary URS in Germany is low [6]. Remarkably, treatment modalities deviate in a highly developed country with a well-equipped health system like Germany. An explanation might be that the G-DRG system gives urologists the option of charging pre-stenting and URS if they stretch the interval between the interventions, thus allowing a treatment modality that is known to facilitate stone extraction and reduce intraoperative complications. Furthermore, a department system in operating urology is missing in Germany. Therefore, a URS is often performed by young and inexperienced surgeons. Another reason for a two-stage stone treatment is the lack of availability of the primary URS on duty. In over 50% of the hospitals, no URS can be done by on-call doctors. Also, urinary tract infection and renal failure are reasons for a two-stage treatment.

According to the S2k guideline, after an uncomplicated URS and stone removal, ureteral stenting is generally not necessary. In the case of residual fragments, complications, or more complex interventions, the postoperative insertion of a ureteral stent seems sensible even though the optimal duration for ureter splinting is unclear [3]. The guidelines of the EAU provide similar recommendations and mention that transient ureteral stent placement after URS has similar results [12]. In Germany, after a primary URS, 7.3% of urological departments usually insert a mono J, and after a secondary URS, 10.5% of urological departments do (Fig. 3). The results of the prospective randomized study (FaST 1) showed that inserting a mono J compared to a DJ catheter after a secondary URS has resulted in a significant increase in quality of life [13]. The question comes up whether German urological departments can afford guideline and evidence-based urolithiasis therapy with constant pressure for cost efficiency.

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The FaST 4 survey shows that majority of German departments of urology opt for prolonged stone therapy due to higher profitability (Fig. 4). The discrepancy between the recommendation of the guidelines and the worldwide propagated procedure is not only evident across Germany but also in data from studies on health care from California. Out of 16,060 included patients with symptomatic urolithiasis, 86.2% had a DJ catheter inserted before laser lithotripsy and 70.5% before stone extraction via basket retrieval [14].

The survey showed that DJ catheters with a lumen of 7 Ch and a length of 28 cm were used with a large majority in Germany. Nestler et al. [15] showed in a prospective randomized study that with an increasing lumen, the urinary stent-associated symptoms occur more often. However, the interventional result is not affected by ureter stenting with a smaller lumen (4.7 Fr) [15]. In addition to the lumen size, increased complaints are observed if the DJ is too long. Therefore, a size-adapted ureteral stent insert is discussed.

Disposable URS devices are used more and more frequently in the treatment of urolithiasis even though there are existing recyclable and flexible URS devices of good quality. Disposable devices are used by 41.4% of the urological departments. Due to higher susceptibility to repairs combined with high repair costs for flexible URS devices, it increases the interest in single-use devices. However, the trade-off to using these disposable single-use URS devices is lower image quality [16].

FaST 4 evaluated the estimated rates of general complications after URS. Postoperative complications usually include fever, ureteral perforations, fornix ruptures, and strictures. A first Cochrane analysis on ureteral stenting after primary URS showed that the data on complications are of moderate to mostly very low quality [10]. Two prospective randomized studies on urinary diversion after secondary URS (FaST 1 and 2) showed an operative revision was never necessary ($n = 0$ out of 64) if a DJ catheter was inserted, was necessary in 5.0% ($n = 5$ out of 121) if a mono J was placed for 6 h, and in 13.5% ($n = 7$ out of 52) if no stent was placed after URS [13, 17].

Metaphylaxis advice is offered by 62.1% of German departments of urology. There is only 1 prospective study on secondary prophylaxis. In this study, a 50% reduction in the recurrence rate was demonstrated in the 5-year follow-up [18]. Given an increasing prevalence (4.7% in 2001) and with recurrence rates of 40–50%, efforts to prevent relapse are essential [2].

The questionnaire on which the FaST 4 study is based is self-written. A limitation of our study is that no objective statements can be made regarding validity and reliability.

The present, anonymous survey allows a representative insight into the therapy of urolithiasis in Germany with a response rate of 72.9% of the questionnaires. The dilemma which urologists face every day between evidence-based medicine and consideration of cost efficiency becomes obvious.

Statement of Ethics

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Ethics approval was not required.

Conflict of Interest Statement

The authors have no conflicts of interest.

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Author Contributions

Alina Reicherz: project development, data analysis, and manuscript writing. Rüveyde Sahin: data collection and management, and data analysis. Lorine Häuser: Manuscript editing. Joachim Noldus: Manuscript editing. Peter Bach: project development, data management, and manuscript editing.

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