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Comparative Evaluation of Diagnostic Quality in Native Low-dose CT without and with Spectral Shaping employing a Tin Filter in Urolithiasis with implanted Ureteral Stent

Vergleichende Untersuchung zur diagnostischen Qualität nativer Niedrigdosis-CT ohne und mit spektraler Filterung mittels Zinnfilter bei Urolithiasis mit einliegender Harnleiterschiene

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ABSTRACT

Purpose Spectral shaping employing a tin filter can be used for dose reduction in CT of the abdomen in patients with urolithiasis. As ureteral stents may be in direct contact with the calculus, a good image quality is mandatory. The goal of this study was to obtain data of the effect of tin filtering on image quality and dose in patients with urolithiasis in direct contact with ureteral stents.

Materials and Methods 84 examinations (conventional low dose vs. modified low dose protocol with tin filtering, randomized) were performed in 65 patients (48 men, 17 women, age 55.0 ± 15.2 years (18–90 years), maximum of one examination per protocol). Image quality and visibility of the calculus was rated on a 5-point-Likert scale by 2 experienced radiologists. Quantitative indicators of image quality were signal-to-noise-(SNR) and contrast-to-noise-ratios (CNR) as well as a figure-of-merit (FOM).

Results With a non-inferiority margin of 0.5 points of the 5-point Likert scale, there was non-inferiority of the examinations with tin filter regarding image quality (95 % CI 4.1–4.3, rejection limit 3.5). Non-inferiority regarding visibility of the calculus could be shown (calculus size: 1–2.4 mm: 95 % CI 3.39–4.12; limit 2.73; 2.4–3.8mm: 95 % CI 4.09–4.47; limit 3.65; > 3.8mm: all maximal ratings). Average values of CNR were significantly higher using tin filters (17.0 vs. 10.6). Doses were significantly reduced in the modified protocol (effective dose 1.2 mSv vs. 1.5 mSv; size-specific dose estimate 2.33 mGy vs. 3.09 mGy) with non-significant effect in the subgroup of patients with BMI ≥ 35.

Conclusion Even with direct contact between a calculus and ureteral stent, radiation reduced examinations by spectral shaping by tin filters are non-inferior to examinations without tin filtering at a concurrent significant dose reduction.

Key points:

- Spectral shaping by tin filter is suitable for dose reduction.
- The image quality in patients with ureteral stents with tin filtering is non-inferior to that in a conventional low-dose protocol.

Citation Format

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ZUSAMMENFASSUNG

Ziel Spektrale Filterung mittels Zinnfilter eignet sich zur Dosisreduktion in der CT des Abdomens bei Urolithiasis. Harnleiterschienen zur Entlastung der Harnstauung können dabei im direkten Kontakt zum Urolithen stehen. Eine hohe Bildqualität ist daher in diesem Kontext von besonderer Bedeutung. Ziel dieser Studie war eine Analyse der Auswirkungen des Einsatzes von Zinnfiltern auf Bildqualität und Dosis von Niedrigdosis-CTs des Abdomens bei Urolithiasis mit direktem Kontakt von Harnsteinen zu Harnleiterschienen.

Material und Methoden 84 Einzeluntersuchungen (konventionelles Niedrigdosis- vs. modifiziertes Niedrigdosis-Protokoll mit Zinnfilterung, Zuteilung randomisiert) wurden bei 65 Patienten (48 Männer, 17 Frauen, mittleres Alter 55,0 ± 15,2 Jahre [18–90 Jahre], maximal eine Untersuchung pro Protokoll) durchgeführt. Die allgemeine Bildqualität sowie die Abgrenzbarkeit des Steins wurden anhand einer 5-Punkte-Likert-Skala durch 2 erfahrene Radiologen beurteilt. Als quantitative Indikatoren der Bildqualität wurden zusätzlich das Signal-zu-Rausch- (SNR) und das Kontrast-zu-Rausch-Verhältnis (CNR) sowie eine figure-of-merit (FOM) als Maß der Dosiseffizienz berechnet.

Ergebnisse Mit einem Non-Inferiority-Margin von 0,5 Stufen der 5-Punkte-Likert-Skala bestand eine Nichtunterlegenheit der Untersuchungen mit Zinnfilter hinsichtlich der allgemeinen Bildqualität (95 %-CI 4,1–4,3; Verwerfgrenze 3,5). Auch hinsichtlich Sichtbarkeit des Harnsteins bestand Nichtunterlegenheit (Größe des Harnsteins: 1–2,4 mm: 95 %-CI 3,39–4,12; Verwerfgrenze 2,73; 2,4–3,8mm: 95 %-CI 4,09–4,47; Verwerfgrenze 3,65; > 3,8mm: durchgehend Maximalbewertung). Der Durchschnittswert des CNR war unter Verwendung des Zinnfilters signifikant erhöht (17,0 zu 10,6). Die Dosis im modifizierten Protokoll war signifikant reduziert (effektive Dosis 1,2 mSv vs. 1,5 mSv, size-specific-dose-estimate 2,33 mGy vs. 3,09 mGy); nur bei der Subgruppenanalyse der Patienten mit BMI > = 35 erreichte diese Dosisreduktion nicht das Signifikanzniveau.

Schlussfolgerung Auch bei direkt an einem Stein angrenzender Harnleiterschiene sind dosisreduzierte Untersuchungen mit spektraler Filterung mittels Zinnfilter konventionellen Niedrigdosis-CT nicht unterlegen bei gleichzeitig signifikanter Dosisreduktion.

Introduction

In Germany, well over 100 000 patients are treated every year as full inpatients due to renal colic associated with nephrolithiasis [1]. The underlying nephrolith is usually confirmed by imaging and evaluated for further therapeutic options. Knowledge of the exact calculus (stone, urolith, concrement) location and size is an important basis for therapy planning and, if necessary, modification. In advance of performing interventional therapies such as extracorporeal shock wave lithotripsy (ESWL), ureterorenoscopy (URS), or percutaneous nephrolithotomy (PCNL), reliable up-to-date information (often repetitive) is needed for both estimating the likelihood of spontaneous or assisted stone passage and procedure selection [2]. Follow-up controls document a progressing stone passage or the success of fragmentation.

Native computed tomography (CT) is the most important diagnostic tool in urolithiasis in addition to ultrasonography of the urogenital tract, which is usually performed initially. In addition to localization of the stone, CT can clarify and document its morphology, possible fragmentation and complications such as urinary retention, fornix rupture or a therapy-related hematoma both initially and in possible follow-up examinations.

The advantages of CT compared to sonography are the independence of the examiner, overall lower susceptibility to artifacts, complete imaging of the urinary tract, as well as the option of determining the stone composition based on its density. Ureteral stents directly adjacent to the calculus can thereby affect the measurability of the size and density of the urolith [3]. Ureteral stents are regularly indicated to relieve urinary retention, making this constellation a common challenge for the diagnostician [2]. A major limitation of the method is the radiation dose associated with CT, especially when it must be applied repeatedly, for example, due to recurrent episodes of ureteral colic [4].

The option of spectral filtering has been introduced into routine diagnostics with the current generation of computer tomographs. This is associated with the possibility of a significant dose reduction with good diagnostic image quality, as has been demonstrated in numerous studies in examinations with a variety of indications [5–8] including urolithiasis [9–11]. However, effects of dose-reducing spectral filtering on image quality with a ureteral stent directly adjacent to a calculus were not explicitly investigated. In this regard, there is the particular problem of the narrow spatial position of the calculus to the ureteral stent, which is itself very radiopaque, leading to difficult delineation of a concrement next to an ureteral stent due to the blurring of the individual image elements according to the point-spread function (PSF) inherent in any non-ideal imaging system. Compared to the conventional protocol, using spectral filtering changes the PSF with the possible result of poorer delineation of the concrement.

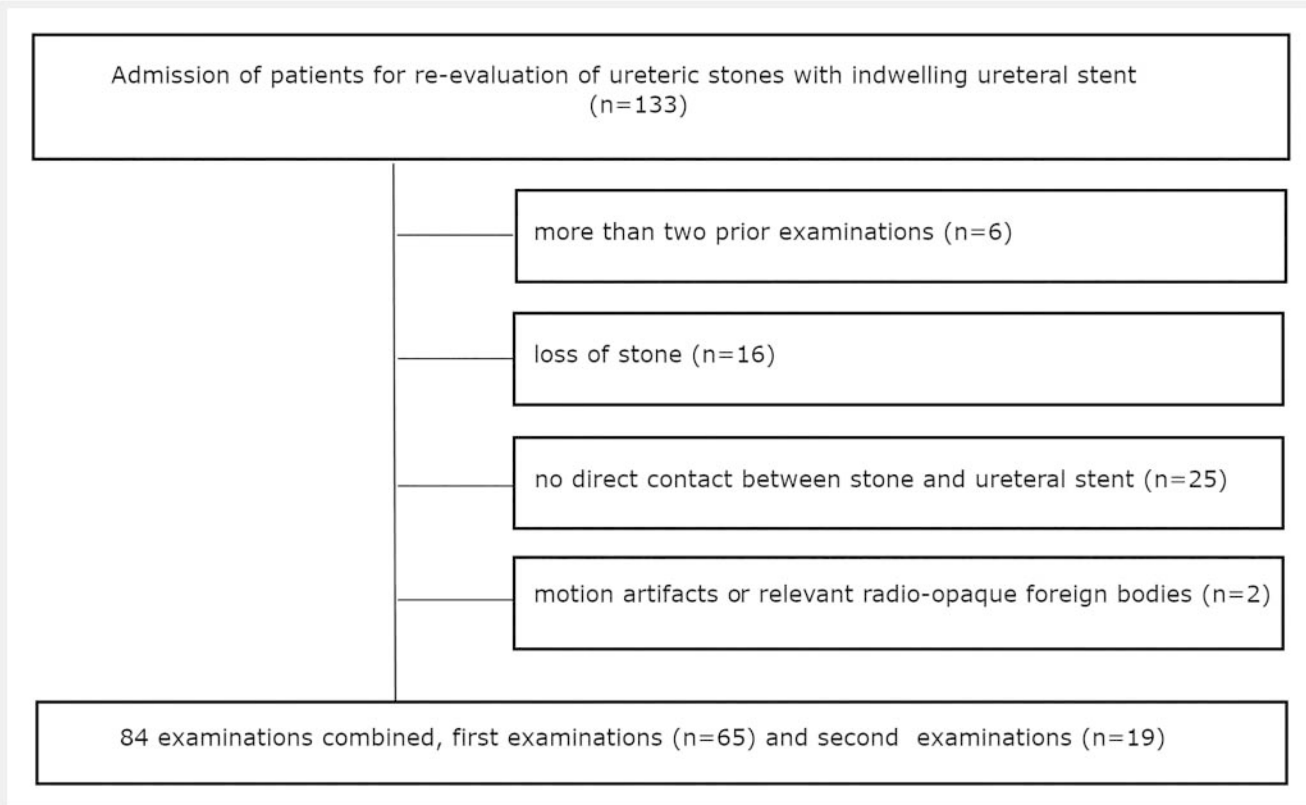
The aim of this study was to evaluate the effect on urolith delineability by using a low-dose protocol with a tin filter versus a conventional examination protocol without a tin filter, characterizability, and dose in patients with an implanted ureteral stent who presented for stone location checks.

Materials and Methods

Patients

In this prospective, randomized, 2-arm comparative study, 65 patients (48 men, 17 women, 18–90 years, mean age 55.0 ± 15.2 years) received 84 native CT scans of the abdomen. Study participants were randomly assigned to two groups, one in which CT acquisition was performed with a tin filter and the other without (study design: ▶ **Fig. 1**).

After informed consent had been given, over a period of 11 months, patients registered for CT stone scans at the urology clinic with ureteral stents (only initial and second in-house examinations), of legal age and able to give consent, were included in this study approved by the responsible ethics committee (ethics



▶ **Fig. 1** Study design.

▶ **Table 1** Patient characteristics, continuous variables are reported as mean ± standard deviation, dichotomous variables as absolute frequencies with percentages in parentheses. Gender distribution, BMI, and effective body diameter related to examinations.

Study participants (examinations)	65 (84)
Age (in years)	55.0 ± 15.2
Men/Women	48 (74 %)/17 (26 %)
Body Mass Index (BMI) [kg/m²]	27.3 ± 5.4
– BMI ≥ 35 kg/m²	11 (7/65)
Effective body diameter	30.9 ± 4.2

vote 389/21). Two study arms were defined and patients were distributed equally. In the case of a second examination of the same person, this patient was assigned to the respective other study arm; additional examinations of the same person were not included in the study. The specific patient characteristics are listed in ▶ **Table 1**.

Examination method

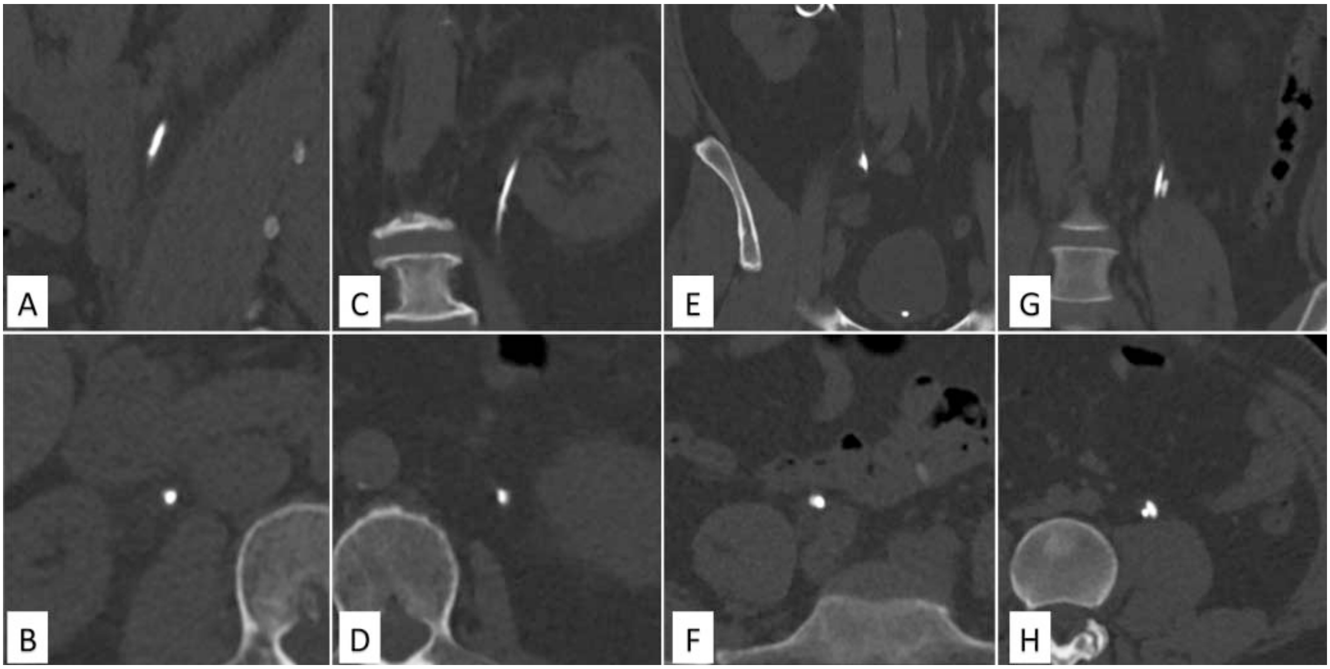
All examinations were performed on a clinical 64-slice whole-body CT scanner (Somatom Go.Top, Siemens, Erlangen, Germany) with the possibility of adding a tin filter. Participants in the study were randomized to a conventional low-dose protocol without tin filtering or a low-dose protocol with additional spectral filtering using tin filters. The following parameters were held constant in both study arms:

- Automatic tube voltage selection (Care kV, Siemens, Erlangen, Germany)
- Tube current modulation (Care Dose 4 D, Siemens, Erlangen, Germany) at constant quality index Q_{ref} @ 120 kV of 30 mAs underlying the tube current modulation.
- Collimation 0.6 mm
- Pitch 0.8

The area of examination was defined according to the clinical question based on the topogram of the area from the upper margin of the left kidney to the middle of the pubic symphysis. Image reconstruction was performed with a slice thickness of 3 mm in the transverse, coronary and sagittal planes. Corresponding to a standard abdominal core, Br31 was used as the reconstruction core in connection with an iterative reconstruction (SAFIRE – strength 3, Siemens, Erlangen, Germany).

Quality assessment

Both the general image quality and distinction of the stone from the ureteral stent were evaluated independently by two experienced radiologists who were blinded to the underlying examination protocol. The results were quantified using a 5-point Likert scale (1: insufficient – stone can only be guessed at if the location is known; 2: poor – stone hardly distinguishable, low diagnostic certainty; 3: moderate – stone moderately distinguishable after



▶ **Fig. 2** Example of quality assessment of stone delineation **A**, **B**) Level 2: poor – stone barely delineable; **C**, **D**) Level 3: moderate – stone moderately delineable on intensive review of the image material; **E**, **F**) Level 4: good – stone well delineated on review of the data set; **G**, **H**) Level 5: excellent – stone readily visible even on cursory review.

intensive review of the image material; 4: good – stone clearly distinguishable when reviewing the data set; 5: excellent – stone clearly visible even on cursory review) (▶ **Fig. 2**) [12].

Due to the expected better delineation of large compared to small stones from the ureteral stent, visual assessment was differentiated with regard to stone size. The stone size was estimated by approximating the stone morphology by an ellipsoid with corresponding semi-axes a_1, a_2, a_3 and from this an effective stone diameter $D_{eff} = \sqrt[3]{a_1 a_2 a_3}$ was determined, which corresponds to the diameter of an equatorial spherical section (circle) with the same cross-section. The use of the effective diameter in contrast to a relation to the cut surface of the calculus, which is also conceivable in this regard, is based on fundamental investigations into the delimitation of round structures in the presence of overlying image noise [13].

Quantitative criteria of image quality

For quantitative assessment of image quality, measurements of X-ray densities in Hounsfield units (HU) and their standard deviations were made using placed regions-of-interest (ROI) within both the urinary stone and the ureteral stent, as well as within five other regions (liver parenchyma, abdominal aorta, psoas major muscle, subcutaneous adipose tissue, extracorporeal air space). The standard deviation (SD) of the HU values of the extracorporeal airspace was used as a measure of image noise. The signal-to-noise ratio (SNR) and the contrast-to-noise ratio (CNR) were calculated from the respective mean density values in HU for the individual ROIs using $SNR = \text{mean value}_{\text{measurement object}}/SD_{air}$ and $CNR = (\text{mean value}_{\text{measurement object}} - \text{mean value}_{\text{fattissue}})/SD_{\text{measurement object}}$. To determine the dose efficiency, a figure of merit (FOM) was calculated for each ROI with FOM = CNR/effective dose^2.

Evaluation of radiation exposure

The computed tomography scanner reported the following indices of radiation exposure: volume-based CT dose index ($CTDI_{vol}$) based on a standard 32 cm phantom, dose-length product (DLP).

The effective dose was calculated as the product of DLP and an abominopelvic conversion factor of 0.015 mSv/mGy cm [14]. Size-specific dose estimates (SSDE) were determined as a product of the $CTDI_{vol}$ with conversion factors dependent on anthropometric measurements of the respective patient (anteroposterior and transverse body diameter with the calculated effective body diameter $= \sqrt{D_{ap} * D_{trans}}$) [15].

Statistics

The data were evaluated using the R 3.6.1 software package (R Foundation for Statistical Computing) in conjunction with R Studio 1.3 based on a significance level of 0.05. Representation is in the format mean ± standard deviation. Tests for normal distribution were performed using the Shapiro-Wilk test and visually by analyzing histograms.

Statistical testing for non-inferiority (NI) of the studies with tin filter was performed by defining an NI margin and comparing the confidence interval with tin filter with the limit for rejecting the NI hypothesis (mean image quality without tin filter – NI margin) [16–18]. A conservative NI margin of 0.5 quality levels was chosen for the 5-point Likert scale. Confidence intervals were calculated using the bootstrapping method [19] when the subjective quality ratings were not normally distributed; in this case BC_a confidence intervals were used.

The necessary sample size was calculated according to the procedure given in [16], assuming a statistical power of 90 % and a one-sided error of the first kind of 2.5 %. Testing for statistical significance was performed depending on the normal distribution of the data using a t-test or Mann-Whitney-Wilcoxon test. Correlation tests were performed using Pearson's correlation coefficient. Cohen's kappa was used to quantify interrater agreement.

Results

Subjective quality assessment

Regarding general image quality, the mean rating by both raters was almost identical across all stone sizes, 4.0 ± 0.4 without and 4.2 ± 0.4 with tin filter ($\kappa = 0.53$).

Using an NI margin of 0.5 rating levels, the NI hypothesis resulted in a rejection limit of 3.5. This led to a confirmation of the NI hypothesis taking into consideration that this was not undercut by the lower limit of the 95 % confidence interval of the assessments with tin filter of 4.1.

The average quality assessment of the stone delineation (image examples: ▶ **Fig. 3**) across all stone sizes was 3.9 ± 0.8 without a tin filter and 4.3 ± 0.7 with a tin filter (statically significant, $p < 0.05$).

The limit size of perfect stone delineation (Λ) corresponds to the effective stone diameter below which the subjective quality assessment of stone delineation (averaged over both examiners) falls below the maximum value of 5. In the data set presented, this corresponded to an effective stone size of 3.8 mm. Above the cutoff size, there is equivalence of delineability across both study protocols.

Subjective delineation of uroliths from stents showed a high correlation with effective stone diameters below the cutoff size (Pearson's correlation coefficient = 0.69). Due to this high correlation, the range of effective stone sizes below Λ was partitioned into two areas to allow statistical analysis in groups of similar stone sizes each. The subdivision was based on the effective stone sizes into size groups A (effective stone diameter [1–2.4 mm]) and B (effective stone diameter [2.4–3.8 mm]), respectively, including the lower limit and excluding the upper limit).

Using an NI margin of 0.5 evaluation levels, the NI hypothesis rejection limit in Group A resulted in 2.73 and in Group B in 3.65, each based on the average stone separability score in the protocol without tin filter. The 95 % confidence intervals of stone separability with tin filter in group A were [3.39–4.12] and in group B [4.09–4.47]. The respective discard limit was not undercut by the lower limit of the confidence interval with tin filter in any of the groups, consistent with the assumption of NI of the study protocol with tin filter. The interrater agreement κ of stone delineability ratings across all stone sizes was 0.64, corresponding to substantial agreement (▶ **Fig. 4**).

Objective quality assessment

Regarding the measurements of SNR and CNR of the stones, a significantly higher CNR and a not significantly different SNR were shown using the tin filter (▶ **Table 2**).

The FOM resulting in combination with the effective radiation exposure of the corresponding examinations showed significantly higher average values when using the tin filter ($p < 0.05$) (▶ **Table 2**).

Radiation exposure

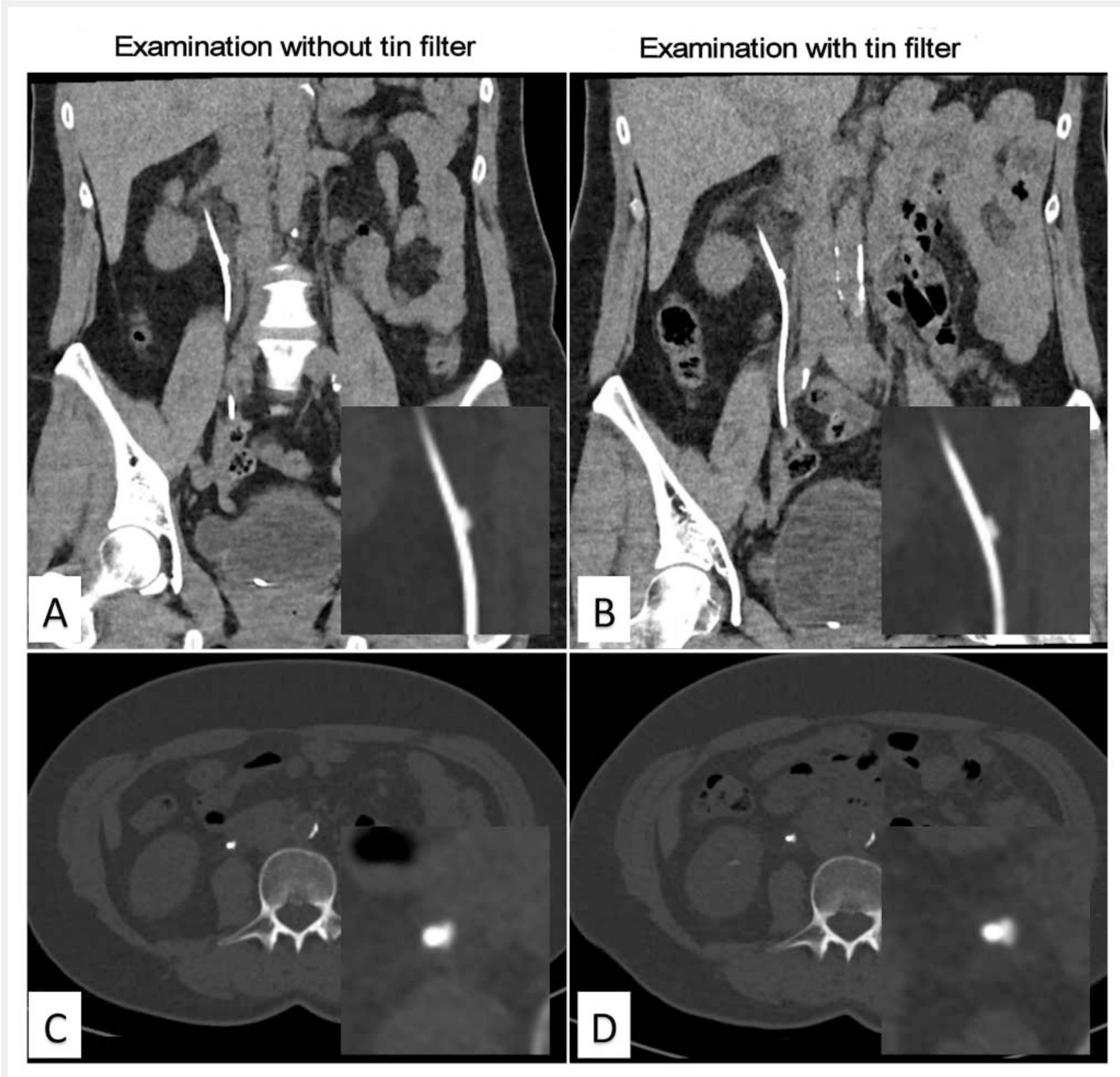
Using spectral filtering by tin filter, there was significantly decreased radiation exposure of patients, both in terms of effective dose with 1.2 ± 0.4 mSv (without tin filter 1.5 ± 0.4 mSv, $p < 0.05$) and in terms of SSDE with 2.33 ± 0.38 mGy (without tin filter 3.09 ± 0.47 mGy, $p < 0.05$). In a subgroup analysis related to body mass index (BMI), the dose reduction did not reach the significance level in the group with BMI ≥ 35. ▶ **Table 3** provides an overview of the parameters of the radiation dose in relation to the use of the tin filter and as a function of BMI.

Discussion

The use of spectral pre-filtering of the X-ray beam (originally used in CT as part of the optimization of dual-source CT [21]), is a common method of reducing radiation dose in X-ray diagnostics. The applicability of the method has been demonstrated in numerous previous studies, both with respect to achievable radiation reduction and regarding consistently high image quality. Applications were made in CT of the trunk including topograms [5–8] as well as in the context of urolithiasis [9–11]. Effects on image quality during stone position checks in urolithiasis and existing therapeutically implanted ureteral stent, on the other hand, have not yet been studied in a dedicated manner, but are of particular interest, because in this case, due to the given PSF of the imaging system, artifacts may locally occur due to the ureteral stent, and the effect of the tin filter on that constellation is not known.

Analogous to the published results, there were no significant differences across both study arms with regard to subjective assessment of overall image quality in this study. Also, with regard to the assessment of the subjective separability of the urinary stone from the stent, which is relevant in the context of this study, according to the diagnostic accuracy in the given clinical question, the NI of the protocol with tin filter was proven in all groups of stone sizes ([1 .. 2.4), [2.4 .. Λ), [Λ .. ∞)). The average rating of stone delineation from the stent was thereby (with the exception of the uroliths > Λ) always greater when using the tin filter. Correspondingly, the objective-quantitative quality parameter CNR was also significantly higher when the tin filter was used. Thus, when a conservatively chosen NI margin was used, the NI hypothesis when using a tin filter was clearly demonstrated in terms of both image quality and delineation of urinary tract stones. The data also suggest the potential for stone delineation improvement beyond this, although the sample size does not provide adequate statistical power for this statement.

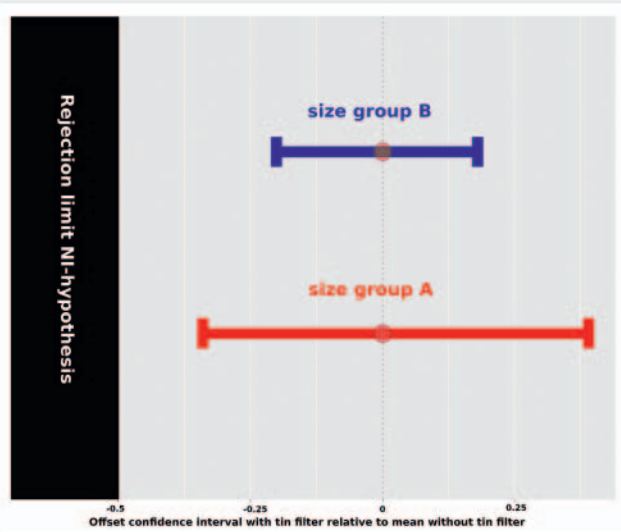
At the same time, a significant reduction in radiation exposure was demonstrated using the tin filter. The mean reductions in ef-



▸ **Fig. 3** Image example of the same patient with right-sided ureteral stent and proximal calculus adjacent to the stent from the medial side, examination at two different times with no intermediate change in findings (temporal difference 14 days, no intermediate therapeutic measures, enlarged image section in the lower right of each image). **A**, **B** coronary in the soft tissue window, **C**, **D** transverse in the bone window. **A**, **C** without tin filter; **B**, **D** with tin filter.

fective dose and SSDE were approximately 20 % and 25 %, respectively. This effect was also seen to a lesser extent in the subgroup of particularly dose-exposed patients with a BMI ≥ 35 [m²/kg], but without reaching the statistical significance level. Compared with some similar published studies, this corresponds to a similar dose reduction [9, 10], although further dose reduction by using higher pitch values seems possible [11]. However, the present study did not focus on reducing the radiation dose by applying special optimizations that might have resulted in maximum dose reduction. The focus here was rather an investigation of how strong the effect is under conditions that are commonly used in practice (examination protocol supplied in principle by the device manufacturer including automatic tube voltage selection and tube current modulation [22]).

This study has some limitations. A larger sample would have been desirable to optimize statistical power and highlight possible differences between various stone types. However, instead of considering all patients with nephroliths and implanted stents, this study focused on nephroliths with direct contact between stone and stent to address this issue, which is more clinically rele-



▶ **Fig. 4** NI testing of the delimitability of stone and stent. 95 % confidence intervals of the individual size groups with tin filter, relative to the mean without tin filter (centered); the rejection limit of the NI hypothesis is not reached in any group.

vant. A higher number of cases would be required to demonstrate the improved stone delineation suggested by our data when examining with tin filters. However, the aim of our study was to test the non-inferiority of the method employing tin filters. For further conclusions, studies (preferably multicenter) with higher case numbers and prospective design will be required.

The present study does not provide any information regarding the delineation of stones with effective diameters below 1 mm, since these did not occur in the sample. However, this appears to be a rather theoretical problem, since spontaneous stone passage of these stones can be excpected, and stent placement is not indicated in such cases.

Conclusions

Low-dose CT protocols demonstrate no loss of image quality or limited delineation of uroliths from ureteral stents when using spectral filtering with tin filters compared with examinations without tin filters. In addition, there is about a 20 percent further dose reduction.

▶ **Table 2** Quantitative image quality parameters.

	SNR –Sn	SNR +Sn	CNR –Sn	CNR +Sn	FOM –Sn	FOM +Sn
Stone	68.9 ± 29.4	79.2 ± 33.1	10.6 ± 6.8*	17.0 ± 9.3*	111.8 ± 143.0*	366.5 ± 457.9*
Stent	245.7 ± 78.6	257.9 ± 61.1	22.3 ± 20.4	24.6 ± 19.4	639.1 ± 1253.1*	841.3 ± 1477.9*
Liver	4.1 ± 1.4*	4.8 ± 1.4*	7.2 ± 1.3	7.3 ± 1.3	42.0 ± 30.9*	54.9 ± 36.2*
Aorta	3.7 ± 1.0	4.0 ± 0.8	6.9 ± 1.1*	6.4 ± 1.1*	37.3 ± 25.0	41.4 ± 22.4
Psoas	3.9 ± 1.0*	4.6 ± 0.9*	7.1 ± 1.3	7.0 ± 1.2	39.7 ± 24.7	50.0 ± 30.3

Legend: SNR = Signal-Noise Ratio, CNR = Contrast-Noise Ratio, FOM = Figure of Merit, –Sn = Protocol without tin filter, +Sn = Protocol mit tin filter.
* = Significant difference across both protocols ($p < 0.05$).

▶ **Table 3** Radiation dose related to the use of a tin filter and as a function of BMI.

	–Sn total	–Sn, –BMI	–Sn, +BMI		+Sn total	+Sn, –BMI	+Sn, +BMI
Effective dose [mSv]	1.5 ± 0.4*	1.4 ± 0.4*	2.0 ± 0.5		1.2 ± 0.4*	1.1 ± 0.3*	1.7 ± 0.7
Effective dose/BMI	0.053 ± 0.011*	0.053 ± 0.012*	0.053 ± 0.011		0.043 ± 0.011*	0.042 ± 0.009*	0.046 ± 0.022
SSDE	3.09 ± 0.47*	3.01 ± 0.43*	3.56 ± 0.45		2.33 ± 0.38*	2.26 ± 0.29*	2.89 ± 0.54
SSDE/BMI	0.11 ± 0.02*	0.12 ± 0.02*	0.093 ± 0.012*		0.09 ± 0.02*	0.088 ± 0.014*	0.078 ± 0018*

Legend: SNR = Signal-Noise Ratio, CNR = Contrast-Noise Ratio, FOM = Figure of Merit, –Sn = Protocol without tin filter, +Sn = Protocol mit tin filter, BMI = Body Mass Index, +BMI: BMI ≥ 35, –BMI: BMI < 35.
* = Significant difference across both protocols ($p < 0.05$).

CLINICAL RELEVANCE OF THE STUDY

- In patients with urinary stones and the associated high probability of follow-up examinations, reduction of radiation exposure while maintaining image quality is of particularly high clinical relevance.
- The use of spectral filtering by means of tin filters is a method for dose reduction that has been well researched in general issues and has found its way into routine clinical diagnostics, but still has evidence gaps in detailed issues.
- Stone position controls with an implanted ureteral stent are potentially repetitive and present a particular challenge due to artifact-related difficulty in delineating uroliths.

Conflict of Interest

The authors declare that they have no conflict of interest.

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