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ORIGINAL ARTICLE

Diagnostic accuracy of third-generation dual-source dual-energy CT: a prospective trial and protocol for clinical implementation

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Abstract

Purpose Uric acid (UA) calculi can be referred to chemolitholysis rather than invasive treatment. Dual-energy computed tomography (DECT) may be able to distinguish between UA and non-UA (NUA) calculi. The aim of this study was to evaluate the validity of third-generation DECT for the first time and to investigate whether combining DECT with clinical parameters can increase its predictive accuracy.

Materials and methods All patients who presented to our emergency department between January 2015 and March 2017 with urinary stones were prospectively included in this observational study and underwent DECT with subsequent interventional stone removal. Stone composition was analyzed using infrared spectrometry as the gold standard. Predictive accuracy of DECT and clinical covariates was computed by assessing univariate and multivariate areas under the curve (AUCs).

Results Of 84 patients with 144 urinary stones, 10 (11.9%) patients had UA stones according to infrared spectrometry, and the remaining stones were NUA or mixed stones. DECT had a positive predictive value of 100% and a negative predictive value of 98.5% for UA stones. The AUC for urine pH alone was 0.71 and 0.97 for DECT plus urine pH. No UA stones were found in patients with a urine pH above > 5.5. Mean DLP was 225.15 ± 128.60 mGy*cm and mean effective dose was 3.38 ± 1.93 mSv.

Conclusions DECT is a safe method for assigning patients to oral chemolitholysis. Clinical preselection of patients based on urinary pH (< 6.0) leads to a more liable use of DECT. Third-generation DECT needs significant lower radiation doses compared to previous generations.

Keywords Urolithiasis · Uric acid · Dual-energy CT · DECT · Third generation · Chemolitholysis · Clinical protocol · Clinical algorithm · Multi-detector CT · Kidney stone

Introduction

The incidence of urinary calculi has increased steadily within the last decades, with a lifetime risk of approximately 12% in men and 6% in women [1, 2]. The current EAU guidelines recommend ultrasound (US) and non-contrast-enhanced CT as the imaging methods of choice in symptomatic colic patients [3]. Conventional CT has been shown to be very sensitive (96.6%) and specific (94.9%) in diagnosing urolithiasis [4], but the stone composition cannot be predicted accurately with conventional CT [5]. An accurate determination of stone composition during initial CT imaging would, however, enhance patient counseling, i.e., either chemolitholysis in patients with uric acid (UA) stones or interventional stone treatment in those with non-uric acid (NUA) calculi [3, 6]. Dual-energy computed tomography

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(DECT) has been currently developed as a technology that might be able to discriminate stone compositions, and to distinguish between UA and NUA calculi immediately [7, 8]. Until now, there are no prospective observational studies available validating the accuracy of DECT by comparing treated calculi with infrared spectrometry as the gold standard in particular not for latest third-generation DECT.

The purpose of this prospective observational study was to evaluate for the first time the validity of a third-generation DECT in predicting UA calculi compared to infrared spectrometry, as well as a possible radiation dose reduction compared to second-generation DECT and to investigate whether combining DECT with clinical parameters can increase its predictive accuracy. To reduce unnecessary use of DECT and for a responsible use of radiation exposure, a reasonable clinical protocol is required.

Materials and methods

Patients

All patients with suspected urolithiasis received a DECT as the imaging procedure in the presence of renal colic or before treatment of a known kidney or ureteral stone between January 2015 and March 2017.

Inclusion criteria for the prospective study were confirmed calculi on DECT, consecutive available urinary stones after an endoscopic procedure and a successful ex vivo analysis. Exclusion criteria were age < 18 years, pregnancy or a renal transplant. Interpreter of CTs and infrared stone analysis were blinded against each other. When several CT examinations were performed for a patient during the observation period, only the first DECT examination was included in this study. Clinical parameters such as sex, age, size, body weight, BMI (kg/m^2), blood UA (mg/dl), blood calcium levels (mmol/l) and urine pH measured with a dip stick test were documented at the time of diagnosis.

Written informed consent was obtained from each subject prior to DECT examinations, and all procedures were performed in accordance with the Helsinki Declaration. The study was approved by local ethics committee (15-01-27).

DECT protocol and image analysis

Unenhanced DECT was performed using a third-generation dual-energy, dual-source CT scanner (SOMATOM Force, Siemens Healthcare, Forchheim, Germany). A 100/Sn150 kV protocol with a tin filter for the high-energy X-ray tube was applied. The imaging parameters were as follows: 32 × 0.6 mm collimation, 319 and 123 quality reference milliampere-second for the 100 and 150 kV tubes, respectively, 0.5 s rotation time, and spiral mode with pitch = 0.7. Exposure was automatically controlled. Dual-energy images were reconstructed using a kernel B30f with a 300 mm field of view based on raw data images with a thickness of 0.6 mm. The radiation dose was provided by the scanner and expressed as computed tomography dose index (CTDI) and dose length product (DLP). Effective dose was calculated as DLP*0.015 (conversion coefficient) [9].

All images were assessed by an experienced uroradiologist who identified each stone on images using specific software. The vendor's specific post-processing software package for dual energy, syngo.via by Siemens Medical Solutions, was used. The software automatically revealed the size, density and ratio of each tagged calculus. Then, the radiologist drew an ROI (region of interest) around each stone in the 100 kV images and an identical ROI in the corresponding 150 kV images to obtain density values in a standard workstation. To differentiate UA from NUA stones, commercial software (syngo.CT DE Calculi Characterization, Siemens Healthcare, Forchheim, Germany) was used. The CT number ratio was calculated voxel by voxel for each stone and was compared with a customized threshold (1.13 for 100/Sn150 kV and 1.21 for 100/Sn150 kV). If the CT number ratio was below the threshold, then the voxel was colored red, indicating a UA stone; for a ratio above the threshold, the voxel was colored blue, indicating an NUA stone.

Based on the reconstructed CT scans, the following stone parameters were recorded: number, localization, size, volume Hounsfield unit, stone composition and the presence of foreign materials, such as ureteral stents.

Stone analysis

To determine stone composition, all calculi were analyzed using infrared spectrometry (Paragon 1000PC, PerkinElmer, Shelton, USA) as the current gold standard with a quantitative composition analysis. Single component stones consisting of pure UA were classified as UA stones, and all other stones were classified as NUA stones. Each stone was analyzed separately, even in patients with multiple stones.

Statistical analysis

Statistical calculations were performed using the Statistical Package for the Social Sciences 24 software (SPSS Inc., Chicago, IL, USA). Data were expressed as the mean ± SD (range). Differences between the means and proportions were calculated using the independent t test and Chi-squared test, respectively. The accuracy of DECT in predicting UA calculi was tested in univariable and multivariable analyses using ROC-derived areas under the curves (AUC). A p value < 0.05 was considered statistically significant.

Results

A total of 84 patients with 144 calculi were included in this analysis: 14 (16.7%) females and 70 (83.3%) males with a mean age of 50.2 ± 16.1 years (range 18–87 years). Fifty-two patients had a single stone and 32 had multiple stones. Mean BMI was 26.9 ± 4.4 kg/m^2 (range 16–42.1 kg/m^2) and did not differ significantly between patients with UA (28.6 ± 5.5 kg/m^2) and NUA (26.6 ± 4.2 kg/m^2) stones ($p = 0.19$), respectively.

Among the patients, 10 (11.9%) had pure UA stones and 74 (88.1%) had NUA stones. Patient characteristics are shown in Table 1. Only age ($p = 0.006$) and urine pH ($p = 0.01$) differed significantly between UA and NUA stone groups.

Comparing the findings of the DECT scans with those of infrared spectrometry revealed 98.6% consistent results. Only two of twelve (16.7%) UA calculi were misdiagnosed as NUA calculi. No NUA calculi were misdiagnosed as an UA stone.

Predicting UA stones and differentiating them from NUA-containing calculi was feasible, with a sensitivity of 84.6%, a specificity of 100%, a positive predictive value of 100% and a negative predictive value of 98.5%. The AUC of the ROC curve was 0.92 for DECT alone (Fig. 1a). To optimize accuracy, a multivariate model was developed. Further possible clinical parameters included BMI, blood UA and urine pH, which exhibited univariate AUCs of 0.56, 0.59 and 0.72, respectively (Fig. 1b–d). The combination of DECT and urine pH resulted in the best predictive model, showing an AUC of 0.97. The odds ratio (OR) of urine pH was 0.30 ($p = 0.02$).

Possible confounders of DECT analysis might be stone volume, stone location and the presence of foreign materials, such as an ureteral stent (Table 2). Misdiagnosed calculi had volumes ranging from 4 to 419 mm^3, and 4 mm^3 was generally the smallest volume (Table 1). One stone in located in the kidney and one in the ureter were misidentified (1.5% vs. 1.3%, respectively). A ureteral stent was indwelling in 15 patients, resulting in a misdiagnosis rate of 4% (1/25 calculi). Radiation doses expressed as CTDI and DLP were reported separately for single-energy (SE) and dual-energy (DE) scans as well as separated by BMI >/<25 kg/m^2 (Table 1). Mean DLP was 225.15 ± 128.60 mGy*cm and mean effective dose was 3.38 ± 1.93 mSv.

Table 1 Patient characteristics separated by uric acid (UA) vs. non-uric acid (NUA) stone composition

Patient characteristics	Uric acid				Non-uric acid				*p* value
	Mean	± SD	Range		Mean	± SD	Range		
Age (years)	62.6	13.7	40.4	76.9	48.1	15.0	18.9	81.0	0.006
BMI (kg/m^2)	28.6	5.5	22.1	42.1	26.6	4.2	16.0	37.4	0.19
Number of stones (*n*)	1.3	0.5	1.0	2.0	1.7	1.1	1.0	7.0	0.45
Volume (mm^3)	1163	1656	4.2	4901	1108	3709	4.2	37,700	0.76
Blood uric acid (mg/dl)	5.9	1.4	4.2	7.8	5.2	1.4	2.3	11.4	0.30
Blood calcium levels (mmol/l)	2.3	0.1	2.1	2.5	2.3	0.1	2.0	2.9	0.82
Urine pH	5.5	0.2	5.0	5.5	6.1	0.6	4.6	7.5	0.01
CTDI SE (mGy)	4.05	2.20	2.00	8.02	3.50	3.13	1.31	22.79	–
< 25 kg/m^2	2.34	0	2.34	2.34	2.59	1.34	1.31	6.10	
> 25 kg/m^2	4.24	2.25	2.00	8.02	3.90	3.62	1.35	22.79	
CTDI DE	19.20	23.10	9.08	80.51	12.11	5.11	1.49	31.48	
< 25 kg/m^2	9.34	0	9.34	9.34	8.65	3.18	1.49	15.90	
> 25 kg/m^2	20.43	24.38	9.08		13.72	4.98	6.27	31.48	
DLP SE (mGy*cm)	178.03	105.64	69.80	391.40	137.97	102.06	47.20	568.40	–
DLP DE	118.37	122.43	60.60	441.00	80.62	40.58	30.50	222.30	
DLP total	284.56	204.58	142.10	832.40	216.66	113.54	85.30	644.90	
< 25 kg/m^2	149.1	0	149.1	149.1	157.97	51.00	85.30	285.90	
> 25 kg/m^2	299.61	211.04	142.10	832.40	245.39	124.61	91.00	644.90	
Effective total dose (mSv)	4.27	3.07	2.13	12.47	3.25	1.70	1.28	9.67	

The values are expressed as the mean, standard deviation and range. Only age and urine pH were significantly different between both groups

BMI body mass index, *SD* standard deviation, *CTDI* CT dose index, *DLP* dose length product, *SE* single energy, *DE* dual energy

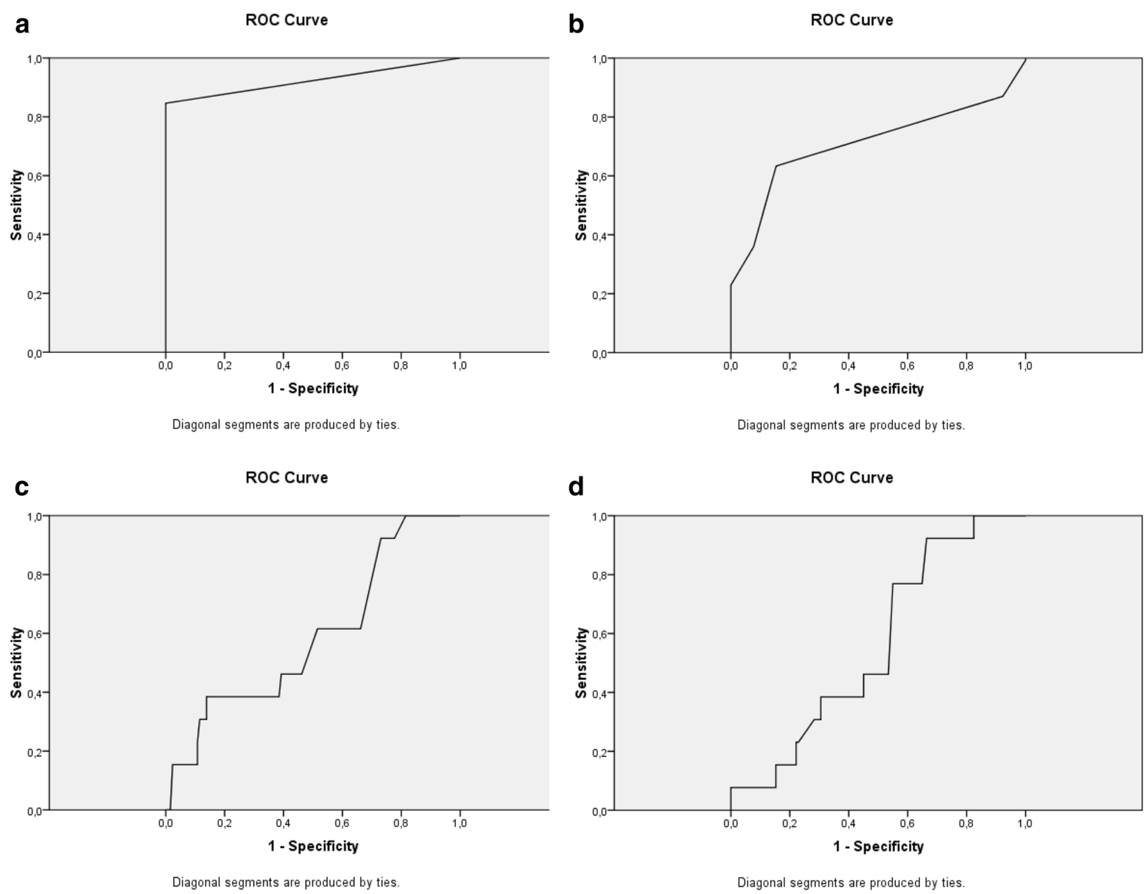

Fig. 1 ROC curves. The area under the curve (AUC) of the ROC curve was **a** 0.92 for DECT alone. The univariate AUCs of **b** urine pH, **c** BMI and **d** blood UA were 0.72, 0.56 and 0.59, respectively

Discussion

To the best of our knowledge, this is the largest prospective observational study to validate the accuracy of third-generation DECT by analyzing treated calculi with infrared spectrometry as the gold standard. The investigated population in our study was comparable to those of other series with regards to patient age [6–8]. However, women were underrepresented in our study, accounting for 16.7% of the population compared with a large analysis of approximately 200,000 stones with a male-to-female ratio of 2.7:1 [6].

Comparing the accuracy between our results (sensitivity: 84.6%, specificity: 100%) and those obtained by previous generation DECT scanners revealed similar findings, with sensitivities ranging from 77.8 to 100% and specificities ranging from 98.1 to 100% [7, 8, 10–15]. In particular, highly accurate specificities are mandatory to preclude scheduling any NUA patients for chemolitholysis by error. The superiority of DECT compared to single-energy CT was previously shown by Bonatti et al. (sensitivity: 100% vs. 94.1%, specificity: 93.4% vs. 72.7%) [11], and Wisenbaugh et al. reported that only 40% of UA and NUA calculi were correctly differentiated with single-energy CT, compared to 93% with DECT [16].

A confounder for accurate DECT analysis may be stone size. As previously described in an in vitro DECT model, very small stones < 3 mm are associated with a specificity of only 88% [17], which is consistent with our experience where 2% of all stones ≤3 mm were misdiagnosed, compared to only 1% of stones > 3 mm. However, stones < 3 mm normally do not require any intervention except for medical expulsive therapy but in case of UA they might benefit from additional chemolitholysis [3]. Only in case of persisting symptoms a surgical stone removal might be indicated. Additionally, a high BMI may complicate accurate DECT findings due to a larger skin-to-stone distance. However, we could not confirm this hypothesis since the BMIs of both misdiagnosed patients (22.1 and 28.9 kg/m^2) were below the upper SD. In recent papers, information concerning BMI was not provided. Another possible confounder is the presence of ureteral stents. In our study, 4% of stones in patients with ureteral stents were diagnosed incorrectly, which is comparable to the findings of Jepperson et al. who reported mischaracterization of stones in 8% of their patients [17].

Table 2 Influence of possible confounders on accuracy of DECT

Possible confounders	Diagnosis by DECT	
	Correct	Incorrect
Localization, *n* (%)		
All	142 (98.6)	2 (1.4)
Kidney	76 (52.8)	1 (0.7)
Ureter	66 (45.8)	1 (0.7)
Uric acid	11 (84.6)	2 (15.4)
Kidney	4 (30.8)	1 (7.7)
Ureter	7 (53.8)	1 (7.7)
Non-uric acid	131 (100)	–
Kidney	72 (55.0)	–
Ureter	69 (45.0)	–
Stone volume (mm^3), mean (SD)		
All	1126 (3592)	212 (293)
Uric acid	1336 (1751)	212 (293)
Non-uric acid	1108 (3709)	–
Foreign material, *n* (%)		
All	24 (96.0)	1 (4.0)
Kidney	16 (64.0)	1 (4.0)
Ureter	8 (32.0)	–
Uric acid	3 (75.0)	1 (25.0)
Kidney	–	1 (25.0)
Ureter	3 (75.0)	–
Non-uric acid	21 (100.0)	–
Kidney	16 (76.2)	–
Ureter	5 (23.8)	–
BMI (kg/m^2), mean (SD)	26.9 (4.4)	25.5 (4.8)

BMI body mass index, *SD* standard deviation

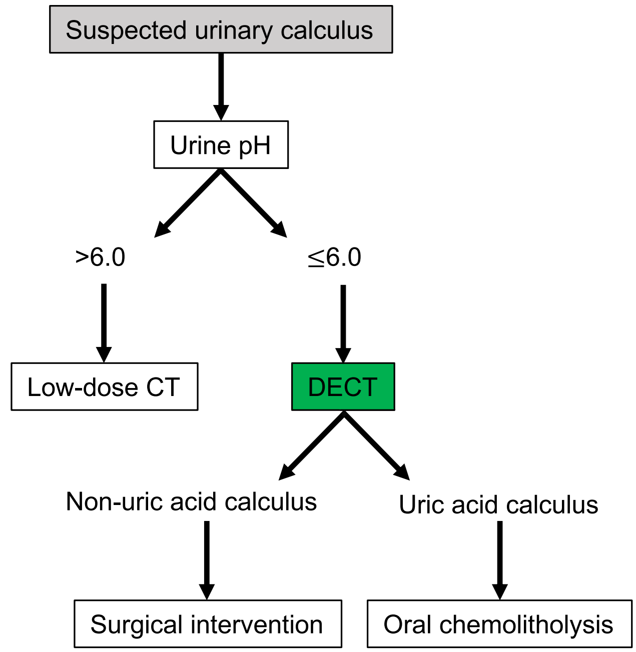

Fig. 2 Flowchart displaying our recommended diagnostic approach for the individualized use of DECT. Since no patient with a urine pH >6.0 had a UA kidney or ureteral stone, these patients would not benefit from DECT

However, the optimal timing for DECT is the first consultation with a symptomatic patient, or with an incidental US finding, which should be validated, or with a symptomatic patient with no stones detected on US; at this time, a ureteral stent is usually not in place.

To our knowledge, this study is the first to provide an efficient DECT-based multivariable model including urine pH to increase the accuracy in predicting UA calculi. A low urine pH is mandatory for the development of UA stones, and the urine pH differed significantly between patients with UA and NUA calculi [18, 19]. However, urine pH alone is imprecise. We also found that 35.1% of the patients with NUA stones had a urine pH that was the same as or even lower than the median urine pH of the UA stone patients. Based on the excellent positive predictive value of DECT of 100% for UA stones and the knowledge that patients with pure UA stones have a urine pH < 6.0, we propose stratification of patients with suspected urolithiasis according to urine pH to select patients with pure UA stones for chemolitholysis. Patients with a urine pH ≤6.0 should receive DECT and those with a urine pH > 6.0 should receive "standard" low-dose CT. This diagnostic algorithm is shown in Fig. 2. With this individualized approach, we would have prevented the additional radiation dose required for DECT in 36.5% of the cases. However, this approach requires further evaluation in larger prospective studies.

The radiation dose of DECT is comparable to that of intravenous pyelography and higher than that of common single-source CT [20, 21]. Comparing our third-generation DECT with previous generations the effective dose could be reduced from 4.18 to 3.38 mSv [8]. Although when comparing with other third-generation DECT our mean DLP was much lower (225.15 mGy*cm vs. 319.40 mGy*cm) [10]. The radiation dose of third-generation DECT can be further reduced by low-dose protocols to a mean DLP of 101 ± 39 mGy*cm; however, this protocol cannot characterize stones ≤5 mm as UA or NUA calculi [22]. Considering radiation dose, our proposed clinical algorithm would only select a subgroup of patients for DECT who are at risk for UA calculi. In these selected patients, a DECT should be used for best diagnostic accuracy.

The NUA stones could have been further divided into different compositions, which would have been especially relevant for estimating the hardness of calculi before scheduling patients for extracorporeal shock wave lithotripsy. However, we did not further subdivide the NUA stones due to the small sample size.

Conclusions

DECT is a safe imaging modality for assigning patients with UA stones to conservative treatment as we could show in the largest prospective study evaluating diagnostic accuracy of third-generation DECT compared to crystallography. No NUA calculi were misdiagnosed as UA calculi which might have delayed necessary stone removal. Furthermore, we could show that third-generation DECT has a lower radiation dose compared to second generation DECT. Our clinical algorithm stratifies patients for an individualized use of DECT to avoid unnecessary radiation dose exposure.

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Author contribution TN project development, data collection and management, data analysis, and manuscript writing. KN data collection and manuscript editing. AN project development and manuscript editing. HI data analysis and manuscript editing. CN manuscript editing. SW manuscript editing. HUS supervision and manuscript editing. CR project development, supervision, and manuscript editing.

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Compliance with ethical standards

Informed consent The study complied with the Declaration of Helsinki and local ethics committee approval (15-01-27) was obtained. All patients provided written informed consent prior to their DECT examinations.

Conflict of interest The authors declare that they have no conflict of interest.

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