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ORIGINAL RESEARCH ARTICLE

Urinary stone assessment in a single-phase may replace the unenhanced and multiphase computed tomography protocol in painless visible haematuria

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ABSTRACT

Objective: Painless visible haematuria (VH) necessitates a computed tomography (CT) usually consisting of one unenhanced and two to three contrast enhanced acquisitions to detect urinary tract stones and malignancy. Recently, we demonstrated that a single nephrographic phase (NP) CT sufficed in detecting malignancy in patients with painless VH. Now, we aim to evaluate the diagnostic performance of single NP CT in stone detection and size measurements in the same cohort.

Material and methods: "A Prospective Trial for Examining Haematuria using Computed Tomography" (PROTEHCT) was a single-center prospective diagnostic study in patients with painless VH between September 2019 and June 2021. All underwent four-phase CT (reference standard) from which a single NP CT (experimental) was extracted. Two randomised readers independently assessed the experimental CT for urinary stones and size. Statistical analysis included diagnostic accuracies and inter-reader agreement (kappa) of experimental CT, and size correlation (Spearman's ρ) between experimental CT and reference standard.

Results: In 308 included patients (median age: 68 years, 250 males), urinary stones (median size 5 mm) were diagnosed in 21%. The per-patient experimental CT sensitivity was 86% (97% for stones ≥ 5 mm), specificity was 98% and accuracy was 96%. The experimental CT sensitivity for detecting kidney stones was 78% (89% for stones ≥ 5 mm), and 100% for bladder and ureteral stones. No missed stone required active treatment. The inter-reader agreement was almost perfect (96%, $k = 0.85$). The correlation in stone size was very strong ($\rho = 0.91$).

Conclusions: A single NP CT is sufficient in detecting and measuring urinary stones in patients with painless VH.

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Haematuria; multidetector computed tomography; prospective study; urinary stones

Introduction

Patients with painless visible haematuria (VH) necessitate a multiphase computed tomography (CT) primarily to detect upper tract urothelial carcinoma (UTUC) and renal cell carcinoma (RCC) [1–4]. However, there is a strong consensus that the CT examination must also be effective in detecting urinary stones [5–7]. A multiphase CT usually consists of an unenhanced (UE) acquisition for stone detection and two to three contrast enhanced acquisitions to detect malignancy. In patients with VH, there is a reported pooled incidence rate of UTUC of 0.4–1.2% and RCC of 1–2%, while the rate of urinary stones is poorly described [3, 4]. To date, there are no CT studies dedicated exclusively to patients with painless VH. Thus, current guidelines are based on research limited to retrospective or selected cohorts, expert opinions and consensus meetings [5–8]. For these reasons, we conducted "A Prospective Trial for Examining Haematuria using Computed Tomography" (PROTEHCT), the very first prospective comparison of a single-phase and a multiphase CT in detecting urinary tract malignancies and stones in patients with painless VH. We have already shown that a single nephrographic phase (NP) CT sufficed in detecting both urothelial carcinoma (UC) and RCC [9, 10]. Thus, the aim of the present study was to assess the diagnostic performance of a single NP CT in detecting and measuring the size of urinary stones in the same cohort.

Materials and methods

All patients referred for CT due to VH between September 2019 and June 2021 were assessed for eligibility. Inclusion criteria were age >18 years and at least one occasion of painless VH. Exclusion criteria were a cystoscopy within 6 months prior to CT, previous or known UC, symptomatic urinary tract infection relieved by antibiotics, symptomatic stone disease, recent catheterisation or instrumentation, estimated glomerular filtration rate <30 mL/min/1.73 m^2, allergy to iodinated contrast media, unable to provide consent for any reason or do not wish to participate for any reason.

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The present study reports on urinary stone assessment, which was a secondary outcome of PROTEHCT. The primary outcome was the difference in diagnostic accuracy between a four-phase and a single NP CT in detecting UC. The prevalence of UC was 14.6%, and the diagnostic accuracy of four-phase and single NP CT was 85.0% and 83.1%, respectively [9]. The prevalence of RCC was 2.3%, and the diagnostic accuracy of four-phase and single NP CT was 97% and 98%, respectively [10].

Study design and ethical approval

This was a single-center, prospective diagnostic CT study. All patients signed a letter of consent, and the study was approved by the regional ethics committee (2019/395) and registered at ClinicalTrials.gov (NCT04077359). Oslo University Hospital funded the study without any external funding.

CT protocol

Patients drank 1 L of water and abstained from urinating for 1 h before undergoing a four-phase abdominopelvic CT (UE, corticomedullary phase [CMP], dual-energy NP and excretory phase [EP]). Imaging was conducted with a 128-multidetector Somatom Definition Edge CT scanner (Siemens Healthineers, Forchheim, Germany) in the supine position, and reconstructed in 3 mm axial, coronal and sagittal planes. Tube voltage was 100 kV for UE and 120 kV for CMP and EP. Dual-energy NP used a single source at 120 kV with gold and tin filters generating twin-beams at 80 and 120 kV from which virtual non-contrast (VNC) images were obtained and reconstructed in 1 mm axial, sagittal and coronal planes. Intravenous Iohexol 350 mg/mL (Omnipaque, GE Healthcare) was administered at 4 mL/s, about 2 mL/kg, after the UE scan. Bolus tracking (200 Hounsfield Unit threshold) in the abdominal aorta initiated CMP at 25 s, NP at 70 s, and EP at 30 min post threshold. The radiation dose of each acquisition in the four-phase CT was registered in 10 random patients.

CT reporting

For each patient, the CT examination was divided into an experimental CT (single NP with VNC only) and a control CT (all four phases). Three uroradiologists with 5–13 years' experience functioned as primary readers and two general radiologists with >20 years' experience functioned as secondary readers. Each experimental and control CT were assessed by one primary and one secondary reader. For each patient, coin tosses assigned which two readers (one primary and one secondary) should score the control, and which two readers (one primary and one secondary) should score the experimental CT. In this way, four independent readers prospectively scored each patient. All readers scored both experimental and control CTs, but never in the same patient.

Any calculus inside the urinary tract was defined as a urinary stone. The CT scans were categorised as "positive" or "negative" per patient, with stratification by the following locations: bladder, ureter and renal collecting system (i.e. kidney). The control CT was considered positive if the UE showed a stone and the EP confirming the location inside the urinary tract. The experimental CT was positive if either VNC and/or NP showed a stone. Stones detected on NP were categorised as "visible" or "invisible" on VNC. Stone size was measured as the largest diameter on UE images of the control CT and on NP images of the experimental CT. In case of multiple stones in one location, only the largest was reported. Readers used multiplanar reconstructions and adjusted window/level settings at the discretion of individual judgement. All readers had access to previous imaging history but each reader was blinded to the other readers' CT reports.

Intervention

Experimental CT: single NP with VNC.
Control CT: all four phases.

Outcomes

The primary outcome was the diagnostic accuracies of the experimental CT in detecting urinary stones. The secondary outcomes were the inter-reader agreement in stone detection, the correlation and agreement in size and the radiation dose.

Reference standard and follow-up

The primary control CT report defined the reference standard. In case of a positive reference standard, a team of urologists decided upon active stone treatment (i.e. decompression of stone obstruction, and/or active stone removal), or conservative management with follow-up. Follow-up ascertainment of active stone treatment was completed in May 2022.

Statistics

Descriptive statistics with 95% confidence interval (CI) according to Wilson were used to calculate the per-patient and per-location diagnostic accuracies of experimental CT in detecting urinary stones [11]. Subgroup analyses were performed according to stone size ≥ 5 mm. The inter-reader agreement in stone detection between the primary and secondary readers was calculated for the experimental and control CT, expressed in percent and Cohen's Kappa and interpreted according to Landis and Koch [12]. We used Spearman's ρ and Bland–Altman plots to assess the correlations and agreements in stone size. Spearman's ρ was interpreted according to Schober [13]. Difference in radiation dose between control and experimental CT was expressed as difference in dose length product DLP (mGycm and percent). We used IBM SPSS Statistics for Windows, Version 28.0 (Armonk, NY, USA), and MedCalc for Windows, version 20.009 (MedCalc Software, Ostend, Belgium) for statistical analyses.

Results

Between September 2019 and June 2021, 308 patients were included for analyses. The median age was 68 years (interquartile

Table 1A. The characteristics of all stones in 308 patients with painless visible haematuria diagnosed at Oslo University Hospital (Aker) between September 2019 and June 2021 who were evaluated with single nephrographic phase computed tomography (single-phase CT) with four-phase CT as reference standard.

Location	Four-phase CT		Single-phase CT							
			Primary reader				Secondary reader			
			Detected stones		Missed stones		Detected stones		Missed stones	
	N	Size (IQR)	*N*	Size (IQR)	*N*	Size* (IQR)	*N*	Size (IQR)	*N*	Size* (IQR)
Kidney	51	5 (2–7)	40	5 (4–8)	11	3 (2–5)	40	4 (3–6)	11	3 (2–6)
Ureter	10	6 (4–13)	10	6 (5–9)	0	n.a.	10	6 (5–12)	0	n.a.
Bladder	15	9 (4–13)	15	9 (4–15)	0	n.a.	13	10 (4–16)	2	7 (1–13)
Total	76	5 (3–9)	65	5 (4–10)	11	3 (2–5)	63	5 (3–10)	13	3 (2–6)

Sizes are all median mm.

CT: computed tomography; N: number of stones; IQR: interquartile range; n.a.: not applicable; Single-phase CT: single nephrographic phase CT; *: size according to the four-phase CT. Four-phase CT was performed by the primary reader.

range [IQR]: 53–77, range 18–96), and 81% (250) were males. A total of 76 stones with a median size of 5 mm (IQR: 3–9) were registered in 64 patients (Table 1A). Thus, the overall prevalence of urinary stone disease was 21% (95% CI: 17–26), with 17% having stones in a single location, 3% in two locations and 1% in all three locations. In males, the prevalence of urinary stone disease was 23% (95% CI: 18–29), and in females 10% (95% CI: 5–21).

During a median follow-up time of 19 months (IQR: 15–25, range 10–31), 32% (95% CI: 22–43, 24/76) of all stones in 38% (95% CI: 27–50, 24/64) patients underwent active stone treatment (Table 1B). No patient underwent active treatment in more than one location.

The performance of experimental CT

For the primary reader, the per-patient sensitivity in detecting urinary stone disease was 86%, and 97% for stones ≥ 5 mm (Table 2). There was no added value of VNC as all detected stones were detected on the NP while four stones were invisible on VNC (Figure 1). The inter-reader agreement between the primary and secondary readers was almost perfect (96%, $k = 0.85$ [95% CI: 0.78–0.93]).

There was a very strong correlation in stone size between the experimental CT and the reference standard ($\rho = 0.91$) (Figure 2). Additionally, there was no difference in the median size, and the 95% limits of agreement (LOA) ranged between −4 to 4 mm.

Kidney

The prevalence of kidney stones was 17% (95% CI: 13–21), and the median size was 5 mm (Table 1A). For the primary reader, the sensitivity was 78%, and 89% for stones ≥ 5 mm (Table 2). The inter-reader agreement between the primary and secondary readers was almost perfect (96%, $k = 0.82$ [95% CI: 0.73–0.92]). Both the primary and secondary readers missed kidney stones in 11 patients of which seven were in the same patients (Figure 3). The median size of the missed stones was 3 mm, and none required active treatment during the follow-up time.

Ureter

The prevalence of ureteral stones was 3% (95% CI: 2–6), and the median size was 6 mm. For the primary reader, the sensitivity, specificity and accuracy were all 100%. The inter-reader agreement between the primary and secondary readers was almost perfect (100%, $k = 0.95$ [95% CI: 0.85–1.0]).

Bladder

The prevalence of bladder stones was 5% (95% CI: 3–8), and the median size was 9 mm. For the primary reader, the sensitivity, specificity and accuracy were all 100%. The inter-reader agreement between the primary and secondary readers was almost perfect (99%, $k = 0.86$ [95% CI: 0.72–0.99]). The secondary reader missed bladder stones in two patients of which the largest stone was 13 mm.

Control CT

The inter-reader agreement between the primary and secondary readers was almost perfect (94%, $k = 0.82$ [95% CI: 0.74–0.90). There was a very strong correlation in stone size between the

Table 1B. The characteristics of stones receiving active and conservative treatment.

Location	Stone treatment							
	Active treatment				Conservative treatment			
	N	%	95% CI	Size (IQR)	*N*	%	95% CI	Size (IQR)
Kidney	10	20	11–32	9 (6–11)	41	80	68–89	4 (2–6)
Ureter	5	50	24–76	6 (5–10)	5	50	24–76	4 (4–18)
Bladder	9	60	36–80	13 (8–17)	6	40	20–64	4 (3–6)

Size are all median mm according to the reference standard.

N: number of stones; CI: confidence interval; IQR: interquartile range.

Table 2. The diagnostic performance of the single-phase CT in detecting urinary stones in 308 patients with painless visible hematuria.

Four-phase CT	Single-phase CT			
	Primary reader		Secondary reader	
	Neg	Pos	Neg	Pos
Urinary stone disease				
Neg	240	4	241	3
Pos	9	55	8	56
	%	**95% CI**	**%**	**95% CI**
Sensitivity	86	75–92	88	77–94
Stones ≥ 5 mm	97	86–100	97	86–100
Specificity	98	96–99	99	97–100
NPV	96	93–98	97	94–98
PPV	93	84–97	95	86–98
Accuracy	96	93–98	96	94–98
Kidney				
Neg	252	5	257	0
Pos	11	40	11	40
	%	**95% CI**	**%**	**95% CI**
Sensitivity	78	65–88	78	65–88
Stones ≥ 5 mm	89	72–96	85	68–94
Specificity	98	96–99	100	99–100
NPV	96	93–98	96	93–98
PPV	89	77–95	100	91–100
Accuracy	95	92–97	96	94–98
Ureter				
Neg	298	0	297	1
Pos	0	10	0	10
	%	**95% CI**	**%**	**95% CI**
Sensitivity	100	72–100	100	72–100
Stones ≥ 5 mm	100	65–100	100	65–100
Specificity	100	99–100	100	98–100
NPV	100	99–100	100	99–100
PPV	100	72–100	91	62–98
Accuracy	100	99–100	100	98–100
Bladder				
Neg	293	0	291	2
Pos	0	15	2	13
	%	**95% CI**	**%**	**95% CI**
Sensitivity	100	80–100	87	62–96
Stones ≥ 5 mm	100	72–100	90	60–98
Specificity	100	99–100	99	98–100
NPV	100	99–100	99	98–100
PPV	100	80–100	87	62–96
Accuracy	100	99–100	99	97–100

CT: computed tomography; CI: confidence interval; NPV: negative predictive value; PPV: positive predictive value; single-phase CT: single nephrographic phase CT. Four-phase CT was performed by the primary reader.

primary and secondary readers (Spearman's ρ = 0.91 [95% CI: 0.85–0.94]), and the 95% LOA ranged between −3 and 4 mm.

Radiation dose

The mean DLP of the control CT was 1278 mGycm (95% CI: 955–1,602) and 533.2 mGycm (95% CI: 457–610) of the experimental CT. The mean DLP reduction was 745 mGycm (95% CI: 486–1,004), indicating a 57% (95% CI: 52–61) dose reduction when using the experimental CT only.

Discussion

In PROTEHCT, we have demonstrated the efficacy of a single NP CT, eliminating the need for a four-phase CT in the detection of both UC and RCC [9, 10]. The present study shows that this simplified CT protocol is also excellent in detecting bladder and ureteral stones. While this protocol failed to detect 22% of all kidney stones, the missed stones were small (median size 3 mm) and required no active treatment during follow-up.

Urinary stone disease (21%) was more common than UC (14.6%) and RCC (2.3%) in PROTEHCT. To the best of our knowledge, no prospective studies have reported the prevalence of urinary stone disease in patients with painless VH, although a retrospective study by Bretlau et al. reported 12% [14]. Given the prevalences of UC and RCC in PROTEHCT corresponding closely to other relevant studies, we assert that our cohort is representative [3, 4, 9, 10].

The per-patient sensitivity of single NP CT in our study was 86–88%, and 97% for stones ≥ 5 mm. The inter-reader agreement was almost perfect (k = 0.85) indicating a high level of robustness. The decision to use a stone size ≥ 5 mm for subgroup analyses was based on a large review showing that almost 75% of ureteral stones <5 mm passed spontaneously [15]. A recent review reported a pooled sensitivity of 93.1% and specificity of 96.6% in detecting stones ≥ 3 mm on low-dose UE CT [16]. However, all studies were conducted in patients with clinical suspicion of urinary stone disease making comparison difficult. To our knowledge, no previous studies have reported per-patient accuracies of contrast-enhanced CT in patients presenting with painless VH.

The prevalence of kidney stones was 17% compared to 7.8% in the study by Bretlau et al. [14]. The single NP CT sensitivity was 78%, and 85–89% for stones ≥ 5 mm. Previous studies report sensitivity values of contrast-enhanced CT between 75 and 100% [17–20]. However, these retrospective studies included high-prevalence cohorts, reported per-stone sensitivities and used various cut off criteria for stone size making comparison difficult. The median size of the kidney stones that were missed by the single NP CT in our study was only 3 mm, and according to the European Association of Urology (EAU), active treatment is not recommended for asymptomatic kidney stones <15 mm [21]. We believe missing small stones in patients with painless VH is acceptable given their minimal clinical significance. Moreover, since the NPV of single NP CT was 96% regardless of stone size, it indicates that single NP CT has an excellent ability to rule out clinically significant kidney stones (Table 2). All patients with recurrent or persisting painless VH are potential candidates for a new workup, primarily to detect UC. This would also be the case if a small kidney stone was detected on a previous CT. Hence, we expect no major impact on the frequency of repeated scans due to missed small kidney stones at the initial workup.

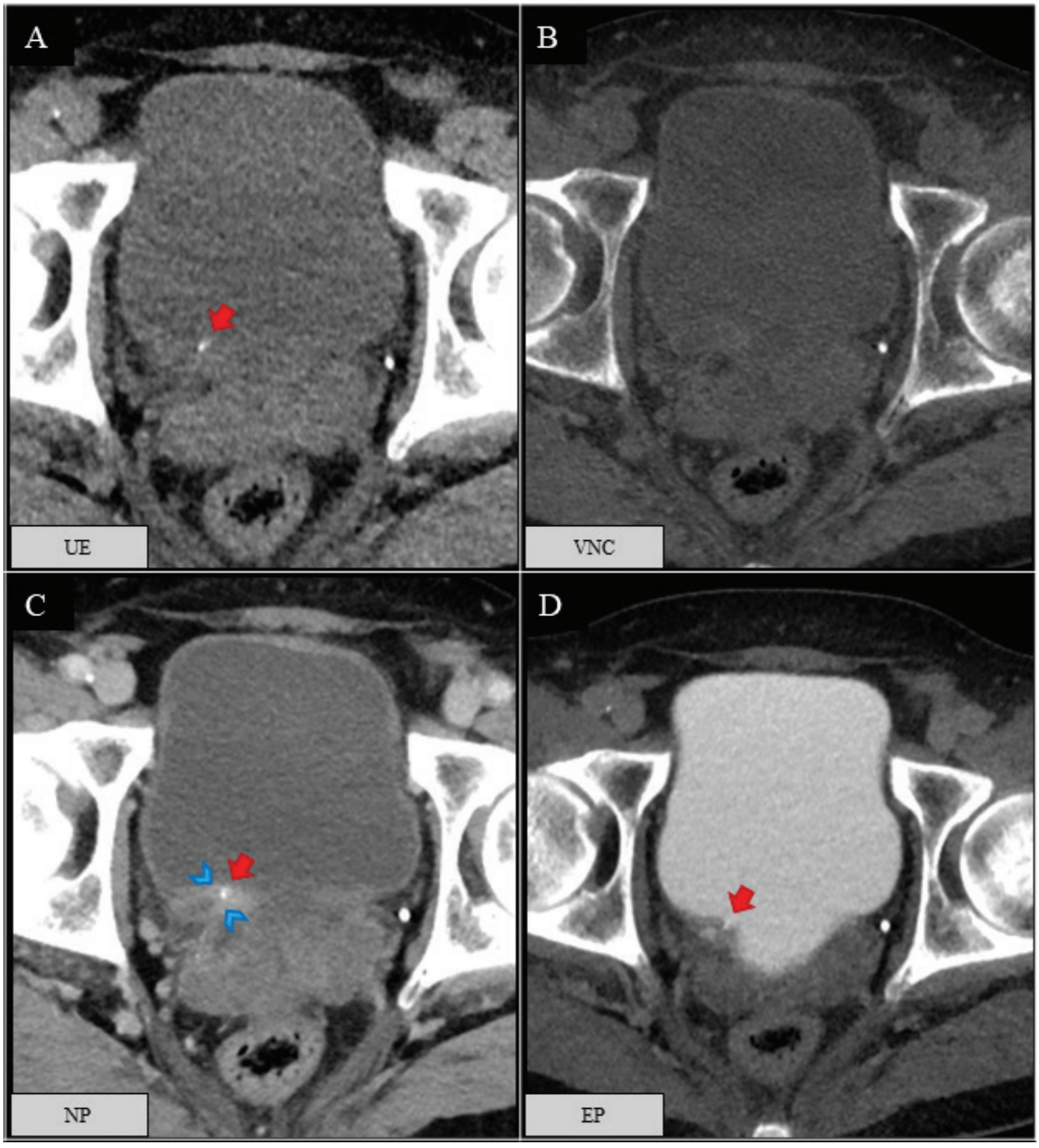

Figure 1. (A–D) A 56-year-old male with a stone (red arrow) close to the ostium in the right ureter. The experimental CT was scored positive for ureteral stone by both readers. The stone was invisible on axial VNC (B). The urothelium was contrast enhancing and thickened (blue arrowheads) on axial NP (C) as a sign of obstruction in the ureter. However, with no clinical signs of renal failure or sepsis, the patient received no immediate active stone treatment. A 3-month follow-up CT showed that the stone had passed spontaneously.

CT: computed tomography; UE: unenhanced; NP: nephrographic phase; EP: excretory phase; VNC: virtual non-contrast.

The prevalence of ureteral stones was 3% in our study, which is comparable to the 2.1% reported by Bretlau et al. [14]. The single NP CT sensitivity was 100% for all readers. It is noteworthy that the prevalence of ureteral stones was higher than UTUC (1.6%) and RCC (2.3%) [9, 10]. This observation, coupled with the potentially severe complications of an obstructed ureter, underlines the importance of achieving a high diagnostic accuracy for ureteral stones [22]. No previous study has reported the diagnostic accuracies of contrast-enhanced CT in detecting ureteral stones.

The prevalence of bladder stones was 5% compared to 1.8% in the study by Bretlau et al. [14]. The primary reader achieved 100% sensitivity, and the secondary reader achieved 87%. One of the two stones that were missed by the secondary reader was

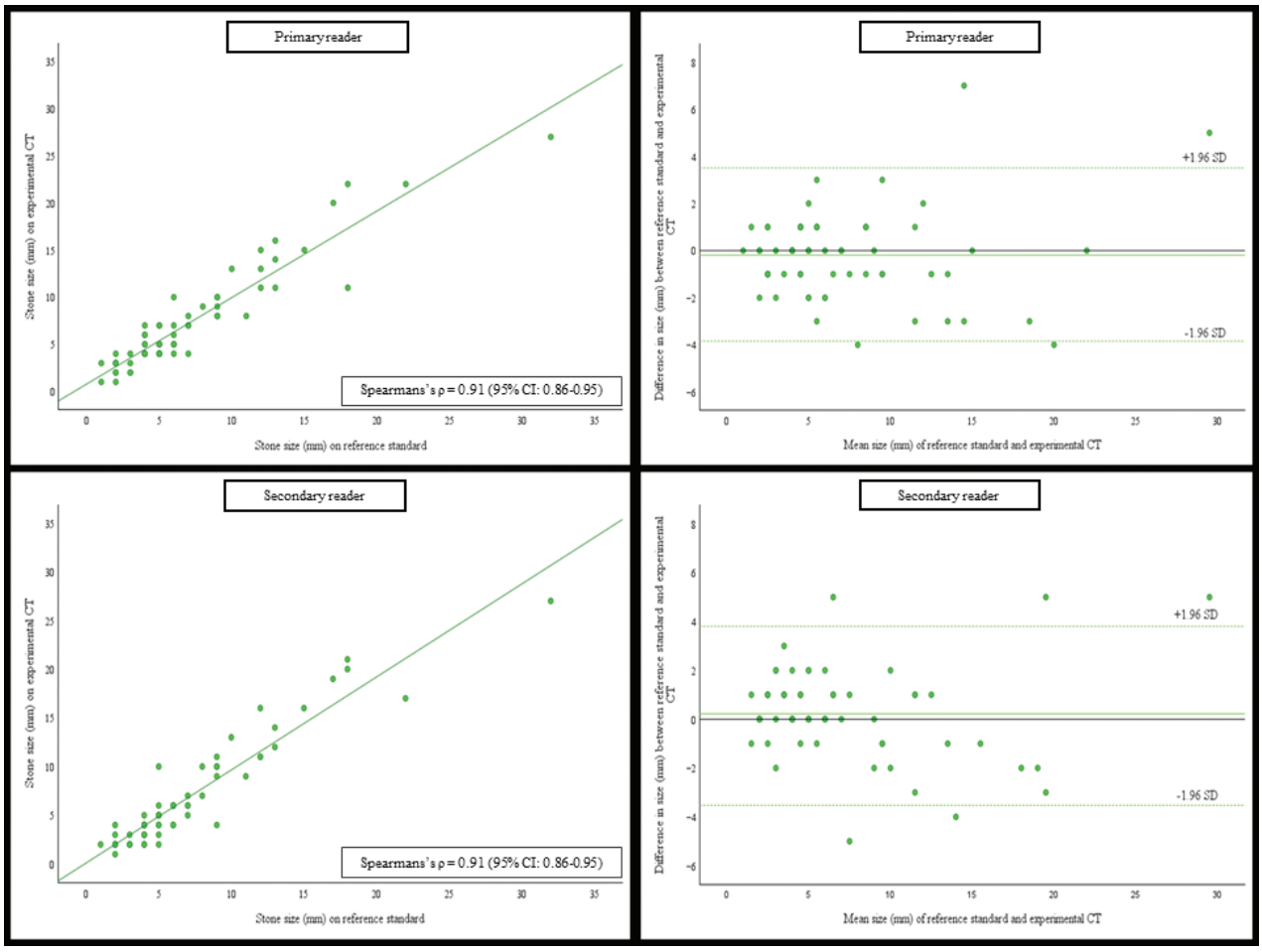

Figure 2. Scatter plots showing the correlation and Bland-Altman plots showing the agreement in stone size between the experimental CT and the reference standard.

CT: computed tomography; CI: confidence interval; SD: standard deviation; reference standard: four-phase CT; Experimental CT: single nephrographic phase CT.

misinterpreted as a calcification in the prostate. The other was either overlooked or misinterpreted as excreted contrast in the bladder.

Accurate measurement of stone size is crucial for treatment planning. We found a very strong correlation between size measurements obtained from single NP CT and four-phase CT (ρ = 0.91). However, the 95% LOA ranged between −4 and 4 mm, indicating a potential for underestimation or overestimation by up to 4 mm when using single NP CT. Whether these inaccuracies are clinically acceptable is a matter of opinion and beyond the scope of this study. Interestingly, we observed a similar degree of discrepancy within the four-phase CT, with 95% LOA ranging from −3 to 4 mm. This suggests that the inconsistencies in stone size are likely attributable to differences between readers and lack of standardised measurements rather than the specific CT protocols.

We chose the single NP as the experimental CT in PROTEHCT as it was the only acquisition to detect all upper tract malignancies in our previous study [23]. Our VNC images were acquired from the NP on a SIEMENS single-source scanner with gold and tin filters, primarily aimed at establishing a base line for contrast enhancement in renal tumors. However, in the context of stone detection, VNC demonstrated no added value, consistent with previous findings on different scanners using other dual-energy techniques [24–26].

PROTEHCT is the first prospective study to evaluate the diagnostic performance of two different CT protocols in patients presenting with painless VH. Of all 308 included patients, 32% (100) patients had one diagnosis (i.e. either urinary stones, UC or RCC) and 3% [8] had overlapping diagnoses (i.e. synchronous urinary stones, UC and/or RCC). Hence, the remaining 65% (200) patients had none of the three diagnoses. At most medical centres, the VH population is substantial consuming a significant number of urological and radiological resources. The primary purpose of the CT is to detect upper tract malignancy, and secondly to detect urinary stones. While the prevalence of urinary stones in patients with painless VH is poorly documented, the prevalences of UTUC and RCC are known to be low [3, 4]. In PROTEHCT we have shown that a single NP CT is no worse than a four-phase CT in detecting UC and RCC, and the current study shows that it also provides excellent predictive values for urinary stone disease. Coupled with the fact that a transition to a single NP CT reduces patient irradiation by approximately 57%, this

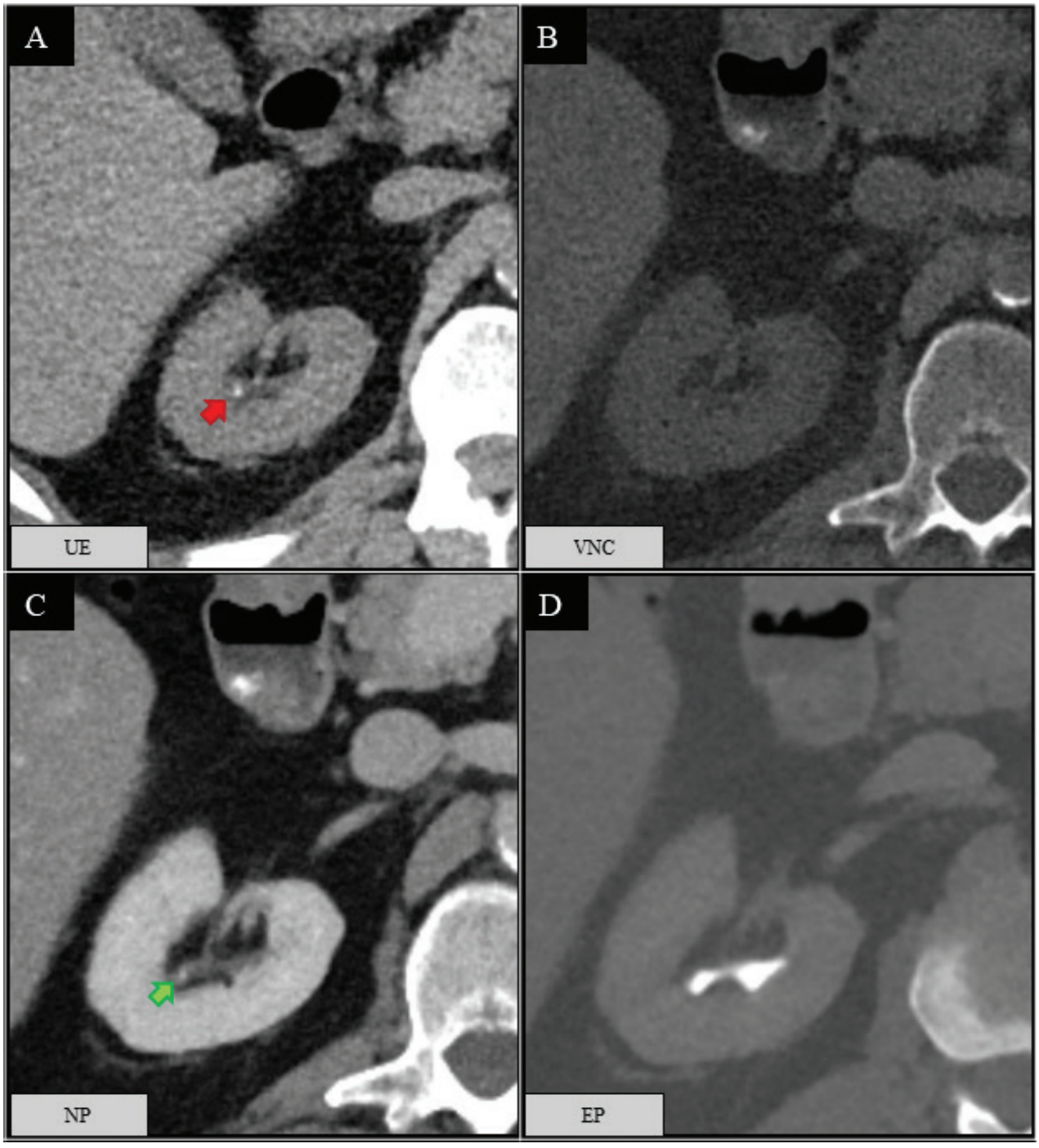

Figure 3. (A–D) A 60-year-old male with a stone (red arrow) in the right kidney. The experimental CT was scored negative for kidney stone by both readers. However, the stone (green arrow) was retrospectively visible on axial NP (C). The patient required no active stone treatment during the follow-up time.
CT: computed tomography; NP: nephrographic phase; UE: unenhanced; VNC: virtual non-contrast; EP: excretory phase.

illustrates that a multiphase CT is no longer warranted. Additionally, a single NP CT will decrease the acquisition and reading time.

Currently, the EAU has no guidelines for assessing patients with VH. For urinary stone disease, they recommend a low-dose UE CT for diagnosing and a contrast enhanced CT if stone removal is planned [27]. For UC and RCC, they provide disease-specific guidelines recommending different multiphase CT protocols depending on the diagnoses [2, 28, 29]. Thus, patients with VH are scanned with a variety of multiphase CTs to adhere to all the guidelines. However, there is only low-level evidence supporting the use of a multiphase CT originating from expert opinions and retrospective studies in highly selected cohorts of which none included patients with painless VH [5–8]. In our opinion, a guideline for the presenting symptom painless VH is overdue, and PROTEHCT provides high-level evidence that a single NP CT suffices as a first-line CT examination.

Limitations

Stone detection was a secondary outcome of PROTEHCT necessitating careful interpretation of the results. Additionally, we cannot report stone density or composition. Since all patients with painless VH are to be investigated regardless of their anticoagulant therapy status or the presence of prostatic disease, we did not record these factors at the time of inclusion. Stone size measurements were conducted without fixed window/level settings or standardised planes. Moreover, in cases of multiple stones in one location, different readers may have measured different stones. All readers had access to previous imaging which may have influenced the diagnostic accuracies since pre-existing urinary stone disease was not an exclusion criterion. Last, since all readers were experienced radiologists, this prompts consideration regarding the generalisability of our findings to less experienced readers.

Conclusions

A single NP CT is sufficient in detecting and measuring the size of urinary stones in patients presenting with painless VH. Although it misses some small kidney stones, none of the missed stones required active treatment during follow-up.

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Disclosure of interest

The authors report no conflict of interest.

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