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ORIGINAL ARTICLE

Identification of ureteral stones at reduced radiation exposure: a pilot study comparing conventional versus digital low-dosage linear slot scanning (Lodox®) radiography

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Abstract

Purpose Digital low-dosage, linear slot scanning radiography (Lodox®) is an imaging modality that can emit down to one-tenth the radiation of conventional X-ray systems. We prospectively evaluated Lodox® as a diagnostic imaging modality in patients with ureterolithiasis.

Methods Conventional kidney–ureter–bladder (KUB) X-ray and Lodox® were performed in 41 patients presenting with acute flank pain due to unilateral ureteral stone confirmed by computed tomography. KUB X-ray and Lodox® images were then reviewed by four blinded readers (urology expert/resident, radiology expert/resident). Identification rates were compared using Pearson's Chi square test. The impact of different parameters on stone identification by Lodox® was evaluated using logistic regression and generalized linear mixed models. Inter-reader agreement was tested using Cohen's kappa coefficient.

Results Median stone size was 5 mm (range 2–12), median stone density was 800 HU (range 200–1500). The identification rates of the urology expert were 68% for KUB X-ray and 90% for Lodox® ($p = 0.014$), and for all four readers 61% for KUB X-ray and 62% for Lodox® ($p = 0.8$). Radiation exposure for KUB X-ray and Lodox® was 0.45 mSv (SD ± 0.64) and 0.027 mSv (SD ± 0.038), respectively. Multivariable analyses showed an association between stone identification by Lodox® and stone size ($p < 0.001$), stone density ($p = 0.005$), lower body mass index ($p = 0.005$), and reader ($p < 0.001$).

Conclusions The high identification rates and low radiation doses of Lodox® make it a promising imaging modality for the diagnosis of ureteral stones. Further validation in larger cohorts, including performance evaluation for renal stones, is warranted.

Trial registration http://www.controlled-trails.com/ISRCTN12915426.

Keywords Lodox® · Radiation exposure · Imaging · Urolithiasis

Introduction

Urolithiasis is a worldwide healthcare problem with a current lifetime risk of 19% in men and 9% in women in Western countries [1]. The incidence and prevalence of stone disease are increasing globally, irrespective of age, sex or race [1, 2]. Patients with urinary stones usually undergo numerous abdominal X-ray examinations for diagnosis, treatment and follow-up. The radiation exposure of a single radiograph is relatively low, but the dose accumulates over time, especially in patients with recurrent stone disease [3]. This is important because there is evidence of an increased risk of secondary, radiation-induced malignancies [4], especially since patients with recurrent stones often have their first stone event at a relatively young age [5]. Therefore, measures to reduce

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radiation exposure are critical. In this context, low-dosage, linear slot scanning radiography (Lodox®) is a diagnostic tool of high interest (Fig. 1a). Developed in the 1980s in South Africa, the Lodox®-Statscan™ was originally used by the DeBeers Diamond Company to detect the theft of diamonds hidden in garb or swallowed. To fulfill this purpose, it was designed to be cost-effective and expeditious while limiting radiation exposure so as to be used on a daily basis. Due to its high-quality 2D radiographic image at a high contrast-to-noise ratio and its substantially lower patient exposure compared to conventional radiography, it was subsequently felt to be suitable for medical use, especially for rapid assessment of the skeletal system [6–13]. It has consequently become part of the primary survey of the Advanced Trauma Life Support Guidelines [14] with around 90 active devices worldwide so far.

To date no data exist on the value of Lodox® as a diagnostic tool in stone disease. In a phantom study, it was found to be at least equal to conventional radiography for the identification of stones of different sizes and chemical composition [7]. The purpose of the current study was to evaluate Lodox® as a diagnostic tool for the identification of symptomatic ureteral stones (Fig. 1b).

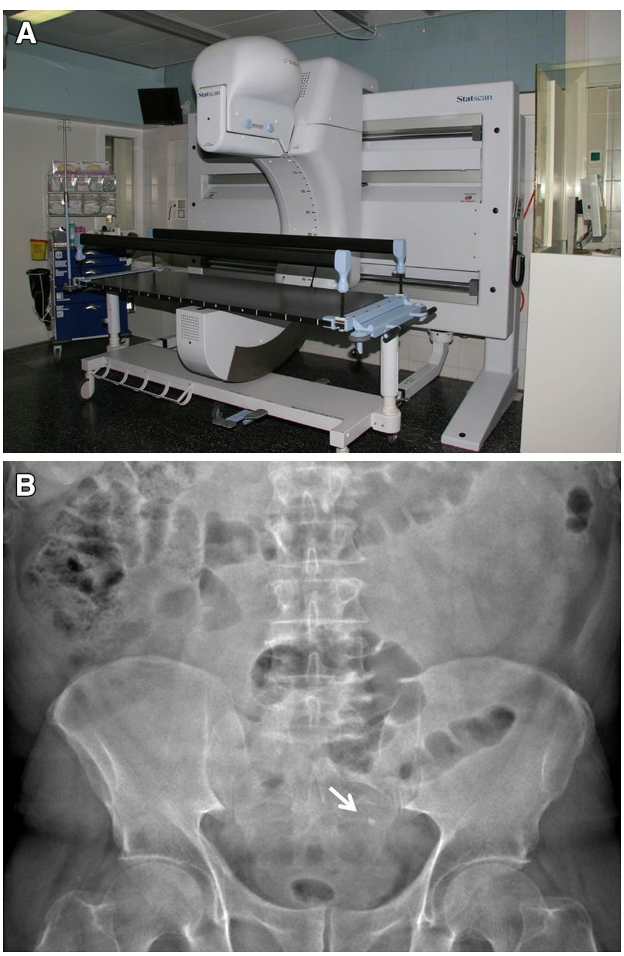

Fig. 1 Lodox-Statscan of the University Hospital of Bern, Switzerland (**a**). Distal ureteral stone detected by Lodox imaging (arrow; **b**)

Patients and methods

From November 2014 to December 2016, 48 patients (37 males and 11 females) presenting with acute flank pain due to a unilateral ureteral stone were recruited. Baseline diagnostic evaluation was performed by low-dose computed tomography (CT) scan at our Emergency Department. If unilateral ureteral stone was detected, kidney–ureter–bladder (KUB) X-ray and Lodox® were performed immediately ($\leq$60 min) after the CT scan. Further stone treatment was performed according to the recommendations of the European Association of Urology guidelines on urolithiasis [15]. Six patients had to be excluded from the study because they had a spontaneous passage of the stone before KUB X-ray and/or Lodox® could be performed ($n=2$) or because the delay between CT scan and KUB X-ray or Lodox® was too long due to other emergency examinations with higher priority ($n=4$). One patient in whom CT scan, KUB X-ray and Lodox® were performed was excluded because review overturned the diagnosis of ureteral stone. Thus, a total of 41 patients were included in the final analysis. All procedures performed in studies involving human participants were in accordance with the ethical standards of the local Ethics Committee national research committee and with the 1964 Helsinki Declaration and its later amendments (http://www.controlled-trails.com/ISRCTN12915426). All patients provided informed consent.

Imaging

Lodox®

The Lodox®-Statscan™ is an imaging system that uses linear slot scanning radiography for the acquisition of images, i.e., the X-ray source and detector move across the region of interest during image acquisition (Fig. 1a). It has an X-ray tube mounted on one end of a C-arm which emits a low-dose collimated fan-beam of X-rays. The C-arm travels along the table length with a full body scan requiring 13 s, with smaller areas requiring proportionately less time [6, 8, 9]. Due to linear slot scanning radiography and several modifications to the imaging chain, the system achieves very low levels of entry and scattered radiation doses [6, 8, 9]. Only the abdomen and pelvis in antero-posterior projection were scanned for the current study. Lodox® had no input in the study and the authors had complete control of the data.

Conventional KUB X-ray

Conventional KUB images were acquired in the antero-posterior projection using a Multix Top/Vertix X-ray system (Siemens AG) with a CXDI 701C Wireless Digital Radiography System (Canon). Tube current was selected automatically at a reference dose of 3.5 μGy, and then adjusted to patient weight if necessary.

Image review

Upon diagnosis of a unilateral ureteral stone in CT scan and patient inclusion in the study, conventional KUB X-ray and Lodox® images were obtained. The KUB X-ray and Lodox® images were then anonymized and read by four readers who were blinded to stone location, size, and density: two residents (one urology [SF] and one radiology resident [AB]), and two experts with 10 (urology [BR]) and 4 years (radiology [VO]) professional experience. The readers were only aware of the side of the stone, reflecting real-life practice since colicky pain due to urinary stones is most often unilateral. The sequence of reading (X-ray or Lodox® first) was randomly chosen. The readers were allowed to adjust window and level settings for optimal visualization of the images. Stone location, if identifiable, was marked on a diagram. The marks on the diagram were compared with the true stone configuration obtained from the CT scan (gold standard).

Dose calculation

Effective dose calculation for CT

The effective radiation dose for CT is given by the product of the dose-length product and the organ-specific conversion factor. According to the International Commission on Radiological Protection publication [16] recommendations, the conversion factor for abdomen CT for an adult is 0.0153 [17].

Effective dose calculation for plain radiographs

Based on model simulations, the effective dose of radiography is given by the product of the dose-area and the organ-specific conversion factor (0.21 mSv/[Gy × cm^2] for abdomen) [18].

Effective dose calculation for Lodox®

Lodox® does not provide radiation dose calculations for each examination, but radiation dosage has been tested with phantom models. The radiation dose of Lodox® relative to the conventional dose varies from 72% (chest) to 2% (pelvis), with a simple average of 6% [6, 8, 9].

Study endpoints and statistical analysis

The primary study endpoint was the stone identification rates of the four readers on conventional KUB X-ray and Lodox® images. Secondary endpoints were the impact of stone and patient parameters (stone size, location, density on CT scan [Hounsfield units (HU)] and composition, body mass index [BMI], patient age and sex) on stone identification by Lodox®.

Since data on stone identification by Lodox® in clinical practice are lacking, the sample size calculation for this pilot study was based on data acquired from a previous phantom study showing identification rates for stones with KUB X-ray and Lodox® of 43% and 64%, respectively [7]. Thus, a sample size of 41 stones was required to gain a statistical power of 80% ($\beta = 0.2$) using a two-sided test at the significance level of 5% ($\alpha = 0.05$). Assuming a drop-out rate of 10%, 45 patients were included in the study. SAS 9.1 statistical software (SAS Institute Inc., Cary, North Carolina) was used for statistical analyses. Pearson's Chi square test was used to compare identification rates of KUB X-ray versus Lodox® for each reader. Inter-reader agreement on stone visibility in Lodox® and KUB X-ray was assessed using Cohen's kappa coefficient [19]. Reader identification rates were compared in a "lesion-to-lesion" manner. Agreement between the readers was graded as follows: < 0.20 poor, 0.21 to 0.40 fair, 0.41 to 0.60 moderate, 0.61 to 0.80 good, 0.81 to 1.00 very good [20]. A multivariable logistic regression was performed to evaluate potential predictors of stone identification by Lodox®, adjusting for size (continuous), location (proximal, mid- or distal ureter), density (continuous), stone composition (calcium oxalate vs. non-calcium oxalate), BMI (continuous), age (continuous), sex and reader), and using the number of interpretations of all four readers as events ($n = 164$). The correlation between reader and stone size for stone identification by Lodox® was assessed using a generalized linear mixed model (GLIMMIX) procedure. A two-sided p value < 0.05 was considered statistically significant.

Results

Median patient age was 50 years (range 25–88 years), median stone size on CT scan was 5 mm (range 2–12 mm) (Table 1). Stone analysis was available in 29/41 (71%) patients; while most patients had calcium oxalate-containing stones, 4 had 100% uric acid stones (Table 1).

Table 1 Patient and stone characteristics

Age [years; median (range)]	50	(25–88)
BMI [kg/m^2; median (range)]	27.5	(18.3–42.1)
Stone size [mm; median (range)]	5	(2–12)
Stone density on CT [HU; median (range)]	900	(200–1500)
Stone location (*n*; %)		
Proximal ureter	17	(41%)
Mid-ureter	5	(12%)
Distal ureter	19	(46%)
Stone composition (*n*; %)		
Calcium oxalate	19	(46%)
Uric acid	4	(10%)
Mixed (≥ 90% calcium oxalate)	3	(7%)
Mixed (< 90% calcium oxalate)	3	(7%)
Not available	12	(29%)

BMI body mass index, *CT* computed tomography, *HU* Hounsfield units

Table 2 Identification rate in Lodox® vs. conventional kidney, ureters and bladder (KUB) X-ray

Reader	Identification rate in Lodox®	Identification rate in KUB X-ray	*p* value
Urology expert	90% (37/41)	68% (28/41)	0.014
Urology resident	68% (28/41)	56% (23/41)	0.3
Radiology expert	44% (18/41)	56% (23/41)	0.3
Radiology resident	46% (19/41)	63% (26/41)	0.2
Total[a]	62% (102/164)	61% (100/164)	0.8

[a]Total number of interpretations (not stones)

Stone identification

The urology expert identified significantly more stones on Lodox® than on conventional KUB X-ray images (37/41 [90%] vs. 28/41 [68%]; $p = 0.01$) (Table 2). There was no significant difference in stone identification rates between conventional KUB X-ray and Lodox® when readings were performed by radiologists or the urology resident. While none of the readers identified any of the four uric acid stones on KUB X-ray images, up to 75% of uric acid stones were identified on Lodox® images: 3/4 (75%) by the urology expert; 2/4 (50%) by the urology resident; 1/4 by the radiologists (25%).

Multivariable analysis

Multivariable logistic regression analysis showed a significant association between stone identification by Lodox® and stone size ($p < 0.001$), stone density on CT scan ($p = 0.005$), lower BMI ($p = 0.004$), and reader ($p < 0.001$). Stone location, stone composition, patient age and sex were not predictors of stone identification by Lodox®. The GLIMMIX procedure showed a statistically significant association between stone identification by Lodox® and stone size for each individual reader (Fig. 2).

Inter-reader agreement

Inter-reader agreement was fair between the urology expert and the urology resident, between the urology resident and the radiology expert, and between the radiology expert and the radiology resident. Inter-reader agreement was poor between the urology expert and the radiology expert, between the urology expert and the radiology resident, and

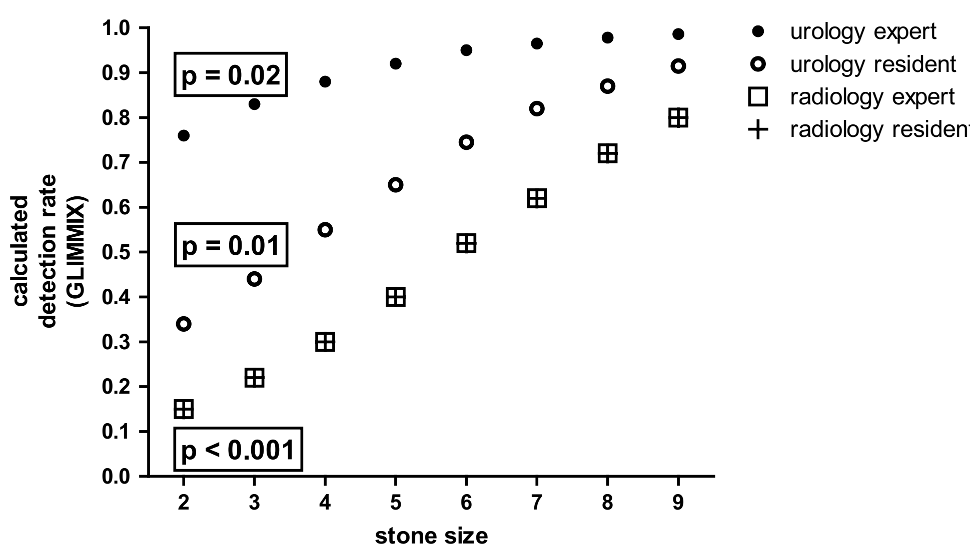

Fig. 2 Correlation of stone size and stone identification with the Lodox®-Statscan™ for the individual readers. There was a significant trend in better identification rate for larger stones for all readers

Table 3 Inter-reader agreement for stone identification by Lodox®

Reader 1	Reader 2	Kappa value
Urology expert	Urology resident	0.38
Urology expert	Radiology expert	0.16
Urology expert	Radiology resident	0.08
Urology resident	Radiology expert	0.25
Urology resident	Radiology resident	0.19
Radiology expert	Radiology resident	0.36

between the urology resident and the radiology resident (Table 3).

Radiation exposure

Average effective radiation doses of CT, conventional abdomen X-ray, and Lodox® were 4.0 mSv (SD ± 2.99), 0.45 mSv (SD ± 0.64) and 0.027 mSv (SD ± 0.038), respectively.

Discussion

Low-dosage, linear slot scanning radiography (Lodox®) is a widely accepted diagnostic modality for the rapid assessment of the skeletal system in emergency trauma situations, providing full-body information within seconds. Its use for the assessment of urinary stones has been evaluated in a phantom model, but never in patients [7]. In the present pilot study, overall identification rate for symptomatic ureteral stones was 62%, which was in line with the performance of conventional KUB X-ray (61%) while exposing the patient to significantly less radiation. Furthermore, we showed that at an expert level, even greater performance with up to 90% stone identification rate may be possible. Lodox® is, therefore, a very promising tool for the assessment of patients who present with acute colicky flank pain due to ureteral stones.

The reasons for the better sensitivity of Lodox® as compared to conventional KUB X-ray are various: a novel scanning technology that significantly reduces the number of scattered X-ray photons that reach the detector, leading to higher contrast; flat-panel detectors which delineate the anatomic structure better at a low patient radiation exposure; and a rescaling and linearization image postprocessing technique [7, 13].

We found that stone identification by Lodox® depends primarily on stone size and density as well as low BMI. Specifically, up to 93% of stones 5 mm or larger could be identified. This is a shared feature with KUB X-ray, where sensitivity is highly dependent on stone parameters [21]. This does not necessarily mean that Lodox® is not clinically useful for smaller stones. Stones less than 5 mm most often pass spontaneously. Thus, if initial diagnostics by Lodox® do not detect any stone in patients with colicky flank pain, it would be acceptable to start symptomatic treatment [15]. A CT scan can be postponed to a later time point if symptoms persist.

A weakness of our study is the rather poor inter-reader agreement for Lodox® between the urologists and the radiologists. While a poor inter-reader agreement between the radiologist resident and the urologist expert may be explained by the discrepancy in clinical experience, the reason for the poor inter-reader agreement between the radiology expert and the urology expert is not clear. Further clarification in larger studies is warranted.

Interestingly, our results suggest that Lodox® has the potential to identify uric acid stones, which are known to be radiolucent in KUB X-ray. Uric acid stones can be dissolved by increasing urinary pH to at least 7.0–7.2 with the application of, e.g., potassium citrate or sodium bicarbonate [15]. For uncomplicated uric acid stones, oral chemolysis on an out-patient basis is the treatment of choice [15, 22]. However, rigid compliance by the patient is required as well as a strict follow-up by ultrasonography or CT scan. Since ultrasonography has low accuracy for the identification of stones, many patients under alkalinization due to uric acid stones are followed by CT imaging. Thus, if validated in this patient group, Lodox® may represent a cheaper and less harmful alternative to CT scan.

CT scan without the use of contrast material is the most sensitive method for detecting renal and ureteral stones and has superseded conventional KUB X-ray or intravenous urography as the gold standard diagnostic modality [15, 23–25]. Although modern low-dose CT protocols entail greatly reduced radiation exposure while preserving a high sensitivity of 97% and specificity of 95% [26], radiation exposure remains significant, in the range of 0.97–1.9 mSv [15]. This is of particular concern in recurrent stone formers who undergo numerous radiographic examinations over a lifetime of stone episodes and follow-up appointments. Furthermore, although the radiation dose of a single KUB X-ray (0.5–1 mSv) is lower than that of a low-dose CT, it still represents a relevant radiation exposure burden [23, 27, 28]. Patients with an acute renal colic receive up to 50 mSv of radiation within the first year of follow-up [29, 30]. Based on the current results, we argue that Lodox® may be used as a low-dose substitute of CT not only for the initial assessment of patients with acute renal colic (together with renal ultrasound that may answer the clinically important question of obstruction by visualizing presence or absence of hydronephrosis and/or ureteral jet), but also for pretreatment stone localization and as a follow-up tool.

A major limitation of the study is the use of estimated radiation dose measurements for the Lodox® system. Numbers were derived from a preliminary study using plastic-encased and water filled validated phantom models representing the abdomen and pelvis of a patient [7]. Furthermore, because Lodox® was not performed in patients with acute flank pain who were not found to have stones on CT scan, another limitation of the study is the inability to assess the specificity of Lodox® for ureteral stones. Altogether, the results of our pilot study are hypothesis-generating and provide a conceptual framework for larger validation studies. Building on this effort, such prospective investigation is ongoing at our institution to expand the evidence on the value of Lodox® in the diagnosis of urinary stones.

Conclusion

Lodox® had an overall identification rate for ureteral stones that was in line with KUB X-ray, while potentially exposing the patient to lower radiation doses. In expert hands, however, the identification rate for ureteral stones was excellent (90%) given that the diagnosis of ureterolithiasis was already known. Therefore, opportunities should be maximized for readers of Lodox® to gather sufficient experience to optimize their diagnostic accuracy. A prospective study with a larger cohort is ongoing to evaluate the value of Lodox® for pretreatment stone localization and as a follow-up tool for stones located in the upper urinary tract.

Author contributions SF: data collection, manuscript writing, and data analysis. EG: data collection and manuscript editing. AB: data collection and manuscript editing. VO: data collection. SM: project and protocol development and data collection. AKE: data collection and manuscript editing. AC: data analysis, data collection, and manuscript editing. GNT: project development and manuscript editing. BR: project and protocol development, data management and collection, data analysis, manuscript writing and editing.

Compliance with ethical standards

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

Informed consent Informed consent was obtained from all individual participants included in the study.

Human rights All the 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.

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