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ORIGINAL ARTICLE

The efficacy of digital fluoroscopic image capture in the evaluation of vesicoureteral reflux in children

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Abstract
Background In accordance with ALARA, minimizing radiation exposure associated with voiding cystourethrograms (VCUG) is of critical importance. Advances in fluoroscopic technology might help achieve this goal.
Objective To determine the efficacy of fluoroscopic image capture compared to conventional digital radiographic spot (DRS) images in voiding cystourethrograms (VCUG) for the evaluation of vesicoureteral reflux (VUR) in children.
Materials and methods The study was a retrospective review of 65 VCUG examinations (130 kidney/ureter units). Each examination consisted of fluoroscopically captured spot (FCS) images and the corresponding DRS images. Each set of images was evaluated by three pediatric radiologists for the diagnosis of VUR for a total of 390 kidney/ureter units reviewed. Using the DRS image set as the reference standard, the efficacy of the FCS images for diagnosing reflux was determined.
Results The diagnostic accuracy of the FCS images in terms of the binary characterization of reflux as negative or positive was 97.2% (379/390). The sensitivity of the FCS images was 92.6% (88/95); the specificity of the FCS images was 98.6% (291/295).
Conclusion Fluoroscopically captured images are adequate in documenting absence of VUR on VCUG examinations, obviating the need for radiographic spot images and resulting in reduction in radiation exposure.

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Introduction

The voiding cystourethrogram (VCUG) is a frequently performed fluoroscopic examination for evaluation of the urinary tract in children. Two of the most common indications include urinary tract infection (UTI) and prenatal hydronephrosis. In addition to demonstrating anatomic abnormalities of the urinary tract, the examination provides a physiologic means of detecting and characterizing vesicoureteral reflux (VUR). It is estimated that the incidence of UTI during childhood is 8% in girls and 2% in boys [1]. Because of the overwhelmingly high incidence of UTI during childhood, the VCUG has become one of the most commonly performed pediatric fluoroscopic examinations, accounting for 30–50% of all fluoroscopic exams in children [2].

The VCUG typically entails a minimum of 30–60 s of fluoroscopy time and traditionally includes four to six standard radiographic spot images [3]. During the exam, children are exposed to ionizing radiation during the real-time fluoroscopy as well as the acquisition of the radiographic spot images. Because of the radiation risks associated with the fluoroscopic VCUG, numerous technological advances in fluoroscopic equipment have been proposed to address the challenge of decreasing radiation exposure while maintaining diagnostic image quality. These include digital radiography, pulsed fluoroscopy, and image capture technology [4,5]. The image capture feature enables the last image of a digital fluoroscopic exposure to be displayed on a monitor and subsequently saved and stored. These images are inherently noisier than digital radiographic spot images as a result of the lower radiation dose utilized within the fluoroscopic mode. Despite the diminished image quality, VUR can be identified on these lower radiation dose images. In 2004, O'Connor and colleagues [6] presented data showing that fluoroscopically captured images could safely replace digital radiographic images for the documentation of VUR.

Application of the image capture function could be a viable approach to further radiation dose reduction in pediatric VCUG examinations. With this in mind, the purpose of this investigation was to determine the efficacy of fluoroscopic image capture in comparison with digital radiographic spot images in voiding cystourethrograms for the evaluation of VUR in children.

Materials and methods

Institutional review board approval was obtained for this study, which was compliant with the Health Insurance Portability and Accountability Act. Patient informed consent was not required by the institutional review board.

The investigation consisted of a retrospective review of the 196 VCUG examinations in children performed during a 7-month period between September 2006 and April 2007 at a busy pediatric radiology department at a university hospital. Seventy-eight of these VCUG examinations included both fluoroscopically captured spot (FCS) images and the corresponding digital radiographic spot (DRS) images. Of the 78 VCUG examinations, 13 were excluded from the study on the basis of an incomplete set of corresponding fluoroscopically captured spot images. After excluding the examinations with an incomplete data set, the study cohort included 65 VCUG examinations. The VCUG examinations included varying numbers of FCS and DRS images. The number of FCS images ranged from 4 to 20, with a mean of 11.1 images. The number of DRS images ranged from 3 to 10, with a mean of 5.2.

The subject population included pediatric inpatients and outpatients, age 1 month to 14 years, mean age 2 years, 3 months (26.6 months). There were 37 girls and 28 boys (mean age for boys was 17.3 months and the mean age for girls was 33.6 months). Indications for the VCUG examinations included urinary tract infection (n=32), prenatal hydronephrosis (n=13), VUR follow-up (n=13), sibling with VUR (n=2), status post-bilateral ureteral reimplantation (n=2), status post-reflux procedure (n=1), spina bifida and neurogenic bladder (n=1), and one patient without known history. All voiding cystourethrograms were acquired as part of the routine medical care of the patient and therefore did not pose any additional risk to the patient.

Each examination was performed on a multipurpose fluoroscopic unit (Axiom Artis, Siemens Medical Solutions, Malvern, PA, USA), utilizing the lowest available pulse rate of 7.5 pulses per second. Upon the installation of this new multipurpose digital fluoroscopic unit at our institution in September 2006, the image capture function was randomly used at times to acquire FCS images prior to acquiring the standard practice DRS images during VCUG examinations as a means of comparing the image quality and utility of the function. Because there is no additional radiation incurred in acquiring these captured fluoroscopic images, there was no additional risk posed to the children during the examinations. The VCUG examinations consisted of the standard spot images including oblique views of the right and left ureterovesical junctions, voiding images of the urethra and right and left renal beds, as well as any additional images necessary to document pathology.

Each of the 65 VCUG examinations were separated into right and left kidney/ureter units, giving a total of 130 kidney/ureter units. The examinations were then divided into two data sets, one consisting of FCS images and the other DRS images. Each data set was independently reviewed for VUR by three fellowship-trained pediatric radiologists with experience ranging from 1 to 9 years. The observers were blinded to all demographic information associated with the examinations. The data sets were reviewed on a PACS workstation (MagicView 1000, Siemens Medical Solutions, Malverne, PA, USA) using diagnostic-quality monitors (Dome C3 Grey, Planar Systems Inc., Beaverton, OR, USA) in two sessions, separated by a minimum of 2 weeks, with the fluoroscopic image data set reviewed first, to eliminate any memory bias. The radiologists recorded the presence or absence of VUR and grade of the VUR if present on a scale of 1 to 5 using the International Reflux System [7], with NR indicating absence of reflux. No attempt was made to resolve disagreement among readers through consensus since the intent was to assess agreement between FCS images and DRS images in terms of data as it would be derived in practice by a single reader.

Statistical methods and statistical analysis

Weighted kappa was used to measure interobserver agreement for grading of reflux for the DRS images and FCS images. Weighted kappa with linear weights was used to assess agreement between the FCS images and the DRS images in terms of the grade of reflux recorded for each kidney/ureter unit by a single reader. Weighted kappa with linear weights was also used to assess agreement between readers in terms of DRS image results among the kidney/ureter units judged to be either grade 2 or grade 3 reflux by at least one reader. A simple kappa was used to assess agreement between the FCS images and the DRS images in terms of the binary characterization of reflux as

Table 1 Evaluation of VUR by individual grade for each kidney/ureter unit

Reflux grade								
FCS image finding	DRS image finding (reference standard)							
	NR	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5	Total	% Correct
NR	291	5	2	0	0	0	298	97.7 (291/298)
Grade 1	4	3	3	0	0	0	10	30 (3/10)
Grade 2	0	3	16	12	2	0	33	48.5 (16/33)
Grade 3	0	0	3	33	2	0	38	86.8 (33/38)
Grade 4	0	0	0	2	6	0	8	75 (6/8)
Grade 5	0	0	0	0	0	3	3	100 (3/3)
Total	295	11	24	47	10	3	390	
% Correct	98.6 (291/295)	27.3 (3/11)	66.7 (16/24)	70.3 (33/47)	60 (6/10)	100 (3/3)	90.2 (350/390)	

low-grade reflux (NR or grades 1–2) versus moderate/high-grade reflux (grades 3–5), insignificant reflux (NR or grade1) versus significant reflux (grades 2–5), and positive versus negative. We interpreted a kappa of 0.6–0.8 to be substantial and a kappa of 0.8–1.0 to be almost perfect [8].

Generalized estimating equations based on a binary logistic regression model (a form of logistic regression for correlated data) was used to derive 95% confidence intervals (CI) for the accuracy of the FCS images in terms of characterization of reflux as low-grade versus moderate/high-grade, insignificant versus significant or positive versus negative relative to the DRS images. This method was also applied to assess differences among readers and differences between the left and right kidney/ureter units in terms of FCS image set accuracy. The dependent variable was the binary indicator of agreement between the FCS images and DRS images with respect to characterization of reflux as positive versus negative, insignificant versus significant reflux, or low-grade versus moderate/high-grade reflux relative to the DRS images for the same unit by the same reader. The model included reader identification and unit (left versus right) as classification factors. The covariance structure was modeled by assuming observations to be correlated when derived for the same subject, with the strength of correlation dependent on whether the observations were derived for the exact same unit. Using the DRS image set as the reference standard, the sensitivity and specificity of the FCS image set for diagnosing low-grade versus moderate/high-grade reflux, insignificant versus significant reflux and positive versus negative reflux were calculated.

Generalized estimating equations based on a binary logistic regression model were also used to assess whether the accuracy of the binary FCS image characterizations of reflux relative to DRS images depended on patient age at the time of imaging. The dependent variable was the binary indicator of agreement between the FCS and DRS image characterizations of reflux for the same unit by the same reader. The model included reader identification and unit (left versus right) as classification factors and patient age as a numeric factor. The covariance structure was modeled by assuming observations to be correlated when derived for the same subject with the strength of correlation dependent on whether the observations were derived for the exact same unit.

Table 2 Characterization of low-grade reflux versus moderate/high-grade reflux

FCS image finding	DRS image finding (reference standard)				
	Low-grade reflux (NR-2)	Moderate/high-grade reflux (3–5)	Total	% Correct	Quantity estimated
Low-grade reflux (NR-2)	327	14	341	95.9 (327/341)	NPV
Moderate/high-grade reflux (3–5)	3	46	49	93.9 (46/49)	PPV
Total	330	60	390		
% Correct	99.1 (327/330)	76.7 (46/60)			
Quantity estimated	Specificity	Sensitivity			

PPV positive predictive value; *NPV* negative predictive value

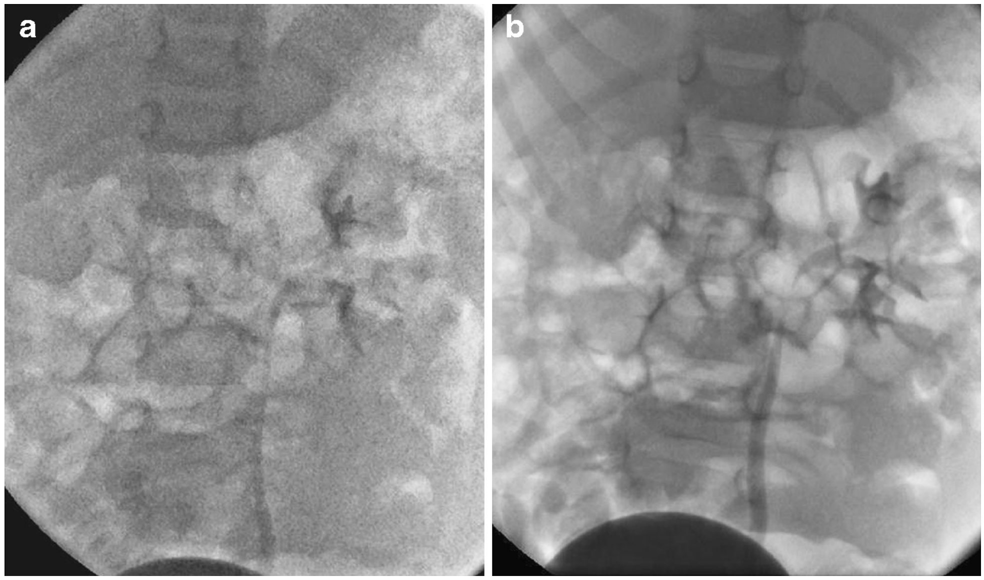

Fig. 1 Example of difficulty distinguishing low-grade reflux from high-grade reflux secondary to the presence of overlying bowel gas. **a** FCS image misinterpreted as grade 2 reflux. **b** Corresponding DRS image demonstrates left grade 3 VUR

During each VCUG examination, the fluoroscopic unit recorded the total radiation dose of the examination in terms of the dose area product (DAP) in units of uGym^2 and the DAP associated with each acquired digital radiographic spot image. The median and interquartile range were used to describe these data. These data were used to quantify the mean dose fraction and standard deviation (SD) with a 95% confidence interval, expressed as a percentage, of the total radiation exposure that resulted directly from the digital radiographic spot image acquisition. These calculations were performed for the cohort of examinations that were positive for VUR and those that were negative for VUR and then for all examinations combined. The Mann-Whitney test was applied to determine the statistical significance of differences in mean dose fraction among the positive and negative examinations.

Results

Table 1 summarizes the data for the evaluation of VUR by individual grade for each kidney/ureter unit. The number of times each of the individual grades 1 through 5 was reported as findings was too small for a meaningful inferential analysis of diagnostic accuracy for each grade of VUR. Of the 295 units diagnosed as NR using the DRS images, 291 units were concordantly diagnosed as NR using the FCS images, and only 4 units of the 295 total units were incorrectly diagnosed as grade 1 reflux.

Table 2 summarizes the results when the findings were characterized as either low-grade reflux (NR, grades 1–2) or moderate/high-grade reflux (grades 3–5). The overall diagnostic accuracy of the FCS images in terms of the binary characterization of reflux as low-grade versus moderate/high-grade was 95.6% (373/390) with a 95% confidence interval from 92.0% to 97.7%. The sensitivity of the FCS images for the detection of high-grade reflux was estimated at 76.7% (46/60) with a 95% CI from 58.1% to 86.0%. This decreased sensitivity was primarily a result of the misinterpretation of grade 3 reflux as grade 2 reflux using the FCS images. Of the 47 units diagnosed with grade 3 reflux using the DRS images, 12 units were incorrectly diagnosed as grade 2 (Fig. 1). The specificity of the FCS images for the detection of low-grade reflux was estimated as 99.1% (327/330) with a 95% CI from 97.2% to 99.7%. The FCS image set was observed to have a positive

Table 3 Characterization of reflux as insignificant (NR or grade 1) versus significant (grades 2–5)

FCS image finding	DRS image finding (reference standard)				
	Insignificant reflux (NR or 1)	Significant reflux (2–5)	Total	% Correct	Quantity estimated
Insignificant reflux (NR or 1)	303	5	308	98.4 (303/308)	NPV
Significant reflux (2–5)	3	79	82	96.3 (79/82)	PPV
Total	306	84	390		
% Correct	99.0 (303/306)	94.0 (79/84)			
Quantity estimated	Specificity	Sensitivity			

PPV positive predictive value; *NPV* negative predictive value

Table 4 Characterization of reflux as either negative (NR) or positive (grades 1–5)

FCS image finding	DRS image finding (reference standard)				
	Negative	Positive	Total	% Correct	Quantity estimated
Negative	291	7	298	97.7 (291/298)	NPV
Positive	4	88	92	95.7 (88/92)	PPV
Total	295	95	390		
% Correct	98.6 (291/295)	92.6 (88/95)			
Quantity estimated	Specificity	Sensitivity			

PPV positive predictive value; *NPV* negative predictive value

predictive value (PPV) of 93.9% (46/49) (95% CI: 84.1% to 97.9%) and a negative predictive value (NPV) of 95.9% (327/341) (95% CI: 89.7% to 97.4%).

Table 3 summarizes the results when the findings were characterized as either insignificant (NR or grade 1) or significant (grades 2–5). The overall diagnostic accuracy of the FCS images in terms of the binary characterization of reflux as insignificant versus significant was 97.9% (382/390) with a 95% CI from 94.7% to 99.4%. The sensitivity of the FCS images for the detection of significant reflux was estimated at 94.0% (79/84) with a 95% CI from 76.0% to 98.1%. The specificity of the FCS image set for the detection of insignificant reflux was estimated as 99.0% (303/306) with a 95% CI from 94.6% to 99.7%. The FCS image set was observed to have a PPV of 96.3% (79/82) (95% CI: 86.2% to 99.1%) and an NPV of 98.4% (303/308) (95% CI: 93.6% to 99.4%).

Table 4 summarizes the results when the findings were characterized as either negative (NR) or positive (grades 1–5) for reflux. The overall diagnostic accuracy of the FCS images in terms of the binary characterization of reflux was 97.2% (379/390) with a 95% CI from 93.7% to 98.8%. The sensitivity of the FCS images for diagnosing the presence of reflux was 92.6% (88/95) with a 95% CI from 78.0% to 96.8% and the specificity of the FCS images was estimated as 98.6% (291/295) with a 95% CI from 94.0% to 99.7%. The FCS image set was observed to have a PPV of 95.7% (88/92) (95% CI: 76.6% to 98.9%) and an NPV of 97.7% (291/298) (95% CI: 92.7% to 98.8%).

The data do not support a statistically significant correlation between decreasing efficacy of FCS image interpretation with decreasing patient age, with *P* values greater than 0.05. Table 5 summarizes these data, which show the percentage of times the assessment of reflux grade based on FCS images agreed with the corresponding result from the DRS images for the binary characterization of reflux relative to patient age. Patient age was stratified into categories of younger than 6 months, 6 months to 1 year, 1 to 2 years and older than 2 years.

The weighted kappa as a measure of agreement between FCS images and DRS images in terms of the grade of reflux recorded for each kidney/ureter unit by a single reader was almost perfect for all readers, at 0.893. The simple kappa as a measure of agreement between FCS images and DRS images was uniformly almost perfect for low-grade versus moderate/high-grade reflux and positive versus negative reflux, and it was substantial for insignificant versus insignificant reflux for a single reader as shown in Table 6. The weighted kappa as a measure of inter-reader agreement with respect to findings from each of the FCS images and DRS images was consistently nearly perfect across all pairs of readers (Table 7). The weighted kappa as a measure of inter-reader agreement for kidney/ureter units judged specifically to be grade 2 or 3 reflux on the DRS images was 0.557, reflecting concordant assessments of grade in 77.3% (58/75). This would be interpreted as moderate agreement.

Table 5 Characterization of reflux relative to patient age

Age (in months)	Binary characterization of reflux		
	Positive vs negative	Significant vs insignificant	Moderate/high-grade vs. low-grade
< 6	98.5% (65/66)	98.5% (65/66)	98.5% (65/66)
6–12	99.1% (107/108)	100% (108/108)	96.3% (104/108)
12>24	95.8% (115/120)	99.2% (119/120)	94.2% (113/120)
< 24	95.8% (92/96)	93.8% (90/96)	94.8% (91/96)
P value	0.3735	0.1799	0.7480

Table 6 The weighted kappa as a measure of agreement between FCS images and DRS images in terms of the grade of reflux recorded by a single reader

Reader	Weighted	Simple		
	Actual	Negative vs. positive	Low vs. moderate/high	Insubstantial vs. substantial
1	0.875	0.915	0.953	0.745
2	0.883	0.936	0.909	0.757
3	0.921	0.917	0.954	0.919
All	0.893	0.919	0.939	0.819

Analysis of the radiation exposure data recorded by the fluoroscopy unit for each VCUG examination revealed a total dose area product (DAP) ranging from 8.6 uGym^2 to 840.7 uGym^2, with a median interquartile range of 29.9 +/−27.8 uGym^2. The DAP resulting from the DRS images for each examination ranged from 4.2 to 504.3 uGym^2 with a median interquartile range of 15.3 +/−19.4 uGym^2. The percentage of the total DAP resulting from the DRS images ranged from 15.6% to 78.6%, with a mean of 58.9% (95% CI: 55.7–62%). The percentage of the total DAP resulting from the DRS images for the positive examinations (n=23) ranged from 41.8% to 78.6%, with a mean of 64.6% (95% CI: 60.5–68.6%). The percentage of the total DAP resulting from the DRS images for the negative examinations (n=42) ranged from 15.6% to 77.8%, with a mean of 55.7% (95% CI: 51.6–59.9%) (Table 8). According to an exact Mann-Whitney test, the percentage of total DAP resulting from the DRS images was significantly higher (P=0.0006) among positive cases than among negative cases.

Discussion

The ALARA (as low as reasonably achievable) principle dictates that radiologic procedures utilizing ionizing radiation be performed using the lowest radiation dose possible that does not compromise the diagnostic accuracy of the examination. The increased radiosensitivity of children renders this an extremely important issue requiring continuous improvement in both technology and technique associated with fluoroscopic examinations to minimize radiation exposure [9]. Many of the technological advances in fluoroscopic equipment have been successful in reducing the radiation exposure associated with the VCUG. During a VCUG, a child is exposed to ionizing radiation during the real-time fluoroscopy as well as during the acquisition of the DRS images. The exclusive utilization of image capture technology could significantly reduce the overall radiation exposure during a VCUG examination. In fact, we found that the radiation exposure resulting from the acquisition of the DRS images in all examinations accounted for more than half of the total exposure, 58.9% in this investigation. This percentage is even higher when only the cases with positive reflux are considered, up to 64.6% in this study, which likely reflects the need to acquire additional radiographic exposures in cases in which reflux is present. For example, if VUR is not visualized until late in the exam following image acquisition of the ureterovesical junctions, this region would require reexamination to assess for any anatomic variations such as ectopic insertion of the ureter or Hutch diverticula. In other positive cases, variations in distention of the renal calyces later in the examination might require the acquisition of additional images.

Table 7 The weighted kappa as a measure of inter-reader agreement with respect to findings from FCS and DRS images

Readers	Method	
	DRS images	FCS images
1 and 2	0.948	0.918
1 and 3	0.949	0.861
2 and 3	0.956	0.894

Although our study consisted of too few data points within each individual grade of reflux for any meaningful inferential statistical analysis of diagnostic accuracy, many important conclusions were drawn following stratification of our data. In the initial stratification of reflux as either negative or positive, the FCS images had an overall diagnostic accuracy of 97.2%. The specificity of the FCS images in demonstrating the absence reflux was as high as 98.6%. These data strongly suggest that fluoroscopic image capture is adequate in documenting the absence of VUR on VCUG examinations, obviating the need to acquire digital radiographic spot images in these negative examinations and thereby reducing the overall radiation exposure.

When these data were stratified into categories composed of insignificant reflux (NR and grade 1) and significant reflux (grades 2–5), the overall diagnostic accuracy of the FCS images was extremely high at 97.9%. The sensitivity and specificity of the FCS images for the detection of grades 2–5 reflux was also quite high, estimated at 94.0% and 99.0%, respectively. This demonstrated that the FCS images were also adequate in distinguishing absence of reflux and grade 1 reflux from higher grades of reflux (grade 2 and above), again supporting the conclusion that fluoroscopic image capture

Table 8 The percentage of total DAP resulting from the DRS images

VCUG examinations	Mean dose fraction (%)	SD (%)	Range	95% CI
Positive (n=23)	64.6	9.4	41.8 to 78.6%	60.5 to 68.6%
Negative (n=42)	55.7	13.3	15.6 to 77.8%	51.6 to 59.9%
All (n=65)	58.9	12.7	15.6 to 78.6%	55.7 to 62.0%

is adequate in documenting the absence of reflux or grade 1 reflux, considered by many to be insignificant. Review of the seven cases in which readers misdiagnosed grade 1 or grade 2 reflux as no reflux revealed a consistent finding of excessive bowel gas. This raises the possibility that the presence of bowel gas obscured visualization of the reflux on the FCS images, decreasing perception (Fig. 2).

Recent data have suggested that the appropriate management of low-grade VUR is different from the management of high-grade VUR. For example, several studies have addressed the rationale for antibiotic prophylaxis in patients with low-grade VUR [10–12]. A group of uncontrolled studies indicated that antibiotic prophylaxis can safely be discontinued in school-age children with low-grade VUR who have normal voiding patterns, absence of hydronephrosis or renal scars, and normal anatomy of the urogenital system [13,14]. Therefore, an important distinction becomes differentiating low-grade reflux from moderate/high-grade reflux. This prompted further stratification of the data into categories of low (NR, grades 1–2) and higher grade (grades 3–5) reflux.

The overall accuracy of the FCS images in terms of the binary characterization of reflux as low-grade versus moderate/high-grade was quite high, estimated at 95.6% (Fig. 3). Additionally, the data revealed very high specificity for the FCS images in the detection of low-grade reflux, estimated as 99.1% in our study, supporting the use of image capture for documentation of absence of reflux. However, the sensitivity of the FCS images in detecting moderate/high-grade reflux, in particular grade 3, was as low as 76.7%. After analyzing the data, it became evident that this decreased sensitivity was primarily a result of the misinterpretation of grade 3 reflux as grade 2 reflux using the FCS images (Fig. 4). It is not surprising that the greatest difficulty reported with the FCS images was in distinguishing grade 2 and grade 3 reflux. Differences between grade 2 and grade 3 reflux can be subtle at times and interpretation can be subjective with respect to the grade of reflux. This is supported by the weighted kappa of 0.557 (moderate agreement) for interobserver agreement regarding grade 2 and grade 3 reflux on the DRS images, currently considered to be the standard of practice diagnostic images. Difficulties in perception of grade 2 versus grade 3 VUR appear to have been magnified in the interpretation of the FCS images by the presence of overlying bowel gas. Interestingly, we found no correlation between the efficacy of FCS image interpretation for reflux and patient age, despite the notion that overlying bowel gas tends to be more extensive in infants.

Our study had several limitations. The first is the potential source of error related to the inherent time gap, albeit short, between the sequential acquisition of the FCS and DRS images. In view of the fact that this was a retrospective study, there was no standard protocol with respect to the timing of FCS and DRS image acquisition. In addition, several different pediatric radiologists performed the VCUG examinations, and given that these images are acquired manually, this also likely contributed to variability in the inherent time gap. Although the exact time gap is not measurable, this interval would be expected to be relatively short, on the order of 1 to 2 s, since the goal of obtaining both sets of images was to anecdotally compare diagnostic

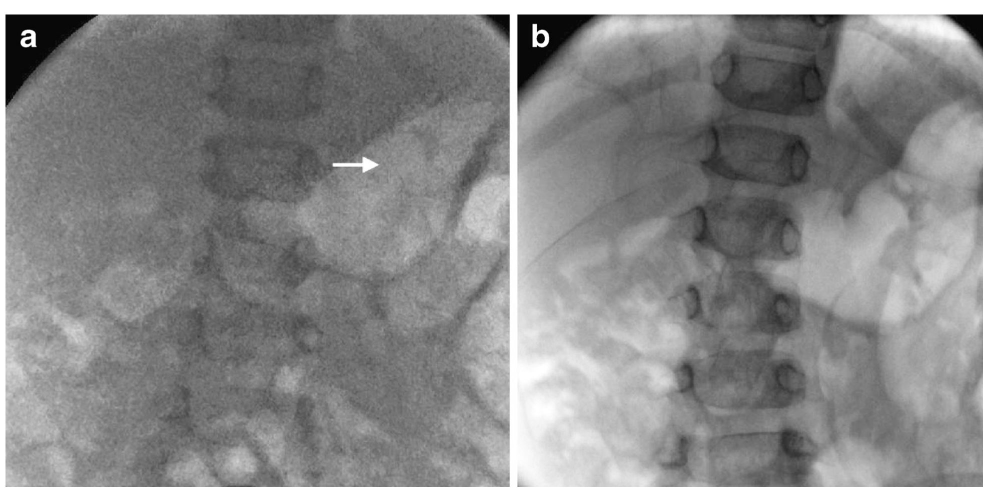

Fig. 2 Example of difficulty distinguishing significant versus insignificant reflux secondary to the presence of overlying bowel gas. **a** FCS image misinterpreted as no reflux. **b** Corresponding DRS image demonstrates left grade 2 VUR

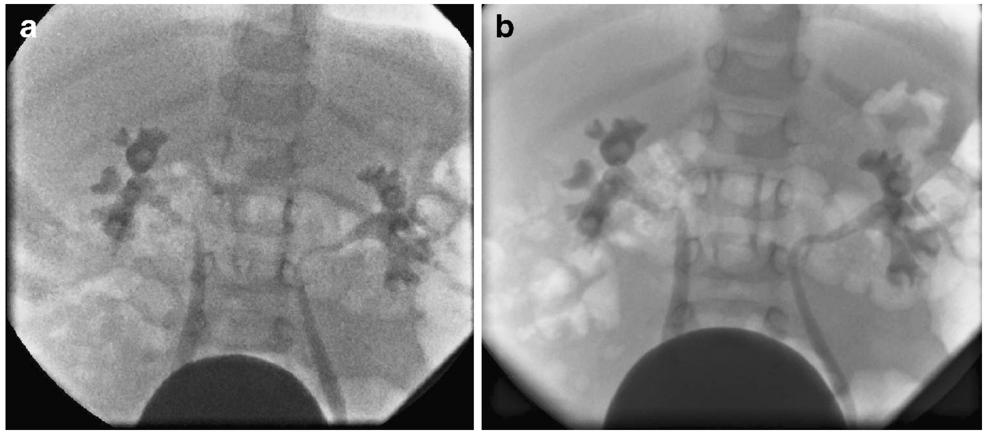

Fig. 3 Example of a concordant diagnosis of grade 3 VUR. **a** FCS image demonstrates left grade 3 VUR. **b** Corresponding DRS image demonstrates left grade 3 VUR

utility of the image capture technology on a case by case basis. This time gap might result in images that do not display the same temporal information, therefore altering the interpretation and diagnostic grade of the study. This might have a particular impact on distinguishing grade 2 and grade 3 reflux because of the transient nature of VUR.

A second limitation of the study was the small sample size with respect to the number of kidney/ureter units with reflux in each individual grade. This precluded statistically significant analysis of the diagnostic accuracy of the image capture technology for the identification of reflux for each individual grade. However, the preponderance of negative examinations is not surprising, given the low incidence of VUR in children having VCUG examinations for the standard indications, estimated at 9% [15]. Research utilizing larger sample sizes would be very helpful in assessing the efficacy of fluoroscopic image capture in the diagnosis of the individual grade of reflux. This might require a multi-center study or long-term prospective study to generate a large enough data set. Despite the relatively small number of cases of reflux in each individual grade, important data were gleaned with respect to the negative cases, most notably the very high accuracy of fluoroscopically captured images in documenting the absence of reflux.

Additionally, it is possible that bias was introduced with respect to the particular VCUG exams that fulfilled the inclusion criteria requiring a complete set of FCS and DRS images. However, the studies that fulfilled the selection

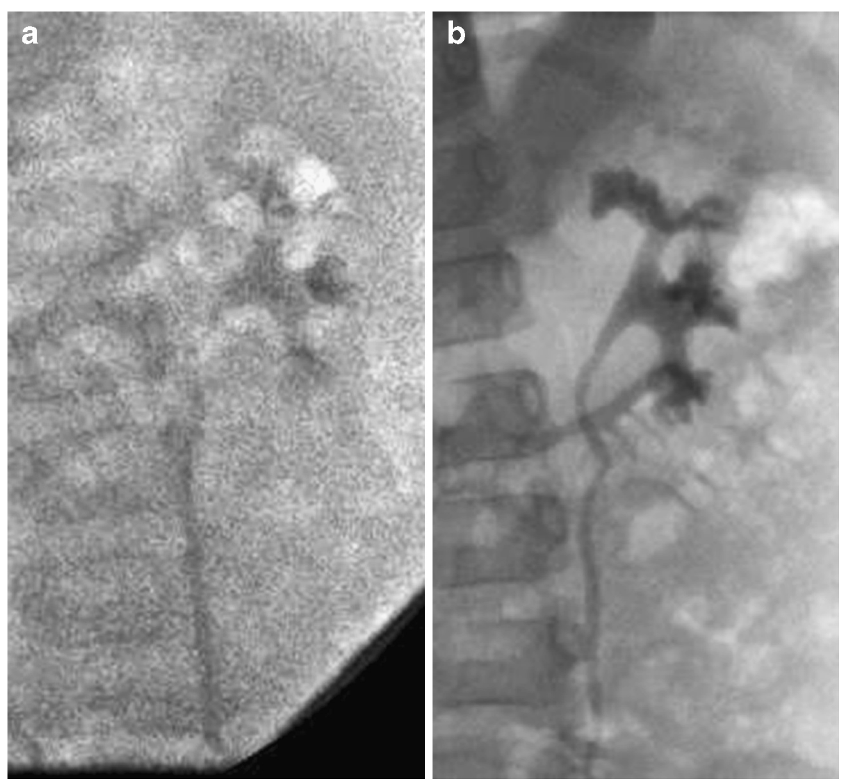

Fig. 4 Example of difficulty distinguishing low-grade reflux from high-grade reflux secondary to the presence of overlying bowel gas. **a** FCS image misinterpreted as grade 2 reflux. **b** Corresponding DRS image demonstrates left grade 3 VUR

criteria were performed by all of the pediatric radiologists, rather than just one or two. All of the VCUG exams that fulfilled the selection criteria were included in the study. The distribution of positive and negative studies included in the study cohort also reflects our usual distribution of positive and negative studies. A prospective study would be necessary to completely eliminate this potential bias.

Finally, it is important to note that the pulse rate used in this study was 7.5 pulses per second, the lowest available on the fluoroscopic equipment utilized in our study. Currently, lower pulse rates are available on other fluoroscopic units and this might have an effect on the efficacy of FCS images. Further investigation might be warranted to evaluate the efficacy of FCS images with lower pulse rates.

Conclusion

Fluoroscopic image capture technology has great utility in the diagnosis of vesicoureteral reflux. Our study suggests that fluoroscopically captured images are adequate in documenting the absence of VUR on VCUG examinations, obviating the need to acquire digital radiographic spot images in these negative examinations. This would ultimately lead to a substantial reduction in the overall radiation exposure of the examination, in accordance with the ALARA principle.

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