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Revised 2019 (Resolution 10)*

ACR-SPR PRACTICE PARAMETER FOR THE PERFORMANCE OF FLUOROSCOPIC AND SONOGRAPHIC VOIDING CYSTOURETHROGRAPHY IN CHILDREN

PREAMBLE

This document is an educational tool designed to assist practitioners in providing appropriate radiologic care for patients. Practice Parameters and Technical Standards are not inflexible rules or requirements of practice and are not intended, nor should they be used, to establish a legal standard of care¹. For these reasons and those set forth below, the American College of Radiology and our collaborating medical specialty societies caution against the use of these documents in litigation in which the clinical decisions of a practitioner are called into question.

The ultimate judgment regarding the propriety of any specific procedure or course of action must be made by the practitioner considering all the circumstances presented. Thus, an approach that differs from the guidance in this document, standing alone, does not necessarily imply that the approach was below the standard of care. To the contrary, a conscientious practitioner may responsibly adopt a course of action different from that set forth in this document when, in the reasonable judgment of the practitioner, such course of action is indicated by variables such as the condition of the patient, limitations of available resources, or advances in knowledge or technology after publication of this document. However, a practitioner who employs an approach substantially different from the guidance in this document may consider documenting in the patient record information sufficient to explain the approach taken.

The practice of medicine involves the science, and the art of dealing with the prevention, diagnosis, alleviation, and treatment of disease. The variety and complexity of human conditions make it impossible to always reach the most appropriate diagnosis or to predict with certainty a particular response to treatment. Therefore, it should be recognized that adherence to the guidance in this document will not assure an accurate diagnosis or a successful outcome. All that should be expected is that the practitioner will follow a reasonable course of action based on current knowledge, available resources, and the needs of the patient to deliver effective and safe medical care. The purpose of this document is to assist practitioners in achieving this objective.

¹ <u>Iowa Medical Society and Iowa Society of Anesthesiologists v. Iowa Board of Nursing</u> 831 N.W.2d 826 (Iowa 2013) Iowa Supreme Court refuses to find that the *ACR Technical Standard for Management of the Use of Radiation in Fluoroscopic Procedures* (Revised 2008) sets a national standard for who may perform fluoroscopic procedures in light of the standard's stated purpose that ACR standards are educational tools and not intended to establish a legal standard of care. See also, <u>Stanley v. McCarver</u>, 63 P.3d 1076 (Ariz. App. 2003) where in a concurring opinion the Court stated that "published standards or guidelines of specialty medical organizations are useful in determining the duty owed or the standard of care applicable in a given situation" even though ACR standards themselves do not establish the standard of care.

I. INTRODUCTION

This practice parameter was revised collaboratively by the American College of Radiology (ACR) and the Society for Pediatric Radiology (SPR).

Voiding cystourethrography (VCUG) is a radiographic and fluoroscopic study of the lower urinary tract. It requires aseptic bladder catheterization, instillation of iodinated contrast media, fluoroscopic observation, and image documentation of the findings. The purpose of the examination is to assess the bladder, the urethra, other opacified structures, the presence or absence of vesicoureteral reflux (VUR), and micturition. Contrast-enhanced voiding urosonography (ceVUS) is an alternative method of assessment, in which ultrasonography of the kidneys is performed after the intravesical administration of a sonographic contrast agent.

II. INDICATIONS AND CONTRAINDICATIONS [1-9]

Clinical indications for VCUG include, but are not limited to, the following:

- Hydronephrosis and/or hydroureter
- Abnormal US (any degree of hydronephrosis, uroepithelial thickening, scarring) after first urinary tract infection (UTI), especially if febrile or non-*Escherichia coli* (*E. coli*)
- Recurrent UTI
- Congenital anomalies of the urinary tract
- Dysfunctional voiding, such as neurogenic dysfunction of the bladder
- Urinary incontinence
- Bladder outlet obstruction
- Postoperative evaluation of the urinary tract
- Dysuria/difficulty voiding
- Hematuria
- Trauma

In some circumstances, a retrograde urethrogram (RUG) may be preferred over a VCUG, particularly in children with trauma or dysuria. There are no absolute contraindications for VCUG. Potential benefits must outweigh the minor risks of the procedure. However, one should proceed with caution if the child has had a significant reaction to iodinated contrast media, known or suspected latex allergy [10], acute UTI, recent urethral or bladder surgery, potential urethral trauma, or high spinal injury (risk of autonomic dysreflexia). The risk of postprocedure UTI is very low. Routine antibiotic prophylaxis is not necessary, but increased vigilance is warranted in children with significant anatomic abnormalities, particularly high-grade VUR [11]. In young infants at risk for UTI antibiotic prophylaxis could be considered for a few days prior to and following the study.

ceVUS is a radiation-free alternative to evaluate for VUR or urethral pathology [12]. See later paragraph.

Nuclear voiding cystography may also be used as an alternative study for the evaluation of reflux in children, especially when detailed anatomic visualization of the urethra, bladder, and kidneys is not required. In the era of modern digital, grid-controlled fluoroscopic equipment with a flat detector, filtration, and low pulse rate, the radiation dose from fluoroscopic VCUG and nuclear VCUG is similar [13,14].

The voiding study chosen will vary depending on locally available equipment, expertise, and personnel.

For the pregnant or potentially pregnant patient, see the <u>ACR–SPR Practice Parameter for Imaging Pregnant or</u> <u>Potentially Pregnant Patients with Ionizing Radiation</u> [15].

III. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

See the <u>ACR-AAPM-SIIM-SPR Practice Parameter for Digital Radiography</u> [16].

IV. SPECIFICATIONS OF EXAMINATION

The written or electronic request for VCUG should provide sufficient information to demonstrate the medical necessity of the examination and allow for its proper performance and interpretation.

Documentation that satisfies medical necessity includes 1) signs and symptoms and/or 2) relevant history (including known diagnoses). The provision of additional information regarding the specific reason for the examination or a provisional diagnosis would be helpful and may at times be needed to allow for the proper performance and interpretation of the examination.

The request for the examination must be originated by a physician or other appropriately licensed health care provider. The accompanying clinical information should be provided by a physician or other appropriately licensed health care provider familiar with the patient's clinical problem or question and consistent with the state scope of practice requirements. (ACR Resolution 35, adopted in 2006 – revised in 2016, Resolution 12-b)

A. Patient Selection and Preparation

The study should be performed only for an appropriate clinical indication. Consultation with referring physicians helps to clarify which children may benefit from VCUG.

B. Technique

Preparation and Sedation

VCUG can typically be performed without sedation when parents and children receive adequate preparation and support. When available, child-life specialists may provide education, distraction and relaxation techniques that are useful in facilitating catheterization as well as patient cooperation during the examination [17,18]. The use of warmed contrast material may decrease patient distress [17,19].

When clinically indicated in select patients, sedation may alleviate distress and can be performed safely, without negatively affecting the examination [17,20,21]. If sedation is used, the child must undergo a presedation evaluation and must be monitored both during and after the examination, as outlined in the current practice parameter (See the <u>ACR–SIR Practice Parameter for Sedation/Analgesia</u> [22]).

Review and Preliminary Imaging

Prior to the start of the examination, it is helpful to review the child's history and prior imaging findings, particularly any recent studies where residual contrast may be present. Formal scout radiographs make a significant contribution to the dose of the study while their yield is relatively low [23]. Instead, a pre-contrast fluoroscopy grab image may be acquired at the start of the study. In those specific situations requiring superior spatial resolution, a digitally acquired spot image or radiograph may be obtained [23-26].

Catheterization

Aseptic bladder catheterization of children should be performed by experienced personnel. Latex precautions should be observed, especially in children with known latex allergy, multiple surgeries, or those with myelomeningocele.

In males, to diminish sensation or pain, a topical anesthetic may be instilled retrograde into the urethra with aseptic technique; anesthetic gel may be applied externally in both males and females [27,28].

The catheter size should be appropriate for the child's age or urethral caliber. In premature or extremely small infants, a 5-French catheter is preferred. Above this age, an 8-French catheter is preferred, unless a smaller catheter is appropriate (such as in the case of urethral stricture) or if there is inability to catheterize with the larger catheter.

A catheter larger than 8-French may be used in adolescents. In order to avoid intravesical looping and knotting of the catheter, which may require invasive retrieval, excessive catheter length should not be inserted into the bladder. Importantly, in uncircumcised males, if the foreskin is retracted at catheterization, it should be repositioned over the glans immediately following catheterization, to avoid secondary paraphimosis.

In girls, the catheter may be secured in place with tape to the perineum or in older girls, to the thigh. In boys, once the catheter is inserted, a strip of tape may be placed on the catheter extending longitudinally along the dorsum of the penis to the symphysis. Circumferential placement of tape around the penis is discouraged. Inflation of a balloon in the bladder to secure the catheter is discouraged as it may obscure pathology.

After catheter placement, the bladder should be drained prior to instillation of contrast media. A sterile urine specimen may be retained for culture if clinically indicated. The size of the catheter should be recorded, unless previously placed in another department.

Contrast Media

Iodinated contrast media (typically 12% to 18% weight/volume solution) should be administered via the bladder catheter by gravity drip. The height of the bottle controls the infusion pressure, while the diameter of the tubing somewhat limits this pressure, making the exact bottle height relatively unimportant. However, 3 feet above the table height is typically sufficient [29]. The amount of contrast agent to be administered depends on the bladder capacity, and can be estimated using the following formulas [30]: <2 years: weight (kg) x 7; > 2 – 14 years: in ounces age in years + 1 and in mL (age in years x 30) + 30; >14 years: 500 ml. The bladder filling should continue until voiding, filling with more than twice the estimated bladder capacity if there is no voiding.

If recent bladder surgery has been performed, such as augmentation, gravity infusion should be performed with the bottle of contrast positioned as low as possible above the table height to assure low-pressure filling. Contrast infusion should be stopped when the patient has symptoms of pain, when contrast refluxes retrograde into the ureters beyond the ureteral stents (if present), or if contrast extravasates.

Very few patients have allergic reactions to intravesical contrast [31]. However, in the event that a patient has had prior anaphylaxis to contrast, one could consider allergy prophylaxis or an alternative imaging study (See the <u>ACR–SPR Practice Parameter for the Use of Intravascular Contrast Media</u> [22] and the <u>ACR Manual on Contrast Media</u> [32]).

Fluoroscopy and Imaging

Pulsed fluoroscopy, last image hold, and fluoroscopic image capture result in reduced radiation dose and should be used when available [24,33]. Video recording of the examination may also be useful for later review. Estimators of radiation exposure, such as fluoroscopic parameters used and fluoroscopy time, should be documented. Fluoroscopy time should be monitored and minimized. The use of antiscatter grids should be limited to older patients, patients weighing more than 40–50 lbs, or when the body part examined is greater than 12 cm in thickness. The examination should be collimated to the region of interest.

Standardization of an optimized imaging sequence should be employed as much as possible. Early-filling last-image capture of the bladder with a small amount of contrast may reveal an intravesical ureterocele or other mass, which might be obscured by larger contrast volume. Early oblique views can be obtained if necessary. While further bladder filling occurs, continuous imaging is not necessary [34].

Oblique radiographs of the bladder are obtained when the bladder is estimated to be full, prior to voiding to profile each ureterovesical junction in relation to the bladder neck (as delineated by the catheter). Concluding a study when reaching the predicted bladder capacity may miss children with functional or neurological abnormalities (eg, infrequent voider syndrome that is characterized by a large capacity bladder). One should be aware that in some patients overdistension of the bladder may result in inability to void [35]. If reflux did not occur prior to voiding

and is seen during voiding, the oblique images of the bladder should be repeated. Lateral imaging of the urinary bladder may be helpful in certain indications such as for evaluation of urachal pathology.

Cyclical filling of the bladder (filling to capacity followed by voiding and refilling 2 to 3 times with the catheter in place) may be helpful in infants (1 year of age or younger) who void at low volumes and in patients with a high pretest probability of reflux to increase detection of reflux. The latter group includes patients with recent UTI, a prior history of reflux, periureteral (Hutch) diverticulum, and evidence of pyelonephritis. Cyclical voiding is also helpful in patients who reflux into a very dilated ureter on the first fill; in these patients the refluxed contrast may be diluted by unopacified urine, and additional voiding cycles will optimize visualization of the ureter and collecting system [36,37]. Cyclical voiding is also helpful in cases of suspected ectopic ureter inserting below the bladder base [38].

When VUR occurs, the degree of reflux should be documented by imaging the renal fossae in the frontal projection. Additionally bladder volume at the onset of reflux may be recorded. Post void residual may be estimated [30].

For optimal imaging of the urethra, the field of view and patient positioning should be prepared before the child begins to void. Visual inspection of the perineum will reveal when the patient begins to void and avoids unnecessary and excessive fluoroscopy. Older males might be able to void more easily if the fluoroscopic table is tilted to 30 to 45 degrees or if they are able to stand.

Once voiding is detected, the male urethra may be imaged prior to removal of the catheter, since pertinent pathology may be demonstrated with the catheter in place [39]. However, it is preferable to also obtain images of the urethra after the catheter has been removed, especially in males. In neonates and young infants who may void sporadically, if the bladder has moderately emptied prior to catheter removal, it is best to wait until it refills before removing the catheter, as the child may not void again without a full bladder.

The entire urethra should be demonstrated during the voiding phase. To image the urethra, boys should be positioned slightly obliquely from the lateral position during voiding, with slight offset of the hips such that they are not superimposed. In most young boys, the entire urethra will be visible on a single voiding image. In adolescent boys, separate images of the posterior and anterior urethra may be necessary. In girls, the urethra is generally imaged in the frontal projection, and catheter removal is not necessary for optimal views. Lateral imaging of the female urethra is performed in special circumstances, such as evaluation of urogenital sinus anomalies.

Images of the renal fossae immediately after voiding should be obtained to document the presence and grade of reflux or its absence. The maximal degree of (VUR) should be accurately described and graded (see Appendix A). When an obstructive process, such as obstruction at the ureteropelvic or ureterovesical junction, coexists with reflux, refluxed contrast will be diluted by the indwelling unopacified urine, with decreased density of the refluxed contrast. In such situations, it is not possible to grade the reflux, since the degree of dilatation is not necessarily secondary to the reflux alone; this situation can lead to significant overestimation of the degree of reflux [40].

If there is concern for coexistent obstruction, the rate of contrast drainage from the pelvicalyceal system and ureter may be estimated by obtaining a delayed image, usually a few minutes after voiding.

If a toilet-trained patient is unable to void during the fluoroscopic portion of the examination, after adequate bladder distension and after a reasonable amount of time and coaxing, he or she may be allowed to void in the restroom if it is sufficiently adjacent to the fluoroscopy room. Postvoid images should be obtained immediately after voiding, with an estimate of the time interval between completion of voiding and imaging recorded. As in postvoid imaging on the table, images should be obtained over the renal fossae and bladder to document the presence or absence of reflux and degree of bladder emptying. This limitation of the voiding portion of the examination must be documented.

Assessment of the study should include the following:

- Appearance of the spine and pelvic bones
- Documentation of opaque calculi, calcifications, or foreign bodies, when present
- Bladder contour, location, capacity, diverticula, and residual volume,
- Bladder lumen filling defects, such as ureteroceles, clot, or other masses
- Absence or presence and greatest degree of reflux including intrarenal reflux
- When during the examination reflux, if present, first occurred
- Site of insertion of ureter(s) when visualized by reflux
- Appearance of the entire urethra
- Presence or absence of extravasation or fistula

V. DOCUMENTATION

The findings of the voiding cystourethrogram should be reported in accordance with the <u>ACR Practice Parameter</u> for Communication of Diagnostic Imaging Findings [41].

VI. RADIATION SAFETY IN IMAGING

Radiologists, medical physicists, non-physician radiology providers, radiologic technologists, and all supervising physicians have a responsibility for safety in the workplace by keeping radiation exposure to staff, and to society as a whole, "as low as reasonably achievable" (ALARA) and to assure that radiation doses to individual patients are appropriate, taking into account the possible risk from radiation exposure and the diagnostic image quality necessary to achieve the clinical objective. All personnel who work with ionizing radiation must understand the key principles of occupational and public radiation protection (justification, optimization of protection, application of dose constraints and limits) and the principles of proper management of radiation dose to patients (justification, optimization including the use of dose reference levels). https://www-publicaea.org/MTCD/Publications/PDF/PUB1775_web.pdf

Nationally developed guidelines, such as the <u>ACR's Appropriateness Criteria</u>®, should be used to help choose the most appropriate imaging procedures to prevent unnecessary radiation exposure.

Facilities should have and adhere to policies and procedures that require ionizing radiation examination protocols (radiography, fluoroscopy, interventional radiology, CT) to vary according to diagnostic requirements and patient body habitus to optimize the relationship between appropriate radiation dose and adequate image quality. Automated dose reduction technologies available on imaging equipment should be used, except when inappropriate for a specific exam. If such technology is not available, appropriate manual techniques should be used.

Additional information regarding patient radiation safety in imaging is available from the following websites – Image Gently® for children (<u>www.imagegently.org</u>) and Image Wisely® for adults (<u>www.imagewisely.org</u>). These advocacy and awareness campaigns provide free educational materials for all stakeholders involved in imaging (patients, technologists, referring providers, medical physicists, and radiologists).

Radiation exposures or other dose indices should be periodically measured by a Qualified Medical Physicist in accordance with the applicable ACR Technical Standards. Monitoring or regular review of dose indices from patient imaging should be performed by comparing the facility's dose information with national benchmarks, such as the ACR Dose Index Registry and relevant publications relying on its data, applicable ACR Practice Parameters, NCRP Report No. 172, Reference Levels and Achievable Doses in Medical and Dental Imaging: Recommendations for the United States or the Conference of Radiation Control Program Director's National Evaluation of X-ray Trends; 2006, 2009, amended 2013, revised 2023 (Res. 2d).

VII. QUALITY CONTROL AND IMPROVEMENT, SAFETY, INFECTION CONTROL, AND PATIENT EDUCATION

Policies and procedures related to quality, patient education, infection control, and safety should be developed and implemented in accordance with the ACR Policy on Quality Control and Improvement, Safety, Infection Control, and Patient Education appearing under the heading *Position Statement on QC & Improvement, Safety, Infection Control, and Patient Education* on the ACR website (<u>https://www.acr.org/Advocacy-and-Economics/ACR-Position-Statements/Quality-Control-and-Improvement)</u>.

Equipment performance monitoring should be in accordance with the <u>ACR–AAPM Technical Standard for</u> <u>Diagnostic Medical Physics Performance Monitoring of Fluoroscopic Equipment</u> [42].

CONTRAST ENHANCED VOIDING UROSONOGRAPHY (ceVUS)

VIII. INTRODUCTION

The intravesical administration of ultrasound (US) contrast agent and the demonstration of refluxing microbubbles into a ureter or renal collecting system is known as contrast enhanced voiding urosonography, or ceVUS [43-45]. In 2016 the Food and Drug Administration (FDA) of the United States approved the use of an US contrast agent (Lumason, Bracco) for use in vesicoureteric reflux detection in children. Studies of ceVUS versus VCUG have demonstrated that ceVUS is more sensitive in detecting vesicoureteric reflux and is comparable in the evaluation of the urethra [44,45]. Unlike VCUG there is no exposure to radiation.

IX. INDICATIONS AND CONTRAINDICATIONS

The indications for ceVUS are the same as for VCUG. The study is contraindicated if one or both kidneys are difficult to visualize sonographically, which may occur in a morbidly obese child or a child with severe lumbar scoliosis [12]. There are no known side effects related to intravesical administration of US contrast agents [46].

X. QUALIFICATIONS AND RESPONSIBILITIES OF PERSONNEL

ceVUS is performed by sonographers or radiologists trained in bladder catheterization and sonography of the bladder, ureters, kidneys and urethra. It is best to have two persons present for the exam; one performing the catheterization and administration of intravesical US contrast and the other performing the US itself. The ceVUS is documented with static images and clips.

XI. SPECIFICATIONS OF EXAMINATION

The request for the study, patient selection and preparation, review of prior imaging and catheterization process are similar to those for VCUGs. The study must be carried out with an US scanner equipped with a contrast specific modality. Scout sonographic images should be obtained prior to catheterization. The US contrast agent is prepared as per the instruction of the manufacturer. The microbubble solution is mixed immediately before its use as the bubbles disintegrate over time.

A 0.2% suspension of the US contrast agent and normal saline may be administered into the bladder catheter via gravity drip. Alternatively, 0.5-1.0 mL of the contrast agent may be administered via the bladder catheter followed by a normal saline infusion [47]. The height of the infusion and the volume of suspension or normal saline administered are similar to those for VCUG.

Bladder filling is carried out under US monitoring with the patient supine. This is followed by alternate scanning of the right and left kidneys (supine or oblique if necessary) and the bladder. During voiding, additional suprapubic and/or transperineal scanning of the urethra are performed with the catheter in place as well as once the catheter has

been removed. Patients may be scanned from the back while sitting on a potty or, in males, while standing and using a urinal, thus allowing a more physiological position for voiding.

Additional postvoid scanning of the bladder and kidneys is subsequently obtained. The appearance of echogenic microbubbles within a ureter or renal collecting systems indicates vesicoureteric reflux. Vesicoureteric reflux is graded in a similar way to VCUG [43]. As with a VCUG, cyclical filling may be necessary in neonates and infants [47].

Assessment and reporting is similar to VCUG with the exception of structures not applicable to US such as the bony pelvis and fluoroscopic radiation.

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APPENDIX A

Grading System of the International Reflux Study of 1985 [30] (See Figure 7 from Pediatric Voiding Cystourethrography, a Pictorial Guide) [34]

- 1. Reflux only into the ureter.
- 2. Reflux into the entire ureter and pelvicalyceal system, no dilatation.
- 3. Mild pelvic or ureteral dilatation, with mild or no blunting of the fornices.
- 4. Moderate dilatation of the pelvis and ureter, with moderate dilation of the calyces.
- 5. Massive ureteral or pyelocalyceal dilatation.

Grading system for contrast enhanced voiding urosonography (ceVUS) is similar to VCUG [43].

*Practice parameters and technical standards are published annually with an effective date of October 1 in the year in which amended, revised or approved by the ACR Council. For practice parameters and technical standards published before 1999, the effective date was January 1 following the year in which the practice parameter or technical standard was amended, revised, or approved by the ACR Council.

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