Purpose To evaluate the diagnostic performance and safety of intravesical administration of a second-generation ultrasound contrast-agent (UCA) for the diagnosis of vesicoureteric reflux (VUR) in children.

Methods and materials 1350 children (587 boys/763 girls, mean-age 2.6y, range 15d-17y) with 2720 pelvi-ureter-units, underwent contrast-enhanced voiding urosonography (ceVUS) to rule out VUR and urethral pathology. A second-generation UCA (SonoVue®, Bracco, Milan) was administered intravesically through 5–8F feeding-tube at a dose of 0.5 ml/bladder filling. Possible adverse-events were monitored during the examination and followed-up for 7 days after the ceVUS by phone-calls. Urine analysis and culture were performed 3–5 d before ceVUS in all children and 24–48 h in any patient reported with adverse-events.

Results VUR was detected in 450/1350(33%) patients (162 boys/288 girls). This was in 653 pelvi-ureter-units (reflux-grade distribution: grade I = 1, grade II = 276, grade III = 266, grade IV = 100, grade V = 10). The urethra was normal in all children. Mean duration of examination was 14 ± 7 min, including urethral imaging. Minor adverse-events were reported in 45 (3.3%) children. These included dysuria (n = 39), abdominal pain (n = 2), increased frequency of micturition (n = 1), vomiting (n = 1), perineal irritation (n = 1), and urinary-tract-infection after ceVUS (n = 1). The onset of adverse-events were subacute in 92% and delayed in 8% and were self-limited non-requiring hospitalisation.

Conclusions There were no serious adverse-events with intravesical use of SonoVue®. Only a few minor adverse-events were reported during ceVUS most likely due to catheterization process. Thus ceVUS with intravesical administration of a second generation UCA (SonoVue®) for VUR and urethral pathology detection is a safe and reliable diagnostic procedure in children.