5-2020

Bladder scanners in the ICN: Summary

Children's Mercy Kansas City

Office of Evidence Based Practice (EBP) – Critically Appraised Topic (CAT): Bladder Scanners in the Neonatal Intensive Care Unit (NICU)

Specific Care Question

In neonates, are bladder scanners able to detect urine and determine urine volume accurately?

Recommendation Based on Current Literature (Best Evidence) Only

No recommendation can be made for or against the use of a bladder scanner prior to urinary catheterization for neonates. After expert review of current literature by the Department of EBP, the overall certainty in the evidence is very low[d]. Although two RCTs performed in children ≤ 36 months of age showed significantly greater success of obtaining a urine sample on first attempt at catheterization, the mean age ranged from 6-12 months the studies (see Table 2). It is not certain if the results would be the same in neonates. Harm of performing a bladder scan was not reported in any study. When there is a lack of scientific evidence, standard work should be developed, implemented, and monitored.

Literature Summary

Background Nurses in the NICU are often asked to use a bladder scanner to assess if neonates have urine in their bladders. A bladder scanner is a portable ultrasound device, designed to scan and calculate urine volume. Bladder scanners use ultrasound to calculate bladder volume (Baumann, Welsh, Rogers, & Newbury, 2008), and have been shown to be useful in bladder retraining programs (Beckers, van der Horst, Frantzen, & Heymans, 2013; Buntsma, Stock, Bevan, & Babl, 2012), prior to suprapubic aspiration of the urinary bladder, and assessing post void residuals in school-age children (Koomen et al., 2008; Massagli, Jaffe, & Cardenas, 1990). However, the shape and location of the urinary bladder changes as children mature. At birth, the bladder is more oval shape with the highest point of the bladder expanding to the level of the umbilicus (Standring, Borely, & Gray, 2016). The urinary bladder does not gain its mature pelvic shape and position until about 6 years of age (Standring et al., 2016). Most of the research on the use of bladder scanners has occurred in adult populations. However, there is a limited amount of research that has been performed in children aged 0 to 36 months of age.

Verathon® BVI™ bladder scanners are the most studied instruments (Beckers, van der Horst, Frantzen, & Heymans, 2013; Bevan et al., 2011; Buntsma, Stock, Bevan, & Babl, 2012; Koomen et al., 2008; Massagli, Jaffe, & Cardenas, 1990; Rosseland, Bentsen, Hopp, Refsum, & Breivik, 2005; Rowe, Price, & Upadhyay, 2014; Wyneski, McMahon, Androulakakis, & Nasrallah, 2005). The Verathon® BVI™ has been updated through the years, starting with the BVI 2000 in 1984, through the Verathon® BVI™ 9400; the most recent instrument is the Verathon® PrimePlus™(Verathon®, 2020). Of note, the BladderScan Prime Plus reports accuracy of ± 7.5 ml on urine volumes of 0-100 mLs and ±7.5% on urine volumes from 100 to 999 mLs (Verathon®, 2020). The FujiFilm Sonosite 180 was studied in two papers (Baumann, McCans, et al., 2008; Witt, Baumann, & McCans, 2005). This instrument has been retired (FujiFilm, 2020). The pediatric intensive care unit at CMH uses the bladder scanner manufactured by Mcube Technology Co., LTD (Mcube Technology Co., 2020). This instrument has not been studied by the included studies. This review will summarize current literature on the topic.

Study characteristics. The search for suitable studies was completed on March 5, 2020. B. Haney RNC-NIC, MSN, CPNP-AC, FELSO and D. Wilderson, MSN, RNC-NIC reviewed the 34 titles and/or abstracts found in the search and identified[b] 14 single studies believed to answer the question. After an in-depth review of the 14 articles[c], 10 answered the question. Two articles were RCTs (Baumann, McCans, et al., 2008; Witt et al., 2005), while the others were cohort studies (Beckers et al., 2013; Bevan et al., 2011; Buntsma et al., 2012; Koomen et al., 2008; Massagli et al., 1990; Rosseland et al., 2005; Rowe et al., 2014; Wyneski et al., 2005). See Figure 1.

Summary by Outcome

Accuracy of Bladder Scanners. Two RCTs (Baumann, McCans, et al., 2008; Witt et al., 2005) measured successful urine volume (≥ 2.5 mL total urine volume) on first catheterization attempt, (*n* = 126). Odds ratio indicated results as counts of attempts, and they are included in the meta-analysis (see Figure 2 & Table 1). The *OR* = 6.13, 95% CI [2.35, 16.02] indicated the scanning with a bladder scanner prior to catheterization was favorable to the comparator, conventional urinary catheterization without ultrasound.

From the cohort studies, effect sizes were measured both as correlations to assess how well the bladder scanner calculated volume correlated with the amount of urine from catheterization, urinary volume assessed in Radiology, or voiding. Correlation coefficients ranged from *r* = .188 ± .12 (Wyneski et al., 2005) to *r* = .96 (Rowe et al., 2014). Mean differences in urine volumes were also reported, range, *MD* = 6.9, 95% CI [-3.5, 17.3] to -18 ml (±19).

Certainty of the evidence for accuracy of bladder scanners. The certainty of the body of evidence was very low based on four factors: *within-study risk of bias*, *consistency among studies, directness of evidence*, and *precision of effect estimates*. The body of evidence was assessed to have very serious risk of bias, very serious imprecision, serious indirectness and very serious inconsistency.

Risk of bias was *very serious* as the outcome assessors in the RCTs included in the meta-analysis (Baumann, McCans, et al., 2008; Witt et al., 2005) were not blinded. For subjects in the bladder scanner group, the nurse knew there was a measurement of bladder diameter of ≥ 2 cm showing a urinary volume of ≥ 2.5 mLs (Baumann, McCans, et al., 2008). Success in this group may have been dependent on this knowledge. In both studies caregivers withdrew from the study if their child was not randomized to the group they preferred, or after one unsuccessful catheterization attempt. Unsuccessful attempts were more frequent in the catheterization without ultrasound group.

Inconsistency among studies was *very serious.* Subject characteristics varied across studies. Subjects included healthy children in one study (Bevan et al., 2011), to children with voiding disorders (Beckers et al., 2013), or children who failed to void after surgery (Koomen et al., 2008; Rosseland et al., 2005). Table 2 details the various diagnoses across studies. The subjects' age ranges also varied widely from children greater than 31 weeks gestational age (Wyneski et al., 2005) to 16.75 years of age (Massagli et al., 1990). Finally, the bladder scanner instrument employed in the study varied. Early studies were performed with the Verathon BVI 2000 (Massagli et al., 1990), while later studies were performed with the Verathon® BVI 9400 (Bevan et al., 2011; Buntsma et al., 2012; Rowe et al., 2014). Two studies used the Sonosite 180 (Baumann, McCans, et al., 2008; Witt et al., 2005). Of note, Verathon® is now marketing the Prime Plus™ bladder scanner, no studies that have employed this instrument have been reported.

Indirectness was *serious*. The population of interest for this CAT is neonates in the NICU, including infants with bladder anomalies. The literature includes one study (*n* = 10) that includes this group (Wyneski et al., 2005). Success in older children may not reflect performance in neonates as changes in bladder anatomy occur over time (Standring et al., 2016).

Imprecision was *very serious*. For the RCTs, confidence intervals are wide, and there are only two RCTs with a total of 126 subjects included in the meta-analysis. For the cohort studies, the findings vary greatly. See Table 2.

Identification of Studies

Search Strategy and Results (see Figure 1)

PubMed

Search: ("bladder scanner" OR "bladder scan" OR "bladder scanning" OR "bladder ultrasound" OR "bladder ultrasonography" OR ("Ultrasonography"[Mesh] AND "Urinary Bladder"[Mesh]) OR "Urinary Bladder/diagnostic imaging"[Mesh]) AND ("Urinary Retention"[Mesh] OR "Urinary Catheterization"[Mesh] OR "bladder Catheterization") AND (infant OR neonatal OR NICU OR newborn OR neonate) Filters: From 2005/01/01 to 2020/12/31

Records identified through database searching *n* = 37

Additional records identified through other sources *n* = 0

Studies Included in this Review

Citation	Study Type
Baumann, McCans, et al. (2008)	RCT
Beckers et al. (2013)	Cohort
Bevan et al. (2011)	Cohort
Buntsma et al. (2012)	Cohort
Koomen et al. (2008)	Cohort
Massagli et al. (1990)	Cohort
Rosseland et al. (2005)	Cohort
Rowe et al. (2014)	Cohort
Witt et al. (2005)	Control trial
Wyneski et al. (2005)	Cohort

Studies Not Included in this Review with Exclusion Rationale

Citation	Reason for exclusion
Baumann et al. (2007)	Assessed satisfaction of caregiver and health care provider with urinary catheterization
Baumann, Welsh, Rogers, and Newbury (2008)	Narrative review, describes the technique of performing a bladder ultrasound, no data is reported
Matsumoto et al. (2019)	Estimating bladder volume with a bladder scanner in adults
Wheeler, O'Riordan, Allareddy, and Speicher (2015)	Included subject from 5 months to 27 years of age, no differentiation by age

Methods Used for Appraisal and Synthesis

[a]The GRADEpro Guideline Development Tool (GDT) is the tool used to create the Summary of Findings table(s) for this analysis.

[b]Rayyan is a web-based software used for the initial screening of titles and / or abstracts for this analysis (Ouzzani, Hammady, Fedorowicz & Elmagarmid, 2017).

[c]Review Manager (Higgins & Green, 2011) is a Cochrane Collaborative computer program used to assess the study characteristics as well as the risk of bias and create the forest plots found in this analysis.

[d]The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram depicts the process in which literature is searched, screened, and eligibility criteria is applied (Moher, Liberati, Tetzlaff, & Altman, 2009).
[e]The United Nations report on the world economic situation was used to delineate economically developed countries from non-developed countries.

[a]GRADEpro GDT: GRADEpro Guideline Development Tool (2015). McMaster University, (developed by Evidence Prime, Inc.). [Software]. Available from gradepro.org.
[b]Ouzzani, M., Hammady, H., Fedorowicz, Z., & Elmagarmid, A. (2016). Rayyan-a web and mobile app for systematic reviews. *Systematic Reviews, 5*(1), 210. doi:10.1186/s13643-016-0384-4
[c]Higgins, J. P. T., & Green, S. e. (2011). *Cochrane Handbook for Systematic Reviews of Interventions [updated March 2011]* (Version 5.1.0 ed.): The Cochrane Collaboration, 2011.
[d]Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). *P*referred *R*eporting *I*tems for *S*ystematic Reviews and *M*eta-*A*nalyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097 **For more information, visit www.prisma-statement.org.**
[e]United Nations Department of Economic and Social Affairs (2019). World Economic Situation and Prospects. Retrieved from https://www.un.org/development/desa/dpad/wp-content/uploads/sites/45/WESP2019_BOOK-web.pdf

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Acronyms Used in this Document

Acronym	Explanation
ABUS	Automated bladder ultrasound
CAT	Critically Appraised Topic
EBP	Evidence Based Practice
MD	Mean Difference
mL	Milliliter
NICU	Neonatal Intensive Care Unit
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	Randomized Control Trial
r_p	Pearson's correlation coefficient for continuous variables
r_s	Spearman's correlation coefficient for ranked or ordinal variables
RTUS	Real-time ultrasound

Date Developed:
April 2020

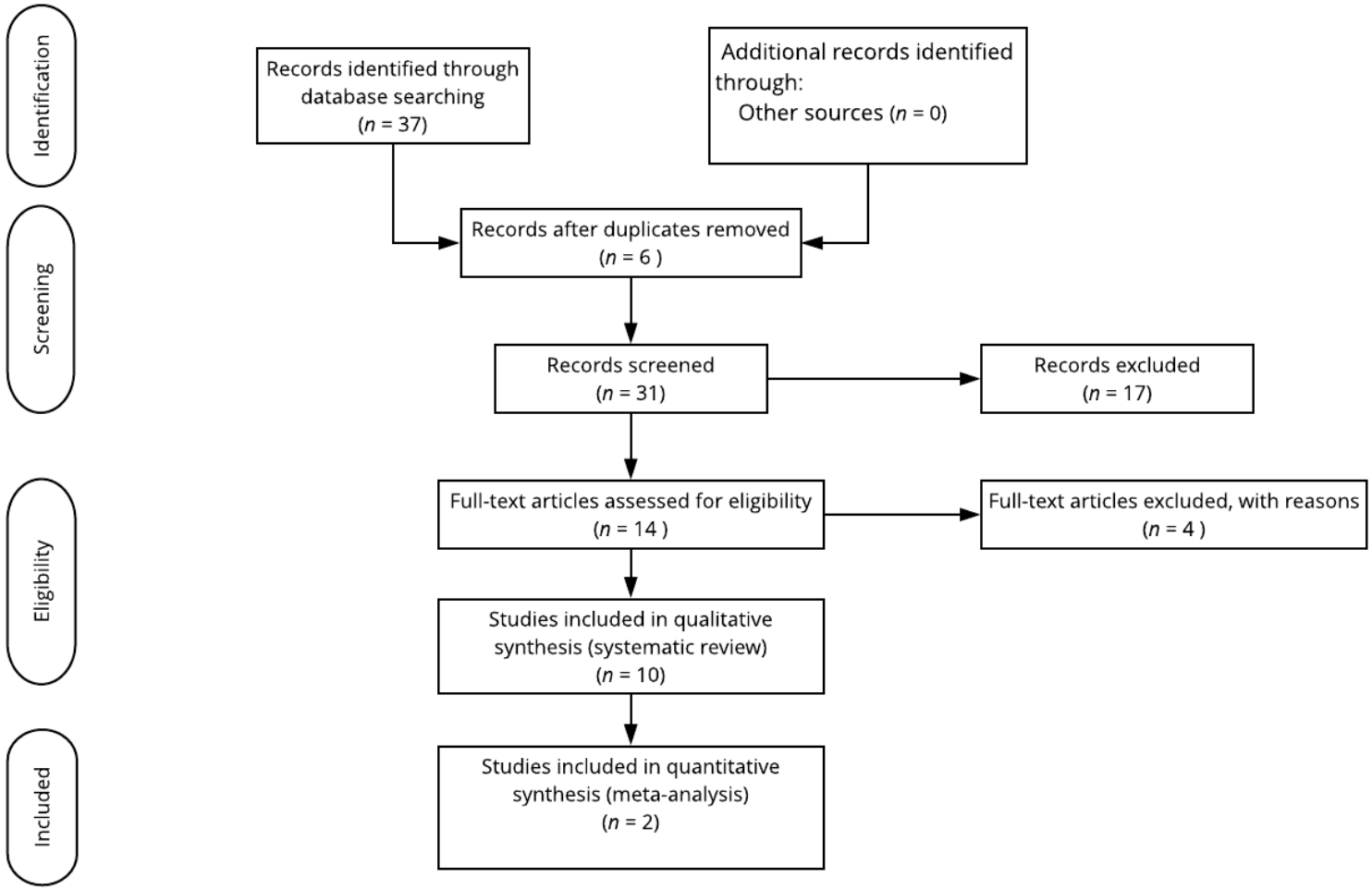

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRIMSA)[d]

Meta-analysis

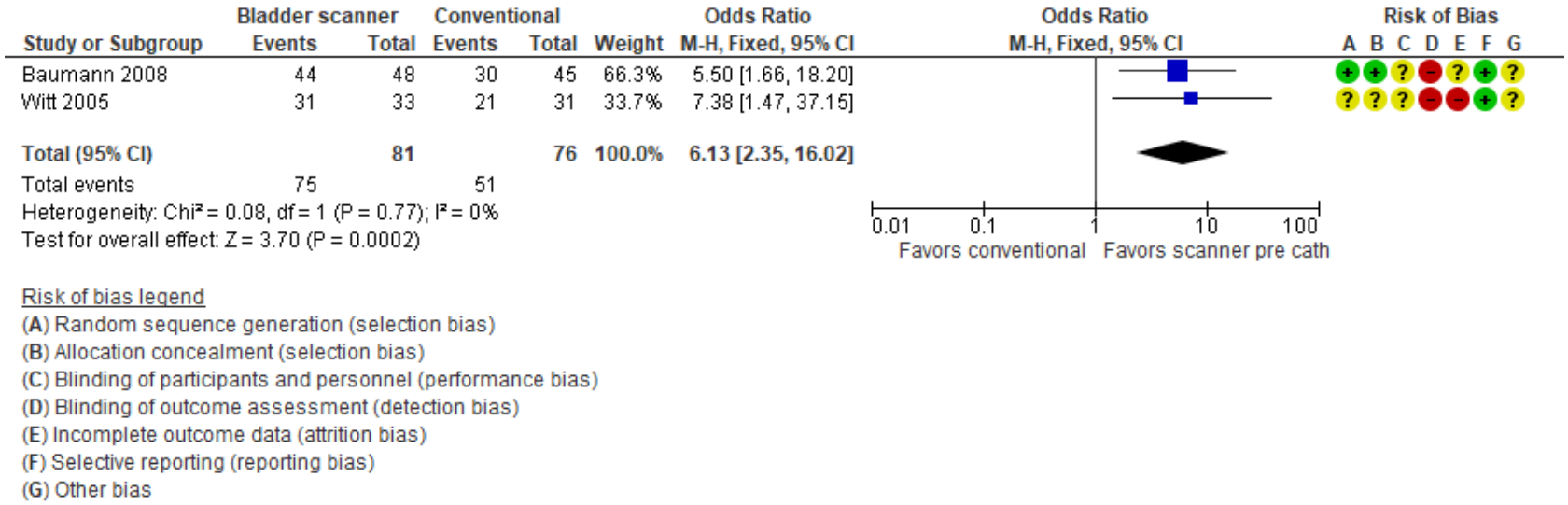

Figure 2. Comparison: Bladder Scan pre-catheterization versus Conventional Catheterization, Outcome: Successful Urine Volume on First Attempt

Table 1.

Summary of Findings Table[a]: Bladder Scan Compared to Conventional Catheterization for Neonates

Certainty assessment							Summary of findings				
№ of participants (studies) Follow-up	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Publication bias**	**Overall certainty of evidence**	**Study event rates (%)**		**Relative effect (95% CI)**	**Anticipated absolute effects**	
							With Conventional	**With Bladder scan**		**Risk with Conventional**	**Risk difference with Bladder scan**
Successful urine volume on first attempt											
157 (2 RCTs)	very serious [a]	very serious [b]	very serious [c]	very serious [d]	none	⨁◯◯◯ VERY LOW	51/76 (67.1%)	75/81 (92.6%)	**OR 6.13** (2.35 to 16.02)	671 per 1,000	**255 more per 1,000** (from 156 more to 299 more)

CI: Confidence interval; OR: Odds ratio

Notes:

a. Outcome assessors in both trials were not blinded to the intervention. In the RCT, randomization was null when caregivers withdrew their child from the study if they were no randomized to the group the caregiver preferred.

b. Subjects varied across studies. Both subject age, and presence of urinary system dysfunction varied. The bladder scanner employed varied across studies. Comparison of results when the technology is changing decreases certainty in the results.

c. The population of interest for this question is neonates. Only one study (*n* = 10) had neonates as subjects. Changes in the anatomy of urinary system with maturity, makes studies in older children and adults indirect.

d. For the two studies that are included in the meta-analysis, the confidence intervals are wide. Additionally, there are two studies (*n* = 157).

Table 2.
Summary of Included Studies

Article	*N*	Age	Diagnosis	Instrument	Reference Standard	Result
Massagli et al. (1990) Cohort	39	Median 5.8 years, range 1 month to 16.75 years	Perceived small bladder capacities	BVI 2000	Urinary catheterization	Mean difference between BVI 2000 urine volume and volume by urinary catheterization was not different, *MD* = 6.9, 95% CI [-3.5, 17.3]
Rosseland et al. (2005) Cohort	48	Median, 3 years Range, (0 to 15 years)	Failed to void after surgery	BVI 3000	Urinary catheterization	For volumes > 100 mL statistics not reported, although the graph of the correlation looks close to 1. For volumes < 100 mL there was disagreement between volume by BVI 3000 and volume by urinary catheter. Separated by age (Bland Altman plot) 0 to 3 years old, *n* = 22, *MD* = -18 mL (±19) ≥ 3 years, *n* = 26, *MD* = 4 ml (±25)
Witt et al. (2005) RCT	64	Mean (SD) Group 1: 7.7 months ± 5.5 Group 2: 9.4 months ± 7.8	Less than 36 months, not toilet trained, required a diagnostic urine sample	Sonosite 180 Plus, L38 broadband linear transducer	Urinary catheterization	Odds of having a successful urine volume on the first attempt *OR* = 7.38 [1.47, 37.15]
Baumann, McCans, et al. (2008) RCT	50	Group 1, months, mean 9.1 [6.4,11.8] Group 2, months. mean, 10.2, [7.7, 12.6]	Less than 36 months Not toilet trained Required catheterization for urine collection	Sonosite 180	Urinary catheterization	Odds of having a successful urine volume on the first attempt *OR* = 5.5 [1.66, 18.20]
Wyneski et al. (2005) Cohort	10	Gestational age, weeks	Neonates with bladder anomalies	BVI 3000	Urinary catheterization	Correlation coefficient across cases was low, *r* = .37 ± .07

		Mean 36 weeks, minimum 31 weeks	(myelodysplasia *n* = 9, and bladder exstrophy *n* = 1)			Correlation coefficient within cases was low, r = .088 ± .12 Significant urinary volume was missed 7-25% of the time
Koomen et al. (2008) Cohort	40	Mean, 2.2 years, range (0 to 10 years)	Surgical patients who required urinary catheterization or those in the pediatric intensive care unit	BVI 6200	Urinary catheterization	Correlation between BVI 6200 measurement and volume from urinary catheterization was low, r = .78, r^2 = .6, 6. Wilcoxon signed ranks test Z = -3.25, p = .001, difference between observed (BVI 6200) and measured volume. Study was stopped when 40/70 needed subjects were studied due to futility.
Bevan et al. (2011) Cohort	61	Mean (SD) 11 ± 6.2 months, range 0 to 24	Healthy children	BVI 9400	Ultrasound	95% limits of agreement between the BVI 9400 and the reference standard [-31, 19 mL] The repeatability coefficient = 20 mL. Repeated measures on the same subject at the same time were within 20 mL of each other. See Table below
Beckers et al. (2013) Cohort	84	Mean (SD) 7.8 ± 3.1 years, range 0 to 16 years	Voiding disorders	BVI 6200	Voided urine volume plus post void residual assessed by ultrasound	Correlation between BVI 6200 measurement and volume obtained by voiding plus post-void residual by ultrasound was significant, r_s = .92, (p < .01) Most urine volumes by BVI 6200 were not within 10% of the volume obtain by the reference standard. Within 10% agreement was determined a priori
Buntsma et al. (2012) Cohort	60	Mean, 5 months, range, 0 to 18.6 months	Only if first method of obtaining a urine specimen was suprapubic aspiration	BVI 9400	Ultrasound	Overall success rate of suprapubic aspiration when BVI 9400 was used 53%, 95% CI [41, 65%] • 0 to 6 months – 52% • 6 to 24 months – 56%

Rowe et al. (2014) Cohort	50	Median 5 years, range (6 weeks to 14 years) Subgroup analysis 1.03 years, range (6 weeks to 2 years)	Scheduled for urodynamics studies or surgery	BVI 9400	Urinary catheterization	All subjects: r^s = .96, *MD* = -2.1 mL (±21) Subgroup analysis, < 36 months r^s = .82, *MD* = -2.6 (±16)

Characteristics of Intervention Studies

Baumann, McCans, et al. (2008)

Characteristics of Study

Methods	Randomized Control Trial
Participants	**Participants:** Children **Setting:** Tertiary care pediatric ED **Randomized into study:** *N* = 95 • **Group 1, Ultrasound arm:** *n* = 49 • **Group 2, Conventional catheterization:** *n* = 46 **Completed Study:** *N* = 93 • **Group 1, Ultrasound arm:** *n* = 48 • **Group 2, Conventional catheterization:** *n* = 45 **Gender, males (as defined by researchers):** • **Group 1, Ultrasound arm:** *n* = 18 (40%) • **Group 2, Conventional catheterization:** *n* = 18 (38%) **Race / ethnicity or nationality[e] (as defined by researchers):**

	Ultrasound arm *n* = 45	Conventional Catheterization *n* = 48
Race		
• African American	16 (33%)	24 (53%)
• White	31 (35%)	21 (47%)
• Asian	1 (2%)	0 (0%)
Ethnicity		
• Hispanic	20 (42%)	16 (36%)

Age, months, mean, 95% CI
- **Group 1, Ultrasound arm:** 9.1 [6.4, 11.8]
- **Group 2, Conventional catheterization:** 10.2, [7.7, 12.6]

Inclusion Criteria:
- </= 36 months
- Not toilet trained
- Required a catheterization for urine

Exclusion Criteria:
- Genital anatomical abnormality

	• Indwelling catheter • Critically ill • Fever **Power Analysis:** Assumption: 2 tailed α of .05. and 80% power, along with an additional 10% recruitment cushion, 92 participants, with at least 42 were needed in each group.
Interventions	**Both:** Placed on an absorbent pad that was pre-weighed. The pad was weighed after the catheterization occurred to collect spilled urine • **Group 1, Ultrasound arm:** Volumetric ultrasound prior to catheterization • **Group 2, Conventional catheterization:** Conventional catheterization Instrument used: Sonosite 180 Plus 5- MHz curved transducer If the transverse diameter of the bladder was >/= 2 cm, a sagittal measure was taken, and urine volume calculated. If urine volume was >/- 2.5 cm^3, catheterization proceeded. If the transverse measure was < 2 cm, no attempts were made until volume exceeded 2 cm^3.
Outcomes	**Primary outcome:** • Success on first attempt of urinary catheterization **Secondary outcome:** • Throughput times **Safety outcome:** • Not reported

Risk of Bias

Bias	**Scholar's judgment**	**Support for judgment**
Random sequence generation (selection bias)	Low risk	Block randomization, do not report block size
Allocation concealment (selection bias)	Low risk	Numbered sealed packets
Blinding of participants and personnel (performance bias)	Unclear risk	Unable to blind
Blinding of outcome assessment (detection bias)	High risk	For the subject in the ultrasound group, the nurse performing the catheterization did not attempt the procedure if the scanned bladder volume was not ≥ 2.5 cm^3.
Incomplete outcome data (attrition bias)	Unclear risk	
Selective reporting (reporting bias)	Low risk	
Other bias	Unclear risk	

Beckers et al. (2013)

Characteristics of Study	
Methods	Cohort
Participants	**Participants:** Children with voiding disorders **Setting:** Urology clinic, The Netherlands **Number enrolled into study:** *N* = 84 **Number completed:** *N* = 84 **Gender, males: (as defined by researchers)** • 58% (49/84) **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in The Netherlands. The authors did not identify race or ethnicity of the participants. **Age, mean years, SD, (range)** • 7.8 ± 3.1 (range 0 - 16 years) ○ 39 subjects weighed < 27 kg **Inclusion criteria:** • Subjects who were in a bladder re-training program **Exclusion criteria:** • Subjects who were unable to void **Covariates identified:** • Time varying confounding - Data was collected over a long timeframe August 2008 to February 2011 • Conventional ultrasound may not be the gold standard, but was considered as such for this study • It is not clear how timing of micturition was managed in subjects who were not toilet trained
Interventions	• Subjects came to clinic and were encouraged to drink well. When the subject felt the need to void, the BVI 6200 was used to estimate bladder volume • The subject then voided into a graduated cylinder, recorded in mLs • Finally, within 2 minutes of voiding, a bladder ultrasound was performed by a pediatric urologist, results recorded in mLs
Outcomes	**Primary outcome(s):** • Agreement between BVI 6200 and voided urine volume and volume determined by ultrasound, if any • Agreement was defined as ± 10% in a Bland-Altman plot **Secondary outcome(s)** • Not reported **Safety outcome(s):** • Not reported *Outcomes of interest to the CMH CAT development team

Notes	**Results:** • Correlation between BVI 6200 volume measurement and void volume plus post void residual by ultrasound, r_s = .92, (p < .01) • The accuracy of BVI for both modules >/= 27 kg and < 27 kg by Bland-Altman analysis shows most values for urine volume by the BVI 6200 are not within the 10% variance define as acceptable a priori

Bevan et al. (2011)

Characteristics of Study	
Methods	**Cohort**
Participants	**Participants:** Healthy children <24 months recruited through advertisements posted at Royal Children's Hospital (RCH) **Setting:** Radiology department of the RCH in Melbourne, Australia, August 2009 and October 2009 **Number completed:** *N* = 61 **Gender, males: (as defined by researchers)** • **Group 1:** *n = 31* (51%) **Race / ethnicity or nationality (as defined by researchers):** • Not reported **Age, mean in months ± standard deviation, range** • 11 ± 6.2 months; 0 to 24 months **Inclusion criteria:** • Healthy children <24 months **Exclusion criteria:** • History of renal tract abnormalities, abdominal surgery, or abdominal scar tissue • Open skin wounds • Wounds in the suprapubic area **Covariates identified:** • Not reported
Interventions	**Both:** • Volume was measured in all patients using both ○ Conventional Real-time Ultrasound (RTUS) (ACUSON S2000, Siemens, Erlangen, Germany) ▪ One qualified sonographer (single volume measurement) ○ Verathon® BladderScan BVI 9400, Automated bladder ultrasound (ABUS) ▪ Two operators (each preformed a set of 3 measurements • Procedure was divided into two time points (1-2 hours apart): ○ Initial bladder volume measurements using both machines ○ Second bladder volume measurements using both machines
Outcomes	**Primary outcomes:** • Determine the repeatability of this device for bladder volume measurements in children aged less than 2 years • Examine the accuracy of the ABUS, with RTUS by a pediatric sonographer as the criterion standard

Notes

Results:

Repeatability and Accuracy of Bladder Scan Ultrasound

	N = 61	Repeatability (Repeatability Coefficient)	Accuracy (95% Limit of Agreement)	Range of Difference Between ABUS and RTUS
0 to < 6 months	28	20 mL	-25 to +14 mL	-40 to +32mL
6 to <12 months	19	17 mL	-38 to +17 mL	-60 to +42mL
12 to <24 months	24	24 mL	-28 to +23 mL	-56 to +36mL
Total	61	20 mL	-31 to +19 mL	-60 to +42mL

- This study showed poor repeatability and accuracy in bladder volume measurements using BladderScan
- There was wide variation between ABUS and RTUS measurements
- The repeatability coefficient within ABUS readings was 20 mL. This means that 95% of the time, repeated measurements on the same subject at the same point in time were within 20 mL of each other.
- The 95% limits of agreement between ABUS and RTUS was –31 to +19 mL.

Buntsma et al. (2012)

Characteristics of Study	
Methods	**Cohort**
Participants	**Participants:** Children 0-24 months who needed a urine specimen obtained by suprapubic aspiration **Setting:** Children's Hospital ED, Melbourne Australia **Number enrolled into study:** *N* = 60 **Number completed:** *N* = 60 **Gender, males: (as defined by researchers)** • **Group 1:** *n = 35* (58%) **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in Australia. The authors did not identify race or ethnicity of the participants **Age, months, mean, range:** 5 (0, 18.6) **Inclusion criteria:** • Only if suprapubic aspiration was the first method of urine collection **Exclusion criteria:** • Stated there were no exclusion criteria **Covariates identified:** • 200 suprapubic aspiration were done in the time frame, only 60 were observed. Reasons for non-inclusion were not reported. • Five subjects had related urinary tract anomalies ○ Renal reflux ○ Bifid kidney ○ Hydronephrosis ○ Hypospadias ○ Abdominal ventriculoperitoneal shunt **Protocol Registration** • Human Ethics Research Committee (HREC #29052A)
Interventions	Objectives of the study: (a) do the measures by the BVI 9400 repeatable in children < 2 years of age, and (b) accuracy of the bladder scanner with real time ultrasound as the reference test **All subjects:** Measures recorded on the same day, interval one hour between measures • Time one: bladder volume measurements ○ Real time ultrasound by qualified sonographer ○ BVI 9400 performed by two pediatric emergency consultants ▪ Each performed a set of three measures • Time two: bladder volume measurements ○ Real time ultrasound by qualified sonographer ○ BVI 9400 performed by two pediatric emergency consultants ▪ Each performed a set of three measures
Outcomes	**Primary outcome(s):**

	• Success rate of suprapubic aspiration when BVI 9400 is used to determine if urine is present **Secondary outcome(s)** • Staff experience • Site of needle insertion • Angle of needle insertion **Safety outcome(s):** • Not reported
Notes	**Results:** Overall success rate- 53%, 95% CI [41, 65%], (32/60) • 0-6 months- 52%, (22/42) • 6-24 months - 56% (10/18) Number of BVI 9400 readings prior to suprapubic aspiration, Median, (range) = 3 (1-6) Success per volume of BSUS reading • 0-9 mL *n* = 8, 63% successful • 10-19 mL, *n* = 25, 35% successful • 20-29 mL, *n* = 11, 82% successful • ± 30 mL, *n* = 16, 63% successful Needle insertion site, needle angle or staff experience did not influence success rate

Koomen et al. (2008)

Characteristics of Study	
Methods	**Cohort**
Participants	**Participants:** Children who required urinary catheterization, either for surgery, or post operatively in the intensive care unit **Setting:** Pediatric Hospital, Rotterdam, The Netherlands **Number enrolled into study:** *N* = 40 **Number completed:** *N* = 40· **Gender, males: (as defined by researchers)** 58% (23/40) **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in The Netherlands. The authors did not identify race or ethnicity of the participants. **Age, mean, range** • 2.2 years (0, 10 years) **Inclusion criteria:** • Surgical patients who required urinary catheterization • Patients in the pediatric intensive care unit who required urinary catheterization **Exclusion criteria:** • Weight > 25 kilograms • History of bladder dysfunction such as vesicoureteral reflux or upper urinary tract dilatations or • Had skin disorders where an ultrasound scanner would touch the skin **Covariates identified:** • Body surface area, age, gender, volume of urine
Interventions	• **Assessment of bladder volume with BladderScan 6200** ○ After anesthesia induction in the operating room, the bladder was scanned, and urinary volume measured before urinary catheterization ○ In the PICU, patients with indwelling catheters were scanned with the catheter in place, Then the bladder was injected with a random amount of sterile saline. An ultrasound was completed by a sonographer blinded to the infused volume. After the scan was complete, the catheter was opened, and urine volume was measured.
Outcomes	Results do NOT go here. (delete) **Primary outcome(s):** • *Correlation of bladder volume by scanner and bladder volume by emptying the bladder with the catheter **Secondary outcome(s)** • Effect of body surface area • Age related differences • Gender related differences

	Safety outcome(s): *Outcomes of interest to the CMH CPG or CAT development team
Notes	**Results:** There was poor correlation between ultrasound and measured volumes, r = .78, r^2 = .6, 6 Wilcoxon signed ranks test (a non-parametric paired t-test) showed significant difference between observed and measured urine volume, Z = -3.25, p = .001 *Mean difference* = - 20%, 95% CI [140, -180%], a measure of bias Analyzing for body surface area, weight, volume of urine, gender, or anatomical difference did not improve correlation. A power analysis was performed, and 70 subjects were required to find a correlation of 0.8 between ultrasound measurement and actual volume of urine drained from bladder. However, after 40 subjects were enrolled, and an interim analysis performed, it was determined further inclusion would be futile.

Massagli et al. (1990)

Characteristics of Study	
Methods	**Cohort**
Participants	**Participants:** Children with neurogenic bladder or vesicoureteral reflux **Setting:** Pediatric Hospital, Seattle, Washington USA **Number enrolled into study:** *N* = 20 **Number completed:** *N* = 20 **Number of urinary catheterizations:** *N* = 39 **Gender, males: (as defined by researchers)** • Not reported **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in Seattle, Washington USA. The authors did not identify race or ethnicity of the participants. **Age, Range** • 1 month to 16.75 years **Inclusion criteria:** • Patients with perceived smaller bladder capacities **Exclusion criteria:** • Not reported **Covariates identified:** Not reported
Interventions	• Bladders were scanned with the BVI 2000 prior to urinary catheterization for routine emptying or prior to urodynamic studies
Outcomes	**Primary outcome(s):** • *Bladder scanner measured volume was compared to true volume by catherization **Secondary outcome(s)** • Not reported **Safety outcome(s):** • Not reported *Outcomes of interest to the CMH CAT development team
Notes	**Results:** There was no difference between urine volumes by ultrasound versus volumes obtained by urinary catheterization, *MD* = 6.9, 95% CI [-3.5, 17.3]

Rosseland et al. (2005)

Characteristics of Study	
Methods	**Cohort**
Participants	**Participants:** Patients in the post-anesthesia care unit, who failed to void after surgery and general anesthesia **Setting:** Oslo, Norway **Number enrolled into study:** *N* = 48 **Number completed:** *N* = 48 **Gender, males: (as defined by researchers)** • 54% male **Race / ethnicity or nationality (as defined by researchers):** The study occurred in Norway. The authors did not identify race or ethnicity of the participants. **Age, median years, range** • 3 years (0, 15 years) **Inclusion criteria:** • Subjects who failed to void after anesthesia **Exclusion criteria:** • Not reported **Covariates identified:** • Not reported
Interventions	• If unable to void after a surgical procedure, a BladderScan BVI 3000 was used to estimate the volume of urine in the bladder. Subsequently a urinary catheter was placed and urine volume was measured • In a subgroup of subjects, who underwent cardiac angiographic procedures, bladder scanner volumes were compared to radiographic confirmation of complete bladder emptying
Outcomes	**Primary outcome(s):** • Agreement of bladder volume by bladder scanner and by emptying the bladder with a catheter **Secondary outcome(s)** • Age related limitation of the bladder scanner **Safety outcome(s):** • Not reported *Outcomes of interest to the CMH CAT development team
Notes	**Results:** • For volumes < 100 mL, disagreement between methods to determine urine volume are larger than when urine volume is greater • In subjects 0-3 years old, *n* = 22, *MD* = -18 mL (±19) • In subjects > 3 years *n* = 26, *MD* = 4 mL (± 25)

Rowe et al. (2014)

Characteristics of Study	
Methods	**Cohort**
Participants	**Participants:** Children **Setting:** Department of Paediatric Surgery and Urology, New Zealand **Number enrolled into study:** *N* = 50 **Number completed:** *N* = 50 • Number of measurement sets: *n* = 59 • Number of successful measurement sets, *n* = 50 **Gender, males: (as defined by researchers)** • 76% (38/50) **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in New Zealand. The authors did not identify race or ethnicity of the participants. · **Age, mean, median, (range)** • Mean = 6.2, Median = 5, (6 weeks to 14 years) • Secondary analysis age group *n* = 12, Mean = 1.03 years, Median 0.96 months, (6 weeks to 2 years) **Inclusion criteria:** • Pediatric subjects who were scheduled for urodynamics or surgery where urethral catheterization would occur **Exclusion criteria:** • No exclusions noted **Covariates identified:** • Not reported
Interventions	For subjects who were undergoing surgery, the bladder scan was performed after anesthetic induction and prior to the insertion of the urinary catheter. For subjects having urodynamic studies, bladder scan was performed prior to the urodynamic catheter being placed, and a second bladder scan was obtained at the end of the urodynamic study, prior to removal of the urodynamic catheter, and bladder emptying.
Outcomes	**Primary outcome(s):** • Correlation of urine volume by bladder scanner vs. volume by urinary catheterization • Mean difference in urine volume by bladder scanner and volume by catheterization **Secondary outcome(s)** • Secondary analysis of children less than 36 months **Safety outcome(s):** • Not reported
Notes	**Results:** **Primary Outcome:** • Non-parametric correlation between measure was high, r_s = .96 • *MD* = -2.1 mL (± 21)

	Secondary Outcome: • Non-parametric correlation between measures was not as strong, r_s = .82 • *MD* = -2.6 mL (± 16)

Witt et al. (2005)

Characteristics of Study	
Methods	Randomized Control Trial
Participants	**Participants:** Pediatrics **Setting:** Pediatric children's hospital emergency department, USA **Randomized into study:** *N* = 65 • **Group 1, Volumetric bladder ultrasound:** *n* = 33 • **Group 2, Conventional catheterization:** *n* = 31 **Completed Study:** *N = 64* • One subject was excluded due to an anatomic abnormality. It is not reported into which group to which they were randomized **Gender, males (as defined by researchers):** • **Group 1:** 39% (13/33) • **Group 2:** 39% (12/31) **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in New Jersey, USA. The authors did not identify race or ethnicity of the participants. **Age, Months, mean (SD)** • **Group 1:** 7.7 (± 5.5) • **Group 2:** 9.4 (±7.8) **Inclusion Criteria:** • Younger than 36 months • Not toilet trained • Required a diagnostic urine sample **Exclusion Criteria:** • Critical illness • Genitourinary abnormalities **Power Analysis:** 54 subjects were required to achieve 80% power and a two-sided α detect a difference of 0.5 in success rates of 65% for conventional catheterization and 95% visual bladder ultrasound.
Interventions	**Both:** if the subject voided within 30 minutes of the start of the enrollment, the study protocol was delayed by 30 minutes. Parents in both groups were given a satisfaction questionnaire. • **Group 1:** Imaging using the Sonosite 180 Plus, L38 broadband linear transducer. Urinary catheterizations only occurred if transverse bladder diameter was ≥ 2 cm. • **Group 2:** Subjects in the conventional catheterization were catheterized immediately after randomization
Outcomes	**Primary outcome(s):** • *Rate of successful urinary catheterization **Secondary outcome(s)**

	• Parent satisfaction **Safety outcome(s):** • Not reported *Outcomes of interest to the CMH CPG or CAT development team
Notes	Although not an outcome, the correlation between actual and estimated urine volumes was good in the group that was scanned $r_p = .75$, $p < .001$

Risk of Bias

Bias	**Scholar's judgment**	**Support for judgment**
Random sequence generation (selection bias)	Unclear risk	Randomization process is not described
Allocation concealment (selection bias)	Unclear risk	Allocation concealment is not described
Blinding of participants and personnel (performance bias)	Unclear risk	State they were unable to blind
Blinding of outcome assessment (detection bias)	High risk	HCP knew bladder diameter was > 2 cm in the scanned group. May have more success if HCP knew bladder was scanned and urine was there.
Incomplete outcome data (attrition bias)	High risk	There was no information on why catheterization was ceased if urine was < 2.5 mL. The number of subjects is not noted. It appears 2 subjects in the bladder scanner group, and 10 subjects in the conventional catheterization group had catheterization attempts halted.
Selective reporting (reporting bias)	Low risk	
Other bias	Unclear risk	

Wyneski et al. (2005)

Characteristics of Study	
Methods	**Cohort** Investigate the accuracy of urine volume obtained by bladder scanner
Participants	**Participants:** Neonates **Setting:** Children's hospital NICU, Ohio, USA **Number enrolled into study:** *N* = 10 • Myelodysplasia, *n* = 9 • Cloacal exstrophy, *n* = 1 **Number completed:** *N* = 10 **Gender, males: (as defined by researchers)** • Not reported **Race / ethnicity or nationality (as defined by researchers):** • The study occurred in Ohio, USA. The authors did not identify race or ethnicity of the participants. **Gestational age, weeks, minimum:** • Mean 36 weeks, minimum 31 weeks **Chronological age:** Not reported **Inclusion criteria:** • Subjects with complex bladder abnormalities **Exclusion criteria:** • Not reported· **Covariates identified:** Not reported
Interventions	**Both:** • Bladder Scanner BVI 3000 was employed • Bladder scan measurement were obtained after nursing witnessed a spontaneous void • Immediately after scan was completed, conventional catheterization was performed.
Outcomes	**Primary outcome(s):** • *Correlation of urine volume by bladder scanner and by conventional catheterization· **Secondary outcome(s)** • Not reported **Safety outcome(s):** • Not reported
Notes	**Results:** • Correlation coefficient across cases *r* = .037 ± .07 • Correlation coefficient within cases *r* = .188 ± .12 • Significant volume was missed 7% to 25% of the time • Scatter plot shows random distribution of the measures.

	• Note: this study was performed in subjects with myelodysplasia. A common practice with children with this diagnosis is to perform clean intermittent urinary catheterization to control bladder pressure, to decrease bladder over extension and decrease the need for bladder augmentation as they grow.

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