



# Cumulative incidence of outcomes and urologic procedures after augmentation cystoplasty

Bruce J. Schlomer<sup>a,\*</sup>, Hillary L. Copp<sup>b</sup>

<sup>a</sup> Baylor College of Medicine and Texas Children's Hospital, 6701 Fannin, MC CCC-620, Houston, TX 77030, USA

<sup>b</sup> University of California San Francisco, CA, USA

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## KEYWORDS

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Spina bifida;  
Bladder exstrophy

**Abstract** *Objective:* Augmentation cystoplasty (AC) is a major surgery that can be associated with long-term morbidity. This study aimed to describe the cumulative incidence of outcomes and urologic procedures in a large cohort of children who underwent AC, identify significant sources of morbidity, and to evaluate baseline factors associated with outcomes of interest. *Methods:* Children  $\leq 18$  years who underwent AC in the Pediatric Health Information System from 1999 to 2010 were included. All follow-up encounters up to June 2012 were included. Cumulative incidences for 15 outcomes and urologic procedures were calculated using non-informative censoring. Sensitivity analyses were performed to determine effect of censoring assumptions and including hospitals without complete datasets. As an exploratory analysis, baseline patient factors were evaluated for associations with outcomes and urologic procedures of interest using multivariable Cox proportional hazards models adjusted for clustering by hospital.

*Results:* 2831 AC patients were identified. Based on cumulative incidence calculations and sensitivity analyses; the cumulative incidence ranges of outcomes and procedures at 1, 3, 5, and 10 years were calculated. Examples of 10-year cumulative incidence ranges are given for the following outcomes and procedures: bladder rupture (2.9–6.4%), small bowel obstruction (5.2–10.3%), bladder stones (13.3–36.0%), pyelonephritis (16.1–37.1%), cystolithopaxy (13.3–35.1%), and reaugmentation (5.2–13.4%). The development of chronic kidney disease was strongly associated with a diagnosis of lower urinary tract obstruction (HR 13.7; 95% CI 9.4–19.9). Bladder neck surgery and stoma creation at time of AC were associated with an increased hazard of bladder rupture (HR 1.9; 95% CI 1.1–3.3) and bladder stones (HR 1.4; 95% CI 1.1–1.8) respectively.

**Abbreviations:** AC, augmentation cystoplasty; CKD, chronic kidney disease; PHIS, Pediatric Health Information System; LUTO, lower urinary tract obstruction; CAM, cloacal or anal malformation; NB, neurogenic bladder unspecified; BEEC, bladder exstrophy epispadias complex; SB, spina bifida.

\* Corresponding author. Tel.: +1 832 822 3513; fax: +1 832 822 3159.

E-mail addresses: [bschlom@texaschildrens.org](mailto:bschlom@texaschildrens.org), [bruceschlomer@gmail.com](mailto:bruceschlomer@gmail.com) (B.J. Schlomer).

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**Conclusions:** Outcomes of interest and urologic procedures after AC are common. Results from this large cohort can be used to counsel patients and families about expectations after AC. Pyelonephritis, chronic kidney disease, further reconstructive surgery, and calculus disease appear to cause significant morbidity. Collaborative efforts are needed to further reduce morbidity in this patient population.

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## Introduction

Augmentation cystoplasty (AC) is a major reconstructive surgery performed in children. Indications include neurogenic and non-neurogenic bladder dysfunction when conservative therapies such as anticholinergic medications and clean intermittent catheterization (CIC) have failed to achieve acceptable urinary continence and/or bladder pressures low enough to avoid renal damage.

Long term outcomes following AC have been reported in single center series [1–4]. The incidence of outcomes can range widely between studies. For example, the incidence of bladder calculi has been reported between 10% and 52% [2,5–7]. A limited number of studies have reported on the risk of spontaneous bladder perforation and chronic kidney disease (CKD) [3,8–10]. In addition, there have been studies that have raised concern about increased risk of malignancy following AC [11,12]. Because of the risk of complications and potential increased risk of malignancy, some groups have suggested utilizing AC more conservatively [13,14]. Recent studies have reported that use of AC has been decreasing in the UK and the USA [13,15]. The cause for decline is unknown but is likely multifactorial with potential reasons including declining incidence of congenital abnormalities such as spina bifida, increased availability and earlier use of anticholinergics and clean intermittent catheterization, more conservative use of AC, and others [13,15].

In the adult urological literature, complications and outcomes after surgery as reported by single center series are often different (usually lower) from those of administrative datasets [16,17]. For guiding informed decision making, it is important to provide patients and families with realistic expectations and administrative data can be useful for this purpose. The goals of our study include to determine the cumulative incidence of outcomes and subsequent urologic procedures after AC in a large administrative dataset; to identify potential outcomes or procedures that are a significant source of morbidity and could potentially be targets for intervention and/or prevention; and to perform an exploratory analysis for patient factors associated with risk of subsequent outcomes or procedures of interest.

## Methods

### Dataset

Following institutional review board approval, data were accessed with the Children's Health Corporation of America

(CHCA; Shawnee Mission, KS) Pediatric Health Information System (PHIS). The PHIS is an administrative and billing dataset from 43 free standing children's hospitals in the USA that contains information from inpatient admissions, ambulatory medical and surgical short stay areas, and emergency department visits. PHIS data are assessed for accuracy through joint efforts of the CHCA, an independent data manager (Thomson Healthcare, Durham, NC), and participating hospitals and has been described previously [18]. A patient will have a unique identifier at a single institution and can be followed longitudinally.

### Patient identification and diagnosis

Patients who underwent AC between January 1999 and December 2010 were identified by ICD-9 procedure code (57.87). Patients were considered to have a primary diagnosis of bladder exstrophy epispadias complex (BEEC) if listed (753.2, 752.62) in any encounter. A primary diagnosis of spina bifida (SB) was assigned if listed (741.0x, 741.9x, 756.17) in any encounter and BEEC was not. A primary diagnosis of congenital lower urinary tract obstruction (LUTO) was assigned if listed (753.6, 596.0) in any encounter and BEEC and SB were not. A primary diagnosis of cloacal or anal malformation (CAM) was assigned if listed (751.5, 751.2) in any encounter and BEEC, SB, and LUTO were not. A primary diagnosis of neurogenic bladder unspecified (NB) (596.5x, 344.61) was assigned if listed in any encounter and BEEC, SB, LUTO, and CAM were not. A primary diagnosis of "other" was assigned if the above five diagnoses were not listed in any encounter.

### Identification of outcomes and procedures

All subsequent encounters (inpatient admissions, ambulatory medical and surgical short stays, and emergency department visits) up to June 2012 were included. Outcomes and procedures were identified by ICD-9 diagnosis or procedure code search. ICD-9 procedure codes were used over CPT codes because ICD-9 codes are available in all years of the PHIS. For chronic kidney disease (CKD), all patient encounters prior to AC were evaluated to ensure it was not present before AC. Appendix A shows the list of ICD-9 codes used to identify outcomes and procedures.

### Statistical analysis

The cumulative incidences of outcomes and procedures were calculated by utilizing the longitudinal nature of the dataset. For primary analysis, non-informative censoring was assumed.

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