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Review Article

Mortality following augmentation cystoplasty: A transitional urologist's viewpoint

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Summary

Introduction
Three complications have been hypothesized to increase patient mortality following enterocystoplasty: spontaneous bladder perforation, bladder neoplasia, and chronic renal failure (CRF). The present study examined risk of their occurrence and discussed ways to improve the quality of care.

Materials and methods
The present transitional clinic followed 385 patients with a history of bladder augmentation using either ileal, sigmoid, or ascending colon. The median age was 37 years (range 16–71). Median follow-up interval after augmentation was 26 years (range 2–59).

Discussion
Spontaneous rupture of the bladder occurred in 3% (13/385), with one associated death (0.25%, 1/385). Spontaneous bladder rupture significantly correlated with substance abuse, non-compliance with catheterization, and mental/physical disabilities that required the use of surrogates to perform and monitor intermittent catheterization ($P < 0.01$).

Of the 203 patients that were followed for ≥10 years, 4% (8/203) developed a bladder tumor. In comparison, 2.5% (5/203) of an age-matched control population, managed by anticholinergics and intermittent catheterization, developed a bladder tumor. Therefore, enterocystoplasty cannot be associated with an increased risk of cancer development ($P = 0.397$).

Chronic renal failure ≥ Stage 3 arose in 15% (58/385), and 1% (4/385) of the patients died as a result of this complication. Obese patients (BMI ≥30) catheterizing per urethra were more likely to be non-compliant with catheterization and develop CRF compared with obese patients with a continent catheterizable stoma ($P > 0.001$). These findings suggest that compliance with intermittent catheterization and renal preservation are enhanced by the presence of a catheterizable abdominal stoma.

Conclusion
The individual's intellectual and physical capability to obey medical directives, refrain from high-risk habits, maintain a healthy weight, and comply with long-term follow-up visits were all critical to the enduring success of bladder augmentation.

Introduction

Goals of reconstructive surgery

The primary purpose of any reconstructive procedure is to provide the highest quality of life with the lowest potential for complications. Success is therefore measured by the operations ability to meet four primary objectives: preservation of life, preservation of renal function, creation or preservation of urinary continence, and creation or preservation of sexual function. One major caveat to consider in reaching these objectives is that at no time should one of the lesser goals trump those that go before it. This review was framed from the viewpoint of a transitional urologist, with its primary objective being to provide the pediatric urologist insight into the long-term success of enterocystoplasty in its ability to meet the first key objective: preservation of life.

Considerations when interpreting the data

The incidence of post-surgical complications following urologic reconstructive surgery varies from study to study. Variation is based on the length of follow-up, the type of augmentation performed, the use of concurrent bladder outlet obstructive procedures, the presence of continent abdominal stomas, and the patient's ability to comply with medical directives [1–6].

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In reviewing any data from a transitional urology clinic it is important to note that during the past three decades there has been a continual evolution in the management of infants and children with congenital urologic abnormalities. Notably, advances in neonatal and pediatric care have resulted in significantly more individuals who are born with a complex congenital anomaly to survive into adulthood [7,8]. In contrast, the use of dietary supplements such as folic acid and the utilization of therapeutic abortions for the treatment of fetuses with severe congenital anomalies have decreased the incidence of these defects [9]. Additionally, the proliferation of ongoing quality care projects that may favorably impact patient care may also have impacted the outcome data [2,10–13]. Indeed, the patients that are currently being seen in transitional clinics and reported on in this paper may not mirror those of future generations.

Bladder augmentation and complications that impact the preservation of life

Three long-term complications of bladder augmentation have been hypothesized or documented to be associated with the subsequent death of the patient: perforation of the bladder augment, development of bladder neoplasia, and the onset of end-stage renal disease (ESRD) [2,14,15].

Method

Study population

The transitional clinic followed 385 patients with a history of bladder augmentation using either ileal, sigmoid, or ascending colon. The median age of patients in this clinic was 37 years (range 16–71). The median age at the time of bladder augmentation was 11 years (range 2–16). Follow-up interval from the time of augment was defined as the number of years the enteric tract had been exposed to urine. In 26 patients, ileal conduits had initially been performed followed by urinary Undiversion, with the incorporation of the conduit into the augmented bladder. In this patient population, the follow-up interval began at the time of ileal conduit formation, not augmentation. Median follow-up interval after the enteric tract was exposed to urine was 26 years (range 2–59) [16,17]. The underlying reasons for a bladder augmentation were: neurogenic bladder in 62% (237/385), exstrophy–epispadias complex in 22% (85/385), PUV in 11% (42/385), and a variety of miscellaneous etiologies in 5% (21/385).

Spontaneous bladder perforation

A total of 3% (13/385) of patients developed a spontaneous rupture of the bladder, with one associated death (0.25%, 1/385). The majority of spontaneous bladder ruptures were directly related to either substance abuse or patient non-compliance with catheterization. Specifically, during a 25-year time span, 203/385 patients, aged 16–53 years, were screened for the presence of alcohol abuse and/or non-compliance with medical directives regarding CIC. Alcohol abuse was defined per criteria outlined by the National Institute on Alcohol Abuse and Alcoholism [18]. Patients were considered to abuse alcohol if the individual: routinely had >14 drinks per week, and/or participated in binge drinking, defined as having >4–5 drinks over a 2-h period at least one day per month [18]. Failure to be compliant with CIC was defined as the patient admitting to catheterizing ≤3 times per day on a routine basis [2,19]. Median age of patients involved in the study was 24 years (range 16–53). Of these patients, 12% (24/203) admitted to a history of alcohol abuse, 17% (4/24) had a coexisting chemical dependency. An additional 6% (12/203) became non-compliant with catheterization, but did not give a history of substance abuse. Of the 36 patients with a history of substance abuse or non-compliance with medical directives, 22% (8/36) experienced spontaneous bladder rupture; 14 bladder ruptures and one death occurred within this patient population. Two of these patients, 0.5% (2/385) of the total patient population, were eventually converted to ileal conduits due to repeated bladder perforations ($n = 3$) and failure to gain sobriety. It is noteworthy that in patients with non-compliance with catheterization, a diagnosis of intellectual disability was present in 50% (6/12). In the 167 patients who were compliant with intermittent catheterization routines and did not have a history of substance abuse, 1% (2/167) had a spontaneous bladder rupture, and no deaths were reported ($P = 0.006$) [2,19].

The 12% incidence of alcohol abuse found in adults with an enterocystoplasty mirrored the rate found within the population of the United States, where 8–17% of individuals become alcohol or substance dependent; this incidence depends upon sex and age of the person [18–20]. The physiological effects and consequences of alcohol consumption following enterocystoplasty cannot be understated. The development of alcohol-induced diuresis, coexisting with impaired mental and physical abilities provoked by alcohol intoxication, provides the 'perfect storm' with which to induce a spontaneous bladder rupture.

It is also important to note the association of mental impairment/deficiency with the failure to be compliant with medical directives [2,19]. Specifically, the correlation between mental impairment and non-compliance with catheterization becomes manifest in the maturing patient, as they become less reliant on their parents, move into group homes and/or their elderly parents develop mental or physical disabilities. Indeed, due to the patient becoming either physically unable to perform catheterization ($n = 2$) or an inability to find surrogates to perform catheterization ($n = 8$), the institution managed 2.5% (10/385) of patients with a chronic, indwelling, 22–24F suprapubic tube (SP). During a median follow-up interval of 7 years following placement of an SP tube (range 2–12), all 10 patients who were managed in this fashion developed complications (Table 1). To prevent mucous plugging of the catheter and stone formation, it was attempted to manage these patients with daily bladder irrigations with >240 ml fluid daily. Unfortunately, a surrogate was often unable to be found to perform this, and non-compliance with this directive was universal. Eventually, due to multiple urologic complications, 20% (2/10) of patients managed with a suprapubic tube, or 0.5% (2/385) of the entire cohort

Table 1 Follow-up of patients managed by a 22–24 F suprapubic tube placed within the augmented bladder.

Complications noted	Percent of patients with complications
Perivesical or intraperitoneal abscesses arising from urine extravasated from augmented bladder or SP tube site	20% (2/10)
Dislodgement of SP tube and loss of tract requiring emergent decompression	30% (3/10)
Repetitive bladder stones	60% (6/10)
Sepsis arising from complications from SP tube management	60% (6/10)
Intermittent obstruction of SP tube requiring ER visit	100% (10/10)
Conversion to ileal conduit due to multiple urologic complications	20% (2/10)

Median follow-up interval of 7 years (range 2–12).
SP, suprapubic; ER, emergency room.
Note: Patients may have had more than one complication or more than one recurrence of the complication.

underwent takedown of their augmented bladder and had conversion to a urinary conduit.

For the last 10 years the present institution has intensively focused efforts on educating the patient before proceeding with an enterocystoplasty, due to the dire consequences of spontaneous bladder rupture and/or complications arising from the management of the augmented bladder with an indwelling suprapubic tube. Specifically, the patient is instructed on the need for catheterization to be performed a minimum of four times daily; the need for large-volume bladder irrigations to prevent bladder stone formation (>250 ml per day); and the necessity to refrain from risky behavior, mainly being excess alcohol intake and use of illegal/illicit drugs [2,19,21]. The institution refuses to proceed with an augmentation until the individual who is undergoing the procedure documents mastery regarding the knowledge and skill to perform the necessary post-operative care. However, it is cautioned that even though this course of preventive treatment has vigorously been pursued, problems can still ensue. Even now, despite strenuous pre-operative instructions and close post-operative follow-up, patients become non-compliant with medical directives. It is therefore felt that it should be mandatory to ask appropriately directed social questions regarding both alcohol consumption and compliance with medical guidelines, as they are a crucial part of long-term patient management.

Neoplasia within bladder augmentations

During the last 30 years the present institution has managed eight patients with tumors that arose within an augmented bladder, which is a total of 2% (8/385) of the total patient population [16,22,23]. Specifically, 4% (8/203) of patients who were followed for ≥10 years developed a bladder tumor. The median age at the time of tumor diagnosis was 51 years (range 30–64). Median time from augmentation to tumor development was 39 years (range 22–53). In the patients who developed a tumor, 75% (6/8) had an adenocarcinoma, and 25% (2/8) developed an urothelial tumor. Median stage of the tumor at the time of diagnosis was 4 (range 2–4). Cancer-specific deaths occurred in 75% (6/8) of the patients, with a median survival of 15 months (range 6–36). In essence, cancer-specific deaths took place in 1.6% (6/385) of the patients (Table 2). When patients who had undergone a bladder augmentation were compared to an age-matched control population with a similar primary congenital bladder abnormality managed with anticholinergics and intermittent catheterization, an increase in the risk of bladder malignancy following an ileal or colonic bladder augment could not be found, and 2.5% (5/203) of the non-augmented patients developed a bladder tumor ($P = 0.397$) [16,23]. These findings suggest that it is the primary bladder dysfunction and/or alterations in the patient's clinical environment, and not the augmentation, that is primarily responsible for the tumor development [16,23].

The development of a malignant tumor within a urinary reservoir or augmented bladder is based on the type of bowel used, the length of time from surgery, the concurrent use of immunosuppressives, a history of viral cystitis, and is related to the primary etiology for primary bladder dysfunction [16,23,24]. Studies have shown that two distinct patient populations appear to be at an increased risk of tumor development following a bladder augmentation; specifically, patients that have undergone a gastric augment and those with an augmentation that are on immunosuppressives [17,22,23,25]. Both of these patient populations appear to have a 2–3 fold increased risk of cancer development compared to those with a primary congenital bladder dysfunction managed by anticholinergics and intermittent catheterization [26,22,23,25].

The question that arises is: should patients with a congenital bladder dysfunction treated by bladder augmentation be routinely screened by annual endoscopy and cytology? It is believed that data to support this recommendation do not exist [2]. Specifically, the World Health Organization recommends annual cancer screening be performed when the four following criteria are met: 1) cancer has a high prevalence in a well-defined patient population; 2) cancer routinely presents at a low treatable stage; 3) screening tests are available that are safe, inexpensive, reliable and reproducible with high specificity and sensitivity; 4) the screening test must allow cancer to be diagnosed at a low treatable stage and result in an improved patient prognosis [17,23].

Currently, epidemiological and pathological findings reveal that tumors arising within a congenitally dysfunctional bladder cannot meet these criteria. Specifically, there is a low risk of malignancy, approximately 1.5% per decade, with 75% of patients presenting with locally

Table 2 Characteristics of patients with bladder augmentation who developed a malignancy.

Patient number	Etiology of bladder dysfunction	Age at diagnosis of cancer	Years since augmentation[b]	Type of augmenting segment	Cancer type and TNM stage	AJCC stage	Cancer specific survival
1	Spina bifida[a]	61	52	Ileum	Urothelial (pT2, N0, M0)	2	NED: 96 months
2	Spina bifida[a]	64	53	Ileum	Urothelial (pT2, N0, M0)	2	NED: 144 months
3	PUV renal transplant	43	25	Ileum	Adenocarcinoma (pT3, N2, M0)	4	DOD: 12 months
4	PUV renal transplant	34	22	Colon	Adenocarcinoma (pT3, N1, M0)	4	DOD: 24 months
5	Exstrophy[a]	51	32	Colon	Adenocarcinoma (pT3, N2, M0)	4	DOD: 36 months
6	Exstrophy	52	47	Ileum	Adenocarcinoma (pT3, N2, M0)	4	DOD: 18 months
7	Exstrophy	30	22	Ileum	Adenocarcinoma (pT4, N2, M1)	4	DOD: 6 months
8	Exstrophy[a]	61	52	Ileum and colon	Adenocarcinoma (pT3, N1, M0)	4	DOD: 12 months

AJCC, American Joint Committee on Cancer; NED, no evidence of disease; DOD, died of disease; PUV, posterior urethral valves; T, tumor stage; N, nodal metastasis; M, distal metastasis.
[a] History of ileal conduit with conduit incorporated into augmentation.
[b] Years since augment includes entire time ileal segment exposed to urine.

advanced disease or nodal metastasis at the time of diagnosis. These tumors are highly aggressive, with a cancer-specific mortality of 75% at 15 months following the diagnosis [16,17,23]. Due to the rapid growth of these highly invasive tumors, routine yearly cystoscopy appears to be unable to diagnose low-stage curable disease [17]. In support of this statement are five case reports where patients were noted to have a normal cystoscopic evaluation of their bladder augmentation, 4—18 months before the diagnosis of an invasive bladder tumor. All five patients eventually succumbed to their tumor [17].

In essence, low-stage medically or surgically curative bladder cancer can rarely be detected by annual screening endoscopic evaluations [17,23,26]. Indeed, it is believed that the costs of annual endoscopic studies is not merited, due to the low prevalence of the disease and its inability to diagnose early stage, curable tumors [16,17,23,26].

Chronic renal failure following bladder augmentation and the increased risk of patient death

One of the primary goals of bladder augmentation is to prevent upper tract deterioration and/or the development of ≥Stage 3 CRF due to high-pressure bladder storage [2]. Specifically, the goal is to avoid the 20% increased risk of cardiovascular death that is associated with ≥Stage 3 CRF [2,15].

To date, 15% (58/385) of the present patients with bladder augmentation have developed ≥Stage 3 CRF, with 1% (4/385) dying as a complication of CRF or renal transplantation. Although some authors have speculated that the onset of renal failure in patients undergoing a bladder augmentation is primarily a consequence of pre-existing renal injury and not the result of the bladder augmentation, it is concerning that individuals who undergo a bladder augmentation can be plagued with problems that may pre-dispose to CRF [1,2,27,28]. Specifically, non-compliance with intermittent catheterization will, from experience, place the patient at a high risk for the development of CRF [1,2,17,28].

The question that arises is how well do bladder augmentations preserve renal function? In this regard, the present study evaluated two dichotomous patient categories: individuals undergoing bladder augmentation with a simultaneous bladder outlet procedure and continent abdominal stoma versus patients with a bladder augmentation that are catheterizing per urethra. Comparison between these two different patient populations is imperative, due to the reportedly 2—5 fold increased risk of complications in patients undergoing a bladder neck procedure, augmentation and continent abdominal stoma compared to individuals with a bladder augmentation catheterizing through the urethra [2,5,29,30]. The present study limited the population to include only persons who had no evidence of renal scarring, as determined by renal ultrasonography, and normal renal clearance values (GFR ≥90 ml/min/1.73 m^2) when they were first evaluated in the transitional clinic. Also, all patients had to have a minimum follow-up interval of 10 years since their augmentation. A total of 45% (173/385) of patients met these two criteria.

The comparison of how well these two different types of surgical procedures have preserved renal function is depicted in Table 3. Perhaps the most telling factor regarding why renal scarring developed following referral to the transitional clinic was the finding that 67% (39/58) of patients who developed new onset of renal scarring did so after they were documented to be non-compliant with intermittent catheterization. It is intriguing to find that the percentage of patients who developed renal scarring and/

Table 3 Comparison of renal deterioration following bladder augmentation with and without bladder neck reconstruction and creation of a continent abdominal stoma.

Patient categories	% of patients with renal scaring or loss of one kidney	% of patients with renal scarring and a history of non-compliance with catheterization[a]	% of patients with ≥Stage 3 chronic renal failure	Median length of follow-up since augmentation (range)
Bladder augmentation with bladder neck reconstruction or sling catheterization via continent stoma $n = 134$	31% (41/134)	56% (24/41)	11% (15/134)	14 years (10–45)
Bladder augmentation without bladder neck reconstruction catheterization through urethra $n = 39$	43% (17/39)	88% (15/17)	36% (14/39)	15 years (10–38)
Statistical evaluation $P=$	0.130	0.028	<0.001	

[a] Non-compliance with catheterization was defined as a ≥3 month period where the individual admitted to catheterizing three times or fewer per day.

or CRF was significantly higher in those catheterizing per urethra compared with through an abdominal stoma (see Table 3). It is noteworthy that >80% of the patients in both categories had their mobility as an adult confined to a wheelchair. Both patient populations were associated with a high incidence of obesity, BMI ≥30, which was approximately 40% of both patient groups: 41%, 16/39 and 39%, 54/134, respectively. Moribund obesity BMI >40 was noted in 8% of both groups: 8%, 3/39 and 8%, 11/134, respectively.

By reviewing the data and the existing literature, it was hypothesized that the degree of non-compliance with intermittent catheterization may be impacted by both mental deficiency and obesity. Specifically, it has been documented that spina bifida patients with mental deficiency are more likely to become obese and subsequently develop impaired mobility as they age [11,13]. It is interesting to note that, within the present patient population, obese patients were more likely to be compliant with intermittent catheterization schedules when an abdominal stoma was present compared with obese patients catheterizing through the urethra: 78% (50/64) vs 37% (7/19), respectively, $P = 0.0008$ (Table 4). Similarly, obese patients catheterizing via an abdominal stoma were significantly less likely to develop CRF than those catheterizing per urethra 16% (10/64) vs 63% (12/19), $P = 0.0003$ (Table 4). Indeed, it is believed that the presence of obesity makes management of the spina bifida patient by a continent stoma both attractive and problematic [2,19]. Attractive because the abdominal stoma makes the catheterization easier to perform when the obese patient is seated in a wheelchair. Problematic in that obesity has been found to be significantly associated with increased complications of the catheterizable stoma, for example: stomal stenosis, stomal retraction, and difficulty with catheterization [31].

The impact of obesity, mental deficiency, and patient non-compliance on mortality following bladder augmentation

The pediatric urologist contemplating performing a bladder augmentation must realize that there is a progressive increase in the incidence of obesity that occurs in the spina

Table 4 Impact of obesity on compliance with intermittent catheterization and onset of chronic renal failure in patients with and without a continent abdominal stoma.

Patient categories	% of patients with renal scarring or loss of one kidney	% of patients that were compliant with catheterization[a]	% of patients with ≥Stage 3 chronic renal failure
Bladder augmentation with bladder neck reconstruction or sling catheterization via continent stoma BMI ≥30 $n = 64$	45% (23/64)	78% (50/64)	16% (10/64)
Bladder augmentation with bladder neck reconstruction or sling catheterization via continent stoma BMI <30 $n = 70$	17% (18/70)	86% (60/70)	7% (5/70)
Statistical evaluation, $P=$	0.1995	0.2524	0.1198
Bladder augmentation without bladder neck reconstruction catheterization through the urethra BMI ≥30 $n = 19$	68% (13/19)	37% (7/19)	63% (12/19)
Bladder augmentation without bladder neck reconstruction catheterization through urethra BMI <30 $n = 20$	20% (4/20)	85% (17/20)	10% (2/20)
Statistical evaluation, $P=$	0.002	0.003	0.008

[a] Non-compliance with catheterization was defined as a ≥3 month period where the individual admitted to catheterizing three times or fewer per day.

bifida patient population with aging. Notably, the incidence of obesity in the adult spina bifida population is four-fold higher than in childhood (<10 years of age), and two-fold greater than that found in adolescence (≥10—19 years) [11,13]. This incidence of obesity, as previously noted, is significantly increased by the presence of mental impairment and associated with further limiting mobility [11,13]. These facts need to be viewed in the context that the median age of bladder augmentation within the United States is at 9 years, a detail that reflects that the majority of obese patients will develop their obesity following urologic reconstruction [2,3,32]. The interplay between obesity, hypertension, hyperlipidemia, diabetes mellitus, nephrolithiasis, compliance with urethral catheterization and an increase in the complications related to a continent abdominal stoma must not be understated. Furthermore, the relationship of these co-morbidities to the onset of CRF should not be minimalized. Indeed, it is believed that the early involvement of dietary consultants and the establishment of a well-balanced diet and weight management are critical in the successful long-term management of this patient population [2,11,31,33].

Conclusion

This study found that assessment of the individual's intellectual and physical capability to comply with medical directives, refrain from high-risk habits, ability to follow a nutritional diet plan, maintain a healthy weight and continue with long-term follow-up visits are critical to the enduring success of a bladder augmentation [2,19].

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Conflict of interest

None.

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