

## IS ORTHOTOPIC BLADDER REPLACEMENT THE NEW GOLD STANDARD? EVIDENCE FROM A SYSTEMATIC REVIEW

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### ABSTRACT

**Purpose:** In this systematic review we determined whether the outcome of orthotopic bladder replacement is superior to that of continent and incontinent urinary diversion.

**Materials and Methods:** We searched MEDLINE, PubMed, EMBASE, CINAHL and the Cochrane Library from January 1990 to January 2003. A total of 3,370 abstracts were reviewed, including all types of studies from prospective, randomized, controlled studies to small, retrospective series. All relevant articles with at least 10 patients and a mean followup of at least 1 year were retrieved. There were no language restrictions. NonEnglish articles were translated. Comparisons were made between the major surgery types, including ileal conduit, continent diversion, bladder reconstruction and bladder replacement. All studies were scored using a predetermined quality assessment checklist to assess internal validity (bias and confounding) and external validity.

**Results:** A total of 405 studies met inclusion criteria. There were 32 prospective and 373 retrospective studies describing a total of 32,795 patients. The majority of studies were incompletely or poorly described and outcomes were often not defined. When they were defined, definitions varied. In clinical outcomes ileal conduit diversions had the lowest operative complications rate but highest reported postoperative morbidity. They also had a higher reported incidence of symptomatic urinary tract infections. The rates of postoperative morbidity, mortality and need for reoperation varied widely among studies even for the same procedure. Of physiological outcomes metabolic acidosis was the most commonly reported metabolic complication in patients with various urinary diversions. The quality of the reported literature was poor. There were no studies of the health economic implications of performing 1 type of surgery vs another type.

**Conclusions:** While enthusiasts regard orthotopic bladder replacement as the new gold standard when lower urinary tract function must be replaced, the level and quality of current evidence are poor. The immediate concern must be to rectify this paucity of evidence with well designed and well reported prospective studies, ideally in a randomized setting, comparing the various major forms of urinary diversion and bladder replacement surgery.

**KEY WORDS:** urinary diversion, outcome assessment (health care), cystectomy, bladder, urologic surgical procedures

Intestinal segments have been used to improve or replace lower urinary tract function for more than a century. The main indication is bladder cancer. There are other indications, such as neurogenic bladder dysfunction, detrusor overactivity and chronic inflammatory conditions, eg interstitial cystitis, tuberculosis, schistosomiasis and post-radiation bladder contraction. Parallel improvements in surgical techniques and anesthesia have made various complex reconstructions possible with acceptable morbidity and mortality. Since the introduction of ileal conduit diversion by Bricker in 1950, intestine has been used in various configurations (continent diversion, bladder reconstruction and bladder replacement), primarily aimed at avoiding the problems associated with an abdominal stoma and urine collecting devices. There are now reports of numerous variations of the major types of such surgery, ie continent diversion, bladder reconstruction and bladder replacement, often with claims of 1 type being better than another type.<sup>1–3</sup> The lack of adherence to a universally accepted standardized terminology, limited objective

outcome evaluation and large differences in the reported experience make decision making difficult for patients and clinicians.

In this article we use the term continent diversion strictly to mean continent cutaneous diversion, ureterosigmoidostomy and the newer variants of ureterosigmoidostomy. By bladder reconstruction we mean that the native bladder remains in situ and is surgically manipulated to improve its function. While for the purpose of this article we only assessed surgical procedures that use intestinal segments as part of bladder reconstruction, eg augmentation cystoplasty or enterocystoplasty, we acknowledge that the true meaning also includes detrusor myectomy or auto-augmentation. The term bladder replacement is used to mean that the native bladder was removed completely and a new reservoir was created, positioned where the native bladder used to be and connected to the native urethra, therefore, allowing patients to void in the natural way. The term undiversion is taken to mean conversion from conduit to bladder reconstruction, bladder replacement or continent diversion.<sup>4</sup>

Time honored ileal conduit urinary diversion remains the mainstay for replacing the lower urinary tract after radical cystectomy at many centers since it can be constructed relatively rapidly and usually provides good and reliable drain-

Submitted for publication September 30, 2004.

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age. However, long-term studies of ileal conduit urinary diversion have shown that there is a high incidence of late complications with progressive deterioration of the upper renal tracts, pyelonephritis and calculous formation.<sup>4,5</sup> In contrast, although continent urinary diversions are reported to result in higher patient satisfaction, it is also recognized that they generally have a higher incidence of early and late complications, and the reoperation rates are higher than those of ileal conduit diversions.<sup>6,7</sup> While there are some large retrospective series in the literature,<sup>2,5,8</sup> systematic assessment of the literature in terms of outcome after surgery, the quality of study design and quality of reporting of such studies have not been evaluated previously. In a recent Cochrane review we identified only 2 randomized trials that addressed the objectives of the review, totaling 164 participants to our knowledge.<sup>9,10</sup> Therefore, it was not possible to perform a meta-analysis to combine trials and comparisons were based on the results of a single trial. No data from eligible trials were available to address 10 of the 14 pre-stated comparisons and data from the 2 eligible trials that were considered were limited. The outcome measures that were reported did not include a large proportion of the outcome measures that we believed were important to address.

We failed to find evidence that continent diversion is better than conduit diversion or vice versa.<sup>4</sup> In conduit diversion our review did not show any evidence that using a segment of ileum is any more advantageous than using a segment of colon or vice versa. Similarly no difference was found in using a freely refluxing or an antireflux technique for conduit diversion. The data reviewed suggested that the use of an afferent ileal tubular segment is less likely to cause upper tract dilatation than antireflux nipples but even this finding should be interpreted cautiously for a number of reasons.<sup>4</sup>

Our study goes beyond randomized trials. We aimed to determine the quality of evidence currently available to support the notion that outcome after bladder replacement is superior to that after continent and incontinent urinary diversion or bladder reconstruction.

#### MATERIALS AND METHODS

**Search strategy.** All relevant studies of intestinal segments transposed into the urinary tract were identified using Medline, PubMed, EMBASE, CINAHL and the Cochrane Library from January 1990 to January 2003. A search from 1990 and thereafter was done, principally because continent forms of diversion, bladder reconstruction and replacement using transposed intestinal segments began to be used more widely from the mid 1980s and, therefore, meaningful long-term followup data would be expected to start appearing in the literature from the 1990s. There were no language restric-

tions. Non-English articles were translated. The articles with at least 10 patients and a mean followup of at least 1 year were retrieved.

**Data extraction and study appraisal.** Articles were categorized broadly into prospective and retrospective studies depending on study design due to the paucity of large series. Two observers independently performed data extraction and in the event of disagreement a consensus was achieved following assessment by a third party. Prospective studies included randomized, controlled trials and nonrandomized, prospective studies. Retrospective studies included articles with and without comparative control groups. Retrospective case studies with less and more than 100 patients were categorized as small and large, respectively.

We reviewers adopted the definitions used in the reported studies. Complications were grouped into clinical, physiological and radiological outcomes. Comparisons were then made between the major types of surgery, namely ileal conduit, continent diversion, bladder reconstruction and bladder replacement.

**Quality assessment.** The quality of each study was assessed against a predetermined checklist addressing the quality of reporting, internal validity (bias and confounding) and external validity.<sup>11,12</sup> Each article was assigned a score in these areas with a maximum achievable total score of 27 (see Appendix).

#### RESULTS

There were 405 eligible studies of the use of transposed intestinal segments, including 7 randomized, controlled trials, 11 prospective cohort studies, 14 comparative prospective studies, 46 retrospective, comparative series and 327 retrospective case series describing a total of 32,795 patients. Table 1 lists studies with meaningful data allowing quality assessment.

**Quality of studies.** The quality of reporting in the literature was assessed using a predetermined quality assessment checklist. The reporting of results in most randomized and prospective studies was poor and scores reflecting study design were also poor (table 1).

**Clinical outcomes.** Operative complications were reported only in retrospective studies with a higher incidence reported for bladder replacement, continent urinary diversion and bladder reconstruction compared with ileal conduit (median 9%, 12% and 17%, respectively, vs 3%, table 2). The operative complications reported were mainly early complications related to the surgical event, such as excessive blood loss and intraoperative rectal injuries.<sup>13</sup> The rates of postoperative morbidity, mortality and need for reoperation varied widely among studies even for the same procedure.<sup>14-25</sup> Continent diversions had the highest reported anastomotic

TABLE 1. Literature quality, as assessed by predetermined checklist

Study Type	No. Studies	Ileal Conduit (6,029 pts)		Continent Diversion (9,277 pts)		Bladder Reconstruction (5,184 pts)		Bladder Replacement (8,218 pts)	
		Median Score (range)	Total No. Pts Reported	Median Score (range)	Total No. Pts Reported	Median Score (range)	Total No. Pts Reported	Median Score (range)	Total No. Pts Reported
RCTs	7	13 (5-17)	187	13 (5-17)	136	13 (5-17)	43	13 (5-17)	130
Prospective:									
Cohorts	11	10 (7-12)	1,130	10 (7-12)	235	10 (7-12)	34	10 (7-12)	313
Concurrent control	13	5 (2-14)	835	5 (2-14)	2,629	5 (2-14)	1,342	5 (2-14)	1,569
Historical control	1	7 (2-12)	48	-	-	-	-	-	-
Retrospective:									
Concurrent control	37	7 (2-12)	962	7 (2-12)	2,088	7 (2-12)	607	7 (2-12)	1,749
Historical control	9	10 (6-13)	102	10 (6-13)	368	10 (6-13)	145	10 (6-13)	125
Retrospective case series:									
Multiple unit large	3	4 (3-10)	330	4 (3-10)	10	-	-	-	0
Large	194	7 (0-12)	2,312	7 (0-12)	3,305	7 (0-12)	2,652	7 (0-12)	3,759
Small	130	8 (2-12)	118	8 (2-12)	506	8 (2-12)	361	8 (2-12)	573

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