Continent catheterizable tubes/stomas in adult neuro-urolological patients: A systematic review

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European Association of Urology

AIMS: To systematically review all available evidence on the effectiveness and complications of continent cutaneous stoma or tube (CCS/T) to treat bladder-emptying difficulties in adult neuro-urolological patients.

METHODS: The search strategy and studies selection were performed on Medline, Embase, and Cochrane using the PICOS method according to the PRISMA statement (CRD42015019212; http://www.crd.york.ac.uk/PROSPERO).

RESULTS: After screening 3,634 abstracts, 11 studies (all retrospective, enrolling 213 patients) were included in a narrative synthesis. Mean follow-up ranged from 21.6 months to 8.7 years (median: 36 months, IQR 28.5-44). At last follow-up, the ability to catheterize rate was ≥84% (except in one study: 58.3%) and the continence rate at stoma was >75%. Data comparing health-related quality-of-life before and after surgery were not available in any study. Overall, 85/213 postoperative events required reoperation: 7 events (7 patients) occurring ≤3 months postoperatively, 22 events (16 patients) >3 months, and 56 events (55 patients) for which the time after surgery was not specified. Sixty additional complications (60 patients) were reported but did not require surgical treatment. Tube stenosis occurred in 4-32% of the cases (median: 14%, IQR 9-24). Complications related to concomitant procedures (augmentation cystoplasty, pouch) included neovesicocutaneous fistulae, bladder stones, and bladder perforations. Risk of bias and confounding was high in all studies.

CONCLUSIONS: CCS/T appears to be an effective treatment option in adult neuro-urolological patients unable to perform intermittent self-catheterization through the urethra. However, the complication rate is meaningful and the quality of evidence is low, especially in terms of long-term outcomes including the impact on the quality-of-life.

KEYWORDS
continent, diversion, intermittent catheterization, neurogenic bladder, reconstruction

INTRODUCTION

In neuro-urolological patients, clean intermittent catheterization (CIC), described by Lapides in 1972, is the gold standard to ensure complete bladder voiding. In case of low
compliance or neurogenic detrusor overactivity, treatments to restore low-pressure bladder must be associated with CIC management in order to protect the upper urinary tract, achieve continence, and enhance the quality of life.  

Continent cutaneous urinary diversion (CCUD) is available for patients who are unable to perform CIC through the urethra owing to upper-limb disability, difficulties in reaching the urethra, or urethral destruction. A CCUD can be performed by using any surgical technique to create a catheterizable stoma or tube (CCS/T) between the bladder and the skin with the aim of enabling bladder emptying without leakage between catheterization (continence).

Various procedures, all using intestinal tissue, exist and can be broken down into three main families:

- tubes with an anti-reflux implantation in a native or augmented bladder as described by Mitrofanoff, Yang-Monti, or Casale;  
- invaginated valves, first described by Kock, can be used as a continent pouch or as an efferent tube only (hemi-Kock). Benchekroun and Mainz pouch I belong in this group;  
- pouches with a continent non-invaginated efferent tube as first described by Rowland et al. and known as Indiana or Miami pouches.

In the setting of neuro-urological patients, all kinds of tubes can be used either as a single procedure to deal with bladder emptying dysfunction or in association with bladder augmentation/substitution in a global reconstruction strategy to address both voiding and storage dysfunctions. Pouches can be used either as a patch after supratrigonal cystectomy (so-called hemi-pouch), thereby avoiding ureteral re-implantation or as an entirely heterotopic continent reservoir.

These procedures have been widely used both in the pediatric population and in non neuro-urological patients in the context of urologic and gynecologic oncology or reconstructive pelvic surgery.

However, data are scarce regarding the long-term effectiveness (ability to catheterize, continence) and complications (including stoma and tube stenosis) of CCUD in neuro-urological patients.

We undertook a systematic review to evaluate all available evidence on the effectiveness and complications of CCS/T to treat bladder-emptying difficulties in adult neuro-urological patients. The primary objectives were to determine if CCS/T make bladder emptying feasible by CIC (self or caregiver) and if CCS/T achieve continence at the stoma in neuro-urological patients. The secondary objectives were to describe and quantify the short and long-term complications related to CCS/T and to determine if CCS/T improved health-related quality-of-life (HRQOL) in neuro-urological patients.

### 2 Evidence Acquisition

#### 2.1 Data sources and searches

This systematic review was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) Statement. The protocol for the review is available at PROSPERO (CRD42015019212; http://www.crd.york.ac.uk/PROSPERO). We systematically searched Embase, Medline, Cochrane Database of Systematic Reviews Cochrane Central Register of Controlled Trials and Health Technology Assessment Database. No language or date restrictions were applied. We additionally searched the reference list of all included studies and any relevant review articles. The search strategies are available in Supplementary Material S1.

#### 2.2 Study selection

We aimed to include all original studies that reported efficacy and/or safety data on CCS/T to treat bladder-emptying difficulties in adult neuro-urological patients including RCTs, comparative non-RCTs, single-arm cohort studies, systematic reviews, and meta-analyses. Non-original articles, conference abstracts, studies not published as full-text, those including fewer than five neuro-urological patients, and non-systematic reviews were excluded. In the event of mixed populations (neuro-urological and non-neuro-urological patients), data from subgroups of neuro-urological patients were included if available. If not reported separately, studies could still be included as long as neuro-urological patients accounted for at least 90% of the total population. Adults were the main focus but studies including pediatric patients partially or completely were retained for discussion although not formally included. All identified abstracts were processed with a software program for bibliography management (EndNote X6, Thomson Reuters, 1500 Spring Garden Street, Fourth Floor, Philadelphia, PA 19130) and sorted according to inclusion and exclusion folders by drag and drop. Four authors (VP, RB, LH, HE) independently reviewed in duplicate the titles and abstracts of all identified studies.

#### 2.3 Data extraction and risk of bias assessment

Data from eligible reports were extracted in duplicate (VP and RB). Discrepancies were resolved by a third reviewer (GK). The variables assessed included year of publication, study type, number of patients, gender, and age, underlying neurological disorder, duration of follow-up, type, and location of CCS/T, concomitant surgical procedures including bladder augmentation/replacement/pouch and urethral surgery, ability to catheterize, continence at stoma, complications, and HRQOL assessment.
In the absence of RCTs, the Cochrane Risk of Bias Assessment tool\textsuperscript{10} could not be used to evaluate the risk of biases. Therefore, a list of the most important potential confounders for efficacy and safety outcomes was developed with clinical content experts (European Association of Urology Neuro-Urology Guidelines Panel) including CCS/T with or without bladder augmentation/bladder replacement/pouch (for HRQOL), underlying neurological disease (multiple sclerosis or not, tetraplegic patients or not), history of multiple previous pelvic surgery, concomitant urethral surgery, and BMI >30 kg/m\textsuperscript{2}.

For each study, we asked whether each confounder was considered and whether, if necessary, the confounder was controlled for in the analysis. The risk of bias was considered to be high if the confounder had not been considered and was imbalanced between patients or not corrected during analysis.\textsuperscript{11} The risk of bias summary and graph were computed in Review Manager 5.2 (Informatics and Knowledge Management Department, Cochrane, London, UK) (Supplementary Material S2).

2.4 | Data synthesis

A meta-analysis was not possible given the paucity of data. Therefore, a narrative synthesis of the data was performed. The primary outcomes were the ability to catheterize successfully by the patients or by a caregiver and the continence rate at the stoma. The primary outcomes were summarized in descriptive tables at <1 year, 1-5 years, and >5-year time points. Secondary outcomes were HRQOL (inter- and intragroup comparisons), stenosis locations (skin/tube/reimplantation), and rates at <1 year, 1-5 years, and >5-year time points, reoperation ≤3 months and >3 months and any additional complications as reported by the authors (e.g., Clavien-Dindo classification of early postoperative complications).

3 | EVIDENCE SYNTHESIS

3.1 | Search results

The PRISMA flow diagram of the literature search and results is shown in Supplementary Material S3. After the screening of 3,634 abstracts, a total of 11 studies were included in a narrative synthesis after title, abstract and full text screening.\textsuperscript{12-22}

3.2 | Characteristics of studies, population, and interventions

All studies were retrospective and included a total of 213 patients: 69 (32.4%) men, 144 women (67.6%) (Tables 1 and 2).

The mean age of patients varied from 19 to 45.4 years. Two studies\textsuperscript{15,21} included a mixed population of neuro-urological and non-urological patients but with neuro-urological counting for >90% of the patients. Patients principally suffered from spinal cord injury ($n=158, 74.2\%$), multiple sclerosis ($n=20, 9.4\%$), and spina bifida ($n=21, 8.2\%$). The proportion of tetraplegic patients was not systematically reported.

Out of the 213 patients, 193 had a CSS/T performed (in one study, 19 patients had an ileovesicostomy (non-continent diversion) and 1 a revision of CCS/T).

A tube with anti-reflux implantation was performed in 107 patients (55.4\%, 107/193). The Mitrofranoff, ($n=54$), Monti ($n=38$), or Casale ($n=15$) techniques were used.

An invaginated valve was created using a Kock, ($n=12$) T-pouch, ($n=5$) Benchekroun, ($n=5$), or an individual undescribed technique ($n=23$) in 45 patients (23.3\%, 45/193).

A pouch with non-invaginated efferent tube was created using the Indiana technique in 41 patients (21.2\%, 41/193).

The umbilicus was the preferred region for stoma location. A concomitant augmentation cystoplasty or pouch was performed in 151 cases (78.2\%, 151/193). Moreover, concomitant urethral outlet surgery (including fascial sling, suburethral sling, bladder neck closure, artificial urinary sphincter) was performed in 45 patients (23.3\%, 45/193).

3.3 | Primary outcomes: Efficacy

Mean follow-up ranged from 1.8 to 8.7 years. The ability to catheterize through the CCS/T and the continence at stoma were never evaluated at different time points (<1 year postoperatively, 1-5 years, and >5 years) but only at last follow-up. The per-study claimed percentage of patients able to catheterize was ≥84\% (range 58.3-100\%) except in one study\textsuperscript{20} (58.3\%). The per-study claimed continence rate at stoma was >75\% (range 75-100\%) in all studies at last follow-up (see Table 3).

3.4 | Secondary outcomes: Safety

The HRQOL was evaluated in four studies\textsuperscript{16,17,19,22} but only two studies used a validated (one specific and one generic) questionnaire.\textsuperscript{17,19} However, data comparing HRQOL before and after surgery were not available (Table 4).

The time of the occurrence of complications was not always clearly reported by the authors. The Clavien-Dindo classification was only used in one study.\textsuperscript{22} Overall, 85 postoperative events required reoperation: 7 events (7 patients) occurring ≤3 months postoperatively, 22 events (16 patients) >3 months, and 56 events (55 patients) for which the time after surgery was not specified in the studies. Sixty additional complications (60 patients) were reported
but did not require surgical treatment. It is of interest to note that one patient died owing to an anesthetic accident during reoperation.12

Stenosis at any site (tube or skin or implantation within the bladder) occurred in 4-33% of the cases. The lowest risk of stenosis was reported with the Indiana pouch (4.2-11.8%)20,21 and the highest risk was observed with the Mitrofanoff or Casale principles (32.3%).19 The actual stenosis rate based on 26 patients reported to have had a stenosis out of 169 patients having undergone CCS/T was 15% (see Table 4).

Other complications related to concomitant procedures (augmentation cystoplasty, pouch) were reported and included neovesicocutaneous fistulae (3.4%),22 bladder stones (20-25%),12,14,22 and bladder perforations (40%).16

### 3.5 Risk of bias and confounding

The risk of confounding was relevant. In particular, a high risk was found in all studies since there were only retrospective studies and the outcomes were never analyzed considering the concomitant augmentation cystoplasty/pouch, concomitant urethral surgery, underlying neurological disease, history of multiple pelvic surgery, and BMI (Supplementary Material S2).

### 4 DISCUSSION

#### 4.1 Principal findings

This report is the first systematic review assessing and appraising all available evidence of CCS/T for treating bladder-emptying difficulties in adult neuro-urological patients. The relatively high proportions of patients able to catheterize and continent at stoma indicate that CCS/T could be effective in the treatment of bladder-emptying difficulties in neuro-urological patients. However, the complication rate was relevant and data assessing the impact of CCS/T on HRQOL were very limited. The most frequent issues were catheterization difficulties due to tube or skin stenosis and bladder stones in patients with augmentation cystoplasty or pouches.12,14,20,22
<table>
<thead>
<tr>
<th>Study (1st author, year)</th>
<th>Number of patients</th>
<th>Type of efferent tube</th>
<th>Concomitant procedures</th>
<th>Stoma location</th>
<th>Augmentation cystoplasty or pouch</th>
<th>Urethral surgery</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aboutaieb, 1996</td>
<td>5</td>
<td>Mitrofanoff 0</td>
<td>Monti 0</td>
<td>Casale 0</td>
<td>Other 5 (100%) Benchekroun pouch</td>
<td>NR</td>
</tr>
<tr>
<td>Sylora, 1997</td>
<td>7</td>
<td>Mitrofanoff 5 (71.4%)</td>
<td>Monti 2 (28.6%)</td>
<td>Casale 0</td>
<td>Other 0</td>
<td>7 (100%) umbilicus</td>
</tr>
<tr>
<td>Van Savage, 2000</td>
<td>8</td>
<td>Mitrofanoff 0</td>
<td>Monti 0</td>
<td>Casale 0</td>
<td>Other 8 (100%) transverse retubularized ileovesicostomy</td>
<td>8 (100%) umbilicus</td>
</tr>
<tr>
<td>Shpall, 2004</td>
<td>39 (19 CCS/T, 19 ileovesicostomy, 1 revision of CCS/T)</td>
<td>Mitrofanoff 8 (42%)</td>
<td>Monti 4 (21.1%)</td>
<td>Casale 0</td>
<td>Other 4 (21.1%) hemi-T valve, 3 (15.8%) hemi-Kock valve</td>
<td>19 (100%) umbilicus</td>
</tr>
<tr>
<td>Pazooki, 2005</td>
<td>10</td>
<td>Mitrofanoff 0</td>
<td>Monti 0</td>
<td>Casale 0</td>
<td>Other 6 (60%) Kock reservoir, 1 (10%) cutaneous double T pouch, 3 (30%) combinations Kock + T pouch</td>
<td>NR</td>
</tr>
<tr>
<td>Touma, 2007</td>
<td>12</td>
<td>Mitrofanoff 0</td>
<td>Monti 0</td>
<td>Casale 12 (100%)</td>
<td>Other 0</td>
<td>12 (100%) umbilicus</td>
</tr>
<tr>
<td>Karsenty, 2008</td>
<td>13</td>
<td>Mitrofanoff 7 (53.8%)</td>
<td>Monti 6 (46.2%)</td>
<td>Casale 0</td>
<td>Other 0</td>
<td>7 (53.8%) umbilicus, 2 (15.4%) midline between umbilicus and pubis, 2 (15.4%) right iliac fossa, 1 (7.7%) paraumbilicus, 1 (7.7%) NR</td>
</tr>
<tr>
<td>Vian, 2009</td>
<td>32</td>
<td>Mitrofanoff 17</td>
<td>Monti 15</td>
<td>Casale 0</td>
<td>Other 0</td>
<td>29 (90.6%) umbilicus, 3 (9.4%) subumbilicus</td>
</tr>
<tr>
<td>Vrijens, 2010</td>
<td>24</td>
<td>Mitrofanoff 2 (8.3%)</td>
<td>Monti 0</td>
<td>Casale 0</td>
<td>Other 7 (29.2%) Indiana pouch, 15 (62.5%) individual pouch</td>
<td>24 (100%) umbilicus</td>
</tr>
<tr>
<td>Khavari, 2012</td>
<td>34</td>
<td>Mitrofanoff 0</td>
<td>Monti 0</td>
<td>Casale 0</td>
<td>Other 34 (100%) Indiana pouch</td>
<td>NR</td>
</tr>
<tr>
<td>Perrouin-Verbe, 2014</td>
<td>29</td>
<td>Mitrofanoff 15 (51.7%)</td>
<td>Monti 11 (37.9%)</td>
<td>Casale 3 (10.4%)</td>
<td>Other 0</td>
<td>28 (96.6%) umbilicus, 1 (3.4%) right iliac fossa</td>
</tr>
</tbody>
</table>

CCS/T, cutaneous continent stoma/tube; NR, not reported.
<table>
<thead>
<tr>
<th>Study (1st author, year)</th>
<th>Number of patients</th>
<th>Follow-up, months, mean (range)</th>
<th>Ability to catheterize</th>
<th>Continence at stoma</th>
<th>Quality of life</th>
<th>Evaluation</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aboutaieb, 1996</td>
<td>5</td>
<td>NR</td>
<td>5/5 (100)</td>
<td>5/5 (100)</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sykora, 1997</td>
<td>7</td>
<td>5-20</td>
<td>7/7 (100)</td>
<td>6/7 (85.7)</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van Savage, 2000</td>
<td>8</td>
<td>36 (18-60)</td>
<td>8/8 (100)</td>
<td>6/8 (75)</td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shpall, 2004</td>
<td>19</td>
<td>36.9 (7-173)</td>
<td>8/10 (80)</td>
<td></td>
<td>Yes</td>
<td>At last follow up: Working capacity: great (n = 3), slightly (n = 2), not influenced (n = 4) Ability to perform daily activities: great (n = 5), slight (n = 1), not influenced (n = 3) Ability to perform leisure activities: great (n = 4), slight (n = 2), not influenced (n = 3) Influence on quality of life: great (n = 5), slight (n = 3), not influenced (n = 1) Patients opinion concerning time of diversion: much earlier (n = 3), earlier (n = 1)</td>
<td></td>
</tr>
<tr>
<td>Pazooki, 2005</td>
<td>10</td>
<td>3.2 (0.5-7.5)</td>
<td>8/10 (80)</td>
<td></td>
<td>Yes</td>
<td>SF-36 scores: energy/fatigue 82, emotional well-being 90, social functioning 81, pain 81, general health 86</td>
<td></td>
</tr>
<tr>
<td>Touma, 2007</td>
<td>12</td>
<td>33.6 (3-69.6)</td>
<td>12/12 (100)</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Karsenty, 2008</td>
<td>12 (1 lost to follow-up)</td>
<td>44 (20-56)</td>
<td>12/12 (100)</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vian, 2009</td>
<td>31 (1 died of spinocellular carcinoma at 8 months)</td>
<td>21.6 (8-37)</td>
<td>26/31 (84)</td>
<td>Yes</td>
<td>SF-36 scores: bother (12.9/36), constraint (11.5/32), fear (7/32), life (2.5/20)</td>
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<td></td>
</tr>
<tr>
<td>Vrijens, 2010</td>
<td>24</td>
<td>8.7 years (6-180)</td>
<td>14/24 (58.3)</td>
<td>No</td>
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<td></td>
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<tr>
<td>Khavari, 2012</td>
<td>34</td>
<td>31</td>
<td>34/34 (100)</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perrouin-Verbe, 2014</td>
<td>29</td>
<td>Median 66 (IQR 50-80)</td>
<td>29/29 (100)</td>
<td>Yes</td>
<td>Asking the patient if situation improved/stable/decreased: 90% improved</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CCS/T, cutaneous continent stoma/tube.
<table>
<thead>
<tr>
<th>Study (1st author, year)</th>
<th>Number of patients</th>
<th>Number of stenosis, n (%)</th>
<th>Time to occurrence</th>
<th>Skin stenosis, n (%)</th>
<th>Tube stenosis, n (%)</th>
<th>Reimplant stenosis, n (%)</th>
<th>Re Operation &lt;3 months</th>
<th>Re Operation &gt;3 months</th>
<th>Re Operation- delay not specified</th>
<th>Additional complications as reported by trialists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aboutaeb, 1996</td>
<td>5</td>
<td>0</td>
<td>NA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>3 reopening of bladder neck 1 valve disinvagination</td>
<td>1 bladder stone at 6 years</td>
<td></td>
<td>1 death due to anaesthesia accident at day 40 due to re-operation (reopening bladder neck)</td>
</tr>
<tr>
<td>Sylora, 1997</td>
<td>7</td>
<td>1 (14.3)</td>
<td>NA</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>1 stomal leakage 1 stomal stenosis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Van Savage, 2000</td>
<td>8</td>
<td>0</td>
<td>NA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>2 stones at 2 years</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shpall, 2004</td>
<td>19</td>
<td>6 (31.6)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>6 vesicourethral fistula 1 retained sponge 1 wound infection 5 bladder stones</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pazooki, 2005</td>
<td>10</td>
<td>0</td>
<td>NA</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4 pouch perforations (2 patients)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Touma, 2007</td>
<td>12</td>
<td>2 (16.6)</td>
<td>&lt;1 year</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>1 injection of bulking agents in the urethra 2 bladder neck closure</td>
<td>1 pelvic abscess</td>
<td></td>
<td>1 ileus at 3 weeks 9 urinary tract infections</td>
</tr>
<tr>
<td>Karsenty, 2008</td>
<td>12 (1 lost to follow-up)</td>
<td>0</td>
<td>NR</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 peritonitis</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vian, 2009</td>
<td>31 (1 died of spindle cell carcinoma at 8 months)</td>
<td>10 (32.3)</td>
<td>&lt;1 year</td>
<td>10 (32.3)</td>
<td>0</td>
<td>0</td>
<td>8 skin stenosis 1 urethral incontinence (sling) 2 urethrocutaneous fistula 1 peritonitis</td>
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<tr>
<td>Vrijens, 2010</td>
<td>24</td>
<td>1 (4.2)</td>
<td>NR</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>4 urethral leakage 1 bleeding 1 abdominal abscess</td>
<td></td>
<td></td>
<td>1 pulmonary embolus 1 pneumonia 1 respiratory</td>
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</table>

(Continues)
<table>
<thead>
<tr>
<th>Study (1st author, year)</th>
<th>Number of patients</th>
<th>Number of stenosis, n (%)</th>
<th>Time to occurrence</th>
<th>Number of skin stenosis, n (%)</th>
<th>Tube stenosis, n (%)</th>
<th>Reimplant stenosis, n (%)</th>
<th>Reason for re-operation and number for each</th>
<th>Reason for re-operation and number for each</th>
<th>Reason for re-operation and number for each</th>
<th>Additional complications as reported by trialists</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khavari, 2012\textsuperscript{21}</td>
<td>34</td>
<td>4 (11.8)</td>
<td>NR</td>
<td>4 (11.8)</td>
<td>0</td>
<td>0</td>
<td>2 stoma revisions at 7 and 17 months (same patient)</td>
<td>3 stoma revisions</td>
<td>1 pyocystis</td>
<td>1 pyocystis</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 removal of anterior bladder wall suture at 48 months</td>
<td>1 explantation of artificial urinary sphincter owing to decubitus ulcer and urethra-cutaneous fistula + 1 native cystectomy with conversion to Indiana pouch</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Perrouin-Verbe, 2014\textsuperscript{22}</td>
<td>29</td>
<td>2 (6.9)</td>
<td>&gt;1 year</td>
<td>1 (3.4)</td>
<td>1 (3.4)</td>
<td>0</td>
<td>1 hemoperitoneum</td>
<td>1 neo-vesico-cutaneous fistulae</td>
<td>1 hemoperitoneum (Clavien IIIb) at day 7</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1 bowel obstruction</td>
<td>3 tubo-cutaneous fistulae (2 patients)</td>
<td>1 sepsis (Clavien II) at day 10</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>1 false passage (Clavien I) at day 30</td>
</tr>
</tbody>
</table>

CCST, cutaneous continent stoma/tube; NR, not reported; NA, not applicable.
4.2 Findings in the context of existing evidence

The aims of the management of neurogenic lower urinary tract dysfunction include protection of the upper urinary tract and improvement of HRQOL by achieving urinary continence and autonomy. Self-catheterization described by Lapides in 1972 is the gold standard to treat neurogenic bladder emptying difficulties. Success of the self-catheterization strategy requires patient motivation, hand dexterity, adequate cognitive function, and a preserved urethra. When CIC through the urethra is difficult or impossible as in patients with impaired upper limb function (33-100% of the population in 6/11 studies), our findings indicate that CCS/T could be a viable alternative to an indwelling catheter. Therefore the creation of a CCS/T by enabling intermittent self-catheterization is likely to reduce the well-described high urinary complications rate of indwelling catheters in adult neuro-urological patients. In the most complex situation, a surgical reanimation program of hand function could even improve tetraplegic patient eligibility for a CSS/T as mentioned in 1 out of 11 studies.

Although the stoma site was primarily the umbilicus and the Mitrofanoff principle was the most reported technique, no robust comparison between the different techniques can be drawn from this review. Nevertheless, in three of the largest and later series, two to four different techniques per team were employed to create CCS/T. These data suggest that several technical options should be mastered in order to achieve the joining of the bladder reservoir (augmented or not) to the skin at the actual abdominal site that enables self-catheterization.

Although the impact of bladder management and particularly of indwelling catheter avoidance on HRQOL has been well demonstrated, actual changes in HRQOL induced by CCS/T were poorly evaluated. No study of this review compared patient status before and after surgery. Only one out of four studies that reported quality-of-life improvement used a validated questionnaire for neuro-urological patients (Qualiveen). Nevertheless, we found two prospective evaluations of HRQOL in a total of 24 tetraplegic women who underwent some form of reconstructive surgery including CCS/T. At a median follow-up of 18-44 months, they demonstrated sustained improvement in several domains of HRQOL such as self-esteem, body image, independence, ability to cope with disability, and sexual satisfaction.

Stenosis and resulting difficulty to catheterize were the main specific complications of CSS/T observed in up to 23% of the neuro-urological case series we reviewed. Although underreporting is very likely, this stenosis rate must be compared with a median rate ranging from 9% to 21% in the largest non neuro-urological specific review with an equivalent rate of difficulty to catheterize or with the highest 28% stenosis rate reported in a case series which included 50% of neuro-urological patients with a 6-year follow-up. The difference between CSS/T techniques (tubes, invaginated valves, or non-invaginated valves) regarding the stenosis rate was not assessed in the neuro-urological patient series and was not different in the review by Ardelt et al.

Very few data addressing the question of long-term results were available. Studies in pediatric populations are interesting regarding this point since they provide long-term information on CCS/T outcomes with follow-up up to 20 years. Moreover, congenital spinal cord malformation (myelomeningocele), a condition resulting in up to 96% suffering with neurogenic bladder dysfunction, is the most common indication for CCS/T along with bladder extrophy. Supplementary Material S4 summarizes data from pediatric studies on CCS/T. The results on the ability to catheterize and continence at stoma did not differ significantly from those of adults. Although the type and frequency of complications were comparable between childhood and adulthood, we learned from pediatric series that most of the complications related to the CCS/T occur within the first 5 years after the initial surgery but can still occur in excess of 15 years following surgery. Even though the time until the occurrence of complications was not always reported in the studies, three studies with the longest follow-up provide some relevant information regarding the time until complications develop in the long-term. In the study by Richter et al., which had a 75-month follow-up, all complications related to the Benchekroun pouch occurred within the first 5 years postoperatively. The study by Liard et al. reported the longest follow-up (20 years). Within the first 5 years postoperatively, 14 complications occurred (4 stomal dilations, 6 stomal surgical revisions, and 4 intravesical implantation revisions). Within the 5-10 year, 10-15 year, and >15-year periods postoperatively, the number of complications were 8, 2, and 5, respectively. Leslie et al. reported that the surgical revision-free (survival) time was 99.1 ± 6.2 months (95% CI 86.6-111.3). An initial peak in the number of reoperations was followed by a relatively stable complication-free period. Nevertheless, delayed problems were detected in otherwise stable channels during long-term follow-up.

In a time-to-event analysis, there were no statistically significant differences in surgical revision rates comparing the use of Mitrofanoff vs. Monti (P = 0.4) or site of skin anastomosis (umbilical vs. lower quadrant, P = 0.8). The rate of the two most frequent complications (stenosis and incontinence) was recorded for early (fewer than 3 years) and late (more than 3 years) follow-up, with 69% stenosis and 65% incontinence (P = 0.7) identified in the first 3 years after the initial operation. Data from pediatric series, therefore, provide some additional points that support CCS/T as a good option to treat bladder-emptying difficulties even in the long term.
4.3 | Implications for practice

Whatever the indication for CSS/T, patients, their families, and caregivers must have clear information regarding the results, demands, and risks of such a surgical program.

In neuro-urological patients, there can be an additional disability such as cognitive impairment, upper-limb limitation, difficulty to undress, or unstable wheelchair balance. This calls for a preoperative multidisciplinary evaluation performed by urologists, rehabilitation physicians, neurologists, occupational therapists, physiotherapists, and psychologists. A functional questionnaire to predict the ability to catheterize has been developed to help in patient selection. If necessary, some patients (C5-C7 tetraplegic) can undergo surgical upper-limb reanimation to enable or improve their self-catheterization through the stoma. Although some studies suggest that the umbilical position could have some advantages such as a straight path from the abdominal wall to the bladder, thereby favoring complete bladder emptying and a good cosmetic result, trials to catheterize in a fake abdominal stoma prior to surgery could help to determine the ideal site for the stoma in individual patients.

In order to implant the tube at the chosen CCS/T site, the surgeon needs to master several techniques including Mitrofanoff, Monti, and/or Casale but also options to concurrently enlarge the bladder while the tube is properly implanted with an effective continence mechanism. A solution to build a heterotopic continent reservoir would be of value to manage difficult cases involving severe bladder neck and urethral damage. Because the main complications related to the CSS/T were catheterization difficulties owing to tube or skin stenosis, V-shaped, VR, or VQZ skin flap options to enlarge the circumference of the stoma and prevent or treat stenosis would be of additional value.

4.4 | Implications for research

Although the findings of our systematic review are favorable, the literature in this particular area is not only primarily retrospective but is of poor scientific quality, leaving a number of unanswered questions. Randomized controlled trials would ethically and logistically be difficult to conduct. However, well-designed prospective cohort studies with clear predefined outcomes at different time points and with comparisons of different procedures are warranted to better understand the short and long-term outcomes of CCS/T in adult neuro-urological patients. Beside complication rates, HRQOL evaluation with standardized questionnaires would be the outcome of utmost importance to be assessed. For this purpose, the Qualiveen® questionnaire specifically developed to assess quality of life related to bladder dysfunction in neuro-urological patients could be associated with the Intermittent Self Catheterization Questionnaire (ISC-Q) which focuses on four domains of self-catheterization (ease of use, convenience, discreetness, and psychological well-being).

Hence, the impact of CCS/T on patient HRQOL should be addressed more comprehensively. Another issue is the long-term outcomes and complications of CCS/T procedures performed in adult patients. Finally, future research will have to identify the patient groups that would benefit most from CCS/T and those would be most at risk for failure or complications.

4.5 | Limitations of this study

Several limitations need to be addressed. The included studies were all retrospective and did not compare one procedure versus another in order to assess outcomes. Long-term follow-up is lacking. The influence of concomitant procedures on outcomes was not addressed by the authors.

Moreover, the studies were small and did not allow for subgroup analyses. A large number of studies on CCS/T had to be excluded from this systematic review because the results were not separately reported for the mixed populations included in the studies (neurological and non-neurological patients). Complications related to CCS/T and concomitant procedures were not addressed in a standardized approach. Finally, the risk of confounding was substantial and more reliable evidence is urgently required.

5 | CONCLUSIONS

The present systematic review indicates that CCUD using CCS/T appears to be an effective treatment option in neuro-urological patients unable to perform CIC through the urethra. However, the complication rate was relevant. Thus, patient information and selection are essential to manage postoperative expectations and outcomes. Moreover, the quality of evidence was low, especially owing to a lack of well-designed long-term prospective studies and evaluation of HRQOL.

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6 | ROLE OF THE SPONSOR

The European Association of Urology had no role in the design and conduct of the study; collection, management,
analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES


**SUPPORTING INFORMATION**

Additional Supporting Information may be found online in the supporting information tab for this article.