Complete Summary

GUIDELINE TITLE

Bladder management for adults with spinal cord injury: a clinical practice guideline for health-care providers.

BIBLIOGRAPHIC SOURCE(S)

Consortium for Spinal Cord Medicine. Bladder management for adults with spinal cord injury: a clinical practice guideline for health care providers. Washington (DC): Paralyzed Veterans of America; 2006 Aug. 50 p. [108 references]

GUIDELINE STATUS

This is the current release of the guideline.

COMPLETE SUMMARY CONTENT

SCOPE
METHODOLOGY - including Rating Scheme and Cost Analysis
RECOMMENDATIONS
EVIDENCE SUPPORTING THE RECOMMENDATIONS
BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS
QUALIFYING STATEMENTS
IMPLEMENTATION OF THE GUIDELINE
INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES
IDENTIFYING INFORMATION AND AVAILABILITY
DISCLAIMER

SCOPE

DISEASE/CONDITION(S)

Neurogenic bladder as a result of spinal cord injury

GUIDELINE CATEGORY

Management
Treatment

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Physical Medicine and Rehabilitation

INTENDED USERS

Advanced Practice Nurses
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To provide both individuals with spinal cord injury and the health-care providers who advise them with the best and most up-to-date information on the wide variety of bladder management techniques available to them

TARGET POPULATION

Adult patients with spinal cord injuries

INTERVENTIONS AND PRACTICES CONSIDERED

Management/Treatment

1. Intermittent catheterization
2. Crede and Valsalva
3. Indwelling catheterization
4. Reflex voiding
5. Alpha-blockers
6. Botulinum toxin injection
7. Endourethral stents
8. Transurethral sphincterotomy
9. Electrical stimulation and posterior sacral rhizotomy
10. Bladder augmentation
11. Continent urinary diversion
12. Urinary diversion
13. Cutaneous Ileovesicostomy

MAJOR OUTCOMES CONSIDERED

- Efficacy and safety of each intervention
- Urodynamic outcomes
- Economic (utilization) outcomes

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Methodology

Metaworks, Inc. performed a systematic review of the literature published since 1993 that describes bladder management after traumatic spinal cord injuries in the adult population. The focus of the review was the evaluation of various modalities of bladder management intended to maintain and preserve a functional urinary tract. In general, the review procedures followed the best methods used in the evolving science of systematic review research. Systematic review is a scientific technique designed to minimize bias and random error by first conducting a comprehensive search of the literature and then use a preplanned process for study selection.

Literature Search

The literature search included both electronic and manual components. Medline (via PubMed) was searched back to 1993 for citations using the following Medical Subject Heading [MeSH] terms and keywords:

1. Bladder, neurogenic [MeSH] OR neurogenic bladder OR neuropathic bladder.
2. Spinal cord injuries [MeSH] OR paraplegia [MeSH] OR quadriplegia [MeSH] OR tetraplegia.
3. Urination disorders (MeSH] OR urinary OR urologic OR bladder OR kidney calculi [MeSH] OR hydronephrosis [MeSH] OR kidney failure [MeSH] OR vesicoureteral reflux [MeSH] OR renal failure.
4. #2 AND #3.
5. #1 OR #4 limits: publication date from 1993 to November 30, 2001, English, human.

In addition, two strategies were used to identify papers that may not have been indexed on Medline by the time of the search cutoff date. The PubMed search included a keyword search for the prior 6 months, using terms indicating spinal cord injury and urologic management, with no limits; and Current Contents was searched for the past year, using similar search terms.

The Cochrane Library and National Guidelines Clearing House were searched for any recent systematic reviews or clinical guidelines on the subject, which could have been sources for further references. A manual check of the reference lists of all accepted papers and of recent reviews was performed to supplement the above electronic searches. Abstracts from the electronic search were downloaded and evaluated using the literature review process described below.

The last step was to search Medline back to 1980 using the same search strategy in order to find relevant reviews and expert opinion papers on bladder management in individuals with SCI.

Study Selection

To be eligible for inclusion in this review, studies had to meet the following criteria.

Exclusion Criteria

Studies were excluded if they contained the following elements:

- Abstracts, letters, comments, editorials
- Animal and in vitro studies
- Pharmacokinetic and pharmacodynamic studies
- Language other than English
- Publication prior to 1993

Inclusion Criteria

Studies were included if they met the following criteria and did not meet any exclusion criteria:

- Any of the following study designs: interventional or observational
- Any geographic location
- Condition of interest: traumatic spinal cord injury in individuals age 13 or older
- Study focus: bladder management

Case reports were set aside and given to the guideline development panel, but they were not extracted for inclusion in the database. Review articles published since 1980 were set aside for possible use in framing the discussion of findings in the systematic review. A complete list of these papers along with abstracts was provided to the guideline development panel for supplemental use in developing the guidelines.

NUMBER OF SOURCE DOCUMENTS

71 papers were accepted for data extraction, with an additional 11 papers that were linked publications

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Levels of Evidence

I. Evidence based on randomized controlled clinical trials (or meta-analysis of such trials) of adequate size to ensure a low risk of incorporating false-positive or false-negative results.
II. Evidence based on randomized controlled trials that were too small to provide level I evidence. These may have shown either positive trends that were not statistically significant or no trends and were associated with a high risk of false-negative results.
III. Evidence based on nonrandomized, controlled or cohort studies, case series, case-controlled studies, or cross-sectional studies.
IV. Evidence based on the opinion of respected authorities or that of expert committees as indicated in published consensus conferences or guidelines.

V. Evidence that expressed the opinion of those individuals who were writing and reviewing these guidelines, based on their experience, knowledge of the relevant literature, and discussion with peers.

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data extraction involves the capturing of various data elements from each study. This task was performed by one investigator using data extraction forms (DEFs) designed specifically for this project. A second investigator established a consensus for all extracted data, and a third investigator arbitrated any disagreements. The consensus versions of the DEFs were entered into MetaHub™, MetaWorks' relational database of clinical trials information.

After 100 percent of the entered data were validated against the consensus DEFs and full consistency and logic checks were performed on the database, the data were locked. After the data passed these quality control measures, they were used to generate evidence tables, which were delivered to the guideline development panel for review.

See the original guideline document for a list of data elements extracted, when possible, from each accepted study.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

The guideline development process adopted by the Consortium for Spinal Cord Medicine consists of twelve steps, leading to panel consensus and organizational endorsement. After the steering committee chooses a topic, a panel of experts is selected. Panel members must have demonstrated leadership in the topic area through independent scientific investigation and publication. Following a detailed explication and specification of the topic by select steering committee and panel members, consultant methodologists review the international literature, prepare evidence tables that grade and rank the quality of research, and conduct statistical meta-analyses and other specialized studies, as needed. The panel chair then assigns specific sections of the topic to the panel members based on their area of expertise. Writing begins on each component using the references and other materials furnished by the methodology support group.

After panel members complete their sections, a draft document is generated during the first full meeting of the panel. The panel incorporates new literature citations and other evidence-based information not previously available. At this point, charts, graphs, algorithms, and other visual aids, as well as a complete bibliography, are added, and the full document is sent to legal counsel for review.

Grading the Guideline Recommendations

After panel members had drafted their sections of the guideline, each recommendation was graded according to the level of scientific evidence supporting it. The framework used by the methodology team is outlined in "Rating Scheme for the Strength of the Recommendations." It should be emphasized that these ratings, like the evidence table ratings, represent the strength of the supporting evidence, not the strength of the recommendation itself. The strength of the recommendation is indicated by the language describing the rationale.

If the literature supporting a recommendation comes from two or more levels, the number and level of the studies are reported (e.g., in the case of a recommendation that is supported by two studies, one a level III, the other a level V, the "Scientific evidence" is indicated as "III/V"). In situations in which no published literature exists, consensus of the panel members and outside expert reviewers was used to develop the recommendation and is indicated as "Expert consensus."

Grading of Panel Consensus

The level of agreement with the recommendation among panel members was assessed as either low, moderate, or strong. Each panel member was asked to indicate his or her level of agreement on a 5-point scale, with 1 corresponding to neutrality and 5 representing maximum agreement. Scores were aggregated across the panel members and an arithmetic mean was calculated. This mean score was then translated into low, moderate, or strong. A panel member could abstain from the voting process for a variety of reasons, including, but not limited to, lack of expertise associated with the particular recommendation.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Strength of Evidence Associated with the Recommendations (Grade of Recommendation)

A. The guideline recommendation is supported by one or more level I studies.
B. The guideline recommendation is supported by one or more level II studies.
C. The guideline recommendation is supported only by one or more level III, IV, or V studies.

Levels of Panel Agreement with Recommendation (Strength of Panel Opinion)

Low - Mean agreement score 1.0 to less than 2.33

Moderate - Mean agreement score 2.33 to less than 3.67

Strong - Mean agreement score 3.67 to 5.0

COST ANALYSIS

The economic considerations for bladder management methods are outlined in Appendix A of the original guideline document.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

After legal analysis to consider antitrust, restraint-of-trade, and health policy matters, the draft document is reviewed by clinical experts from each of the consortium organizations plus other select clinical experts and consumers. The review comments are assembled, analyzed, and entered into a database, and the document is revised to reflect the reviewers' comments. The draft document is distributed to all consortium organization steering committee members. Final technical details are negotiated among the panel chair, members of the organizations' boards, and expert panelists. If substantive changes are required, the draft receives a final legal review. The document is then ready for editing, formatting, and preparation for publication.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Rating schemes for the levels of scientific evidence (I, II, III, IV, V), grade of recommendation (A, B, C) and the strength of panel opinion (Low, Moderate, Strong) are defined at the end of the "Major Recommendations" field.

Intermittent Catheterization

1. Consider intermittent catheterization for individuals who have sufficient hand skills or a willing caregiver to perform the catheterization.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Consider avoiding intermittent catheterization in individuals with spinal cord injury (SCI) who have one or more of the following:
   - Inability to catheterize themselves
   - A caregiver who is unwilling to perform catheterization
   - Abnormal urethral anatomy such as stricture, false passages, and bladder neck obstruction
   - Bladder capacity less than 200 mL
   - Poor cognition, little motivation, or inability or unwillingness to adhere to the catheterization time schedule
   - High fluid intake regimen
   - Adverse reaction to passing a catheter into the genital area multiple times a day
   - Tendency to develop autonomic dysreflexia with bladder filling despite treatment

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Advise individuals with SCI of the potential for complications with intermittent catheterization, such as:
    - Urinary tract infections
    - Bladder overdistention
    - Urinary incontinence
    - Urethral trauma with hematuria
    - Urethral false passages
    - Urethral stricture
    - Autonomic dysreflexia (in those with injuries at T6 and above)
    - Bladder stones

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

4. If bladder volumes consistently exceed 500 mL, adjust fluid intake, increase frequency of intermittent catheterization, or consider an alternative bladder management method.

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

5. Institute clean intermittent catheterization teaching and training for individuals prior to discharge from the acute phase of rehabilitation.

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

6. Consider sterile catheterization for individuals with recurrent symptomatic infections occurring with clean intermittent catheterization.

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

7. Investigate and provide treatment for individuals on intermittent catheterization who leak urine between catheterizations.

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

8. Monitor individuals using this method of bladder management.

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

Credé and Valsalva

1. Consider the use of Credé and Valsalva for individuals who have lower motor neuron injuries with low outlet resistance or who have had a sphincterotomy.

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Consider avoiding Credé and Valsalva as primary methods of bladder emptying.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Consider avoiding Credé and Valsalva methods in individuals with:
   - Detrusor sphincter dyssynergia
   - Bladder outlet obstruction
   - Vesicoureteral reflux
   - Hydronephrosis

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

4. Advise individuals with SCI of the potential for complications with Credé and Valsalva, such as:
   - Incomplete bladder emptying
   - High intravesical pressure
   - Developing and/or worsening vesicoureteral reflux
   - Developing and/or worsening hydronephrosis
   - Abdominal bruising
   - Possible hernia, pelvic organ prolapse, or hemorrhoids

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Indwelling Catheterization

1. Consider indwelling catheterization for individuals with:
   - Poor hand skills
   - High fluid intake
   - Cognitive impairment or active substance abuse
   - Elevated detrusor pressures managed with anticholinergic medications or other means
   - Lack of success with other less invasive bladder management methods
   - Need for temporary management of vesicoureteral reflux
   - Limited assistance from a caregiver, making another type of bladder management not feasible

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Consider using suprapubic catheterization for individuals with:
   - Urethral abnormalities, such as stricture, false passages, bladder neck obstruction, or urethral fistula
   - Urethral discomfort
   - Recurrent urethral catheter obstruction

- Difficulty with urethral catheter insertion
- Perineal skin breakdown as a result of urine leakage secondary to urethral incompetence
- Psychological considerations such as body image or personal preference
- A desire to improve sexual genital function
- Prostatitis, urethritis, or epididymo-orchitis

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Consider avoiding urethral catheterization in individuals with SCI:
    - Immediately following acute SCI if urethral injury is suspected, especially after pelvic trauma (blood at the urethral meatus and perineal and scrotal hematomas may be indicative of urethral trauma)
    - If bladder capacity is small, with forceful uninhibited contractions despite treatment

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

4. Consider indwelling catheterization for individuals who are at risk of genitourinary complications because of elevated detrusor pressures.

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

5. Advise individuals of the long-term complications associated with indwelling catheterization, which include:
    - Bladder stones
    - Kidney stones
    - Urethral erosions
    - Epididymitis
    - Recurrent symptomatic urinary tract infections
    - Incontinence
    - Pyelonephritis
    - Hydronephrosis from bladder wall thickening or fibrosis
    - Bladder cancer

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

6. Conduct more frequent cystoscopic evaluations for individuals with chronic indwelling catheters than for those with nonindwelling methods of bladder management.

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

7. Consider the use of anticholinergics in individuals with suprasacral lesions using chronic indwelling catheterization.

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Reflex Voiding

1. Consider using reflex voiding for males who demonstrate post-spinal shock with adequate bladder contractions and have:
    - Sufficient hand skills to put on a condom catheter and empty the leg bag, or a willing caregiver
    - Poor compliance with fluid restriction
    - Small bladder capacity
    - Small post-void residual volumes
    - Ability to maintain a condom catheter in place

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

2. Conduct a thorough urodynamic evaluation to determine whether reflex voiding is a suitable method for a particular individual.

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

3. Consider not using reflex voiding as a method of bladder management in individuals who:
    - Have insufficient hand skills or caregiver assistance
    - Are unable to maintain a condom catheter in place
    - Are female
    - Have incomplete bladder emptying despite treatment to facilitate voiding
    - Have high-pressure voiding despite treatment to facilitate voiding
    - Develop autonomic dysreflexia despite treatment to facilitate voiding

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

4. Advise individuals of the potential for complications with reflex voiding, such as:
    - Condom catheter leakage and/or failure
    - Penile skin breakdown from external condom catheter
    - Urethral fistula
    - Symptomatic urinary tract infection (UTI)
    - Poor bladder emptying
    - High intravesical voiding pressures
    - Autonomic dysreflexia in those with injuries at T6 and above

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

5. First consider the use of the following nonsurgical methods to help decrease detrusor sphincter dyssynergia in individuals who use reflex voiding as their method of bladder management:
    - Alpha-blockers
    - Botulinum toxin injection into the urinary sphincter mechanism

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

6. To ensure low-pressure voiding during reflex voiding, consider the use of two surgical methods:
    - Transurethral sphincterotomy
    - Endourethral stents

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

Alpha-Blockers

1. Consider the use of alpha-blockers on their own or as a supplement to other forms of treatment, such as transurethral sphincterotomy.

    (Scientific evidence–II/III; Grade of recommendation–B/C; Strength of panel opinion–Strong)

2. Consider avoiding alpha-blockers in individuals who have symptomatic hypotension.

    (Scientific evidence–II/III; Grade of recommendation–B/C; Strength of panel opinion–Strong)

3. When first prescribing, instruct the individual to take alpha-blockers at night, when supine. These instructions are particularly important for individuals with high-level spinal cord injuries because of the potential for orthostatic hypotension.

    (Scientific evidence–II/III; Grade of recommendation–B/C; Strength of panel opinion–Strong)

4. Use phosphodiesterase inhibitors with caution in individuals with a high-level SCI who are on alphablockers. Particular caution should be used if alpha-blockers and phosphodiesterase (PDE5) inhibitors are prescribed together.

    (Scientific evidence–II/III; Grade of recommendation–B/C; Strength of panel opinion–Strong)

5. Advise individuals of the potential for complications of alpha-blockers, such as orthostatic hypotension.

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

Botulinum Toxin Injection

1. Consider the use of botulinum toxin injections into the sphincter to help improve voiding in individuals with SCI with detrusor sphincter dyssynergia.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Monitor individuals after botulinum toxin injections and inform them that onset may be delayed up to 1 week and that the drug may lose its effectiveness in 3 to 6 months.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Consider avoiding the injection of botulinum toxin into the sphincter of SCI individuals who:
   - Have a neuromuscular disease
   - Have a known allergy to or previous adverse effect from botulinum toxin
   - Are currently on an aminoglycoside
   - Have insufficient hand skills or caregiver assistance
   - Are unable to maintain a condom catheter
   - Are female

   (*Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)*

4. Advise individuals with SCI of the potential for complications of botulinum toxin injections into the sphincter, such as:
   - Autonomic dysreflexia during the injection (T6 and above)
   - Hematuria during the injection

   (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

5. Consider injecting botulinum toxin into the detrusor muscle of individuals on intermittent catheterization with detrusor overactivity.

   (Scientific evidence–I/III; Grade of recommendation–A/C; Strength of panel opinion–Strong)

Endourethral Stents

1. Consider endourethral stents to treat detrusor sphincter dyssynergia in individuals who want to reflex void and:
   - Have insufficient hand skills or caregiver assistance to perform intermittent catheterization
   - Have a repeated history of autonomic dysreflexia
   - Experience difficult catheterization due to false passages in the urethra or secondary bladder neck obstruction

- Have inadequate bladder drainage with severe bladder wall changes, drop in renal function, vesicoureteral reflux, and/or stone disease
- Have prostate-ejaculatory reflux with the potential for repeated epididymo-orchitis
- Experience failure with or intolerance to anticholinergic medications for intermittent catheterization
- Experience failure with or intolerance to alpha-blockers with reflex voiding

(Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

2. Consider the endourethral stent method of drainage as an alternative to transurethral sphincterotomy in individuals with SCI.

   (Scientific evidence–II; Grade of recommendation–B; Strength of panel opinion–Strong)

3. Consider avoiding endourethral stents in individuals who:
   - Have insufficient hand skills or caregiver assistance to manage a condom catheter
   - Are unable to maintain a condom catheter
   - Are female
   - Have urethral abnormalities

   (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

4. Advise individuals of the potential for complications of endourethral stents, such as:
   - Stone encrustation
   - Stent migration
   - Persistence of autonomic dysreflexia
   - Possible need for removal or replacement
   - Difficulty with removal
   - Possible urethral stricture after removal of stent
   - Urethral trauma
   - Tissue growth into the stent blocking urine flow
   - Urethral pain

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Transurethral Sphincterotomy

1. Consider transurethral sphincterotomy (TURS) to treat detrusor sphincter dyssynergia in males with SCI who want to use reflex voiding and who:
   - Have insufficient hand skills or caregiver assistance to perform intermittent catheterization
   - Have a repeated history of autonomic dysreflexia with a noncompliant bladder

- Experience difficult catheterization due to false passages in the urethra or secondary bladder neck obstruction
- Have inadequate bladder drainage with severe bladder wall changes, drop in renal function, vesicoureteral reflex, and/or stone disease
- Have prostate-ejaculatory reflux with the potential for repeated epididymo-orchitis
- Experience failure with or intolerance to anticholinergic medications for intermittent catheterization
- Experience failure with or intolerance to alpha-blockers with reflex voiding

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Consider avoiding sphincterotomy in males with a small retractable penis unable to hold an external collecting device unless a penile implant is planned following transurethral sphincterotomy.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Advise individuals with SCI of the potential for complications of a sphincterotomy, such as:
   - Significant intraoperative and perioperative bleeding
   - Clot retention
   - Prolonged drainage with a large diameter catheter
   - Urethral stricture
   - Erectile dysfunction
   - Ejaculatory dysfunction
   - Reoperation in 30 to 60 percent of cases

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

4. Consider laser sphincterotomy the procedure of choice for transurethral sphincterotomy, depending upon the availability of laser equipment.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Electrical Stimulation and Posterior Sacral Rhizotomy

1. Consider electrical stimulation and posterior sacral rhizotomy in individuals with:
   - High post-void residual volumes
   - Chronic or recurrent urinary tract infection
   - Problems with catheters
   - Reflex incontinence
   - Reduced bladder capacity and compliance, caused by detrusor hyperreflexia
   - Intolerance of anticholinergic medication

- Detrusor sphincter dyssynergia
- Autonomic dysreflexia

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Avoid electrical stimulation combined with posterior sacral rhizotomy for:
    - Individuals who have poor or absent bladder contractions
    - Individuals who are unable to expand the bladder due to fibrosis
    - Females who are unable to transfer or be transferred or to manage clothing
    - Males who are unwilling to lose reflex erection

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Advise individuals with SCI of the potential for complications of posterior sacral rhizotomy, such as:
    - Loss of reflex erection and reflex ejaculation
    - Loss of sacral sensation
    - Reduction of reflex defecation
    - Transient nerve damage (rarely long term)

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

4. Advise individuals with SCI of the potential for complications of electrical stimulation, such as:
    - Contamination of the device
    - Malfunction of the device
    - Transient nerve damage (rarely long term)

    (Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

Bladder Augmentation

1. Consider bladder augmentation for individuals who have:
    - Intractable involuntary bladder contractions causing incontinence
    - The ability and motivation to perform intermittent catheterization.
    - The desire to convert from reflex voiding to an intermittent catheterization program
    - A high risk for upper tract deterioration secondary to hydronephrosis and/or ureterovesical reflux as a result of high pressure detrusor sphincter dyssynergia

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Consider bladder augmentation for females with paraplegia.

(Scientific evidence–None; Grade of recommendation–None; Strength of panel opinion–Strong)

3. Consider bladder augmentation for individuals who are at high risk for upper tract deterioration secondary to hydronephrosis and/or ureterovesical reflux as a result of high pressures, secondary to poor bladder wall compliance, and/or detrusor sphincter dyssynergia.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

4. Avoid augmentation for individuals who have:
   - Inflammatory bowel disease
   - Pelvic irradiation
   - Severe abdominal adhesions from previous surgery
   - Compromised renal function

   (Scientific evidence–II/III; Grade of recommendation–B/C; Strength of panel opinion–Strong)

5. Advise individuals of both the early and late complications of reconstructive surgery using intestinal segments.

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Continent Urinary Diversion

1. Consider a continent urinary diversion for:
   - Individuals in whom it is not feasible to augment the native bladder
   - Individuals who cannot access their native urethra because of congenital abnormalities, spasticity, obesity, contracture, or tetraplegia, or who require closure of an incompetent bladder neck
   - Females with tetraplegia in whom a chronic indwelling catheter has caused urethral erosion
   - Males with SCI with unsalvageable bladders secondary to urethral fistula and sacral pressure ulcers
   - Individuals with bladder cancer requiring cystectomy

   (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Urinary Diversion

1. Consider urinary diversion in the following circumstances:
   - Lower urinary complications secondary to indwelling catheters
   - Urethrocutaneous fistulas
   - Perineal pressure ulcers
   - Urethral destruction in females
   - Hydronephrosis secondary to a thickened bladder wall
   - Hydronephrosis secondary to vesicoureteral reflux or failed reimplant

- Bladder malignancy requiring cystectomy

(Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Use urinary diversion with caution in individuals who are too debilitated to undergo a major surgical procedure or who have one of the following conditions:
    - Inflammatory bowel disease
    - Pelvic irradiation
    - Severe abdominal adhesions from previous surgery
    - Compromised renal function

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

3. Advise individuals undergoing urinary diversion of the following potential complications:
    - Early complications associated with any major intestinal surgery, including anesthetic complications
    - Prolonged ileus (more common in SCI)
    - Intestinal or urinary leak
    - Sepsis and wound infection
    - Ureteroileal stricture
    - Stomal stenosis
    - Parastomal hernia
    - Intestinal obstruction due to adhesions
    - Urinary infection and stone disease

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Cutaneous Ileovesicostomy

1. Consider cutaneous ileovesicostomy for individuals who require urinary diversion with normal ureterovesical junctions.

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

2. Be prepared to perform secondary procedures that may be needed to prevent urethral incontinence (for example, on the bladder neck in conjunction with augmentation or suprapubic cystostomy or cutaneous ileovesicostomy).

    (Scientific evidence–III; Grade of recommendation–C; Strength of panel opinion–Strong)

Definitions:

Levels of Evidence

I. Evidence based on randomized controlled clinical trials (or meta-analysis of such trials) of adequate size to ensure a low risk of incorporating false-positive or false-negative results.
II. Evidence based on randomized controlled trials that were too small to provide level I evidence. These may have shown either positive trends that were not statistically significant or no trends and were associated with a high risk of false-negative results.
III. Evidence based on nonrandomized, controlled or cohort studies, case series, case-controlled studies, or cross-sectional studies.
IV. Evidence based on the opinion of respected authorities or that of expert committees as indicated in published consensus conferences or guidelines.
V. Evidence that expressed the opinion of those individuals who were writing and reviewing these guidelines, based on their experience, knowledge of the relevant literature, and discussion with peers.

Strength of Evidence Associated with the Recommendations (Grade of Recommendation)

A. The guideline recommendation is supported by one or more level I studies.
B. The guideline recommendation is supported by one or more level II studies.
C. The guideline recommendation is supported only by one or more level III, IV, or V studies.

Levels of Panel Agreement with Recommendation (Strength of Panel Opinion)

Low - Mean agreement score 1.0 to less than 2.33

Moderate - Mean agreement score 2.33 to less than 3.67

Strong - Mean agreement score 3.67 to 5.0

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is specifically stated for each recommendation (see "Major Recommendations" field).

A list of references is provided in the original guideline document, which includes all sources used by the guideline development panel to support their recommendations. It provides the level of scientific evidence (I-V) for each graded article.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- The goal of bladder management in adults with spinal cord injury is to maintain and preserve a functional, infection-free genitourinary system by preventing upper and lower tract complications with a management system that is compatible with an injury-free lifestyle.
- The ultimate goal of therapy is to achieve and maintain adequate bladder drainage with low-pressure urine storage and voiding.

POTENTIAL HARMS

Potential complications with intermittent catheterization are:

- Urinary tract infections
- Bladder overdistention
- Urinary incontinence
- Urethral trauma with hematuria
- Urethral false passages
- Urethral stricture
- Autonomic dysreflexia (in those with injuries at T6 and above)
- Bladder stones

Potential complications with Credé and Valsalva are:

- Incomplete bladder emptying
- High intravesical pressure
- Developing and/or worsening vesicoureteral reflux
- Developing and/or worsening hydronephrosis
- Abdominal bruising
- Possible hernia, pelvic organ prolapse, or hemorrhoids

Long-term complications associated with indwelling catheterization include:

- Bladder stones
- Kidney stones
- Urethral erosions
- Epididymitis
- Recurrent symptomatic urinary tract infections
- Incontinence
- Pyelonephritis
- Hydronephrosis from bladder wall thickening or fibrosis
- Bladder cancer

Potential complications with reflex voiding are:

- Condom catheter leakage and/or failure
- Penile skin breakdown from external condom catheter
- Urethral fistula
- Symptomatic urinary tract infection (UTI)

- Poor bladder emptying
- High intravesical voiding pressures
- Autonomic dysreflexia in those with injuries at T6 and above

Potential complications of alpha-blockers include orthostatic hypotension.

Potential complications of botulinum toxin injections into the sphincter are:

- Autonomic dysreflexia during the injection (T6 and above)
- Hematuria during the injection

Potential complications of endourethral stents are:

- Stone encrustation
- Stent migration
- Persistence of autonomic dysreflexia
- Possible need for removal or replacement
- Difficulty with removal
- Possible urethral stricture after removal of stent
- Urethral trauma
- Tissue growth into the stent blocking urine flow
- Urethral pain

Potential complications of a sphincterotomy are:

- Significant intraoperative and perioperative bleeding
- Clot retention
- Prolonged drainage with a large diameter catheter
- Urethral stricture
- Erectile dysfunction
- Ejaculatory dysfunction
- Reoperation in 30 to 60 percent of cases

Potential complications of posterior sacral rhizotomy are:

- Loss of reflex erection and reflex ejaculation
- Loss of sacral sensation
- Reduction of reflex defecation
- Transient nerve damage (rarely long term)

Potential complications of electrical stimulation are:

- Contamination of the device
- Malfunction of the device
- Transient nerve damage (rarely long term)

Potential perioperative complications of reconstructive surgery using intestinal segments include:

- Anesthetic complications
- Postoperative ileus and small bowel obstruction

- Wound separations and infections
- Mucus production causing blockage
- Bowel disturbances
- Persistent urine leakage
- Bladder perforation
- Development of bladder stones
- Vitamin B12 deficiencies
- Potential or late development of bladder cancer

Potential complications of urinary diversion are:

- Early complications associated with any major intestinal surgery, including anesthetic complications
- Prolonged ileus (more common in spinal cord injury [SCI])
- Intestinal or urinary leak
- Sepsis and wound infection
- Ureteroileal stricture
- Stomal stenosis
- Parastomal hernia
- Intestinal obstruction due to adhesions
- Urinary infection and stone disease

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guideline has been prepared based on the scientific and professional information available in 2006. Users of this guideline should periodically review this material to ensure that the advice herein is consistent with current reasonable clinical practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Consortium for Spinal Cord Medicine. Bladder management for adults with spinal cord injury: a clinical practice guideline for health care providers. Washington (DC): Paralyzed Veterans of America; 2006 Aug. 50 p. [108 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006 Aug

GUIDELINE DEVELOPER(S)

Consortium for Spinal Cord Medicine - Private Nonprofit Organization

GUIDELINE DEVELOPER COMMENT

Consortium Member Organizations include: American Academy of Orthopedic Surgeons, American Academy of Physical Medicine and Rehabilitation, American Association of Neurological Surgeons, American Association of Spinal Cord Injury Nurses, American Association of Spinal Cord Injury Psychologists and Social Workers, American College of Emergency Physicians, American Congress of Rehabilitation Medicine, American Occupational Therapy Association, American Paraplegia Society, American Physical Therapy Association, American Psychological Association, American Spinal Injury Association, Association of Academic Physiatrists, Association of Rehabilitation Nurses, Christopher Reeve Paralysis Foundation, Congress of Neurological Surgeons, Insurance Rehabilitation Study Group, International Spinal Cord Society, Paralyzed Veterans of America, United Spinal Association, U.S. Department of Veterans Affairs

SOURCE(S) OF FUNDING

Consortium for Spinal Cord Medicine

GUIDELINE COMMITTEE

Guideline Development Panel

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Paralyzed Veterans of America (PVA) Web site.

Print copies: Available from the Consortium for Spinal Cord Medicine, Clinical Practice Guidelines, 801 18th Street, NW, Washington, DC 20006.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI Institute on October 2, 2007.

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