Bladder Management for Adults with Spinal Cord Injury: A Clinical Practice Guideline for Health-Care Providers
Consortium for Spinal Cord Medicine
Member Organizations

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 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
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Administrative and financial support provided by Paralyzed Veterans of America

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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.

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Foreword

Neurogenic bladder occurs in most individuals who have a spinal cord injury (SCI). During World War I, 39 percent of those with spinal cord injury died from acute urinary tract infections (UTIs). During World War II, this number dropped to 10 percent, but the most common cause of death from spinal cord injury became renal failure.

Currently, although UTIs occur frequently in those with SCI, death from this cause is extremely unusual. And less than 3 percent of deaths following SCI are now attributable to chronic renal failure. This dramatic decline in morbidity and mortality from urological causes has been a result of the advent of antibiotics, effective bladder management, and frequent monitoring of the upper and lower urinary tracts.

This guideline was developed to describe the various methods of bladder management in adults with SCI. The panel decided to address this guideline not only to caregivers who are familiar with SCI, but also to those who infrequently manage individuals with SCI. The panel also decided not to recommend one single method of management, but rather to discuss the indications, advantages and disadvantages, nursing issues, and economic considerations of each of the most popular methods. There are a couple of reasons for this. The first is that there is no strong scientific evidence that one method is superior to another. The second is that health-care providers who are familiar with the various methods can offer the best help and advice to the individuals in their care.

It is important that individuals with SCI understand the pros and cons of the various methods of bladder management in a fair and unbiased way. Patient education should include a balanced discussion of the effect each method will have on health, lifestyle, and sexuality; as the comparative cost of each method and the availability of expert follow-up. The decision of which method to choose can then be made after all of the various factors have been weighed.

In developing this guideline, panel members looked carefully at the scientific literature and at expert opinion. The goal was to provide both individuals with SCI 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. The guideline recommendations consider who is—and who is not—a good candidate for each method as well as the associated contraindications. In doing so the panel sought to list the most common attributes of each method, based on the literature, rather than try to discuss every possible reason why a particular method should or should not be used.

I hope this guideline will help you in your practice as you care for and educate SCI individuals with neurogenic bladders. I also hope that the guideline will stimulate further clinical studies in this important area.

Todd A. Linsenmeyer, MD
Chairman
Preface

Urological complications, including urinary tract infections and renal failure, were at one time the number one killer of persons with spinal cord injury. Thanks primarily to dramatic improvements in the management of the neurogenic bladder over the past 40 years, the lifespan of people with SCI now approaches that of the general population. Although UTIs continue to be a frequent complication for many with SCI, renal failure is rare.

No other organ system has been studied as extensively in SCI as the urological system. And no other organ system has sparked such heated debate among specialists in terms of management in SCI. The Consortium for Spinal Cord Medicine brought together a team of experts in SCI urologic management to weigh the scientific evidence available and produce a document that identifies the very best practices for modern bladder management in individuals with SCI. Here in one document are the various options for bladder management, laid out in clear and concise language, and accompanied by the scientific arguments for the use of each option.

Individuals today have lots of options available for safe management of the bladder following SCI. However, as with many decisions in medicine, there is rarely one perfect solution that will meet each person’s needs. A comprehensive assessment of the options available is necessary to find the management approach that will best fit his or her unique anatomy, neurophysiology, functional abilities, medical comorbidities, and social life. The decision often requires choosing the best option from among several imperfect solutions. To make the process successful requires the expertise of many persons, the most important of whom is the individual with SCI. Because compliance with any bladder management approach is the key to its success, it is essential for the individual with SCI to be both knowledgeable about and comfortable with daily implementation of the program.

This document is the ninth clinical practice guideline published by the Consortium for Spinal Cord Medicine under the auspices of the Paralyzed Veterans of America. It offers exceptional insight into the appropriate management techniques of the neurogenic bladder based on science and clinical expertise. It does not prescribe one bladder management technique over another, but rather provides a compendium of management options, many of which may be appropriate for any one individual.

In creating this document, each distinguished guideline development panel member brought to the table her or his energy, dedication, and passion for the care of people with SCI. The panel worked as a magnificent team under the leadership of panel chair Todd Linsenmeyer, MD, who deserves special thanks from the consortium steering committee for his enduring commitment and leadership. Special thanks also go to representatives of the consortium’s 21 member organizations, who thoughtfully and critically reviewed the draft in its various forms. Their input was essential to making this document one that will improve both the quality of care and the quality of life for persons with SCI.

Michael Priebe, MD
Chair, Steering Committee
Acknowledgments

The chairman and members of the bladder management guideline development panel wish to express special appreciation to the individuals and professional organizations who are members of the Consortium for Spinal Cord Medicine and to the expert clinicians and health-care providers who reviewed the draft document. Special thanks go to the consumers, advocacy organizations, and staff of the numerous medical facilities and spinal cord injury rehabilitation centers who contributed their time and expertise to the development of this guideline.

Karen Schoelles, MD, and colleagues at MetaWorks, Inc., Medford, Massachusetts, served as consultant methodologists. They masterfully conducted the initial and secondary-level literature searches, evaluated the quality and strength of the scientific evidence, constructed evidence tables, and graded the quality of research for all identified literature citations. This included an evaluation of currently used grading schema and development of a new, innovative method for grading specialized spinal cord injury and related rehabilitation research.

Members of the consortium steering committee, representing 22 professional, payer, and consumer organizations, were joined in the guideline development process by more than 35 expert reviewers. Through their critical analysis and thoughtful comments, the recommendations were refined and additional supporting evidence from the scientific literature was identified. The quality of the technical assistance by these dedicated reviewers contributed significantly to the professional consensus building that is achieved through the guideline development process. Attorney William H. Archambault conducted a comprehensive analysis of the legal and health policy issues associated with this complex, multifaceted topic.

The guideline development panel is grateful for the many technical support services provided by various departments of the Paralyzed Veterans of America. In particular, the panel recognizes J. Paul Thomas and Kim S. Nalle in the consortium coordinating office for their help in organizing and managing the process; James A. Angelo and Kelly Saxton in the PVA Communications Program for their guidance in writing, formatting, and creating art; and medical editor Joellen Talbot for her excellent technical review and editing of the clinical practice guideline. Appreciation is expressed for the steadfast commitment and enthusiastic advocacy of the entire PVA board of directors and of PVA's senior officers, including National President Randy L. Pleva, Sr.; Immediate Past President Joseph L. Fox, Sr.; Acting Executive Director Homer S. Townsend, Jr.; Acting Deputy Executive Director Louis Irvin; and Director of Research, Education, and Practice Guidelines Thomas E. Stripling. Their generous financial support has made the Consortium for Spinal Cord Medicine and its guideline development process a success.
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Summary of Recommendations

Intermittent Catheterization

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

2. Consider avoiding intermittent catheterization in individuals with 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.

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.

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

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

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

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

8. Monitor individuals using this method of bladder management.

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.

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

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

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.
Indwelling Catheterization

1. Consider indwelling catheterization for individuals with:
   - Poor hand skills.
   - High fluid intake.
   - Cognitive impairment or active substance abuse.
   - Elevated detrusor pressures.
   - 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.

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.

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.

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

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.

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

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

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.

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

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.

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

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.

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

**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.

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

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.

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

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

**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.

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.

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.

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.

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

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

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.

4. Advise individuals of the potential for complications of endourethral stents, such as:
   - Tissue growth into the stent blocking urine flow.
   - Urethral pain.

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 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.

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 TURS.

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.

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

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.

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).

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).

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.

2. Consider bladder augmentation for females with paraplegia.

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.

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

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

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.

**Urinary Diversion**

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

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.

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.
   - Ureterosigmoidostomy.
   - Stomal stenosis.
   - Parastomal hernia.
   - Intestinal obstruction due to adhesions.
   - Urinary infection and stone disease.

**Cutaneous Ileovesicostomy**

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

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).
The Consortium for Spinal Cord Medicine

Seventeen organizations, including the Paralyzed Veterans of America, joined in a consortium in June 1995 to develop clinical practice guidelines in spinal cord medicine. A steering committee governs consortium operation, leading the guideline development process, identifying topics, and selecting panels of experts for each topic. The steering committee is composed of one representative with clinical practice guideline experience from each consortium member organization. PVA provides financial resources, administrative support, and programmatic coordination of consortium activities.

After studying the processes used to develop other guidelines, the consortium steering committee unanimously agreed on a new, modified, clinical/epidemiologic evidence-based model derived from the Agency for Health Care Research and Quality (AHRQ). The model is:

- Interdisciplinary, to reflect the varied perspectives of the spinal cord medicine practice community.
- Responsive, with a timeline of 12 months for completion of each set of guidelines.
- Reality-based, to make the best use of the time and energy of the busy clinicians who serve as panel members and field expert reviewers.

The consortium’s approach to the development of evidence-based guidelines is both innovative and cost-efficient. The process recognizes the specialized needs of the national spinal cord medicine community, encourages the participation of both payer representatives and consumers with spinal cord injury, and emphasizes the use of graded evidence available in the international scientific literature.

The Consortium for Spinal Cord Medicine is unique to the clinical practice guidelines field in that it employs highly effective management strategies based on the availability of resources in the health-care community; it is coordinated by a recognized national consumer organization with a reputation for providing effective service and advocacy for people with spinal cord injury and disease; and it includes third-party and reinsurance payer organizations at every level of the development and dissemination processes. The consortium expects to initiate work on two or more topics per year, with evaluation and revision of previously completed guidelines as new research demands.

Guideline Development Process

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.

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.
The benefits of clinical practice guidelines for the spinal cord medicine practice community are numerous. Among the more significant applications and results are the following:

- Clinical practice options and care standards.
- Medical and health professional education and training.
- Building blocks for pathways and algorithms.
- Evaluation studies of guidelines use and outcomes.
- Research gap identification.
- Cost and policy studies for improved quantification.
- Primary source for consumer information and public education.
- Knowledge base for improved professional consensus building.

**Methodology**

**Grading of the Scientific Evidence**

**OBJECTIVE**

The objective of this Metaworks, Inc., project was to provide methodologic support services for the development of clinical practice guidelines by the Consortium for Spinal Cord Medicine, sponsored by the Paralyzed Veterans of America. The main component of the project was to conduct a systematic review of the recent English language literature on bladder management of individuals with spinal cord injuries. The focus of the review was the evaluation of various types of bladder management methods, taking into consideration each one’s advantages/indications, disadvantages/contraindications, impact on prevention of upper tract (kidney) and lower tract (bladder) complications, and consequences on social life (e.g., lifestyle independence, sexuality, cost).

**BACKGROUND**

Bladder management is a crucial element in improved outcomes for individuals with spinal cord injury. The goal 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. There is no “gold standard” for methods of bladder management, so this review is intended to provide insight into each method and to help individuals with SCI choose the approach that will work best for them.

**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 (Cook, Mulrow, and Haynes, 1997; Sacks et al., 1987). 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:

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 search.
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.

**SEARCH YIELD**

The searches yielded 1,421 abstracts. When all the abstracts were downloaded, a level 1 screening was performed in which the abstracts were reviewed against the exclusion criteria. The full article was obtained for all accepted abstracts and for those abstracts for which a clear determination could not be made. The full articles of 214 accepted studies underwent a level 2 screening in which both the inclusion and exclusion criteria were applied. After the level 2 screening was completed, all accepted articles were then eligible for data extraction. Any study that was rejected at this level was reviewed by two researchers and listed in a reject log. This process resulted in 71 papers being accepted for data extraction. An additional 11 papers were linked publications (additional publications for a given cohort of individuals).

**DATA EXTRACTION AND DATABASE DEVELOPMENT**

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. The following data elements were extracted, when possible, from each accepted study.

**Study Characteristics**

- Author and/or study name.
- Publication year.
- Geographic location (North America, Europe, Other).
- Study design: interventional (RCT, nRCT, UCS) or observational (prospective or retrospective cohort).
- Level of evidence (I–III).
- Study quality score (for RCTs only).
- Industry sponsorship (company name or not reported).
- Study duration and/or follow-up.
- Study sample (number of individuals enrolled).
- Voiding method (intermittent catheter, indwelling catheter, reflex voiding, Credé/Valsalva).
- Procedure/treatment to facilitate bladder management (e.g., surgery, pharmacology, acupuncture).
Special population or condition (e.g., females, acute phase, detrusor-external sphincter dyssynergia, bladder cancer, autonomic dysreflexia).

Type of outcomes available (clinical, complications, quality of life, urodynamics, utilization/cost).

Study primary objective.

Authors’ conclusions.

Baseline Individual Characteristics (For each treatment group)

Total number of individuals enrolled/assessed.

Age (mean or median, range).

Gender distribution (males/females).

Race (White, Hispanic, Black, Asian, other).

Duration of spinal cord injury (mean or median, range).

Level of injury (cervical, thoracic, sacral, lumbar, composite).

Spinal cord lesions: complete, incomplete.

Previous sphincterotomy (number of individuals).

Method of bladder drainage (intermittent catheter, indwelling catheter, reflex voiding, other).

Number of individuals with:
- Continence or incontinence.
- Areflexia.
- Detrusor-external sphincter dyssynergia.
- Autonomic dysreflexia.
- Poor bladder compliance.
- Recurrent urinary tract infections.
- Vesicoureteral reflux.
- Hydronephrosis.
- Chronic pyelonephritis.
- Other urologic complications.

Urodynamic evaluation:
- Bladder capacity (ml).
- Maximum detrusor pressure (cm H₂O).
- Compliance (ml/cm H₂O).
- Post-void residual volume (ml).
- Other urodynamic measures (maximum end-filling pressure, leak point pressure, urethral closure pressure, duration of contraction).

Interventions (To manage bladder emptying)

Techniques: intermittent catheterization, reflex voiding, Credé/Valsalva.

Devices: indwelling catheters (urethral Foley, suprapubic).

Surgery: sphincterotomy, endourethral stents, rhizotomy and neurostimulator implantation, other urologic surgery.

Pharmacological management: local/systemic (anticholinergic medications, alpha-blockers, botulinum toxin injection).

Other: acupuncture.

Clinical Outcomes (Efficacy and safety of each intervention)

Assessment time point.

Definition of response/success.

Number of individuals with response/success.

Method of bladder drainage.

Medications used to facilitate bladder drainage.

Number of individuals with:
- Continence.
- Incontinence (improved/no change/worse/present or new).
- Areflexia.
- Poor bladder compliance.
- Detrusor-external sphincter dyssynergia (improved/no change/worse/present or new).
- Autonomic dysreflexia (improved/no change/worse/present or new).
- Recurrent urinary infections (improved/no change/worse/present or new).
- Vesicoureteral reflux (improved/no change/worse/present or new).
• Hydronephrosis (improved/no change/worse/present or new).
• Bladder neck obstruction (improved/no change/worse/present or new).
• Bladder calculi.
• Renal calculi.
• Chronic pyelonephritis.
• Renal failure.
• Urethral stricture.
• Other urologic complications.

Complications of the intervention.
Number of deaths.

Urodynamic Outcomes
- Bladder capacity (ml).
- Maximum detrusor pressure (cm H₂O).
- Compliance (ml/cm H₂O).
- Post-void residual volume (ml).
- Other.

Economic (Utilization) Outcomes
- Hospitalization frequency (number of individuals hospitalized per unit time).
- Emergency room visits (per unit time).
- Cost of treatment (hospitalizations, emergency room visits, pharmacy, other).
- Humanistic outcomes:
  - Quality of life before and after intervention or therapy.
  - Quality of life instrument name and score or number of individuals with improved/worse/no change.

EVIDENCE ANALYSIS
All studies accepted for data extraction were given a grade for Level of Evidence using the criteria described below. In addition, randomized clinical trials were assessed using the Jadad Quality Score Assessment (“Index to Measure the Likelihood of Bias in Pain Research Reports”). Industry sponsorship was also noted.

Levels of Evidence
The concept of levels of evidence grew out of the work of the Canadian Task Force for the Periodic Health Examination, which tied recommendations for preventive health measures to an assessment of the supporting evidence in the published literature.

For this review, the assignment of levels of evidence was based on the following criteria from the Steering Committee on Clinical Practice Guidelines for the Care and Treatment of Breast Cancer published by the Canadian Medical Association:

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.

These five levels of evidence do not directly describe the quality or credibility of evidence. Rather, they indicate the nature of the evidence being used. In general, a randomized, controlled trial has the greatest credibility (level I); however, it may have defects that diminish its value, and these should be noted. Evidence that is based on too few observations to give a statistically significant result is classified as level II. In general, level III studies carry less credibility than level I or II studies, but credibility is increased when consistent results are obtained from several level III studies carried out at different times and in different places.

Decisions must often be made in the absence of published evidence. In these situations it is necessary to use the opinion of experts based on their knowledge and clinical experience. All such evi-
evidence is classified as “opinion” (levels IV and V). A distinction is made between the published opinion of authorities (level IV) and the opinion of those who contributed to these guidelines (level V). However, it should be noted that by the time level V evidence has gone through the exhaustive consensus-building process used in the preparation of these guidelines, it has achieved a level of credibility that is at least equivalent to level IV evidence.

## 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 Table 1. 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.

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>The guideline recommendation is supported by one or more level I studies.</td>
</tr>
<tr>
<td>B</td>
<td>The guideline recommendation is supported by one or more level II studies.</td>
</tr>
<tr>
<td>C</td>
<td>The guideline recommendation is supported only by one or more level III, IV, or V studies.</td>
</tr>
</tbody>
</table>


Category A requires that the recommendation be supported by scientific evidence from at least one properly designed and implemented randomized, controlled trial, providing statistical results that consistently support the guideline statement. Category B requires that the recommendation be supported by scientific evidence from at least one small randomized trial with uncertain results; this category also may include small randomized trials with certain results where statistical power is low. Category C recommendations are supported by either nonrandomized, controlled trials or by trials for which no controls are used.

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, as shown in Table 2. 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.

### Table 2

<table>
<thead>
<tr>
<th>Levels of Panel Agreement with Recommendations</th>
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<tbody>
<tr>
<td>Level</td>
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<td>Low</td>
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<tr>
<td>Moderate</td>
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<tr>
<td>Strong</td>
</tr>
</tbody>
</table>

## References


Other useful sources include the following: Canadian Task Force on Preventive Health Care, www.cdphc.org

Centre for Evidence Based Medicine, www.minervation.com/cebm/docs/levels.html

The Scottish Intercollegiate Guidelines Network, www.sign.ac.uk/

Introduction

More than 200,000 people in the United States live with a spinal cord injury (SCI) as a result of trauma. Each year approximately 10,000 new injuries occur. The average age of injury is 30.7. At the time of discharge from acute rehabilitation centers, 53 percent have tetraplegia, 46 percent have paraplegia, and less than 1 percent experience complete neurologic recovery; 48 percent have complete injuries, and 52 percent have incomplete injuries. When considering treatment options, it is important to note that 11 percent of individuals with SCI have an associated head injury, which may make it more difficult for them to comply with certain bladder management programs.

The vast majority of those with SCI and neurologic impairment also have voiding dysfunctions. Even those who are able to ambulate and who have very incomplete injuries may have abnormalities in bladder function, causing social issues, such as urinary incontinence. Discussions often focus on a person’s “neuroanatomy and neurophysiology of the urinary tract.” However, changes in the lower tract may cause upper and lower tract complications, often have a direct impact on the kidneys. These voiding dysfunctions may cause upper and lower tract complications. Three important goals when deciding on a bladder management program are to: (1) preserve the upper tract, (2) minimize lower tract complications, and (3) be compatible with the person’s lifestyle.

Anatomy and Physiology of the Upper and Lower Urinary Tracts

When considering the various types of bladder management, it is important to understand the neuroanatomy and neurophysiology of the urinary tract. Discussions often focus on a person’s “neurogenic bladder.” However, changes in the lower tract may cause poor drainage or high bladder pressures, often have a direct impact on the kidneys. Therefore, even though this discussion will treat the kidneys and bladder separately as part of the upper and lower urinary tracts, one needs to consider them as a single unit.

Upper Urinary Tract

The kidney consists of two parts, the renal parenchyma and the collecting system. The renal parenchyma secretes, concentrates, and excretes urine into the collecting system. Peristaltic waves propel urine down the ureters to the bladder. Ureteral dilatation for any reason results in inefficient propulsion of the urine bolus, which can delay drainage proximal to that point. This can result in further dilatation and over time lead to hydronephrosis.

Beginning at the place where the ureters connect to the bladder (ureterovesical junction), the ureters tunnel obliquely between the muscular and submucosal layers of the bladder wall 1 to 2 cm before opening into the bladder at the ureteral orifices. This submucosal tunnel is designed to allow urine to flow into the bladder and to prevent reflux into the ureter. Any increase in intravesical pressure simultaneously compresses the submucosal ureter and effectively creates a one-way valve. This configuration is important in preventing reflux.

Unfortunately, this same configuration can inhibit urine drainage from the kidneys if there are sustained high intravesical (bladder wall) pressures.

Lower Urinary Tract

Anatomically, the bladder is divided into the detrusor and the trigone. The detrusor is composed of smooth muscle bundles that freely crisscross and interlace with each other. Near the bladder neck, the muscle fibers assume three distinct layers. The circular arrangement of the smooth muscles at the bladder neck allows them to act as a functional sphincter. The trigone is located at the inferior base of the bladder and extends from the ureteral orifices to the bladder neck.

Traditionally, the urethra has been thought to have two distinct sphincters, the internal and the external, or rhabdosphincter. The internal sphincter is not a true anatomic sphincter. Instead, in both males and females, the term refers to the junction of the bladder neck and proximal urethra, formed from the circular arrangement of connective tissue and smooth muscle fibers that extend from the bladder. This area is considered to be a functional sphincter because there is a progressive increase in tone with bladder filling so that the urethral pressure is greater than the intravesical pressure. These smooth muscle fibers also extend submucosally down the urethra and lie above the external sphincter. The internal urethral sphincter has been described as being under the control of the autonomic system. This area has a large number of sympathetic alpha-receptors, which cause closure when stimulated.

The external urethral sphincter has somatic innervation from the sacral region (S2–S4) via the pudendal nerve, allowing the sphincter to be closed at will. In males, the external sphincter has
the bulk of the fibers found at the membranous urethra, but fibers also run up to the bladder neck. In females, striated skeletal muscle fibers circle the upper two-thirds of the urethra. In non-SCI individuals, it is under voluntary control.

Changes frequently occur after SCI. In those with SCI, the distinction between the internal and external sphincter becomes less clear. There may be substantial invasion of the alpha-adrenergic nerve fibers in the smooth and striated muscle in the urethra of individuals with SCI with lower motor neuron lesions. Moreover, those with SCI frequently do not have control of their external sphincter. If the sphincter does not relax when the bladder is relaxing (detrusor sphincter dyssynergia), high pressures often build in the bladder, which can affect kidney drainage. In those with sacral injuries, there may be less ability of the sphincter to contract, allowing urinary incontinence to occur. This will be discussed further when discussing the various types of SCI.

**Neuroanatomy of the Lower Urinary Tract**

Bladder storage and emptying is a function of interactions among the peripheral parasym pathetic, sympathetic, and somatic innervation of the lower urinary tract. Additionally, there is modulation from the central nervous system.

The parasympathetic efferent (motor) supply originates from the sacral cord at S2–S4. Sacral efferents travel via the pelvic nerves to provide excitatory input to the bladder. Parasympathetic bladder receptors are called cholinergic because the primary postganglionic neurotransmitter is acetylcholine. These receptors are distributed throughout the bladder. Stimulation causes a bladder contraction.

The sympathetic efferent nerve supply to the bladder and urethra begins in the intermediolateral gray column from T11 through L2 and provides inhibitory input to the bladder. Sympathetic impulses travel a relatively short distance to the lumbar sympathetic paravertebral (sympathetic) ganglia. From here the sympathetic impulses travel over long postganglionic fibers in the hypogastric nerves to synapse at alpha- and beta-adrenergic receptors within the bladder and urethra. The primary postganglionic neurotransmitter for the sympathetic system is norepinephrine.

Sympathetic efferent stimulation facilitates bladder storage. This is because of the strategic location of the adrenergic receptors. Beta-adrenergic receptors predominate in the superior portion (i.e., body) of the bladder. Stimulation of beta receptors causes smooth muscle relaxation so the bladder wall relaxes. Alpha-receptors have a higher density near the base of the bladder and prostatic urethra; stimulation of these receptors causes smooth muscle contractions of the sphincter and prostate, which increases the outlet resistance of the bladder and prostatic urethra.

After SCI, changes in receptor location, density, and sensitivity may occur. Evidence exists that there is invasion of alpha-receptors into the external striated sphincter so that it responds to alpha stimulation. Moreover, when smooth muscle is denervated, its sensitivity to a given amount of neurotransmitter increases (i.e., denervation supersensitivity). As a result, smaller doses of various pharmacologic agents would be expected to have a much more pronounced effect in those with SCI as compared to those with nonneurogenic bladders.

Recently scientists have been gaining a better understanding of the afferent (sensory) system of the bladder. The most important afferents pass to the sacral cord via the pelvic nerves. These afferents are of two types: small myelinated A-delta and unmyelinated (C) fibers. The small myelinated A-delta fibers respond in a graded fashion to bladder distention and are essential for normal voiding. The unmyelinated (C) fibers have been termed “silent C-fibers” because they do not respond to bladder distention and therefore are not essential for normal voiding. These “silent C-fibers” exhibit spontaneous firing when they are activated by chemical or cold temperature irritation at the bladder wall. These unmyelinated (C) fibers have been found to “wake up” and respond to distention and to stimulate uninhibited (involuntary) bladder contractions in animals with suprasacral SCI. This has been further confirmed in studies with two C-fiber neurotoxins, capsaicin and resiniferous (RTX) toxin. Both of these experimental agents dramatically block uninhibited bladder contractions. Further work is being done on their potential for clinical use.

**Voiding Centers**

Facilitation and inhibition of voiding is under three main centers, the sacral micturition center; the pontine micturition center, and the higher centers (cerebral cortex).

The sacral micturition center (S2–S4) is primarily a reflex center in which efferent parasympathetic impulses to the bladder cause a bladder contraction, and afferent impulses to the sacral micturition center provide feedback regarding bladder fullness.

The pontine micturition center is primarily responsible for coordinating relaxation of the urinary sphincter when the bladder contracts. Suprasacral SCI disrupts the signals from the pontine micturition center, which is why detrusor
sphincter dyssynergia is common in those with suprasacral SCI. The net effect of the cerebral cortex on micturition is inhibitory to the sacral micturition center. Because suprasacral SCI also disrupts the inhibitory impulses from the cerebral cortex, those with suprasacral SCI frequently have small bladder capacities with involuntary (uninhibited) bladder contractions.

**Classification of Voiding Dysfunction**

**SUPRAPONTINE LESIONS**

Any suprapontine lesion may affect voiding. Lesions may result from cerebrovascular disease, hydrocephalus, intracranial neoplasms, traumatic brain injury, Parkinson’s disease, and multiple sclerosis. The expected urodynamic finding following a suprapontine lesion is detrusor hyperreflexia (overactive bladder) without detrusor sphincter dyssynergia (DSD). Normally the sphincter should remain relaxed during the bladder contraction. Detrusor sphincter dyssynergia occurs when the sphincter intermittently tightens during the contraction. It is important to note that the voiding dysfunction may be very different from expectations due to various factors, such as medications, prostate obstruction, and possible normal bladder function but poor cognition.

**SUPRASACRAL SPINAL CORD LESIONS**

Traumatic suprasacral SCI results in an initial period of spinal shock, during which there is detrusor areflexia. During this phase, the bladder has no contractions. The neurophysiology for spinal shock and its recovery is not known. Recovery of bladder function usually follows recovery of skeletal muscle reflexes. Uninhibited bladder contractions gradually return after 6 to 8 weeks.

Clinically, a person with a traumatic suprasacral SCI may begin having episodes of urinary incontinence and various visceral sensations, such as tingling, flushing, increased lower extremity spasms, or autonomic dysreflexia with the onset of uninhibited contractions. As uninhibited bladder contractions become stronger, the post-void residuals (PVRs) decrease. Eventually these individuals develop uninhibited contractions. Unfortunately, high intravesical voiding pressures usually are required for the development of a balanced bladder. It has been found that high voiding pressures and prolonged duration of the bladder contractions may cause hydronephrosis and renal deterioration. Urodynamic studies are used to determine these voiding parameters.

Detrusor-external sphincter dyssynergia (DESD) also commonly occurs following suprasacral lesions. DESD is defined as intermittent or complete failure of relaxation of the urinary sphincter during a bladder contraction and voiding. It has been reported to occur in 96 percent of individuals with suprasacral lesions. In addition to DESD, internal sphincter dyssynergia also has been reported, often occurring at the same time as detrusor-external sphincter dyssynergia. In this guideline the term detrusor sphincter dyssynergia will be used throughout to refer to the entire sphincter mechanism—internal and external sphincter.

**SACRAL LESIONS**

A variety of lesions can affect the sacral cord or roots. Damage to the sacral cord or roots generally results in a highly compliant acontractile bladder; however, particularly in individuals with partial injuries, the areflexia may be accompanied by decreased bladder compliance resulting in progressive increases in intravesical pressure with filling (Herschorn and Hewitt, 1998). The exact mechanism by which sacral parasympathetic decentralization of the bladder causes decreased compliance is unknown.

It has been noted that the external sphincter is not affected to the same extent as the detrusor. This is because the pelvic nerve innervation to the bladder usually arises one segment higher than the pudendal nerve innervation to the sphincter. Also, the nuclei are located in different portions of the sacral cord, with the detrusor nuclei located in the intermediolateral cell column and the pudendal nuclei located in the ventral gray matter. This combination of detrusor areflexia and an intact sphincter helps contribute to bladder overdistention and decompensation.

**Urologic Evaluation**

Generally, a urologic evaluation is done every year; although there is no consensus among doctors on the frequency this type of exam should be performed or the range of tests that should be included.

The important components of the urologic evaluation are an assessment of both the upper and lower tracts. Upper tract evaluations include tests that evaluate function, such as renal scans and tests that evaluate anatomy, such as ultrasound, CT scans, and intravenous pyelograms (IVP). Renal scans are frequently used to screen the upper tract because they are not user dependent, do not have a risk of allergic reactions, do not require a bowel prep, and cause much less radiation exposure than a CT scan or IVP.

Lower tract evaluations include urodynamics to determine bladder function, cystograms to eval-
uate for vesicoureteral reflux, and cystoscopy to evaluate bladder anatomy. It should be noted that urodynamics is an important evaluation for determining bladder function. Unfortunately, history, level of injury, and signs and symptoms alone are not enough to determine if a person is experiencing high intravesical pressures, which may cause renal complications over time.

**Urology Follow-up**

No studies have been done on the optimum frequency of follow-up evaluations. Many medical centers evaluate upper and lower tract functioning on an annual basis. Urological evaluations are done more frequently if an individual is having problems, changing medications, or altering bladder management in some way.

**DEFINITION OF URINARY TRACT INFECTION**

Urinary tract infections (UTIs) are mentioned throughout the guideline. Because of the number of definitions of urinary tract infections that exist, the guideline development panel decided to use the definition for symptomatic UTIs agreed upon by the National Institute on Disability and Rehabilitation Research (NIDRR) Consensus Statement, “Prevention and Management of Urinary Tract Infection among People with SCI” (1992). This definition states that three criteria must be met for an individual to be considered as having a UTI: (1) significant bacteriuria, (2) pyuria (increased white blood cells in the urine), and (3) signs and symptoms.

Criteria for significant bacteriuria (the number of bacteria that signify that the bacteria are truly from the bladder and not just a contaminant) depend on the method of bladder management being used:

- For those on intermittent catheterization = $10^2$ colony forming units (cfu).
- For those using clean-void specimens from catheter-free males who use external condom collecting devices = 104 cfu.
- For those with specimens from indwelling catheters, any detectable concentration (Gribble, 1994).

Because a UTI implies bacteriuria with tissue invasion, leukocytes in the urine (pyuria) are generated by the mucosal lining. This tissue invasion also results in signs and symptoms, which may include one or more of the following: (1) leukocytes (increased white blood cells, or WBCs) in the urine generated by the mucosal lining (on rare occasions gram positive bacteria do not provoke a WBC response); (2) discomfort or pain over the kidney or bladder, or during urination; (3) onset of urinary incontinence; (4) increased spasticity; (5) autonomic dysreflexia; (6) cloudy urine with increased odor; (7) malaise, lethargy, or sense of unease (NIDRR Consensus Statement, 1992).

**AUTONOMIC DYSREFLEXIA**

Autonomic dysreflexia is another term mentioned throughout this guideline. Autonomic dysreflexia can occur in individuals who have a spinal cord injury at thoracic level 6 (T6) or above. It occurs as a result of any noxious stimuli. The most common causes are bladder distention (which provokes uninhibited bladder contractions and sphincter dyssynergia) and bowel problems such as constipation and impaction.

The most dramatic problem associated with autonomic dysreflexia is a sudden severe elevation in blood pressure. Those with an SCI at or above T6 frequently have a normal systolic blood pressure in the 90–110 mm Hg range. Autonomic dysreflexia is frequently defined in adults as a systolic blood pressure greater than 140 mm Hg. Another definition is a systolic blood pressure 20 to 40 mm Hg above baseline. Systolic blood pressures elevations more than 15–20 mm Hg above baseline in adolescents with SCI or more than 15 mm Hg above baseline in children may be a sign of autonomic dysreflexia.

Other common problems that can occur in autonomic dysreflexia include severe headache, sweating, flushing, goose bumps, chills, feelings of anxiety, and a slower pulse rate. However, about 30 percent to 40 percent of people with autonomic dysreflexia have elevated blood pressures with few if any other symptoms (silent dysreflexia).

If autonomic dysreflexia occurs, immediately sit the person up (if the person is supine), loosen any clothing or constrictive devices, monitor the blood pressure and pulse frequently, and quickly survey the individual for possible causes, beginning with the urinary system. If the cause is not obvious, seek immediate emergency treatment.

For more information on autonomic dysreflexia see:

- A written copy of the guideline may be downloaded for free at www.pva.org.
Recommendations

Intermittent Catheterization

Intermittent catheterization is a method by which an individual with SCI or his or her caregiver empty the bladder at a specified time frequency by inserting a catheter into the bladder, draining the bladder, and then removing the catheter. Intermittent catheterization does not require an intact sacral micturition reflex to be present. The method is an effective alternative during spinal shock when the bladder is not contracting. Intermittent catheterization provides complete bladder emptying and offers a practical means of obtaining a catheter-free state.

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).

   **Rationale:** Intermittent catheterization provides a method of emptying the neurogenic bladder without leaving an indwelling catheter and lessens the frequency of long-term complications such as hydronephrosis, bladder and renal calculi, and autonomic dysreflexia encountered with other methods of neurogenic bladder management (Bennett et al., 1995; Chai et al., 1995; Chua, Tow, and Tan, 1996; Dmochowski, Ganabathi, and Leach, 1995; Giannantoni et al., 1998; Perkash and Giroux, 1993). Intermittent catheterization should not be used in individuals who do not have adequate hand function to perform the procedure themselves or who do not have a caregiver willing and able to perform this function. Additionally, an alternative to intermittent catheterization may be needed in individuals with:

   - Abnormal urethral anatomy such as stricture, false passages, and bladder neck obstruction.
   - Bladder capacity less than 200 ml.
   - Poor cognition, little motivation, inability or unwillingness to adhere to the catheterization time schedule or the fluid intake regimen, or adverse reaction toward having to pass the catheter into the genital area multiple times a day.

2. **Consider avoiding intermittent catheterization in individuals with 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)

   **Rationale:** Intermittent catheterization requires insertion of a catheter into the bladder at a routine time interval to prevent overdistention of the bladder. Inability to catheterize oneself and/or lack of a willing caregiver to perform the catheterization may lead to bladder overdistention. Urethral abnormalities may make it difficult to pass the catheter into the bladder to prevent bladder overdistention. High fluid intake may require frequent catheterization, which may not be practical. Aversion to passing a catheter into the bladder may lead to overdistention. Upper tract complications can still occur with intermittent catheterization in the presence of high bladder pressures (Dmochowski, Ganabathi, and Leach, 1995; Giannantoni et al., 1998; Weld and Dmochowski, 2000; Weld et al., 2000; Zermann et al., 2000).

3. **Advise individuals with SCI of the potential for complications with intermittent catheterization, such as:**

   - Urinary tract infections.
   - Bladder overdistention.
   - Urinary incontinence.
1. Urethral trauma with hematuria.

2. Urethral false passages.

3. Urethral stricture.

4. Autonomic dysreflexia (in those with injuries at T6 and above).

5. Bladder stones.

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

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

8. Monitor individuals using this method of bladder management.

**Rationale:** Lower infection rates can be achieved with sterile techniques and with prelubricated self-contained catheter sets (Giannantoni et al., 2001; Waller et al., 1995).

**Rationale:** Individuals may leak urine between catheterizations for various reasons, such as urinary tract infections, problems with the bladder or sphincter, or problems with fluid intake. Upper tract complications still occur with intermittent catheterization in the presence of high bladder pressures (Dmochowski, Ganabathi, and Leach, 1995; Giannantoni et al., 1998; Weld and Dmochowski, 2000; Weld et al., 2000; Zermann et al., 2000). Bladder capacity can be increased, and uninhibited contractions can be decreased, with the use of anticholinergic medications or with botulinum toxin injections (see Botulinum Toxin Injection).

**Nursing Considerations for Intermittent Catheterization**

Individuals who choose intermittent catheterization for bladder management will need education on proper techniques and care as well as routine follow-up to detect potential complications. There are many variations on intermittent catheter technique and care. One example follows.

**Catheter selection:** The catheter should be easy to insert without trauma or curling in the
urethra. If a latex allergy is present, nonlatex catheters must be used. A nonlatex product with straight tip is recommended. (For types of catheters and economic considerations, see appendix A.)

**Hand washing.** Hands should be washed or aseptic towelettes used both before and after catheterization.

**Technique.** Follow the procedure recommended by the prescribing institution, health-care professional, national guideline, or health-care organization.

**Catheter care.** To control introduction of bacteria into the bladder, catheters must be washed after every use. Rinsing and allowing catheters to air-dry between each use was found to be the most effective means of keeping the bacteria count low on catheters (Lavallee et al., 1995). Catheters should be cleaned with mild soap and water, air-dried, and placed in a paper bag until ready to reuse. If recurrent urinary tract infections are a problem, latex catheters can be sterilized by heating them in a microwave oven (Mervine and Temple, 1997).

**Recurrent urinary tract infections.** Symptoms of UTIs need to be investigated and documented as follows:

- **Technique and bladder check:** The catheterization technique should be assessed and the bladder checked for stones, mucus, or other debris.

- **Single-use catheter:** If no reason for UTIs can be found, a single-use catheter may be used to see if UTIs subside.

- **Single-use hydrophilic catheter:** If urethral irritation appears to be the cause, a single-use hydrophilic catheter may be tried. Sterile water for injection, which may or may not be included with the catheter, needs to be used to activate this type of catheter.

- **Antibacterial catheter:** If UTIs continue, a single-use catheter impregnated with an antibacterial substance may be tried.

**Touchless catheter.** When toilet facilities are not readily available, such as during sports activities or travel, a touchless catheter with a collection device may be a good alternative. These catheters, which are contained within the collection device, lubricate themselves as they are introduced into the urethra by a prelubricated outlet on the bag. When the bladder is drained, the catheter is withdrawn from the urethra and returned to the collection device, the top is capped, and the entire device discarded without ever being touched directly by the hands.

**Fluids.** Fluid consumption should be moderate and spaced throughout the day.

**Timing.** Catheterization typically occurs every 4–6 hours so that the amount of urine obtained with each collection is less than 500 ml. Individuals may need to awaken at night to catheterize.

**Assistance required.** Adequate hand function and sufficient cognitive ability are needed to insert the catheter or else a caregiver must be available to do so.

**Cosmesis.** No changes will be noted.

**Interference with social/sexual functioning.** None.

**Medications.** If urinary leakage and a high-pressure bladder (as determined by urodynamic studies) are creating difficulties, medications will be prescribed to help with overactive bladder. If urinary leakage is the result of an incompetent sphincter, additional medication may be prescribed. If the problem is catheterization at the bladder neck, an alpha-blocker may be prescribed to relax the bladder neck and facilitate catheterization.

**Reversibility.** This method can be discontinued at any time.

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Credé and Valsalva

Credé is a method of applying suprapubic pressure to express urine from the bladder. Credé is usually used when the bladder is flaccid or a bladder contraction needs to be augmented. The effectiveness of Credé is limited by sphincter pressure.

Valsalva is a method in which an individual uses the abdominal muscles and the diaphragm to empty the bladder. Valsalva is used when the bladder is flaccid from spinal cord injury affecting the sacral reflex arc or when the bladder contracts but does not empty completely. Valsalva increases intraabdominal pressure but does not ensure complete bladder emptying.
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)

**Rationale:** The use of Credé and Valsalva to empty the bladder may be appropriate in individuals with lower motor neuron injuries in which the bladder is flaccid and there is low outlet resistance. In this setting, Credé or Valsalva can manually empty the bladder. Emptying is more difficult if there is bladder outlet resistance or obstruction. Silent complications of the upper tract are not uncommon with this technique and should be routinely monitored (Chang et al., 2000; Giannantoni et al., 1998).

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

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

**Rationale:** Credé and Valsalva increase bladder pressure but do not empty the bladder effectively. Complications are frequent (Chang et al., 2000; Giannantoni et al., 1998). Individuals may experience inguinal hernias or prolapsed rectum due to excessive abdominal pressure.

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)

**Rationale:** During Credé and Valsalva voiding, there is an increase in intraabdominal and intravesical pressure, which may worsen hydronephrosis or reflux in the face of the bladder outlet obstruction or detrusor sphincter dyssynergia (Chang et al., 2000; Giannantoni et al., 1998). Increased intraabdominal and intravesical pressure increases sphincter activity and therefore detrusor sphincter dyssynergia. Hydronephrosis, vesicoureteral reflux, incomplete bladder emptying, urinary tract infections, and renal stones are potential complications of this method (Chang et al., 2000; Giannantoni et al., 1998; Weld and Dmochowski, 2000; Weld et al., 2000; Zermann et al., 2000).

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)

**Rationale:** Credé and Valsalva increase bladder pressure but do not empty the bladder effectively and can lead to complications from both high intravesical and abdominal pressure. Complications are frequent (Chang et al., 2000; Giannantoni et al., 1998; Weld and Dmochowski, 2000; Weld et al., 2000; Zermann et al., 2000).

## Indwelling Catheterization

Indwelling catheterization is a method of bladder management in which a catheter is inserted into the bladder and maintained in place for an extended period of time. Because there is an open conduit to the storage device, as bladder filling occurs, urine is continually emptied. Successful indwelling catheterization does not require bladder contractions, nor does it require coordinated action of the sphincter mechanism. Because complete bladder filling often does not occur and individuals who use indwelling catheterization tend to have uninhibited bladder contractions, bladder capacity and compliance tend to decrease over time. Indwelling catheterization can be accomplished by inserting a catheter through the urethra or by surgically placing a suprapubic catheter into the lower abdomen cephalic to the pubic bone. Although the care of and complications relating to both types of indwelling catheters are similar, a suprapubic catheter is less traumatic to the urethra and offers the possibility of genital activity with less preparation and fewer complications.

Indwelling catheterization is used in any individual with acute central nervous system trauma because it allows precise monitoring of urinary output, especially when maintaining fluid balance is critical. Additionally, indwelling catheterization is...
often used by individuals with chronic SCI who are unable to perform intermittent catheterization or reflex voiding, have uncontrollable urinary incontinence, have difficulty wearing continence devices, or have an acute medical condition warranting catheterization, or by those who prefer indwelling catheterization because it offers greater expediency and compatibility with their lifestyle.

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)

   **Rationale:** Multiple factors influence choice of bladder management method and subsequent success with bladder management after SCI. These include but are not limited to age, gender, medical comorbidities, body habitus, decade of injury, level and completeness of SCI, hand function, need for and availability of caregiver assistance, and spasticity (Bennett et al., 1995; MacDiarmid et al., 1995; Mitsui et al., 2000; Singh and Thomas, 1997; Yavuzer et al., 2000).

   The lack of an adequate external collecting system for females eliminates some bladder management options that are available to males. Upper extremity impairment due to cervical SCI or other abnormality, obesity, and spasticity make intermittent catheterization challenging for both males and females. As a result, females with tetraplegia with complete injuries are more likely to use indwelling catheterization (Singh and Thomas, 1997).

   Individuals with tetraplegia, regardless of gender, report greater satisfaction with suprapubic catheter use compared to clean intermittent catheterization (Mitsui et al., 2000). When intermittent catheterization is attempted, continued long-term use is less common among females, individuals with tetraplegia, and those with complete SCI because of the need for caregiver assistance, severe spasticity that interferes with intermittent catheterization, incontinence despite anticholinergic use, and lack of an external collecting device (Yavuzer et al., 2000). Therefore, it is common for females and individuals with high, complete tetraplegia either to choose indwelling catheterization or to have their health-care provider recommend it (Bennett et al., 1995). Each individual needs his or her choice of bladder management method individualized, based on the advantages and disadvantages of each method. Despite the additional complications associated with indwelling catheter use, this method—when well managed—is generally preferred over other methods if they cannot be performed properly.

   Risk of symptomatic infection is at least comparable to and may be more in individuals with indwelling catheters than those managing their bladders with clean intermittent catheterization. Although it is common for individuals using indwelling catheters to have asymptomatic bacteriuria, the significance of this is unknown. Conflicting data exist related to the risk of symptomatic infection in individuals using indwelling catheters versus other methods of bladder management. Reports indicate lower or relatively equal proportions of symptomatic urinary tract infection in individuals using indwelling catheterization compared with intermittent catheterization (Mitsui et al., 2000; Singh and Thomas, 1997). Retrospective studies report that individuals using indwelling catheterization tend to have more recurrent urinary tract infections (Larsen et al., 1997) and pyelonephritis (Weld and Dmochowski, 2000) than those using other bladder management methods. However, the proportion of symptomatic UTI is relatively low given the fairly universal bacteriuria in this population. For these reasons, the value of prophylactic antibiotics in this population remains unclear and is generally unwarranted except in select instances.

   Lastly, the use of indwelling catheterization is often effective as an initial and/or temporary treatment for vesicoureteral reflux. Further evaluation and follow-up is needed to determine the effectiveness of the indwelling catheter for this problem.

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 due to 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 epididymoorchitis.

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

**Rationale:** Suprapubic catheterization has several proven or theoretic benefits over urethral catheterization after SCI. In cases of urethral injury or abnormality, suprapubic catheterization is clinically indicated to prevent further urethral trauma. Complications, such as epididymitis, tend to be higher with urethral catheterization versus suprapubic catheterization, intermittent catheterization, and spontaneous voiding (Weld and Dmochowski, 2000). Additionally, for some people, sexual function and self-image may be enhanced with a suprapubic as opposed to an indwelling urethral catheter. Some individuals prefer a suprapubic catheter to a urethral catheter for comfort and convenience. Suprapubic catheters may be especially beneficial for females who are considering an indwelling catheter because females are more likely than males to have leakage around a urethral catheter as a result of incompetence (Bennett et al., 1995).

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)

**Rationale:** Instrumentation can further exacerbate urethral injury, which can lead to long-term complications such as stricture or difficulty voiding. Most urethral injuries are associated with clear traumatic events, such as blunt trauma after a motor vehicle crash, a penetrating injury due to a gun shot or stab wound, a sporting accident, fall, or an iatrogenic injury from a traumatic catheter placement. It is imperative that urethral trauma be diagnosed quickly and efficiently so that effective treatment measures can be implemented to prevent serious long-term complications. Often, urethral injuries accompany major trauma and immediate repair is unlikely because other life-threatening injuries preclude treatment (Koraitim, 1999; Sandler and McCallum, 2000).

Urethral injury should be suspected after pelvic fracture, traumatic catheterization, or penetrating injury near the urethra. Symptoms after SCI include hematuria, blood at the meatus, or a high-riding prostate gland. Diagnosis may require a high index of suspicion and is made by retrograde urethrogram. Placement of a urethral catheter should be avoided as this could result in further injury. In these cases, placement of a suprapubic catheter is preferred (Addison and Mould, 2000; Koraitim, 1996).

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

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

**Rationale:** Upper tract abnormalities can result from increased detrusor pressure. Leak point pressure above 40 cm H2O is associated with upper urinary tract deterioration. In a comparison of urodynamic changes over time in individuals with SCI, maximum detrusor pressure was lower and there was less bladder trabeculation in individuals using indwelling catheters than in those using clean intermittent catheterization, external collection, and spontaneous voiding (Cardenas, Mayo, and Turner, 1995; Weld, Graney, and Dmochowski, 2000). Bladder compliance is typically lower for individuals using indwelling catheters (Cardenas, Mayo, and Turner, 1995; Weld, Graney, and Dmochowski, 2000). The possible mechanism for this is the constant decompression of the bladder caused by the catheter and inflammation and infections related to the catheter leading to vesical wall fibrosis.

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)

**Rationale:** Multiple retrospective studies have shown that the complication rate is higher for someone using indwelling catheterization than other methods of bladder management (Larsen et al., 1997; Weld and Dmochowski, 2000; Weld et al., 2000). Specifically, strong evidence supports the increased risk of bladder stones (Mitsui et al., 2000; Larsen et al., 1997; MacDiarmid et al., 1995; Weld and Dmochowski, 2000) and renal stones (Mitsui et al., 2000; Larsen et al., 1997) in individuals using indwelling catheters, especially in the first six months after injury. The etiology of this phenomenon early after injury is likely multifactorial, with bladder management method, frequency of infection, and bone demineralization all playing roles. Recurrent bladder stones tend to be more common in females using indwelling catheters (Singh and Thomas, 1997). This could be due to the heightened inflammation and bacteriuria associated with indwelling catheter use.

Several factors may play a role in the deterioration of upper tract function in those managing their bladders with indwelling catheters (Weld et al., 2000). Mean serum creatinine is higher and mean creatinine clearance is lower for individuals managing their bladders with indwelling catheters compared with clean intermittent catheterization or spontaneous voiding. Proteinuria is higher for individuals using indwelling catheters (Weld et al., 2000). Bladders managed with long-term indwelling catheters tend to have lower compliance than those managed with intermittent catheterization or spontaneous voiding (MacDiarmid et al., 1995; Weld, Graney, and Dmochowski, 2000). This lower compliance can contribute to the development of pyelonephritis, upper tract stones, and vesicoureteral reflux (Weld, Graney, and Dmochowski, 2000; Weld and Dmochowski, 2000), which can further compromise upper tract function.

Lower tract complications are also prevalent after indwelling urethral catheter use. Although both indwelling catheterization and intermittent catheterization increase the risk of symptomatic lower tract infection, epididymitis, recurrent symptomatic urinary tract infection, and pyelonephritis seem to be elevated in relation to indwelling catheter use (Weld and Dmochowski, 2000).

Multiple retrospective studies have shown that the rate of bladder cancer is higher in individuals with SCI who manage their bladders with long-term indwelling catheters longer than 8 to 10 years (Groah et al., 2002; Stonehill et al., 1996; West et al., 1999). This risk could be due in part to the higher risk of recurrent infection, stones, and inflammation associated with catheter use. Although not necessarily the predominant histologic type of cancer, squamous cell carcinoma is more common in those using indwelling catheterization (Groah et al., 2002; Stonehill et al., 1996), and prognosis for survival after squamous cell cancer diagnosis is poor (Groah et al., 2002). However, it should also be noted that squamous cell cancer is rare, so even though there is a greater incidence in those with spinal cord injury, the number of individuals who develop squamous cell bladder cancer is actually low. The other type of bladder cancer—transitional cell—has known risk factors regardless of whether or not there is a spinal cord injury. For these reasons it is prudent to counsel individuals about the other risk factors for bladder cancer, such as smoking and certain occupational exposures, and then monitor them for this potential problem.

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)

**Rationale:** Recurrent urinary tract infection and bladder stones are risk factors for bladder cancer, and these complications tend to be more common in individuals using indwelling catheters. Often the neurogenic bladder uroepithelium has an abnormal appearance, characterized by mucosal erythema, edema, vascular telangiectasia, and histologic changes, which emphasizes the need for surveillance. Surveillance is therefore recommended for individuals with SCI using indwelling catheters long term. Options include cystoscopy, cytology, and random bladder biopsy. Other methods currently being developed may be options in the future.
Squamous cell carcinoma, which is a more aggressive type of cancer than transitional cell carcinoma, tends to occur more frequently in the SCI population using indwelling catheters compared with the non-SCI population, although it is not necessarily the predominant histologic type of bladder cancer in people with SCI who develop bladder cancer (Groah et al., 2002; West et al., 1999). Typically, squamous cell cancer is more common in underdeveloped countries where schistosomiasis infection (bilharzia) is endemic. The pathologic process involved in the development of squamous cell carcinoma of the bladder after schistosomiasis infection could also be due to recurrent bladder stones resulting from the parasitic infection or nitrates released in persons infected causing chronic inflammation. Hence, there may be similarities between the squamous cell cancer seen in individuals who manage their bladders with indwelling catheters and that seen in people infected with schistosomiasis, which can further help us understand the pathologic process after SCI.

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)

**Rationale:** Regular use of anticholinergics may be associated with improved bladder compliance, lower bladder leak point pressures, and less hydronephrosis, while infection rate, vesicoureteral reflux, renal scars, stones, and serum creatinine levels are not altered (Kim et al., 1997). Kim et al. reported that fewer individuals who managed their bladders with indwelling catheters and used oxybutynin had abnormal bladder compliance, abnormal bladder leak point pressures, and hydronephrosis.

**Nursing Considerations for Indwelling Catheters**

Individuals who choose indwelling catheterization for bladder management will need education on catheter care as well as routine follow-up to detect potential complications. There are many variations to indwelling catheter technique and care. One example follows:

**Catheter selection.** The type of catheter to be used will depend on the individual’s needs and condition. Individuals should be asked if they are allergic to latex, though nonlatex catheters are preferred to prevent a latex allergy from developing. Most catheters have 5 ml or 30 ml balloons. (For types of catheters and economic considerations, see appendix A.)

**Urethral catheters.** For urethral catheters #14Fr–16Fr is recommended. The balloon is gently filled with 5 to 10 ml of sterile water. Silicone catheters need to have the full 10 ml placed in their balloons because they are more porous in a drained bladder. Indwelling urethral catheters are replaced every 2 to 4 weeks by the individual or a knowledgeable caregiver. The longer a catheter is left in place the greater risk of catheter encrustation. Therefore in those with a history of catheter encrustation or bladder stones, strong consideration should be given to catheter changes every 1 to 2 weeks.

**Suprapubic catheters.** Suprapubic catheters (#22Fr–24Fr is recommended) are inserted by a qualified physician or other health-care provider who is trained in changing suprapubic catheters. There should be strong consideration to increasing the frequency of catheter change to every 1 to 2 weeks in those who develop catheter encrustation or stones. After that, the catheter is changed every 4 weeks by a knowledgeable caregiver. Suprapubic tubes are replaced immediately upon removal so that the tract to the bladder is not allowed to close.

**Anchoring the catheter.** A belt, tape, or other device is used to secure the catheter to the abdomen or thigh. Alternating sides to which the catheter is attached prevents urethral erosion and irritation of the legs and abdomen. A gauge tracheostomy pad or two folded 4x4s can be placed on either side of the suprapubic site to provide cushioning and prevent loose gauze fibers from entering into the suprapubic opening.

**Clogged catheters.** If concretions cause blockage and impede drainage, a silicone catheter can be used, or 30 mls of Renacidin can be instilled daily for 20–30 minutes and then allowed to drain to keep the catheter patent.

**Irrigation.** Daily irrigation of the catheter with normal saline or sterile water is not recommended because irrigation denudes the uroepithelium (Elliot et al., 1989).

**Intolerance to inflated catheter balloon.** If the stimulus of the catheter balloon causes autonomic dysreflexia, an anticholinergic medication may help suppress the uninhibited contractions and autonomic dysreflexia.
**Personal care.** The genital area is cleaned daily with mild soap and water.

**Care of equipment.** If daytime and nighttime urinary collection devices are being reused, they should be cleaned daily. A 1:10 solution of bleach to water has been shown to afford effective cleansing (Dille and Kirchhoff, 1993).

**Fluid intake.** Maintaining a high fluid intake (greater than 2000 ml) is encouraged to facilitate mechanical washout, decrease solute concentration, and lessen the likelihood of stone formation.

**Assistance required.** Because either the individual or a caregiver can maintain the catheter, individuals with minimal function and limited assistance are suitable for this method of bladder management.

**Cosmesis.** A leg bag is worn during the day and a nighttime collection device is used overnight. The leg bag can be concealed under clothing. Cloth bags can be made or purchased to conceal the large nighttime collection device.

**Interference with social/sexual function.** Indwelling urethral catheters may need to be removed for intercourse. Some males disconnect the catheter, bend it back over the penis, and place a condom over the penis and catheter for intercourse. This method may cause urethral irritation and a subsequent UTI. Males who are concerned about fertility may find that removal of the catheter decreases colonization and increases fertility.

Suprapubic catheters have advantages for both males and females. Both can have intercourse without having to be concerned about a catheter. Females who opt for suprapubic placement can avoid the enlargement of the urethra and subsequent urinary leakage common with urethral catheters.

**Medications.** If the catheter tip and balloon irritate the trigone of the bladder, an anticholinergic medication may be prescribed to prevent involuntary detrusor contractions and urinary leakage.

**Reversibility.** The catheter can be removed if an alternative type of treatment can be found that affords a low-pressure bladder and periodic bladder emptying.

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**Reflex Voiding**

Reflex voiding is a method that depends on an intact sacral micturition reflex. As bladder filling begins, sensory afferents begin to feed this information into the sacral cord. Continued bladder filling eventually triggers sacral efferents to cause an uninhibited (involuntary) bladder contraction. But because of the spinal cord injury, coordinated relaxation of the sphincter mechanism is absent; thus, detrusor sphincter dyssynergia is usually present. Despite dyssynergia between the bladder contractions and sphincter relaxation, voiding occurs because the sphincter relaxes intermittently during the bladder contractions. However, detrusor sphincter dyssynergia frequently results in elevated voiding pressures, which can then cause poor drainage and complications to the upper tract. Another problem that commonly occurs in those with detrusor sphincter dyssynergia is poor drainage of the bladder. In those with spinal injuries at T6 and above, autonomic dysreflexia can occur when the bladder contracts against a dyssynergic sphincter. Autonomic dysreflexia can also occur from bladder distention from incomplete bladder emptying.

Because the bladder contractions are involuntary with little or no warning, individuals who reflex void require a collecting device. The presence of detrusor sphincter dyssynergia frequently necessitates other interventions (e.g., suprapubic bladder tapping, alpha-blockers, botulinum toxin injection, urethral stents, or sphincterotomy) to allow the bladder to empty effectively and prevent upper tract complications.

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 have 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)

**Rationale:** A reflex (uninhibited) bladder contraction adequate for bladder emptying is needed for those who are considering reflex voiding as their method of bladder management. It should be...
noted that as the bladder develops reflex contractions to keep the bladder from getting distended, the bladder loses its capacity. This will make it very difficult to revert back to intermittent catheterization. Males can use external collecting devices very effectively, but no such device exists for females. In rare instances, reflex voiding may be used in females if they wear incontinence padding. However, incontinence padding has its own disadvantages. First, it requires frequent changing, thus making it both labor intensive and expensive (see appendix A), and, second, wearers risk skin breakdown.

Reflex voiding is suited to those with poor hand function because there is no need to undress or catheterize with this technique. However, some help from a caregiver will be needed if a person does not have enough hand function to change a condom catheter or empty a leg bag. Leg bags need to be emptied periodically; however, there are electronic devices that will allow the bag to empty. Reflex voiding is also suited to those with poor compliance or unwillingness to limit fluid intake because the bladder will contract reflexively and empty whenever it reaches a certain volume. Finally, this method is suited to those with a small bladder capacity, since a large bladder capacity is needed for intermittent catheterization.

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)

Rationale: To void reflexively, a person needs to have uninhibited bladder contractions. However, individuals with spinal cord injury usually have detrusor sphincter dyssynergia. Problems can result, such as high voiding pressures (which can cause upper tract damage), autonomic dysreflexia, and high post-void residuals. A urodynamic evaluation will provide information on bladder and sphincter function and determine the need for any additional intervention prior to reflex voiding.

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)

Rationale: An important requirement for reflex voiding is the ability to put on a condom catheter and have it stay in place. If this is not possible, another method of bladder management should be used. Unfortunately, there are no collecting devices for females, so reflex voiding is not a practical method for them.

Detrusor sphincter dyssynergia frequently occurs in those who void reflexively. This results in a number of problems, such as autonomic dysreflexia, incomplete bladder emptying, and high voiding pressures. Both nonsurgical (see recommendation 4) and surgical (see recommendation 5) methods have been developed to treat detrusor sphincter dyssynergia. If problems continue despite treatment, then alternative methods of bladder management are needed.

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.
- 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)

Rationale: Most complications from reflex voiding center on the external condom catheter and detrusor sphincter dyssynergia. One of the most common problems is condom catheter failure in which the condom catheter falls off. (This problem is discussed in more detail in the nursing considerations section.) Skin breakdowns may occur when a condom catheter is too tight or is taken off too frequently. A urethral fistula, which is extremely unusual, may occur for the same reasons. Other complications—symptomatic UTI,
poor bladder emptying, high intravesical voiding pressures, and autonomic dysreflexia—are frequently a result of detrusor sphincter dyssynergia.

5. First consider 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)*

*Rationale:* Because individuals with spinal cord injury usually have detrusor sphincter dyssynergia, problems may result, such as high voiding pressures (which can cause upper tract damage), autonomic dysreflexia, and high post-void residuals. A trial of nonsurgical treatments is recommended prior to surgery because they are easy to reverse if a person chooses to try a different method of bladder management instead. (See *Alpha-Blockers and Botulinum Toxin Injection* for a description of and rationale for each method.)

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)*

*Rationale:* Because individuals with spinal cord injury usually have detrusor sphincter dyssynergia, problems may result, such as high voiding pressures (which can cause upper tract damage), autonomic dysreflexia, and high post-void residuals. One or more different methods may be needed to reduce detrusor sphincter dyssynergia. (See *Transurethral Sphincterotomy and Urethral Stents* for a description of and rationale for each method.)

### Nursing Considerations for Reflex Voiding

Individuals who choose reflex voiding for bladder management should determine the type of collecting device to be used prior to the treatment intervention. Individuals will need to understand in advance how the treatment intervention will alter care of the bladder. There are a number of variations on reflex voiding technique and care. The following is one example.

**Proper use and care of external condom catheter.** The condom catheter is applied securely to avoid leakage and constriction for 24 hours. To avoid skin maceration and breakdown, the glans is washed daily when the condom is changed, the skin is aired for 20–30 minutes, and the condom is reapplied. To prevent pressure ulcers, alternate legs are used to anchor the tubing.

**Care of equipment.** Daytime and nighttime urinary collection devices are cleaned daily. A 1:10 solution of bleach to water has been shown to provide effective cleansing (Dille and Kirchhoff, 1993).

**Assistance required.** The individual or a caregiver can apply the condom catheter, empty the urine receptacle, clean the equipment, provide daily hygienic care, and perform daily skin assessment. An electronic emptying device that affixes to the wheelchair can assist with emptying the urine receptacle.

**Cosmesis.** A leg bag is worn during the day and a nighttime drainage bag is used at night. Loose clothing should be worn to accommodate the leg bag.

**Interference with social/sexual function.** Urine leakage may occur during sexual activity. Use of a regular condom may be an option for management.

**Other.** Individual anatomy and allergies to latex or adhesive are considerations when choosing a condom catheter. The appropriate size self-adhesive condom (small to extra large) and the appropriate length (short, extra wide with adhesive) must be determined. Individuals with allergies to the adhesive can use nonadhesive condoms, which are available from most of the pharmaceutical companies that make condoms.


### Alpha-Blockers

Alpha-blockers are a nonsurgical method to treat detrusor sphincter dyssynergia and low bladder pressure during voiding.

Alpha-adrenergic receptors have been identified in the proximal urethra, prostate, and bladder neck. Alpha-adrenergic blockers have been found to lower urethral resistance and improve voiding. Though earlier adrenergic blockers were less urologic-specific, they were commonly used for med-
ical treatment of lower urinary tract dysfunction in individuals with SCI (Abrams et al., 2003). More specific adrenergic blockers (against alpha 1-A adrenergic receptors) are now being used to treat lower urinary tract dysfunction associated with high urethral resistance in individuals with SCI (Abrams et al., 1982). Understanding the risks, benefits, and contraindications of the different alpha-blockers will help the individual with SCI make an informed decision on the type of bladder management to be tried.

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)

   **Rationale:** Level II and III evidence suggests that urodynamic changes—including less urethral resistance and improved urinary flow rate—have been seen in individuals treated with alpha-adrenergic blockers. When urethral resistance is lessened, detrusor overactivity might also improve (Thomas et al., 1984).

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)

   Alpha-blockers have the potential to lower blood pressure, which can be a particular concern in individuals with high-level spinal cord injuries because their normal systolic blood pressure is frequently 90–110mm Hg (Thomas et al., 1984).

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)

   **Rationale:** The risk of orthostatic hypotension will be minimized if the person is in a supine position for the night. Clarification of necessary antihypertensive medications with the primary care provider will prevent individuals from being overmedicated (Thomas et al., 1984).

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

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

   **Rationale:** Phosphodiesterase (PDE5) inhibitors may lower blood pressure, which can be a potential problem, particularly for individuals with a high-level SCI who already have a low baseline blood pressure. A number of individuals with spinal cord injuries take alpha-blockers to improve voiding. Furthermore, individuals with high-level injuries frequently may need nitropaste if they develop autonomic dysreflexia. Combining PDE5 inhibitors with nitrates may cause a precipitous lowering of blood pressure (Thomas et al., 1984).

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)

   **Rationale:** Instruct individuals with SCI to take alpha-blockers at night, when supine. These instructions are particularly important for those with high-level spinal cord injuries because of the potential for orthostatic hypotension and other complications associated with alpha-blockers. A thorough review of all of the potential complications will help the individual with SCI to make an informed decision on the method of bladder management to be used.

### Nursing Considerations for Alpha-Blockers

Whether alpha-blockers are used alone or as a supplement to other forms of treatment, individuals receiving alpha-blockers will need to be aware of some necessary precautions and other issues pertaining to the medicine’s use. The type and dose of this and other medications must be done under the care and advice of a physician.

**Review of medications.** To avoid potentially harmful side effects, the use of other antihypertensive agents and phosphodiesterase inhibitors should be reviewed by the prescribing physician prior to beginning an alpha-blocker medication.

**Introduction of an alpha-blocker.** When an alpha-blocker is first started, the individual should be observed for signs and symptoms of syncope: dizziness, nausea, and sweating. If feelings of lightheadedness occur, the individual should be placed in a recumbent position and monitored closely.
**Precautions.** Alpha-blockers may affect positioning, urgency, urge incontinence, and stress urinary incontinence. The individual is instructed to take the medication at night when lying down, to dangle the feet and sit up slowly to allow time for the body to accommodate to changes in blood pressure, to avoid driving or the use of heavy machinery when the drug is first administered, and to report any side effects to the physician.

**Medication system.** To ensure that all medications are taken as prescribed, a medication dispenser or similar system should be developed.

**Bladder diary.** A record of all bladder activity can be useful in some settings to evaluate emptying and fluid intake.

**Assistance required.** Specific considerations for the individual and caregiver include: (a) adequate hand function to open the medication bottle; (b) the ability to remember to take the medication as prescribed; (c) the ability to transfer quickly to the toilet; and (d) the ability to access the genital area. Individuals who experience a decrease in level of energy should find that this side effect lessens over time as the body accommodates to the medication.

**Cosmesis.** Standing or transferring will require more time as the individual adjusts to changes in blood pressure.

**Interference with social/sexual function.** Some individuals have noted a change in ejaculatory function, in which case dosing or medication may need to be altered.

**Medications.** To prevent drug interactions or overdosing, the urologist should be aware of all other medications being taken.

**Reversibility.** Alpha-blockers can be stopped at any time and the body will return to its normal function.

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**Botulinum Toxin Injection**

Coordinated relaxation of the sphincter mechanism may be absent in individuals with SCI. Consequently, detrusor sphincter dyssynergia usually is present. Other interventions frequently are needed to allow the bladder to empty effectively and to prevent upper tract complications. One modality is the transurethral or transperineal injection of botulinum toxin into the urinary sphincter mechanism. Botulinum can also be used to treat the neurogenic overactive bladder, by injecting it directly into the bladder wall proper.

Botulinum toxin inhibits acetylcholine release at the neuromuscular junction, which in turn blocks neuromuscular contraction and relaxes muscles that are either spastic or overactive. It can, therefore, relax sphincter spasticity in those with detrusor sphincter dyssynergia. Lack of permanence is both an advantage and a disadvantage of botulinum toxin injections, which frequently lose effectiveness after 3 to 6 months when the nerve endings resprout. Thus, reinjections usually are necessary. There is no limit to the number of reinjections that may be required.

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)
   
   **Rationale:** Schurch et al. (1996) reported that after botulinum toxin was injected into 21 individuals with detrusor sphincter dyssynergia, urethral pressures were significantly reduced with a concurrent decrease in post-void residual volumes in 38 percent of individuals.

2. **Monitor and inform individuals after botulinum toxin injections that onset is 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)
   
   **Rationale:** Botulinum toxin inhibits acetylcholine release at the neuromuscular junction, which in turn blocks neuromuscular contraction and relaxes muscles that are either spastic or overactive. Over time, reinnervation of the neuromuscular junction occurs. For detrusor sphincter dyssynergia, botulinum toxin injected into the external sphincter has been reported to remain effective for 2 to 3 months (Dyksra et al., 1990).

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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)

**Rationale:** Botulinum toxin has the potential to exacerbate a neuromuscular disease. It also can have an increased effect if a person is undergoing aminoglycoside antibiotic treatment since aminoglycosides have been implicated in the induction and/or exacerbation of neuromuscular blockade. Another reason to avoid botulinum toxin injection is the inability to put on a condom catheter or to have one stay in place, since a condom catheter is needed for reflex voiding.

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)

**Rationale:** Botulinum toxin is usually injected into the sphincter under direct visualization through a cystoscope. Both the injection and the cystoscopy have the potential to cause autonomic dysreflexia and/or hematuria during the procedure.

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

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

**Rationale:** Botulinum toxin inhibits acetylcholine release at the neuromuscular junction, which in turn blocks neuromuscular contraction and relaxes muscles that are either spastic or overactive. Therefore, botulinum toxin can suppress the muscle activity of the sphincter mechanism or an overactive bladder. Studies indicate that botulinum toxin injected into the bladder wall (100 to 300 units) can suppress an overactive bladder, which has been confirmed by cystometry (Schurch et al., 1996, 2005). As in the sphincter, the effects wear off after 3 to 6 months so the injections need to be repeated. Botulinum toxin injection into the bladder can be used for both males and females because it does not require use of an external condom catheter as a collection device. NOTE: This technique is not presently approved by the U.S. Food and Drug Administration for this indication.

**Nursing Considerations for Botulinum Toxin Injection**

This procedure is typically performed as same-day surgery. Toileting issues—including the ability to transfer to the toilet, access the genital area easily, and collect and contain urine—need to be addressed prior to surgery. The temporary nature of this treatment is an important consideration.

**Pretreatment baseline data.** Baseline data are needed to evaluate postoperative outcomes and to determine the need for further treatment. Bladder diaries and urodynamics can provide subjective and objective evidence that will assist the health-care provider in evaluating the degree of improvement in function of the bladder and external sphincter.

- A diary of fluid intake, incontinence, voiding, and catheterization times and amounts will provide a record of actual occurrences.
- Baseline urodynamics will provide objective evidence of bladder and external sphincter function.

**Postprocedure.** It usually takes about 2 weeks for the botulinum toxin to begin working, and 4 weeks to have its maximal effect. Therefore, the prebotulinum toxin method of bladder management will need to be maintained for several weeks after the injections.

**Applications for males.** Botox injected into the external urethral sphincter facilitates urine emptying and requires a continuous collection device to contain urine.

**Assistance required, cosmesis, and interference with social/sexual function.** See Nursing Considerations for Reflex Voiding.
Medications. Additional medications, such as an alpha-blocker for the bladder neck, may be needed to facilitate emptying.

Applications for males and females. Botox injected into the bladder muscle facilitates urine storage and catheterization to empty the bladder.

Assistance required. Adequate hand function and sufficient cognitive ability to be aware that the bladder needs emptying are needed, or a caregiver must be available to empty the bladder.

Cosmesis and interference with social/sexual function. See Nursing Considerations for Intermittent Catheterization.

Medications. Additional medications may be needed to provide effective storage at low pressure.

Reversibility. The effects of botulinum toxin injection are not permanent.

Urethral Stents

Urethral strictures and benign prostatic hyperplasia were the initial indications for urethral stents—the endolumenal wire prosthesis. Urethral stents also have been used in males with spinal cord injury who reflexively void and have detrusor-external sphincter dyssynergia (DSD), a condition in which bladder contractions are simultaneously associated with sphincter contractions resulting in an obstructed urethra. Despite the dyssynergic sphincter, urine leakage occurs because the sphincter relaxes intermittently.

A urethral stent provides a treatment option for circumventing urethral obstruction without a surgical procedure, such as transurethral external sphincterotomy (TURS). One type of frequently used stent consists of a woven, self-expanding, tubular metallic mesh, which is available in lengths of 20, 25, and 30 mm. It is made of a super alloy that expands to an unconstrained diameter of 14 mm (42F) when deployed from the insertion tool. This feature allows continuous drainage of the bladder; therefore, individuals with SCI will require a urinary collecting device (external condom catheter and leg bag) at all times. The geometry, elastic property, and radial force of the metallic stent mesh allow it to maintain an in-situ position continuously and thus prevent obstruction due to the dyssynergic external urethral sphincter.

The requirements for anesthesia during stent placement vary among individuals. Individuals with severe spasticity and a history of autonomic dysreflexia require general or spinal anesthesia. The stent is inserted through a preloaded insertion device with a zero-degree cystoscopic lens and deployed with the proximal end extending to the caudal end of the verumontanum so that it does not completely block the ejaculatory ducts. The distal end of the prosthesis extends into the bulbar urethra.

1. Consider urethral 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 urethral stent method of drainage as an alternative to TURS in individuals with SCI.

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

Rationale: In a study of 153 individuals at 15 medical centers, sphincter prosthesis placement had documented clinical success with up to 2 years of follow-up (Chancellor et al., 1999). The simplicity of its placement and its minimal surgical morbidity make it an attractive modality for treating DSD. Stent placement may be indicated in individuals with previous failed external sphincterotomy performed by less experienced urologists. Chancellor et al. (1999) reported reversible clinical outcomes after sphincter stent removal in...
participants with DSD. Several nonrandomized studies have been conducted on the use of different stents for the treatment of DSD with acceptable results (Denys et al., 2004).

It is recommended that individuals return for follow-up every 6 months after stent placement. They will be monitored for such problems as difficulty emptying the bladder due to obstructing stent hyperplasia and autonomic dysreflexia, which may require the use of alpha-blockers and/or transurethral bladder neck resection or incisions.

3. Consider avoiding urethral 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.

(Rationale: An important aspect of the urethral stent/reflex voiding method of bladder management is that the individual must have the ability to put on a condom catheter and have it stay in place. If this is not possible, another method of bladder management is recommended. Because the stent is put in place with an insertion tool, it may be technically difficult to place the stent in the correct position if the individual has urethral abnormalities, such as a urethral diverticulum or strictures. There is some concern that the stent may migrate if the person has had a previous transurethral procedure, such as a sphincterotomy.

4. Advise individuals of the potential for complications of urethral 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.

(Rationale: In a multicenter study, 8.5 percent of the study participants required bladder neck surgery after the stent placement; longer follow-up in a small series reported bladder neck surgery following stent placement in 5 out of 7 participants with DSD (Shah, Kapoor, and Badlani, 2003). However, over the long term, stents can undergo encrustations, and a definite risk remains that the stent will migrate into the bladder, necessitating stent removal or replacement. In a longer follow-up study (up to 7 years), stents were explanted in 22 percent of the participants with DSD. Migration and/or inappropriate placement were blamed as the cause for removal in 38.4 percent of the cases. Other reported complications and problems include irritative symptoms, persistence of autonomic dysreflexia, calculus formation, prostatic infections, tissue growth, and difficulty in removing the stent.

Nursing Considerations for Urethral Stents

The success of this bladder management option will depend upon the individual’s ability to alter care. A thorough objective and subjective assessment is essential prior to surgery.

Preoperative. The focus of care is on the individual’s physical and emotional well-being and on the person’s ability to alter care to facilitate the surgical intervention.

Postoperative. The focus of care is on preventing movement of the stent by altering the individual’s activities of daily living.

Assistance required. Assistance with transfers will be needed until the stent is adequately epithelized. Individuals with paraplegia should use a slide board to prevent extension of the pelvic area. Individuals with tetraplegia will need to use a mechanical lift until the endourethral stents are stabilized, in approximately 1–3 months.

Care of equipment, cosmesis, and interference with social/sexual functioning. See Nursing Considerations for Reflex Voiding.

Reversibility. The stent is removable, although the procedure can be difficult and result in urethral scarring and/or stricture. Permanent urinary incontinence will not occur, however, the
external sphincter will be intact after the stent is removed, creating continence.

Other. If the stent is in place and an indwelling urethral catheter is needed, leakage will occur around the catheter. A #14FR urethral catheter is typically used to prevent de-epithelializing the stent and causing irritation. If the stent is in place and a suprapubic catheter is placed, some leakage from the urethra will occur, especially during transfers and other activities that put strain on the body.


Transurethral Sphincterotomy

Transurethral resection of the external urinary sphincter (TURS) is a reasonable option for adequately draining the bladder to prevent and manage urologic complications in males with SCI or myelopathic disorders who void reflexively and have detrusor sphincter dyssynergia. The procedure helps to decrease urinary outflow resistance due to detrusor sphincter dyssynergia. The objective is to reduce the intravesical voiding pressure mediated by bladder contractions against a contracted external urethral sphincter. The goals of sphincterotomy are to stabilize or improve renal function, prevent urosepsis, and ameliorate autonomic dysreflexia. This is considered to be an irreversible procedure. Following TURS, with lower detrusor leak point pressure, it is possible to stabilize or eliminate vesicoureteral reflux and thus eliminate the need for chronic indwelling catheterization in some males. After a successful sphincterotomy, an improvement in bladder emptying and stabilization of the upper urinary tract can be reasonably expected in 70 percent to 90 percent of individuals (Wein, Raezer, and Benson, 1976).

Following TURS, the individual is expected to have urinary incontinence. Bladder drainage is provided with an external condom catheter connected to a leg bag, which needs changing and cleaning only once a day. This method reduces the amount of time a caregiver must devote to intermittent catheterization and gives much more independence to the individual. This method also eliminates the necessity for an indwelling catheter in individuals who have been unsuccessful with that device or who do not want to continue intermittent catheterization. Individuals can be up in a wheelchair most of the day and available to engage in a productive vocation.

1. Consider transurethral sphincterotomy 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 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–III; Grade of recommendation–C; Strength of panel opinion–Strong)

   **Rationale:** Tetraplegic males with poor hand function cannot self-catheterize their bladders. They also are prone to autonomic dysreflexia, which can create an emergency situation necessitating catheterization of the bladder at odd times, such as in the middle of night. Reflex voiding is easy following sphincterotomy. Gentle tapping in the suprapubic region also can trigger voiding and help bladder decompression. Following sphincterotomy, there is usually significant relief from autonomic dysreflexia (Perkash et al., 1992).

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 TURS.

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

   **Rationale:** Males with a small retractile penis cannot hold the external condom drainage device that is necessary to collect urine following TURS. A semirigid penile implant may be required (Perkash et al., 1992). The incidence of infection and implant failure has been much higher in persons with SCI than in those without. But in properly selected individuals, with adequate control of
urinary tract infection immediately before surgery, the failure rate has been about 8 percent (Perkash et al., 1992).

3. Advise males 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 percent to 60 percent of cases.

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

**Rationale:** Several complications have been reported following electrosurgical TURS: (a) significant intraoperative and perioperative bleeding, (b) clot retention, (c) prolonged drainage with a large diameter catheter, (d) urethral strictures, (e) impotence, and (f) reoperation in 30 percent to 60 percent of cases (Juma, Mostafavi, and Joseph, 1995; Vapnek, Couillard, and Stone, 1994). In 14 percent of the initial TURS failures, an additional bladder neck incision or a transurethral resection of the prostate was performed to improve urodynamic parameters (Noll, Sauerwein, and Stohrer, 1995). The majority of failures of TURS have been attributed to inadequate surgery, postdiathermy TURS strictures of the bulbous urethra, and poor detrusor contractility.

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)

**Rationale:** Transurethral external sphincterotomy can be performed with either a diathermy electrode (knife) or with a laser at the 12 o’clock position (Perkash, 1996). Incision usually starts just proximal to the verumontanum and extends into the proximal bulbous urethra. It is deepened until all muscle fibers have been cut. Significantly reduced morbidity and minimal to nil blood loss have been reported following laser sphincterotomy (Noll, Sauerwein, and Stohrer, 1995; Perkash, 1996). Both contact and beam lasers have been applied through the standard cystoscope (Perkash, 1996). The laser energy is delivered fiber optically through a reusable contact laser probe screwed on to the tip of a rigid fiber, or through almost the direct contact of end fiber or side fire through a side firing probe for the delivery of Holmium laser (HO:YAG). A usual setting of 1.5 JX15 or 20 hertz seems ideal. Free beam laser leads to coagulative necrosis; therefore, it is not a suitable choice for TURS. Contact laser, an end fiber, or a side fiber delivering HO:YAG is similar to using a knife: It requires repeated passes to cut and vaporize all fibers just short of cutting spongy tissue, as is also done using a diathermy knife, to prevent perforation of the urethra. Research findings indicate a significantly reduced incidence of operative and perioperative bleeding as well as a reduced incidence (about 7 percent to 15 percent) of repeat sphincterotomy following use of the contact laser (Noll, Sauerwein, and Stohrer, 1995; Perkash, 1996), compared to a repeat rate of more than 30 percent following the use of electrocautery in the reported series mentioned above. Laser sphincterotomy is, therefore, the procedure of choice depending upon the availability of laser equipment.

Following TURS, an indwelling catheter may be placed instead of external condom drainage. Leakage of urine around an indwelling catheter may occur, which happens more often if a simultaneous transurethral resection of the prostate also has been performed. This leaves a wide open prostatic fossa where collection of urine evokes the urethra-urethral reflex with almost constant leakage of urine around the catheter.

There is a significantly higher incidence of upper tract damage and of persisting external-detrusor sphincter dyssynergia in individuals with bladder leak point pressure greater than 40 cm water following surgery (Kim, Kattan, and Boone, 1998). Thus, a bladder leak point pressure below 40 cm water seems to be a useful urodynamic parameter for the successful outcome of TURS (Juma, Mostafavi, and Joseph, 1995; Vapnek, Couillard, and Stone, 1994).

**Nursing Considerations for Transurethral Sphincterotomy**

Individuals need to be aware that this irreversible surgical procedure will render them incontinent of urine, that urine will be contained in a bag on the outside of the body, and that erectile function may be affected. A thorough assessment for appropriateness of the procedure is essential.
Preoperative. The focus of care is on the individual’s physical and emotional well-being and on the person’s ability to alter care to facilitate the surgical intervention.

Postoperative. The focus of care is on maintaining homeostasis through adequate hydration and fluid elimination (Joseph et al., 1998).

Care of equipment, assistance required, and cosmesis. See Nursing Considerations for Reflex Voiding.

Interference with social/sexual function. A decrease in erectile function and in the ability to be urine-free during sexual activities may be observed. Although the risk of impotence is reported in the literature (Zedjlilik, 1992), a lower pressure system and removal of the indwelling catheter may improve fertility.

Medications. Alpha-blockers may be given to open the bladder neck to facilitate emptying.

Reversibility. This procedure is permanent and cannot be reversed.

Electrical Stimulation and Posterior Sacral Rhizotomy

Electrical stimulation of the sacral parasympathetic nerves (S2–4) produces bladder contraction. Stimulation of these segmental nerves also activates somatic motor nerves causing sphincter contraction, which might be expected to prevent micturition. However, the smooth muscle of the bladder and the striated muscle of the external sphincter have different rates of contraction and relaxation and can be made to contract alternately by an intermittent pattern of stimulation, producing safe and effective voiding of the neurogenic bladder.

Electrodes are implanted surgically on the sacral nerves or nerve roots in the spinal canal and attached by subcutaneous wires to a stimulator placed under the skin of the abdomen or chest. The stimulator is powered and controlled by radio transmission from a battery-powered remote control operated by the user when voiding is desired.

Many of the complications of the neurogenic bladder are due to hyperreflexia of the detrusor and/or sphincter, and this hyperreflexia can be abolished by posterior sacral rhizotomy. The implant usually is combined with a rhizotomy to reduce reflex incontinence, increase bladder capacity and compliance, protect the upper tracts, and reduce autonomic dysreflexia. However, rhizotomy also abolishes reflex erection, reflex ejaculation, and sacral sensation, if these are present, and can reduce reflex defecation. The rhizotomy is an irreversible procedure.

NOTE: As of March 2006, the electrical stimulation system was awaiting reapproval by the U.S. Food and Drug Administration, although the device is available in other countries.

The combination of implantation and rhizotomy in appropriate individuals can reduce urological complications and the long-term costs of bladder management (Creasey and Dahlberg, 2001).

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, due to detrusor hyperreflexia.
   - Intolerance of anticholinergic medication.
   - Detrusor sphincter dyssynergia.
   - Autonomic dysreflexia.

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

Rationale: Electrical stimulation of sacral efferent nerves produces voiding with consistently low residual volumes (Schurch, Rodic, and Jeanmonod, 1997; van der Aa et al., 1999). This results in low rates of urinary tract infection and a reduced need for indwelling and intermittent catheterization (Creasey and Dahlberg, 2001; Egon et al., 1998; van Kerrebroeck, Koldewijn, and Debruyne, 1993; van Kerrebroeck et al., 1997).

Posterior rhizotomy from S2–4 greatly reduces reflex incontinence (van Kerrebroeck et al., 1997; Schurch, Rodic, and Jeanmonod, 1997) and increases bladder capacity and compliance (Egon et al., 1998; Koldewijn et al., 1994; van Kerre-
broeck et al., 1997; van der Aa et al., 1999). As a result, the use of anticholinergic medication is greatly reduced (Creasey and Dahlberg, 2001). The rhizotomy also reduces sphincter spasticity, allowing good flow rates of urine, and abolishes autonomic dysreflexia caused by contraction or distention of the bladder (Egon et al., 1998; Koldewijn et al., 1994, Schurch, Rodic, and Jeanmonod, 1997; Schurch et al., 1998).

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)

   **Rationale:** Electrical stimulation activates the sacral parasympathetic nerves to the bladder; these must therefore be intact, even if descending tracts in the spinal cord have been damaged. The simplest way to determine if they are intact is to demonstrate reflex bladder contraction on bladder filling. This may require testing in the absence of anticholinergic medication (Chua, Tow, and Tan, 1996; Egon et al., 1998; Schurch, Rodic, and Jeanmonod, 1997).

   Bladder capacity in the absence of reflex contraction should be large enough to allow several hours between voids (van Kerrebroeck et al., 1997). This capacity can be tested while inhibiting reflex contraction using anticholinergic medication or spinal, caudal, or general anesthesia.

   Restoring the ability to void via the urethra requires the ability to collect urine in a toilet, bottle, or leg bag. Tetraplegic females who void via the urethra need to be able to transfer or be transferred onto a toilet, commode, or bedpan. Tetraplegic males who cannot manage a urine bottle should be assessed for their ability to retain a condom drainage system (Creasey and Dahlberg, 2001).

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.

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–None)

   **Rationale:** The risk is 1 percent that the implant will become infected. The risk of faults in the implant is 1 fault per 20 implant-years; faults are treated by repair or replacement of the implant, and individuals can revert to intermittent or indwelling catheterization while awaiting repair (Brindley, 1995). The external controller may develop faults, but it can be repaired or replaced without surgery. Sacral nerves may be damaged accidentally by applying electrodes incorrectly.

### Nursing Considerations for Electrical Stimulation

Individuals who choose this method of bladder management will have to learn how to use the device. A thorough assessment for appropriateness of the procedure is essential.

**Preoperative.** The individual’s physical and emotional well-being will be assessed. The ability to manipulate the device and to capture urine, either in a receptacle or on the toilet, will be determined prior to treatment intervention.

**Intraoperative.** During the surgery, efforts will be made to ensure safety and prevent complications, such as deep vein thrombosis and pressure ulcers.
Postoperative. The focus is on maintenance of homeostasis through adequate hydration and fluid elimination. Timed voiding and fluid regulation will prevent overdistention of the bladder (which can reduce bladder contractility and emptying). This practice will afford efficient use of the sacral reflex arc and adequate emptying of the bladder. Bladder contractility will usually recover if further overdistention is prevented through temporary catheterization. The device should not be dropped on a hard surface or in water. Equipment failure and other difficulties, such as fatigue of the detrusor muscle, may arise.

Assistance required. The type of assistance needed will be determined based on the individual’s functional ability, specifically on hand function (with and without assistive devices), and on the ability to transfer independently to a toilet and access the genital area. A caregiver can assist with care.

Cosmesis. Transfer to the toilet and use of the device mimic normal toileting. If hand function is limited, occupational therapy can devise a holder for the transmitter that will allow the individual to hang it from the neck or waist in a pouch for easy access. The transmitter coil can be taped to the receiver site on the abdomen. For males, a condom can be worn to collect urine (see Nursing Considerations for Reflex Voiding for proper use and care of condom catheters and equipment). It is possible to turn the device on and off using gross motor movement.

Interference with social/sexual function. A complete posterior rhizotomy will prevent reflex erection. Other methods of producing erection can be used, and the stimulator can produce erection in some males.

Medications. Some individuals may be placed on alpha-adrenergic medication to tighten the bladder neck and assist with continence. Males may be placed on an alpha-blocker to facilitate opening of the bladder neck. After rhizotomy, anticholinergic medication is no longer needed for the bladder.

Reversibility. Individuals can stop using the device at any time. Internal components are usually left in place, unless contaminated. The rhizotomy is not reversible.

Other. See Nursing Considerations for Reflex Voiding.

Bladder Augmentation

Bladder augmentation, or augmentation cystoplasty, is a surgical procedure that increases bladder capacity by augmenting the bladder using intestinal segments. These segments, which include the ileum, colon, or stomach, are used to create a low-pressure intraabdominal reservoir free of disturbing shifts of fluid and electrolytes. The scientific principle of Laplace’s Law \( T = \frac{PR}{2} \), which states that the larger the vessel radius, the larger the wall tension required to withstand a given internal fluid pressure, is used to detubularize these intestinal segments, thereby converting a cylinder into a sphere, which decreases the pressure by increasing the radius. Detubularization improves reservoir capacity and compliance. The specific goals of decreasing intravesical pressure are to restore urinary continence and preserve upper urinary tracts by alleviating reflux and hydronephrosis. Bladder augmentation can be combined with a continent abdominal stoma using a tapered or intussuscepted segment of bowel.

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)

   Rationale: Following bladder augmentation, individuals with SCI with incontinence secondary to intractable detrusor hyperreflexia have demonstrated long-term success in their ability to preserve continence. Bladder augmentation increases bladder capacity and bladder wall compliance. The findings are supported by urodynamic data that demonstrate increased maximal cystometric capacity and decreased detrusor pressures (Chartier-Kastler et al., 2000).
2. Consider bladder augmentation for females with paraplegia.

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

*Rationale:* No effective external collecting device exists for females. Long-term studies have demonstrated excellent continence rates with acceptable complications rates for females with paraplegia who have undergone bladder augmentation (Venn and Mundy, 1998). Augmentation procedures often can be combined with simultaneous procedures on the bladder outlet, preferably at the time of the original procedure. These procedures may include a fascial sling, closure of the bladder neck, or insertion of an artificial urinary sphincter (Khoury et al., 1992).

Excellent continence rates have been achieved by constructing a continent abdominal stoma at the time of augmentation using the appendix (Mitrofanoff), tapered ileal cecal segments, or tapered ileum. This modification is especially adaptable to individuals who cannot access their native urethra because of congenital abnormalities, obesity, or spasticity, or who require closure of an incompetent bladder neck. It is equally adaptable to tetraplegics who retain pincer grip or who can be assisted with the aid of a hand brace (Cain, Casale, and Rink, 1998; Casale, 1999; Sutton et al., 1998).

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)

*Rationale:* Vesicoureteral reflux resolves in the majority of cases following bladder augmentation alone. However, occasional reimplantation procedures may be required if there is severe hydronephrosis. Long-term studies have demonstrated stability of the upper tracts following augmentation as well as improvement in mild to moderate hydronephrosis (Khastgir et al., 2003; Kuo, 1997).

4. Avoid augmentation in individuals with:
   - 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)

*Rationale:* Individuals with creatinine greater than 3 mg/dL have been excluded from consideration for augmentation if the rise in creatinine was not attributed to obstruction but rather related to compromised renal function (Kuo, 1997). Individuals with compromised renal function will be prone to develop hyperchloremic acidosis secondary to profound fluid and electrolyte shifts through the bowel wall. An individual with renal insufficiency might be considered for a gastrocystoplasty because of decreased chloride reabsorption, mucus production, and a low incidence of perforation (Chancellor et al., 1993; Kurzrock, Baskin, and Kogan, 1998).

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)

*Rationale:* Possible perioperative complications 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.

Increased mucus production is common and may cause blockage during catheterization, but this complication usually will resolve with time. Bowel disturbances, such as diarrhea, are fairly common in the first month, but have been shown to diminish in subsequent follow-up visits. Bladder complications include persistent leakage, bladder perforation, or the development of bladder stones requiring endoscopic removal. Pyuria in augmented segments is common; however, symptomatic infections are rare. There have been scattered reports of carcinoma in bladder augmentation, but as yet no causal relationship to bladder augmentation has been established. Long-term follow-up will be required to answer this question (Khastgir et al., 2003; Kuo, 1997).
Individuals should be advised that these are highly technical procedures and should be performed only at centers with experienced surgeons and excellent ancillary support.

**Nursing Considerations for Bladder Augmentation**

The success of this bladder management option hinges on both objective and subjective assessments of the individual’s and caretaker’s ability to provide the necessary follow-up care.

**Preoperative.** The individual and his or her family are assessed to make sure they understand the procedure and the changes in lifestyle that will be necessary. The family’s ability to accommodate these changes is critical if bladder management is going to succeed (Hicken, Putzke, and Richards, 2001).

**Perioperative.** Prior to surgery, the individual will receive bowel cleansing, antibiotics, a low-residue diet, adequate hydration, and confirmation of the site (if applicable), as determined by the surgeon and by institution procedure and policy. If the individual will have a stoma, a wound and continence therapist or other qualified health-care provider will mark the site, the location of which will depend on body physique (bony prominences or skin creases), old abdominal scars, hand function, and usual beltline of clothing. The individual will be evaluated both lying down and sitting up in a chair; self-care is easier when the individual can see the stoma.

**Postoperative.** The focus is on maintenance of homeostasis through adequate hydration and fluid elimination.

**Assistance required.** Adequate hand function and sufficient cognitive ability are needed to insert the catheter and irrigate the augmented bladder, or a caregiver must be available to do so.

**Cosmesis.** There will be an abdominal incision and scar. If the individual is unable to use the urethra for catheterization, an abdominal stoma will be created in the right or left lower quadrant, about the size of a small cherry; the bladder neck may or may not be closed, and the individual will catheterize through the stoma.

**Interference with social/sexual function.** Body image issues may need to be addressed if an abdominal stoma is created.

**Medications.** Normal saline is used to irrigate the augmented bladder to rid the augmented segment of mucus and a nidus for infection. An anticholinergic medication may be needed if pressures within the bladder are not within the normal range.

**Reversibility.** This procedure is not reversible.


**Continent Urinary Diversion**

Continent urinary diversion employs the same principles as those used for bladder augmentation, except these cases require total diversion of urine with or without complete removal of the bladder. The most common procedures used for continent urinary diversion are: (a) the Kock pouch, which is based on the concept of an intussuscepted nipple at both the afferent and efferent limbs of a detubularized segment of ileum, or (b) a modification of the Indiana pouch using a tapered segment of ileum as a continent stoma and a detubularized segment of colon.

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)

**Rationale:** Clinical studies have shown improved quality of life, particularly in the area of sexuality of females with tetraplegia, following continent diversion (Moreno et al., 1995; Plancke, Delaere, and Pons, 1999). A continent stoma may
be created on the abdominal wall, which makes catheterization of the bladder possible for individuals with SCI who have questionable ability to catheterize their native urethra and who are motivated and able to access an abdominal stoma. Such individuals are good candidates for a continent diversion and have shown improved quality of life (Zomminck et al., 2003).

**Urinary Diversion**

Urinary diversion, which diverts the flow of urine from the bladder, is normally a secondary form of bladder management when primary methods have failed. The ureters are transected just above the bladder and connected to a segment of intestine, which is in turn brought to the skin of the lower abdominal wall. Different segments of the intestine have been used for this purpose, but a segment of terminal ileum remains the most popular. An external appliance is placed over the stoma to collect urine externally. The appliance can be connected to a leg bag during the day and a bed bag at night. Modern appliances stay in place well and often only have to be changed weekly.

Urinary diversion is normally used when bladder complications prevent restoration of an adequate bladder. Diversion may be used as an alternative to augmentation cystoplasty or continent diversion when hand function does not permit self-catheterization. As with any form of bladder management, the primary goals are to preserve the upper urinary tract and prevent unacceptable incontinence.

1. **Consider urinary diversion for individuals in the following circumstances:**
   - Lower urinary complications secondary to indwelling catheters.
   - Urethrocystourethral 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)*

   **Rationale:** Indwelling catheters may result in urethral damage, which often is difficult to correct surgically. Urethral erosion in both males and females and urethrocystourethral fistulas in males all present challenges for reconstructive surgery. Urinary diversion can circumvent these problems and provide satisfactory continence. The method is preferable to continent diversion in individuals who have poor hand function and cannot perform self-catheterization. Poorly compliant or thick-walled bladders may result in obstruction at the ureterovesical junction. These bladders are not suitable for ureteral reimplantation, and diversion may be used to relieve upper tract obstruction and prevent further renal damage (Creasey and Dahlberg, 2001).

   An increased incidence of bladder tumors has been noted in individuals using indwelling catheters for a long period of time. Cystectomy is often required as these tumors may not be discovered until late in the course of the disease. These individuals are usually older and often not good candidates for intermittent catheterization after years of an indwelling catheter (Chua, Tow, and Tan, 1996; West et al., 1999).

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)*

   **Rationale:** Individuals who have bowel disease or who are in poor health generally should be excluded from urinary diversion, and alternate bladder management methods should be used (Creasey and Dahlberg, 2001). Inflammatory small bowel disease and prior pelvic irradiation both increase the risk of ureterointestinal stricture and urinary leak as well as postoperative bowel complications (McDougal, 2002.)

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)

Rationale: All of these complications are well recognized with major intestinal surgery and with ileal conduit urinary diversion. Individuals with SCI are more prone to prolonged ileus and are often slower to recover than able-bodied individuals (Creasey and Dahlberg, 2001).

Nursing Considerations for Urinary Diversion

The success of this bladder management option hinges on both objective and subjective assessments of the individual’s ability to alter his or her care. Individuals who can accept the necessary lifestyle changes are able to successfully adapt to the storage of urine in an external appliance and to changes in body image.

Preoperative. The focus is on preparing the individual and his or her family to accommodate changes in lifestyle.

Perioperative. Prior to surgery, the individual will receive bowel cleansing, antibiotics, a low-residue diet, adequate hydration, and confirmation of the site (if applicable), as determined by the surgeon and by institution procedure and policy. If the individual will have a stoma, a wound and continence therapist or other qualified health-care provider will mark the site, the location of which will depend on body physique (bony prominences or skin creases), old abdominal scars, hand function, and usual bellline of clothing. The individual will be evaluated both lying down and sitting up in a chair; self-care is easier if the individual can see the stoma.

Postoperative. The focus is on maintenance of homeostasis through adequate hydration and fluid elimination.

Assistance required. Preferably, individuals should be independent in their care; otherwise a knowledgeable caregiver needs to be available to assist with emptying the collection bag, changing the appliance every 5–7 days, cleaning the stoma, and assessing skin integrity at the stoma site and surrounding area. Some individuals may feel overwhelmed after the surgery and need the assistance of health-care providers and family members until they can gradually assume their own care.

Cosmesis. Individuals who experience a change in self-image because they can no longer toilet normally will need an opportunity to verbalize their feelings and may need additional time to adjust, both physically and mentally. Most will not have to sacrifice stylish clothing to accommodate the urine collection device, though constricting clothing should be avoided.

Interference with social/sexual function. After the normal postoperative period and upon the physician’s advisement, sexual activities may be resumed. Any limitations will be dictated by the individual and not by the procedure itself. If desired, appliance covers can may be made or purchased. Consultation with a mental health professional may help to alleviate any lingering fears about the procedure or about changes in the perceptions of others.

Reversibility. It is possible but not probable to reverse this procedure if the bladder is intact.

Cutaneous Ileovesicostomy

Cutaneous ileovesicostomy is a variant of urinary diversion in which a segment of ileum is connected to the bladder and then brought to the lower abdominal wall. Externally, it is similar to ileal conduit diversion. Rather than dividing the ureters and connecting them to the ileal segment, the ileal segment is connected to the bladder. This method has the advantage of leaving the ureterovesical juncture intact and providing low pressure egress of urine to an external collector.

1. Consider cutaneous ileovesicostomy for individuals who require urinary diversion with normal ureterovesical junctions.
Indwelling catheters may result in urethral damage that is difficult to correct surgically and may result in urinary incontinence. In contrast to diversion, cutaneous ileovesicostomy requires preservation of the bladder and possibly closure of the bladder outlet. The method does, however, preserve the ureterovesical juncture and perhaps provide protection of the upper urinary tract (Juma, Mostafavi, and Joseph, 1995; Stonehill et al., 1996).

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

Individuals with an incontinent bladder outlet may continue to leak urine with either a suprapubic cystostomy or cutaneous ileovesicostomy. Bladder neck closure at the time of surgery will usually prevent this. The procedure must be done meticulously or fistulas can occur (Bennett et al., 1992; Juma, Mostafavi, and Joseph, 1995; Stonehill et al., 1996).

Recommendations for Future Research

With regard to SCI bladder management, the initial and secondary-level literature searches, grading of the quality of research for identified literature citations, panel discussions, and field reviews revealed a number of areas that need further research. These include:

- Prospective studies on SCI nursing bladder management issues.
- Impact of various types of bladder management on the quality of life following SCI.
- Prospective studies on risks, complications, and benefits of current SCI bladder management methods.
- Prospective studies on comparing the risks, complications, and benefits of currently used SCI bladder management methods.
- Prospective evaluations on the impact of pharmacological treatment of bladder and sphincter function following SCI.
- Role of newer modalities, such as botulinum toxin, stem cell research, and tissue cloning on SCI bladder management.
- Effective ways to educate patients on bladder management following SCI.
Appendix A:
Economic Considerations of Bladder Management Methods (as of 2006)

<table>
<thead>
<tr>
<th>Method</th>
<th>Products and Services</th>
<th>Provider</th>
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</thead>
<tbody>
<tr>
<td>Intermittent Catheterization</td>
<td>Catheterization supplies <em>(reusable: 8/month; single-use: 8/day)</em>&lt;br&gt;- Straight nonlatex catheter: female, $.43; male, $.52 each&lt;br&gt;- Hydrophilic catheter: $.78–$1 each&lt;br&gt;- Antibacterial catheter: female, $.54; male, $.61 each&lt;br&gt;- Touchless catheter kit: $2.71 each</td>
<td>VA: shared cost of prescriptions relating to service connection&lt;br&gt;VA: shared cost of prescriptions relating to service connection; condom cost increases with size and type&lt;br&gt;HMO: part of monthly fees&lt;br&gt;PPO: shared cost depending on deductible&lt;br&gt;Medicare or Medi-Cal: shared cost</td>
</tr>
<tr>
<td>Indwelling Catheterization</td>
<td>Cost of daily condom, catheters, leg bag, and nighttime collection bag&lt;br&gt;Condom: approx. $.55–$1.50 qd&lt;br&gt;Catheters (every 2–4 weeks):&lt;br&gt;- Latex catheters w/5ml balloon: $1.30–1.50&lt;br&gt;- Silver-coated catheters w/5ml balloon: $8.91&lt;br&gt;- Silastic-coated catheters w/5ml balloon: $7.30&lt;br&gt;- Teflon coated catheters w/5ml balloon: $10&lt;br&gt;- 100% silicone catheter w/5ml balloon: $3.20&lt;br&gt;- Hydrophilic catheters w/5ml balloon: $10&lt;br&gt;Automatic leg bag drainer: $700–$800 installed on an electric wheelchair&lt;br&gt;Leg bag (4/month): approx. $1.76 each&lt;br&gt;Permanent leg bag: $7–$10&lt;br&gt;Cystoflow drainage bag (1/month); 1000ml urinary drainage bag: approx. $4.02 each</td>
<td>VA: shared cost of prescriptions relating to service connection&lt;br&gt;HMO: part of monthly fees&lt;br&gt;PPO: shared cost depending on deductible&lt;br&gt;Medicare or Medi-Cal: shared cost</td>
</tr>
<tr>
<td>Alpha-Blockers</td>
<td>Cost of drug: depends on type of insurance. A brand-name drug will be more expensive than a generic; however, the generic may not be as effective.</td>
<td>VA: shared cost of prescriptions relating to service connection&lt;br&gt;HMO: part of monthly fees&lt;br&gt;PPO: shared cost depending on deductible&lt;br&gt;Medicare or Medi-Cal: shared cost</td>
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<tr>
<td>Botulinum Toxin Injection</td>
<td>Cost of procedure: depends on type of insurance&lt;br&gt;Cost of daily condom, leg bag, and nighttime collection bag&lt;br&gt;- Condom: approx. $.55–$.75 each qd&lt;br&gt;- Leg bag (4/month): approx. $1.76 each&lt;br&gt;- 1000ml urinary drainage bag (1/month): $4.02&lt;br&gt;Cost of incontinence padding: depends on the size and shape of the individual, amount of urine leaked or voided in a day, and individual’s ability to transfer and void into the toilet</td>
<td>VA: shared cost of prescriptions relating to service connection; condom cost increases with size and type&lt;br&gt;HMO: part of monthly fees&lt;br&gt;PPO: shared cost depending on deductible&lt;br&gt;Medicare or Medi-Cal: shared cost</td>
</tr>
<tr>
<td>Endourethral Stent</td>
<td>Cost of procedure: depends on type of insurance&lt;br&gt;Cost of daily condom, leg bag, and nighttime collection bag&lt;br&gt;- Condom: approx. $.55–$.75 each qd&lt;br&gt;- Leg bag (4/month): approx. $1.76 each&lt;br&gt;- 1000ml urinary drainage bag (1/month): $4.02</td>
<td>VA: shared cost of prescriptions relating to service connection; condom cost increases with size and type&lt;br&gt;HMO: part of monthly fees&lt;br&gt;PPO: shared cost depending on deductible&lt;br&gt;Medicare or Medi-Cal</td>
</tr>
</tbody>
</table>
### BLADDER MANAGEMENT FOR ADULTS WITH SPINAL CORD INJURY

<table>
<thead>
<tr>
<th>Method</th>
<th>Products and Services</th>
<th>Provider</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transurethral Sphincterotomy</td>
<td>- Cost of daily condom, leg bag, and nighttime collection bag</td>
<td>- VA: shared cost of prescriptions relating to service connection; condom cost increases with size and type</td>
</tr>
<tr>
<td></td>
<td>- Condom: approx. $.55–$.75 each qd</td>
<td>- HMO: part of monthly fees</td>
</tr>
<tr>
<td></td>
<td>- Leg bag (4/month): approx. $1.76 each</td>
<td>- PPO: shared cost depending on deductible</td>
</tr>
<tr>
<td></td>
<td>- 1000ml urinary drainage bag (1/month): $4.02</td>
<td>- Medicare or Medi-Cal: shared cost; surgery $50,000</td>
</tr>
<tr>
<td></td>
<td>- Automatic leg bag drainer: $700–$800 installed on an electric wheelchair</td>
<td></td>
</tr>
<tr>
<td>Electrical Stimulation and Posterior Sacral Rhizotomy</td>
<td>- Cost of surgical rhizotomy and implantation of device: depends on type of insurance</td>
<td>- VA: shared cost of prescriptions relating to service connection; condom cost increases with size and type</td>
</tr>
<tr>
<td></td>
<td>- Replacement of transmitter, wires, and transmitter faceplate:</td>
<td>- HMO: part of monthly fees</td>
</tr>
<tr>
<td></td>
<td>- (approx. every 5 years)</td>
<td>- PPO: shared cost depending on deductible</td>
</tr>
<tr>
<td></td>
<td>- Cost of daily condom, leg bag, and nighttime collection bag</td>
<td>- Medicare or Medi-Cal: shared cost</td>
</tr>
<tr>
<td></td>
<td>- Condom: approx. $.55–$.75 each qd</td>
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<td></td>
</tr>
<tr>
<td>Bladder Augmentation</td>
<td>- Cost of surgery: depends on type of insurance</td>
<td>- VA: shared cost of prescriptions relating to service connection</td>
</tr>
<tr>
<td></td>
<td>- Catheterization supplies (reusable: 8/month; single-use: 8/day)</td>
<td>- HMO: part of monthly fees</td>
</tr>
<tr>
<td></td>
<td>- Straight nonlatex catheter: female, $.43; male, $.52 each</td>
<td>- PPO: shared cost depending on deductible</td>
</tr>
<tr>
<td></td>
<td>- Hydrophilic catheter: $.78–$1 each</td>
<td>- Medicare or Medi-Cal: shared cost</td>
</tr>
<tr>
<td></td>
<td>- Antibacterial catheter: female, $.54; male, $.61 each</td>
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<tr>
<td></td>
<td>- Touchless catheter kit: $2.71 each</td>
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<tr>
<td>Urinary Diversion</td>
<td>- Cost of surgery: depends on type of insurance</td>
<td>- VA: shared cost of prescriptions relating to service connection</td>
</tr>
<tr>
<td></td>
<td>- Cost of ostomy appliance, skin protectants, and accessories</td>
<td>- HMO: part of monthly fees</td>
</tr>
<tr>
<td></td>
<td>- Bard stoma urinary pouch (one every 5–7 days): $4.88 each</td>
<td>- PPO: shared cost depending on deductible</td>
</tr>
<tr>
<td></td>
<td>- Irrigation sleeve (depends on frequency of needed irrigation): $1.97 each</td>
<td>- Medicare or Medi-Cal: shared cost</td>
</tr>
<tr>
<td></td>
<td>- Skin barrier/water (depends on frequency of change): $4.91 each</td>
<td></td>
</tr>
</tbody>
</table>
The following list of references includes all the sources used by the guideline development panel to support its recommendations. The list also indicates the strength of scientific evidence (1–5) for each graded reference. A graded reference is one that was evaluated by the methodology team, following the protocol described in Methodology, to determine whether it met the inclusion criteria established by the panel and methodology team. If a citation is not labeled, it was graded by the methodologists but did not meet the level of evidence criteria or was used in the Introduction only. Unlabeled citations are included because they were considered by the panel to enhance the understanding of the guideline recommendations.


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