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## The Worldwide Economic Impact of Neurogenic Bladder

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### Abstract

Costs of neurogenic bladder vary widely and depend on a number of factors including severity of disease, symptomatology, patient insurance, and devices required. Recognition of how each treatment strategy will impact the patient financially could help guide selection of treatment as well as improve compliance with the chosen regimen. We have attempted to provide an overview of long term cost considerations for the neurogenic bladder patient. Armed with this information, the practitioner can better help the patient select a bladder care regimen that balances the desire to both minimize symptoms now and preserve urinary tract integrity for the future, yet still remain cost effective.

### Keywords

Costs and cost analysis; Urinary bladder - neurogenic; Urinary retention; Health expenditures; Urinary incontinence; Urinary bladder - overactive; Incontinence pads; Intermittent urethral catheterization

## INTRODUCTION

Neurogenic bladder is characterized by damage to the central nervous system (CNS), autonomic nervous system (ANS), or sympathetic nervous system (SNS) and can result in the inability of the patient to store urine (urinary frequency, urgency, or incontinence) or fully empty the bladder on command (urinary retention)<sup>1</sup>. It presents a long-term challenge for both the patient and the physician and has the potential of amassing significant long-term costs. Some causes include multiple sclerosis (MS), spinal cord injury (SCI), traumatic brain injury (TBI), cerebrovascular accident (CVA), spina bifida, cerebral palsy, transverse myelitis, and diabetes mellitus (DM)<sup>2</sup>. Because of variability in hospital charges and insurance billing, it can often be challenging for the patient and physician to accurately predict the lifetime costs of this condition. Fortunately, many of the same symptoms affecting neurogenic bladder patients affect non-neurogenic overactive bladder patients as well, making it possible to extrapolate cost data from non-neurogenic overactive bladder studies when making estimates.

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Compliance with Ethics Guideline

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Human and Animal Rights and Informed Consent

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Surgical intervention for neurogenic bladder (continent or incontinent diversion, augmentation, sling, or artificial sphincter placement, for example) carries a cost that is certainly a major contributor to the global cost of neurogenic bladder to the medical system and to society, but it can be argued that surgical intervention has the potential to cure incontinence, possibly resulting in a net cost savings. However, because the bulk of the costs of surgery often lie with insurance companies, governments, or with the hospital (when bills are not paid), these interventions don't necessarily represent long-term tangible costs to the individual. Often more apparent to the patient and family are the ongoing direct costs related to supplies needed to stay dry (pads, diapers, liners) and to empty fully (catheters, drainage supplies, and lubricant). With this chronic condition the patient will also require close surveillance and consistent care in an effort to avoid the common complications of a neurogenic bladder, namely urinary tract infections (UTI), stones, pressure ulcers, and high storage pressures leading to renal damage. Surveillance for these complications will remain necessary throughout the patient's life<sup>3\*</sup>, amassing office copays, laboratory tests, and urinary tract imaging in addition to time lost from work. Each of these aspects impacts cost and should be considered when selecting a treatment plan. Some have suggested that shifting responsibility for cost savings to physicians could save costs at the grassroots level, but may also potentially compromise the patient-doctor relationship, traditionally understood as the doctor always advocating for the patient's best interest.<sup>4</sup> It is important to keep this in mind when analyzing cost containment in healthcare.

### Behavior Training

Behavior training is first line therapy for patients with non-neurogenic OAB according to the 2012 AUA Guidelines document<sup>5</sup>. When considering neurogenic bladder, there is less evidence and the benefit is not as clear, leading the authors of the European Guidelines on Neurogenic Lower Urinary Tract Dysfunction to conclude it "may be useful". Some of this is based on evidence that it is specifically helpful in patients suffering from MS<sup>3, 6\*</sup>. Compared with daily medication or surgery, behavior training has an obvious cost benefit once the patient has completed supervised therapy, but studies investigating efficacy are lacking. This may be due to the hypothesis that behavior therapy and biofeedback therapy utilize the body's neural pathways to effect lasting change, and these are altered in the neurogenic bladder.

### Devices/Disposables For Urinary Retention

Many patients with neurogenic bladder have difficulty fully emptying the bladder and the preferred management is intermittent self-catheterization performed by the patient or a caregiver.<sup>7\*\*</sup> In their review of best practices in catheterization, Newman *et al.* find that intermittent catheterization leads to fewer complications and infections than placement of an indwelling catheter.<sup>7\*\*</sup> Choice of approach to intermittent catheterization has substantial impact on long-term costs of neurogenic bladder. The number of catheterizations required per day will vary from patient to patient, based on liquid intake, bladder compliance, presence of reflux and renal function, but a general "rule of thumb" is to catheterize frequently enough to maintain a maximum bladder volume of 500mL.<sup>8</sup> To do so, patients typically will require a 12-14 French catheter 4-6 times per day.<sup>9</sup> Patients may choose to perform clean or aseptic intermittent catheterization. Clean catheterization allows for the

reuse of catheters.<sup>10</sup> Although this method of catheterization is not endorsed on the packaging and is considered off-label use in the USA,<sup>7, 11</sup> this has become an often-used strategy for limiting the cost of supplies. Long term costs of this strategy then depend on how many times the catheter is reused before disposal, as well as the lubricant needed for each use. Recent studies show that about half of United States patients (56%) who perform intermittent catheterization reuse their catheters, and many experts encourage this practice in low income areas and in developing countries where economic constraints limit the availability of these devices.<sup>7\*\*</sup> Choice of cleaning method (soap and water, microwave sterilization, etc...) there have been no published randomized controlled trials that compare either cost or efficacy of sterilization and reuse.<sup>7\*\*</sup> Aseptic technique, in contrast, involves kits that provide sterile gloves and catheters that either come as a self-contained prelubricated kit or whose hydrophilic coating becomes a lubricant when wet.<sup>10</sup> In order to be considered aseptic technique, these catheters are single use only and one study found at the single use requirement of aseptic technique had the biggest impact on cost. The authors report single use catheter technique costs approximately £28 /\$46/ €36.4 per week<sup>10</sup>. Multiple use catheterization is far cheaper, costing approximately £0.5 /\$1/€0.8 per catheter plus the cost of lubricant.<sup>10</sup> One innovative strategy discussed in the literature is volume dependent intermittent catheterization (VDIC). This technique reduces the number of catheters used by reducing the frequency of intermittent catheterization by postponing catheterization if bladder volume falls below a pre-determined “threshold volume”. This measurement is done by bladder ultrasound. The authors were able to realize a 46% reduction in cost with no obvious adverse effects<sup>12</sup>.

### Costs of Urinary Tract Infections

Also contributing to the cost of neurogenic bladder and intermittent catheterization are urinary tract infections (UTIs), which necessitate clinic visits, testing, antibiotic treatment, and at times hospitalization. Urinary tract infections are one of the most common side effects of neurogenic bladder and they often result from clean intermittent catheterization.<sup>7, 10\*\*</sup> Retained urine, introduction of foreign bacteria into the urinary tract, and breaks in the bladder urothelium and urethral lining all increase the risk of infection.<sup>7\*\*</sup> A number of variations in clean intermittent catheterization (CIC) technique have been advocated, however an abridged Cochrane Review of catheterization techniques found no convincing evidence that incidence of asymptomatic urinary tract infection was affected by catheterization technique (aseptic versus clean), type of catheter (coated, uncoated, single-use, multiple-use), or self-catheterization versus catheterization by a caregiver.<sup>8</sup> Trials comparing single use (sterile) catheter versus multiple use (clean) catheter found no significant difference in incidence of symptomatic UTI or weeks to onset of UTI.<sup>10</sup> Furthermore, another study found that fewer antibiotic prescriptions were needed for those performing sterile catheterization, costing 43% less than the cost for those utilizing cleaned, reused catheters and non-sterile technique. Yet because the sterile kits were so costly the total cost of performing sterile catheterization was 277% of those using non sterile technique.<sup>13</sup> In order to predict the expected costs for a particular patient, it can be helpful to consider those characteristics that contribute to a higher frequency of urinary tract infections: higher catheterization volumes (resulting from infrequent catheterizations or increased fluid intake), female gender (women report more UTIs than men), catheterization

by a caregiver (non-self catheterization), business of lifestyle, and mobility impairment.<sup>7••</sup> Furthermore, it has been noted that the longer the time frame that an individual catheterizes, the higher the incidence of UTI.<sup>14</sup>

### Devices/Disposables For Urinary Incontinence

For those neurogenic bladder patients who experience incontinence, a number of incontinence devices are available, each with variable cost and availability. A 2007 Cochrane review<sup>15</sup> compares the cost and efficacy of four kinds of incontinence devices: disposable inserts, disposable menstrual pads, washable pants with an integrated washable inserts, and washable inserts. This review found that while leakage protection was best using disposable inserts designed for incontinence, disposable menstrual pads were the cheapest option and that although disposable inserts were the preferred option for many women, disposable menstrual pads were acceptable in some situations due to their decreased cost. This review recommended that the practitioner work with the patient to choose. Ultimately, patients may opt to use all kinds of incontinence devices in order to obtain optimum continence when necessary but take advantage of less costly options when possible. Many experts advocate this technique since there is no clear benefit to skin health for any of the above mentioned incontinence devices and freedom of choice has been shown to improve patient satisfaction.<sup>15</sup>

When discussing incontinence products, costs for neurogenic bladder may be similar to those of overactive bladder (OAB). In five European countries (Germany, Italy, Spain, Sweden, and the United Kingdom), investigators noted the average annual direct costs of OAB (not necessarily neurogenic bladder) ranged from €269 to €706 per patient per year. The largest contributor to cost was the use of incontinence pads, which would likely be true for neurogenic bladder patients as well, and was attributed to 63% of the annual per patient cost of OAB. On a larger scale, the cost to health care systems for all five countries was estimated at €4.2 billion in 2000<sup>16</sup>.

### Cost of Procedural Intervention

Some have suggested that procedural intervention may save costs related to disposables and catheters, which are very visible to the patient, but very few studies have been published to prove this claim. Further complicating matters, it is difficult to discern cost savings versus cost shifting – which may falsely support the choice of one versus the other based on cost. For example, During the 1990s, outpatient spending for overactive bladder rose dramatically compared to operative costs. Looking closely, however, this was not inherently due to one treatment modality being more expensive than the other, but rather because a shift in costs occurred from inpatient procedures to procedures not requiring hospitalization as advances were made in outpatient treatment.<sup>17</sup> One form of procedural intervention, OnabotulinumtoxinA, was studied in the widely quoted ABC trial to examine the hypothesis that there may be a difference in effectiveness between onabotulinum toxin therapy over a 6 month period and a comparable anticholinergic. Although the investigators found no difference in the reduction in incontinence episodes (–1.6 vs. –1.7), there was a significant difference in the number of patients reporting “cure” by the study criteria (27% vs. 13%, respectively, p=0.003).<sup>18</sup> One team of investigators found that onabotulinumtoxinA (BoNT-

A) used to treat refractory neurogenic detrusor overactivity from SCI or MS was more effective than “best supportive care” alone, adding 0.4 Quality Adjusted Life years (QALY), at an increased cost of £1,689 over 5 years<sup>19</sup>. The authors felt this was cost effective, but leave the question unanswered regarding how much the system should be willing to pay for one additional QALY. Another study compared cost estimates and effectiveness (based on QALY gained) of sacral nerve stimulation versus BoNT-A, finding cost of sacral nerve stimulation to be greater (\$15,743 versus \$4,392) but that it was also marginally more effective (1.73 versus 1.63 QALYs).<sup>20</sup> Another study projected 10-year costs of BoNT-A. They found that costs increased in a specialist setting versus non-specialist setting, and costs increased proportional to baseline comorbidity. Patients requiring more than 4 catheterizations per day had a significantly higher 10 year projected cost. Additionally, when comparing 10-year costs of BoNT-A to 10-year costs of clam cystoplasty, they found that costs were the same or lower for BoNT-A injections where the symptoms responded to the injections. However, if urgency, frequency, and incontinence remained severe enough to require 4 or more catheterization episodes per day cystoplasty was the less costly choice.<sup>21</sup>

### System Wide Cost of Urinary Incontinence

Urinary incontinence is a common symptom of neurogenic bladder. In the USA, investigators estimated the annual direct costs for urinary incontinence in 2007 for adults over 25 years old, not necessarily just those with neurogenic bladder, was \$65.9 billion. Direct costs are the main driver of the overall cost of UII in the United States, and the personal costs were significant<sup>22</sup>.

### Surveillance

Surveillance of patients with neurogenic bladder is intended to monitor for the common sequelae of neurogenic bladder, most notably urinary tract infection, upper tract deterioration, stones, and malignancy. Malignancy in neurogenic bladder, although rare, does carry a higher likelihood than in those with normal bladder function because of chronic catheterization, frequent UTIs, and stone disease.<sup>23</sup> Additionally, due to the need for intermittent catheterization, frequent introduction of bacteria into the urinary tract combined with urine stasis from incomplete emptying can predispose to urinary tract infection. There is a balance that is struck between the detection and overtreatment of asymptomatic bacteriuria versus the potential for the progression to bacteremia and sepsis. Both extremes have potential to increase the cost burden for such patients, and as such it is recommended that physicians discuss the pros and cons of each strategy with their patients.

Recommendations for the care and surveillance of neurogenic bladder vary based on the cause of the condition as well as how long neurogenic symptoms have been present. Although guidelines do exist for the care and surveillance of patients with neurogenic bladder,<sup>3</sup> an optimal follow-up schedule has not been definitively agreed upon. The 2012 American Urologic Association Joint Guideline on Urodynamics makes 5 recommendations specific to neurogenic bladder<sup>24</sup>. The recommendations are:

1. A post void residual assessment initially and “as part of ongoing follow up as appropriate”

2. An initial cystometrogram (CMG) and “as part of ongoing follow up as appropriate”
3. An initial pressure flow study (PFS) and “as part of ongoing follow up as appropriate”
4. Videourodynamics with fluoroscopy and “as part of ongoing follow up as appropriate”
5. An EMG in combination with CMG and “as part of ongoing follow up as appropriate”

For victims of spinal cord injury specifically, a 2011 review of recommendations for primary care physicians suggests initial evaluation of these patients should include urinalysis, urine culture and sensitivity, serum blood urea nitrogen/creatinine, creatinine clearance, and urodynamics.<sup>25</sup> Follow up of these patients includes urinalysis and ultrasound every six months, urine culture whenever symptoms occur, urologic follow-up yearly, and urodynamic evaluation every 1-2 years.<sup>26</sup> For those patients using intermittent self-catheterization, many urologists advocate for regular cystoscopy and random and targeted bladder biopsies in addition to regular urine cytology.<sup>7\*\*</sup> Office copays, laboratory analysis, imaging, and treatment - even when covered by insurance carries intangible costs. Care often require time missed from work for either the patient or their caregiver, in addition to associated copays. Nevertheless, patients with neurogenic bladder represent heavy users of the healthcare system. Indeed, Manack *et al.* report that 40% of these patients attend at least one urology visit over 1 year and 33% were hospitalized during that time<sup>1\*</sup>.

Although patients with OAB typically utilize less care per year than patients suffering from neurogenic bladder, practice patterns that impact the cost of OAB likely impact the cost of neurogenic bladder in a similar way. One European study utilized data from the Prospective Urinary Incontinence Research study, specifically looking at cost of treatment in Germany, Spain and the UK/Ireland. Investigators combined health insurance cost estimates with individual cost for pads and other treatments and noted that practice patterns varied significantly by country. In the UK treatment was most often administered by general practitioners, while in Germany and Spain patients were more likely to have consulted a specialist. This pattern was associated with Mean total urinary incontinence-related costs per patient per year ranging from €359 in the UK/Ireland to €15 in Germany and €655 in Spain, suggesting that access to a specialist increases cost. Quality of life and patient satisfaction were not investigated<sup>27</sup>.

## CONCLUSION

The costs associated with neurogenic bladder appear to be greater than those associated with non-neurogenic OAB. Direct costs are not easy to calculate in any region, even regions that participate in government-sponsored healthcare, making estimates and models important surrogates for determining cost of care. As cost awareness takes a more prominent role in healthcare worldwide more transparency in healthcare expenditures and actual reimbursement will be called for. Regional differences will appear. The clinician will



undoubtedly be asked to play a role in cost-containment, and it benefits clinicians to educate themselves about the relative costs of the treatments they recommend.

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