Interpretable urodynamics studies are difficult to obtain in children, many of whom exhibit significant behavioral distress during catheterization. To address the needs of these children, researchers developed a sedation service and reviewed the literature that supported the creation of this service. This article will present the authors’ experience in creating a service to meet the needs of these children as well as the initial outcomes of the sedation service.

Key Words: Pediatrics, sedation, anesthesia, catheterization, behavioral distress, urodynamics, children.

There is growing evidence that minimal sedation does not adversely affect bladder function during bladder function studies. Many institutions have reported on the use of minimal sedation to meet the needs of patients who experience behavioral distress during urethral catheterization. In preparing to begin a pediatric urodynamics sedation service, an extensive review of the existing literature on creating a sedation service for pediatric urodynamics procedures was conducted. This article will present the authors’ experience in creating a service to meet the needs of these children as well as the initial outcomes of the sedation service.

Between 100 and 140 urodynamics procedures are performed in the authors’ pediatric urology practice yearly. Approximately 50% of these children catheterize daily and tolerate urodynamics procedures with minimal discomfort or anxiety. Fifty percent are children with sensation and do not routinely catheterize. Fifty percent are children with sensation and do not routinely catheterize. The diagnoses of these sensate children who require urodynamics include, but are not limited to, children with posterior urethral valves, new onset incontinence, dysfunctional voiding, tethered cord, spinal tumor, and multiple sclerosis. It has been the experience of the authors that 47% of sensate children experience behavioral distress that limits the interpretability of urodynamics testing (Sweeney et al., 2008). Most of these children are between the ages of 2 months and 15 years. To improve patient comfort and the ability to obtain interpretable urodynamics results, the authors’ service developed a urology sedation service. An extensive literature review was conducted on the impact of sedation on bladder function and the facility’s guidelines for the credentialing of sedation providers and performing sedation within the institution was reviewed.

INTERNAL CHART REVIEW

A retrospective chart review was conducted to identify which children displayed behavioral distress during catheterization, and subsequently, would require rescheduling of their urodynamics with sedation. It was discovered that the child’s age (age 3 to 7 years) was the most predictive characteristic for requiring sedation. Other variables, such as developmental disabilities, physical/sexual abuse, stage of toilet training, and prior catheterizations, were not deemed statistically significant (Sweeney et al., 2008). Based on these results, an extensive literature review on how to create a sedation service was performed.

LITERATURE REVIEW

Urodynamics

Urodynamics testing involves the use of urethral catheters and rectal pressure monitors to assess bladder compliance and capacity. To identify the underlying pathophysiology that may ad-
versely affect bladder function, a patient must participate in the urodynamics test by coughing on demand and indicating first sensation, first desire, strong desire, and void at will (Schafer et al., 2002).

Reducing Anxiety and Behavioral Distress

To minimize any anxiety or discomfort during urodynamics, urodynamics nurses should provide pre-procedure education, utilize distraction techniques (for example, blowing bubbles, pinwheels, books, movies, music), urethral numbing with 1% lidocaine jelly, and emotional support by allowing parents in the room during the test (Akil et al., 2005; Bozkurt et al., 1996; Elder & Longenecker, 1995; Goodman, Kilborn, & Pearce, 2003; Keidan et al., 2005; Stokland, Andreasson, Jacobsson, Jodal, & Ljung, 2003). Despite these steps to comfort the child during urodynamics testing, some children may exhibit extreme behavioral distress, which renders sufficient artifact that the test results are deemed non-interpretable. Behavioral distress is indicated by various behaviors, such as crying, clinging to the parent, expressions of verbal fear or verbal pain, screaming, utilizing stalling tactics, refusal to enter the room and needing to be carried, flailing of limbs, refusal to follow instructions regarding body placement, need for physical restraint, and excessive muscular rigidity (clenched fists, white knuckles, gritted teeth, clenched jaw, wrinkled brow, eyes clenched shut, body stiffness) (Katz, Kellerman, & Siegel, 1980).

Effect of Midazolam on Bladder Dynamics

Midazolam (Versed®) can be used for procedural anxiety. Although midazolam has not been routinely used for pediatric urodynamics procedures, it has been shown to reduce anxiety associated with catheterization for voiding cystourethrography (VCUG) without obscuring the presence of reflux or post-void residual (Elder & Longenecker, 1995; Keidan et al., 2005; Stokland et al., 2003). To date, only Bozkurt et al. (1996) have studied the effects of midazolam on pediatric urodynamics. They found no significant difference between urodynamics performed on children with and without nasal midazolam.

After the authors’ institution reviewed the literature on urodynamics and voiding cystourethrogram (Akil et al., 2005; Ameda et al., 1997; Bozkurt et al., 1996; Elder & Longenecker, 1995; Keidan et al., 2005; Koff, Solomon, Lane, & Lieding, 1980; Merguerian, Corbett, & Cravero, 2006; Stokland et al., 2003), it was believed that sedation (oral, nasal, IV, general anesthesia) would not adversely obscure the urodynamics investigation of neuropathic bladders, evidence of tethered cord, or presence of posterior urethral valve bladder syndrome (pressures greater than 40 mmHg and small or flaccid bladders).

Qualifying Children for Sedation

The institution’s guidelines for procedures with sedation reflect the recommendations of the American Society of Anesthesiology (ASA) and the American Academy of Pediatrics (AAP) (American Society of Anesthesiology [ASA], 1996). Sedation protocols at the institution are based on the degree of sedation required and Mallampati airway classification. The ASA classifies sedation into four categories – minimal, moderate, deep, and general anesthesia (see Table 1) (Malviya, Voepel-Lewis, Tait, & Merkel, 2000). Mallampati classifications assess a patient’s airway and screen for degree of risk during sedation. The urology sedation service at the institution provides minimal sedation for children with Mallampati airway classes I and II. Children with Mallampati airways III and IV are referred to the anesthesia department for sedation in the operating room (see Figure 1).

### Table 1. ASA Levels of Sedation, Minimal, Moderate, Deep, and General Anesthesia

<table>
<thead>
<tr>
<th>Characteristics of Levels of Sedation</th>
<th>Awake</th>
<th>Minimal</th>
<th>Moderate</th>
<th>Deep</th>
<th>General Anesthesia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Loss of protective airway reflexes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Loss of airway control</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Respiratory depression</td>
<td>No²</td>
<td>No²</td>
<td>No³</td>
<td>Yes⁴</td>
<td>Yes⁴</td>
</tr>
<tr>
<td>Response to verbal stimulation</td>
<td>Yes</td>
<td>Yes</td>
<td>No⁵</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Response to tactile stimulus</td>
<td>Yes</td>
<td>Yes</td>
<td>No⁵</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Loss of other motor reflexes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Depressed consciousness</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

**Key:**

1. Minimal sedation occurs in an awake patient with a relaxed consciousness.
2. No change in baseline respiratory rate (RR) or SaO₂.
3. No more than 5% change in SaO₂ or 40% change in RR from baseline.
4. Patient requires airway support.
5. Patient responds to persistent verbal/tactile stimulation.
Sedation Agents

Selection of midazolam as the primary sedating agent stems from the authors’ prior research on the effects of sedation on bladder function and the institution’s use of midazolam in other departments (Akil et al., 2005; Ameda et al., 1997; Ashton, 1994; Bozkurt et al., 1996; Elder & Longenecker, 1995).

DEVELOPMENT OF A SEDATION SERVICE/CREDENTIALING PROVIDERS

The development of a pediatric urology sedation service requires adequate facilities, and the credentialing of sedation and analgesia providers (SAP) and sedation monitors. Sedation monitoring documentation is specific to the level of sedation provided; it reflects the care provided and patient’s response.

The institution requires that sedation be performed by a credentialed sedation and analgesia provider in a medically supervised setting. In this facility, a pediatric code team must be available and an attending anesthesiologist must be available via emergency pager (Connecticut Children’s Medical Center, 1996). Minimum monitoring requirements according to level of sedation are outlined by the facility (see Table 2).

A credentialed SAP is a physician, nurse practitioner, or physician’s assistant who can prescribe and supervise sedation. Credentialing occurs under the auspices of the director of anesthesiology, the surgeon-in-chief, or physician-in-chief, and is reviewed on a biennial basis. The requirements for SAP credentialing consist of a working knowledge of sedation principles and the hospital’s sedation and analgesia policy, review of the SAP education provided by the anesthesia department, completion of a qualifying examination, documentation of adequate bag/mask airway management, and/or completion of an appropriate life-support skills course. House staff physician credentialing also includes documentation of a

Table 2. Connecticut Children’s Medical Center Requirements for Monitoring for Various Stages of Sedation

<table>
<thead>
<tr>
<th></th>
<th>Minimal</th>
<th>Moderate</th>
<th>Deep</th>
<th>General Anesthesia¹</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medically supervised setting</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes¹</td>
</tr>
<tr>
<td><strong>Resuscitation equipment² immediately available</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Pulse oximetry</strong></td>
<td>Yes³</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Cardiac monitoring</strong></td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Vital signs (include level of sedation)</strong></td>
<td>Yes⁴</td>
<td>Yes⁴</td>
<td>Yes⁴</td>
<td>Yes⁴</td>
</tr>
<tr>
<td><strong>Maximum interval for recording vital signs</strong></td>
<td>20 mins.</td>
<td>10 mins.</td>
<td>5 mins.</td>
<td>5 mins.</td>
</tr>
<tr>
<td><strong>Intravenous access</strong></td>
<td>No</td>
<td>Yes⁵</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Staff required</strong></td>
<td>Sedation monitor and SAP or sedation monitor and individual performing procedure with SAP aware</td>
<td>Sedation monitor and SAP not performing procedure</td>
<td>Sedation Monitor and Anesthesiology LHCP</td>
<td></td>
</tr>
</tbody>
</table>

Key:
¹ Patient must be under the supervision of an attending anesthesiologist.
² Oxygen, suction, code cart, manual resuscitator (Ambu-Bag™), code cart.
³ Pulse oximetry will be continuous and recorded q 5 minutes in the event of that other tactile monitoring (blood pressure cuff) cannot be used within the maximum interval. Oximetry can be monitored by health care personnel in a medical supervised setting, assuming a licensed health care provider monitoring the patient q 20 minutes is immediately available.
⁴ In locations where respiratory rate is difficult to assess within required intervals, a continuous monitor (apnea or end-tidal CO₂ monitor) should be used.
⁵ When moderate sedation is achieved via a non-intravenous route, the SAP may choose not to establish intravenous access. However, in each case, a licensed health care provider with the ability to establish IV access must be immediately available during the period of moderate sedation.

Source: Connecticut Children’s Medical Center, 1996.
minimum of three observed successful sedations, which are observed by another credentialed SAP.

The sedation monitor is a licensed health care provider, nurse, nurse practitioner, physician, or physician’s assistant. The sedation monitor is responsible for administration of sedatives and/or analgesics used and the required patient monitoring during the sedation event. The credentialing of a sedation monitor requires a working knowledge of sedation policy and procedure, sedation assessment, and airway management skills. The sedation monitor’s skill checklist includes both oral and written evaluation methods.

Pre-sedation evaluation of the patient’s airway is done in accordance with the ASA Risk Classifications and Mallampati classifications (ASA, 1996). The urodynamics suite is equipped with oxygen, suction, blood pressure, and pulse oximetry capability. Children who required stronger sedation than midazolam are given moderate sedation in the hematology/oncology sedation suite or in the operating room (see Table 3).

A pre-sedation assessment must be performed by a provider (usually the primary care provider) one week before the procedure. The health and physical examination must include past medical history, current medications, medication allergies, immunization status, review of systems, and a complete physical examination. The night before the procedure, the family is contacted by the service and instructed on nothing by mouth (NPO) guidelines (see Table 4) (Connecticut Children’s Medical Center, 1996).

On the day of sedation, a baseline evaluation is performed (vital signs, weight, NPO status, pre-sedation score). If there is any change in pre-sedation assessment, a re-evaluation for sedation will be performed. Before the procedure begins, a final verification “time out” is required, during which unique patient identifiers are reviewed (patient name, date of birth, need for urodynamics with sedation, and verification of operator privileges).

The SAP is responsible for explaining and obtaining informed consent from the parent or legal guardian; this includes risks, benefits, associated risks, and alternatives to sedation. The most common risks cited include inadequate sedation, over sedation with respiratory depression, allergic reaction, and paradoxical reactions.

All medications/fluid administration before and during sedation must have a SAP order documented on an order sheet according to hospital policy. The order must also be documented on the sedation and analgesia flow sheet, which includes the patient’s vital signs, sedation assessment during the procedure and recovery period, patient/family discharge instructions, and patient education.

Patients must be observed according to the minimum monitoring requirements until they achieve an “awake” state, at which time, discharge is permissible. Criteria for “awake” state include negative loss of protective airway reflexes, negative loss of airway control, negative respiratory depression, positive response to verbal stimulus, positive response to tactile stimulus, negative loss of other motor reflexes, and negative depressed consciousness. Either two sedation monitors or an SAP and a sedation monitor must be physically present until the patient is deemed awake.

The SAP discharging the patient is responsible for providing the appropriate discharge instructions for the type of drugs that are administered. The family must be given a phone number to call if problems occur; they should also receive appropriate follow-up provider names, phone numbers, and any medication instructions that might be needed. Sedation monitors escort the family to their car(s) and ensure that the patient is appropriately secured in either a car seat or seat belt. If the patient is under 2 years of age, the family is strongly encouraged to have an adult sit in the back seat of the car next to the child as an extra precaution. Families are instructed to keep the patient within arms reach for the rest of the day. If the patient falls asleep, the family is instructed to have the child sleep on his or her side. The sedation monitor makes a follow-up phone call later that same evening.

All sedation outcomes are reviewed by the authors’ department of anesthesia. Copies of patient evaluations and sedation outcomes/adverse events are for-
warded to the anesthesia department for review. SAPs renew their sedation privileges yearly and recertify for airway management.

**AUTHORS’ EXPERIENCE WITH SEDATION**

After the sedation credentialing process was identified, staff were credentialed within a month. Three staff members—one doctor, one nurse practitioner, and one nurse—were currently credentialed as sedation providers. The facility provides sedation within the guidelines of the institution’s Department of Anesthesia, and the urodynamics laboratory had already been fitted with appropriate resources for minimal sedation (oxygen, suction, pulse oximetry, close proximity to a code button and crash cart, and an in-house code team). After the institution approved credentialing, a physician and a nurse practitioner became SAPs, and one nurse became a sedation monitor.

Before sedation providers and sedation monitors were credentialed, many patients requiring sedation for urodynamics received general anesthesia. At the time this article was written, the urology sedation service had performed 58 urodynamics studies with sedation (37 male, 21 female, ages 2 months to 15 years of age). Seven patients received intranasal midazolam, 29 were given oral midazolam, 2 received IV sedation, and 20 had general anesthesia. Of the 20 patients who underwent general anesthesia, 15 had two tests, once while under anesthesia and once while awake in the PACU. Only two patients had adverse reactions to oral midazolam, with paradoxical reactions to their sedation. Two hours are set aside for a pediatric urodynamics study. If a child is receiving minimal sedation, 4 hours are blocked.

**Sedation Agents Used**

For minimal sedation, midazolam was used for anxiolysis and its short-acting properties. Time to peak oral concentration ranges from 0.72 to 0.95 hours. The elimination half-life for oral concentration is 0.78 to 3.3 hours. Dysphoric reactions or paradoxical reactions to midazolam are an uncommon side effect (Golparvar, Saghaei, Sajedi, & Razavi, 2004; Massanari, Novitsky, & Reinstein, 1997; Weinbroum, Szold, Ogorek, & Flaishon, 2001).

Nasal midazolam IV formulation of 5 mg/1ml was chosen if the child was at risk for spitting out the oral midazolam. The child inhales 0.5 to 1 cc per nostril. In a child under the age of 3, nasal midazolam required the parent to hold the child, while the provider instilled midazolam into the child’s nostrils. This form of midazolam is bitter-tasting, and many children cough after intranasal administration. Onset of action was brief (5 to 10 minutes), and duration of sedation was usually 1 hour. Of the seven children who had intranasal midazolam, none had any adverse reactions.

Oral midazolam is available in a 2 mg/ml ratio. Given the volume of medication that would be required to provide greater than 5 mg, midazolam IV formulation of 5 mg/1ml was used. Because the required volume of midazolam IV formulation is less, it was preferable to the oral formulation despite the bitter taste. Onset of action was slightly longer than nasal (10 to 40 minutes), and the duration of sedation lasts longer (<2 hours). Two patients had adverse reactions with oral midazolam, which were dysphoric reactions (becoming agitated, combative, and crying). In one case, the test was incomplete due to the child’s significant agitation.

Moderate sedation was performed with IV medication in two patients. Intravenous fentanyl, ketamine, and midazolam were used in the setting of the hematology/oncology conscious sedation suite. Indications were urinary retention and incontinence post-chemotherapy. Both cases were uneventful, and no adverse reactions were noted. Oncology nurses recovered the patient, so urology nurses were only required for the amount of time needed to complete the test.

Urodynamics under general anesthesia is costly and involves the use of multiple resources and staffing. Time required for urology nurses to perform urodynamics under general anesthesia involves performing the test in the OR and waiting until the patient is awake enough in the PACU to participate in the “awake state” study. None of the 20 children who had urodynamics testing under general anesthesia had adverse reactions. Urodynamics studies under general anesthesia were able to demonstrate maximum bladder capacity, filling pressures, and presence of uninhibited contractions, but were unable to indicate voiding pressures in 14 patients (70%). Urodynamics testing performed in the awake post-anesthesia state were either performed in the OR suite or in the PACU setting (4 patients).

Performing urodynamics in the PACU posed its own set of unique challenges. In some patients, the post-anesthesia emergence phenomenon (Vlajkovic & Sindjelic, 2007) caused great agita-

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**Table 4. Connecticut Children’s Medical Center NPO Guidelines for Sedation**

<table>
<thead>
<tr>
<th>Solids</th>
<th>General Liquids</th>
<th>Clear Liquids</th>
<th>Breast Milk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newborns</td>
<td>NA</td>
<td>6 hours</td>
<td>2 hours</td>
</tr>
<tr>
<td>Infants</td>
<td>6 to 8 hours</td>
<td>6 hours</td>
<td>2 hours</td>
</tr>
<tr>
<td>Children</td>
<td>6 to 8 hours</td>
<td>6 hours</td>
<td>2 hours</td>
</tr>
</tbody>
</table>
tion, and patients were unable to cooperate with reporting sensation or voiding with the catheter in place. In children who had urodynamics both with anesthesia and in the awake state, four were unable to void under general anesthesia, and three voided during their second test in the PACU. In children where the catheter fell out, the catheter was not reinserted, and an awake state urodynamics study was not obtained.

CONCLUSIONS

The review of literature and the authors’ clinical experience demonstrate the building evidence that sedation can be used to assess bladder compliance and capacity. Given the developmental challenges of performing invasive urologic procedures on children, urology sedation services provide alternative methods to obtain quality urodynamics. Behavioral distress can interfere with obtaining clinically reliable urodynamics results. Chart and literature reviews suggest that pediatric urology services can offer a variety of sedation methods for meeting the needs of these children. By screening children for sedation, pediatric urology programs can properly allocate nursing resources in the urodynamics laboratory.

IMPLICATIONS FOR FUTURE RESEARCH

The challenge for the future is to find a sedation medication that best utilizes resources and provides optimal comfort for the child during catheterization. Further investigation by these authors on the use of other sedation medications with less potential for side effects, faster onset, and shorter recovery time, such as dexmedetomidine (Zub, Berkenbosch, & Tobias, 2005) and nitrous oxide (Zier, Drake, McCormick, Clinch, & Cornfield, 2007), will be conducted.

References


