CLEAN INTERMITTENT CATHETERIZATION:
OVERVIEW OF RESULTS IN 194 PATIENTS WITH SPINA BIFIDA

Agnes Jeruto RN, Dan Poenaru MD, Richard Bransford MD

AIC Bethany Crippled Children’s Centre Of Kenya

Mailing address:
Dan Poenaru MD
PO Box 20, Kijabe 00220, Kenya
Phone: 254-20-32046.500;
Fax: 254-20-32046.355
E-mail: mededdir.kh@kijabe.net
Abstract

Clean intermittent catheterization (CIC) is a life-saving procedure in children with spina bifida, but its effectiveness in Kenya has not been previously documented. The current study analyzed the application of CIC in a series of 194 patients with spina bifida who fulfilled set criteria for placement on the CIC programme. Caregivers were taught the technique and were provided with the necessary supplies. Leak point pressure (LPP) and post-voiding residual (PVR) data obtained correlated with development of hydronephrosis. Out of 176 children alive on CIC, 74% were continent (20% spontaneously, 37% with CIC, and 17% with CIC and imipramine). 18 children died of disease-related complications.

A CIC program is both feasible and effective in Kenya. Economic barriers must be overcome and further parent education is needed in order to offer all Kenyan children with spina bifida a good standard of care.
The commonest cause of neurogenic bladder dysfunction in children is the abnormal development of the spinal canal\textsuperscript{1}. Children with spina bifida have a high probability of renal complications, including hydronephrosis and renal failure. These complications are due to abnormal urodynamic properties of the lower urinary tract, which vary among patients with spina bifida.

The ability to identify which infants are at highest risk of urinary tract deterioration has prompted the initiation of prophylactic therapy. Such therapy includes clean intermittent catheterization (CIC) to avoid high intravesical pressures, and the use of medications which relax the external sphincter\textsuperscript{2}. This treatment has led to a significant decrease in hydronephrosis, reflux, and the need for corrective procedures\textsuperscript{3}.

Continence is another issue as children with spina bifida reach school age. It is managed primarily with CIC and drug therapy. When this treatment is unsuccessful, bladder augmentation and continent urinary diversion procedures can be considered\textsuperscript{1}.

The effectiveness of the CIC technique has been thoroughly documented in western countries, but to our knowledge there is limited information on its application in developing countries where significantly different social and financial factors are at play. The purpose of the current study was therefore to assess a CIC program instituted in Kenya and attempt to identify its feasibility and effectiveness.

**Patients & Methods**

AIC Bethany Crippled Children Centre of Kenya (BCCCK) opened in mid-1998. In the past 5 years, over 400 patients with spina bifida were treated at the centre.
Infants with spina bifida routinely undergo bladder evaluation three days following closure of the spinal defect. The evaluation includes LPP, PVR, renal US, serum creatinine, and urinalysis. The urodynamic assessment is performed by a trained nurse in the presence of the parent, and the assessment is combined with parental teaching of CIC. Follow-up assessments are then performed regularly. These include urodynamic studies at 6 months, 18 months, then yearly, and ultrasound and serum creatinine yearly. Most of the follow-up is obtained through a network of 10 ambulatory clinics situated in various locations throughout Kenya, with visits every 6-8 weeks in each location.

Clean intermittent catheterization was introduced in February 1999. Indications for CIC include:

1. leak point pressure (LPP) >=30cm;
2. post-void residual (PVR) >=10cc;
3. abnormal renal ultrasound (US), serum creatinine or urinalysis;
4. recurrent urinary tract infections (UTIs);
5. need for social continence in school-age children.

Failure of the CIC prompted the start of pharmacological treatment, using imipramine (Tofranil®) 12.5mg once daily (between 5 and 12 years age) or twice daily (over the age of 12). Criteria for starting medication included incompliant children over the age of 5 and all school-age children experiencing significant urinary incontinence. Clinical incontinence was defined as significant leakage of urine on a regular basis. Continence was defined either as “spontaneous” (i.e. achieved without any treatment), or “social” (i.e. achieved when active therapy was needed to successfully avoid leakage).
Data were collected prospectively on all patients treated at BCCCK between February 1999 and August 2003 and then entered in an Excel® spreadsheet. Data collected included patient demographics, defect type and location, all surgical interventions, all urodynamic and urological assessments, as well as follow-up clinical status and urinary continence.

Results

Out of 416 patients seen with spina bifida during the study period, 66 were lost to follow-up or had died. All children were infants with a median age of 1.4 months (range, 1 day to 12 years). Repair of the spinal defect was carried out in all within 2 weeks of presentation, with clinically open defects being repaired more urgently.

Out of the remaining 350 children, urodynamic studies were done in 245 patients (70%). One hundred and ninety–four of these (79.2%) fulfilled the criteria for initiating CIC and were therefore placed in the CIC programme. Eighteen of these patients (9.3%) have died from disease-related complications, leaving 176 currently on CIC. Spinal lesion levels in these children were 67% thoracic, 22% lumbar, and 11% sacral.

Renal US was performed on 110 patients, revealing 9 cases of hydronephrosis (8.2%) , 1 atrophic kidney and 1 cystic kidney. Serum creatinine was done also in 110 patients, and was abnormally elevated in 9 (8.2%). Based on urine microscopic analysis (but not necessarily culture), 39 of 110 tested patients had UTIs (35.5%), and in 9 cases the infections were recurrent.

The results of urodynamic studies both initially and in follow-up are correlated in table 1.
Clinical continence data were obtained in 132 patients (53%). Social continence was obtained in 96 children (74%). Continence was spontaneous in 26 children (19.7%), with the help of CIC in 48 (36.4%), and with both CIC and medication in 22 children (16.7%).

The mean follow-up period was 14.6 months (range, 2 weeks to 12.2 years). Six children at follow-up were found to have stopped the CIC. Reasons found for children stopping CIC were mostly economic (having funds to buy the catheters and the lubricant when they run out of supplies provided free of charge), as well as fear and lack of sense of need to continue the daily catheterizations.

**Discussion**

An abnormal urinary tract is found radiologically in 10-15% of newborns with spina bifida⁴, and untreated up to 50% of children by the age of 2 years develop high-pressure vesicoureteral reflux (VUR), upper tract dilatation (hydronephrosis), and stasis predisposing to repeated urinary tract infections (UTIs)⁵. These complications are due to abnormal urodynamic properties of the lower urinary tract. There are 3 types of urinary tract dynamics found in children with spina bifida, based on bladder contractility patterns and external sphincter activity: synergic, dyssynergic with or without detrusor hypertonicity (detrusor-sphincter dyssynergia, DSD), and completely denervated¹. DSD is the most frequent anomaly, occurring when the external sphincter fails to relax during a detrusor contraction. This is often associated with a poorly compliant bladder emptying only at high pressures. Children with DSD have a particularly high chance of later urinary tract deterioration¹, and must therefore be identified early. Only 6% of children with spina bifida are spared neurologic involvement of the bladder⁶.
CIC was first described by Lapides et al in 1972\textsuperscript{7}, and has become the standard treatment of spina bifida children with DSD and/or incontinence. Current recommendations include starting CIC in the newborn period, because it is easy to master by parents and is more acceptable to children as they grow up\textsuperscript{8}. Moreover, an aggressive approach with immediate neonatal institution of CIC and pharmacotherapy has been shown to reduce the need in later life for surgical procedures\textsuperscript{9,10}. In fact urological surgery should only be required by a small minority of children with spina bifida\textsuperscript{11}. Urodynamic testing must be continued on a yearly basis because of neurological changes in children with spina bifida as they grow\textsuperscript{1}.

The study focuses on a large group of children who have been managed by a uniform protocol over several years. Not all newborns with spina bifida seen in our institution had a bladder evaluation done, because of occasional limitations in the availability of nursing personnel trained in the process. The majority of the children assessed however fulfilled the criteria for CIC, which is a finding consistent with other programs\textsuperscript{12}. For resource reasons, many children were unable to undergo the rest of the assessment, including renal ultrasound and serum creatinine. The limited results available however show a proportion of hydronephrosis and elevated serum creatinine (8\%) consistent with literature data\textsuperscript{4}.

The use of CIC and pharmacotherapy has been shown in the literature to improve bladder urodynamics (LPP), hydronephrosis, and VUR in a majority of the patients\textsuperscript{11}. The results presented in our table 1 do not show a similar significant improvement over time. We suspect that the main reason for this is the short follow-up time – several years are necessary to see an improvement in most parameters.

Pharmacotherapeutic agents used for the bladder dysfunction of spina bifida have been typically anticholinergics such as propantheline bromide, tolterodine, and
oxybutynin chloride\textsuperscript{1}. Tricyclic antidepressants such as imipramine have been shown to have a direct relaxant effect on the bladder smooth muscle, as well as being sympathomimetic and centrally active\textsuperscript{13}. Their effects are additive to anticholinergics, and therefore can be used in combination. Our protocol uses imipramine as the principal drug in the regimen.

Continence data are relatively limited, yet show in our study the encouraging fact that most (74\%) children can be rendered socially continent with a combination of CIC and medication. This result is consistent with data reported in the literature\textsuperscript{11}.

No CIC program is absolutely complete in its follow-up, and patients are often lost for various reasons. The use of CIC in developing countries is even more dependent on financial restraints than elsewhere. Even simple materials and supplies can be prohibitive in cost to the average patient. It is therefore critical to attempt to simplify the program as much as possible. Recent evidence has shown that clean (as opposed to sterile) catheters used multiple times without gloves or antibiotic coverage are not associated with an increased risk of UTIs\textsuperscript{14}. Our program has in fact been based on this principle, yet catheter and lubricant cost have still been a problem for some families. The ability to provide these materials free of charges or at lower cost would obviously make a difference in the number of patients who are maintained on CIC. Good parental education is another key factor. Our experience leads us to believe that a nurse educator is able to best communicate with the (typically) mothers, and therefore is preferable to a physician.

We conclude that a CIC program is both feasible and effective in Kenya. Such a program can effectively prevent later renal damage and promote urinary continence. It therefore promotes not only better quality of life for patients with spina bifida, but can contribute to their successful integration and meaningful employment in the
society. Economic barriers must be overcome and further parent education is needed in order to offer all Kenyan children with spina bifida a good standard of care.
Table 1: correlation of urodynamic and ultrasonic studies in children studied

<table>
<thead>
<tr>
<th>LPP</th>
<th>Number (%)</th>
<th># subsequent normal (%)</th>
<th>Hi PVR</th>
</tr>
</thead>
<tbody>
<tr>
<td>&gt;39cm</td>
<td>60 (24%)</td>
<td>5 (2%)</td>
<td>33</td>
</tr>
<tr>
<td>35-39cm</td>
<td>31 (12%)</td>
<td>2 (0.8%)</td>
<td>26</td>
</tr>
<tr>
<td>30-34cm</td>
<td>26 (10%)</td>
<td>14 (5.6%)</td>
<td>11</td>
</tr>
<tr>
<td>&lt;30cm</td>
<td>132 (53%)</td>
<td>132 (53%)</td>
<td>21</td>
</tr>
<tr>
<td>Total</td>
<td>249</td>
<td>153 (61.4%)</td>
<td>91</td>
</tr>
</tbody>
</table>

Key: LPP= leak point pressure; PVR = post-void residual
References


