Is an artificial sphincter the best choice for incontinent boys with Spina Bifida? Review of our long term experience with the AS-800 artificial sphincter

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Objective: *We describe our long-term experience in a uniform population of Spina Bifida boys all treated with the AS-800 model artificial urinary sphincter (AUS) and compare our results to other treatment modalities available to children with neurogenic incontinence.*

Materials and methods: *The complete medical records of 30 patients with insertion of the AS-800 were reviewed. All were boys having Spina Bifida with only one having prior bladder neck reconstruction. The mean age at insertion was 12.6 years and the average follow up was 6.5 years. Anticholinergic agents and self-intermittent catheterization were used concomitantly to the AUS in 21 and 22 patients respectively.*

Results: *In our series, 19 (63%) patients were completely dry, 6 (20%) were slightly wet, 5 (17%) were incontinent. The mean lifetime of all artificial sphincters was 4.7 years with no statistically significant difference in survival of those inserted at the bladder neck and bulbar urethra (4.6 and 4.9 years respectively). However, a survival analysis revealed a sharp drop after 100 months with only 8.3% of the sphincters implanted lasting beyond this point. There were a total of 32 revisions performed in 17 patients constituting a 0.164 revision rate/patient-years. The other surgical treatment available to these children is bladder neck reconstruction with reported continence rates ranging from 61% to 76% at about 2 years follow up.*

Conclusions: *In our experience, the AS-800 model artificial sphincter has a long term survival which rarely exceeds 8 to 9 years putting into question whether it or bladder neck reconstruction is the best long term solution for treating children with neurogenic incontinence. This question may be only answered by a randomized, controlled trial comparing these two modalities.*

Key Words: artificial urinary sphincter, continence, Spina Bifida

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Introduction

Lapides first introduced clean intermittent catheterization[1] in 1972 thus providing an option for

the management of neurogenic bladder dysfunction. There have been a number of innovations in the management of these patients since that time.[2] Pharmacological manipulation of the lower urinary tract has contributed to a significant number of these patients achieving urinary continence. Despite all these progresses, there remains a significant number of patients with neurogenic bladders who fail to reach urinary control.

The etiology of incontinence remains complex in Spina Bifida children and may result from detrusor hyperreflexia or areflexia, reduced detrusor compliance, as well as uncoordinated or inadequate sphincter function.[3-5] Another element which adds to the complexity of the problem is that the characteristics and urodynamic parameters of these children change with growth.[6-8] For that reason, it is common place to manage as conservatively as possible these children until the beginning of puberty and to consider more invasive treatment modalities at a later age. Issues of compliance with management also make it difficult to intervene at a young age.

Since first introduced, the artificial urinary sphincter (AUS) has allowed a number of carefully selected patients to achieve continence.[9,10] The AUS has undergone several changes with the present day model AS-800 (American Medical Systems, Minnetonka, Minnesota) offering several advantages over the previous models, including complete control of cuff inflation and nonsurgical delayed activation.[11] However, some of the problems and concerns with the AUS include mechanical failure, infection, and erosion.[12] Long term studies of children with neurogenic incontinence treated with the AUS are limited by the fact diverse patient populations and different artificial sphincter models were studied.[13-15] In the present study, we describe our long term experience in a homogeneous population of boys with Spina Bifida all treated with the AS-800 model artificial sphincter.

Materials and methods

Study Population

From 1984 to 1998, there were 37 boys who underwent insertion of the AS-800 for the treatment of urinary incontinence at the Shriner's Hospital for Children, Canadian Unit, Montreal (Table 1). All artificial sphincters were initially placed at the bladder neck and deactivated for 6 weeks. Seven patients were lost to follow up and were excluded from the study. The medical records of the remaining 30 patients were reviewed and data for each patient were obtained. The 30 boys had congenital neurogenic bladder dysfunction as a result of Spina Bifida. Girls do not appear in this review because of surgical preference for bladder neck slings in these patients. The 30 patients had a mean age of 12.6 years at insertion (range 9 to 19 years) and a mean follow up of 6.5 years (range 36 to 177 months).

Five patients had prior attempts at surgical correction of incontinence with four having previous collagen injections and only one having a bladder neck reconstruction. Prior to AUS insertion, anticholinergic therapy (oxybutynin) was used in 21 patients (70%) and self intermittent catheterization (CIC) in 22 patients (73%). All patients had a pre-operative urodynamic investigation with a mean detrusor leak point pressure being 37.9 mm Hg (Table 2). All

TABLE 1. **Characteristics of patients receiving an implanted AUS**

	No. of patients (%)
Spina Bifada	30 (100%)
Previous bladder neck surgery	
Collagen injection	4 (13%)
Bladder neck reconstruction	1 (3%)
None	25 (83%)
Other surgery	
Ileocystoplasty	
- Prior to AUS insertion	1 (3%)
- At the time of AUS insertion	3 (10%)
- Following AUS insertion	11 (37%)
None	
Drug therapy	
Anticholinergics (oxybutynin)	21 (70%)
None	9 (30%)
Intermittent catheterization	
Yes	22 (73%)

TABLE 2. **Detrusor leak point pressure (LPP) of patients prior to AUS insertion**

	No. of patients (%)
LPP value (mm Hg)	
0 to 20	5 (17%)
21 to 30	7 (23%)
31 to 40	6 (20%)
41 to 50	2 (6%)
50 to 70	5 (17%)
Not available	5 (17%)
Total	30

patients were found to have stable bladder with a capacity corresponding to their age except for those having a bladder augmentation procedure at the time of the AUS insertion. Ileocystoplasty was performed before, after, or at the time of cuff insertion (Table 1) if the patient had a small capacity low compliant and/or unstable bladder.

For this review, patients were asked in telephone interviews by one experienced urology clinical nurse to qualify their degree of urinary continence using a standardized questionnaire. Being completely dry was defined as dryness for more than 4 hours, slightly wet was defined as minor losses of urine but still being socially continent, and incontinence was defined as the involuntary loss of urine causing social and/or personal discomfort.

The choice of position of cuff insertion (bladder neck versus bulbous urethra) was left entirely at the discretion of the surgeon. However, those placed at the bulbous urethra were done at the time of revisions of devices initially inserted at the bladder neck. No other parameter dictated our choice for the positioning of the cuff. The site and size of the cuff, as well as water pressure in the reservoir are reported in Table 3. There were a total of 48 AUS inserted with 34 inserted at the bladder neck and 14 inserted at the bulbous urethra. Of those placed at the bladder neck, the mean age of patients at the time of insertion was 12.6 years, the mean cuff size was 6.5 cm (range 4 cm to 10 cm) and pressure in the reservoir ranged from 51 cm to 80 cm H_2O. In those placed at the bulbous urethra, the mean age was 14.6 years, the cuff size was either 4 cm or 4.5 cm and all received a reservoir pressure ranging from 61 cm to 70 cm H_2O.

TABLE 3. **Features of AUS inserted at bladder neck and bulbous urethra**

	No. Patients	
	Bladder neck (N=34)	**Bulbous urethra (N=14)**
Cuff size		
4.0 cm	2	8
4.5 cm	3	6
5.0 cm	1	0
5.5 cm	1	0
6.0 cm	3	0
6.5 cm	6	0
7.0 cm	6	0
7.5 cm	4	0
8.0 cm	5	0
8.5 cm	0	0
9.0 cm	2	0
9.5 cm	0	0
10.0 cm	1	0

TABLE 4. **Reasons for revisions to artificial sphincters**

	No. of Revisions (%)
Mechanical failure	4 (13%)
Reservoir leak	13 (41%)
Sphincter malfunction	5 (16%)
Erosion of sphincter	5 (16%)
Infection	6 (16%)
Inappropriate sized cuff	
Cuff too large	4 (13%)

All revisions done on the AUS and reasons for all the revisions including device related reasons, infection, and inappropriate cuff sizes were documented as seen in Table 4.

Statistical analysis

Statistical analyses of the survival differences of artificial sphincters inserted in patients with and without bladder neck reconstruction as well as the survival differences of those inserted at the bladder neck and bulbous urethra were performed using unpaired Student's *t tests* and were both found to be non-significant with $p< 0.05$. A survival analysis of the artificial sphincters (survival until time to failure and/or removal) was also performed using a Kaplan-Meier analysis.

Results

Of the 30 patients, 25 patients (83%) still had a functional AUS in place at their last follow up. The mean lifetime of the artificial sphincter was 4.7 years with a range from 3 to 177 months. The survival analysis of the sphincters revealed that 50% of the sphincters lasted more than 40 months and the survival curve sharply declined beyond 100 months (8.3 years) as seen in Figure 1. Of the sphincters inserted, only four had a survival greater than 100 months which constitutes only 8.3% of the sphincters placed. At their most recent follow up, 19 of the patients (63%) were found to be completely continent, 6 (20%) were slightly wet, and 5 (17%) were incontinent. At the completion of our study, 16 of 21 patients were still using anticholinergic agents and

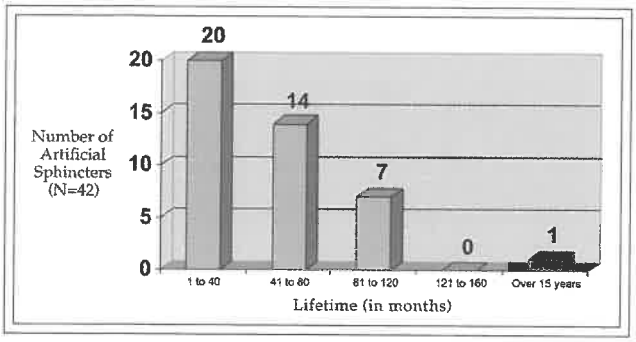

Figure 1. Lifetime of AUS in patients.

all 22 patients were still doing CIC. Therefore, 8 of the 30 patients were able to void voluntarily.

As previously mentioned, a total of 48 artificial sphincters were placed at the bladder neck. After revision, 34 remained at the bladder neck while 14 cuffs were transferred to the bulbous urethra. The mean length of survival of the AUS inserted at the bladder neck was 4.6 years (range 9 to 177 months) whereas the mean survival of those inserted at the bulbous urethra was 4.9 years (range 45 to 110 months).

There was a total of 32 revisions conducted on the artificial sphincters constituting a 0.164 revision rate / patient-years. The reasons for revisions included 22 due to mechanical failure, 6 due to infection (all requiring removal of the AUS), and 4 due to the cuff being too large. There were five cases of sphincter erosion and they occurred at a mean length of 5.1 years after their insertion (range 27-85 months). The 32 revisions were conducted in 17 patients i.e. 13 patients (43%) required no revisions. Of the patients with no revisions, 12 (92%) were completely dry and 1 was incontinent. As well, the mean length of follow up in these patients was 7.4 years with a range from 22 to 177 months. Of the patients using CIC, 16 (73%) had revisions whereas the remaining 6 patients had no revisions to the AUS. Similarly of those not using CIC, 5 (63%) had revisions and 3 had none.

In 15 patients (50%), an ileocystoplasty at (n=3) or subsequent (n= 12) to the sphincter insertion had been performed whereas the remaining 15 patients had no ensuing surgical procedures for incontinence. Of the patients with ileocystoplasties, 11 of 15 patients (73%) were doing CIC after the procedure. Of those using anticholinergic agents, 9 of 16 patients (56%) had had an ileocystoplasty. The persistence of uninhibited bladder contractions associated with various degrees of urinary incontinence or a high storage pressure explain the maintenance of the pharmacologic treatment.

The status of the patients upper urinary tract was examined by ultrasound prior and post AUS insertion and 19 patients were found to have normal urinary tracts, 6 patients were found to have post-operative unilateral hydronephrosis, and in 5 patients, the status of the upper urinary tract was not available prior to AUS insertion. In the patients with unilateral hydronephrosis post AUS insertion, there was no worsening of this condition with the appropriate use of anticholinergics and CIC.

Discussion

The treatment of neurogenic incontinence has remained a highly debated issue between those in favor of artificial sphincters and those in favor of bladder neck reconstruction. Several long term studies have been done using artificial sphincters in children with neurogenic incontinence however these have each had their own limitations. In a previous study by Kryger, a group of 32 patients underwent sphincter insertion and were followed for over 15 years.[15] This study was however limited by the fact several models of artificial sphincters were inserted and although the authors expect better results with the present AS-800 model, these conclusions are difficult to draw with only 34% of their patients having this model initially in place. In another study by Simeoni, 107 children underwent implantation of the AS-800 model however the studied population consisted of a heterogeneous group of 74 boys and 33 girls suffering from either Spina Bifida, sacral agenesis, or medullary lipoma.[14] As such, our study offers a unique opportunity to study the success of the present day AS-800 model in a group of boys all with Spina Bifida all treated at the same center.

In our study, AUS insertion led to an overall rate of continence or significantly improved urinary control in 83% of patients at a mean follow up of 6.5 years. Our reported continence rates are quite comparable to other contemporary studies by Levesque[13] and Gonzalez[18] in which artificial urinary sphincters had reported continence rates of 83% and 84% respectively at a 5 year follow up.

In our survival analysis, we found the mean survival of the AS-800 model artificial sphincter to be 4.7 years however we noted a sharp decline beyond 100 months (8.3 years) with only 8.3% of sphincters lasting beyond this point thus, the majority of the artificial sphincters implanted will fail and need to be removed with time. This significant drop in sphincter survival with time should be regarded as a severe limitation of this treatment modality in the

long-term care of neurogenic incontinence.

A total of 32 revisions were performed in our patients constituting a 0.164 revision rate/patient-years (16.4% revisions/patient-years) and all these revisions were performed in 57% of our patients. As such, there were more revisions performed than primary artificial sphincter insertions (32 versus 30) and this important revision rate must be addressed by the surgeon when discussing this treatment option with patients and their families. The revisions were mostly due to malfunction or erosion of the sphincter which is consistent with what has been reported.[19] In the study by Kryger, 13 of 32 patients (40.6%) had the AUS removed due to erosion or infection which they state are early and preventable complications.[15] However in the present study, we have shown that erosion is usually a later complication occurring at a mean of 5.1 years after sphincter insertion therefore, this complication may be an inherent risk of having a foreign body in place for an extensive period of time. Infection which usually occurred less than 6 months post-operatively was not a common reason for sphincter revision but was shown in this study to be significant as all patients with AUS infection required its removal. In 43% of patients, revisions were not required and our findings are consistent with the litterature.[14]

Most artificial sphincters were inserted at the bladder neck (71%) whereas the remaining 29% were inserted at the bulbous urethra. There was a statistically significant difference in the mean age of patients with cuffs inserted at both sites. The children who had the device placed at the bladder neck were younger (mean age 11.8 years) whereas those placed at the bulbous urethra had a mean age of 14.6 years. No other differences other than age were noted between the patients with bladder neck or bulbar urethra placement of artificial sphincters. The mean survival of the AUS inserted at the bladder neck was 4.6 years whereas the mean for those inserted at the bulbous urethra was 4.9 years and these were not found to be statistically different. To our knowledge, this is the first study looking at the survival of artificial sphincters inserted at the bladder neck and bulbous urethra and showing no statistically significant difference. In addition, no specific factors were identified that could predict failure of the AUS at the bladder neck.

According to Bosco et al., previous bladder reconstruction expose patients to a higher erosion rate.[19] However our study did not show significant difference in complication rate whether bladder reconstruction had been performed or not although our findings are obviously limited by our small number of patients with prior bladder reconstruction. In the present series, four patients (13%) had urethral collagen injections prior to AUS insertion. The mean AUS survival of those with prior incontinence surgery (collagen injection or bladder neck reconstruction) was 52.6 months (not statistically different using two-tailed unpaired t-test, $p<0.05$). Furthermore, previous collagen injections never created any surgical difficulty for implantation.

Following artificial sphincter insertion, a number of patients have a decrease in bladder compliance and an increase in bladder storage pressure explaining why bladder augmentation surgery is commonly performed at the time or following AUS insertion. In this study, 50% of patients had an ileocystoplasty of which 37% of these were performed after the AUS insertion. In our patients, it was difficult to predict the need for a secondary enterocystoplasty.

Several potential criticisms of our study include the fact patients were contacted by telephone interviews and 7 of 37 patients were lost to follow up. However, these were unavoidable limitations to our study as the Shriner's hospital for Children is a national referral center for handicap children and patients were tracked down and contacted throughout the entire country. Furthermore, our hospital does not follow patients older than 21 years old making their long term follow up more difficult. However, other similar studies have used telephone interviews as a means of communicating with patients with success.[15] As well, we report a rate of loss to follow up of 19% which some may consider avoidable with more stringent follow up practices however this rate is significantly lower than the 29% reported in the study by Kryger.

In addressing the role of the AUS in treating neurogenic incontinence, one must compare it to other treatment modalities available to patients. As such, the experience with bladder neck reconstruction is an essential consideration Table 5. Bladder neck reconstruction was first introduced by Young in 1919 and consists of lengthening the most proximal segment of the urethra and tubulizing it using portions of the detrusor muscle from the funneled part of the bladder base.[20] Leadbetter modified this procedure and in a retrospective study, he reported 76% of patients to be completely continent and requiring no pads at a follow up of two years.[21] Similarly, Tanagho proposed a modified technique whereby a tubulized segment of the anterior bladder wall was used to reconstruct the bladder neck.[22] In a reported series using the Tanagho technique, a heterogeneous study group had a 70% rate of total continence.[23] Pippi-Salle et al. described an anterior bladder flap to create a flap-valve mechanism at the level of the bladder neck.[24] Intermittent catheterization was

TABLE 5. **Previous studies on the various bladder neck reconstruction techniques**

Study	Continence rate (%)	Length of follow up (months)
Leadbetter et al.[21]	76%	24
Tanagho et al.[23]	70%	22
Pippi-Salle et al.[24]	70%	26
Hayes et al.[25]	61%	28

made easier with this method and the procedure was as reliable as other bladder neck reconstruction techniques. Using this procedure, a continence rate of 70% has been reported at a mean length of follow up of 26 months with 78% of patients requiring ileocystoplasties. In another study by Hayes, an overall continence rate of 61% was reported at a mean length of follow up of 28 months with 82% of patients undergoing ileocystoplasties.[25] Although many complications of bladder neck reconstruction can be avoided by the appropriate selection of patients, careful surgical technique, and consistent long-term follow up of patients, it nevertheless remains that persistent urinary continence, recurrent urinary tract infections, and upper urinary tract infections remain potential complications. A comparison between the results of the Pippi Salle procedure and artificial sphincter placement are difficult in view of the fact only short follow up studies have been done using this bladder neck reconstruction technique.

This study of the long term outcome of the AS-800 model in a homogeneous group of boys with Spina Bifida has shown a worrisome drop in sphincter survival beyond 8 to 9 years. The reasons why artificial sphincters fail in most our patients beyond 8 to 9 years remains poorly understood. Although our findings need corroboration from future studies, they raise a significant concern about the artificial sphincter as a long term treatment for neurogenic incontinence in boys with Spina Bifida. □

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