

**F.16 What are the long term risks (renal impairment, hydronephrosis, urinary tract stones, urinary tract infection, malignancy (bladder cancer) associated with the long-term use of intermittent catheterisation, indwelling catheters (supra pubic and urethral) and penile sheath collection/pads? What is the quality of life associated with the above?**

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Bennett CJ, Young MN, Adkins RH et al. Comparison of bladder management complication outcomes in female spinal	Retrospective observational study  Birmingham, Alabama	N=70	Female patients with spinal cord injury undergoing follow-up by a urology service  Intermittent catheterisation (N=23): 18 paraplegics and 5 tetraplegics, mean 8.5	Intermittent catheter  Indwelling catheter	Reflex voiding and padding	Years of bladder management ranged from 2 to 33 yrs  Frequency of follow up not	Reflux Hydronephrosis Bladder calculi Renal calculi	None reported

cord injury patients. Journal of Urology. 1995; 153(5):1458-1460. Ref ID: BENNETT1995			yrs ( $\pm$ 4,7 yrs)  Reflex voiding and padding (N=25): 7 paraplegics and 18 tetraplegics, mean 15.8 yrs ( $\pm$ 7.3 yrs)  Indwelling catheter (N=22): 11 paraplegics and 11 tetraplegics, mean 16.7 yrs ( $\pm$ 9.0 yrs) (no patient was maintained on a suprapubic catheter)			stated		
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## Complications reported by duration of follow-up

Complication	Intermittent catheterisation (n=23)	Padding (n=25)			Indwelling catheter (n=22)		
Duration of follow-up	2-10 yrs (n=17)	2-10 yrs (n=7)	11-23 (n=14)	2-10 yrs (n=7)	11-23 (n=9)	24-33 (n=6)	
Reflux	1	-	-	2	4	4	
Hydronephrosis	-	1	-	4	2	-	
Bladder calculi	1	-	-	1	3	12	
Renal calculi	-	-	3	-	1	2	

None of the 6 patients on intermittent catheterisation for 11 to 23 yrs or the 4 on padding for 24 to 33 yrs reported any complications.

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Cameron AP, Wallner LP, Forchheimer MB et al. Medical and psychosocial complications associated with method of bladder management after traumatic spinal cord injury. Archives of Physical Medicine and Rehabilitation. 2011; 92(3):449-456. Ref ID: CAMERON2011	Retrospective observational study  USA	N=24762  N=1564 excluded	Patients with new spinal cord injury (SCI) entered in the National SCI database  Patient population: mean time post injury (psychosocial outcomes) ranged from 6.3 to 11.1 yrs. Age at injury ranged from mean 27.8 to 37.0 yrs	At discharge: 18.2% voiding, 23.9% used indwelling catheterisation, 12.7% condom catheterisation, and 45.1% intermittent catheterisation	Different bladder management techniques	1 to 30 yrs	Incidence of stones SWLS (5 item measure of life satisfaction) Self perceived health status	National Institute on Disability and Rehabilitation Research
Effect								
Variable				Odds of stone $\geq$ 1 (OR 95%CI)				
Year 1								
Indwelling catheter				1				
Voiding				0.48 (0.39 to 1.28)				
Condom				0.71 (0.39 to 1.28)				

Clean intermittent catheterisation	0.92 (0.59 to 1.42)
Year 5	
Indwelling catheter	1
Voiding	0.42 (0.21 to 0.85)
Condom	0.68 (0.40 to 1.16)
Clean intermittent catheterisation	0.56 (0.34 to 0.94)
Year 30	
Indwelling catheter	1
Voiding	N?A
Condom	0.18 (0.011 to 2.85)
Clean intermittent catheterisation	2.15 (0.28 to 17.0)

Variable	SWLS	Perceived health status
Indwelling catheter	18.56 (SD0.44) (reference)	2.83 (SD0.06) (reference)
Voiding	19.96 (0.46) (p<0.0005)	2.98 (0.06) (p<0.0005)
Condom	18.75 (0.50) (p=0.56)	2.74 (0.07) (p=0.03)
Clean intermittent catheterisation	18.77 (0.44) (p=0.39)	2.76 (0.06) (p=0.04)

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Cardenas DD, Mayo ME. Bacteriuria with	Prospective case study Country:USA	N = 705 Loss to	557 /705 (79%) were men: 51% quadriplegic, 49% paraplegic	n/a	n/a	1 year	Bacteriuria with fever (BWF)	Spinal Cord Grant from the National

fever after spinal cord injury. Archives of Physical Medicine and Rehabilitation. 1987; 68(5 Pt 1):291-293. Ref ID: CARDENAS1987	(Seattle)	follow up: 371 turned up to the 1 year follow up appointment (53%)	Number of patients by system of drainage at discharge from hospital						Institute of Handicapped Research, Department of Education Washington
				N(%)					
			Intermittent catheterisation	259(36.8)					
			Indwelling catheter	114(16.2)					
			Voiding: external collector	110(15.6)					
			Voiding: no external collector	102(14.5)					
			Normal voiding	64(9.1)					
			Other*	35(4.9)					
	Diversion**	21 (3.0)							
		All patients treated at the Northwest Regional Spinal Cord Injury Center between 1974 and 1984.							
		Of all patient 64 (9.1%) had normal voiding at discharge from hospital							
			* Other includes cystocath and suprapubic catheter						
			** Diversion = ileal conduit and vesicostomy.						

Effects

At discharge there was no significant difference in rate of bacteriuria with fever (BWF) between those with self intermittent catheterization, those with intermittent catheterisation by someone else and those with an indwelling catheter.

Rates of BWF at hospital discharge and at 1 year follow up N (%):

	At discharge	At 1 year follow up
Self intermittent catheterisation	77/155 (50)	33/62 (53)
Intermittent catheterisation by other	60/103 (58)	20/24 (83)
Indwelling catheter	48/114 (42)	25/57 (44)

Examining only those who were on the same system of drainage at discharge from the initial rehabilitation and at year 1 follow-up, the patients on intermittent catheterisation by someone else (ICO) were more likely to have experienced at least one episode of BWF than the group on self intermittent catheterisation and patients with indwelling catheter ( $p < 0.025$ ).

Authors' conclusions:

Those patients unable to perform their own intermittent catheterisation appeared to be at greater risk to develop episodes of bacteriuria with fever.

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Chen Y, DeVivo MJ, Roseman JM. Current trend and risk factors for kidney stones in persons with spinal cord injury: A longitudinal study. Spinal Cord. 2000;	Prospective observational study, USA	N=8314	Patients entered into a National spinal cord injury database 1986-1999  Inclusion criteria included: admission to a model system of care within 365 days of injury, clinically discernible degree of spinal cord neurologic impairment on admission	Abnormal concretion in either the kidney or ureter documented by x-ray evidence of its location' Stones that were passed spontaneously before x-ray	na	Mean 3 yrs (range 7 mths to 13 yrs)  Annual check	Stones in the kidney or ureter	National Institute on Disability and Rehabilitation Research, Office of Special Education and Rehabilitation Services, United States Department of Education,

38(6):346-353. Ref ID: CHEN2000			Patient characteristics: Women 18.5%: men 81.5%, age: 15-24 35.5%, 25-34 26.3%, 35-44 16.9%, 45-54 9.5%, 55-80 11.8%, neurologic level: minimal deficit 5.5%, paraplegic ( incomplete) 20.4%, paraplegic (complete) 27.9%, tetraplegic (incomplete) 27.8%, tetraplegic (complete) 18.1%, unknown 0.2%	evidence could be obtained were excluded			Washington DC
Effect							
Incidence of stones in the kidney or ureter							
Bladder management at discharge	N	%	No. of stones 5-yr cumulative incidence	%	P		
Catheter-free	1710	20.6	20	1.6	0.002		
Indwelling urethral catheter	1027	12.4	49	6.9			
Condom catheter	563	6.8	25	5.1			
Intermittent catheter	4407	53.0	179	5.0			
Suprapubic catheter	296	3.6	8	2.7			
Other	248	3.0	5	3.4			
Unknown	63	0.8	0				

Risk factors for kidney stones occurring before and after the first year post injury  
Multivariate cox regression model

	Year one RR (adjusted) (95%CI)	Year 2 and later RR (adjusted) (95%CI)
Catheter-free	1.0	1.0
Indwelling urethral catheter	1.3 (0.6 to 2.7)	2.5 (1.1 to 5.7)
Condom catheter	1.3 (0.6 to 2.8)	2.0 (0.9 to 4.6)
Intermittent catheter	1.2 (0.6 to 2.1)	2.4 (1.2 to 5.2)
Suprapubic catheter	0.3 (0.1 to 1.3)	2.6 (1.1 to 6.3)
Other	0.6 (0.1 to 2.6)	4.2 (1.7 to 10.6)

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow- up	Outcome measures	Source of funding
Dahlberg A, Perttil I et al. Bladder management in persons with spinal cord lesion. Spinal Cord. 2004;	Cross-sectional study. Finland	N=129	Patients with traumatic spinal cord injury leading to permanent neurological deficits  Normal voiding 14 (11%),	Clean intermittent catheterisation Mixed Catheter or conduit	Normal voiding, controlled voiding, suprapubic tapping, compression or straining	One year	Urinary tract infections (with symptoms, confirmed by urinary culture and treated with	None reported

42(12):694-698. Ref ID: DAHLBERG2004			controlled voiding, 15 (12%), clean intermittent catheterisation 16 (12%), mixed (clean intermittent catheterisation in daily use) but subjects also used other methods, suprapubic tapping 31 (24%), compression or straining 16 (12%), catheter or conduit 7 (5%)				antibiotics)	
Effect								
Urinary tract infection								
Data extracted from graph								
Bladder management				Urinary tract infection % (95%CI)				
Normal voiding				6 (2 to 36%)				
Controlled voiding				20 (5 to 50%)				
Clean intermittent catheterisation				70 (43 to 90)				
Mixed (using clean intermittent catheterisation plus other method)				72 (58 to 90)				
Suprapubic tapping				48 (30 to 68)				
Compression or straining				31 (11 to 59)				

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
D.M. Dewire, R.S. Owens, G.A. Anderson, M.A. Gottlieb,	Retrospective cohort study. USA.	N=57 (n=32 with catheter and n=25 non catheter.)	Medical records of 57 consecutive patients who sustained a traumatic cervical spinal cord injury between 1970 and 1980 included.	Chronic indwelling catheter.	No chronic indwelling catheter.	Mean follow-up 12 years Frequency of follow	Urological Complications.	None reported

<p>H. Lepor, "A Comparison of the Urologic Complications Associated with Long-Term Management of Quadriplegic Patients with and without Chronic Indwelling Urinary Catheters," Journal of Urology, 147: 1069-1072, 1992</p> <p>REF ID DEWIRE 1992</p>			<p>Note: no patients lost to follow-up.</p> <p>Patient characteristics: mean age of the patient population at injury was 36 yrs. The majority of the patients sustained spinal cord injury after a motor vehicle accident (31), diving accident (10) or fall (8).</p>			<p>up one yeR</p>		
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Effect

Urological complications:

Complication	Total (n=57)	Catheterised group (n=32)	Non-catheterised group (n=25)	p-value (diff b/w catheterised and non catheterised group)
Renal stone	14	8	6	0.93
Bladder stone	18	13	5	0.10

Pyelonephritis	13	8	5	0.66
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Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Suzanne L. Groah, , David A. Weitzenkamp, Daniel P. Lammertse, Gale G. Whiteneck, Dennis C. Lezotte, Richard F. Hamman. Excess risk of bladder cancer in spinal cord injury: Evidence for an association between indwelling catheter use and bladder cancer. Archives of	Historical cohort study.  Denver, Colorado, USA	N=3670 (n=1628 in NIDC, n=314 in multi and n=1728 in IDC)	Participants included listed in the database who incurred spinal cord injury (SCI) between 1950 and 1997 and who were known to have survived at least 1 year.  Inclusion criteria: Participants were eligible for the study if initial screening cystoscopy, performed at any time post- SCI, documented the presence or absence of bladder cancer.  Patient characteristics: Mean age at SCI (yrs) – 30 years (in NIDC); 29 years (in multi); 29 years (in IDC).	groups:  Indwelling catheter (IDC).  Non indwelling catheter (NIDC).  Multi (using both dwelling and non dwelling)	See interventions	Mean follow-up: 2 years.	Diagnosis of bladder cancer.  Death from any cause.	None reported

<p>Physical Medicine and Rehabilitation Volume 83, Issue 3, Pages 346-351, March 2002.</p>			<p>Mean age at diagnosis of bladder cancer: 48 years.</p> <p>Mean duration of SCI at time of diagnosis was 20 years.</p> <p>Median duration of bladder management: NIDC- 9.8 years (in NIDC); 7.3 years (in multi).</p> <p>IDC - 6.9 years (in NIDC); 11.8 years (in IDC).</p> <p>American spinal injury classification (ASIA): A- 47 % (NIDC); 60% (multi); 65% (IDC) B-14% (NIDC); 18% (Multi); 20% (IDC) C- 13% (NIDC); 9% (Multi); 11% (IDC). D- 25%(NIDC); 13% (Multi); 4% (IDC) E- 1% (NIDC); 0%( Multi); 0% (IDC).</p>					
<p>Effect</p> <p>Analyses of potential risk factors for bladder cancer revealed a significantly greater proportion of participants who used IDC (46% of IDC group, 39% of multi group) developed bladder calculi compared with 10% in the NIDC group (<math>\chi^2 = 537.64, p &lt; 0.001</math>). Thirty one (31%) of the IDC group had a history of pyelonephritis, compared</p>								

with 33% of the NIDC group(  $x^2 = 1.4, p=0.24$ ). There were no documented cases of bladder schistosomiasis in any of the cohorts.

Age- adjusted analyses revealed that increasing exposure to IDC use was associated with bladder cancer in SCI. The IDC group had an age –adjusted rate of 77 per 100,000 person-years, compared with rates of 56.1 and 18.6 per 100,000 person-years in the multi and NIDC groups, respectively.

Age and gender adjustment for development of bladder cancer:

After age and gender adjustment, participants with SCI were 15.2 (95% CI, 9.2 -23.3) times likely to develop bladder than the general population. Of those using IDC only as their method of bladder management, the observed 15 cases of bladder cancer were compared with an expected 0.6 cases, yielding a ratio of 25.4 (95%, 14.0 -41.9).

Bladder management method	Observed	Expected	Observed/expected	95% CI
NIDC	3	0.6	5.0	1.1- 14.6
Multi	3	0.2	15.8	3.6-46.1
IDC	15	0.6	25.4	14.0-41.9
All SCI	21	1.4	15.2	9.2-23.3

Cox regression models to independently examine bladder management method, age at SCI, gender, ASIA classification, level of SCI and history of bladder calculi.

Risk factor	RR (95% CI)	P –value
Bladder management technique		
IDC use:	4.9 (1.3-13.8)	0.02
Multiple catheter use:	4.0 (0.8-20.2)	0.49
Age at SCI	1.1 (1.1-1.2)	0.01
Male gender	1.9 (0.6-6.8)	0.83
History of bladder calculi	1.1 (0.5-2.9)	0.34
Cervical level of SCI	0.5 (0.1-4.2)	0.76
ASIA impairment scale class A	Not reported due to high variability	Not significant

Calculations of attributable risk (AR) revealed that IDC was responsible for 34.1 cases of bladder cancer per 100,000 person-years of SCI. This yielded an AR percentage of 55.8% for IDC use, whereas male gender and bladder calculi were responsible for fewer cases of bladder cancer, at 32.9% and 10.7% respectively. In those using IDC only, IDC was responsible for 58.4 cases per 100,000 person-years, or 64.8% of all bladder cancer occurring in the IDC population.

At the completion of the study, 13 persons with bladder cancer had died, with the cause of death identified as bladder cancer in 12.

Of the 12, 10 had solely used IDC, where as 2 used multiple techniques. There were no bladder cancer deaths in the NIDC group.

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Hansen RB, Biering S, Kristensen JK. Urinary calculi following traumatic spinal cord injury. Scandinavian Journal of Urology & Nephrology. 2007; 41(2):115-119. Ref ID: HANSEN2007	Retrospective observational study, Copenhagen	N=235 (patients with urological investigations)	Patients from the Clinical for Spinal Cord Injuries, Copenhagen with a traumatic spinal cord injury (SCI) contracted before January 1991 who were still alive at the time of receiving a follow-up questionnaire in 2001 Patients characteristics: Mean age 50.5 yrs (range 28 to 84) and mean follow-up time was 24.1 yrs (range 10 to 45 yrs. 126 paraplegic and 110 tetraplegic	Data collected from medical records. Results included plain radiography of the abdomen and i.v urography	na	Duration of bladder management 24.1 yrs (range 10 to 45 yrs)  Frequency of follow-up 70% yearly or every other year	Renal calculi	Medicon Valley Academy and Coloplast A/S
Effect								
		Participants with renal calculi			Participants without renal			

	(%)		calculi (%)	
	Initial discharge (n=46)	Follow-up (n=47)	Initial discharge (n=186)	Follow-up (n=188)
Normal bladder emptying	13	9	12	8
Suprapubic tapping	54	28	58	32
Abdominal pressure	17	19	19	15
Crede manoeuvre	2	23	6	19
Intermittent catheterisation	11	40	13	39
Indwelling catheter	7	19	9	15

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Ku JH, Jung TY, Lee JK et al. Risk factors for urinary stone formation in men with spinal cord injury: a 17-year follow-up study. BJU Int. 2006; 97(4):790-793. Ref ID: KU2006	Retrospective observational study  Korea	N=140	Inclusion criteria: Men with an age at injury of $\geq$ 18 yrs, discernible neurological lesion, traumatic spinal cord injury (SCI), voiding spontaneously or a neurogenic bladder managed by clean intermittent catheterisation, suprapubic cystostomy or indwelling urethral catheter, injured before 1987, and followed from 1987 to 2003.  Exclusion criteria: If patients missed two or	Clean intermittent catheterisation, Indwelling urethral catheter	Spontaneous voiding, suprapubic cystostomy	Annually for 17 yrs (between 1987-2003)	Kidney, ureter or bladder stones (first occurrence)	None reported

		more consecutive annual visits, or had an ileal conduit or bladder augmentation					
Effect							
Bladder stone							
	Spontaneous voiding (SV)	Clean intermittent catheterisation (CIC)	Suprapubic cystostomy (SPC)	Urethral catheter (UC)			
Accumulated incidence (%)	14 (30)	5 (15)	15 (42)*	5 (21)			
Episodes/100 person-years	2.0	0.89	5.1	1.7			
Renal stones							
	Spontaneous voiding	Clean intermittent catheterisation	Suprapubic cystostomy	Urethral catheter			
Accumulated incidence (%)	6 (13)	3 (9)	4 (11)	8 (33)**			
Episodes/100 person-years	0.88	0.54	0.65	2.5			
* <0.05 in the CIC vs SPC group by chi-square test							
** <0.05 in the SV vs the UC group, the CIC vs UC group, and the SPC vs the UC group by Fisher's exact test							
Multivariate analysis							
Bladder management	Bladder stone OR adjusted (95%CI)	p	Renal stone OR adjusted (95%CI)	p			
Spontaneous voiding (SV)	1.0		1.0				
Clean intermittent catheterisation	0.53 (0.16 to 1.8)	0.30	0.89 (0.17 to 4.6)	0.89			
Suprapubic cystostomy	1.5 (0.56 to 3.9)	0.43	0.71 (0.16 to 3.2)	0.66			
Urethral catheter	0.89 (0.24 to 3.3)	0.86	5.7 (1.3 to 25)	0.021			

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Ku JH, Choi WJ, Lee KY et al. Complications of the upper urinary tract in patients with spinal cord injury: a long-term follow-up study. Urol Res. 2005; 33(6):435-439. Ref ID: KU2005	Retrospective observational study  Korea	N=179	Inclusion criteria: male patients, age at injury 18 yrs or above, neurologic lesion, traumatic spinal cord injury, follow up for 10 yrs or longer from date of injury, follow up until 2003  Patient characteristics: age at injury range 22-24 yrs, duration of follow up 29-35 yrs	Follow up included microbiological confirmation of significant bacteria in the presence of relevant symptoms and plain film radiographs	na	Yearly follow-up for at least 10 yrs	Pyelonephritis Renal calculi	None reported

## Effect

## Incidence of the complications of upper urinary tract

	Urethral catheter	Intermittent catheterisation	Suprapubic cystostomy	Crede manoeuvre or reflex voiding	Condom catheter
Pyelonephritis	12 (41.4%)	20 (41.7%)	13 (31.0%)	10 (26.3%)	6 (27.3%)
Renal calculi	6 (20.7%)	6 (12.5%)	15 (35.7%)	13 (34.2%)	4 (18.2%)
Upper tract deterioration	15 (51.7%)	18 (37.5%)	11 (26.2%)	9 (23.7%)	5 (22.7%)

## Multivariate risk factors for complications of the upper urinary tract

## Adjusted odds ratio (95% CI)

	Pyelonephritis	Renal calculi	Upper tract deterioration
Urethral catheter	1.0	1.0	1.0
Intermittent catheter	0.930 (0.352-2.455)	0.526 (0.147 to 1.888)	0.330 (0.114 to 0.958)
Suprapubic catheter	0.532 (0.186 to 1.519)	1.827 (0.581 to 5.745)	0.097 (0.026 to 0.359)
Crede manoeuvre or reflex voiding	0.464 (0.158 to 1.366)	1.856 (0.579 to 5.955)	0.123 (0.035 to 0.428)
Condom catheter	0.502 (0.148 to 1.704)	0.746 (0.177 to 3.137)	0.200 (0.051 to 0.780)

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding																					
Larsen LD, Chamberlin DA, Khonsari F, Ahlering TE. Retrospective analysis of urologic complication in male patients with spinal cord injury managed with and without indwelling	Retrospective cohort study.  USA  Groups well matched for age and years of follow up, but differed for existence of an external sphincterotomy which could confound.	N=204 (142 were followed up).	Male; mean age 34; All receiving continuous long term medical care at a veterans centre. <table border="1"> <thead> <tr> <th></th> <th>Indwelling catheter</th> <th>No catheter</th> </tr> </thead> <tbody> <tr> <td>n</td> <td>56</td> <td>86</td> </tr> <tr> <td>Age at injury</td> <td>33</td> <td>35</td> </tr> <tr> <td>Years of follow up</td> <td>12</td> <td>12</td> </tr> <tr> <td>Cx SCI</td> <td>36/56</td> <td>48/86</td> </tr> <tr> <td>ThLx SCI</td> <td>20/50</td> <td>38/86</td> </tr> <tr> <td>External sphincterotomy</td> <td>16</td> <td>47</td> </tr> </tbody> </table>		Indwelling catheter	No catheter	n	56	86	Age at injury	33	35	Years of follow up	12	12	Cx SCI	36/56	48/86	ThLx SCI	20/50	38/86	External sphincterotomy	16	47	Chronic indwelling catheterisation (n=56)	No indwelling catheter (n=86). [spontaneous voiding 54, clean intermittent catheterisation 14, external striated sphincterotomy coupled with condom catheter drainage 16]	Mean 12 years  Frequency of follow-up unclear	Symptomatic UTIs Bladder stones Renal stones Renal dysfunction	None reported
	Indwelling catheter	No catheter																											
n	56	86																											
Age at injury	33	35																											
Years of follow up	12	12																											
Cx SCI	36/56	48/86																											
ThLx SCI	20/50	38/86																											
External sphincterotomy	16	47																											

urinary catheters. Adult urology 1997; 50: 418-422	Patients given choice of the 2 treatment options, with advice on the best option for their particular problems. This would also create a bias between groups.							
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## Effects

Adverse event	Indwelling catheter	Non catheterised	p
All complications	49/56	28/86	Not stated
Symptomatic UTIs (1 episode)	6/56	35/86	0.0001
Symptomatic UTIs (> 1 episode)	42/56	11/86	0.0001
Urosepsis	12/56	7/86	0.023
Leading to death	2/56	0/86	
Bladder stones	34/56	10/86	0.0001
Renal stones	18/56	6/86	0.0001
Recurrent pyelonephritis	7/56	2/86	0.015
Parenchymal thinning	13/56	4/86	0.0009

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
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Lindehall B, Moller A, Hjalmas K, Jodal U, Abrahamson K. Psychosocial factors in teenagers and young adults with myelomeningocele and clean intermittent catheterisation. Scandinavian Journal of Urology and Nephrology 2008; 42: 539-544	Qualitative. Semi structured interviews. Sweden. Two people analysed tapescripts, and a thematic approach was used.	N=22	26 were selected at random from 41 eligible myelomeningocele patients who had been using Clean Intermittent catheterisation (CIC) for at least 5 years and were at least 13 years old. 26 rather than all 41 were included because of the time-consuming nature of the qualitative analysis. The 41 eligible patients were all those complying with inclusion criteria who had been part of a cohort of children with myelomeningocele (MMC) followed from birth and taught CIC from an early age. 4 of the 26 were not included because of problems understanding the questions.  15 females and 7 males. Age range 13-26 yrs. Age at which CIC began was 6-15 yrs. The follow up period to the interview was 5-12 years. 12 were in wheelchairs permanently, 3 occasionally, 3 used crutches and 4 walked without support. 12 were at mainstream schools, 2 in special schools for learning difficulties and 8 were working.	The experience of the use of CIC.	NA	NA	Semi-structured interviews (conducted by the urotherapist), according to an interview protocol, elicited thoughts and feelings on the following: To whom, and what, information was given to others. Attitude to be being catheterised by someone else. Attitude to their and other disabilities Attitudes towards friendship, aspects of sexuality and fertility.	
Effects: The participants perceived the experience of long term CIC use as follows: Telling peers of their use of CIC was deemed as difficult but important and satisfying. Peer reactions ranged from disgust (catheter insertion) to childish (use of diapers) to admiration. Those not in wheelchairs experienced less belief from others about their CIC use, and some of these wished they were in a wheelchair to increase acceptance of their CIC use. Lack of medical staff understanding of CIC was perceived as a major problem. All disliked being catheterised by someone else, but in medical appointments most were reticent at stating this, and the clinician would do the catheterisation. Most of the participants rated their incontinence as a mild disability, and rated non-MMC disabilities they didn't have, such as blindness, as more severe.								

8 participants had no friends at all. Two others spoke of friends, but on later investigation these were really casual acquaintances. 12 had a best friend. 15 found it easy to make friends but harder to keep them. Barriers to friendship were perceived as an inability to run, the use of crutches or the need for diapers. 12 were currently involved with a partner. Finding a partner was strongly desired by 17, but they found it difficult to realise this wish. None knew of the effects of their condition on sexual function, and felt that a medical professional should give them more information on this. Some could not imagine a future without children of their own. 19 were preoccupied with thoughts of parenthood in the future, but 9 were unsure if they would be able to do this. Of the 3 female adults in a relationship, one had had a healthy baby. At the end of the interview the participants were invited to ask anything. 2 males and 2 females asked: "How am I going to find someone to marry?". Overall all participants were satisfied with CIC and would not want to return to their previous voiding technique. Most, after 5 years experience, did not find it a problem in daily life. Overall, CIC was regarded as positive and most of the children's negative experiences were related to their overall disability, independent of CIC.

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Maynard FM, Diokno AC. Clean intermittent catheterization for spinal cord injury patients. <i>Journal of Urology</i> . 1982; 128(3):477-480. Ref ID: MAYNARD1982	Retrospective observational study  USA	N=65  N=28 with complete urologic follow up (outcomes extracted for this group only)	Patients with traumatic spinal cord injury who were discharged from hospital between 1972 and 1977 on clean intermittent catheterisation for the management of neurogenic bladder  Patient characteristics: 50 men and 15 women, 36 paraplegia (23 complete and 13 incomplete) and 29 with quadriplegia (13 complete and 16 incomplete). The period after injury until	Excretory Urography		Mean 3.7 yrs (range 1 to 7.5 yrs)  Frequency of follow up unclear	Cystolithiasis Urinary tract infections Hydronephrosis	None reported

			clean intermittent catheterisation was started was > 6 mths in 11 patients and < 6 months in 54.					
<p>Effect</p> <p>Urinary tract infections</p> <p>12/28 patients had received treatment for one or more urinary tract infection</p> <p>Hydronephrosis</p> <p>0/28 of the patients had hydronephrosis</p>								

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
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McGuire EJ, Savastano J. Comparative urological outcome in women with spinal cord injury. Urological neurology and urodynamics 1986; 135: 730-731	Prospective observational study. No rationale for grouping of patients given.	N=35	Female; age range 19-76. SCI.			Foley catheter (indwelling)	Intermittent catheterisation	Mean 6 years (range 2-12 years)  Frequency of follow up 6 monthly for two years then yearly	Symptomatic UTIs Recurrent bladder stones	None reported.
				Indwelling catheter	Intermittent catheterisation					
			n	13	22					
			Level of SCI							
C5-C7	8/13	6/22								
T1-T12	4/13	9/22								
T12 and below	0/13	7/22								
Myelomen-ingocele incomplete	1/13 1/13	0/22 1/22								

Effects

Adverse event	Indwelling catheter	Intermittent catheterisation	p
Symptomatic (febrile) UTIs	12/13	7/22	Not stated
Recurrent bladder stones	13/13	0/13	Not stated
Upper tract abnormalities (bilat pyelonephritic scarring with clubbing)	7/13	0/22	Not stated

Reference	Study type Evidence	Number of	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of
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	level	patients						funding
Nwadiaro H C; Nnamonu M I; Ramiyl V M; Igun G O. Comparative analysis of urethral catheterization versus suprapubic cystostomy in management of neurogenic bladder in spinal injured patients. Nigerian journal of medicine : journal of the National Association of Resident Doctors of Nigeria 2007;16(4):318- 21.  REF ID ARO 2007	Retrospective and prospective cohort study .  Retrospective study spanned from Jan 1 1984 to Dec 1989 while the prospective study was undertaken from Jan 1990 to June 2005  Nigeria.	N=125 (n=85 UC and n=40 SPC)	A total of 125 patients with complete spinal cord lesion managed between Jan 1 1984 and June 30, 2005.  Patient characteristics: The median of presentation for UC was 28 years vs. 32 for SPC. Male to female ratio compared was 13:1 for UC vs. 19:1 for SPC. The three commonest causes of SCI were road traffic accident (58%) resulting in 60% of injuries in UC vs. 61% in SPC, falls (36%) 36% vs. 35% respectively and cave-in injuries (4%) 35 vs. 2% respectively. In UC, 26% were stable injuries vs. 25% in SPC. Injury to the cervico-thoracic spine is 41% vs. 45% for UC and SPC groups respectively. Injuries involving the thoraco-lumbar spine in UC were 59% vs. 55% in SPC group.	Urethral catheterisation (U.C)  Supra-pubic cystostomy (SPC).	see interventions.	1 year	Episodes and timings of UTI.  Urinary /blood culture  Mortality.	None reported
Effect								

## Episodes and timing of urinary infections post admission

Timing (weeks)	Urethral catheterisation (n=85)	Supra-pubic cystostomy (n=40)	Total (n=125)
1,2	12 (20%)	6 (14%)	16 (13%)
2,4	10(16%)	3 (21%)	13 (10%)
4,6	33(52%)	1 (7%)	34 (27%)
6,8	4 (6%)	2 (14%)	6 (4%)
8,10	2 (3%)	1 (7%)	3 (2%)
10,12	2(3%)	1 (7%)	3 (2%)

Urinary tract infection occurred relatively late at 4-6 weeks in UC compared to 2-3 weeks in SPC.

Organisms cultured from urine/blood in SCI patients :

Bacteria	U.C (n=85)	SPC (n=40)	Total (n=125)
Klebsiella	22 (6) (26%)	6 (2) (12%)	28 (8) (22%)
E.coli	17 (3) (20%)	2 (1) (4%)	19 (4) (15%)
Proteus	14 (3) (16%)	1 (0) (2%)	15 (3) (12%)
Pseudomonas	4 (1) (5%)	1 (0) (2%)	5 (1) (4%)
Staph.aureus	3 (0) (4%)	4 (0) (8%)	7 (0) (6%)

Note: blood culture results are in brackets.

Mortality: SPC was associated with significantly lower mortality figure at one year, 9% vs. 36% for UC (P<0.05).

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Oh SJ, Ku JH, Jeon HG et al. Health-related quality of life of patients using clean intermittent catheterization for neurogenic bladder secondary to spinal cord injury. Urology. 2005; 65(2):306-310. Ref ID: OH2005	Prospective observational study, Korea	N=132	<p>Patients who were neurologically stable and using clean intermittent catheterisation because of neurogenic bladder secondary to spinal cord injury</p> <p>Patient population: mean age 41.8yrs (SE 1.4), male:female 81:51, duration of injury 67.8mths (SE 8.6), injury level cervical: noncervical 36:96, paraplegic: tetraplegic 24: 108, duration of catheterisation 24.2 mths (SE 3.1), catheterisation type caregiver n=44, self n=88</p>	Na	Na	Duration of catheterisation 24.2 months	SF-36 (Health-related QoL). Eight dimensions: physical function, role limitations owing to physical health problems, bodily pain, general health perception, energy and vitality, social function, role limitations owing to emotional problems and mental health. Greater scores representing better health	None reported

**Effect**

Comparison of SF-36 scores of patients and controls (general population) with respect to sex.

Domain	Male mean (SE)			Female mean (SE)		
	Patients (n=81)	Controls (n=90)	P value	Patients (n=51)	Controls (n=60)	P value
Physical functioning	18.4 (3.2)	85.3 (1.7)	<0.001	28.3 (4.4)	72.0 (2.3)	<0.001

Role-physical functioning	26.2 (4.5)	81.8 (2.9)	<0.001	30.9 (5.7)	71.2 (3.6)	<0.001
Role-emotional functioning	29.2 (4.8)	70.2 (3.4)	<0.001	38.6 (6.4)	60.8 (3.9)	0.002
Vitality	43.6 (2.4)	52.7 (2.0)	0.005	42.3 (3.0)	48.8 (1.9)	0.064
Mental health	55.6 (2.4)	67.2 (1.7)	<0.001	51.9 (3.1)	64.6 (1.7)	<0.001
Social functioning	49.5 (2.9)	85.2 (1.8)	<0.001	54.4 (4.0)	81.7 (2.1)	<0.001
Bodily pain	62.4 (3.3)	81.4 (1.8)	<0.001	60.5 (4.0)	70.9 (2.1)	0.025
General health	46.9 (2.1)	54.7 (1.5)	0.002	44.0 (2.3)	51.7 (1.8)	0.013

Comparison of SF-36 scores of patients and controls (general population) with respect to age

Domain	< 50 yr			≥ 50 yr		
	Patients (n=90)	Controls (n=100)	P value	Patients (n=41)	Controls (n=50)	P value
Physical functioning	20.1 (3.0)	83.5 (1.7)	<0.001	27.1 (5.1)	74.9 (2.3)	<0.001
Role-physical functioning	28.3 (4.2)	81.0 (2.9)	<0.001	27.4 (6.6)	73.0 (3.6)	0.001
Role-emotional functioning	32.6 (4.7)	66.9 (3.4)	<0.001	33.3 (7.0)	64.4 (4.0)	<0.001
Vitality	46.8 (2.1)	51.0 (1.9)	0.146	34.9 (3.5)	50.9 (2.1)	<0.001
Mental health	56.2 (2.2)	63.7 (1.7)	0.005	49.7 (3.7)	68.4 (1.8)	<0.001
Social functioning	54.0 (2.8)	84.2 (1.7)	<0.001	45.7 (4.3)	83.3 (2.2)	<0.001
Bodily pain	64.4 (2.9)	80.0 (1.7)	<0.001	55.7 (5.2)	72.7 (2.3)	0.004
General health	47.1 (1.8)	54.4 (1.6)	0.003	42.9 (3.2)	52.1 (1.6)	0.006

The patient SF-36 scores were significantly lower than those of the general population. When both patients and controls were divided into two subgroups according to sex, male patients had significantly lower scores for all dimensions than did male controls. Significant differences in all dimension scores, except in the energy and vitality scores, were also observed between the female patients and female controls.

When patients and controls were subdivided into two groups according to age, patients younger than 50 yrs had significantly lower scores for all dimensions, except for

energy and vitality, than did controls younger than 50 yrs. Significant differences in all dimension scores were also found between patients and controls 50 yrs old or older.

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding																														
J. Ord, D. Lunn, J. Reynard Bladder management and risk of bladder stone formation in spinal cord injured patients.  The Journal of urology, Vol. 170, No. 5. (November 2003), pp. 1734-1737.  REF ID : ORD 2003	Retrospective cohort study  United Kingdom.	N=457	<p>Patients included were those admitted to Stoke Mandeville Hospital Spinal injuries centre between 1985 and 1990 with greater than 6 months follow-up.</p> <p>Patient characteristics:</p> <table border="1"> <thead> <tr> <th></th> <th>Exp. voiding</th> <th>Catheter</th> <th>sphinct</th> <th>ISC</th> </tr> </thead> <tbody> <tr> <td>No. of pt episodes</td> <td>240</td> <td>162</td> <td>55</td> <td>70</td> </tr> <tr> <td>Av. Age</td> <td>34</td> <td>40</td> <td>33</td> <td>29</td> </tr> <tr> <td>% male</td> <td>88</td> <td>70</td> <td>100</td> <td>57</td> </tr> <tr> <td>AV injury level</td> <td>T6</td> <td>T5</td> <td>T3</td> <td>T9</td> </tr> <tr> <td>%complete spinal injury</td> <td>41</td> <td>65</td> <td>84</td> <td>78</td> </tr> </tbody> </table>		Exp. voiding	Catheter	sphinct	ISC	No. of pt episodes	240	162	55	70	Av. Age	34	40	33	29	% male	88	70	100	57	AV injury level	T6	T5	T3	T9	%complete spinal injury	41	65	84	78	<p>Expression voiding with or without condom.</p> <p>Indwelling catheters.</p> <p>Sphincterotomy.</p> <p>Intermittent self-catheterisation (ISC)</p>	See interventions.	<p>Median follow-up: 60 months</p> <p>Frequency of follow up yearly</p>	Risk of bladder stone formation	None reported.
	Exp. voiding	Catheter	sphinct	ISC																																		
No. of pt episodes	240	162	55	70																																		
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%complete spinal injury	41	65	84	78																																		
<p>Effect</p> <p>A total of 327 patients remained on definitive management for the full duration of follow-up, while 100 changed management during follow-up, some more than once</p>																																						

(expression voiding and condom drainage 27%, condom drainage and external sphincterotomy 11% and indwelling catheter 13%). Thus, the catheter and sphincterotomy groups were more likely to remain on definitive treatment, whereas those starting on expression voiding with condom drainage were more likely to change.

Risk of bladder stones:

Bladder management type	Mean follow-up(years)	No. of bladder stones/no. of pts	% forming bladder stones (no./ total no.)	Total group follow-up (years)	% absolute annual risk stone formation
Condom+sphincterotomy	8.4	0	0 (0/55)	463	0
ISC	6.75	1/1	1.5 (1/70)	480	0.2
Expression voiding with or without condom	6.3	7/7	3 (7/240)	1,515	0.5
Indwelling catheter	5.9	59/35	23 (35/152)	789	4% (first stone), 16% (subsequent stones)

Results of Cox- regression analysis: Although age, sex, and injury level were not significantly explanatory variables, degree of injury was considered ( $p=0.02$ ) in the model. After correcting for degree of injury, both forms of indwelling catheter was found to have a high risk of bladder stone formation compared with ISC or condom drainage with or without sphincterotomy.

The hazard ratio was 10.5 ( $p<0.0005$ , 95% CI 4.0-27.5) for patients with supra pubic catheters and 12.8 ( $p<0.005$ , 95% 5.1-31.9) for those with indwelling catheters. Bladder stones were no more likely to form in patients with supra pubic catheters than in those with indwelling urethral catheters (hazard ratio 1.2,  $p=0.6$ ).

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Pannek J, Kullik B. Does	Prospective observational	N=41	Patients with neurogenic lower urinary tract	Urodynamically assessed as a	Urodynamically assessed as a	Mean time between	Qualiveen questionnaire	None reported

optimizing bladder management equal optimizing quality of life? Correlation between health-related quality of life and urodynamic parameters in patients with spinal cord lesions. Urology. 2009; 74(2):263-266. Ref ID: PANNEK2009	study, Germany		dysfunction due to a spinal cord lesion who were performing intermittent self-catheterisation  Inclusion criteria: interval between the occurrence of the spinal cord injury and examination of $\geq 1$ yr  Patient population: male: female 31:10, injury level cervical 9, thoracic 23, lumbar 9, age at examination mean 39.5 yrs (range 18 to 72), age at spinal cord lesion mean 27.0 yrs (range 14 to 61), spinal cord lesion duration mean 14 yrs (range 1 to 22)	“treatment success”. Success was defined as a bladder capacity of $\geq 360$ mL, a maximum detrusor pressure $\leq$ cmH <sub>2</sub> O, the absence of autonomic dysregulation, and continence	“treatment failure”. Failure was diagnosed when any of the “success” criteria were not satisfied	spinal cord injury and examination 4 yrs	(quality of life). Four scales: constraints, limitations, fears and feelings. The greater the score of a scale, the worse the perception of the items on the scale	
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Effect

All patients were performing intermittent self catheterisation and receiving anticholinergic treatment. Bladder management was classified as successful in 14/41 (34%) and unsuccessful in 27/41 (66%). Of the 14 patients classified as having successful treatment, 10 were treated with oral anticholinergic drugs, and 4 had received additional intradetrusor botulinum toxin (BTX-A) injections. The 27 patients with treatment failure had either presented because of decreasing efficacy of BTX-A injections (n=16) despite anticholinergic medication or had demonstrated significant detrusor overactivity despite maximal oral anticholinergic treatment (n=11).

Qualiveen scale scores in relation to bladder function after correction for depression

	Bladder management mean (SD)		
Scale	Success (n=14)	Failure (n=27)	P value
Limitations	37.2 (22.10)	48.6 (18.29)	.0544
Constraints	39.2 (21.44)	52.9 (25.68)	.0377

Fears	20.0 (16.40)	44.7 (19.65)	.0014
Feelings	12.7 (15.22)	39.8 (27.69)	.0182

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Sugimura T, Arnold E, English S, Moore J. Chronic suprapubic catheterisation in the management of patients with spinal cord injuries: analysis of upper and lower urinary tract complication. BJU Int. 2008; 101: 1396-1400	Retrospective observational study. New Zealand.	N= 149	<p>Inclusion: Patients attending a hospital in New Zealand with SCI who continued to use the suprapubic catheter for &gt;3 months.</p> <p>Patient characteristics: Newly diagnosed SCI patients with either paraplegia or quadriplegia. 25 patients had used some other form of bladder emptying before changing to a suprapubic catheter (urethral catheter – 12, ISC – 7, external sphincterotomy – 3, bladder neck incision – 1,</p>	A strict protocol to minimise complications was followed. The suprapubic catheter was irrigated weekly with normal saline, and the catheter was changed every 2 weeks while the patient was in hospital. This was continued at home, through close	NA	<p>68 (3-179) months</p> <p>Frequency of follow up variable</p>	<p>Existence of caliectasis</p> <p>Existence of hydronephrosis</p> <p>Existence of renal scarring</p> <p>Vesiculoureteral reflux</p> <p>Symptomatic UTIs</p> <p>Existence of calculi</p>	None reported

			coposuspension – 1, urethral stent – 1).	surveillance from the medical team.				
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Effects

Adverse event	Number with adverse effect
All complications	76/149
Symptomatic UTIs	45/149
Bladder stones	33/149
Low grade superficial TCC (?transitional cell carcinoma)	1/149
All renal complications	20/149
Renal calculi	12/149
Renal scarring	9/149
All vesicoureteral reflux (VUR)	21/149 (bilateral in 5)
VUR with renal stones	3/149
VUR with renal scarring	1/149
VUR with renal stones and scarring	1/149
Urethral incontinence	11/149

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Waites KB,	Prospectiv	N=64	Traumatic SCI patients with neurogenic	Intermittent	Condom	1 year	Incidence of UTIs	None

Canupp KC, DeVivo MJ. Epidemiology and risk factors for urinary tract infection following spinal cord injury. Arch Phys med Rehabil 1993; 74: 691-695.	observational study.		bladder and discharged from the initial hospitalisation. No age given.  Exclusion: severe concurrent illness; known vesicoureteral or intrarenal reflux; urinary calculi; severely diminished renal function; indwelling or suprapubic catheters.	Catheterisation	with urine bag	Frequency of follow up monthly		stated
Effects								
Adverse event			Intermittent catheterisation	Condom and collection bag	p			
Urinary tract infection			17.2 infections/ person-year	18.9 infections/ person-year	NS			

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding										
Weld KJ, Dmochowski RR. Effect of bladder management on urological complication in spinal cord injured patients. The	Retrospective (chart review) observational study. USA.	N=316	313 males and 3 females with post-traumatic SCI. All receiving continuous long term physical care at a SC unit. Groups equivalent for all variables below (P>0.05)	All were on some form of bladder management. Although some patients changed their method during their	NA	18.3 (12.4) yrs since injury.  Frequency of follow up unclear	Pyelonephritis  VUR  Renal stones  Bladder stones	Not given										
			<table border="1"> <tr> <td></td> <td>Urethral n=114</td> <td>CIC n=92</td> <td>Spontaneous n=74</td> <td>Suprapubic n=36</td> </tr> <tr> <td>age</td> <td>36.8 (10.4)</td> <td>41.0 (12.6)</td> <td>38.1 (11.8)</td> <td>33.9 (13.8)</td> </tr> </table>		Urethral n=114	CIC n=92	Spontaneous n=74	Suprapubic n=36	age	36.8 (10.4)	41.0 (12.6)	38.1 (11.8)	33.9 (13.8)					
	Urethral n=114	CIC n=92	Spontaneous n=74	Suprapubic n=36														
age	36.8 (10.4)	41.0 (12.6)	38.1 (11.8)	33.9 (13.8)														

Journal of Urology. 2000; 163: 768-772	Follow up (yrs)	18.1 (12.1)	18.0 (12.6)	19.3 (13.0)	17.8 (12.4)	stay, the predominant method used was chosen.
	Suprasacral (%)	89	79	85	89	
	Complete (%)	21	12	10	9	

Effects: Estimated from figures, but all likely to be accurate to within 1%.

Complications	Urethral n=114	CIC n=92	Spontaneous n=74	Suprapubic n=36	p
All	61/114	25/92	24/74	16/36	
pyelonephritis	8%	1%	1.5%	3%	<0.001
Renal stone	55%	22%	20%	36%	<0.001
Bladder stone	28%	0%	8%	22%	<0.001
VUR	23%	7%	8%	28%	0.001
Upper tract deterioration	30%	16%	27%	39%	0.038