G.5.2 Catheter type

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Bull 1991 [53] Study design: RCT Setting: England, Community Duration of follow-up: 16 weeks	Patient group: Patients undergoing long-term urethral catheterisation Inclusion criteria: Patients aged over 18 years undergoing long-term urethral catheterisation assessed to be mentally sound. Reasons for catheterisation included atonic bladder, prostate cancer, spinal injury, MS, paralysis, Parkinson's disease, incontinence, retention, prostatic enlargement and post TURP incontinence. Exclusion criteria: Patients with known sensitivity to hydrogel materials All patients N: 69 Age (mean): Drop outs: Male:female: 57:12 Group 1 N: 36 Age (mean): 75.61 (12.6) Drop outs: 9 Male:female: 31:5	Catheters were changed as necessary, patients assessed at biweekly intervals and patients kept a daily diary card recording comfort, pain and leakage on a 3 point scale (1 = good, 2 = average and 3 = bad). Any patient who required admission to hospital for more than 4 days was withdrawn from the study Group 1 Bard Biocath Foley catheter. A latex substrate coated on the inner and outer surfaces with a special hydrophilic polymer (hydrogel) Group 2 Dow Corning Silastic catheter (silicone elastomer coated	'Mean catheter time in situ, days (SD) (Student's unpaired t test)	Group 1: 89.61 (36.31) Group 2: 56.7 (38.8) p value: 0.0014	Funding: Not stated Limitations: Additional outcomes: Number of patients requiring 1 or more catheter changes and total numbers of catheter changes. Patient reported leakage. Patient preference to the catheter they were randomised to compared to their previous. Washouts, bypassing episodes (missing data from control group). Notes: Standard deviation not given for several continuous outcomes, which therefore cannot be entered into a meta-analysis.
			Encrustation leading to catheter change	Group 1: 11 Group 2: 9	
			Mean diary score	Comfort Group 1: 1.22 Group 2: 1.30 p value: not sig Pain Group 1: 1.14 Group 2: 1.24 p value: not sig	
			Mean pH over study period	Group1: 6.3 Group 2: 6..6 p value: not sig	
			Catheter related adverse events	Group1: 1 – reason not stated Group 2: 7 – 5 pain, 1 catheter did not drain, 1 catheter was repeatedly expelled.	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Mean days catheter change: 77 (66.9) Group 2 N: 33 Age (mean): 70.03 (16.6) Drop outs: 12 Male:female: 26:7 Mean days catheter change: 60 (22.6)	catheter)			

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Cardenas 2009 [59] Study design: RCT Setting: USA. Seattle. Duration of follow-up: 1 year	Patient group: Patients with spinal cord injury (SCI) Inclusion criteria: SCI 6 months or more ago, self reported history of ≥2 UTIs during the past year, use of IC with a noncoated catheter and an open system, no plan to change the method of bladder drainage during the study period, naïve to hydrophilic catheters and at least 18 years of age. Exclusion criteria: Patients with evidence of upper urinary tract abnormalities or renal or bladder calculi in a screening renal ultrasound. All patients N: 56 Drop outs: 11 (1 dropped out at subjects request, 3 lost to follow up, 3 discontinued as a result of placement of an indwelling Foley catheter, 3 withdrew as a result of nonurologic medical complications, and 1 withdrew as a result of developing renal stones Group 1 N: 22 Mean age (SD): 42.3 (10.4) Male/Female: 17/5 Group 2 N: 23 Mean age (SD): 40.1 (9.3) Male/female: 12/11	After randomisation patients were instructed how to use the hydrophilic catheter or how to use proper clean technique for those in the control group. The definition of a symptomatic UTI is significant bacteriurea (>105 cfu/mL) plus at least 1 sign or symptom suggestive of a UTI (self reported from a diary). Urine was collected at intervals of 6, 9 and 12 months, whereas the symptom diary was collected on a monthly basis. Subjects visited their regular health provider as normal for treatment of UTIs. Group 1 LoFric hydrophilic coated PVC catheter Group 2 Control catheter. Patients used their usual noncoated catheter with clean technique, but used a new catheter with each catheterization.	Total UTI at 1 year (t test) Total antibiotic treatment episodes at 1 year Subjects who had at least 1 UTI Subjects who had at least 1 antibiotic treatment episode	Group1: 1.18 (1.3) Group 2: 1.00 (1.0) p value: 0.61 Group1: 0.77 (0.87) Group 2: 1.65 (1.46) p value: 0.02 Group1: 12 Group 2: 14 p value: 0.67 Group1: 11 Group 2: 16 p value: 0.18	Funding: No commercial party had a direct financial interest in the result of the research reported. Limitations: Imbalance in male: female ratio between groups. Small sample size – author states that it may have been underpowered. Use of self reported symptoms to determine symptomatic UTIs.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
DeRidder 2005 [95] Study design: RCT Setting: Multi-centre (5 in Spain, 3 in Belgium) Duration of follow-up: 1 year	Patient group: Men with spinal cord injury presenting with functional neurogenic bladder-sphincter disorders. Inclusion criteria: Men aged 16 or over that have been injured less than 6 months Exclusion criteria: Patients with symptomatic UTI, urethral stenosis or fibrosis were excluded, as were mentally unstable patients and those participating in another clinical trial. During the trial, those that received prophylactic antiseptic or antibiotic treatment or used a permanent catheter was used for a period of more than 10 days were also excluded. All patients N: 123 Group 1 N: 61 Mean age (SD): 37.5 (14.6) Group 2 N: 62 Mean age (SD): 36.7 (14.6)	Both catheters were available for the study in size Ch10, 12 and 14. Patients kept a log book of symptoms and had visits at day 15 then 1, 2, 3, 6, 9 and 12 months. Group 1 Hydrophilic-coated SpeediCath polyurethane catheter (Coloplast). Single use ready-to-use catheter. Group 2 Uncoated PVC catheter, which were lubricated manually with a water-soluble lubricant gel, containing no active ingredients and delivered in 5g sachets (Aquagel lubricating Jelly, Adams Healthcare Ecolab.). Catheters are reused.	UTI – (clinical infection with symptoms of UTI and for which treatment was prescribed)	1 or more during the study. Group1: 39 Group 2: 51 No UTI Group1: 22 Group 2: 11 p value: 0.02	Funding: Not stated Limitations: High drop out rate (54%) due to restored urinary function and thus no further need for catheterisation, change of bladder management to an indwelling catheter and withdrawal of consent. There was a higher number of patients with microscopic hematuria and bacteriuria in the intervention group compared to control – actual numbers not stated but p = 0.02 and 0.03 respectively. Additional outcomes: (list additional outcomes reported in paper but not recorded in this table) Notes: Majority of patients had urethral indwelling catheters prior to trial. Patients still hospitalised at study inclusion.
			Mean catheterisations per day	Group1: 3.4 Group 2: 3.6	
			Haematuria	Group1: 38/55 Group 2: 32/59	
			Stenosis	Group1: 0 Group 2: 1 p value: not sig	
			Patients/helpers who were very satisfied with the catheter	6 months Group1: 10 Group 2: 6 p value: not sig 12 months Group1: 9 Group 2: 7 p value: not sig	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Giannantoni 2001 [150] Study design: Randomised crossover trial Setting: Rehabilitation hospital, Italy Duration of follow-up: 7 weeks in each arm	Patient group: Neurogenic bladder due to recent spinal cord injury Inclusion criteria: Exclusion criteria: All patients N: 18 Age (SD): 38.2 (16.4) Drop outs: 0 Male/Female: 16/2	All patients were transferred from the intensive care unit with an indwelling catheter. Subsequently trained to perform intermittent catheterisation independently. Intermittent catheterisation was performed every 5 hours. Group 1 Sterile, single use pvc, silicone coated catheter (Orlycatnel: Nelaton, Orly General Supply, Italy). Lubricated by the patient using a gel. Group 2. Prelubricated non-hydrophilic catheter.(Isantcath: Hollister, Illinois). Silicone coated catheter prelubricated with glicerol polymethacrylate and propylene glycerol gel.	Symptomatic UTI (cloudy and odorous urine, onset of urinary incontinence, increased spasticity, automatic dysreflexia, increased sweating and malaise or a sense of unease associated with pyuria and significant bacteriuria)	Group 1: 12/54 Group 2: 4/54 P = 0.003	Funding: not stated Limitations: Where 54 is stated as the n number please note that this is a sum of 3 measurements per patients (i.e. 3 x18). Therefore sample size seems larger than it actually is. Additional outcomes: Additional patient demographics. Urethral wall trauma
			Asymptomatic bacteriuria (uropathogenic colonization of the urinary tract without symptoms of infection)	Group 1: 18/54 Group 2: 8/54	
			Patient satisfaction (visual analogue scale)	Learning Group1: 1.1 (2.7) Group 2: 1.1 (2.7) p = 0.16 Inserting Group1: 6.7 (3.4) Group 2: 3.6 (3.7) p = 0.00007 Extracting Group1: 5.0 (3.4) Group 2: 3.0 (3.0) p = 0.004 Comfort Group1: 5.8 (3.9) Group 2: 2.5 (3.1) p = 0.00002 Handling ease Group1: 5.0 (3.4) Group 2: 1.4 (2.3) p = 0.000004 Mean satisfaction score Group1: 2.33 (1.06) Group 2: 4.72 (2.13) p = 0.022	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Pachler 1999 [346] Study design: Randomised prospective crossover trial Setting: Community, Denmark Duration of follow-up: 3 weeks	Patient group: Patients with urinary retention caused by prostatic enlargement. Inclusion criteria: Men with urinary retention Exclusion criteria: All patients N: 43 Age (mean): Drop outs: 11 (5 had no lasting need for intermittent catheterisation, 3 didn't enter the study, 2 could not insert the non-hydrophilic catheter and did not want to use the hydrophilic catheter and 1 developed a rash around the external urethral meatus while using the non hydrophilic catheter. Crossover trial (all patients used both intervention) N: 32 Age (mean): 71.3 (range 50-87) 1st 3 weeks 20 patients in group 1and 12 in group 2.	Patients were taught how to perform clean intermittent self catheterisation by a specially trained nurse in the outpatient clinic. Patients used one catheter for 3 weeks then transferred to the other type for 3 weeks. Group 1 Prelubricated, (hydrophilic coated), disposable PVC catheter (Lofric, AstraZenenca, UK) Group 2 Non-hydrophilic PVC catheter (Mentor, Santa Barbara) plus lubrication (gel) applied by the patient. This catheter was used several times within 24h and was then discarded. After each use it was rinsed under lukewarm water and left to dry on a clean towel.	Bacteriuria (growth of >104 c.f.u./mL was considered significant)	Group 1: 14 Group 2: 17 p value: not significant	Funding: Not stated. Limitations: Small sample size, crossover study. Notes: Questionnaire completed after 3 weeks of using each type of catheter.
			Problems in introducing the catheter	None Group 1: 31 Group 2: 30 Some Group1: 1 Group 2: 2 Many Group1: 0 Group 2: 0 p value: not significant	
			Burning sensation when introducing the catheter	None Group1: 30 Group 2: 31 Some Group1: 2 Group 2: 1 Many Group1: 0 Group 2: 0 p value: not significant	
			Pain when introducing the catheter	None Group 1: 29 Group 2: 30 Some Group1: 3 Group 2: 2	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				Many Group1: 0 Group 2: 0 p value: not significant	
			Burning sensation or pain after removal of the catheter	None Group1: 30 Group 2: 30 Some Group1: 2 Group 2: 2 Many Group1: 0 Group 2: 0 p value: not significant	
			Handling of catheter before introduction	Easy Group1: 30 Group 2: 25 Tolerable Group1: 1 Group 2: 6 Troublesome Group1: 1 Group 2: 1 p value: not significant	
			Handling of catheter after use	Easy Group1: 30 Group 2: 27 Tolerable Group1: 2 Group 2: 3	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
				<u>Troublesome</u> Group1: 0 Group 2: 2 p value: not significant	
			Transient gross haematuria	Group 1: 14 Group 2: 17 p value: not significant	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Sutherland 1996 [455] Study design: RCT Setting: Community, USA Duration of follow-up: 8 weeks	Patient group: Men with neurogenic bladder due to spinal cord injury, Hinman syndrome or spinal dysraphism Inclusion criteria: Boys who were adept at performing clean intermittent catheterisation and who had voiding dysfunction due to spinal dysraphism, spinal cord injury or non-neurogenic bladder. Exclusion criteria: Patients with a history of urethral pathology (false passage, stricture or bladder neck reconstructive surgery) All patients N: 33 Age (mean): Drop outs: 3 Group 1 N: 17 Age (mean): 11.7 (3.8) Drop outs: 1 Group 2 N: 16 Age (mean): 12.1 (5.7) Drop outs: 2	Follow-up – weekly urine C&S and microscopy x 8 weeks. Group 1 Hydrophilic coated PVC catheter (Lofric) single use Group 2 PVC reused catheter (Mentor). Non-hydrophilic polyvinyl chloride catheter.	Microscopic Haematuria > 3 red blood cells per high powered field	Group 1: 6 Group 2: 11	Funding: not stated Limitations: Unclear allocation concealment and randomisation Additional outcomes: Additional patient deomgraphics. Notes: No difference in bacteriuria between the groups
			Bacteriuria When suspected on the basis of symptoms and urinalysis, a urine culture was obtained. Positive cultures defined as10x5 CFU/ml- subjects were treated and reentered into the trial 1 week after cessation of antibiotic therapy.	Group 1: 3 Group 2: 4	
			Visual analogue scale for satisfaction (0 = most and 10 = least favourable)	Convenience Group 1: 3.3 (2.8) Group 2: 4.9 (2.7) P <0.05 Handling Group 1: 3.8 (2.7) Group 2: 3.8 (2.6) Comfort with insertion Group 1: 2.7 (2.4) Group 2: 4.2 (2.6) P <0.05 General opinion Group1: 3.3 (3) Group 2: 3.9 (2.1)	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Vapnek 2003 [480] Study design: RCT Setting: 3 American sites Duration of follow-up: 12 months	Patient group: Men who perform intermittent self-catheterisation used to manage neurogenic bladder Inclusion criteria: Men able to perform intermittent self catheterisation. Exclusion criteria: Patients with a history of vesicoureteral reflux, unexplained hematuria or bladder calculi, those requiring prophylactic antibiotics and those considered incapable of following the study schedule were excluded from the analysis. All patients N: 62 Age (mean): Drop outs: Group 1 N: 31 Age (mean +/- SD): 39.8 (12.9) Drop outs: 1 (used both catheter types) 8	Following enrolment, patients presented for follow up once every 3 months for 1 year. A 3 month supply of catheters was issued at each visit. Patients were instructed to use clean technique and discard each catheter after 1 use. Most catheters were 14Fr, but some patients preferred 16Fr or 12Fr Group 1 Hydrophilic coated LoFric catheter. Plastic catheter - polyolefin-based elastomer. 120 catheters were issued monthly. Group 2 Standard polyvinyl chloride catheter. 30 catheters were issued monthly. Patients were instructed to clean and reuse the catheter 4 or 5 times before	Urinary tract infection (SD) (Baseline self reported, but during study this was self reported plus quarterly urine cultures)	Baseline Group1: 0.45 (0.62) Group 2: 0.20 (0.2) 3 months Group1: 0.16 Group 2: 0.23 6 months Group1: 0.12 Group 2: 0.17 9 months Group1: 0.12 Group 2: 0.16 12 months Group1: 0.13 (0.18) Group 2: 0.14 (0.14) p value: NS	Funding: Lead author declared financial interest and/or other relationship with Pharmacia and Merck. Limitations: Catheters re-used up to 5 times a day for control, where as intervention is single use only. Baseline rates of UTI differ.
			Microscopic hematuria (SD) (Degree of hematuria and pyuria was classified as none (0) ,mild (1), moderate (2) or heavy (3) according to the number of cells per high power field.)	3 months Group1: 0.21 Group 2: 0.71 6 months Group1: 0.28 Group 2: 0.63 9 months Group1: 0.30	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	Group 2 N: 31 Age (mean +/- SD): 39.6 (16.0) Drop outs: 5	discarding at the end of the day.		Group 2: 0.63 12 months Group1: 0.31 (0.46) Group 2: 0.65 (0.69) p value: 0.027	
			Microscopic pyuria	<u>3 months</u> Group1: 1.6 Group 2: 1.4 <u>6 months</u> Group1: 1.6 Group 2: 1.5 <u>9 months</u> Group1: 1.6 Group 2: 1.6 <u>12 months</u> Group1: 1.7 Group 2: 1.6 p value: NS	
			Bacteriuria	Measured, but not reported. p value: NS	
			Adverse events	Group1: 3 (1 gross haematuria, 1 episode of epididymitis, 1 infected penile prothesis requiring surgical removal) Group 2: 3 (1 gross haematuria, 1 episode of epididymitis, 1 bladder stone). p value: NS	

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
Duffy 1995 [110] Study design: RCT Setting: 3 long term care sites, USA Duration of follow-up: mean 63 days in each group, range 15 to 107 days	Patient group: Residents of long term care facilities Inclusion criteria: Patients with indwelling catheters for relief of residual urine, were currently managed by intermittent catheterisation, or had significant residual urine and had an anticipated length of stay of at least 110 days. Exclusion criteria: Patients with a medical diagnosis of urethral stricture, which would put the patient at high risk for complication, or the presence of combativeness (striking out or kicking at the nurse caregiver) or other behavioural problems, which would make a program of intermittent catheterisation impossible for staff to carry out. All patients N: 82 Drop outs: 2 Group 1 N: 38 Age (mean +/- SD): 70.9 (12.1) 20 completed 90 day protocol Group 2	Consistency was assured across sites by preliminary and bimonthly staff inservice programs plus reliability checks on the nursing care units. Group 1 Clean intermittent catheterisation. Does not require a sterile field and can be done in bed or chair as patient desires. No cleaning of the meatus was done if normal daily hygiene (daily cleansing with soap and water) appeared sufficient and there was no obvious contamination with stool or other drainage. However, after the 1st use and for each catheterisation done during a one week period, the catheter was washed with mild soap and running water, dried on a clean, lint free towel and stored at the patient's bedside in a clean, dry container. Clean catheters were replaced each week. Group 2 Sterile intermittent catheterisation. This required all sterile equipment for each catheterisation, setting up of a sterile field with drapes, and cleansing of the urinary meatus	Number of symptomatic UTIs Catheter replacement / frequency of catheter change, at day 15, Mean (SD)	Group1: 29 treatment episodes/2452 days Group 2: 35 treatment episodes/2672 days Group1: 11.8/1000 days Group 2: 13.1/1000 days Group1: 3.0 (+/- 1.1) Group 2: 2.8 (+/- 1.1) P = 0.455	Funding: Supported by a grant from the Department of Health Services Research and Development, Department of Veteran Affairs, Washington, DC. Limitations: Catheterisation was performed by nurses, rather than by the patient. Length of time enrolled in study varied. Additional outcomes: Risk factors for UTI, primary diagnosis and cause of residual urine. (no statistical significance between groups) Notes: Drop out of the study before end of 90 day protocol were: death unrelated to study, request for discontinuation, hospitalisation of the patient for >21 days for an unrelated problem, subject discharged from facility, combativeness, reduction in volume of

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	N: 42 Age (mean +/- SD): 72.6 (10.8) 19 completed 90 day protocol	with Betadine before catheterisation. All catheterisation was supplied by the pharmacy in a sterile condition.			residual urine so that patient no longer required catheterisation, and end of study funding period.

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
King 1992 [224] <u>Study design:</u> RCT <u>Setting:</u> Inpatient rehab, USA. <u>Duration of follow-up:</u> 28 days, or until infection occurred. (range 1-28)	<u>Patient group:</u> Patients with spinal cord injuries (SCI) <u>Inclusion criteria:</u> Patients admitted to an inpatient rehab programme at any time postinjury, placed on intermittent catheterisation either before or during their hospitalisation. Also, if catheterisation was performed every 6 hours, had normal serum creatinine, and urinalysis, no prophylactic antibiotics, absence of drug-resistant organism on urine culture and bacteremia less than 10,000 colonies/ml <u>Exclusion criteria:</u> Patients were discontinued from the study before 28 days if catheterisations were ordered less frequently than every 6 hours or if they were discharged. All patients N: 46 Drop outs: 2 <u>Group 1</u>	Patients with sufficient hand function and willingness to learn were taught self catheterisation. Others were catheterised by a nurse or family member. Group 1 Clean intermittent catheterisation Patients did not wear gloves; staff and family care givers wore non sterile gloves. A sterile catheter was used at the beginning of each 24 hour period. The catheter was lubricated, and the urinary meatal area was cleansed with a castile soap wipe. After each use the catheter was washed with bar soap, rinsed with tap water, dried, and stored in a plastic bag for reuse. Group 2 Sterile intermittent catheterisation. Carried out using a sterile	Number of symptomatic UTIs Number of catheterisation per risk days (no. of study days on which the subject did not meet the criteria for infection.	Group1: 5 Group 2: 3 Group1: 1497 catheterisation/256 days Group 2: 1758.5 catheterisation/311 days	<u>Funding:</u> Supported by a grant from The American Association of Spinal Cord Injury Nurses and was supplemented by the Rehabilitation Institute Foundation. <u>Limitations:</u> Not possible to estimate total time on intermittent catheterisation (61% clean and 74% of sterile group started intermittent catheterisation in acute setting. <u>Additional outcomes:</u> Bacteriurea

Study details	Patients	Interventions	Outcome measures	Effect size	Comments
	N: 23 Age (mean +/- SD): 27.9 (10.3) Drop outs: 3 patients catheterised less than 2 weeks <u>Group 2</u> N: 23 Age (mean +/- SD): 32.8 (13.7) Drop outs: 1 catheterised <2 weeks	catheterisation kit for each procedure and following principles of asepsis such that care was taken to avoid contaminating the catheter. The external meatus was cleansed with povidone iodine before sterile catheterisation.			<u>Notes:</u> 35 patients catheterised every ≤4h 10 every 6h 1 every 4h in the day and 6 at night.