APPENDICES FOR

GUIDELINE FOR PREVENTION OF CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

Appendix 1A: Search Strategy for Guidelines

Database	Platform
National Guideline Clearinghouse	http://www.guideline.gov/
MEDLINE	OVID
Cochrane Library HTA	Wiley Interscience
NIH Consensus Development Program	http://consensus.nih.gov/
USPSTF	http://www.ahrq.gov/clinic/uspstfix.htm

1. NATIONAL GUIDELINE CLEARINGHOUSE

Keyword	Search Results
"urinary tract infection"	79
"urinary catheterization"	10

2. MEDLINE

#	Search History	Results
1	exp Urinary Tract Infections/	32372
2	exp Urinary Catheterization/	10749
3	1 or 2	40511
4	limit 3 to (guideline or practice guideline)	56

3. COCHRANE LIBRARY

#	Search History	Results
#1	MeSH descriptor Urinary Tract Infections explode all trees	1776
#2	MeSH descriptor Urinary Catheterization explode all trees	431
#3	(#1 OR #2)	14

4. NIH Consensus Development Program

No relevant guidelines were found

5. USPSTF

No relevant guidelines were found

3 relevant guidelines were identified

Appendix 1B: Search Strategy for Systematic Reviews/Primary Literature

MEDLINE

#	Search History	Results
PHASE 1: SEARCH TERMS FOR CATHETERIZATION		
1	exp Urinary Catheterization/	10644
2	((urinary or urethral) adj10 catheter$).mp.	13343
3	(intermittent$ adj10 catheter$).mp.	2172
4	(condom adj10 catheter$).mp.	151
5	(suprapubic$ adj10 catheter$).mp.	698
6	exp Catheters, Indwelling/	12177
7	(indwelling adj10 catheter).mp.	2949
8	(urin$ or urethra$ or bladder).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	393621
9	6 or 7	14224
10	8 and 9	2791
11	1 or 2 or 3 or 4 or 5 or 10	15311
PHASE 2: SEARCH TERMS FOR INFECTION AND OBSTRUCTION		
12	exp Urinary Tract Infections/ not exp Schistosomiasis/	30322
13	exp Cross Infection/ not exp Pneumonia, Ventilator-Associated/	32716
14	(urinary adj tract adj infection$).mp.	32950
15	UTI.mp.	2941
16	catheter associated urinary tract infection$.mp.	170
17	((cross adj10 infection$) or (nosocomial adj10 infection$)).mp.	38890
18	exp disease transmission, vertical/ or exp disease vectors/	28529
19	exp Disease Transmission/	34951
20	19 not 18	6422

21	nosocomial urinary tract infection$.mp.	196
22	Bacteremia/	11127
23	funguria.mp.	50
24	Biofilms/	5608
25	encrustation.mp.	331
26	exopolysaccharide.mp.	1270
27	(obstruct$ or block$).mp.	606421
28	exp Urethral Obstruction/	7225
29	12 or 13 or 14 or 15 or 16 or 17 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28	701714
PHASE 3: SEARCH TERMS FOR DIAGNOSTICS AND INTERVENTIONS		
30	Antibiotic Prophylaxis/	4920
31	exp bronchoalveolar lavage/ or exp gastric lavage/ or exp peritoneal lavage/ or exp vaginal douching/	4517
32	exp Irrigation/	17246
33	32 not 31	12729
34	Lubrication/	1164
35	exp antiparasitic agents/ or exp antiviral agents/	346651
36	exp Anti-Infective Agents/	959273
37	36 not 35	612622
38	Chlorhexidine/ or Povidone-Iodine/	5743
39	Hydrogen-Ion Concentration/	198534
40	(bacteriologic$ adj10 monitoring).mp.	156
41	(bladder adj10 irrigat$).mp.	537
42	(bladder adj10 washout).mp.	91
43	(bladder adj10 instillation).mp.	811
44	((open or closed) adj10 drainage).mp.	1820
45	(meatus or meatal).mp.	3763
46	urinary dipstick$.mp.	56
47	exp kidney function tests/ or exp urinary catheterization/	58228
48	exp Diagnostic Techniques, Urological/	83022
49	48 not 47	24794

50	exp Education, Nursing/	57406
51	exp Hygiene/ not exp Oral Hygiene/	11771
52	exp Infection Control/ not exp Infection Control, Dental/	37395
53	exp Inservice Training/	17316
54	exp Nursing Care/	97685
55	(quality adj improvement).mp.	6840
56	exp Medical Informatics/	139920
57	Patient Education/	48433
58	exp Gels/ or gel.mp. or gels.mp.	319351
59	((antibiotic or antiseptic or silver) adj10 (coat$ or impregnated)).mp. [mp=title, original title, abstract, name of substance word, subject heading word]	1406
60	exp Total Quality Management/	9150
61	exp Quality Assurance, Health Care/	166322
62	30 or 33 or 34 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59 or 60 or 61	1633474
PHASE 4: COMBINING THE PHASES		
63	11 and 29 **(Phase 1 AND Phase 2)**	6381
64	11 and 62 **(Phase 1 AND Phase 3)**	3214
65	63 or 64 **(Phase 1 AND Phase 2) OR (Phase 1 AND Phase 3)**	7645
PHASE 5: FILTERING FOR PUBLICATION TYPES		
66	(addresses or bibliography or biography or clinical conference or comment or congresses or consensus development conference or consensus development conference nih or dictionary or directory or duplicate publication or editorial or festschrift or historial article or interview or lectures or legal cases or news or newspaper article or patient education handout).pt.	846798
67	65 not 66	7523
PHASE 6: LIMITING TO HUMANS AND ENGLISH LANGUAGE		
68	limit 67 to (humans and english language)	5332

EMBASE

#	Search History	Results
PHASE 1: SEARCH TERMS FOR CATHETERIZATION		
1	exp Bladder Catheterization/	1837
2	exp SUPRAPUBIC CATHETER/	147
3	exp CONDOM CATHETER/	9
4	exp BALLOON CATHETER/	6278
5	exp Urine Catheter/	1614
6	exp Intermittent Catheterization/	1013
7	exp Indwelling Catheter/	2167
8	(urin$ or urethra$ or bladder).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	310690
9	7 and 8	913
10	1 or 2 or 3 or 4 or 5 or 6 or 9	10938
PHASE 2: SEARCH TERMS FOR INFECTION AND OBSTRUCTION		
11	exp Urinary Tract Infection/	28449
12	exp Cross Infection/	882
13	nosocomial infection.mp. or exp Hospital Infection/	20126
14	(urinary adj tract adj infection$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	29735
15	uti.mp.	2992
16	Bacteremia/	12751
17	Bacteriuria/	2296
18	exp asymptomatic bacteriuria/ or exp leukocyturia/	639
19	exp Catheter Infection/	4426
20	disease transmission/ or bacterial transmission/ or fungus transmission/	23017
21	funguria.mp.	43
22	exp Biofilm/	7195
23	encrustation.mp.	270
24	exp EXOPOLYSACCHARIDE/	503
25	(obstruct$ or block$).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	611065

26	urethral obstruction.mp. or exp Urethra Stenosis/	1032
27	or/11-26	701440
PHASE 3: SEARCH TERMS FOR DIAGNOSTICS AND INTERVENTIONS		
28	exp Antibiotic Prophylaxis/	10045
29	exp BLADDER IRRIGATION/	736
30	exp LUBRICATION/	885
31	Urinary Tract Antiinfective Agent/	98
32	exp CHLORHEXIDINE/	4717
33	exp Povidone Iodine/	4559
34	exp Ph/	98612
35	(bacteriologic$ adj monitoring).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	72
36	exp CLOSED DRAINAGE/	5
37	open drainage.mp.	254
38	(meatus or meatal).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	3008
39	urinary dipstick.mp.	39
40	exp diagnostic test/ or exp laboratory test/	275882
41	exp Nursing Education/	2047
42	exp PERSONAL HYGIENE/ or exp HOSPITAL HYGIENE/	5405
43	infection control/	22250
44	inservice training.mp. or exp Education/	245192
45	exp Nursing Care/ or exp Patient Care/	189701
46	quality improvement.mp. or exp Total Quality Management/	5105
47	exp Medical Informatics/	3313
48	exp Patient Education/	23613
49	gels.mp. or exp Gel/	31972
50	((antibiotic or antiseptic or silver) adj10 (coat$ or impregnated)).mp. [mp=title, abstract, subject headings, heading word, drug trade name, original title, device manufacturer, drug manufacturer name]	1225
51	or/28-50	845675
PHASE 4: COMBINING THE PHASES		
52	10 and 27 **(Phase 1 AND Phase 2)**	3509

53	10 and 51 **(Phase 1 AND Phase 3)**	1396
54	52 or 53 **(Phase 1 AND Phase 2) OR (Phase 1 AND Phase 3)**	4266
PHASE 5: FILTERING FOR PUBLICATION TYPES		
55	(book or conference paper or editorial or note or proceeding).pt.	967981
56	54 not 55	3900
PHASE 6: LIMITING TO HUMANS AND ENGLISH LANGUAGE		
57	limit 56 to (human and english language)	3089

CINAHL

#	Search History	Results
PHASE 1: SEARCH TERMS FOR CATHETERIZATION		
1	exp Urinary Catheterization/	1171
2	((urinary or urethral) adj10 catheter$).mp.	1982
3	exp Catheters, Urinary/	715
4	exp Urinary Catheterization, Intermittent/ or (intermittent$ adj10 catheter$).mp.	434
5	exp condom catheters/ or (condom adj10 catheter$).mp.	78
6	(suprapubic$ adj10 catheter$).mp.	79
7	(indwelling adj10 catheter).mp.	270
8	(urin$ or urethra$ or bladder).mp. [mp=title, subject heading word, abstract, instrumentation]	16101
9	7 and 8	180
10	1 or 2 or 3 or 4 or 5 or 6 or 9	2148
PHASE 2: SEARCH TERMS FOR INFECTION AND OBSTRUCTION		
11	exp Urinary Tract Infections/	2215
12	exp Cross Infection/	9178
13	(urinary adj tract adj infection$).mp.	2549
14	UTI.mp.	414
15	catheter associated urinary tract infection$.mp.	74

16	((cross adj10 infection$) or (nosocomial adj10 infection$)).mp.	9443
17	exp disease transmission, vertical/ or exp disease vectors/	1718
18	exp Disease Transmission/	2888
19	18 not 17	1170
20	nosocomial urinary tract infection$.mp.	44
21	Bacteremia/	1081
22	funguria.mp.	1
23	Biofilms/	271
24	encrustation.mp.	38
25	exopolysaccharide.mp.	4
26	(obstruct$ or block$).mp.	19609
27	11 or 12 or 13 or 14 or 15 or 16 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26	33789
PHASE 3: SEARCH TERMS FOR DIAGNOSTICS AND INTERVENTIONS		
28	Antibiotic Prophylaxis/	1433
29	lubrication.mp.	83
30	exp antitubercular agents/ or exp antiviral agents/ or exp leprostatic agents/ or exp antiparasitic agents/	9776
31	exp Antiinfective Agents/	23827
32	31 not 30	15091
33	Chlorhexidine/ or Povidone-Iodine/	719
34	Hydrogen-Ion Concentration/	1152
35	(bacteriologic$ adj10 monitoring).mp.	9
36	(bladder adj10 irrigat$).mp.	38
37	(bladder adj10 washout).mp.	8
38	(bladder adj10 instillation).mp.	22
39	exp DRAINAGE/ or exp CLOSED DRAINAGE/	1961
40	((open or closed) adj10 drainage).mp.	159
41	(meatus or meatal).mp.	75
42	urinary dipstick$.mp.	2
43	exp Diagnosis, Urologic/	4186
44	exp kidney function tests/ or exp urinary catheterization/	2087

45	43 not 44	2297
46	exp Education, Nursing/	32413
47	exp Urologic Nursing/	535
48	exp Hygiene/	766
49	exp Infection Control/	20325
50	exp Nursing Care/	139877
51	(quality adj improvement).mp.	10239
52	exp Medical Informatics/ or exp nursing informatics	1811
53	Patient Education/	23144
54	exp Gels/ or gel.mp. or gels.mp.	1956
55	((antibiotic or antiseptic or silver) adj10 (coat$ or impregnated)).mp. [mp=title, subject heading word, abstract, instrumentation]	119
56	exp Catheter Care, Urinary/	179
57	exp Urinary Bladder Irrigation/ or exp catheter irrigation, urinary/	26
58	exp Staff Development/	11367
59	exp Quality Improvement/	11174
60	28 or 29 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 45 or 46 or 47 or 48 or 49 or 50 or 51 or 52 or 53 or 54 or 55 or 56 or 57 or 58 or 59	239992
PHASE 4: COMBINING THE PHASES		
61	10 and 27 **(Phase 1 AND Phase 2)**	828
62	10 and 60 **(Phase 1 AND Phase 3)**	956
63	61 or 62 **(Phase 1 AND Phase 2) OR (Phase 1 AND Phase 3)**	1328
PHASE 5: FILTERING FOR PUBLICATION TYPES		
64	(abstract or accreditation or anecdote or audiovisual or bibliography or biography or book or book chapter or cartoon or classification term or "code of ethics" or commentary or computer program or consumer patient teaching materials or diagnostic images or directories or editorial or equations & formulas or exam questions or forms or games or glossary or historical material or interview or journal description or legal cases or listservs or obituary or pamphlet or pamphlet chapter or pictorial or poetry or proceedings or questions & answers or research term definition or response or software or "tables or charts" or tracings or website).pt.	510619
65	63 not 64	867
PHASE 6: LIMITING TO ENGLISH LANGUAGE		
66	limit 65 to english	839

COCHRANE

#	Search History	Results
#1	MeSH descriptor Urinary Catheterization explode all trees	431
#2	MeSH descriptor Urinary Tract Infections explode all trees	1776
#3	#1 AND #2	219
Search results contained 4 Cochrane Reviews, 5 other reviews, 185 clinical trials, 3 Technology Assessments and 22 economic evaluations		

APPENDIX 2: EVIDENCE AND GRADE TABLES

Question 1: Who should receive urinary catheterization?

A. Is urinary catheterization necessary?

TABLE 1: IS URINARY CATHETERIZATION NECESSARY FOR:

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
1. Operative Catheterization							
Phipps, 2006 [1]	Systematic review	1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults	Randomized and quasi-randomized trials	39 RCTs	*Note: All results are RR(95% CI) unless otherwise noted* *1. Using a urinary catheter vs. not using a urinary catheter* **Retention of urine** (1 study) – 0.12(0.03-0.47) **UTI** (4 studies) – 1.35(0.75-2.45) **Recatheterization** (3 studies) – 0.32(0.14-0.70) **Post-op urethral stricture** (1 study) – 1.14(0.90-1.44) **Post-op hematuria** (1 study) – 0.73(0.40-1.33) *2. Urethral catheterization vs. suprapubic catheterization* **UTI:** Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. **Recatheterization** (2 studies) – 3.66(1.41-9.49) **Post-op hematuria** (1 study) – 5.00(0.21-116.31) **Length of hospital stay in days** (1 study) [WMD(95% CI)] – 1.10(0.30-1.90) **Catheter lockage or bypassing** [OR(95% CI)] (2 studies) – 0.20(0.02-1.72)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						3. One type of catheter vs. another type of catheter **UTI:** Urethral foley catheter with extra drainage hole vs. unmodified foley catheter(1 study) – 0.40(0.15-1.04) **Positive urine culture:** Silver coated bardex catheters vs. latex catheters(1 study) – 0.53(0.20-1.45) *4. One type of catheter management vs. another* **Retention of urine:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.99(0.06-15.54) **Dysuria:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.99(0.06-15.54) **UTI:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.61(0.33-1.14) Cefotaxime 1 hr prior to catheter removal vs. none (1 study) – 0.08(0.00-1.30) Neomycin/Sulfamethiozole vs. placebo (1 study) – 0.18(0.06-0.55) **Positive urine culture:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 1.06(0.70-1.51) **Recatheterization -** Neomycin/Sulfamethiozole vs. placebo (1 study) – 0.50(0.24-1.04) *5. Larger diameter catheter vs. Smaller diameter catheter* No trials found *6. Bladder irrigation* No trials found	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						7. Shorter duration vs. longer duration catheter **Retention of urine:** 1 day vs. 3 days(1 study) – 0.80(0.38-1.69) 1-2 days vs. until urine clear(1 study) – 1.02(0.07-15.87) 1 day vs. 2 days (1 study) – 4.64(0.23-94.28) 3 days vs. 28 days (1 study) – 3.00(0.13-69.52) **Post-op urethral stricture:** <1 week vs. 2 weeks (2 studies) – 1.23(0.82-1.84) 3 days vs. 28 days (1 study) – 1.00(0.73-1.36) **UTI:** Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were not significant **Recatheterization:** 1 day vs. 2 days (1 study) – 1.03(0.23-4.71) 1 day vs. 3 days (2 studies) – 1.04(0.36-3.01) 1 day vs. 5 days (1 study) – 4.55(1.68-12.37) 4-6 days vs. 14 days (1 study) – 1.86(0.14-25.38) 1-2 days vs. until urine clear(2 studies) – 0.72(0.24-2.20) **Post-op hematuria:** 1-2 days vs. until urine clear(1 study) – 2.04(0.19-21.81) 1 day vs. 2 days (2 studies) – 1.16(0.34-3.90) **Urinary leakage or incontinence:** 1-2 days vs. until urine clear(2 studies) – 0.43(0.07-2.88) *8. Clamp and release vs. free catheter drainage:* **UTI** (1 study) – 4.00(1.55-10.29) **Delay in return to normal bladder function** (1 study) - 2.50(1.16-5.39)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						9. Catheter removal at one time of day vs. another time of day **UTI:** 0000 hrs vs. 0600 hrs (1 study) – 1.31(0.65-2.66) **Recatheterization:** 0000 hrs vs. 0600 hrs (4 studies) – 0.61(0.34-1.12) 6-7 am vs. 10-11 pm (1 study) – 1.36(0.32-5.77) **Time to first void in hours**[WMD(95% CI)]: 0000 hrs vs. 0600 hrs (1 study) – 0.60(-0.96 to 2.16) **Volume of first void in ml** [WMD(95% CI)]: 0000 hrs vs. 0600 hrs (1 study) – 53.00(4.27-101.73) *10. Trial of void protocol vs. none* No trials found *11. Prefilling bladder prior to catheter removal vs. removal without prefilling* **Recatheterization** [OR(95% CI)] (1 study) – 4.52(0.79-25.97) **Discharge on day of catheter removal** (1 study) – 1.36(0.47-3.91)	
Tang, 2005 [2]	RCT	1,2,3,4,5,6,7,8	To compare the outcomes of patients undergoing routine urethral catheterization and non-catheterization before gynecological laparoscopy with respect to bladder injury, postoperative urinary symptoms and UTI	Women undergoing elective or emergency laparoscopy.	279	**Bacteriuria:** Catheterization vs. no catheterization – 13/131 vs. 5/131; P=0.09 **Symptomatic UTI:** Catheterization vs. no catheterization – 5/131 vs. 3/131; statistical differences were not reported **Bladder injury:** There were no events in either group **Recatheterization:** Catheterization vs. no catheterization – 3/131 vs. 4/131; P=1.00 Catheterization was significantly associated with operative time > 90 min	F/U 1 week post-op UTI defined as bacterial count > 10^5 cfu/ml in the urine culture on a mid-stream urine sample. Recatheterization - postoperatively, if the patient failed to pass urine after 6h, the bladder would be catheterized. 80% power at an alpha of 0.05 to show a significant reduction in UTI in the non-catheterized patients from 12.5% to 2.5%.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						(P<0.01)	
Iorio, 2000 [3]	RCT	1	To compare preoperative insertion of an indwelling catheter for 24 hours with postoperative insertion of a catheter on an as needed basis only if symptoms of urinary retention developed.	Patients undergoing unilateral total knee arthroplasty	652	**Unspecified UTI:** Short-term indwelling catheter vs. catheter inserted as needed – 5/306 vs. 6/346; P>0.05 **Length of hospital stay (days):** Short-term indwelling catheter vs. catheter inserted as needed – 4.56 vs. 4.29; P>0.05 **Hospital costs:** Short-term indwelling catheter vs. catheter inserted as needed – $9071 vs. $8581; P<0.01	F/U unclear UTI not defined Power not reported
Liu, 1999 [4]	RCT	1,7,8	To evaluate the necessity of urethral catheterization. Patients were randomized to either receive or not receive preoperative urinary bladder catheterization. For those patients randomized to receive a catheter (Foley), the catheter was inserted after induction of anesthesia and removed at the termination of the surgery.	Patients undergoing elective laparoscopic cholecystectomy	261	**Unspecified UTI:** Catheter vs. no catheter – 3/127 vs. 0/134; no significant differences **Urinary retention:** Catheter vs. no catheter – 1/127 vs. 1/134; no significant differences **Postoperative bleeding:** Catheter vs. no catheter – 1/127 vs. 2/134; statistical differences were not reported **Wound infection:** Catheter vs. no catheter – 3/127 vs. 1/134; statistical differences were not reported **Visceral injury:** Catheter vs. no catheter – 0/127 vs. 0/134; statistical differences were not reported **Retained common bile duct stones:** Catheter vs. no catheter – 0/127 vs. 2/134; statistical differences were not reported **Cystic duct stump leak:** Catheter vs. no catheter – 0/127 vs. 1/134; statistical differences were not reported	F/U 1 week post-op UTI not defined Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Normelli, 1993 [5]	RCT	1	To study the effect of the use of an intaoperative indwelling urethral catheter when compared with no intraoperative catheter. All patients were if necessary intermittently catheterized in the postoperative period.	Patients admitted for spinal surgery	32	**Bacteriuria:** Catheter vs. no catheter – 7/16 vs. 2/16; P≥0.05 **Largest urine volume at one catheterization (mean in ml):** Catheter vs. no catheter – 528 vs. 713; P≥0.05 **Days until voiding (mean):** 3.1 vs. 3.1; statistical differences were not reported **Recatheterization:** 14/16 vs. 14/16; statistical differences were not reported	F/U one week postoperatively Positive culture was defined as ≥ 10^5 cfu/ml. Not known how sample was obtained. The outcome of recatheterization denotes postoperative intermittent catheterization Power not reported
Carpiniello, 1988 [6]	RCT	1	To evaluate the effect of early bladder decompression either perioperatively or after joint replacement (via straight catheterization in the recovery room) on the incidence of urinary tract infections and subsequent catheterizations. Patients were randomized into 3 groups – straight catheterization performed in the recovery room (SC); Foley catheter inserted immediately preoperatively and removed 24 hours postoperatively (FC); no catheterization performed in the recovery room (NC)	Elderly female patients undergoing total joint replacement.	77	**Bacteriuria:** SC vs. NC – 5/31 vs. 2/23 FC vs. NC – 1/23 vs. 2/23 **Recatheterization** SC vs. NC – 20/31 vs. 13/23 FC vs. NC – 1/23 vs. 13/23 There were no events of deep sepsis in any of the three groups. [No significant differences between SC and NC groups. No statistical comparisons were made between SC and FC groups)	F/U for duration of postoperative period – specifics unclear. Positive culture was defined as ≥ 10^5 cfu/ml on a mid-stream urine sample The outcome of recatheterization for the SC and NC groups denotes the number of patients catheterized after recovery room. For the FC group, it is no. of people recatheterized after Foley removal Power not reported
Akhtar, 1985 [7]	RCT	1,6,7,8,9	To determine if bladder catheterization was necessary in patients undergoing laparoscopy. No further details on catheterization were provided.	Patients undergoing laparoscopy	83	**Bacteriuria:** *Intention to treat* - Catheterization vs. no catheterization – 9/42 vs. 5/41; P=0.03 *Per protocol* - Catheterization vs. no catheterization – 9/42 vs. 4/34; P=0.049 **Symptomatic UTI:** *Intention to treat* - Catheterization vs. no catheterization – 5/42 vs. 1/41 *Per protocol* - Catheterization vs. no catheterization – 5/42 vs. 1/34; [Statistical differences were not reported for this outcome]	F/U 6 days after laparoscopy Infection was considered present if there were > 10^5 organisms/ml on a midstream urine specimen. The composite outcome of symptoms and infection was also measured. Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Chaudhuri, 1983 [8]	RCT	1	To compare short term indwelling catheterization (inserted immediately prior to operation and removed after a mean period of 22 hours) with no catheterization	Women undergoing cesarean section	173	**Bacteriuria:** Catheter vs. no catheter – 30/141 vs. 3/32; a chi-squared statistic of 2.39 was reported, no significant differences	F/U post-operatively UTI (significant bacteriuria) was deemed to have been present when the viable count was > 10^5 organisms/ml of a clean catch urine specimen Power not reported
Kumar, 2006 [9]	Retrospective controlled study	1,3	To investigate the rate of urinary retention after knee arthroplasty and identifying risk factors for urinary retention	Patients undergoing total knee arthroplasty	142	**Unspecified UTI:** No postoperative UTI occurred in any patient. **Postoperative urinary retention:** Preoperative catheterization vs. no catheterization – 2/19 vs. 28/123; statistical differences were not reported for this outcome **Deep joint sepsis:** Preoperative catheterization vs. no catheterization – 1/19 vs. 2/123; statistical differences were not reported for this outcome Factors predicting those at significant risk of retention following knee arthroplasty - a past medical history of urinary retention (P=0.05) and postoperative morphine requirement (P=0.04)	Mean F/U ~2 years UTI not defined Power not reported
Miskry, 2001 [10]	Prospective study with historical controls	1,3	To examine the feasibility of non-catheterization in patients undergoing laparoscopy. Patients in the intervention group were catheterized if bladder filling interfered with surgery, or postoperatively if they failed to pass urine with 6 h. All historical controls were routinely catheterized	Patients scheduled to undergo gynecological operative laparoscopy	80	**Bacteriuria:** No catheterization vs. catheterization – 1/40 vs. 5/40; P=0.20 **Recatheterization:** 5 patients (12.5%) in the no catheterization group had to be catheterized intra and post-operatively (data only for test group) **Bladder injury:** There were no cases of intra-operative bladder trauma in either of the groups Catheterization was significantly associated with operative time > 100	F/U unclear Infection was considered to be present if there were ≥ 10^5 micro-organisms/ml of urine on mid-stream or catheter specimen of urine Power was not reported, but it was suggested that the study was not powered to detect differences in infection.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						min (P<0.01)	
Barnes, 1998 [11]	Retrospective Controlled Study	1,3, 4,	To evaluate the utility of urethral catheterization in patients undergoing hysterectomy and cesarean section	Patients undergoing hysterectomy or cesarean section	329	**Bacteriuria:** Catheter pre or postoperatively vs. never catheterized– 21/251 vs. 0/70; P<0.05	F/U perioperatively A colony count > 10^6 per ml and pyuria were the criteria to diagnose an infection in patients with urinary symptoms or unexplained fever. Power not reported
2. Urinary retention							
No studies were identified							
3. Urinary incontinence							
McMurdo, 1992 [12]	RCT (also included data on non-randomized patients)	1,2,7	To compare the costs and effects of management of intractable urinary incontinence by urinary catheterization or incontinence pads	Elderly female patients with intractable urinary incontinence	78 randomized and 27 non-randomized patients	**Urine infection:** The median of the proportion of urine cultures positive – 0.7 vs. 1.0 **Equipment costs:** Catheter vs. pads - £19.20-24.65 vs. £8.79-11.35 per patient per week. (The difference was mainly because of the cost of catheter care) **Nursing time:** Catheter vs. pads - 15.4 vs. 29 h per patient per week **Antibacterial treatment:** Catheter vs. pads – 73% vs. 40% [Statistical differences were not reported]	F/U 26 weeks UTI not clearly defined Power not reported
Ouslander, 1987 [13]	Prospective controlled study	1,3,4,6	To examine the frequency of UTI and bacteriuria among patients managed with and without external catheters (EC)	Male nursing home patients with incontinence due to various neurological disorders (Note: Data on 30 continent patients	62	**Symptomatic UTI:** EC continuously vs. No catheter - 12/30 vs. 1/13; P<0.05 EC at night only vs. no catheter – 3/19 vs. 1/13; statistical differences not clearly reported EC continuously vs. EC at night only	Mean F/U 5.4 months Significant bacteriuria defined as a growth of > 10^5 colonies on clean catch urine specimens.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
				were not included)		– 12/30 vs. 3/19; P>0.05 **Bacteriuria:** EC continuously vs. No catheter - 26/30 vs. 6/13; P<0.05 EC at night only vs. no catheter – 10/19 vs. 6/13; P>0.05 EC continuously vs. EC at night only – 26/30 vs.10/19; P<0.05 **Bacteriuria and pyuria:** EC continuously vs. No catheter - 12/30 vs. 3/13; P>0.05 EC at night only vs. no catheter – 7/19 vs. 3/13; P>0.05 EC continuously vs. EC at night only – 12/30 vs. 7/19; P>0.05 **Risk factors for symptomatic UTI:** *Univariate Analysis:* All results P values. Age – NS Length of time in the facility – NS Diabetic – NS Katz ADL score – NS Mental status score – NS % Ideal body weight – NS Skinfold thickness – NS Serum creatinine (mg/dl) – NS Albumin - <0.01 Hb (g/dl) – NS Stool incontinence – NS Past genitourinary diagnoses – NS Catheter manipulation – NS Suppressive antibiotic therapy – NS Urinary acidifier - NS	Symptomatic UTI was defined as an episode in which: 1) the patient had one or more symptoms or signs of a UTI 2) other sources of fever had been excluded 3) the patient was treated with an antimicrobial for a urinary source of infection and 4) a urine culture grew 10^5 cfu of at least one pathogen. With 30 patients in each group, the power to detect differences of 30% in the proportion of patients developing infections was 75%
Rannikko, 1986 [14]	Prospective controlled study	1,3	To compare bed-pads and long-term indwelling catheters in the treatment of urinary incontinence	Elderly women with incontinence and dementia	22	**Bacteriuria:** At the end of 6 months, all the patients in both groups had significant bacteriuria, Proteus species being the most common pathogen. Development of multiple resistance observed in both groups. **Cost:** Indwelling catheter significantly more economical (P<0.01)	F/U 6 months Significant bacteriuria was defined as ≥ 10^5 cfu/ml. Not known how sample was obtained. Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Nordqvist, 1984 [15]	Prospective controlled study	1,3	To study the clinical and economic consequences of catheter-free geriatric care. Patients in the test group, i.e. catheter-free group underwent a continence training program in the 6 months preceding the study. Patients in the control group had indwelling catheters.	Patients in a geriatric hospital.	Not specified.	**Antibiotic prescription:** Test 90% less than in control wards. **Cost:** Cost of laundry, hygiene and storage articles in test 46% of that in the control wards. **Mortality:** Test vs. Control - 65% vs. 72% No statistical differences were reported.	F/U 4 years UTI not measured Power not reported
4. Bladder Outlet Obstruction							
Egilmez, 2006 [16]	Prospective controlled study	1,3,4,6,7	To compare intraurethral metal stent with indwelling urinary catheter on the incidence of CA-UTI	Patients with bladder outlet obstruction	110	**Bacteriuria:** Indwelling catheter vs. intraurethral stent – 27/34 vs. 42/76; RR(95% CI) = 1.4(1.2-2.0) RR (95% CI) after adjustment for infected urine at the time of insertion – 1.5(1.2-2.1) RR (95% CI) after adjustment for clean urine at the time of insertion – 2.5(1.4-3.8) RR (95% CI) after adjustment for prior UTI – 1.8(1.0-3.0) RR (95% CI) estimates after adjustment for either diabetes or age were the same - 1.4(0.8-2.2). **Symptomatic UTI:** Indwelling catheter vs. intraurethral stent –13/34 vs. 4/76; statistical differences were not reported	F/U 1 month UTI was defined as ≥ 10^5 cfu/ml on a mid-stream urine sample. Symptomatic UTI was measured but not defined. Power not reported
5. Immobility							
No studies were identified							
6. Spinal Cord Injury/Neurogenic Bladder							
Adults							

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
De Ruz, 2000 [17]	Prospective controlled study	1,3,4,6,7	To identify risk factors for UTI	Adult spinal cord injury patients with injury ≤ 60 days before enrolment, neurogenic bladder dysfunction and injury below C4	128	**Symptomatic UTI:** All results OR(95% CI) *1. Univariate analysis* Age older than 40 yrs – 1.38(1.01-1.88) Hyperreflexic bladder – 1.38(1.03-1.86) Cervical injury – 1.39(1.04-1.85) Functional independence measure score < 74 – 1.49(1.08-2.06) Indwelling catheterization greater than 30 days – 1.53(1.12-2.10) Vesicoureteral reflux – 1.77(1.12-2.81) Invasive procedure – 4.26(3.15-5.76) Indwelling catheter – 7.77(5.80-10.40) Clean intermittent catheterization – 0.42(0.31-0.58) Condom catheter – 0.24(0.15-0.40) Suprapubic catheterization – 0.04(0.04-0.19) Normal voiding – 0.04(0.01-0.17) Patient sex, time of evolution, type of injury, co-morbidity, etiology, lithiasis, surgery, previous antimicrobial treatment and immunosuppression were not associated. *2. Multivariate analysis - Model 1 (Defined all risk factors in patients who presented with at least UTI episode during hospitalization)* Cervical injury – 2.99(1.12-7.97) Invasive procedure – 2.62(1.02-6.69) Indwelling catheterization greater than 30 days – 4.04(1.24-13.06) *3. Multivariate analysis - Model 2 (Defined risk factors in patients who presented with repeat UTIs during*	F/U 38 months UTI was defined as a colony count of ≥ 10^5 cfu/ml without a fever of 38 C and two symptoms, including bladder overdistension, lower abdominal pain, increased urinary incontinence, increased spasticity, autonomic hyperreflexia, and/or increased sweating and malaise Bacteriuria was defined as a colony count of ≥ 10^5 cfu/ml and no fever or other symptoms Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						hospitalization) Functional independence measure score < 74 – 9.96(2.33-42.11) Vesicoureteral reflux – 22.86(2.31-225.87) **Bacteriuria:** All results OR(95% CI) Indwelling catheter – 2.70(2.32-3.20) Clean intermittent catheterization – 1.16(1.01-1.35) Condom catheter – 0.46(0.38-0.56) Suprapubic catheterization – 0.06(0.04-0.10) Normal voiding – 0.05(0.03-0.10)	
Larsen, 1997 [18]	Retrospective controlled study	1,3	To compare the long term urologic complications in male patients with spinal cord injury managed with and without indwelling urinary catheters	Spinal cord injured patients who received continuous long term medical care	204	**Patients with ≥ 1 Symptomatic UTI:** Indwelling catheter vs. no indwelling catheter – 48/56 vs. 46/86; P<0.01 **Urosepsis:** Indwelling catheter vs. no indwelling catheter – 12/56 vs. 7/86; P=0.02 **Recurrent pyelonephritis:** Indwelling catheter vs. no indwelling catheter – 7/56 vs. 2/86; P=0.02 **Epididymitis:** Indwelling catheter vs. no indwelling catheter – 12/56 vs. 8/86; P=0.04 **Deaths:** Indwelling catheter vs. no indwelling catheter – 5/56 vs. 3/86; statistical differences were not reported **Gross hematuria:** Indwelling catheter vs. no indwelling catheter – 23/56 vs. 6/86; P<0.01 **Bladder stones:** Indwelling catheter vs. no indwelling catheter – 34/56 vs. 10/86; P<0.01	F/U 7 years UTI not defined, but labeled as symptomatic UTI Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Renal stones: Indwelling catheter vs. no indwelling catheter – 18/56 vs. 6/86; P<0.01 **Urethral fistula:** Indwelling catheter vs. no indwelling catheter – 5/56 vs. 10/86; P=0.01 **Urethral erosion:** Indwelling catheter vs. no indwelling catheter – 12/56 vs. 6/86; P<0.01 **Urethral stricture:** Indwelling catheter vs. no indwelling catheter – 13/56 vs. 4/86; P<0.01 **Urethral abscess:** Indwelling catheter vs. no indwelling catheter – 5/56 vs. 0/86; P=0.01	
Children							
Geraniotis, 1988 [19]	RCT	1	To examine the hypothesis that the prophylactic use of clean intermittent catheterization in infants and children with meningomyelocele would prevent urinary tract deterioration.	Infants and children with meningomyelocele and bladder sphincter incoordination	21	**Urinary tract deterioration:** Clean intermittent catheterization vs. self-voiding – 1/10 vs. 6/11; P=0.045	F/U 6-36 months UTI not defined and not reported clearly in the self-voiding group Power not reported
Kochakarn, 2004 [20]	Retrospective controlled study	1,3	To compare the results of long term clean intermittent catheterization treatment for neurogenic bladder in children when it was performed early (< 1 year of age) and late (> 3 years of age)	Children with meningomyelocele	67	**Unspecified UTI (recurrent upper UTI):** Early treatment vs. late treatment – 9/36 vs. 14/31; P=0.08 **Hydronephrosis:** Early treatment vs. late treatment – 10/36 vs. 18/31; P=0.01 **Augmentation cytoplasty:** Early treatment vs. late treatment – 5/36 vs. 10/31; P=0.07 **Increased BUN or serum creatinine:** Early treatment vs. late	F/U 11 years UTI not defined Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						treatment – 12/36 vs. 19/31; P=0.02	
Ehrlich, 1982 [21]	Prospective controlled study	1,3,4	To compare clean intermittent catheterization with urinary diversion for patients with neurogenic bladder	Children with meningomyelocele	33	**Symptomatic UTI:** Clean intermittent catheterization vs. ileal loop diversion - 5/24 vs. 1/9; not significant **Bacteriuria:** Clean intermittent catheterization vs. ileal loop diversion – 85/231 vs. 34/55; P<0.01 (Ns are no. of cultures)	F/U 1 year A positive urine culture was defined as ≥ 10^4 colonies/ml. A symptomatic UTI was defined as the onset of pyuria in association with one or more of: fever, malaise, abdominal pain, and/or a transient change in serum creatinine level or creatinine clearance Power not reported

GRADE Table

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Catheter vs. no catheter for operative patients	Symptomatic UTI*	2 RCT [2, 7]	2 RCTs did not report statistical differences [2, 7]	High	0	0	-1	-1	0	0	0	0	Low	Low
	Bacteriuria/ Unspecified UTI*	1 SR [1] 7 RCT [2-8] 3 OBS [9-11]	1 SR showed no significant differences [1] . 1 RCT [7] and 1 OBS [11] showed a significantly decreased risk with no catheterization. The other RCTs [2-6, 8] and the 2 OBS [9, 10] showed no significant differences, although there was some suggestion of increased risk with catheterization in higher quality studies	High	-1	0	0	0	0	0	0	0	Moderate	
	Urinary Retention*	1 SR [1]	The SR showed a significantly decreased risk of urinary retention	High	-1	-1	0	0	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
		1 RCT [4] 1 OBS [9]	with catheterization [1] . In the RCT, no significant differences were found [4] and in the OBS [9] , statistical differences were not reported.											
	Recatheterization*	1 SR [1] 3 RCT [2, 5, 6] 1 OBS [10]	The SR showed a significantly decreased risk of recatheterization with the use of a urinary catheter [1] . 3 RCTs showed no significant differences [2, 5, 6] . In the OBS, comparative data were not provided.	High	0	-1	0	-1	0	0	0	0	Low	
	Length of Stay/Hospitalization	1 RCT [3]	No significant differences were found	High	-1	0	0	-1	0	0	0	0	Low	
	Bladder injury*	1 RCT [2] 1 OBS [10]	There were no events in either group in both studies	High	0	0	0	-1	-1	0	0	0	Low	
Catheter vs. no catheter for incontinent patients	Symptomatic UTI*	1 OBS [13]	Having no catheter had a significantly reduced risk compared with wearing the catheter continuously.	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/Unspecified UTI*	1 RCT [12] 2 OBS [13, 14]	In 1 OBS, having no catheter had a significantly reduced risk compared with wearing the catheter continuously. No significant differences were found between having a catheter at night only and having no catheter [13] . In the other OBS, all patients in both groups had bacteriuria [14] . Statistical differences were not reported in the RCT [12] .	High	-1	-1	0	0	0	0	0	0	Low	
	Mortality	1 OBS [15]	Statistical differences were not reported	Low	0	0	0	-1	0	0	0	0	Very Low	
	Nursing time	1 RCT [12]	Statistical differences were not reported	High	-1	0	0	-1	0	0	0	0	Low	
Catheter vs. stent for bladder outlet	Symptomatic UTI*	1 OBS [16]	Statistical differences were not reported; although there was a suggestion that stent was better than catheter	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
obstruction	Bacteriuria*	1 OBS [16]	There was an increased risk of bacteriuria with the use of indwelling catheter	Low	0	0	0	0	0	0	0	0	Low	
Catheter vs. no catheter for spinal cord injury patients	Symptomatic UTI*	2 OBS [17, 18]	Significantly reduced with no catheterization in both studies	Low	0	0	0	0	0	0	0	0	Low	Very Low
	Bacteriuria*	1 OBS [17]	Significantly reduced with no catheterization	Low	0	0	0	-1	0	0	0	0	Very Low	
	Urinary complications*	1 OBS [18]	Significantly reduced with no catheterization	Low	0	0	0	-1	0	0	0	0	Very Low	
	Mortality	1 OBS [18]	Statistical differences were not reported	Low	0	0	0	-1	0	0	0	0	Very Low	
Catheter vs. no catheter for children with neurogenic bladder	Symptomatic UTI*	1 OBS [21]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria/ Unspecified UTI*	2 OBS [20, 21]	Ileal loop diversion had a significantly greater risk when compared with clean intermittent catheterization in 1 OBS [21] . There were no significant differences in early vs. late clean intermittent catheterization in the other OBS [20] .	Low	0	0	-1	0	0	0	0	0	Very Low	
	Urinary tract deterioration/Hydronephrosis*	1 RCT [19] 1 OBS [20]	Clean intermittent catheterization significantly reduced urinary tract deterioration in the RCT [19] and when used early as in the OBS [20]	High	-1	0	-1	0	0	0	0	0	Low	

* These modifiers can impact the GRADE by 1 or 2 points

B. What are the risk factors for CA-UTI?

TABLE 2: RISK FACTORS FOR CA-UTI

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
1. Spinal cord injury/Neurogenic Bladder							
Seki, 2004 [22]	Retrospective controlled study	1,3,4,6,7	To identify the factors for febrile UTI	Children with myelodysplasia who were treated by clean intermittent catheterization	76	**Febrile UTI:** *Univariate Analysis:* All results P value Age – 0.03 Sex – 0.29 Hydronephrosis – 0.50 Vesicoureteral reflux – 0.03 Bladder trabeculation – 0.03 Maximum urethral closing pressure – 1.00 Bladder compliance <10 - <0.01 Detrusor overactivity - <0.01 Detrusor sphincter dyssynergia – 0.14 *Multivariate Analysis:* All results OR(95% CI) or P values Age – 1.02 (1.00 – 1.03); P=0.01 Sex – 0.84 Hydronephrosis – 1.00 Vesicoureteral reflux – 4.50(1.04-19.40) Bladder trabeculation – 0.89 Maximum urethral closing pressure – 0.07 Bladder compliance <10 – 10.80(2.17-54.00) Detrusor overactivity – 6.31(1.14-34.90) Detrusor sphincter dyssynergia – 0.86	F/U 3 years Febrile UTI consisted of a positive urine culture associated with pyuria in a patient with a temperature of ≥ 38.5 C, symptoms or signs of UTI and no other apparent infection. A urine culture was considered to be positive when ≥ 10^4 organisms of a single or predominant species of urine were found in urine culture specimens. Power not reported
De Ruz, 2000 [17]	Prospective cohort study	1,3,4,6,7	To identify risk factors for UTI	Adult spinal cord injury patients with injury ≤ 60 days before enrolment, neurogenic bladder dysfunction and injury below C4	128	**Symptomatic UTI:** All results OR(95% CI) *1. Univariate analysis* Age older than 40 yrs – 1.38(1.01-1.88) Hyperreflexic bladder – 1.38(1.03-1.86) Cervical injury – 1.39(1.04-1.85) Functional independence measure score < 74 – 1.49(1.08-2.06) Indwelling catheterization greater than 30 days – 1.53(1.12-2.10) Vesicoureteral reflux – 1.77(1.12-2.81) Invasive procedure – 4.26(3.15-5.76) Indwelling catheter – 7.77(5.80-10.40) Clean intermittent catheterization – 0.42(0.31-0.58) Condom catheter – 0.24(0.15-0.40) Suprapubic catheterization – 0.04(0.04-0.19) Normal voiding – 0.04(0.01-0.17)	F/U 38 months UTI was defined as a colony count of ≥ 10^5 cfu/ml without a fever of 38 C and two symptoms, including bladder overdistension, lower abdominal pain, increased urinary incontinence, increased spasticity, autonomic hyperreflexia, and/or increased sweating and malaise Bacteriuria was defined as a colony count of ≥ 10^5 cfu/ml and no fever or other symptoms Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Patient sex, time of evolution, type of injury, co-morbidity, etiology, lithiasis, surgery, previous antimicrobial treatment and immunosuppression were not associated. *2. Multivariate analysis - Model 1 (Defined all risk factors in patients who presented with at least UTI episode during hospitalization)* Cervical injury – 2.99(1.12-7.97) Invasive procedure – 2.62(1.02-6.69) Indwelling catheterization greater than 30 days – 4.04(1.24-13.06) *3. Multivariate analysis - Model 2 (Defined risk factors in patients who presented with repeat UTIs during hospitalization)* Functional independence measure score < 74 – 9.96(2.33-42.11) Vesicoureteral reflux – 22.86(2.31-225.87) **Bacteriuria:** All results OR(95% CI) Indwelling catheter – 2.70(2.32-3.20) Clean intermittent catheterization – 1.16(1.01-1.35) Condom catheter – 0.46(0.38-0.56) Suprapubic catheterization – 0.06(0.04-0.10) Normal voiding – 0.05(0.03-0.10)	
Keheller, 1996 [23]	Retrospective controlled study	1,3,4,6	To identify risk factors for the development of symptomatic bacteriuria	Children undergoing clean intermittent catheterization	159	**Symptomatic bacteriuria:** *Univariate Analysis:* All results P value Frequency of catheterization **–** 0.28 Reuse of the catheter – 0.12 Cleansing and storage of the catheter – 0.72 Cleansing of the urethral meatus – 0.07 Bowel management – 0.06 Prophylactic antibiotics – 0.96 (Only univariate analysis was reported)	F/U 1 year Symptomatic bacteriuria was defined as a colony count of > 10^5 colonies/ml of one organism and the presence of one or more of the following symptoms: increased urinary incontinence between catheterizations, abdominal or flank pain, temperature elevation of at least 99 F, chills or malaise Power not reported
Waites, 1993 [24]	Prospective cohort study	1,2,3,6	To estimate frequency and evaluate risk factors for UTI	Spinal cord injury patients (received condom or intermittent	71	**Bacteriuria:** *Univariate Analysis:* All results are incidence rate ratio – IRR(95% CI) Female vs. male – 1.2(0.9-1.6)	F/U 1 year UTI was defined as a culture or dip

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
				catheterization)		Black vs. white – 1.6(1.3-1.9) Quadriplegic vs. paraplegic – 1.1(0.9-1.3) Frankel grade (a) Sensory preserved vs. motor non-functional – 1.5(1.0-2.3) (b) Complete vs. motor non-functional – 1.3(1.0-1.7) Satisfactory vs. excellent hygiene – 1.6(1.3-2.0) Condom vs. intermittent catheter – 1.1(0.9-1.4) Condom change frequency less than daily vs. daily – 2.2(1.6-3.1) Age > 50 vs. ≤ 50 – 1.1(0.7-1.6) Years since injury ≤5 vs. > 5 – 1.2(0.9-1.5) Annual income < $10,000 vs. ≥ $10,000 – 1.1(0.8-1.5) Education 0-11 years vs. 12+ - 1.1(0.9-1.4) Antimicrobial prophylaxis was stated to be NS (Only univariate analysis was reported)	slide containing ≥ 10^5 cfu/ml on clean-catch or catheterized specimen. Power not reported
2. Intensive Care Unit							
van der Kooi, 2007 [25]	Prospective controlled study	1,3,4,6,7	To examine the incidence of and risk factors for device-associated infections and mortality	Patients without an initial infection staying in the ICU for at least 48 hours	2644	**Symptomatic UTI:** *Univariate Analysis:* All results OR(95% CI) Duration of catheterization 5-9 days vs. 1-4 days – 1.6(1.0-2.4); P<0.05 Duration of catheterization ≥ 10 days vs. 1-4 days – 3.3(2.2-4.9) Duration was not included in the multivariate model *Multivariate Analysis:* All results RR(95% CI) Female sex– 1.4(1.0-1.8) P>0.05 Impaired immunity – 2.5(1.5-4.0) Acute admission vs. planned admission – 1.8(1.0-3.3); P>0.05 Systemic antibiotics at admission – 0.5(0.3-1.0); P<0.05 **Mortality:** *Univariate Analysis:* CA-UTI vs. not – 30.9% vs. 20.2%; P=0.06. It was not significantly associated with mortality in a multivariate model, though estimates were not provided.	F/U until discharge, death or day of withholding treatment CA-UTI according to CDC definition Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Multivariate Analysis: All results OR(95% CI) for mortality associated with having a urinary catheter Age 40-70 years vs. ≤ 39 years – 1.6(1.0-2.5); P<0.05 Age ≥ 70 years vs. ≤ 39 years – 2.8(1.8-4.4) APACHE II ≥ 20 vs. 0-19 – 1.9(1.5-2.4) Internal medicine vs. Surgery/Traumatology – 1.9(1.4-2.7) Cardiology/Cardiosurgery vs. Surgery/Traumatology – 2.6(1.8-3.8) Neurology/Neurosurgery vs. Surgery/Traumatology – 1.8(1.2-2.7) Acute admission vs. planned admission – 1.4(1.0-1.8); P<0.05 Systemic antibiotics at admission– 1.5(1.1-2.3) Ventilation– 4.8(3.3-7.0) Central venous catheter – 1.8(1.3-2.5)	
Bochicchio, 2003 [26]	Prospective controlled study	1,3,4,6,7	To identify risk factors for UTI	Critically ill trauma patients admitted to the ICU. Presence of catheter not stated as an explicit inclusion criterion.	1172	**Symptomatic UTI:** *Multivariate Analysis:* All results P values Old age – P<0.01 (specifics not provided) Female sex - P<0.01 **Mortality:** Unclear if analysis was multivariate CA-UTI vs. not – 39% vs. 15%; P<0.01 **Increased catheter days:** *Univariate Analysis:* All results P value Obesity - <0.01 COPD – 0.02 Alcohol abuse, coronary disease, smoking, hypertension, diabetes, stroke and drug abuse were NS	Study duration 2 years CA-UTI according to CDC definition Power not reported
Leone, 2003 [27]	Prospective controlled study	1,3,6,7	To determine the risk factors for CA-UTI	ICU patients requiring bladder drainage for longer than 48 hours	1987	**Bacteriuria:** *Univariate Analysis:* All results P value Female sex – <0.01 Age – 0.94 Admission diagnosis – 0.65 Antibiotics – 0.46 SAPS II Score – 0.05 Drainage System (simple vs. complex) – 0.19 Duration of catheterization in days - <0.01 Length of ICU stay in days - <0.01	F/U until 24 hrs after catheter removal Bacteriuria was defined according to CDC definition of asymptomatic bacteriuria Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Multivariate Analysis: All results OR(95% CI) Female sex –3.48(1.72-7.06) Length of ICU stay in days - 1.09(1.04-1.15) Duration of catheterization in days - 1.07(1.01-1.13) SAPS II Score - 1.02(1.00-1.04); P<0.05 Antibiotic use - 0.40(0.19-0.85)	
Tissot, 2001 [28]	Prospective controlled study	1,3,6,7	To identify risk factors for catheter associated bacteriuria	Catheterized medical ICU patients	137	**Bacteriuria:** *Univariate Analysis:* All results OR(95% CI) Female sex –3.0(1.4-6.5) Duration of catheterization > 11 days – 5.7(2.4-13.3) Prior antibiotic exposure – 0.19(0.08-0.40) Age > 60 years – 1.9(0.9-4.0) Immunosuppression – 0.45(0.1-1.5) SAPS II at admission > 42 points – 1.01(0.99-1.03) Diabetes mellitus – 1.3(0.5-3.6) Neurologic disorders – 1.4(0.3-9.2) *Multivariate Analysis:* All results OR(95% CI) Female sex –5.1(1.9-13.5) Duration of catheterization > 11 days - OR(95% CI) = 19.4(5.5-68.7) Prior antibiotic exposure - 0.06(0.02-0.21)	F/U until discharge or death Bacteriuria was defined as a quantitative culture containing ≥ 10^5 organisms/ml of the same organism and no more than two species. Power not reported
3. TURP							
Darouiche, 1999 [29]	RCT	1,2,5,6,7,8	To examine the efficacy of bladder catheters impregnated with minocycline and rifampin in reducing catheter-associated bacteriuria when compared with regular catheters.	Patients ≥ 35 years with prostate cancer who required the insertion of a bladder catheter while undergoing radical prostatectomy	141	Survival analysis showed that it took significantly longer for patients who received the antimicrobial impregnated catheter to develop bacteriuria than those who received the control catheter (P <0.01 on log-rank test) **Bacteriuria on day 7:** Antibiotic-coated catheter vs. control catheter – 15.2% vs. 39.7%; P<0.05 **Bacteriuria on day 14:** Antibiotic-coated catheter vs. control catheter – 58.5% vs. 83.5%;	F/U 14 days after surgery Urine samples were collected from the sampling port and bacteriuria was defined as ≥ 10^4 cfu/ml Symptomatic UTI was measured, but not defined Power not reported The data on risk factors was

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						P<0.05 **Symptomatic UTI:** Antibiotic-coated catheter vs. control catheter - 1/56 vs. 6/68; P=0.13 **Risk factors for bacteriuria:** *Multivariate Analysis:* All results OR(95% CI) Use of uncoated catheter –2.79(1.19-6.56) Lack of local application of antimicrobial agents - 4.54(1.30-15.90) Violation of catheter care - 8.72(1.50-50.90) Presence of an immunosuppressive condition - 13.69(2.23-84.00) (Only multivariate analysis was reported)	considered to be observational for the purposes of this section.
Colau, 2001 [30]	Prospective controlled study	1,3,6,7	To investigate the risk factors for bacteriuria	Patients requiring TURP	128	**Bacteriuria:** *Univariate Analysis:* Significant factors were operating time, disconnection of the closed urine drainage system and postoperative catheterization ≥ 3 days. Age, ASA score, surgeon, weight, resection rate and blood loss were not significant (The quantitative results are not presented here as the baseline groups were not clearly specified for most comparisons) *Multivariate Analysis:* All results OR(95% CI) Operating time > 52 min – 9.0(2.1-39.0) Disconnection of the closed urine drainage system – 26.3(6.1-113.5) Duration of catheterization > 3 days – 4.1(0.8-21.8)	F/U 1 month postoperatively Patients with ≥ 10^5 cfu/ml (with ≤ 2 bacterial strains) with one or a maximim of 2 bacterial strains on a mid-stream urine specimen were considered to present with bacteriuria Power not reported
4. Nursing Homes							
Ouslander, 1987 [31]	Prospective controlled study	1,3,4,6	To identify risk factors associated with symptomatic UTI	Male nursing home patients with catheters	54	**Symptomatic UTI:** *Univariate Analysis:* All results P values. Age 65+ – NS Diabetes – NS Stool incontinence –NS Hb level in gm/dl <13 – NS Hb level in gm/dl <11– NS Albumin level in gm/dl <3.5 – <0.05 Albumin level in gm/dl <3.2 – NS H/O urinary retention – NS	F/U until discharge, death or catheter removal Symptomatic UTI was defined as an episode in which: 1) the patient had one or more symptoms or signs of a UTI 2) other sources of fever had been excluded 3) the patient was treated with an antimicrobial for a urinary source of infection and 4) a urine culture grew 10^5

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Catheter blockage – NS Urinary acidifier - NS Prophylactic antibiotic - NS Antibiotic therapy for a non-urinary source – NS Suprapubic vs. Indwelling - NS (Only univariate analysis was reported)	cfu of at least one pathogen. Power not reported
Ouslander, 1987 [13]	Prospective controlled study	1,3,4,6	To examine the frequency of UTI and bacteriuria among patients managed with and without external catheters (EC)	Male nursing home patients with incontinence due to various neurological disorders (Note: Data on 30 continent patients were not included)	62	**Symptomatic UTI:** EC continuously vs. No catheter - 12/30 vs. 1/13; P<0.05 EC at night only vs. no catheter – 3/19 vs. 1/13; statistical differences not clearly reported EC continuously vs. EC at night only – 12/30 vs. 3/19; P>0.05 **Bacteriuria:** EC continuously vs. No catheter - 26/30 vs. 6/13; P<0.05 EC at night only vs. no catheter – 10/19 vs. 6/13; P>0.05 EC continuously vs. EC at night only – 26/30 vs.10/19; P<0.05 **Bacteriuria and pyuria:** EC continuously vs. No catheter - 12/30 vs. 3/13; P>0.05 EC at night only vs. no catheter – 7/19 vs. 3/13; P>0.05 EC continuously vs. EC at night only – 12/30 vs. 7/19; P>0.05 **Symptomatic UTI:** *Univariate Analysis:* All results P values. Age – NS Length of time in the facility – NS Diabetic – NS Katz ADL score – NS Mental status score – NS % Ideal body weight – NS Skinfold thickness – NS Serum creatinine (mg/dl) – NS Albumin - <0.01 Hb (g/dl) – NS Stool incontinence – NS Past genitourinary diagnoses – NS Catheter manipulation – NS Suppressive antibiotic therapy – NS	Mean F/U 5.4 months Significant bacteriuria defined as a growth of > 10^5 colonies on clean catch urine specimens. Symptomatic UTI was defined as an episode in which: 1) the patient had one or more symptoms or signs of a UTI 2) other sources of fever had been excluded 3) the patient was treated with an antimicrobial for a urinary source of infection and 4) a urine culture grew 10^5 cfu of at least one pathogen. With 30 patients in each group, the power to detect differences of 30% in the proportion of patients developing infections was 75%

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Urinary acidifier - NS	
5. Hospital or unspecified							
Hazelett, 2006 [32]	Retrospective cohort study	1,3	To determine the frequency and appropriateness of indwelling catheter use and its association with UTI	Patients admitted to an acute care hospital from an ED with an indwelling urinary catheter	379	**Administration of indwelling catheter:** Age ≥ 65 vs. < 65 – 30% vs. 12%; P<0.01 **UTI by discharge:** Indwelling catheter vs. no indwelling catheter – 28% vs. 10%; P<0.01 **Inappropriate placement of urinary catheters:** UTI vs. no UTI – 11/24 vs. 93/200; statistical differences were not reported	Study duration 3 months The presence of a UTI on admission was defined as (1) an admission urine culture with ≥ 10^5 organisms/ml or (2) the diagnosis and treatment of UTI by the ED physician Catheter appropriateness was determined using published criteria. Indwelling urinary catheters were considered appropriate for surgery, accurate measurement of intake and output, urinary retention, urinary incontinence posing a risk to the patient, urinary obstruction, altered blood pressure or blood volume status requiring accurate urine measurement, urine measurement in an uncooperative patient, bladder irrigation for a urinary tract hemorrhage and palliative care for the terminally ill.
Tambyah, 2002 [33]	Prospective controlled study	1,3	To determine the additional direct costs of hospitalization attributable to CA-UTI	Hospitalized patients scheduled to receive an indwelling urethral catheter who were expected to be catheterized for more than 24 hours	1497	**Infection:** Female vs. male – RR(95% CI) = 1.7(1.6-2.0) (The main question was that of cost. Gender was the only risk factor reported)	F/u until discharge CA-UTI defined as > 10^3 cfu/ml of bacteriuria or funguria Power not reported
Johnson, 1990 [34]	Prospective controlled study	1,3,6,7	To evaluate a silver-oxide coated catheter in the prevention of UTI during acute bladder catheterization in a general hospital population and characterizing the clinical and microbiologic correlates of CA-UTI in this setting.	Patients ≥ 17 years who had received a study catheter that was expected to remain indwelling for at least 24 h.	482	**Bacteriuria:** *Univariate Analysis:* All results RR (P value) Male sex – 0.5(P<0.01) Antimicrobials during final 48 h – 0.3(P<0.01) Catheter care violations – 2.7(P<0.01) Serum creatinine ≥ 2 mg/dl – 2.1(P=0.04) Not at strict bed rest – 0(P=0.06) Duration of catheterization > 7 days – 2.1(P=0.01)	F/U unclear A patient was considered to have UTI when two consecutively collected catheter urine specimens grew the same microorganism in concentrations of ≥ 10^2 cfu/ml or if the last available urine specimen of the patient before catheter removal had ≥ 10^5 cfu/ml

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						No association with UTI was seen for infection at another site, presence of an underlying genitourinary abnormality, advanced age or admitting service. ORs were not provided for the same *Multivariate Analysis:* All results OR (P value) Antimicrobials during final 48 h – 0.3 (P<0.01) Female sex – 2.0 (P=0.02) Renal dysfunction – 2.6 (P=0.02) Catheter care violations – NS (OR not provided) **Bacteriuria:** Silver coated catheter vs. Control – 19/207 vs. 28/275; P=0.95 After stratification by sex and antimicrobial use, a protective effect of the silver catheter was seen among women not receiving antimicrobials (P=0.04). There were no significant differences in the other three groups (men receiving antimicrobials, men not receiving antimicrobials, women receiving antimicrobials) **Median duration of catheterization (days):** Silver coated catheter vs. Control – 3 vs. 4; P=0.03	A sample size of 105 patients per group was needed to detect a 67% reduction in the incidence of UTI with the silver catheter at 5% significance level and 80% power.
Lima, 1990 [35]	Retrospective controlled study	1,3,4,6,7 (Scale III)	To test the hypothesis that diarrhea and resultant local environmental microbial contamination might result in a higher risk for nosocomial infections.	Hospitalized patients	84	**UTI rate:** With nosocomial diarrhea vs. without nosocomial diarrhea – 9/33 vs. 1/45; RR(95% CI) = 12.27(1.64-92.20) **UTI rate (per 1000 patient days):** With nosocomial diarrhea vs. without nosocomial diarrhea – 24.9 vs. 2.4; IRR(95% CI) = 10.3(1.7-63.1) **CA-UTI rate:** With nosocomial diarrhea vs. without nosocomial diarrhea – 8/16 vs. 1/19; RR(95% CI) = 9.5(1.5-58.5)	F/U until onset of the first nosocomial infection Nosocomial diarrhea was defined as the passage of three or more stools per day with onset > 72 hr after hospitalization Power not reported
Jacono, 1988 [36]	Retrospective controlled study	1,3,6,7	To examine the characteristics of patients who developed a nosocomial UTI	Patients admitted to either one of two units and had been catheterized – one unit cared for patients with acute conditions while the other unit provided	71	**Bacteriuria:** Females had a greater risk than males. Statistical differences were not reported. The effect of a meatal anti-bacterial agent was assessed in a pre-post fashion and it was found to result in a non-significant decrease in infection rate	F/U unclear Noscomial UTI was defined as sterile urine culture upon admission and (1) Bacterial growth measuring < 10^5 organisms/ml but with a WBC count > 5/hpf or (2) Bacterial count > 10^5

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
				long term care		in males, but a paradoxical increase in females	organisms/ml Power not reported
Mulhall, 1988 [37]	Prospective controlled study	1,3,6,7	To identify risk factors for bacteriuria during indwelling urethral catheterization	Newly catheterized patients > 16 years old in whom the catheter remained in situ for longer than 24 hours	220	**Incidence of bacteriuria:** Was recorded in 97 (44%) of 220 patients. In 42 of these 97 patients, bacteriuria was present by 48 hrs of catheterization and in 55 patients, bacteriuria occurred after this time. A multivariate analysis of the relationship between bacteriuria and the following factors was made – sex, age, diagnosis, medical specialty of care, reason for catheterization, person performing the catheterization (no details provided), place of catheterization (no details provided), use of antimicrobial therapy, the number of days the catheter was in situ, disconnection of the drainage system, fecal incontinence, presence of another catheterized patient in adjacent bed or same ward or health district **Bacteriuria by 48 hours after catheterization:** *Multivariate Analysis:* All results P value Patients catheterized because of urinary incontinence were significantly more likely to have bacteriuria than other patients (<0.01) Patients receiving antimicrobial therapy prior to catheterization were significantly less likely to have bacteriuria than other patients (<0.01) Patients cared for in surgical, genito-urinary and gynecological specialties were significantly less likely to have bacteriuria than patients in medical, orthopedic or neurological specialties(<0.01) Other factors were not significantly related (>0.05) (Only multivariate analysis was reported) **Bacteriuria more than 48 hours after catheterization:** *Multivariate Analysis:* All results P value The risk of developing bacteriuria between days 3 and 21: Significantly increased for each day the	F/U 21 days Bacteriuria was defined as > 10^4 organisms/ml on two consecutive days. Urine cultured was aspirated from the catheter tubing. Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						catheter was in situ(<0.01) Significantly decreased with the use of antimicrobial therapy(<0.01) Other factors were not significantly related (>0.05) (Only multivariate analysis was reported)	
Platt, 1986 [38]	Prospective controlled study	1,3,6,7	To identify risk factors for nosocomial UTI	Adult medical and surgical inpatients who were undergoing bladder catheterization	1458	**Bacteriuria:** *Univariate Analysis:* All results P values Increased duration of catheterization – <0.01 (OR not clearly reported) Lack of urinemeter drainage – <0.01 Colonization of drainage bag – <0.01 Diabetes – <0.01 Absence of systemic antibiotics during catheter courses shorter than 6 days – <0.01 Female sex – <0.01 Drainage during surgery or measurement of output – <0.01 Creatinine level > 2 vs. < 1 – <0.01 Lack of use of pre-sealed junction catheters– 0.20 Prior indwelling catheterization – <0.01 Hospital service – <0.01 Person inserting catheter RN vs. MD – <0.01 Disconnection of collection junction – <0.01 Age – <0.01 Drainage-bag change – <0.01 Prior UTI during current hospitalization – <0.01 No systemic antibiotic in week before catheterization – <0.01 Bag-outlet-tube error – <0.01 Agent used for catheter insertion and meatal care – 0.01 Catheter change – 0.02 Non-white vs. white – 0.05 Fatal vs. non-fatal illness – 0.13 *Multivariate Analysis:* All results OR(95% CI) Adjusted for duration of catheterization, urinemeter drainage, colonization of drainage bag, diabetes, systemic antibiotics, sex, indication for catheter drainage, creatinine level and catheter with	F/U until discharge UTI defined as recovery of ≥ 10^5 cfu/ml of bacteria or yeasts. Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						unsealed collection junction Increased duration of catheterization – P<0.01 (OR not clearly reported) Lack of urinemeter drainage – 2.0(1.2-3.8) Colonization of drainage bag – 3.8(2.1-7.4) Diabetes – 2.3(1.5-3.6) Absence of systemic antibiotics during catheter courses shorter than 6 days – P<0.01 Female sex – 2.5(1.6-4.0) Drainage during surgery or measurement of output – 2.0(1.2-3.6) Creatinine level > 2 vs. < 1 – 2.1(1.0-4.3) Lack of pre-sealed junction catheters – P=0.03(OR not reported) Prior indwelling catheterization – 2.3(1.2-4.6) Hospital service – P=0.49 (OR not clearly reported) Person inserting catheter RN vs. MD – 1.0(0.3-3.7) Disconnection of collection junction – 1.14(0.7-1.8) Old age (vs. a younger age) – 1.3(0.4-4.0) Drainage-bag change – 1.0(0.6-1.7) Prior UTI during current hospitalization – 1.5(0.9-2.5) No systemic antibiotic in week before catheterization – 1.1(0.5-2.2) Bag-outlet-tube error – 0.8(0.4-1.8) Agent used for catheter insertion and meatal care (benzalkonium chloride vs. povidone-iodine) – 1.43(0.5-4.1) Catheter change – 0.8(0.4-1.5) Non-white vs. white – 1.6(0.7-4.0) Fatal vs. non-fatal illness – 1.0(0.6-1.7) (Because results of the univariate and multivariate analyses were presented for each of the variables examined, only the ORs of the multivariate analysis are presented here)	
Shapiro, 1984 [39]	Prospective controlled study	1,3,6,7	To identify risk factors for catheter associated bacteriuria	Patients catheterized for > 24 hours	112	**Bacteriuria:** *Univariate Analysis:* All results OR(95% CI) Orthopedics ward vs. cardiac surgery ward – 60(7.5-74.4)	F/U until discharge or death Bacteriuria was defined as a single culture of 10^2 cfu/ml of aspirated urine if

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Neurology ward vs. cardiac surgery ward – 14.0(2.6-75.7) Urology ward vs. cardiac surgery ward – 4.3(0.8-22.8) Neurosurgery ward vs. cardiac surgery ward – 4.4(1.0-19.6) Intensive care unit – 1.6(0.6-4.6) Age > 74 years – 2.8(1.1-7.6) Female sex – 1.7(0.7-4.0) Arabs vs. Jews – 2.9(1.0-8.5) BUN < 25 mg/dl – 2.8(0.9-8.2) Indication for catheterization – incontinence/existent outflow obstruction vs. output measurement or prevention of obstruction – 6.6(2.7-15.9) Catheter inserted outside operating theater – 4.3(1.9-9.8) Duration of hospitalization > 7 days – 1.4(0.5-3.5) Lack of administration of antimicrobial drugs – 1.8(0.8-4.1) Unsatisfactory catheter care – 3.9(1.5-9.8) Prolonged duration (> 7 days) of catheterization – 47.2(16.6-134.2) Extrapelvic vs. pelvic operation – P>0.10 (OR not provided) Steroids – P = NS (OR not provided) Bedridden vs. mobile – P=NS(OR not provided) *Multivariate Analysis:* All results OR(95% CI) adjusted for all variables entering the regression equation Orthopedics ward vs. cardiac surgery ward – 51.1(7.6-341.0) Urology ward vs. cardiac surgery ward – 4.1(1.1-15.7) Insertion of a catheter after the sixth day of hospitalization – 8.6(3.5-21.1) Prolonged duration (> 7 days) of catheterization – 6.8(2.8-16.8) Arabs vs. jews – 6.5(2.4-17.1) Location of catheter insertion outside operation theatre – 5.3(1.7-16.7)	systemic antibiotics had been administered within one day after obtaining the culture; otherwise two consecutive cultures of 10^5 cfu/ml were required. Bacteriuria was regarded as catheter-acquired if the first positive urine culture had been preceded by a sterile culture Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
						Lack of administration of systemic antibiotics – 3.9(1.9-8.3) Unsatisfactory catheter care – 3.1(1.7-5.6)	
Pien, 1983 [40]	Prospective controlled study	1,3,6	To evaluate risk factors for nosocomial UTI	Hospitalized patients with indwelling closed drainage catheterization	90	**Bacteriuria:** *Univariate Analysis:* All results P values Female Sex – 0.7 Age> 50 – P value was reported as 3.0 Severity of illness – 0.15 Surgical illness – <0.02 (Only univariate analysis was reported)	F/U until catheter removal, discharge or death A colony count of ≥ 100 colonies per ml was considered to be significant bacteriuria Power not reported
Hartstein, 1981 [41]	Prospective controlled study	1,3	To identify risk factors for UTI	Patients with indwelling urinary catheter	108	**Bacteriuria:** *Univariate Analysis:* All results P values Exposure to antibiotics – <0.05 Duration of catheterization – <0.05 Age – >0.05 Sex - >0.05 Maintenance of closed system - >0.05 Underlying host disease status - >0.05 Catheter type (Teflon-coated latex vs. silicon) - >0.05 Reason for catheterization (different types of surgery) - >0.05 (Only univariate analysis was reported)	F/U until discharge or death A UTI was defined as ≥ 10^4 cfu/ml in the catheter or midstream specimen of urine Power not reported
Garibaldi, 1980 [42]	Prospective controlled study	1,3,6,7	To examine whether meatal colonization is a major risk factor for catheter associated bacteriuria	Patients needing an indwelling urinary catheter	1213	**Bacteriuria:** Positive meatal culture vs. negative meatal culture – 110/612 vs. 28/601; <0.01 Bacteriuria was significantly higher in patients with positive meatal cultures than in patients with negative meatal cultures in all subgroups divided on basis of gender, age (≥50 vs < 50), receipt of antibiotics, and service (medical or surgical) **Positive meatal culture:** *Univariate Analysis:* All results P values Females – <0.01 Age > 50 years – NS No systemic antibiotics - <0.01 Medical treatment (vs. Surgical) - <0.01	F/U unclear A meatal culture was considered positive if gram negative bacilli or enterococci were isolated from the meatal swab Bacteriuria was defined as ≥ 10^5 colonies of gram-negative rods or enterococci per ml of urine collected by aseptic puncture of a sampling port in the drainage tube Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
Hirsh, 1979 [43]	Prospective controlled study	1,3	To determine whether the use of a condom catheter collecting system was associated with UTI. Patients were classified into two groups in one of which they were either cooperative or because of paralysis were unable to manipulate the collecting system. Patients were identified as being uncooperative if they manipulated, pulled off or repeatedly caused kinking of the collecting system	Male inpatients on the medical or surgical services of a VA hospital	Unclear	**UTI:** Cooperative vs. uncooperative – 0/79 vs. 8/15; statistical differences were not reported	F/U unclear Bacteriuria defined as ≥ 10^3 colonies per ml Power not reported
Garibaldi, 1974 [44]	Prospective controlled study	1,3,6	To identify risk factors for bacteriuria during indwelling urethral catheterization	Inpatients who received indwelling urethral catheters and urinary drainage systems	405	**Bacteriuria:** *Univariate Analysis:* All results P values Female vs. male – <0.01 Age > 50 yrs vs. < 50 yrs – NS Rapidly fatal vs. non-fatal illness – <0.01 Non-surgical vs. surgical illness – NS ICU – NS Violations in catheter care - NS Licensed nurse (vs. RN or MD) - <0.01 Administration of systemic antibiotics – <0.01 (Only univariate analysis was reported)	Study period 2 months Colony counts of ≥ 10^2 organisms/ml indicated bacterial colonization of bladder urine. Power not reported
6. Home care							
Wilde, 2003 [45]	Retrospective controlled study	1,3,4,6	To investigate whether factors related to urine flow were associated with the risk of developing a UTI	Subjects in a home care agency with indwelling urinary catheterization for at least 3 months	24	**Symptomatic UTI:** *Univariate Analysis:* All results P values. Catheter blockage – 0.02 Urine output < 1200 ml – 0.04 Bloody urine – NS Pulling catheter - NS Sluggish urine - NS Leaking - NS Position blocked urine flow - NS (Only univariate analysis was reported)	Study period 2 months UTI was diagnosed based on (1) new pain in the back over the kidney region or pain/tenderness over the bladder region (2) change in character of urine (3) lab tests showing new urine infection or blood in urine with a previous negative test (4) a medical diagnosis of UTI as written in the record Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results*	Comments
White, 1995 [46]	Retrospective controlled study	1,3,4,6,7	To determine the characters of those who acquire UTI and the influence of the interval between catheter changes on the incidence of UTI	Home care patients with catheters	106	**Symptomatic UTI:** *Multivariate Analysis:* All results RH(95% CI) [RH = Relative Hazard] Catheter change interval ≤ 4 wk (compared to less frequently) –11.94(5.46-26.22) Number of nurses changing catheter – 1.38(1.22-1.65) Age – 0.99(0.98-1.01) Ambulatory care group – 1.01(0.99-1.03) Female sex –0.72(0.34-1.53) (Only multivariate analysis was reported)	F/U until the end of home care, hospitalization or death UTI according to CDC definition Power not reported

* The direction of effect for all risk factors mentioned is to increase the risk of the outcomes examined

GRADE Table

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Old age	Symptomatic UTI*	5 OBS [13, 17, 26, 31, 46]	Independent risk factor in 1 OBS [26] , possible risk factor in 1 OBS [17] Not found to be a risk factor in 3 OBS [13, 31, 46]	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria*	11 OBS [24, 27, 28, 30, 34, 37-41, 44]	Possible risk factor in 2 OBS [38, 39] Not found to be a risk factor in 9 OBS [24, 27, 28, 30, 34, 37, 40, 41, 44]	Low	0	0	0	0	0	0	0	0	Low	
Female sex	Symptomatic UTI*	4 OBS [17, 25, 26, 46]	Independent risk factor in 1 OBS [26] Not found to be a risk factor in 3 OBS [17, 25, 46]	Low	0	0	0	0	0	0	0	0	Low	Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Bacteriuria*	11 OBS [24, 27, 28, 33, 34, 37-41, 44]	Independent risk factor in 4 OBS [27, 28, 34, 38] , possible risk factor in 2 OBS [33, 44] Not found to be a risk factor in 5 OBS [24, 37, 39-41]	Low	0	0	0	0	0	+1	0	0	Moderate	
Prolonged duration of catheterization	Symptomatic UTI*	2 OBS [17, 25]	Independent risk factor in 1 OBS [17] , possible risk factor in 1 OBS [25]	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria*	8 OBS [27, 28, 30, 34, 37-39, 41]	Independent risk factor in 5 OBS [27, 28, 37-39] , possible risk factor in 3 OBS [30, 34, 41]	Low	0	0	0	0	0	+1	+1	0	High	
Lack of administration of antibiotics	Symptomatic UTI*	4 OBS [13, 17, 25, 31]	Independent risk factor in 1 OBS [25] Not found to be a risk factor in 3 OBS [13, 17, 31]	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria*	9 OBS [24, 27, 28, 34, 37-39, 41, 44]	Independent risk factor in 6 OBS [27, 28, 34, 37-39] , possible risk factor in 2 OBS [41, 44] Not found to be a risk factor in 1 OBS [24]	Low	0	0	0	0	0	+1	0	0	Moderate	
Impaired immunity	Symptomatic UTI*	2 OBS [17, 25]	Independent risk factor in 1 OBS [25] Not found to be a risk factor in 1 OBS [17]	Low	0	0	0	0	0	0	0	0	Low	Very Low
	Bacteriuria*	1 OBS [29] 1 OBS [28]	Independent risk factor in 1 OBS [29]	Low	0	-1	0	0	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
			Not found to be a risk factor in 1 OBS [28]											
Disconnection of the drainage system	Bacteriuria*	4 OBS [30, 37, 38, 41]	Independent risk factor in 1 OBS [30] , possible risk factor in 1 OBS [38] Not found to be a risk factor in 2 OBS [37, 41]	Low	0	0	0	0	0	0	0	0	Low	Low
Diabetes	Symptomatic UTI*	2 OBS [13, 31]	Not found to be a risk factor in 2 OBS [13, 31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria*	2 OBS [28, 38]	Independent risk factor in 1 OBS [38] Not found to be a risk factor in 1 OBS [28]	Low	0	0	0	0	0	0	0	0	Low	
Renal dysfunction	Symptomatic UTI*	2 OBS [13, 31]	Not found to be a risk factor in 2 OBS [13, 31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria*	3 OBS [34, 38, 39]	Independent risk factor in 2 OBS [34, 38] Not found to be a risk factor in 1 OBS [39]	Low	0	0	0	0	0	0	0	0	Low	
Surgical illness	Bacteriuria*	2 OBS [40, 44]	Possible risk factor in 1 OBS [40] Not found to be a risk factor in 1 OBS [44]	Low	0	0	0	0	-1	0	0	0	Very Low	Very Low
Severity of illness	Bacteriuria*	5 OBS [27, 28, 38, 40, 44]	Independent risk factor in 1 OBS [27] , possible risk factor in 1 OBS [44] Not found to be a risk factor in 3	Low	0	0	0	0	0	0	0	0	Low	Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
			OBS [28, 38, 40]											
Orthopedic population	Bacteriuria*	2 OBS [37, 39]	Independent risk factor in 2 OBS [37, 39]	Low	0	0	0	0	0	0	0	0	Low	Low
Neurology population	Bacteriuria*	3 OBS [28, 37, 39]	Independent risk factor in 1 OBS [37] , possible risk factor in 1 OBS [39] Not found to be a risk factor in 1 OBS [28]	Low	0	0	0	0	0	0	0	0	Low	Low
Intensive care unit	Bacteriuria*	2 OBS [39, 44]	Not found to be a risk factor in 2 OBS [39, 44]	Low	0	0	0	0	0	0	0	0	Low	Low
Catheter insertion outside of operating room	Bacteriuria*	2 OBS [37, 39]	Independent risk factor in 1 OBS [39] Not found to be a risk factor in 1 OBS [37]	Low	0	0	0	0	0	0	0	0	Low	Low
Person performing catheterization – Nurse vs. MD or LPN vs. (RN or MD)	Bacteriuria*	3 OBS [37, 38, 44]	Possible risk factor in 2 OBS [38, 44] Not found to be a risk factor in 1 OBS [37]	Low	0	0	0	0	0	0	0	0	Low	Low
Incontinence as a reason for catheterization	Bacteriuria*	2 OBS [37, 39]	Independent risk factor in 1 OBS [37] , possible risk factor in 1 OBS [39]	Low	0	0	0	0	0	0	0	0	Low	Low
Catheter blockage	Symptomatic UTI*	2 OBS [31, 45]	Possible risk factor in 1 OBS [45] Not found to be a risk factor in 1 OBS [31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Low albumin level	Symptomatic UTI*	2 OBS [13, 31]	Possible risk factor in 2 OBS [13, 31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Low hemoglobin level	Symptomatic UTI*	2 OBS [13, 31]	Not found to be a risk factor in 2 OBS [13, 31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Stool incontinence	Symptomatic UTI*	2 OBS [13, 31]	Not found to be a risk factor in 2 OBS [13, 31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Urinary acidifier	Symptomatic UTI*	2 OBS [13, 31]	Not found to be a risk factor in 2 OBS [13, 31]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
Race (non-white vs. white)	Bacteriuria*	2 OBS [24, 38]	Possible risk factor in 2 OBS [24, 38]	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low

* These modifiers can impact the GRADE by 1 or 2 points
Definitions: “Independent risk factor” implies it was significant in a multivariate analysis, “possible risk factor” implies it was significant in a univariate analysis

C. What populations are at highest risk of mortality from urinary catheters?

TABLE 3: RISK FACTORS FOR MORTALITY AMONG CATHETERIZED PATIENTS

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
van der Kooi, 2007 [25]	Prospective controlled study	1,3,4,6,7	To examine the incidence of and risk factors for device-associated infections and mortality	Patients without an initial infection staying in the ICU for at least 48 hours	2644	**Symptomatic UTI:** *Univariate Analysis:* All results OR(95% CI) Duration of catheterization 5-9 days vs. 1-4 days – 1.6(1.0-2.4); P<0.05 Duration of catheterization ≥ 10 days vs. 1-4 days – 3.3(2.2-4.9)	F/U until discharge, death or day of withholding treatment CA-UTI according to CDC definition

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Duration was not included in the multivariate model *Multivariate Analysis:* All results RR(95% CI) Female sex– 1.4(1.0-1.8) P>0.05 Impaired immunity – 2.5(1.5-4.0) Acute admission vs. planned admission – 1.8(1.0-3.3); P>0.05 Systemic antibiotics at admission – 0.5(0.3-1.0); P<0.05 **Mortality:** *Univariate Analysis:* CA-UTI vs. not – 30.9% vs. 20.2%; P=0.06. It was not significantly associated with mortality in a multivariate model, though estimates were not provided. *Multivariate Analysis:* All results OR(95% CI) for mortality associated with having a urinary catheter Age 40-70 years vs. ≤ 39 years – 1.6(1.0-2.5); P<0.05 Age ≥ 70 years vs. ≤ 39 years – 2.8(1.8-4.4) APACHE II ≥ 20 vs. 0-19 – 1.9(1.5-2.4) Internal medicine vs. Surgery/Traumatology – 1.9(1.4-2.7) Cardiology/Cardiosurgery vs. Surgery/Traumatology – 2.6(1.8-3.8) Neurology/Neurosurgery vs. Surgery/Traumatology – 1.8(1.2-2.7) Acute admission vs. planned admission – 1.4(1.0-1.8); P<0.05 Systemic antibiotics at admission– 1.5(1.1-2.3) Ventilation– 4.8(3.3-7.0) Central venous catheter – 1.8(1.3-2.5)	Power not reported
Platt, 1982 [47]	Prospective controlled study	1,3,6,7	To identify risk factors for mortality among catheterized patients	Hospitalized patients catheterized ≥ 24 hours	1458	**Mortality:** *Univariate analysis:* All results are OR(P value) Fatal vs. non-fatal illness – 6.0(<0.01) Medicine vs. general surgery – 6.9(<0.01) Infection – 5.6(<0.01) Duration of catheterization (days) - ≥ 6 vs 1 – 7.5(<0.01) Lack of urine-meter drainage – 3.5(<0.01) Creatinine at insertion > 2 mg/dl vs < 1 mg/dl – 5.3(<0.01) Prior indwelling catheterization – 4.0(<0.01) Drainage-bag change – 3.0(<0.01) Person inserting catheter other than MD or RN vs. MD – 3.8(<0.01) Collection-junction break – 2.5(<0.01) Lack of systemic antibiotics in week before	F/U until discharge or death UTI defined as recovery of ≥ 10^5 cfu/ml Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						catheterization – 2.7(<0.01) Prior UTI during current hospitalization – 2.5(<0.01) Colonization of drainage bag – 3.5(<0.01) Catheter change – 2.4(0.01) Bag-outlet-tube error – 3.0(0.01) Age(yr) > 70 vs. <30 – 8.0(0.02) Lack of systemic antibiotics during catheterization – 2.0(0.02) Lack of preconnected presealed junction – 1.6(0.04) Female sex – 1.5(0.08) Povidone-iodine vs. soap – 1.5(0.25) Non-white vs. white – 1.2(0.65) *Multivariate analysis:* All results are OR(95% CI) Infection – 2.8(1.5-5.1) Age (yr) > 70 vs. < 30 – 7.0(0.9-57.5) (P=0.01 for the overall risk factor) Fatal vs. non-fatal illness – 5.2(3.1-8.7) Medicine vs. general surgery – 3.4(1.9-6.0) Duration of catheterization (days) - ≥ 6 vs 1 – 4.1(1.9-9.1) Creatinine at insertion > 2 mg/dl vs < 1 mg/dl – 2.9(1.3-6.4) Person inserting catheter other than MD or RN vs. MD – 2.2(1.0-4.8)	

GRADE Table

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Old age	Mortality*	2 OBS [25, 47]	Independent risk factor in 2 OBS [25, 47]	Low	0	0	0	0	0	0	0	0	Low	Low
Severity of illness	Mortality*	2 OBS [25, 47]	Independent risk factor in 2 OBS [25,	Low	0	0	0	0	0	0	0	0	Low	Low

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
			47											
Internal medicine (vs. surgery)	Mortality*	2 OBS [25, 47]	Independent risk factor in 2 OBS [25, 47]	Low	0	0	0	0	0	0	0	0	Low	Low
Administration of antibiotics	Mortality*	2 OBS [25, 47]	Administration of antibiotics was an independent risk factor in 1 OBS [25] and lack of administration of antibiotics was a possible risk factor in 1 OBS [47]	Low	0	-1	0	0	0	0	0	0	Very Low	Very Low
CA-UTI	Mortality*	2 OBS [25, 47]	Independent risk factor in 1 OBS [47] Not found to be a risk factor in 1 OBS [25]	Low	0	0	0	0	0	0	0	0	Low	Low

* These modifiers can impact the GRADE by 1 or 2 points
Definitions: “Independent risk factor” implies it was significant in a multivariate analysis, “possible risk factor” implies it was significant in a univariate analysis

Question 2: For those who may require urinary catheters, what are the best practices?

A. What are the risks and benefits associated with different approaches to catheterization?

TABLE 4: RISKS AND BENEFITS ASSOCIATED WITH DIFFERENT APPROACHES TO CATHETERIZATION

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
1. Condom vs. indwelling							

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Short-term							
Saint, 2006 [48]	RCT	1,2,4,6,7,8,9	To compare condom and indwelling urinary catheters in terms of infection risk and patient satisfaction	Hospitalized men ≥ 40 years who required a urinary collection device at a VA medical center and were not bacteriuric	75	**Bacteriuria:** Indwelling vs. condom catheter – 17/41 vs. 13/34; statistical differences were not reported *Incidence (per 1000 patient days):* Indwelling vs. condom catheter – 111 vs. 61; P=0.11 *Median days to outcome:* Indwelling vs. condom catheter – 7 vs. 13; P=0.15 **Mortality:** Indwelling vs. condom catheter – 4/41 vs. 2/34; statistical differences were not reported **Bacteriuria, symptomatic UTI or death:** Indwelling vs. condom catheter – 20/41 vs. 15/34; statistical differences were not reported *Incidence (per 1000 patient days):* Indwelling vs. condom catheter – 131 vs. 70; P=0.07 *Median days to outcome* **-** Indwelling vs. condom catheter – 7 vs. 11; P=0.09 *Univariate Analysis:* All results HR (95% CI) indwelling vs. condom catheter All patients – 1.82(0.90-3.67) Patients without dementia – 3.47(0.94-12.74) Patients with dementia – 0.86(0.23-3.27) *Multivariate Analysis:* All results HR (95% CI) indwelling vs. condom catheter (Adjusted for age, MMSE score, history of UTI and history of catheterization) All patients – 2.11(1.03-4.31)	F/U 30 days Bacteriuria was defined as ≥ 10^3 cfu/ml of a single or predominant species of bacteria. Symptomatic UTI was defined as bacteriuria accompanied by onset of one or more of the following symptoms or signs: fever > 38 C, dysuria or other irritative voiding symptoms, or suprapubic, flank or pelvic pain thought to be related to the urinary tract. Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Patients without dementia – 4.84(1.46-16.02) [N=44 for patients without dementia] Patients with dementia – 1.20(0.33-4.35) [N=41 for patients with dementia] **Patient satisfaction outcomes:** All results P value for the outcome's association with condom catheter Increased comfort – 0.02 Decreased pain – 0.02 Convenience – 0.74 Restriction of daily activity – 0.16 Embarrassment – 0.23	
Saint, 2006 [49]	Retrospective controlled study	1,3,4,6,7	To determine the risk factors for nosocomial urinary tract related bacteremia A patient from whom a urine culture and a blood culture grew the same organism ≥ 48 hours after admission was considered a case. Control patients were those with significant bacteriuria (≥ 10^5 cfu/ml) detected ≥ 48 hours after admission who did not have a positive blood culture	Hospitalized patients with condom or indwelling catheters	237	**Bacteremia:** Condom vs. indwelling – 0/6 vs. 83/203; P = 0.08 **Risk factors for nosocomial urinary tract related bacteremia**: *Multivariate analysis* All results OR[95% CI Immunosuppresant therapy within 14 days – 8.13(1.02-64.83) History of malignancy – 1.94(1.06-3.55) Male sex – 1.88(1.62-2.18) Smoking within the past 5 years – 1.26(1.01-1.57) Number of hospital days before detecting bacteriuria – 1.03(1.01-1.04) Antibiotic use within 3 days of detecting bacteriuria – 0.76(0.68-0.85) Patients with diabetes < 70 years – 6.19(1.30-29.40) Patients with diabetes ≥ 70 years – 0.11(0.02-0.83) Patients < 70 years using corticosteroids within 7 days – 14.24(4.76-42.63) Patients ≥ 70 years using corticosteroids within 7 days – 0.08(0.02-0.34) Data were also collected on race, age, site of medical care, HIV infection, prostatic hypertrophy, urolithiasis and serum creatinine level, but they were not included in the final multivariate model.	F/U unclear Bacteriuria defined as ≥ 10^5 cfu/ml Nosocomial urinary tract related bacteremia defined as when a urine culture and a blood culture grew the same organism ≥ 48 hours after admission Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Long-term							
Saint, 1999 [50]	Prospective controlled study (based on a survey)	1,3,6,7	To determine the beliefs of older male patients and nursing staff about the relative merits and problems of condom and indwelling catheters	Men hospitalized on medical, rehabilitation and nursing home units using either an indwelling or a condom catheter and all members of the nursing staff on these units	104 patients and 99 nurses	**Results of patient interviews**: *Multivariate analysis* All results OR[95% CI] for condom vs. indwelling unless otherwise noted Comfort – 4.2(1.1-15.6) Pain – 0.17(0.05-0.64) Restriction – 0.23(0.07-0.75) Convenience – P=0.40 (OR not reported) Embarrassment – P=0.50 (OR not reported) **Results of nurse interviews:** Most of the nursing staff respondents believed that condom catheters were less painful, less embarrassing, less restrictive for patients and were easier to apply, but they also believed that they fell off and leaked more often. Statistical differences were not reported for these comparisons. *Univariate analysis* Results P value Nursing time – 5-10 minutes more per shift managing the condom catheter (<0.01) *Multivariate analysis* All results OR [95% CI] Nursing convenience No. of patients cared for in the past year (P=0.04) [Interpretation: The greater the experience with condom catheters, the more likely the nurse would prefer them] Patient comfort As the number of minutes spent managing the indwelling catheter increased, the more likely the respondent was to prefer the condom catheter (P=0.04) As the number of minutes spent managing the condom catheter increased, the more likely the respondent was to prefer the indwelling catheter (P=0.07) For both nursing convenience and patient comfort, the respondent's type of licensure,	F/U N/A UTI not measured Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						nursing experience, gender, hospital unit were not significant predictors	
2. Intermittent vs. indwelling							
Short-term							
Niel-Weise, 2006 [51]	Systematic Review	1,2,3,4,5,6,7,8	To determine the advantages and disadvantages of alternative approaches to catheterization for short term bladder drainage in adults	All randomized and quasi-randomized trials comparing catheter route of insertion for adults catheterized for up to 14 days	17 trials	*1. Urethral catheterization vs. Suprapubic catheterization* (all results RR[95% CI] unless otherwise noted) **Bacteriuria (symptomatic and asymptomatic)** (14 studies) – 2.60(2.12-3.18) **Bacteriuria (symptomatic and asymptomatic) in males** (2 studies) – 1.71(0.87-3.36) **Bacteriuria (symptomatic and asymptomatic) in females** (2 studies) – 4.23(1.87-9.54) **Bacteriuria (symptomatic and asymptomatic) after colposuspension** (1 study) – 7.41(1.02-54.10) **Bacteriuria (symptomatic and asymptomatic) after vaginal repair** (1 study) – 1.60(0.82-3.14) **Bacteriuria (symptomatic and asymptomatic) without antibiotic prophylaxis** (1 study) – 6.28(2.49-15.79) **Bacteriuria (symptomatic and asymptomatic) with antibiotic prophylaxis** (1 study) – 6.88(0.35-133.64) **Bacteriuria (symptomatic and asymptomatic) after gynecological surgery** (7 studies) – 2.46(1.95-3.10) **Bacteriuria (symptomatic and asymptomatic) after abdominal surgery** (3 studies) – 1.90(1.14-3.17) **Bacteriuria (symptomatic)** (1 study) – 1.16(0.54-2.48) **Recatheterization** (8 studies) – 4.72(2.94-7.56)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Number of patients catheterized > 5 days (1 study) – 0.62(0.49-0.80) **Mean duration of catheterization** (1 study) – WMD (95% CI) = -1.60(-2.80 to -0.40) Unit of measurement was not specified. 8 other studies reported duration of catheterization, but data were not sufficient to calculate statistical differences. **Number of patients with pain** (2 studies) – 9.30(2.96-29.21) **Number of catheter days with pain** (1 study) – 6.95(3.03-15.92) **Discomfort** (4 studies) – 2.98(2.31-3.85) **Catheter obstruction** (2 studies) – 0.18(0.02-1.49) **Gross hematuria** (2 studies) – 0.97(0.25-3.74) **Microscopic hematuria** (2 studies) – 0.93(0.72-1.20) **Pyuria** (2 studies) – 2.09(1.63-2.68) **Number of patients with febrile morbidity** (1 study) - WMD(95% CI) = 13.50(10.94-16.06) **Number of patients needing antibiotic therapy** (1 study) – 2.78(1.47-5.28) **Number of patients requiring drugs for relief of dysuria** (1 study) – 1.68(1.23-2.28) **Mean hospital stay** (1 study) - WMD(95% CI) = 1.10(0.30 to 1.90) **Number of patients with extended hospital stay** (1 study) – 1.79(1.01-3.16) **Number of patients leaving hospital with catheter** (1 study) – 3.33(1.28-8.67) *2. Urethral catheterization vs. intermittent catheterization* (all results RR[95% CI] unless otherwise noted) **Number of patients with no return of bladder function 48 h after surgery** (1 study)– 0.55(0.30-1.02) **Bacteriuria (symptomatic and asymptomatic)** (2 studies) – 2.90(1.44-5.84)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Urinary symptoms immediately after surgery (1 study) – 1.54(0.65-3.63) **Postoperative pyrexia** (1 study) – 1.11(0.63-1.95)	
Tang, 2006 [52]	RCT	1,2,7	To compare the use of intermittent vs. indwelling urinary catheterization. Subjects in the indwelling catheter group were treated with indwelling urinary catheterization and trial without catheter was performed at least once weekly. Indwelling urinary catheter was reinserted if post-voiding residual volume (PVRU) ≥300 ml. If the trial without catheter were successful, PVRU would be monitored by bladder scan at least daily until day 14. Subjects in the intermittent catheter group had PVRU monitored by bladder scan three times a day. Intermittent catheterization would be performed either when PVRU ≥ 500 ml but remained asymptomatic or when PVRU ≥ 300 ml with symptoms of retention.	Female patients of age ≥ 65 years with urinary retention (PVRU ≥ 300 ml) admitted to a female geriatric rehabilitation ward	81	**Symptomatic UTI:** Intermittent vs. indwelling – 1/22 vs. 0/34; P=0.40 **Bacteriuria:** Intermittent vs. indwelling – 14/22 vs. 21/34; P=0.89 **Subjects being catheter free and having a PVRU < 150 ml:** Intermittent vs. indwelling – 16/27 vs. 27/39; P=0.40 **Mean PVRU on day 14 (ml)** – Intermittent vs. indwelling – 77.6 vs. 54.4; P=0.14 **Mean time to become catheter free (days):** Intermittent vs. indwelling – 8.6 vs. 9.2; P=0.61 **Median number of catheterizations** - Intermittent vs. indwelling – 1 vs. 3; P=0.03	F/U 14 days Bacteriuria was defined as a growth of ≥ 10^5 bacteria per ml Symptomatic UTI was defined as either having fever in the absence of other sites of infection with or without symptoms of dysuria or suprapubic discomfort. Sample size of 80 to detect an increase in the proportion of weaning patients off catheter from 42% in the indwelling group to 75% in the intermittent group with 80% power and an alpha of 0.05.
Turi, 2006 [53]	RCT	1	To compare the incidence of complications in patients practicing clean intermittent catheterization vs indwelling catheter	Patients selected from outpatient department during evaluation for symptoms of bladder outlet obstruction or post-operative cases of stricture urethra or referred patients	80	**Pyelonephritis:** Clean intermittent vs. indwelling – 2/40 vs. 10/40; P<0.05 **Epididymo-orchitis:** Clean intermittent vs. indwelling – 1/40 vs. 3/40; P>0.05 **Urosepsis:** Clean intermittent vs. indwelling – 0/40 vs. 2/40; P>0.05	F/U 6 months A colony count of > 100 colonies per ml was considered to be significant bacteriuria Power not reported
Tangtrakul, 1994 [54]	RCT	1	To compare the incidence of UTI using intermittent vs. indwelling catheterization. Patients in the intermittent catheterization group were catheterized with a straight catheter just before the operation and were treated postoperatively	Women who underwent cesarean section and had no history of UTI	98	**Bacteriuria:** Intermittent vs. indwelling – 16/51 vs. 9/47; P>0.05 **Urinary retention requiring recatheterization:** Intermittent vs. indwelling – 20/51 vs. 0/47; statistical differences were not reported	F/U unclear UTI was defined as ≥ 10^5 organisms/ml Urinary retention was defined as inability to void in

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			with intermittent catheterization for urinary retention (defined as unable to void in the presence of clinically apparent bladder distension, or at least every 6 hours while awake). Any patient requiring catheterization more than twice would have a Foley catheter inserted for 24 hours. Patients in the other group had an indwelling Foley catheter placed just before the operation and it was removed on the following day				the presence of clinically apparent bladder distension, or at least every 6 hours while awake Power not reported
Skelly, 1992 [55]	RCT	1,2,6,7,8	To compare the use of indwelling catheters and intermittent catheterization in the management of urinary retention after surgical repair of hip fractures. Indwelling catheters were left in place for 48 hours. If the patient could not void, in-out catheterization was done at 8 hour intervals during the 24 hours. If voiding was still not possible, an indwelling catheter was inserted for another 48 hours. If residual urine was > 150 ml, retention was considered to be unresolved and an indwelling catheter was inserted for another 48 hours. At the end of 5 days, all patients who were not yet voiding underwent intermittent catheterization and were followed up until voiding resumed. Intermittent catheterization was done at 6-8 hour intervals in the intermittent group. Catheterization was stopped when the residual amount of urine after voiding was < 150 ml on two consecutive occasions.	Patients ≥ 60 years admitted with hip fracture and a residual urine volume of >150 ml after initial monitoring.	67	**Bacteriuria on post-op day 5:** Intermittent vs. indwelling – 12/32 vs. 11/35; P>0.05 **Return of voiding on post-op day 5:** Intermittent vs. indwelling – 21/32 vs. 13/35; P<0.01 **Mean number of days for return of voiding:** Intermittent vs. indwelling – 5.1 vs. 9.4; P<0.01 **Mortality after post-op day 5:** Intermittent vs. indwelling – 2/32 vs. 5/35; statistical differences were not reported	F/U until resumption of voiding. A colony count ≥ 10^5 per ml was used to diagnose an infection Power not reported
Michelson, 1988 [56]	RCT	1,6,7,8	To examine the efficacy and risks of two methods of urinary bladder management after total joint replacement surgery. In the indwelling group, indwelling	Patients undergoing total hip and knee replacement	96 patients undergoing 100 hip or knee replacements	**Urinary retention:** Intermittent vs. indwelling – 52% vs. 27%; P<0.01 **Postoperative bacteriuria**: Intermittent vs. indwelling (among	F/U 7 days Urinary infection defined as ≥ 10^4 cfu/ml

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			catheters were placed during the operation and removed the next morning. Thereafter urinary retention was treated with intermittent straight catheterization. If retention continued beyond 36-48 hours after the removal of catheter, another indwelling catheter was placed which remained in place for 48 hours. In the intermittent group, urinary retention was treated by sterile intermittent catheterization as needed.			patients with negative preoperative urinary cultures) – 7/47 vs. 4/36; P>0.05 No catheter vs. any catheter – 17% vs. 5.6% > 0.05 Long term indwelling vs. any other catheterization – 35% vs. 6% - <0.05 **Bladder overdistension (>700 ml):** Intermittent vs. indwelling – 25/56 vs. 3/44; P<0.01 **Risk factors for urinary retention:** *Univariate analysis*: All results P values Age > 60 yrs – <0.05 (P<0.01 in the indwelling group, but P>0.05 in the intermittent group) Sex- > 0.05 (except men < 60 years undergoing intermittent catheterization < 0.05) On the basis of a previous history of urinary symptoms, post-surgical retention or genitourinary surgery, it was not possible to identify prospectively patients who would require postoperative catheterization. 4 or more risk factors were present in only 20% of patients with retention and 19% of patients without retention.	Urinary retention was defined as inability to void in the presence of clinically apparent bladder distension, or at least every 6 hours while awake Power not reported
Johansson, 2002 [57]	Prospective Controlled Study	1,3	The aims of the study were (1) to describe the occurrence of UTI among patients with hip fracture before and after surgery (2) to compare intermittent catheters vs. indwelling catheters and (3) to compare the length of hospital stay among people with and without infection.	Patients admitted to the hospital with traumatic hip fracture.	144	**Risk factors for bacteriuria:** *Univariate analysis:* All results P values Female sex (vs. male sex) – 92.7% vs. 7.3%; statistical differences not reported Age - >0.05 Diabetes - > 0.05 **Bacteriuria:** Intermittent vs. indwelling (among patients who were free of UTI at admission) – 20/63 vs. 11/26; statistical differences were not reported **Length of stay –** Significantly longer hospital stay among patients with UTI (P≤0.05)	F/U one week after last catheterization. Bacteriuria was defined as ≥ 10^5 bacteria/ml Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Oishi, 1995 [58]	Retrospective controlled study	1,3,4	To compare an as needed **straight catheterization protocol** (patients underwent straight catheterization if they did not void within 8 hours of their surgery and then 6 hours pro re nata for an inability to void; if bladder volume > 500 ml, an indwelling catheter placed for 48 hours) with **indwelling catheterization protocol** (indwelling catheter placed during surgery and removed on the morning of the third post-op day)	Patients undergoing primary total hip arthroplasty	95	**UTI:** Straight catheterization protocol vs. indwelling catheterization protocol – 0/49 vs. 1/46; P>0.10 **Bacteriuria:** Straight catheterization protocol vs. indwelling catheterization protocol – 0/49 vs. 1/46; P>0.10 **Bladder distension:** Straight catheterization protocol vs. indwelling catheterization protocol – 20/49 vs. 3/46; P<0.01 **Urinary retention:** Straight catheterization protocol vs. indwelling catheterization protocol – 41/49 vs. 3/46; P<0.01	F/U until catheter removal UTI was defined as a catheterized urine specimen with bacteriuria in conjunction with abnormal leukocyte count (>2/hpf) Bacteriuria was defined as a catheterized urine specimen with > 10^5 colonies of bacteria with a urine leukocyte count ≤ 2/hpf Bladder distension was defined as urine volume > 500 ml obtained at catheterization Urinary retention was defined as an inability to void following catheterization Power not reported
Ritter, 1989 [59]	Prospective controlled study	1,3,	To compare different urinary tract catheterization protocols for urinary retention – (1) in-out urethral catheterization as needed (2) in-out catheterization on the index episode and by anchorage of the closed system catheterization device if a second retention episode occurred and (3) intraoperative sterile anchoring of a closed drainage system	Joint arthroplasty patients	601	**Bacteriuria:** Group 1 vs. Group 2 – 1/165 vs. 2/295; P=0.20 Group 1 vs. Group 3 – 1/165 vs. 0/140; P=0.31 Group 2 vs. Group 3 – 2/295 vs. 0/140; P=0.54	F/U until discharge UTI was defined as > 10^5 cfu/ml. Power not reported
Furuhata, 1988 [60]	Prospective Pre-post study	1,3	To evaluate the utility of intermittent catheterization in patients with urinary retention or residual urine	Patients undergoing surgery for prostatic hypertrophy	259	**Postoperative bacteriuria:** Intermittent catheterization vs. spontaneous voiding – 38/76 vs. 47/119 Indwelling catheterization vs. spontaneous voiding – 26/31 vs. 47/119 Intermittent catheterization vs. indwelling catheterization – 38/76 vs. 26/31 (No significant differences)	F/U 1-2 weeks after surgery Bacteriuria was defined as a bacteria count in culture of ≥ 10^5cells/ml or evidence of many cells after simple staining of urine sediment.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
							Power not reported
Long-term							
Shekelle, 1999 [61]	Systematic review	1,2,3,4,5,6,7,8	To identify risk factors for UTI	Controlled trials in adults and adolescents with neurogenic bladder dysfunction addressing the issue of risk factors for recurrent UTI	22 studies	**Sex:** Two studies reported a higher risk for UTI in females, while 4 other studies did not. The authors concluded that the effect of being a female on the risk of UTI in people with neurogenic bladder remained unanswered. **Level of function:** Four studies did not find an increased rate of UTI among patients with tetraplegia compared with patients with paraplegia. Three other studies reported significant increases in infection in persons with complete lesions while 3 studies did not. The authors felt that given the conflicting nature of the results, no conclusions could be drawn about the effect of completeness of lesion on the risk of UTI. **Bladder physiology:** As the residual volume increased to 300 ml, the rate of UTI over time increased between 4 and 5 fold. Another study reported that a > 20% post void residual was associated with complications. It was likely that increased bladder residual volume was a risk factor for UTI in persons with neurogenic bladder. **Method of drainage:** Results were consistent in 7 of 8 studies that persons using intermittent catheterization had fewer infections than those with indwelling catheters and (when studied) persons voiding without catheters had the lowest rate of UTI in all groups Two RCTs did not report significant differences in UTI between sterile and clean methods for intermittent catheterization. Another non-randomized controlled trial found	Qualitative SR. Studies were determined to be too clinically heterogeneous to support statistical pooling or risk prediction modeling.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						that a sheathed catheter (which amounted to a sterile method) resulted in fewer episodes of bacteriuria when compared with a standard catheter. The authors concluded that the evidence neither supported nor refuted the need to utilize sterile as opposed to clean, intermittent catheterization The authors concluded that the optimum frequency for change of condom catheters was unknown. **Time since injury:** The study measuring UTI in the most rigorous fashion among 3 studies addressing this issue found that a longer time since injury was significantly associated with a higher occurrence of UTI. **Laboratory findings:** A prospective cohort study reported that symptomatic UTIs occurred more frequently following relapsing (regrowth of same bacterium) asymptomatic bacteriuria than recurrent (regrowth of different bacterium) asymptomatic bacteriuria; P <0.03 There were no studies or the data were scarce assessing the effect of socioeconomic and insurance status; psychosocial, behavioral and hygiene factors and domicile on the risk of UTI	
Vickrey, 1999 [62]	Systematic review	1,2,3,4,7,8	To answer the following key questions: (1) What combinations of signs, symptoms and laboratory findings are associated with infection risks to persons with paralysis due to neurogenic bladder? (2) What are the risk factors for recurrent UTIs? (3) What are the risks and benefits of long-term use of antibiotic prophylaxis?	Studies of adults and adolescents with neurogenic bladder due to non-acute spinal cord dysfunction and relevant to a key question.	306 studies	**Indwelling vs. intermittent catheterization** Indwelling catheterization was associated with more frequent infections than that involving intermittent catheterization, which in turn was associated with more frequent infections than methods not involving a catheter. **Antibiotic prophylaxis** Antibiotic prophylaxis significantly reduced bacteriuria among acute spinal cord injury patients (P<0.05) and there was a trend	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						for reduction in bacteriuria among non-acute spinal cord patients (P=0.06). However, antibiotic prophylaxis was not associated with a reduced number of symptomatic infections in the populations studied. Antibiotic prophylaxis resulted in a two-fold increase in the occurrence of antibiotic resistant bacteria.	
3. Suprapubic vs. indwelling							
Short-term							
McPhail, 2006 [63]	Systematic Review	1,2,3,4,5,7,8	To compare suprapubic and transurethral catheterization	RCTs in general/abdominal surgery	6 RCTs	*All results RR(95% CI)* **Bacteriuria** (5 studies): Transurethral catheterization vs. Suprapubic catheterization – 2.02(1.34-3.04) **Recatheterization** (6 studies): Transurethral catheterization vs. Suprapubic catheterization – 1.97(0.68-5.74) **Pain or discomfort** (4 studies): Transurethral catheterization vs. Suprapubic catheterization – 2.94(1.41-6.14)	
Niel-Weise, 2006 [51]	Systematic Review	1,2,3,4,5,6,7,8	To determine the advantages and disadvantages of alternative approaches to catheterization for short term bladder drainage in adults	All randomized and quasi-randomized trials comparing catheter route of insertion for adults catheterized for up to 14 days	17 trials	*1. Urethral catheterization vs. Suprapubic catheterization* (all results RR[95% CI] unless otherwise noted) **Bacteriuria (symptomatic and asymptomatic)** (14 studies) – 2.60(2.12-3.18) **Bacteriuria (symptomatic and asymptomatic) in males** (2 studies) – 1.71(0.87-3.36) **Bacteriuria (symptomatic and asymptomatic) in females** (2 studies) – 4.23(1.87-9.54) **Bacteriuria (symptomatic and asymptomatic) after colposuspension** (1 study) – 7.41(1.02-54.10)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Bacteriuria (symptomatic and asymptomatic) after vaginal repair (1 study) – 1.60(0.82-3.14) **Bacteriuria (symptomatic and asymptomatic) without antibiotic prophylaxis** (1 study) – 6.28(2.49-15.79) **Bacteriuria (symptomatic and asymptomatic) with antibiotic prophylaxis** (1 study) – 6.88(0.35-133.64) **Bacteriuria (symptomatic and asymptomatic) after gynecological surgery** (7 studies) – 2.46(1.95-3.10) **Bacteriuria (symptomatic and asymptomatic) after abdominal surgery** (3 studies) – 1.90(1.14-3.17) **Bacteriuria (symptomatic)** (1 study) – 1.16(0.54-2.48) **Recatheterization** (8 studies) – 4.72(2.94-7.56) **Number of patients catheterized > 5 days** (1 study) – 0.62(0.49-0.80) **Mean duration of catheterization** (1 study) – WMD (95% CI) = -1.60(-2.80 to -0.40) Unit of measurement was not specified. 8 other studies reported duration of catheterization, but data were not sufficient to calculate statistical differences. **Number of patients with pain** (2 studies) – 9.30(2.96-29.21) **Number of catheter days with pain** (1 study) – 6.95(3.03-15.92) **Discomfort** (4 studies) – 2.98(2.31-3.85) **Catheter obstruction** (2 studies) – 0.18(0.02-1.49) **Gross hematuria** (2 studies) – 0.97(0.25-3.74) **Microscopic hematuria** (2 studies) – 0.93(0.72-1.20) **Pyuria** (2 studies) – 2.09(1.63-2.68) **Number of patients with febrile morbidity** (1 study) - WMD(95% CI) = 13.50(10.94-16.06) **Number of patients needing antibiotic**	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						therapy (1 study) – 2.78(1.47-5.28) **Number of patients requiring drugs for relief of dysuria** (1 study) – 1.68(1.23-2.28) **Mean hospital stay** (1 study) - WMD(95% CI) = 1.10(0.30 to 1.90) **Number of patients with extended hospital stay** (1 study) – 1.79(1.01-3.16) **Number of patients leaving hospital with catheter** (1 study) – 3.33(1.28-8.67) *2. Urethral catheterization vs. intermittent catheterization* (all results RR[95% CI] unless otherwise noted) **Number of patients with no return of bladder function 48 h after surgery** (1 study)– 0.55(0.30-1.02) **Bacteriuria (symptomatic and asymptomatic)** (2 studies) – 2.90(1.44-5.84) **Urinary symptoms immediately after surgery** (1 study) – 1.54(0.65-3.63) **Postoperative pyrexia** (1 study) – 1.11(0.63-1.95)	
Phipps, 2006 [1]	Systematic review	1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults	Randomized and quasi-randomized trials	39 RCTs	*Note: All results are RR(95% CI) unless otherwise noted* *1. Using a urinary catheter vs. not using a urinary catheter* **Retention of urine** (1 study) – 0.12(0.03-0.47) **UTI** (4 studies) – 1.35(0.75-2.45) **Recatheterization** (3 studies) – 0.32(0.14-0.70) **Post-op urethral stricture** (1 study) – 1.14(0.90-1.44) **Post-op hematuria** (1 study) – 0.73(0.40-1.33) *2. Urethral catheterization vs. suprapubic catheterization* **UTI:** Heterogeneous results, not combined. Of four trials, two suggested a	.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						moderate increase, one a large increase and one a large decrease. **Recatheterization** (2 studies) – 3.66(1.41-9.49) **Post-op hematuria** (1 study) – 5.00(0.21-116.31) **Length of hospital stay in days** (1 study) [WMD(95% CI)] – 1.10(0.30-1.90) **Catheter lockage or bypassing** [OR(95% CI)] (2 studies) – 0.20(0.02-1.72) *3. One type of catheter vs. another type of catheter* **UTI:** Urethral foley catheter with extra drainage hole vs. unmodified foley catheter(1 study) – 0.40(0.15-1.04) **Positive urine culture:** Silver coated bardex catheters vs. latex catheters(1 study) – 0.53(0.20-1.45) *4. One type of catheter management vs. another* **Retention of urine:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.99(0.06-15.54) **Dysuria:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.99(0.06-15.54) **UTI:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.61(0.33-1.14) Cefotaxime 1 hr prior to catheter removal vs. none (1 study) – 0.08(0.00-1.30) Neomycin/Sulfamethiozole vs. placebo (1 study) – 0.18(0.06-0.55) **Positive urine culture:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 1.06(0.70-1.51) **Recatheterization -** Neomycin/Sulfamethiozole vs. placebo (1 study) – 0.50(0.24-1.04)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						5. Larger diameter catheter vs. Smaller diameter catheter No trials found *6. Bladder irrigation* No trials found *7. Shorter duration vs. longer duration catheter* **Retention of urine:** 1 day vs. 3 days(1 study) – 0.80(0.38-1.69) 1-2 days vs. until urine clear(1 study) – 1.02(0.07-15.87) 1 day vs. 2 days (1 study) – 4.64(0.23-94.28) 3 days vs. 28 days (1 study) – 3.00(0.13-69.52) **Post-op urethral stricture:** <1 week vs. 2 weeks (2 studies) – 1.23(0.82-1.84) 3 days vs. 28 days (1 study) – 1.00(0.73-1.36) **UTI:** Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were not significant **Recatheterization:** 1 day vs. 2 days (1 study) – 1.03(0.23-4.71) 1 day vs. 3 days (2 studies) – 1.04(0.36-3.01) 1 day vs. 5 days (1 study) – 4.55(1.68-12.37) 4-6 days vs. 14 days (1 study) – 1.86(0.14-25.38) 1-2 days vs. until urine clear(2 studies) – 0.72(0.24-2.20) **Post-op hematuria:** 1-2 days vs. until urine clear(1 study) – 2.04(0.19-21.81) 1 day vs. 2 days (2 studies) – 1.16(0.34-3.90) **Urinary leakage or incontinence:** 1-2 days vs. until urine clear(2 studies) – 0.43(0.07-2.88) *8. Clamp and release vs. free catheter*	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						drainage: **UTI** (1 study) – 4.00(1.55-10.29) **Delay in return to normal bladder function** (1 study) - 2.50(1.16-5.39) *9. Catheter removal at one time of day vs. another time of day* **UTI:** 0000 hrs vs. 0600 hrs (1 study) – 1.31(0.65-2.66) **Recatheterization:** 0000 hrs vs. 0600 hrs (4 studies) – 0.61(0.34-1.12) 6-7 am vs. 10-11 pm (1 study) – 1.36(0.32-5.77) **Time to first void in hours**[WMD(95% CI)]: 0000 hrs vs. 0600 hrs (1 study) – 0.60(-0.96 to 2.16) **Volume of first void in ml** [WMD(95% CI)]: 0000 hrs vs. 0600 hrs (1 study) – 53.00(4.27-101.73) *10. Trial of void protocol vs. none* No trials found *11. Prefilling bladder prior to catheter removal vs. removal without prefilling* **Recatheterization** [OR(95% CI)] (1 study) – 4.52(0.79-25.97) **Discharge on day of catheter removal** (1 study) – 1.36(0.47-3.91)	
Branagan, 2002 [64]	Systematic review	1,2,3	To compare the use of suprapubic and urethral catheters	Patients undergoing elective colorectal surgery	5 RCTs	**UTI:** 3 studies reported a significant increase in the urethral catheterization group **Urinary retention:** No difference between the two groups in 3 studies **Duration of catheterization:** Was increased in the suprapubic group in 2 studies and there were no differences in two other studies **Pain/ discomfort:** 2 studies reported an increase in the urethral catheterization group	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Patient preference: Suprapubic catheter was shown to be preferred by patients in 3 studies	
Baan, 2003 [65]	RCT	1,2,4,7,8,9	To compare the effects of suprapubic catheterization vs. transurethral catheterization	Adult patients without UTI undergoing a major abdominal procedure requiring a standard bladder catheterization.	146	**Symptomatic UTI:** *Intention to treat:* Suprapubic vs. transurethral – 9/75 vs. 8/71; RR(95% CI) = 1.06(0.43-2.61) *Per-protcol:* Suprapubic vs. transurethral – 8/65 vs. 8/68; P>0.05 **Recatheterization**: Suprapubic vs. transurethral – 9/75 vs. 4/71; statistical differences not reported **Median duration of catheterization (days):** Suprapubic vs. transurethral – 6.5 vs. 4.9; P> 0.05 **Patient satisfaction outcomes:** *All results %, P values for Suprapubic vs. Transurethral* *During catheterization:* Pain in the abdomen – 12 vs. 8; > 0.05 Burning pain – 6 vs. 7; > 0.05 Leakage of urine – 6 vs. 10; > 0.05 False urge – 31 vs. 45; > 0.05 Blood loss – 4 vs. 2; > 0.05 *After catheterization:* Unpleasant removal – 27 vs. 46; > 0.05 No spontaneous voiding – 4 vs. 12; > 0.05 Burning pain during voiding – 10 vs. 15; > 0.05 Incontinence – 4 vs. 9; > 0.05 Abdominal cramps – 8 vs. 5; > 0.05 Overall score (on 5 point likert scale) – Suprapubic vs. transurethral – 8.4 vs. 8.5 **Risk factors for Symptomatic UTI:** *Univariate analysis:* All results RR(95% CI) Female sex – 4.16(1.40-12.20) Recatheterization – 7.16(3.30-15.60)	F/U 6 weeks after surgery UTI was defined as at least one or more of the clinical symptoms (fever, increased micturition frequency, burning pain during voidance and a pain in the lower abdomen), a positive sediment (>10 leukocytes), and a positive urine culture (>10^5 bacterial colonies and <3 bacterial species) 62 patients in each group to decrease UTI from 30 to 8% with a power of 90% and an alpha of 5%

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Duration of catheterization > 7 days – 3.40(1.43-8.04) Relaparotomy – P = 0.07	
Dunn, 2005 [66]	Retrospective cohort study	1,3	To evaluate the outcomes of patients with suprapubic vs. transurethral catheterization	Patients undergoing Burch cystourethropexy	217	Ns in the two respective groups were not reported **Bacteriuria:** Suprapubic vs. transurethral – 2 vs. 3; P = 1.00 **Post-op fever:** Suprapubic vs. transurethral – 0 vs. 1; P = 1.00 **Hospital stay (days):** Suprapubic vs. transurethral – 3.0 vs. 3.5; P = 1.00 **Visits for pain (days):** Suprapubic vs. transurethral – 2.5 vs. 3.5; P<0.01 **Duration of catheterization (days):** Suprapubic vs. transurethral – 9.61 vs. 7.82; P<0.01	F/U unclear UTI was diagnosed by the presence of WBC, RBC, leukocytes and positive culture. Power not reported
Alli, 2003 [67]	Prospective controlled study	1,3	To compare urethral catheterization with combined urethral and suprapubic drainage after repair of intraperitoneal bladder injuries	Patients with intraperitoneal bladder injuries	42	Ns in the two respective groups were not reported **Mortality** – Urethral vs. combined – 3 vs. 4; P = 0.68 **Morbidity** – Urethral vs. combined – 1 vs. 9; P<0.01 **Undefined UTI** – Urethral vs. combined – 1 vs. 4; statistical differences were not reported **Failure to micturate** – Urethral vs. combined – 0 vs. 4; P = 0.04 **Hospital stay (days)** – Urethral vs. combined – 9.1 vs. 15.5; P = 0.03	F/U unclear. Study period was 24 months. UTI not defined Power not reported
Horgan, 1992 [68]	Prospective controlled study	1,3	To compare suprapubic and urethral routes of catheterization	Patients with acute urinary retention due to prostatomegaly who required catheterization	86	**Bacteriuria:** Suprapubic vs. urethral – 10/56 vs. 12/30; P<0.05 **Stricture:** Suprapubic vs. urethral – 0/56 vs. 5/30; P<0.01 **Epididymo-orchitis:** Suprapubic vs. urethral – 0/56 vs. 2/30; statistical differences were not reported **Septicemia:** Suprapubic vs. urethral – 0/56 vs. 1/30; RR(95% CI) statistical differences were not reported	F/U 48 hrs post-op UTI defined as ≥ 10^5 cfu/ml Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Dislodgement: Suprapubic vs. urethral – 12/56 vs. 1/30; statistical differences were not reported	
Dinneen, 1990 [69]	Prospective pre-post study	1,3	To compare suprapubic and urethral catheters	Patients undergoing aortic surgery	131	**Bacteriuria:** Suprapubic vs. urethral – 7/86 vs. 16/45; P<0.05 **Stricture:** Suprapubic vs. urethral – 0/100 vs. 11/52; P<0.01	F/U unclear Bacteriuria defined as > 100,000 bacteria per ml Power not reported Ns and events for bacteriuria are number of urine cultures and not number of patients
van Nagell, 1972 [70]	Prospective controlled study	1,3	To compare suprapubic with urethral drainage	Patients undergoing radical hysterectomy	102	**Bacteriuria:** Suprapubic vs. urethral – 19/84 vs. 8/18; statistical differences were not reported **Fistula:** Suprapubic vs. urethral – 6/84 vs. 2/18; statistical differences were not reported **Intraoperative complications:** Suprapubic vs. urethral – 13/84 vs. 1/18; statistical differences were not reported	F/U until catheter removal Urinary infection defined as > 10^5 colonies/ml Power not reported
Hofmeister, 1970 [71]	Prospective controlled study	1,3	To compare suprapubic versus Foley drainage	Gynecological patients	448	**Postoperative bacteriuria:** Suprapubic vs. Foley for 3-5 days – 9/96 vs. 21/195; statistical differences were not reported Suprapubic vs. Foley for 1 day – 9/96 vs. 4/146; statistical differences were not reported **Postperative morbidity:** Suprapubic vs. Foley – 32.7% vs. 21%; statistical differences were not reported **Satisfactory voiding within 6-8 days:** Suprapubic vs. Foley – 31.8% vs. 16.8%; statistical differences were not reported	F/U 2-3 months Bacteriuria defined as > 10,000 bacteria per ml was considered significant bacteriuria Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Postoperative LOS (> 14 days): Suprapubic vs. Foley – 42/107 vs. 19/195; statistical differences were not reported	
Long-term							
No studies were identified							
4. Suprapubic vs. intermittent							
Short-term							
Jannelli, 2007 [72]	RCT	1,2,6,7,8,9	To compare the risk of significant bacteriuria between clean intermittent self-catheterization (starting post-op day 1) and suprapubic catheterization	Women without pre-op bacteriuria scheduled for surgery for stress urinary incontinence or anterior vaginal wall prolapse.	244	**Bacteriuria:** Clean intermittent vs. suprapubic – 31% vs. 23%; P=0.23 **Patient satisfaction:** All results are mean scores on visual analog scale for clean intermittent vs. suprapubic Overall pain – 3.4 vs. 3.4; P=0.85 Pain from the catheter – 1.4 vs. 1.9; P=0.13 Ease of catheter use – 2.5 vs. 1.4; P<0.01 Frustration – 2.7 vs. 1.6; P=0.01 Limitation on social activities – 1.3 vs. 1.2; P=0.83 Interest in using the method again – 7.1 vs. 8.4; P < 0.01 **Mean duration of catheterization (days):** Clean intermittent vs. suprapubic – 5.3 vs. 5.2; P=0.97	F/U post-op day 7 Significant bacteriuria was defined as > 10^5 cfu/ml A sample size of 113 patients per group was needed in order to detect a decrease in significant bacteriuria from 25% to 10% with 80% power and an alpha of 0.05
Roberts, 2006 [73]	RCT	1,6,7,8,9	To assess the potential benefits of intermittent self-catheterization (starting post-op day 5 until residual urine volume < 100 ml) over suprapubic catheterization in postoperative bladder care (until residual urine volume < 100 ml)	Women with early stage cervical cancer following radical hysterectomy	40	**Bacteriuria:** All results intermittent vs. suprapubic Day 3 – 8/19 vs. 1/17; P=0.05 Day 5 – 12/19 vs. 3/17; P<0.01 Day 7 – 7/19 vs. 6/17; P=0.4 Day 14 – 4/19 vs. 9/17; P=0.16 Day 21 – 2/19 vs. 2/17; P=0.21 **Median length and requirement for**	F/U 21 days UTI defined as positive urine culture Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						bladder care (days): Intermittent vs. suprapubic – 17 vs. 20; P=0.83 **Urinary symptom questionnaire:** There were significant differences in the frequency of nocturia (P<0.01) and bladder emptying (P=0.05), but the direction of effect was not reported. **Patient acceptability questionnaire:** Intermittent catheterization was significantly more acceptable (P<0.01), allowed greater freedom to lead a normal life (P=0.00), fewer disturbances at night (P<0.01) and caused lesser anxiety/embarrassment (P<0.01) **Quality of life questionnaire:** There were significant differences between nausea/vomiting and insomnia, but the direction of effect was not reported.	
Long-term							
Noll, 1988 [74]	Retrospective pre-post study	1,3	To compare intermittent catheterization and suprapubic catheterization	Patients with traumatic spinal cord injury	86	**Undefined UTI within the first 35 days post-injury:** Intermittent vs. suprapubic – 71.9% vs. 50% ; P<0.05 **Time to first infection:** P>0.05	F/U unclear UTI not defined Power not reported
5. Clean intermittent vs. sterile intermittent							
Short-term							
Carapeti, 1996 [75]	RCT	1	To compare sterile vs. non sterile urethral catheterization	General surgical patients to be catheterized pre-operatively after induction of anesthesia	156	**All UTI:** Non-sterile vs. sterile – 9/82 vs. 7/74; P>0.10 Female vs. male – 10/84 vs. 6/72; P>0.10 **Cost (£):**Non-sterile vs. sterile – 3.06 vs. 7.49; statistical differences were not reported	F/U 3rd post-operative day UTI was defined as bacteriuria > 10^5 with or without clinical symptoms Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Long-term							
Shekelle, 1999 [61]	Systematic review	1,2,3,4,5,6,7,8	To identify risk factors for UTI	Controlled trials in adults and adolescents with neurogenic bladder dysfunction addressing the issue of risk factors for recurrent UTI	22	**Sex:** Two studies reported a higher risk for UTI in females, while 4 other studies did not. The authors concluded that the effect of being a female on the risk of UTI in people with neurogenic bladder remained unanswered. **Level of function:** Four studies did not find an increased rate of UTI among patients with tetraplegia compared with patients with paraplegia. Three other studies reported significant increases in infection in persons with complete lesions while 3 studies did not. The authors felt that given the conflicting nature of the results, no conclusions could be drawn about the effect of completeness of lesion on the risk of UTI. **Bladder physiology:** As the residual volume increased to 300 ml, the rate of UTI over time increased between 4 and 5 fold. Another study reported that a > 20% post void residual was associated with complications. It was likely that increased bladder residual volume was a risk factor for UTI in persons with neurogenic bladder. **Method of drainage:** Results were consistent in 7 of 8 studies that persons using intermittent catheterization had fewer infections than those with indwelling catheters and (when studied) persons voiding without catheters had the lowest rate of UTI in all groups Two RCTs did not report significant differences in UTI between sterile and clean methods for intermittent catheterization. Another non-randomized controlled trial found that a sheathed catheter (which amounted to a sterile method) resulted in fewer episodes	Qualitative SR. Studies were determined to be too clinically heterogeneous to support statistical pooling or risk prediction modeling.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						of bacteriuria when compared with a standard catheter. The authors concluded that the evidence neither supported nor refuted the need to utilize sterile as opposed to clean, intermittent catheterization The authors concluded that the optimum frequency for change of condom catheters was unknown. **Time since injury:** The study measuring UTI in the most rigorous fashion among 3 studies addressing this issue found that a longer time since injury was significantly associated with a higher occurrence of UTI. **Laboratory findings:** A prospective cohort study reported that symptomatic UTIs occurred more frequently following relapsing (regrowth of same bacterium) asymptomatic bacteriuria than recurrent (regrowth of different bacterium) asymptomatic bacteriuria; P <0.03 There were no studies or the data were scarce assessing the effect of socioeconomic and insurance status; psychosocial, behavioral and hygiene factors and domicile on the risk of UTI	
Moore, 2006 [76]	RCT	1,2,6,7,8	To compare the onset of symptomatic UTI in patients randomized to clean vs. sterile intermittent catheterization technique	Adults with recent quadriplegia due to spinal cord injury who required on-going intermittent catheterization	36	**Symptomatic UTI:** Clean vs. sterile – 6/16 vs. 9/20; P>0.05 **Time to onset of symptomatic UTI (weeks):** Clean vs. sterile – 3.0 vs. 3.6 (P=0.49) ; HR(95% CI) - 1.25(0.44-3.59) **Bacteriuria:** Clean vs. sterile – 7/16 vs. 9/20; statistical differences were not reported **Cost (£):** Clean vs. sterile – 3.4 vs. 7.5; statistical differences were not reported	F/U during hospitalization or until patients began self-catheterization, were placed on antibiotics, developed a symptomatic UTI, were discharged from hospital or requested withdrawal Symptomatic UTI was defined as ≥10^5 cfu/ml, pyuria (>10 WBC/hpf) any of the following symptoms: chills, fever(≥ 38 C), general malaise increased spasticity and/or autonomic dysreflexia and the

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
							presence of usual pathogens Asymptomatic bacteriuria was defined as ≥10^5 cfu/ml, with one or more usual pathogens identified, absence of symptoms and absence of pyuria Post-hoc power analysis suggested that the study sample size was capable of detecting a hazard ratio of 2.7 for symptomatic UTI at an alpha of 0.05 with 80% power.
Schlager, 2001 [77]	Crossover RCT	1	To compare single-use sterile catheters and reused clean catheters	Patients with myelomenigocele who had neurogenic bladder with reflux and were on intermittent catheterization 4 times per day.	10	**Bacteriuria:** Clean vs. Sterile – 76% vs. 73%; P=0.54	F/U 8 months Bacteriuria was defined as a ≥ 10^4 cfu/ml of urine obtained by bladder catheterization. Power not reported
Prieto-Fingerhut, 1997 [78]	RCT	1	To determine the effect of nonsterile and sterile intermittent catheterization on the incidence of UTI	Patients with spinal cord injury	29	**Symptomatic UTI:** Nonsterile vs. sterile – 9/15 vs. 8/14; statistical differences were not reported **UTI:** Nonsterile vs. sterile – 42.4% vs. 28.6%; P>0.05 (based on the results of culture; not sure what it represents) **Bacteriuria:** Nonsterile vs. sterile – 51.5% vs. 39.3%; P>0.05 **Pyuria:** Nonsterile vs. sterile –54.5% vs. 34.0%; P>0.05 **Cost:** *All results nonsterile vs. sterile* Antibiotic therapy - $640 vs. $275 Catheterization kits - $1584 vs. $5880 Total cost - $2224 vs. $6155 (Statistical differences were not reported for this outcome)	F/U unclear UTI defined using the criteria published by the National Institute on Disability and Rehabilitaion Research Bacteriuria defined as > 10,000 organisms/ml of urine. Pyuria defined as > 5 WBC/hpf Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Duffy, 1995 [79]	RCT	1,7	To compare the safety and cost of clean vs. sterile intermittent bladder catheterization	Residents of long-term care facilities with urinary retention	82	**Symptomatic UTI:** Clean vs. sterile – 20/38 vs. 22/42; P>0.05 **Time to symptomatic UTI:** Clean vs. sterile – P=0.71 (it was measured in terms of the days to first treatment episode) **Number of treatment episodes:** Clean vs. sterile – 0.01/day vs. 0.01/day; statistical differences not clearly reported **Average cost per catheterization:** Clean vs. sterile – $4.00 vs. $6.25; P<0.01 **Antibiotic cost for the first treatment episode:** Clean vs. sterile – P>0.05 **Mean nursing time (minutes):** Clean vs. sterile – 8 vs. 9; P<0.01 **Risk factors for symptomatic UTI:** History of UTI (defined as ≥2 symptomatic episodes of UTI within the past 6 months) - P<0.05	F/U 90 days UTI was defined as – (1) The presence of > 10^5 colonies/ml of a single organism coupled with the presence of one or more signs or symptoms of UTI (2) Bacteriuria of a lesser colony count coupled with one or more symptoms or signs of UTI (3) The presence of one or more signs or symptoms of UTI coupled with > 10 WBCs/hpf on urinalysis Post-hoc power analysis showed 61% power to detect a 50% reduction in UTI at an alpha of 5%
Moore, 1993 [80]	Crossover RCT	1,4,7,8	To compare clean intermittent self catheterization and sterile single use catheterization	Children with spina bifida	30	**Bacteriuria:** Clean vs. sterile – 68/180 vs. 68/180; P>0.05 *Catheterization by Self vs. Parent* Females, clean catheters – 39% vs. 40%; P>0.05 Females, sterile catheters – 36% vs. 42%; P>0.05 Males, clean catheters – 43% vs. 25%; P>0.05 Males, sterile catheters – 33% vs. 37%; P>0.05	F/U 12 months Positive culture defined as ≥ 10^3 cfu/ml Power not reported Ns and events in the results column are the number of urine samples and not the number of patients
Joseph, 1991 [81]	RCT	1,6	To compare clean and sterile catheterization	Nursing home patients	14	**Symptomatic UTI:** Clean vs. sterile – 2/8 vs. 3/6; statistical differences were not reported **Major UTI:** Clean vs. sterile – 1/8 vs. 1/6; statistical differences were not reported **Deaths:** Clean vs. sterile – 0/8 vs. 0/6;	F/U ~ 12 weeks Bacteriuria defined as a urine culture > 10^5 bacteria/ml Major UTI defined as temperature > 38 C, bacteriuria nd transfer to acute

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						statistical differences were not reported **Bacteremia:** Clean vs. sterile – 0/8 vs. 0/6; statistical differences were not reported **Cost per catheterization:** Clean vs. sterile – $0.48 vs. $2.03; statistical differences were not reported	care. Minor UTI were diagnosed on the basis of dysuria or frequency without elevation of temperature. Power not reported
Anderson, 1980 [82]	Prospective study with historical controls	1,3	To compare the infection rates of patients on non-sterile intermittent catheterization and antibiotic prophylaxis (oral nitrofurantoin/bladder instillation of neomycin and polymixin) with a historical control group of patients on sterile intermittent catheterization and the same prophylaxis	Male patients with acute (<30 days) spinal cord injury.	50	**Bacteriuria (per 1000 catheterizations:** Non-sterile vs. sterile – 8.3 vs. 2.8; P<0.05 Frequency of catheter change – 4 hours vs. 8 hours – 6.1 vs. 13.9 (P<0.05)	F/U 28 weeks A bacterial count of more than 10^4 cfu/L indicated infection. Power not reported
6. Comparison among multiple methods							
Short-term							
No studies identified							
Long-term							
De Ruz, 2000 [17]	Prospective cohort study	1,3,4,6,7	To identify risk factors for UTI	Adult spinal cord injury patients with injury ≤ 60 days before enrollment, neurogenic bladder dysfunction and injury below C4	128	**Symptomatic UTI:** All results OR(95% CI) *1. Univariate analysis* Age older than 40 yrs – 1.38(1.01-1.88) Hyperreflexic bladder – 1.38(1.03-1.86) Cervical injury – 1.39(1.04-1.85) Functional independence measure score < 74 – 1.49(1.08-2.06) Indwelling catheterization greater than 30 days – 1.53(1.12-2.10) Vesicoureteral reflux – 1.77(1.12-2.81) Invasive procedure – 4.26(3.15-5.76) Indwelling catheter – 7.77(5.80-10.40) Clean intermittent catheterization – 0.42(0.31-0.58)	F/U 38 months UTI was defined as a colony count of ≥ 10^5 cfu/ml without a fever of 38 C and two symptoms, including bladder overdistension, lower abdominal pain, increased urinary incontinence, increased spasticity, autonomic hyperreflexia, and/or increased sweating and malaise Bacteriuria was defined as a colony count of ≥ 10^5 cfu/ml

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Condom catheter – 0.24(0.15-0.40) Suprapubic catheterization – 0.04(0.04-0.19) Normal voiding – 0.04(0.01-0.17) Patient sex, time of evolution, type of injury, co-morbidity, etiology, lithiasis, surgery, previous antimicrobial treatment and immunosuppression were not associated. *2. Multivariate analysis - Model 1 (Defined all risk factors in patients who presented with at least UTI episode during hospitalization)* Cervical injury – 2.99(1.12-7.97) Invasive procedure – 2.62(1.02-6.69) Indwelling catheterization greater than 30 days – 4.04(1.24-13.06) *3. Multivariate analysis - Model 2 (Defined risk factors in patients who presented with repeat UTIs during hospitalization)* Functional independence measure score < 74 – 9.96(2.33-42.11) Vesicoureteral reflux – 22.86(2.31-225.87) **Bacteriuria:** All results OR(95% CI) Indwelling catheter – 2.70(2.32-3.20) Clean intermittent catheterization – 1.16(1.01-1.35) Condom catheter – 0.46(0.38-0.56) Suprapubic catheterization – 0.06(0.04-0.10) Normal voiding – 0.05(0.03-0.10)	and no fever or other symptoms Power not reported
Weld, 2000 [83]	Retrospective Controlled Study	1,3,4	To compare the bladder management methods of chronic urethral catheterization, clean intermittent catheterization, spontaneous voiding and suprapubic catheterization in spinal cord injury patients.	Patients with post-traumatic spinal cord injury.	316	**Epididymitis:** Urethral had a higher rate than suprapubic (P<0.01), intermittent (P<0.01) and spontaneous voiding (P<0.01) groups. Spontaneous had a higher rate than intermittent group (P<0.01) No other significant differences **Pyelonephritis:** Urethral had a higher rate than	Mean F/U 18 years UTI not defined Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						intermittent group (P<0.01) No other significant differences **Upper tract calculi:** Urethral had a higher rate than intermittent (P<0.01) and spontaneous voiding (P<0.01) groups No other significant differences **Bladder calculi:** Intermittent had a lower rate than suprapubic (P<0.01) and spontaneous voiding (P<0.01) groups No other significant differences **Urethral stricture:** Urethral had a higher rate than suprapubic (P<0.01), intermittent (P<0.01) and spontaneous voiding (P<0.01) groups. No other significant differences **Periurethral abscess:** Urethral had a higher rate than intermittent group (P<0.01) No other significant differences **Vesicoureteral reflux:** Intermittent had a lower rate than urethral (P<0.01) and suprapubic (P<0.01) groups Spontaneous had a lower rate than suprapubic group (P<0.01) No other significant differences **Abnormal upper tract:** Intermittent had a lower rate than urethral (P<0.01) and suprapubic (P<0.01) groups No other significant differences	
Lloyd, 1986[84]	Prospective controlled study	1,3	To compare different methods of initial bladder management in spinal cord injured patients – (1) intermittent catheterization program within 36 hours of injury (2) suprapubic trocar within 36 hours of	Spinal cord injured patients	204	**Bacteriuria:** *All results in the order of the groups given in study objective* Infections between hospitalization and discharge from the hospital – 21/21; 21/21; 105/106; 23/23; 31/33 (No significant differences)	F/U 1 year Urine cultures were considered positive if colony counts were 10^5 colonies/ml for clean catch specimens or

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			injury (3) urethral catheters in place for more than 36 hours before intermittent catheterization was begun (4) indwelling urethral catheter drainage throughout the hospitalization and discharged from the hospital with indwelling catheters (5) intermittent catheterization in a community hospital			Sterile at first annual follow-up visit – 5/17; 7/19; 36/99; 0/17; 11/29 ((No significant differences) Infected > 1 time after discharge from hospital – 12/18; 14/20; 77/97; 17/17; 21/29 (No significant differences) **Chills and fever (≥1 episode):** *All results in the order of the groups given in study objective* From injury to hospital discharge – 4/21; 4/21; 9/104; 4/23; 2/33(No significant differences) Discharge to 1 year after injury – 4/17; 8/18; 26/97; 8/16; 6/22(No significant differences) **Urinary complications:** *All results in the order of the groups given in study objective* *At hospital discharge* Orchitis-epididymitis – 0/21; 0/21; 2/106; 0/23; 2/33 Penile skin – 0/21; 1/21; 2/106; 0/23; 2/33 Bladder calculi – 1/21; 3/21; 13/106; 2/23; 4/33 Renal calculi – 0/21; 0/21; 1/106; 1/23; 1/33 Hyperreflexia – 1/21; 0/21; 5/106; 1/23; 1/33 *At 1 year after injury* Orchitis-epididymitis – 1/21; 0/21; 2/106; 0/23; 1/33 Penile skin – 2/21; 2/21; 11/106; 0/23; 5/33 Bladder calculi – 1/21; 2/21; 9/106; 4/23; 6/33 Renal calculi – 1/21; 0/21; 1/106; 1/23; 1/33 Hyperreflexia – 0/21; 1/21; 5/106; 1/23; 1/33 (No significant differences) **Severe pyelocaliectasis (% of renal**	1000 colonies per ml for catheter specimens Power not reported.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						units) *All results in the order of the groups given in study objective* At hospital discharge – 0; 0; 0; 0; 0 (No significant differences) At 1 year after injury – 0; 0; 3.2; 0; 0 (No significant differences) **Urinary procedures:** *All results in the order of the groups given in study objective* <u>*At hospital discharge*</u> Cystoscopy – 7/21; 11/21; 39/106; 3/23; 11/33 External sphincterotomy/bladder neck reconstruction – 1/21; 1/21; 1/106; 0/23; 0/33 Litholapaxy – 1/21; 0/21; 12/106; 2/23; 3/33 Cystolithotomy – 0/21; 0/21; 1/106; 0/23; 0/33 Cystotomy – 0/21; 0/21; 0/106; 0/23; 0/33 <u>*At 1 year after injury*</u> Cystoscopy – 1/21; 3/21; 21/106; 6/23; 5/33 External sphincterotomy/bladder neck reconstruction – 0/21; 4/21; 3/106; 0/23; 0/33 Litholapaxy – 1/21; 1/21; 8/106; 4/23; 5/33 Cystolithotomy – 0/21; 0/21; 1/106; 0/23; 0/33 Cystotomy – 0/21; 0/21; 1/106; 0/23; 1/33 (No significant differences)	

GRADE Table

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE	Increase GRADE	GRADE of Evidence for Outcome	Overall GRADE of Evidence Base

					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Condom vs. indwelling catheterization	Bacteriuria, symptomatic UTI or death*	1 RCT [48]	Significantly increased risk with indwelling catheterization, particularly in men without dementia	High	0	0	0	-1	0	0	0	0	Moderate	Moderate
	Bacteriuria*	1 RCT [48]	No significant differences were found	High	0	0	0	-1	0	0	0	0	Moderate	
	Bacteremia	1 OBS [49]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	
	Mortality	1 RCT [48]	Statistical differences were not reported	High	-1	0	0	-1	0	0	0	0	Low	
	Patient satisfaction*	1 RCT [48] 1 OBS [50]	Significantly increased comfort and decreased pain with condom catheterization in both studies. Also a significant decrease in restriction in the OBS [50]	High	0	0	0	0	0	0	0	0	High	
Intermittent vs. indwelling catheterization	Symptomatic UTI*	2 RCT [52, 53] 1 OBS [83]	Significantly decreased risk of pyelonephritis with intermittent catheterization 1 RCT [53] and 1 OBS [83] . No significant differences were found in the other RCT [52]	High	-2	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/Unspecified UTI*	3 SR [51, 61, 62] 4 RCT [52, 54-56] 5 OBS [57-60, 84]	Significantly decreased risk with intermittent catheterization in 1 SR [51] . 2 SRs noted a decreased risk with intermittent catheterization, but statistical differences were not reported [61, 62] . No significant differences were found in 4 RCTs [52, 54-56] and 4 OBS [58-60, 84] . Statistical differences were not reported in 1 OBS [57]	High	0	0	-1	0	0	0	0	0	Moderate	
	Bacteremia	1 RCT [53]	No significant differences were found	High	-1	0	0	-1	0	0	0	0	Low	
	Urinary retention*	1 SR [51] 4 RCT [52, 54-56] 1 OBS [58]	Significantly increased risk with intermittent catheterization in 1 RCT [56] and 1 OBS [58] . and decreased risk in 1 RCT [55] . Suggestions of increased risk were found in 1 SR [51] and 2 RCTs [52, 54] , although no significant differences were reported.	High	0	-1	0	0	0	0	0	0	Moderate	
	Calculi	2 OBS [83, 84]	Significantly decreased risk of upper tract calculi with intermittent catheterization, but no significant differences in bladder calculi in 1 OBS [83] . No significant differences in upper or lower tract calculi were found in the other OBS [84]	Low	-1	0	0	0	0	0	0	0	Very Low	
	Stricture	1 OBS [83]	Significantly decreased risk with intermittent catheterization	Low	-1	0	0	0	0	0	0	0	Very Low	
	Vesicoureteral reflux	1 OBS [83]	Significantly decreased risk with intermittent catheterization	Low	-1	0	0	0	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Mortality	1 RCT [55]	Statistical differences were not reported	High	-1	0	0	-1	0	0	0	0	Low	
Suprapubic vs. indwelling urethral catheterization	Symptomatic UTI*	1 SR [51] 1 RCT [65] 1 OBS [83]	No significant differences were found	High	0	0	0	-1	0	0	0	0	Moderate	Moderate
	Bacteriuria/Unspecified UTI*	4 SR [1, 51, 63, 64] 6 OBS [66, 68-71, 84]	Significantly increased risk with indwelling catheterization in 3 SR [51, 63, 64] and 2 OBS [68, 69]. Discrepant results in 1 SR [1]. No significant differences were found in 2 OBS [66, 84]. Statistical differences were not reported in 2 OBS [70, 71]	High	0	-1	0	0	0	0	0	0	Moderate	
	Bacteremia	1 OBS [68]	Statistical differences were not reported	Low	0	0	0	-1	0	0	0	0	Very Low	
	Recatheterization*	3 SR [1, 51, 63] 1 RCT [65]	Significantly increased risk with indwelling catheterization in 2 SRs [1, 51]. No significant differences were found in 1 SR [63]. Statistical differences were not reported in the RCT [65]	High	0	0	0	0	0	0	0	0	High	
	Urinary retention	1 SR [64] 1 OBS [71]	No significant differences were found in the SR [64]. Statistical differences were not reported in the OBS [71] .	High	-1	0	0	-1	0	0	0	0	Low	
	Hospital length of stay	2 SR [1, 51] 2 OBS [66, 71]	Significantly increased risk with indwelling catheterization in 2 SRs [1, 51]. No significant differences in 1 OBS [66]. Statistical differences were not reported in 1 OBS [71]	High	-1	0	0	-1	0	0	0	0	Low	
	Duration of catheterization*	2 SR [51, 64] 1 OBS [66]	Significantly increased risk with suprapubic catheterization in 1 SR [51] and 1 OBS [66]. Suggestion of increase in 1 SR [64].	High	0	0	0	-1	0	0	0	0	Moderate	
	Pain/discomfort*	3 SR [51, 63, 64]	Significantly increased risk with indwelling catheterization in all studies	High	0	0	0	0	0	0	0	0	High	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
		1 OBS [66]												
	Patient satisfaction*	1 SR [64] 1 RCT [65]	Suprapubic catheter was shown to be preferred in 1 SR [64] . No significant differences in patient satisfaction outcomes were found in 1 RCT [65]	High	0	-1	0	0	0	0	0	0	Moderate	
	Stricture*	3 OBS [68, 69, 83]	Significantly increased risk with indwelling catheterization in all studies	Low	0	0	0	0	0	+1	0	0	Moderate	
	Dislodgement	1 OBS [68]	Statistical differences were not reported	Low	0	0	0	-1	0	0	0	0	Very Low	
	Calculi	2 OBS [83, 84]	No significant differences were found	Low	-1	0	0	0	0	0	0	0	Very Low	
	Vesicoureteral reflux	1 OBS [83]	No significant differences were found	Low	-1	0	0	0	0	0	0	0	Very Low	
Suprapubic vs. intermittent catheterization	Symptomatic UTI*	1 OBS [83]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria/Unspecified UTI*	2 RCT [72, 73] 2 OBS [74, 84]	Significantly increased risk with intermittent catheterization in 1 OBS [74] and during early follow-up in 1 RCT [73] . No significant differences were found in 1 RCT [72] , 1 OBS [84] and during late follow-up in 1 RCT [73]	High	0	-1	-1	0	0	0	0	0	Low	
	Duration of catheterization*	2 RCT [72, 73]	No significant differences were found	High	0	0	-1	0	0	0	0	0	Moderate	
	Patient satisfaction*	2 RCT [72, 73]	1 RCT [72] showed mixed results. The other RCT [73] showed significantly improved patient acceptability with intermittent catheterization.	High	0	-1	-2	0	0	0	0	0	Very Low	
	Stricture*	1 OBS [83]	No significant differences were found	Low	-1	0	0	0	0	0	0	0	Very Low	
	Calculi*	2 OBS [83,	Significantly decreased risk of bladder calculi with intermittent	Low	-1	0	0	0	0	0	0	0	Very Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
		[84]	catheterization, but no significant differences in upper tract calculi in 1 OBS [83] . No significant differences in upper or lower tract calculi were found in the other OBS [84]											
	Abnormal upper tract*	1 OBS [83]	Significantly decreased risk with intermittent catheterization	Low	-1	0	0	0	0	0	0	0	Very Low	
	Vesicoureteral reflux*	1 OBS [83]	Significantly decreased risk with intermittent catheterization	Low	-1	0	0	0	0	0	0	0	Very Low	
Clean vs. sterile intermittent catheterization	Symptomatic UTI*	4 RCT [76, 78, 79, 81]	No significant differences were found in 2 RCTs [76, 79] . Statistical differences were not reported in 2 RCTs [78, 81]	High	-1	0	0	0	0	0	0	0	Moderate	Moderate
	Bacteriuria/Unspecified UTI*	1 SR [61] 6 RCT [75-78, 80, 81] 1 OBS [82]	Significantly decreased risk with the sterile method in the OBS [82] . No significant differences were found in 1 SR [61] and 4 RCTs[75, 77, 78, 80] . Statistical differences were not reported in 2 RCTs [76, 81]	High	-1	0	0	0	0	0	0	0	Moderate	
	Time to infection	2 RCT [76, 79]	No significant differences were found	High	-1	0	0	0	0	0	0	0	Moderate	
	Nursing time	1 RCT [79]	Significantly decreased with the clean method	High	-1	0	0	-1	0	0	0	0	Low	
	Mortality	1 RCT [81]	Statistical differences were not reported	High	-1	0	0	-1	0	0	0	0	Low	

* These modifiers can impact the GRADE by 1 or 2 points

B. What are the risks and benefits associated with different catheters or collecting systems?

TABLE 5: RISKS AND BENEFITS ASSOCIATED WITH DIFFERENT CATHETERS OR COLLECTING SYSTEMS

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
1. Silver-coated Catheter							
Brosnahan, 2006 [85]	Systematic review	1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization	All randomized and quasi randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults	18 trials	*Note: All results are RR(95% CI) unless otherwise noted* *1. Antiseptic vs. standard catheter* **Bacteriuria:** Silver oxide catheters vs. standard catheters (duration not specified) (3 studies) - 0.89(0.68-1.15) Silver alloy catheters vs. standard catheters (patients catheterized for < 1 week) (5 studies) - 0.36(0.24-0.52) Silver alloy catheters vs. standard catheters (patients catheterized for > 1 week) (3 studies) - 0.67(0.50-0.90) Silver oxide catheters vs. standard catheters in women (duration not specified) (1 study) – 0.63(0.45-0.89) Silver oxide catheters vs. standard catheters in men (duration not specified) (1 study) – 1.62(0.91-2.88) Silver oxide catheters vs. standard catheters in all participants receiving systemic antibiotics (duration not specified) (1 study) – 0.67(0.45-0.99) Silver oxide catheters vs. standard catheters in women receiving systemic antibiotics (duration not specified) (1 study) – 0.50(0.31-0.79) Silver oxide catheters vs. standard catheters in men receiving systemic antibiotics (duration not specified) (1 study) – 1.02(0.49-2.13) **Symptomatic UTI:** Silver alloy catheters vs. standard catheters (7 studies) - 0.60(0.50-0.73) **Urethral secretions:** Silver oxide catheters vs. standard catheters (duration not specified) (1 study) – 0.72(0.25-2.03) **Pain:**	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Silver oxide catheters vs. standard catheters (duration not specified) (1 study) – 1.43(0.48-4.27) *2. Antibiotic impregnated vs. standard catheter* **Bacteriuria:** Patients catheterized for < 1 week (1 study) - 0.36(0.18-0.73) Patients catheterized for > 1 week (1 study) - 0.94(0.86-1.03) **Symptomatic UTI** (1 study) - 0.20(0.03-1.63) *3. One type of standard catheter vs. another standard catheter* **Bacteriuria:** Silicone vs. latex (1 study) – 1.07(0.23-5.01) **Symptomatic UTI:** Hydron coated latex vs. plain latex (1 study) – 0.94(0.66-1.34) Hydron coated latex vs. PVC balloon (1 study) – 0.87(0.63-1.19) PVC balloon vs. plain latex (1 study) – 1.09(0.81-1.45) Hydrogel vs. silicone (1 study) – 0.82(0.46-1.47) **Burning in urethra:** Silicon vs. non-silicone (1 study) – 0.28(0.13-0.60) **Urethritis:** Silicon vs. latex (1 study) – 0.09(0.01-0.68) **Urethral reaction:** *All results WMD (95% CI)* Hydrogel coated latex vs. siliconised latex (1 study) – 0.00(-3.51 to 3.51) Full silicone vs. hydrogel coated latex (1 study): -16.00(-18.84 to -13.16) Full silicone vs. siliconised latex (1 study): -16.00(-18.96 to -13.04)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Crnich, 2007 [86]	Meta-analysis	NA	To test the hypothesis that the efficacy of silver-hydrogel coated (silver-alloy) catheters differs on the basis of whether the control catheter is latex or silicone	Randomized or quasi-randomized trials of nitrofurazone-coated or silver alloy-coated antimicrobial urinary catheters short term (<30 days) bladder drainage.	7 trials	**Symptomatic UTI:** Silver-alloy vs. latex (4 studies) – RR(95% CI) = 0.35(0.23-0.55) Silver-alloy vs. silicone (4 studies) – RR(95% CI) = 0.82(0.70-0.96)	It was a reanalysis of the data reviewed by Johnson et al [87]
Johnson, 2006 [87]	Systematic Review	1,2,3,4,7,8	To assess antimicrobial (nitrofurazone-coated or silver alloy-coated) urinary catheters for preventing CA-UTI	Randomized or quasi-randomized trials of nitrofurazone-coated or silver alloy-coated antimicrobial urinary catheters short term (<30 days) bladder drainage.	12 trials	**Bacteriuria:** Range of RRs (12 studies) – 0.08 to 0.94 (95% CI included 1.0 for 7 studies) Range of RRs for nitrofurazone coated catheters (3 studies)– 0.08 to 0.68 (95% CI included 1.0 in all 3 studies) Range of RRs for pre-1995 silver coated catheters (4 studies) – 0.24 to 0.45 (95% CI was less than 1.0 for all studies) Range of RRs for post-1995 silver coated catheters(5 studies) – 0.53 to 0.94 (95% CI included 1.0 for 4 studies) (The difference between the median RRs for pre and post 1995 studies was statistically significant; P<0.01) The apparent protective effect of the test catheter was greater when the control catheter was latex rather than silicone. Studies involving urologic patients yielded larger effect sizes than those involving other types of patients, as did studies that excluded patients receiving antimicrobial agent therapy (Quantitative summaries not available) **Microbial resistance:** Among studies that reported microbiological outcomes by study group, no evidence suggested that test catheter recipients experienced an increased incidence of specific microbial types that are typically resistant to the antimicrobial compound used.	
Niël-Weise, 2002 [88]	Systematic review	1,2,3,4,7,8	To compare the effectiveness of silver-coated vs. uncoated catheters for the prevention of UTI in catheterized patients.	RCTs, clinical trials and systematic reviews/meta-analyses which included patients undergoing bladder catheterization with either a silver-coated or an uncoated catheter.	6 primary studies and 1 meta-analysis	**Bacteriuria:** Only 3 of the included studies demonstrated a significant effect favoring silver-coated catheters, and these were graded as poor quality by the authors. The study with the highest quality score did not	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						demonstrate significant results. No meta-analyses were performed. The authors concluded that additional studies were required before silver-coated catheters could be recommended.	
Saint, 1998 [89]	Systematic review	1,2,3,4,6,7,8	To compare silver-coated urinary catheters with standard non-coated indwelling catheters	Trials that used a silver-coated catheter in the treatment group, an uncoated urinary catheter in the control group and reported sufficient data to calculate effect estimates for bacteriuria	8 trials	*All results OR(95% CI) Silver coated vs. control catheter* **Bacteriuria:** All silver-coated catheters vs. control (8 studies) – 0.59(0.42-0.84) Silver alloy catheters vs. control (4 studies) - 0.24(0.11-0.52) Silver oxide catheters vs. control (4 studies) – 0.79(0.56-1.10) **Sensitivity analyses:** *Based on the type of randomization procedure* Truly randomized trials (6 studies)-0.27(0.13-0.58) Quasi-randomized trials (2 studies) - 0.87(0.64-1.18) *Based on gender* Women – 0.57(0.38-0.86) Men – 1.18(0.65-2.14)	
Reiche, 2000 [90]	RCT	1,2,4,7,8	To test the effect on UTI of a newly designed urine-collecting system containing an antibacterial device which slowly releases silver ions onto the inner surface of the system	Adults needing continuous indwelling bladder catheterization	170	**Bacteriuria:** Antibacterial system vs. control system – 16/83 vs. 21/87; HR(95% CI) = 0.68(0.33-1.28) Log rank chi-squared = 1.55; P=0.11 *Among patients receiving antibiotics:* Antibacterial system vs. control system – 4/35 vs. 7/33; P=0.62	F/U 10 days The infection outcome was bacteriuria. Specific criteria unclear. Power not reported
Seymour, 2006 [91]	Retrospective pre-post study	1,3	To evaluate the rate of UTI after introduction of a silver alloy coated catheter as compared to a standard catheter	Adult inpatients who underwent insertion of a Foley catheter	117	**Undefined UTI:** Silver coated catheter vs. standard catheter – 3.2% vs. 11.1%; statistical differences were not reported **Bacteremia:** Silver coated catheter vs. standard catheter – 0/63 vs. 1/54; statistical differences were not reported **Antibiotic usage:** Silver coated catheter vs. standard catheter – 31/63 vs. 30/54;	F/U until 3 days after catheter removal, discharge from hospital or for a maximum of 28 days after catheterization UTI not defined Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						statistical differences were not reported **Device rate (CA-UTI/1000 catheter days):** Decreased by 69.9%; statistical differences were not reported **Mean length of stay (days):** Silver coated catheter vs. standard catheter – 17 vs. 20; statistical differences were not reported **Cost (£):** £9140 saved by UTI reduction and £3583 saved by reduction of excess bed days; statistical differences were not reported	
Srinivasan, 2006 [92]	Prospective pre-post study	1,3,4,6,7	To evaluate the efficacy of silicone-based urinary catheters coated with silver alloy both on the internal and external surfaces when compared with non-silver silicone catheters	Adult inpatients who had indwelling Foley catheters for > 48 hours	3036	*All results IRR(95% CI) per 1000 catheter days; silver coated vs. control catheter unless otherwise noted* **Unspecified:** Overall – 116/1165 vs. 218/1871; RR(95% CI) = 0.88(0.70-1.11) ICU – 0.80(0.48-1.33) Non ICU – 0.90(0.70-1.16) Preconnected systems – 0.80(0.57-1.12) Component systems – 1.08(0.77-1.49) **Catheter associated BSI:** 9/1165 vs. 7/1871; 2.13(0.96-4.76) **Risk factors for UTI:** *Results HR(95% CI)* *Univariate analysis* Female sex – 2.34(1.86-2.96) Silver-coated catheter – 0.92(0.73-1.15) Hospital service – NS (HR not reported) *Multivariate analysis* Female sex – 2.26(1.78-2.89) Silver-coated catheter – NS (HR not reported) Hospital service – NS (HR not reported)	F/U until 7 days after catheter removal NUTIs were identified by criteria set forth by the CDC Sample size of 1497 patients per catheter type to detect a 20% reduction in the incidence of UTI with 80% power and an alpha of 5%

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Gentry, 2005 [93]	Retrospective pre-post study	1,3,4	To determine whether the use of a silver-alloy hydrogel-coated catheter reduced the incidence of CA-UTI.	Adult patients who underwent insertion of an indwelling urinary catheter for continuous bladder drainage for >24 hours.	133	**Symptomatic UTI:** Silver-coated catheter vs. standard catheter – 5.1% vs. 7.7%; statistical differences were not reported **Device rate (per 1000 catheter days):** Silver-coated catheter vs. standard catheter – 5.1% vs. 9.9%; statistical differences were not reported **Duration of catheterization (days):** Silver-coated catheter vs. standard catheter – 9.9 vs. 7.3; statistical differences were not reported **Cost:** It was estimated that two UTI were potentially avoided with the intervention resulting in a cost saving of £ 2,654	F/U 7-10 days after catheter removal or discharge, whichever was sooner Device rate was defined as the number of new CAUTI divided by the number of urinary catheter days multiplied by 1000 Power not reported
Madeo, 2004 [94]	Prospective pre-post study	1,3	To evaluate the impact of using silver alloy urinary catheters in reducing the incidence of urinary tract infections	Patients admitted into the general ICU, neurosurgical ICU or the high dependency unit requiring a urinary catheter	188	**Bacteriuria/unspecified UTI:** Silver vs. Control – 16/94 vs. 17/94; P>0.05. No differences were observed by gender. **Days to develop bacteriuria:** Silver vs. Control – 24.00 vs. 12.06; P=0.06. No differences were observed by gender. **Duration of catheterization:** P>0.05	F/U until 10 days after catheter removal Bacteriuria was defined as a positive urine culture with 10^5 cfu/ml with 2 or less species and present with classical signs/symptoms relating to a urine infection (adaptation of CDC definitions) Power not reported
Rupp, 2004 [95]	Prospective study with historical controls	3,4	To determine the efficacy of a silver-alloy, hydrogel-coated, urinary catheter in the prevention of CA-UTI, to assess the cost-effectiveness of the coated catheter, and to test the emergence of silver-resistance in urinary microbial isolates.	10 patient care units in a tertiary medical center	Not specified	**Symptomatic UTI and asymptomatic bacteriuria (per 1000 catheter days):** Silver coated catheter vs. standard catheter - 2.62 vs 6.13; P<0.01 [Risk reduction (95% CI) – 57% (27% - 75%)] **Cost:** Cost savings were $13,469 to $535,452 one year following the introduction of the coated catheter and $5811 to $484,070 two years following introduction	F/U unclear UTI classified based on CDC definition Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Microbial resistance: No silver resistant microbes were discovered in the susceptibility tests.	
Lai, 2002 [96]	Retrospective study with historical control	3,4	To assess the efficacy of silver-hydrogel coated (alloy) urinary catheters in reducing nosocomial UTI. Surveillance for nosocomial UTI was performed during 4 months when the silver coated catheter was being used and rates were compared to baseline rates before the introduction of the catheter.	Hospitalized patients at a university medical center.	Not specified	**Unspecified UTI (per 1000 patient days):** Silver-coated catheter vs. non-coated catheter – 2.7 vs. 4.9; P=0.10 **Cost:** The estimated cost savings using the silver coated catheter ranged from $12,564 to $142,315	F/U unclear UTI were defined according to CDC criteria Power not reported
Newton, 2002 [97]	Retrospective pre-post study	1,3,4	To compare the incidence of urinary tract infections with silver alloy impregnated or standard latex catheters.	Patients admitted with a diagnosis of acute burns who required a Foley catheter	1098	**Symptomatic UTI (per 1000 catheter days):** Silver-coated catheter vs. standard catheter – 4.4 vs. 7.2; P=0.03	F/U unclear UTI was defined based on CDC criteria for SUTI only Power not reported Patients receiving silver-coated catheters also had new catheters placed on admission
Bologna, 1999 [98]	Prospective pre-post study	1,3,4,6,7	To compare the efficacy of a hydrogel/silver ion-coated (alloy) urinary catheter with standard latex catheters in reducing nosocomial UTI.	ICU patients at five different institutions	Not specified	**Device use ratio (the number of device days per number of patient days)**: Silver-coated catheter vs. standard catheter – 0.78 vs. 0.76; P=0.31 **Unspecified UTI (infections per 1000 catheter days):** *Unadjusted:* Silver-coated catheter vs. standard catheter – 4.5 vs. 7.1; P=0.01 *Adjusted:* Silver-coated catheter vs. standard catheter – 4.9 vs. 8.1; P=0.13 (Adjusted to five different hospitals, three different types of ICU, time of year and patients severity) **Cost:**	Baseline period ranged from 3-12 months at the hospitals and the intervention period ranged from 7-19 months. Nosocomial UTIs were defined according to the CDC criteria Power not reported

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						The total cost savings were estimated at $98, 021.	
Johnson, 1990 [34]	Prospective controlled study	1,3,6,7	To evaluate a silver-oxide coated catheter in the prevention of UTI during acute bladder catheterization in a general hospital population and characterizing the clinical and microbiologic correlates of CA-UTI in this setting.	Patients ≥ 17 years who had received a study catheter that was expected to remain indwelling for at least 24 h.	482	**Bacteriuria:** Silver coated catheter vs. Control – 19/207 vs. 28/275; P=0.95 After stratification by sex and antimicrobial use, a protective effect of the silver catheter was seen among women not receiving antimicrobials (P=0.04). There were no significant differences in the other three groups (men receiving antimicrobials, men not receiving antimicrobials, women receiving antimicrobials) **Risk factors for bacteriuria:** *Univariate Analysis:* All results RR (P value) Male sex – 0.5(P<0.01) Antimicrobials during final 48 h – 0.3(P<0.01) Catheter care violations – 2.7(P<0.01) Serum creatinine ≥ 2 mg/dl – 2.1(P=0.04) Not at strict bed rest – 0(P=0.06) Duration of catheterization > 7 days – 2.1(P=0.01) No association with UTI was seen for infection at another site, presence of an underlying genitourinary abnormality, advanced age or admitting service. ORs were not provided for the same *Multivariate Analysis:* All results OR (P value) Antimicrobials during final 48 h – 0.3 (P<0.01) Female sex – 2.0 (P=0.02) Renal dysfunction – 2.6 (P=0.02) Catheter care violations – NS (OR not provided) **Median duration of catheterization (days):** Silver coated catheter vs. Control – 3 vs. 4; P=0.03	F/U unclear A patient was considered to have UTI when two consecutively collected catheter urine specimens grew the same microorganism in concentrations of ≥ 10^2 cfu/ml or if the last available urine specimen of the patient before catheter removal had ≥ 10^5 cfu/ml A sample size of 105 patients per group was needed to detect a 67% reduction in the incidence of UTI with the silver catheter at 5% significance level and 80% power.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Akiyama, 1979 [99]	Prospective controlled study	3	To compare an open drainage system using the oligodynamic action of silver ions with the conventional open drainage system. The test system consisted of a Foley catheter coated in part with fine silver powder and a silver plated connector fitted between the catheter and the drainage tube.	Postoperative patients and patients with urinary retention	122	**Bacteriuria:** Test vs. control – 0/102 vs. 20/20; statistical differences were not reported **Fever:** Test vs. control – 0/102 vs. 5/20; statistical differences were not reported **Urethral discharge:** Test vs. control – 0/102 vs.15/20; statistical differences were not reported **Itching or burning sensation:** Test vs. control – 0/102 vs.4/20; statistical differences were not reported **Reddening or edema of external meatus:** Test vs. control – 0/102 vs.2/20; statistical differences were not reported **Duration of catheterization (range in days):** Test vs. control – 4-77 vs.3-4; statistical differences were not reported	F/U 1-4 months Bacteriuria was defined as a catheter urine specimen with ≥ 10^5 colonies per ml Power not reported
Plowman, 2001 [100]	Economic analysis	1,3,4,5,6	To develop an economic model to assess the economic burden of nosocomial UTIs and to examine the potential cost-effectiveness of silver-alloy coated catheters The economic analysis was conducted from the perspective of the hospital sector. Cost and event rate estimates were obtained from public databases and/or published literature.	Adult, non-day case patients admitted to the medical and surgical specialties of NHS hospitals throughout England.	NA	**Cost:** A 14.6% reduction in the incidence of UTI in catheterized medical patients and a 11.4% reduction in catheterized surgical patients would cover the cost of using silver alloy coated catheters. **Sensitivity analysis:** Examined the reductions needed under the assumptions of lower and higher incidence of nosocomial UTI. With a lower incidence, greater reduction in UTI was needed and with a higher incidence, lower reductions in UTI were needed to make silver-coated catheter cost-effective.	
Saint, 2000 [101]	Economic analysis	1,2,3,4,5,6	To assess the clinical and economic impact of using silver alloy urinary catheters in hospitalized patients when compared with standard non-coated catheters	The hypothetical cohort in the decision-analytic model consisted of patients admitted to hospitals on general medical, surgical, urologic and intensive care services requiring the short-term use (2-10 days) of indwelling	NA	**Cost:** Use of silver alloy catheters resulted in estimated cost savings of $4.09 per patient compared with standard catheter use ($20.87 vs $16.78). **One-way sensitivity analysis:** Probability of developing bacteriuria in the	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			The analysis was performed from the perspective of the health care payer and the time horizon was defined as the period of hospitalization. Costs were estimated from published literature, local hospital costs and oral communication. Event rates were estimated from the published literature.	urethral catheterization.		control group would have to be < 15% for silver coated catheters to not be cost saving. The probability of symptomatic UTI (without bacteremia) after developing bacteriuria would have to be < 5% for the silver coated catheters to not provide cost savings. At a relative risk reduction associated with silver-coated catheters of 25% or greater, the clinical and economic superiority persisted. The cost of a silver-coated catheter would have to average $9.40 more than a standard catheter for the silver-coated catheters to not be cost saving. **Multivariate sensitivity analysis using Monte Carlo simulation:** This revealed a cost difference ranging from a savings of $17.22 to an increase in overall cost of $3.19 per catheterized patient. In the simulation, silver-coated catheters provided clinical benefits over standard catheters in all patients and cost savings in 84% of patients.	
2. Antibiotic-coated Catheter							
Brosnahan, 2006 [85]	Systematic review	1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization	All randomized and quasi randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults	18 trials	*Note: All results are RR(95% CI) unless otherwise noted* *<u>1. Antiseptic vs. standard catheter</u>* **Bacteriuria:** Silver oxide catheters vs. standard catheters (duration not specified) (3 studies) - 0.89(0.68-1.15) Silver alloy catheters vs. standard catheters (patients catheterized for < 1 week) (5 studies) - 0.36(0.24-0.52) Silver alloy catheters vs. standard catheters (patients catheterized for > 1 week) (3 studies) - 0.67(0.50-0.90) Silver oxide catheters vs. standard catheters in women (duration not specified)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						(1 study) – 0.63(0.45-0.89) Silver oxide catheters vs. standard catheters in men (duration not specified) (1 study) – 1.62(0.91-2.88) Silver oxide catheters vs. standard catheters in all participants receiving systemic antibiotics (duration not specified) (1 study) – 0.67(0.45-0.99) Silver oxide catheters vs. standard catheters in women receiving systemic antibiotics (duration not specified) (1 study) – 0.50(0.31-0.79) Silver oxide catheters vs. standard catheters in men receiving systemic antibiotics (duration not specified) (1 study) – 1.02(0.49-2.13) **Symptomatic UTI:** Silver alloy catheters vs. standard catheters (7 studies) - 0.60(0.50-0.73) **Urethral secretions:** Silver oxide catheters vs. standard catheters (duration not specified) (1 study) – 0.72(0.25-2.03) **Pain:** Silver oxide catheters vs. standard catheters (duration not specified) (1 study) – 1.43(0.48-4.27) *2. Antibiotic impregnated vs. standard catheter* **Bacteriuria:** Patients catheterized for < 1 week (1 study) - 0.36(0.18-0.73) Patients catheterized for > 1 week (1 study) - 0.94(0.86-1.03) **Symptomatic UTI** (1 study) - 0.20(0.03-1.63) *3. One type of standard catheter vs. another standard catheter* **Bacteriuria:** Silicone vs. latex (1 study) – 1.07(0.23-5.01) **Symptomatic UTI:**	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Hydron coated latex vs. plain latex (1 study) – 0.94(0.66-1.34) Hydron coated latex vs. PVC balloon (1 study) – 0.87(0.63-1.19) PVC balloon vs. plain latex (1 study) – 1.09(0.81-1.45) Hydrogel vs. silicone (1 study) – 0.82(0.46-1.47) **Burning in urethra:** Silicon vs. non-silicone (1 study) – 0.28(0.13-0.60) **Urethritis:** Silicon vs. latex (1 study) – 0.09(0.01-0.68) **Urethral reaction:** *All results WMD (95% CI)* Hydrogel coated latex vs. siliconised latex (1 study) – 0.00(-3.51 to 3.51) Full silicone vs. hydrogel coated latex (1 study): -16.00(-18.84 to -13.16) Full silicone vs. siliconised latex (1 study): -16.00(-18.96 to -13.04)	
Johnson, 2006 [87]	Systematic Review	1,2,3,4,7,8	To assess antimicrobial (nitrofurazone-coated or silver alloy-coated) urinary catheters for preventing CA-UTI	Randomized or quasi-randomized trials of nitrofurazone-coated or silver alloy-coated antimicrobial urinary catheters short term (<30 days) bladder drainage.	12 trials	**Bacteriuria:** Range of RRs (12 studies) – 0.08 to 0.94 (95% CI included 1.0 for 7 studies) Range of RRs for nitrofurazone coated catheters (3 studies)– 0.08 to 0.68 (95% CI included 1.0 in all 3 studies) Range of RRs for pre-1995 silver coated catheters (4 studies) – 0.24 to 0.45 (95% CI was less than 1.0 for all studies) Range of RRs for post-1995 silver coated catheters(5 studies) – 0.53 to 0.94 (95% CI included 1.0 for 4 studies) (The difference between the median RRs for pre and post 1995 studies was statistically significant; P<0.01) The apparent protective effect of the test catheter was greater when the control catheter was latex rather than silicone. Studies involving urologic patients yielded larger effect sizes than those involving other types of patients, as did studies that excluded	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						patients receiving antimicrobial agent therapy (Quantitative summaries not available) **Microbial resistance:** Among studies that reported microbiological outcomes by study group, no evidence suggested that test catheter recipients experienced an increased incidence of specific microbial types that are typically resistant to the antimicrobial compound used.	
Butler, 1968 [102]	Prospective controlled study	1,3	To evaluate the individual effects of (1) lubrication of the catheter with antibiotic (polymyxin) containing material (2) use of catheters impregnated with antimicrobial materials – TMTS (tetramethyl-thiuramdisulfide) or CTHA (cyclic thiohydroxamic acid)	Catheterized patients	758	**Bacteriuria**: *(1) Lubricated catheter vs. control* Developed in 50% of patients after 8.6 days and 11.6 days with polymyxin and placebo lubricants respectively. No statistically significant differences were seen. *(2) Antibiotic impregnated catheter vs. control* No statistically significant differences were seen when impregnated and control catheters were compared.	F/U until catheter removal, discharge or death Bacteriuria was defined as $> 10^5$ colonies/ml Power not reported
Mooro, 1966 [103]	Prospective controlled study	1,3	To test the effect of furacin urethral inserts on the prevention of catheter fever	Patients needing urethral manipulations	200	**Fever:** With insert vs. without insert – 4/100 vs. 18/100; statistical differences were not reported **Ascending infection:** With insert vs. without insert – 0/100 vs. 2/100; statistical differences were not reported	F/U not reported UTI not defined Power not reported
3. Hydrophilic catheters							
Brosnahan, 2006 [85]	Systematic review	1,2,3,4,5,6,7,8	To determine the effect of type of indwelling urethral catheter on the risk of UTI in adults who undergo short-term urinary catheterization	All randomized and quasi randomized trials comparing types of indwelling urinary catheters for short term (≤ 14 days) catheterization in hospitalized adults	18 trials	*Note: All results are RR(95% CI) unless otherwise noted* *1. Antiseptic vs. standard catheter* **Bacteriuria:** Silver oxide catheters vs. standard catheters (duration not specified) (3 studies) - 0.89(0.68-1.15) Silver alloy catheters vs. standard catheters (patients catheterized for < 1 week) (5 studies) - 0.36(0.24-0.52) Silver alloy catheters vs. standard	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						catheters (patients catheterized for > 1 week) (3 studies) - 0.67(0.50-0.90) Silver oxide catheters vs. standard catheters in women (duration not specified) (1 study) – 0.63(0.45-0.89) Silver oxide catheters vs. standard catheters in men (duration not specified) (1 study) – 1.62(0.91-2.88) Silver oxide catheters vs. standard catheters in all participants receiving systemic antibiotics (duration not specified) (1 study) – 0.67(0.45-0.99) Silver oxide catheters vs. standard catheters in women receiving systemic antibiotics (duration not specified) (1 study) – 0.50(0.31-0.79) Silver oxide catheters vs. standard catheters in men receiving systemic antibiotics (duration not specified) (1 study) – 1.02(0.49-2.13) **Symptomatic UTI:** Silver alloy catheters vs. standard catheters (7 studies) - 0.60(0.50-0.73) **Urethral secretions:** Silver oxide catheters vs. standard catheters (duration not specified) (1 study) – 0.72(0.25-2.03) **Pain:** Silver oxide catheters vs. standard catheters (duration not specified) (1 study) – 1.43(0.48-4.27) *2. Antibiotic impregnated vs. standard catheter* **Bacteriuria:** Patients catheterized for < 1 week (1 study) - 0.36(0.18-0.73) Patients catheterized for > 1 week (1 study) - 0.94(0.86-1.03) **Symptomatic UTI** (1 study) - 0.20(0.03-1.63) *3. One type of standard catheter vs. another standard catheter*	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Bacteriuria: Silicone vs. latex (1 study) – 1.07(0.23-5.01) **Symptomatic UTI:** Hydron coated latex vs. plain latex (1 study) – 0.94(0.66-1.34) Hydron coated latex vs. PVC balloon (1 study) – 0.87(0.63-1.19) PVC balloon vs. plain latex (1 study) – 1.09(0.81-1.45) Hydrogel vs. silicone (1 study) – 0.82(0.46-1.47) **Burning in urethra:** Silicon vs. non-silicone (1 study) – 0.28(0.13-0.60) **Urethritis:** Silicon vs. latex (1 study) – 0.09(0.01-0.68) **Urethral reaction:** *All results WMD (95% CI)* Hydrogel coated latex vs. siliconised latex (1 study) – 0.00(-3.51 to 3.51) Full silicone vs. hydrogel coated latex (1 study): -16.00(-18.84 to -13.16) Full silicone vs. siliconised latex (1 study): -16.00(-18.96 to -13.04)	
De Ridder, 2005 [104]	RCT	1,2,6,7	To compare the performance of hydrophilic-coated catheters vs. uncoated polyvinyl chloride (PVC) catheters. The hydrophilic coating consisted primarily of polyvinyl-pyrrolidone. In the uncoated group, catheters were lubricated manually using a water-soluble lubricant gel.	Male spinal cord injured patients who were ≥ 16 years, had been injured < 6 months and presented with neurogenic bladder emptying disorders, needing intermittent catheterization at least 3 times a day.	123	**Symptomatic UTI:** Hydrophilic-coated vs. uncoated – 39/61 vs. 51/62; P=0.02 **Mean number of catheterizations per day:** Hydrophilic-coated vs. uncoated – 3.4 vs. 3.6; P>0.05 **Bleeding:** Hydrophilic-coated vs. uncoated – 38/55 vs. 32/59; P>0.05 **Bacteriuria:** No significant differences except at the initial study visit where there was a higher incidence in the hydrophilic group (P=0.03). The difference was eliminated at day 15. **Hematuria:**	F/U 12 months. UTI was defined as a clinical infection with symptoms of UTI and for which treatment was prescribed. The study was powered at 90% with an alpha of 0.05 to detect differences in symptomatic UTI and hematuria. Though the sample size was met, there was a very high rate of dropouts.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						No significant differences except at the initial study visit where there was a higher incidence in the hydrophilic group (P=0.02). The difference was eliminated at day 15. **Leukocyturia:** P>0.05 **Satisfaction for patients/care providers:** *6 months* Hydrophilic-coated vs. uncoated – 33.0% vs. 15.4% ; P>0.05 *6 months* Hydrophilic-coated vs. uncoated – 36.0% vs. 21.9%; P>0.05	
Stensballe, 2005 [105]	Crossover RCT	1,2,4,5,7	To compare (1) a hydrophilic catheter with a ready-to-use coating (2) a hydrophilic coated catheter where water is added 30s prior to use and (3) an uncoated silicon/PVC catheter with gel concerning withdrawal friction force and urethral micro-trauma.	Adult volunteers with negative urine dipstick at the first visit and without experience of recurrent UTI	49	**Mean withdrawal friction force (Newton):** Ready-to-use hydrophilic vs. hydrophilic with water added vs. Uncoated – 0.14 vs. 0.28 vs. 0.20; P<0.01 All pairwise comparisons were also statistically significant (P<0.05) **Hematuria:** Ready-to-use hydrophilic vs. hydrophilic with water added vs. Uncoated – 58% vs. 40% vs. 67%; P<0.01 Pairwise comparison between the latter two catheters was also statistically significant (P<0.01) **Bacteriuria:** Not reported stratified by the type of catheter. Was found in 6 participants, 2 of whom were symptomatic **Pain during insertion:** Ready-to-use hydrophilic vs. hydrophilic with water added vs. Uncoated – 0% vs. 0% vs. 22%; P<0.01 All pairwise comparisons were also statistically significant (P<0.05)	F/U unclear Significant bacteriuria defined as > 10^5 cfu/ml A sample size of 35 would have 90% power to detect a mean difference of 0.07N in the withdrawal friction force at an alpha of 0.05

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Pain during withdrawal: P<0.01 on overall comparison of the three groups. Pairwise comparison significant only for ready-to-use vs. uncoated (P<0.01) [Group-wise data not provided] **Dysuria:** Ready-to-use hydrophilic vs. hydrophilic with water added vs. Uncoated – 30% vs. 32% vs. 55%; P<0.01 No significant differences were seen in the pairwise comparisons. **Catheter preference:** All hydrophilic vs. uncoated – 93% vs. 2%; statistical differences were not reported	
Cindolo, 2004 [106]	RCT	1,5,7	To compare a hydrophilic catheter to the standard polyvinyl chloride catheter with regard to bacteriological safety and overall comfort	Patients with histologically proven primary bladder cancer eligible to receive intravesical immunochemoprophylaxis	100	**Symptomatic UTI:** 2/50 vs. 7/50; statistical differences were not reported **Bacteriuria:** Hydrophilic vs. standard – 3.5% vs. 7.4%; P<0.01 **Mean VAS score for discomfort:** Hydrophilic vs. standard – 1.3% vs. 2.1%; P<0.01 **Hematuria:** None **Stricture:** None	F/U 2 days after instillation Symptomatic UTI not defined but referred as such Significant bacteriuria defined as > 10^5 cfu/ml Power not reported
Vapnek, 2003 [107]	RCT	1,6,7	To compare a hydrophilic coated with a standard PVC catheter.	Male patients who performed clean intermittent self-catheterization to manage neurogenic bladder	62	**Symptomatic UTI:** Hydrophilic vs. Standard – P>0.3. However, the rate of decline from baseline was significant in the hydrophilic group (P=0.01), but not in the standard group **Bacteriuria at 3 months:** Hydrophilic vs. Standard – 21/27 vs. 20/28; statistical differences were not reported **Hematuria:** Significantly decreased in hydrophilic group (P=0.03)	F/U 1 year UTI defined as ≥ 10^5 cfu/ml and at least one clinical symptom such as fever, chills, malodorous urine, increased spasticity or malaise Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Pyuria: No significant differences **Adverse events:** Hydrophilic vs. Standard – 3/23 vs. 3/26; statistical differences were not reported	
Monson, 1974 [108]	RCT	1,3,7	To assess the efficacy of a hydrophilic, polymer-coated catheter in reducing bacteriuria	Community hospital patients receiving urinary catheters with initially sterile urine specimen and who were followed for ≥ 1 day. All patients received a closed drainage system.	287	**Bacteriuria:** Hydrophilic vs. control - P>0.05	F/U until catheter removal, discharge or death Infection assessed by culturing the catheter specimen of urine Power not reported
Pachler, 1999 [109]	Prospective controlled crossover study	1,2,3	To compare a pre-lubricated hydrophilic polyvinyl chloride (PVC) catheter or a non-hydrophilic PVC catheter self-lubricated by the patient using gel. Patients used one catheter for 3 weeks nd transferred to the other for 3 weeks.	Patients with urinary retention caused by prostatic enlargement who performed clean intermittent self-catheterization.	43	**Cystitis:** One in each group. P>0.05 **Bacteriuria:** None **Hematuria:** 2 in each group; P>0.05 **Epididymitis:** None **Urethritis:** None	F/U 6 weeks. Significant bacteriuria was defined as > 10^4 cfu/ml Power not reported
4. Other Catheter Types							
Shafik, 1993 [110]	RCT	1	To assess the safety and efficacy of an electrified catheter when compared with a nonelectrified catheter in reducing UTI	Patients in whom hemorrhoidectomy was to be done	24	**UTI:** Electrified vs. non-electrified – 0/12 vs. 7/12; statistical differences were not reported **Bacteremia:** None in either group	F/U 1 week UTI was defined as a pathogen count of > 10^5 cfu/ml Power not reported
Chen, 2005 [111]	Prospective pre-post study	1,3	To compare the safety, effectiveness and patient satisfaction of an intraurethral valve-pump catheter versus clean intermittent catheterization	Women with hypocontractile or acontractile bladder without contraindication to having medical magnetic device or other concurrent conditions of the lower urinary tract	273	**UTI:** Test vs. control – 30% vs. 23%; statistical differences were not reported **Bacteriuria:** Test vs. control – 56% vs. 26%; statistical differences were not reported **Discomfort:** Test vs. control – 31% vs. 4%; statistical differences were not reported	F/U unclear UTI not defined Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Incontinence: Test vs. control – 61% vs. 4%; statistical differences were not reported **Hematuria:** Test vs. control – 8% vs. 1%; statistical differences were not reported **Frequency/ urgency:** Test vs. control – 22% vs. 6%; statistical differences were not reported **Post-void residual (ml):** Test vs. control – 16.1 vs. 20.3; P>0.05 **Mean quality of life score:** Test vs. control - 25.9 vs. 42.2; P<0.01	
5. Drainage Systems							
Phipps, 2006 [1]	Systematic review	1,2,3,4,5,6,7,8	To establish the optimal way to manage urinary catheters following urogenital surgery in adults	Randomized and quasi-randomized trials	39 RCTs	*Note: All results are RR(95% CI) unless otherwise noted* *1. Using a urinary catheter vs. not using a urinary catheter* **Retention of urine** (1 study) – 0.12(0.03-0.47) **UTI** (4 studies) – 1.35(0.75-2.45) **Recatheterization** (3 studies) – 0.32(0.14-0.70) **Post-op urethral stricture** (1 study) – 1.14(0.90-1.44) **Post-op hematuria** (1 study) – 0.73(0.40-1.33) *2. Urethral catheterization vs. suprapubic catheterization* **UTI:** Heterogeneous results, not combined. Of four trials, two suggested a moderate increase, one a large increase and one a large decrease. **Recatheterization** (2 studies) – 3.66(1.41-9.49) **Post-op hematuria** (1 study) –	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						5.00(0.21-116.31) **Length of hospital stay in days** (1 study) [WMD(95% CI)] – 1.10(0.30-1.90) **Catheter lockage or bypassing** [OR(95% CI)] (2 studies) – 0.20(0.02-1.72) *3. One type of catheter vs. another type of catheter* **UTI:** Urethral foley catheter with extra drainage hole vs. unmodified foley catheter(1 study) – 0.40(0.15-1.04) **Positive urine culture:** Silver coated bardex catheters vs. latex catheters(1 study) – 0.53(0.20-1.45) *4. One type of catheter management vs. another* **Retention of urine:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.99(0.06-15.54) **Dysuria:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.99(0.06-15.54) **UTI:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 0.61(0.33-1.14) Cefotaxime 1 hr prior to catheter removal vs. none (1 study) – 0.08(0.00-1.30) Neomycin/Sulfamethiozole vs. placebo (1 study) – 0.18(0.06-0.55) **Positive urine culture:** Vaginal cleansing before catheter insertion vs. vaginal cleansing after catheter insertion(1 study) – 1.06(0.70-1.51) **Recatheterization -** Neomycin/Sulfamethiozole vs. placebo (1 study) – 0.50(0.24-1.04) *5. Larger diameter catheter vs. Smaller diameter catheter* No trials found *6. Bladder irrigation*	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						No trials found *7. Shorter duration vs. longer duration catheter* **Retention of urine:** 1 day vs. 3 days(1 study) – 0.80(0.38-1.69) 1-2 days vs. until urine clear(1 study) – 1.02(0.07-15.87) 1 day vs. 2 days (1 study) – 4.64(0.23-94.28) 3 days vs. 28 days (1 study) – 3.00(0.13-69.52) **Post-op urethral stricture:** <1 week vs. 2 weeks (2 studies) – 1.23(0.82-1.84) 3 days vs. 28 days (1 study) – 1.00(0.73-1.36) **UTI:** Heterogeneous results, not combined. Shorter duration had lower risk of UTIs but the results were not significant **Recatheterization:** 1 day vs. 2 days (1 study) – 1.03(0.23-4.71) 1 day vs. 3 days (2 studies) – 1.04(0.36-3.01) 1 day vs. 5 days (1 study) – 4.55(1.68-12.37) 4-6 days vs. 14 days (1 study) – 1.86(0.14-25.38) 1-2 days vs. until urine clear(2 studies) – 0.72(0.24-2.20) **Post-op hematuria:** 1-2 days vs. until urine clear(1 study) – 2.04(0.19-21.81) 1 day vs. 2 days (2 studies) – 1.16(0.34-3.90) **Urinary leakage or incontinence:** 1-2 days vs. until urine clear(2 studies) – 0.43(0.07-2.88) *8. Clamp and release vs. free catheter drainage:* **UTI** (1 study) – 4.00(1.55-10.29) **Delay in return to normal bladder function** (1 study) - 2.50(1.16-5.39)	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						9. Catheter removal at one time of day vs. another time of day **UTI:** 0000 hrs vs. 0600 hrs (1 study) – 1.31(0.65-2.66) **Recatheterization:** 0000 hrs vs. 0600 hrs (4 studies) – 0.61(0.34-1.12) 6-7 am vs. 10-11 pm (1 study) – 1.36(0.32-5.77) **Time to first void in hours**[WMD(95% CI)]: 0000 hrs vs. 0600 hrs (1 study) – 0.60(-0.96 to 2.16) **Volume of first void in ml** [WMD(95% CI)]: 0000 hrs vs. 0600 hrs (1 study) – 53.00(4.27-101.73) *10. Trial of void protocol vs. none* No trials found *11. Prefilling bladder prior to catheter removal vs. removal without prefilling* **Recatheterization** [OR(95% CI)] (1 study) – 4.52(0.79-25.97) **Discharge on day of catheter removal** (1 study) – 1.36(0.47-3.91)	
van den Eijkel, 2006 [112]	Systematic review	1,2,3,4	To assess the evidence for the benefit of catheter valves for indwelling urinary catheters	Randomized and quasi-randomized controlled trials comparing the use of catheter valves with catheter bag drainage system in subjects aged ≥ 16 years.	4 trials	**Bacteriuria (2 studies):** Catheter valve vs. catheter bag - RD (95% CI) = -9% (-25 to +7%) **Bladder spasms (1 study):** No significant differences **Pain (1 study):** No significant differences **Incontinence (1 study):** No significant differences **Patient preference (2 studies):** Statistically significant preference for the catheter valve in both included studies (P<0.05)	
Leone, 2003 [113]	RCT	1,2,7,8,9	To compare the rate of acquisition of bacteriuria between a complex closed	ICU patients who had an initial culture free of bacterial growth and an indwelling urethral	314	**Bacteriuria:** Complex vs. two chamber – 14/162 vs. 12/149; P>0.05	F/U for until a day after removal of the catheter.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			drainage system and a two-chamber drainage system. The two chamber drainage system contained a foley catheter connected to an output measure recipient and a urine collection bag. The complex drainage system consisted of a preconnected coated latex catheter, a tamper-discouraging seal at the catheter drainage tubing junction, a drip chamber, an anti-reflux valve, a drainage bag vent and a povidone-iodine releasing cartridge at the drain port of the urine collection bag.	catheter for > 48 hours.		**Onset of bacteriuria (days):** Complex vs. two chamber – 7.8 vs. 12.4; P<0.05 Probability of remaining uninfected until removal of the catheter showed no significant differences between the two groups on log rank test (P=0.22) **Length of ICU stay (days):** Complex vs. two chamber – 19 vs. 29; P<0.05 **Duration of catheterization (days):** Complex vs. two chamber – 15 vs. 21.5; P<0.05	CDC's definition of asymptomatic bacteriuria was used 300 patients were needed to provide 80% power to detect a 10% difference in bacteriuria between the two groups.
Huth, 1992 [114]	RCT	1,2,3,6,7	To evaluate the efficacy of a junction seal applied after catheter insertion for preventing bacteriuria and reducing mortality. The seal was wrapping of the drainage tube junction with an adhesive tape.	Patients undergoing transurethral catheterization at a community hospital	1740	**Death at hospital discharge:** Tape seal vs. no tape seal – 60/903 vs. 67/837; P=0.32 **Bacteriuria:** Tape seal vs. no tape seal – 124/903 vs. 125/837; OR(95% CI) = 0.91(0.69-1.20) Survival curve analysis of patients stratified by gender and antibiotic use revealed no significant differences in the rate of bacteriuria between treatment groups. **Duration of catheterization (days):** Tape seal vs. no tape seal – 4.0 vs. 4.1; P=NS **Risk factors for bacteriuria:** *Multivariate analysis: All results OR(95% CI)* Lack of antibiotic use –3.69(2.84-4.80) Female gender –2.73(2.07-3.61) Age, hospital service, catheter care violations and treatment randomization were not significant	F/U until catheter removal or patient discharge Bacteriuria was defined as a urine specimen containing ≥ 1000 cfu/ml of bacteria or yeast It was estimated that a final study population of 686 patients in each group would be needed to detect a 33% reduction in the infection rate at an alpha of 0.05 with 80% power

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
Classen, 1991 [115]	RCT	1,5	To assess the prevention of bacteriuria in patients using a three-way system that included a hydrophilic polymer-coated and preconnected sealed catheter system, daily catheter care, and disinfection of the outflow tube of the drainage bag with povidone-iodine (i.e. methods to block bacterial entry at the urethral insertion site, at the catheter drainage tube junction, and at the outflow tube)	Hospitalized patients with catheters	606	**Bacteriuria:** Treated vs. control – 14/300 vs. 15/306; P=NS **Duration of catheterization (days):** P=NS	F/U until the duration of the first catheterization Bacteriuria was defined as a colony count of ≥1000 cfu/ml with gram negative bacilli, enterococci or both A sample size of 560 patients would be required to have a 70% power to detect a 50% reduction in the incidence of bacteriuria, based on an expected 12% incidence of bacteriuria in the control population
Al-Juburi, 1989 [116]	RCT	1	To evaluate a new drainage system consisting of: 1) a cartridge that released PVP-I into the outlet tube of the urine collection bag 2) a hydrophilic surface coated catheter 3) an antireflux mechanism 4) a tamper-discouraging seal at the catheter-drainage tubing connection This system was compared with a standard closed drainage system *(control group*) that just had an antireflux mechanism.	Patients on most services of a university hospital who had an initial urine culture free of bacterial growth and an indwelling urethral catheter for more than 48 hours.	109	**Bacteriuria during first 5 days of catheterization:** Test vs. Control – 1/52 vs. 10/57; P<0.01 **Bacteriuria during entire time catheterized:** Test vs. Control – 3/52 vs. 13/57; P<0.01 **Mean number of days catheterized without infection:** Test vs. Control – 3.3 vs. 4.0; P=NS **Mean day of first appearance of microorganisms in bag urine:** Test vs. Control – 5.3 vs. 3.9; P=NS **Mean day of first appearance of microorganisms in bladder urine:** Test vs. Control – 5.7 vs. 5.3; P=NS	F/U for the duration of catheterization UTI was determined by the presence of microorganisms in the bladder urine. Power not reported
DeGroot-Kosolcharoen, 1988 [117]	RCT	1	To compare a pre-connected closed drainage system with a standard system that had the Foley catheter attached to the closed drainage	Male surgical and medical patients	202	**Bacteriuria:** Preconnected closed drainage vs. standard closed drainage – 11/97 vs. 14/105; P>0.05 **Symptomatic UTI:** Preconnected closed	F/U until 5 days after catheter removal Catheter associated bacteriuria was defined as

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			bag after it had been inserted			drainage vs. standard closed drainage – 3/97 vs. 1/105; P>0.05 **Duration of catheterization (days):** Preconnected closed drainage vs. standard closed drainage – 6.4 vs. 7.6; P>0.05 **Costs:** Cost savings with pre-connected system - $4 Reduction in bacteriuria needed to realize cost savings – 8%	the onset of bacteriuria (>10^3 cfu/ml) after insertion of catheter or within five days of catheter removal CAUTI was defined as the onset of bacteriuria accompanied with signs and symptoms (fever > 99 F orally, not accompanied by other events in the clinical course, and accompanied by chills, burning, or lower back discomfort, or isolation of the same organism in urine and blood) Power not reported
Klarskov, 1986 [118]	RCT	1,6	To test a urinary drainage system in which the catheter was preconnected and sealed with tape to the drainage tube which was connected to a vented drip chamber and non-return valve. This was compared with a regular system consisting of a Foley catheter with exchangeable collecting bags with non-return valves.	Female patients > 16 years referred for urological or gynecological surgery, which routinely included an indwelling urethral catheter for ≥ 3 days	60	**Bacteriuria:** Test system vs. control system – 1/30 vs. 9/30; P<0.05 **Urethral discharge:** Test system vs. control system – 8/30 vs. 8/30; statistical differences were not reported **Suprapubic pain/ urethral burning:** Test system vs. control system – 6/30 vs. 4/30; statistical differences were not reported **Incontinence:** Test system vs. control system – 3/30 vs. 0/30; statistical differences were not reported	F/U not reported Bacteriuria defined as ≥ 10^5 colonies/ml Power not reported
Platt, 1983 [119]	RCT	1,2,5	To compare preconnected sealed junction catheters and unsealed junction catheters	Catheterized inpatients	1476	**Bacteriuria:** *1. Subjects who received an antibiotic* Unsealed vs. sealed – 48/643 vs. 46/613; RR(95% CI) = 1.0(0.7-1.5) *2. Subjects who received no antibiotic*	F/U unclear Infection was defined as the presence of ≥ 10^5 cfu/ml of any organism in

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
						Unsealed vs. sealed – 29/108 vs. 11/112; RR(95% CI) = 2.7(1.5-5.0) **Mortality:** *1. Subjects who received an antibiotic* Unsealed vs. sealed – 32/643 vs. 26/613; RR(95% CI) = 1.2(0.6-2.2) *2. Subjects who received no antibiotic* Unsealed vs. sealed – 15/108 vs. 4/112; RR(95% CI) = 3.4(1.1-10.7) **Catheter disconnections:** Unsealed vs. sealed – RR(95% CI) = 1.2(1.0-1.5); P=0.04 **Median duration of catheterization (days):** Unsealed vs. sealed - 3 vs. 3; P>0.05 **Colonization of drainage bag:** Unsealed vs. sealed – 35/759 vs. 28/735; statistical differences were not reported	catheter urine It was calculated that a sample size of 1500 was needed to reduce bacteriuria from 15% for the unsealed catheters to 10% for sealed catheters
Keys, 1979 [120]	RCT	1,6	To compare a top vented (air vent on the top of the catheter connector) vs. a bag vented (on the upper face of the drainage bag) closed drainage system	Adult patients requiring indwelling urinary catheterization	236	**Bacteriuria:** Top vented vs. bag vented – 16/113 vs. 13/123; P>0.05 Antibiotic vs. no antibiotic – 15/202 vs. 10/34; statistical differences not reported **Time of onset of bacteriuria:** Top vented vs. bag vented – P>0.05	F/U unclear Bacteriuria defined as ≥10,000 cfu/ml urine Power not reported
Monson, 1977 [121]	RCT	1,3,5	To compare a top vented urinary drainage system with an otherwise identical non-vented drainage system.	Patients in a community hospital	506	**Bacteriuria:** Vented vs. non-vented – 26% vs. 66%; P<0.05 Vented vs. non-vented (males) – 12/91 vs. 12/99; P>0.05 Vented vs. non-vented (females) – 17/160 vs. 40/156; P<0.05 **Hemoglobinuria:** Vented vs. non-vented – 90% vs. 90%; statistical differences not reported	F/U until discharge, death or catheter removal Power not reported Significant bacteriuria was defined as a catheter urine specimen with ≥ 10^5 colonies per ml in 2 consecutive specimens
Cleland, 1971 [122]	RCT	1	To test the effectiveness of perineal care and a specific type of drainage system in preventing bacteriuria. Effect of	Adult female patients in whom a catheter was in place for at least 60 hours.	184	**Bacteriuria:** *Perineal care* – A vs. B vs. C vs. D vs. E – 20/35 vs. 18/38 vs. 15/26 vs. 25/46 vs. 20/39; P>0.05 *Perineal care stratified by drainage*	F/U unclear Bacteriuria was defined as ≥ 10^5

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			antimicrobial prophylaxis was also reported (observational data) Perineal care – (A) Twice daily perineal care – mechanical cleansing using a hexachlorophene soap solution (B) Same as A, but with sterile gloves (C) Dressings with bacitracin-neomycin ointment (D) Combination of B and C (E) No perineal care Two drainage systems were compared in which one of them had an air barrier between bag and tubing and the air vent was protected against accidental wetting (designated as "Test drainage system" for the purposes of the review. Antimicrobial prophylaxis was classified as bacteriostatic, narrow/ broad spectrum bactericidal			*system* Test drainage system – A vs. B vs. C vs. D vs. E – 10/17 vs. 8/17 vs. 9/12 vs. 12/24 vs. 10/17; P>0.05 Control drainage system – A vs. B vs. C vs. D vs. E – 10/18 vs. 10/21 vs. 6/14 vs. 13/22 vs. 10/22; P>0.05 *Test drainage system vs. control drainage system* – 49/87 vs. 49/97; P>0.05 *Antibiotic prophylaxis* Bacteriostatic vs. broad spectrum bactericidal vs. narrow spectrum bactericidal vs. none – 10/21 vs. 9/38 vs. 7/11 vs. 62/82; P<0.01 *Braod spectrum antibiotic prophylaxis stratified by risk* High risk - Broad spectrum bactericidal vs. no prophylaxis – 6/15 vs. 29/33; P<0.01 Low risk - Broad spectrum bactericidal vs. no prophylaxis – 3/23 vs. 33/49; P<0.01	colonies/ml of one pathogenic species in the catheterized specimen. Power not reported
Wille, 1993 [123]	Prospective controlled study	1,3	To compare the incidence of nosocomial bacteriuria using two closed urinary drainage systems. A simple closed drainage system containing an antireflux valve was compared with a complex drainage system containing: 1. a preconnected, coated catheter 2. a tamper discouraging seal at the catheter-drainage tubing junction 3. a drip chamber	Patients > 16 years in the departments of neurology, urology and gynecology who needed continuous bladder drainage.	181	**Bacteriuria:** Complex drainage system vs. simple drainage system – 34% vs. 36%; P>0.05 **Median duration of catheterization (days):** Complex drainage system vs. simple drainage system – 5 vs. 5; P> 0.05 **Time of onset of bacteriuria:** Complex drainage system vs. simple drainage system ; P> 0.05	F/U unclear A catheter-associated bacteriuria was defined as ≥ 10^5 cfu/ml Power not reported

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			4. an antireflux valve 5. a hydrophobic drainage bag vent 6. a povidone-iodine releasing cartridge in line with the outlet tube of the urine collection bag				
Danchaivijitr, 1988 [124]	Prospective controlled study	1,3,4	To compare open vs. closed urinary drainage system	Patients admitted to medical wards who had indwelliing urethral catheters	53	**All UTI:** Open vs. closed – 13/32 vs. 6/21; P>0.05 **Symptomatic UTI:** Open vs. closed – 7/32 vs. 3/21; P>0.05 **Bacteremia:** Open vs. closed – 3/32 vs. 1/21; P>0.05 **Death due to UTI related infections:** Open vs. closed – 5/32 vs. 1/21; P>0.05 **Duration of catheterization (days) -** Open vs. closed – 5.28 vs. 4.57; P> 0.05 **Cost:** The cost of maintaining the open was about 3 times that of the closed drainage system	F/U until discharge or death UTI not defined Power not reported
Lanara, 1988 [125]	Prospective controlled study	1,3	To study the prevalence of UTI in catheterized inpatients in relation to the type of drainage system	Patients who had a Foley catheter inserted in the hospital and it remained within the bladder for a minimum of 10 days.	532	**Bacteriuria:** Closed system vs. open system – 68/270 vs. 79/203; P<0.01 Closed system with chlorhexidine added vs. open system – 6/40 vs. 79/203; P<0.01 Closed system vs. closed system with chlorhexidine added – 68/270 vs. 6/40; P>0.1 **Risk factors for bacteriuria:** *Univariate analysis:* All results P values Women - <0.01 Age ≥ 60 < 0.01 Medical (vs. urological patients) <0.05 Surgical (vs. urological patients) > 0.05	F/U unclear UTI defined as ≥ 10^5 bacteria/ml 48 hours after catheterization in the hospital Power not reported
Islam, 1977 [126]	Prospective controlled study	1,3	To compare two urinary drainage systems – System 1(the catheter drained via a connecting tube into a sterile disposable plastic bag with a	Patients requiring continuous catheter drainage	200	**Bacteriuria:** System 1 vs. System 2 – 23/69 vs. 24/79; P>0.05 **Risk factors for bacteriuria:** *Univariate analysis:* All results P values	F/U 4 months Significant bacteriuria defined as > 10^5 /ml

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			flutter valve to prevent retrograde flow) and System 2 (connected by a sterile tube to a drainable plastic bag with an outlet tap at the bottom through which chlorhexidine solution was introduced)			Type of operative procedure – >0.05 Antimicrobial agents - >0.05 Duration of catheterization - <0.05 It was noted that infection occurred more frequently in patients whose catheter needed to be changed or whose bladder was washed with sterile saline. But statistical differences were not reported.	Power not reported
Hardyck, 1998 [127]	Retrospective controlled study	1,3,4,6,7	To compare a non-drainable bag (NDB) system (containing a bacteria inhibiting polymer that inhibits biofilm formation) with the usual Foley drainable bag (DB) system.	Elderly home care patients	82	**Mean no. of symptomatic UTI:** *All patients* NDB vs. DB – 1.11 vs. 22.14; P<0.01 *After adjusting for the duration of time each device was used* NDB vs. DB – 2.80 vs. 12.1; P<0.01 **Costs:** The cost for the non-hospitalization UTIs was estimated at $1,153,665 for DBs when compared with $57,890 for NDBs. The corresponding hospital costs were $274,170 and $15,540 respectively. No formal cost analyses were performed.	F/U unclear UTI was defined as bacterial counts > 10^5 /ml and isolation of pathogenic organisms accompanied by fever, chills, flank pain and strong urine odor. Power not reported
Montagnino, 1988 [128]	Retrospective controlled study	1,3	To compare the incidence of UTI in children managed with a closed urinary drainage system and open double diapering system (1 diaper applied normally and then sandwiching the catheter between this and a second diaper)	Children managed by an intubated urinary diversion after undergoing repair of hypospadias and/or chordee for a complication of previous urethral surgery	100	**Bacteriuria:** Open double diapering system vs. closed drainage system – 12/50 vs. 12/50; P>0.05	F/U until catheter removal Positive urine culture defined as a catheter urine specimen with ≥ 10^4 colonies per ml Power not reported
Madeo, 2005 [129]	Prospective pre-post study	1,3,4,6,7	To determine whether the use of a pre-connect urinary catheter system reduced the incidence of nosocomial UTI	Patients in medical wards	205	**Symptomatic UTI (per 1000 catheter days):** Pre-connect catheter vs. conventional catheter – 22.4 vs. 37.8; IRR (95% CI) = 0.59(0.35-0.99) **Median number of days to symptomatic UTI:** Pre-connect catheter vs. conventional catheter – 6 vs. 10; P=0.045	F/U during 2 periods of 6 month surveillance UTI based on CDC definitions Power not reported
Leone, 2001 [130]	Prospective pre-post study	1,3	To compare the rate of acquisition of bacteriuria between a complex closed	ICU patients who had an initial culture free of bacterial growth and an indwelling urethral	224	**Bacteriuria:** Complex vs. two chamber – 15/111 vs. 12/113; P>0.05	F/U for until a day after removal of the catheter.

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			drainage system and a two-chamber drainage system. The two chamber drainage system contained a foley catheter connected to an output measure recipient and a urine collection bag. The complex drainage system consisted of a preconnected coated latex catheter, a tamper-discouraging seal at the catheter drainage tubing junction, a drip chamber, an anti-reflux valve, a drainage bag vent and a povidone-iodine releasing cartridge at the drain port of the urine collection bag.	catheter for > 48 hours.		**Onset of bacteriuria (days after catheterization):** Complex vs. two chamber – 13 vs. 14; P>0.05 **Duration of catheterization (days):** Complex vs. two chamber – 19 vs. 19; P>0.05 **ICU length of stay (days) –** 22 vs. 25; P>0.05 **Risk factors for bacteriuria:** *Univariate analysis:* All results P values Duration of catheterization - <0.05 ICU length of stay - <0.05 Women - < 0.05	UTI defined as ≥ 10^5 cfu/ml
Blenkharn, 1985 [131]	Prospective pre-post study	1,3	To compare two different kinds of closed urinary drainage systems. The conventional system consisted of a urine meter and a chamber connected to a re-usable collecting bag. The test system (Ureofix 500) consisted of a similar urine meter and a chamber with 4 interconnected compartments connected to a single-use disposable collecting bag. It further had a drip chamber with baffle plate to protect the catheter connection tube from retrograde transmission of organisms	All patients > 16 years admitted to a general ICU	1088	**Bacteriuria:** Test system vs. conventional system – 70/576 vs. 137/512; P<0.01 **Duration of catheterization (days) -** Test system vs. conventional system – 2.4 vs. 2.7; P>0.05	F/U unclear Counts of bacteria of a single species > 10^5 /ml or of two or more species, one of which was present in numbers > 10^4 /ml was considered significant Power not reported
Platt, 1989 [132]	Economic analysis	3,4,5,6	To assess the implications of four strategies for catheter care on the number of infections, the number of deaths and the cost of hospitalization – (1) antimicrobial prophylaxis for all catheterized patients (2) use of catheters with sealed junctions for all patients (3) use of	Not specifically defined. Implicit for patients requiring catheterization	Not applicable	**Risks and costs per patient:** *1. Antibiotic prophylaxis for all patients* Infection – 0.07 Death - 0.02 Cost - $37 *2. Sealed junction catheter for all patients* Infection – 0.08 Death - 0.02	

Author, Yr (Reference)	Study Design	Quality	Study Objective	Population and Setting	N	Results	Comments
			catheters with sealed junctions only for patients who are not receiving antimicrobial prophylaxis for some other reason (4) no antibiotic prophylaxis and no junction seals Costs and event rates were obtained from the published literature.			Cost - $42 *3. Sealed junction catheter if no antibiotic* Infection – 0.08 Death - 0.02 Cost - $41 *4. No antibiotic prophylaxis and no junction seals* Infection – 0.11 Death - 0.02 Cost - $55 **Sensitivity analysis:** The overall cost of each life saved by routine use of sealed catheters compared with selective use of these catheters was $4793. This cost was $1798 in a high risk population whose risk of death without infection was 5% (and whose risk of death with infection was 12.84%). However, routine use of sealed junction catheters was less expensive than selective use of those catheters if their extra cost was less than $3.13 Sensitivity analysis indicated that the overall cost of the antibiotic prophylaxis strategy exceeded that of routine use of sealed junction catheters for costs of antibiotic greater than $35, as was the case for most parenteral antibiotic regimens. When there was no extra cost of sealed junction catheters, their use was less expensive than the oral prophylaxis strategy if the total cost of oral prophylaxis was greater than $15 For costs of infection between $25 and $114, the strategy of selective use of sealed junction catheters was least expensive. For costs greater than $114, oral prophylaxis was least expensive. For costs greater than $641, routine use of sealed junction catheters was the next least expensive after oral prophylaxis	

GRADE Table

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
Silver-coated catheter vs. control	Symptomatic UTI*	2 OBS [93, 97]	Significantly decreased risk with silver-alloy catheters in 1 OBS [97] . Statistical differences were not reported in 1 OBS [93]	Low	0	0	0	0	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	4 SR [85, 87-89] 1 MA [86] 1 RCT [90] 7 OBS [91, 92, 94-96, 98, 99]	Significantly decreased risk with silver alloy catheters in 2 SRs [85, 89] , 1 MA [86] and 1 OBS [95] . There was a possible decrease in risk in 1 OBS [98] . 2 SRs found no significant differences with silver-oxide catheters [85, 89] , although there was a significantly decreased risk in women in 1 SR [85] . 2 SRs that did not pool data found a decreased risk with silver-coated catheters, particularly when compared with latex rather than silicone catheters [87] , or in studies of poorer quality [88] . The effect of silver alloy catheters was more pronounced when compared with latex catheters rather than silicone catheters in1 MA [86] and at <1 week of catheterization than at >1 week in 1 SR [85] . No significant differences were found in 1 RCT [90] and 3 OBS [92, 94, 96] .Statistical differences were not reported in 2 OBS [91, 99] .	High	0	0	-1	0	0	0	0	0	Moderate	
	Time to bacteriuria	1 OBS [94]	No significant differences were found, although there was a suggestion of decrease	Low	0	0	0	-1	0	0	0	0	Very Low	
	Bacteremia	2 OBS [91, 92]	No significant differences were found in 1 OBS [92] . Statistical differences were not reported in the other OBS [91]	Low	0	0	0	-1	0	0	0	0	Very Low	
	Duration of catheterization	4 OBS [34, 93, 94, 99]	Significantly decreased risk with silver-oxide catheters in 1 OBS [34] . No significant differences were found in 1 OBS [94] and statistical differences were not reported in 2 OBS [93, 99]	Low	-1	0	0	0	0	0	0	0	Very Low	
	Antimicrobial resistance*	1 SR [87] 1 OBS [95]	No antimicrobial resistance was found with the use of silver coated catheters	High	-1	0	0	-1	0	0	0	0	Low	
	Urethral discharge*	1 SR [85]	No significant differences were found in the SR [85] . Statistical	High	-1	0	0	-1	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
		1 OBS [99]	differences were not reported in the OBS [99]											
	Pain/itching/burning*	1 SR [85] 1 OBS [99]	No significant differences were found in the SR [85] . Statistical differences were not reported in the OBS [99]	High	0	0	-1	-1	0	0	0	0	Low	
Antibiotic-coated catheter vs. control	Symptomatic UTI*	1 SR [85]	No significant differences were found	High	-1	0	0	-1	0	0	0	0	Low	Low
	Bacteriuria/unspecified UTI*	2 SR [85, 87] 1 OBS [102]	Significantly decreased risk if catheterization < 1 week but not if catheterization > 1 week in 1 SR [85] . No significant differences were found in the other SR [87] and the OBS [102]	High	0	0	-2	0	0	0	0	0	Low	
	Antimicrobial resistance*	1 SR [87]	No antimicrobial resistance was found	High	0	0	-2	0	0	0	0	0	Low	
Hydrophilic coated catheter vs. control	Symptomatic UTI*	3 RCT [104, 106, 107] 1 OBS [109]	Significantly decreased risk in 1 RCT of long term intermittent catheterization [104] . No significant differences were found in 1 RCT [107] and 1 OBS [109] . Statistical differences were not reported in 1 RCT [106]	High	-1	-1	0	0	0	0	0	0	Low	Very Low
	Bacteriuria/unspecified UTI*	1 SR [85] 4 RCT [104, 106-108] 1 OBS [109]	Significantly decreased risk in 1 RCT [106] . No significant differences were found in 1 SR [85] , 3 RCTs [104, 107, 108] and 1 OBS [109]	High	-1	-1	-1	0	0	0	0	0	Very Low	
	Hematuria*	4 RCT [104-107] 1 OBS [109]	Significantly decreased risk in 2 RCTs [105, 107] . No significant differences were found in 2 RCTs [104, 106] and 1 OBS [109]	High	-1	-1	0	0	0	0	0	0	Low	
	Urethritis	1 OBS [109]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	
	Patient satisfaction*	2 RCT [104, 105]	No significant differences were found in 1 RCT [104] . Statistical differences were not reported in 1 RCT [105] . However, there was a suggestion of increased satisfaction in both	High	0	0	0	-1	0	0	0	0	Moderate	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
	Pain/discomfort*	2 RCT [105, 106]	Significantly decreased risk in both RCTs	High	0	0	0	-1	0	0	0	0	Moderate	
	Dysuria	1 RCT [105]	No significant differences were found	High	0	0	-1	-1	0	0	0	0	Low	
	Stricture	1 RCT [106]	No significant differences were found	High	0	0	-1	-1	0	0	0	0	Low	
Closed vs. open drainage system	Symptomatic UTI*	1 OBS [124]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	Very Low
	Bacteriuria*	1 OBS [125]	Significantly decreased risk	Low	-1	0	0	0	0	0	0	0	Very Low	
	Bacteremia*	1 OBS [124]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	
	Mortality*	1 OBS [124]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	
	Duration of catheterization	1 OBS [124]	No significant differences were found	Low	0	0	0	-1	0	0	0	0	Very Low	
Complex vs. simple drainage system	Bacteriuria*	4 RCT [113, 115, 116, 118] 3 OBS [123, 130, 131]	Significantly decreased risk in 2 RCTs [116, 118] and 1 OBS [131], all of which were published prior to 1990. No significant differences were found in 2 RCTs [113, 115] and 2 OBS [123, 130]	High	0	-1	-1	0	0	0	0	0	Low	Low
	Time to bacteriuria	2 RCT [113, 116] 2 OBS [123, 130]	Significantly decreased risk in 1 RCT [113]. No significant differences were found in 1 RCT [116] and 2 OBS [123, 130]	High	0	-1	-1	0	0	0	0	0	Low	
	Length of ICU stay	1 RCT [113] 1 OBS [130]	Significantly decreased risk in 1 RCT [113]. No significant differences were found in 1 OBS [130]	High	0	-1	-1	0	0	0	0	0	Low	
	Duration of catheterization	2 RCT [113, 115] 3 OBS [123,	Significantly decreased risk in 1 RCT [113]. No significant differences were found in 1 RCT [115] and 3 OBS [123, 130, 131]	High	0	-1	-1	0	0	0	0	0	Low	

Comparison	Outcome	Quantity and type of evidence	Findings	Starting grade	Decrease GRADE					Increase GRADE			GRADE of Evidence for Outcome	Overall GRADE of Evidence Base
					Study Quality*	Consistency	Directness*	Precision	Publication Bias	Large Magnitude*	Dose-response	Confounders		
		130, 131												
	Urethral discharge	1 RCT [118]	No significant differences were found	High	-1	0	0	-1	0	0	0	0	Low	
	Incontinence	1 RCT [118]	No significant differences were found	High	-1	0	0	-1	0	0	0	0	Low	
Pre-connected/Sealed junction catheter vs. control	Symptomatic UTI*	1 RCT [117] 1 OBS [129]	Significantly decreased risk in 1 OBS [129] . No significant differences were found in 1 RCT [117]	High	-1	-1	0	0	0	0	0	0	Low	Low
	Bacteriuria*	3 RCT [114, 117, 119]	Significantly decreased in patients not receiving antibiotics in 1 RCT [119] . No significant differences were found in 2 RCTs [114, 117]	High	-1	0	0	0	0	0	0	0	Moderate	
	Mortality	2 RCT [114, 119]	Significantly decreased in patients not receiving antibiotics in 1 RCT [119] . No significant differences were found in 1 RCT [114]	High	-1	0	0	0	0	0	0	0	Moderate	
	Time to symptomatic UTI	1 OBS [129]	Significantly decreased	Low	0	0	0	0	0	0	0	0	Low	
	Duration of catheterization	3 RCT [114, 117, 119]	No significant differences were found	High	-1	0	0	0	0	0	0	0	Moderate	
Catheter valve vs. catheter bag	Bacteriuria/unspecified UTI*	1 SR [112]	No significant differences were found	High	0	0	0	-1	0	0	0	0	Moderate	Moderate
	Pain/bladder spasms*	1 SR [112]	No significant differences were found	High	0	0	0	-1	0	0	0	0	Moderate	
	Incontinence	1 SR [112]	No significant differences were found	High	0	0	0	-1	0	0	0	0	Moderate	
	Patient satisfaction*	1 SR [112]	Significantly increased for catheter valve	High	0	0	0	-1	0	0	0	0	Moderate	

* These modifiers can impact the GRADE by 1 or 2 points

C. What are the risks and benefits associated with different catheter management techniques?

TABLE 6: CATHETER MANAGEMENT TECHNIQUES

GRADE Table

D. What are the risks and benefits associated with different systems changes?

TABLE 7: SYSTEMS CHANGES

GRADE Table

Question 3: What are the best methods to manage catheter-associated complications?

A. What are the best methods to manage an obstructed urinary catheter?

TABLE 8: MANAGEMENT OF OBSTRUCTED URINARY CATHETER

GRADE Table

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APPENDIX 3: QUALITY CHECKLISTS

I. Systematic Reviews

1. Search terms described
2. Databases searched described
3. Inclusion/exclusion criteria described
4. Numbers of included/excluded studies along with reasons for exclusions described
5. Studies screened by two independent reviewers for inclusion
6. Data extracted by two independent reviewers
7. Individual study quality assessed
8. Heterogeneity between study results assessed qualitatively and/or quantitatively

II. Randomized Controlled Trials

1. Described as randomized
2. Randomization appropriately performed
3. Described as double-blind
4. Outcome assessor blinded
5. Study participant blinded
6. Investigator blinded
7. Attrition described
8. Attrition smaller than 10-15% of assigned patients
9. Attrition appropriately analyzed (i.e. intention-to-treat analysis for superiority studies)

III. Cohort Studies/Case Control Studies

1. All study groups derived from similar source/reference populations

2. Attrition not significantly different across all study groups
3. The measure of exposure is valid
4. The measure of outcome is valid
5. Investigators blinded to endpoint assessment
6. Potential confounders identified
7. Statistical adjustment for potential confounders performed

IV. Diagnostic Studies

1. Valid selection of study sample (i.e. consecutive or randomly selected subjects)
2. Valid reference standard
3. Diagnostic test and reference standard performed independently on each subject
4. Diagnostic test and reference standard evaluated independently on each subject (blinding)

V. Economic Evaluations

1. Perspective defined (e.g. societal, payer, provider)
2. Time horizon defined
3. Decision tree(s) or rule(s) explicit
4. Sources of cost estimates presented
5. Sources of event rate estimates presented
6. Sensitivity analyses performed