National Institute for Health and Care Excellence

Final

Renal and ureteric stones: assessment and management

Stents before surgery

NICE guideline NG118

Intervention evidence review (H)

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Final

This evidence review was developed by the National Guideline Centre

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1.1 Review question: Is inserting a stent clinically and cost-effective before surgical treatment in people with renal or ureteric stones?

1.2 Introduction

Ureteric JJ stents are used in stone management to relieve obstruction and uncontrollable pain in the emergency setting. In the elective setting the rationale for their use before surgery is that they will improve stone fragment passage, reduce complications, and reduce readmissions. There is particular concern that shock wave lithotripsy (SWL) for larger stones will result in stone fragments failing to pass resulting in the need for ancillary procedures and that pre-stenting will reduce this risk. However JJ stents are known to have adverse effects, and significant “stent symptoms” (for example, frequency, haematuria and pain) affecting patients quality of life are seen in 80% of cases.

There are no national agreed guidelines to the use of stents before SWL and practice varies. This questions aims to address this variation in practice.

1.3 PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	People (adults, children and young people) with symptomatic and asymptomatic renal or ureteric stones
Interventions	Insertion of a stent followed by a surgical procedure (SWL, or URS/RIRS or PCNL)
Comparisons	Surgical procedure (SWL, or URS/RIRS or PCNL) alone
Outcomes	Critical outcomes: • Stone-free state (including residual fragment) • Recurrence • Use of healthcare services (length of stay, readmission, retreatment or ancillary procedure) • Kidney function • Quality of life • Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) • Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) • Failure to treat (inaccessible stone, stone not seen/reached) • Stent symptoms (dysuria, irritative symptoms, haematuria, frequency, urgency, nocturia) Important outcomes: • Pain intensity (visual analogue scale)
Study design	Randomised controlled trials (RCTs) If no RCT evidence for children is available, cohort studies will be considered.

Key confounders	• Stone site • Stone size

1.4 Clinical evidence

1.4.1 Included studies

Five randomised studies and two non-randomised studies were included in the review;[2, 4, 35, 38, 50, 53, 70] these are summarised in Table 4 below. Evidence from these studies is summarised in the clinical evidence summary below (Table 4). All included studies compared stent placement followed by SWL to SWL alone. All RCTs were in the adult population. No RCT evidence was identified for children and young people, so the search was extended to non-randomised studies. Two non-randomised studies were identified for inclusion; [4, 38]. See also the study selection flow chart in appendix C, study evidence tables in appendix D, forest plots in appendix E and GRADE tables in appendix H.

1.4.1.1 Heterogeneity

For the comparison of stent before SWL versus SWL alone in the adult, renal, 10-20mm strata, there was substantial heterogeneity between the studies when they were meta-analysed for the outcomes of stent symptoms (haematuria). Pre-specified subgroup analyses did not explain the heterogeneity. A random effects meta-analysis was therefore applied to these outcomes, and the evidence was downgraded for inconsistency in GRADE.

1.4.2 Excluded studies

See the excluded studies list in appendix I

1.4.3 Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review

Study	Intervention and comparison	Population	Outcomes	Comments
Adults, renal, 10-20mm				
Mohayuddin 2009[50]	Intervention (n=40): a JJ stent (4.8Fr) was placed before SWL, and removed at 3 months or once the stone disappeared. SWL was performed using an electromagnetic machine. 3000 shockwaves were given at a rate of 70 per minute, and the energy was kept between 4 and 6. Comparison (n=40): SWL with no stent placement.	n=80 People with radio opaque renal pelvic stone in which the greatest diameter was 2cm Stone size (mean, SD): stent group 19.5 (0.138); no stent group 19.3 (0.126) Age (mean, SD), years: stent group 34.3 (11.35); no stent group 32.13 (11.5) Number of SWL sessions (mean): stent group 1.63; no stent group 1.55 Gender not reported Pakistan	Stone free state (3 months): not defined. Assessed by X ray KUB and ultrasound KUB Readmission (3 months): defined as hospital visits and admissions Ancillary procedures (3 months) Minor adverse events (3 months): fever Stent symptoms (3 months): urgency, dysuria, frequency, haematuria, nocturia	Readmission downgraded for indirectness due to including hospital visits
Musa 2008[53]	Intervention (n=60): stenting prior to SWL, using 5 Fr DJ stents, followed by SWL using the electrohydrolic spark gap lithotripter under general anesthesia at KV ranges between 14-22 and shockwave rate of 75/min. The stent was removed after 2 weeks.	n=120 People with renal calculi between 10-20 mm who presented for elective ESWL	Stone-free state (3 months): not defined, assessed by plain abdominal film Retreatment (3 months): number of people requiring a second SWL session	

Study	Intervention and comparison	Population	Outcomes	Comments
	Comparison (n=60): no stenting, followed by SWL as above All patients received 1g ceftriaxone intravenously prior to the operative procedure.	Stone size (mean, range), mm: stent group 16.8 (10-20); no stent group 16.6 (10-20) Age (mean), years: stent group 39; no stent group 37.5 Male to female ratio 78:42 Yemen	Readmission (3 months) Stent symptoms (48 hours): haematuria	
Sharma 2017[70]	Intervention (n=31): DJ stenting was done 1 week before ESWL procedure and the procedure was accomplished with the DJ stent in situ. The stent was kept until the completion of 3 sittings, done 4 weeks apart, or it was removed earlier upon clearance of the stones Comparison (n=27): ESWL without any stenting	n=58 People with renal stone disease and a stone between 15-20mm Stone size (mean, SD), mm: stent group 14.3 (3.1); no stent group 13.8 (3.0) Age (mean, SD), years: stent group 40.4 (12.7); no stent group 32.8 (8.4) Number of SWL sittings (mean): stent group 2.2; no stent group 2.0 Male to female ratio 33:25 India	Stone-free state (4 weeks): complete clearance or a clinically insignificant residual fragment (CIRF) of less than 4 mm. Significant residual fragments (4 weeks): defined as >4mm residual fragment Insignificant residual fragment (4 weeks): defined as fragment <4 mm Minor adverse events (4 weeks): UTI, fever Stent symptoms (4 weeks): haematuria	
Adults, renal, >20mm				
Al-Awadi 1999[2]	Intervention (n=200): ESWL using the Siemens LithoStar 2-Plus machine, giving 6000 shocks per stone per session, with treatment repeated	n=400 People with unilateral renal	Stone-free state (time-point not reported): not defined, assessed by KUB, ultrasonography and IVU	

Study	Intervention and comparison	Population	Outcomes	Comments
	weekly until the patients became stone-free. Stents were inserted before ESWL and removed within a week of the patients becoming stone-free Comparison (n=200): ESWL without any stenting	calculi (mean diameter 1.5–3.5 cm) Stone size: 15-20mm 8%; >20mm 92% Age (mean, SD): 43 (18.7) Male to female ratio 337:63 Kuwait	Retreatment (time-point not reported) Minor adverse events (time-point not reported): fever Failed technology (time-point not reported)	
Adults, ureteric, 10-20mm				
Ghoneim 2010[35]	Intervention (n=30): JJ stenting followed by SWL. A single 6F JJ stent was placed 1 week before SWL and removed after radiological evidence of no sizeable fragments. Comparison (n=30): SWL with no stent placement.	n=60 People with solitary, radio-opaque, impacted upper ureteral stone <20mm Stone size (mean SD), mm: stent group 10.23 (0.38); no stent group 10 (0.43) Age (mean, SD), years: stent group 43.1 (11.5); no stent group 40.7 (10.6) Number of SWL sessions (mean, SD): stent group 2 (0.14); no stent group 1.97 (0.16) Male to female ratio 39: 21 Egypt	Stone free state (3 months): defined as complete stone clearance with no visible fragments on radiological studies or fragments ≤4mm. Stone free state includes those with multiple SWL sessions Retreatment (3 months) Minor adverse events (3 months): fever Stent symptoms (3 months): dysuria, haematuria	
Children, renal, <10mm (non-randomised studies)				

Study	Intervention and comparison	Population	Outcomes	Comments
Gunduz 2017[38]	Intervention (n=10): Before SWL treatment, a placed 3 Fr 16 cm JJ stent was placed under general anaesthesia. An Elmed Complit System was used with 11-13 kV, 60 frequency, and 1,000-1,200 shots in patients 2-4 years old, and 11-14 kV, 70 frequency, and 1,0001,500 shots in patients over 4 years old. The stent was removed at 5 days if the patient was stone free, or SWL was repeated 1 week later, up to 2 times Comparison (n=10): SWL with no JJ stents inserted. SWL as in the intervention group	n=20 Children with renal calculi Stone size (mean, range): stent group 9 (7-15); no stent group 9 (7-16) Age (mean, range): stent group 4 (3-5); no stent group 4.5 (2-12) Male to female ratio 7:13 Turkey	Stone-free state (time-point not reported) Retreatment (time-point not reported): number of patients with 2 or 3 sessions of SWL Ancillary procedures (time-point not reported)	Non-randomised study
Children, renal, staghorn (non-randomised studies)				
Al-Busaidy, 2003[4]	Intervention (n=23): ESWL with a 4Fr (8-10 or 12-16cm) double-J ureteral stent which was inserted immediately before ESWL. ESWL involved delivering a maximum of 4000 shocks per session. Further ESWL sessions were at 3 week intervals. The stent was removed 3 weeks after the last ESWL session Comparison (n=19): ESWL without prophylactic ureteral stenting. ESWL as in the intervention group.	n=42 Children with staghorn calculi Stone size (mean, SD), mm: stent group 32 (5); no stent group 32 (6) Age (mean, SD), years: stent group 6.3 (3.5); no stent group 5.7 (3.6) Number of SWL sessions (mean, SD): stent group 2.6 (0.9); no stent group 2.5 (0.7) Male to female 29:13 Oman	Stone-free state (3 months after the last ESWL session): defined as the complete absence of residual stone fragments of any size on plain abdominal x-ray and renal ultrasound Length of stay (time-point not reported) Readmission (time-point not reported) Ancillary procedures (time-point not reported)	Non-randomised study

Study	Intervention and comparison	Population	Outcomes	Comments
			Major adverse events (time-point not reported): sepsis	

See appendix D for full evidence tables.

1.4.4 Quality assessment of clinical studies included in the evidence review

1.4.4.1 Adults, ureteric, 10-20mm

Table 3: Clinical evidence summary: Stent followed by SWL versus SWL alone

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Stone free	60 (1 study) 3 months	⊕⊕⊖⊖ LOW[1,2] due to risk of bias, imprecision	RR 1.04 (0.86 to 1.25)	Moderate	
				867 per 1000	35 more per 1000 (from 121 fewer to 217 more)
Retreatment	60 (1 study) 3 months	⊕⊖⊖⊖ VERY LOW[1,2] due to risk of bias, imprecision	RR 1.15 (0.83 to 1.59)	Moderate	
				667 per 1000	100 more per 1000 (from 113 fewer to 394 more)
Minor adverse events (fever)	60 (1 study) 3 months	⊕⊖⊖⊖ VERY LOW[1,2] due to risk of bias, imprecision	RR 0.5 (0.05 to 5.22)	Moderate	
				67 per 1000	34 fewer per 1000 (from 64 fewer to 283 more)
Stent symptoms (dysuria)	60 (1 study) 3 months	⊕⊕⊖⊖ LOW[1] due to risk of bias	RR 2.57 (1.26 to 5.24)	Moderate	
				233 per 1000	366 more per 1000 (from 61 more to 988 more)
				Moderate	

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Stent symptoms (Microscopic haematuria)	60 (1 study) 3 months	⊕⊕⊖⊖ LOW1 due to risk of bias	RR 2.88 (1.54 to 5.37)	267 per 1000	502 more per 1000 (from 144 more to 1000 more)
Stent symptoms (Gross haematuria)	60 (1 study) 3 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 4 (0.47 to 33.73)	Moderate	
				33 per 1000	99 more per 1000 (from 17 fewer to 1000 more)
1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias 2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.					

1.4.4.2 Adults, renal, 10-20mm

Table 4: Clinical evidence summary: Stent followed by SWL versus SWL alone

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Stone free state	258 (3 studies) 1-3 months	⊕⊕⊖⊖ LOW1 due to risk of bias	RR 0.97 (0.86 to 1.08)	Moderate	
				825 per 1000	25 fewer per 1000 (from 115 fewer to 66 more)
Clinically insignificant residual fragment	58 (1 study) 4 weeks	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 1 (0.6 to 1.64)	Moderate	
				519 per 1000	0 fewer per 1000 (from 208 fewer to 332 more)
Clinically significant residual fragment	58 (1 study) 4 weeks	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 0.96 (0.48 to 1.9)	Moderate	
				370 per 1000	15 fewer per 1000 (from 192 fewer to 333 more)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Readmission	200 (2 studies) 3 months	⨁⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, indirectness, imprecision	RR 1 (0.26 to 3.91)	Moderate	
				46 per 1000	0 fewer per 1000 (from 34 fewer to 134 more)
Retreatment	120 (1 study) 3 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 1.67 (0.42 to 6.66)	Moderate	
				50 per 1000	33 more per 1000 (from 29 fewer to 283 more)
Ancillary procedure	80 (1 study) 3 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 1 (0.06 to 15.44)	Moderate	
				25 per 1000	0 fewer per 1000 (from 24 fewer to 361 more)
Minor adverse events (UTI)	58 (1 study) 4 weeks	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 0.44 (0.04 to 4.54)	Moderate	
				74 per 1000	41 fewer per 1000 (from 71 fewer to 262 more)
Minor adverse events (fever)	138 (2 studies) 1-3 months	⨁⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 3.48 (0.59 to 20.65)	Moderate	
				13 per 1000	32 more per 1000 (from 5 fewer to 255 more)
Stent symptoms (urgency)	80 (1 study) 3 months	⨁⨁⨁⊖ MODERATE1 due to risk of bias	RR 4.75 (1.77 to 12.72)	Moderate	
				100 per 1000	375 more per 1000 (from 77 more to 1000 more)
Stent symptoms (dysuria)	80 (1 study) 3 months	⨁⨁⨁⊖ MODERATE1 due to risk of bias	RR 3.83 (1.75 to 8.4)	Moderate	
				150 per 1000	425 more per 1000 (from 113 more to 1000 more)
Stent symptoms (frequency)	80 (1 study) 3 months	⨁⨁⨁⊖ MODERATE1 due to risk of bias	RR 6 (1.92 to 18.78)	Moderate	
				75 per 1000	375 more per 1000 (from 69 more to 1000 more)
Stent symptoms (haematuria)				Moderate	

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
	258 (3 studies) 48 hours - 3 months	⊕⊖⊖⊖ VERY LOW1,2,4 due to risk of bias, inconsistency, imprecision	RR 1.04 (0.56 to 1.93)	317 per 1000	13 more per 1000 (from 139 fewer to 295 more)
Stent symptoms (nocturia)	80 (1 study) 3 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 5 (0.61 to 40.91)	Moderate	
				25 per 1000	100 more per 1000 (from 10 fewer to 998 more)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
3 Downgraded by 1 increment if the outcome definition reported did not meet definition of outcome in protocol
4 Downgraded by 1 or 2 increments because heterogeneity, I2= 63%, p= > 0.1, unexplained by subgroup analysis

1.4.4.3 Adults, renal, >20 mm

Table 5: Clinical evidence summary: Stent followed by SWL versus SWL alone

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Stone free state	400 (1 study) time-point not reported	⊕⊕⊕⊖ MODERATE1 due to risk of bias	RR 0.99 (0.91 to 1.07)	Moderate	
				870 per 1000	9 fewer per 1000 (from 78 fewer to 61 more)
Retreatment	38 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, indirectness, imprecision	RR 0.54 (0.07 to 4.34)	Moderate	
				154 per 1000	71 fewer per 1000 (from 143 fewer to 514 more)
				Moderate	

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Minor adverse events (fever)	38 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2,3 due to risk of bias, indirectness, imprecision	RR 1.08 (0.23 to 5.12)	154 per 1000	12 more per 1000 (from 119 fewer to 634 more)
Failed technology	400 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	Peto OR 7.46 (0.77 to 72.16)	Moderate	
				0 per 1000	15 more per 1000 (from 4 fewer to 34 more)4

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the outcome definition reported did not meet definition of outcome in protocol
3 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
4 Risk difference calculated in Review Manager

1.4.4.4 Children, renal, <10mm

Table 6: Clinical evidence summary: Stent followed by SWL versus SWL alone

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Stone free state	20 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 1.24 (0.87 to 1.75)	Moderate	
				800 per 1000	192 more per 1000 (from 104 fewer to 600 more)
Retreatment	20 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 0.67 (0.27 to 1.66)	Moderate	
				600 per 1000	198 fewer per 1000 (from 438 fewer to 396 more)
Ancillary procedures				Moderate	

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
	20 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	Peto OR 0.14 (0 to 6.82)	100 per 1000	85 fewer per 1000 (from 100 fewer to 331 more)
Stent symptoms (hematuria)	20 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 3 (0.37 to 24.17)	Moderate	
				100 per 1000	200 more per 1000 (from 63 fewer to 1000 more)
Stent symptoms (dysuria)	20 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 0.5 (0.05 to 4.67)	Moderate	
				200 per 1000	100 fewer per 1000 (from 190 fewer to 734 more)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

1.4.4.5 Children, renal, staghorn

Table 7: Clinical evidence summary: Stent followed by SWL versus SWL alone

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Stone free state	42 (1 study) 3 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	RR 0.99 (0.72 to 1.36)	Moderate	
				790 per 1000	8 fewer per 1000 (from 221 fewer to 284 more)
Length of stay (days)	42 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean length of stay (days) in the control groups was 6.4	The mean length of stay (days) in the intervention groups was 1.8 lower (3.36 to 0.24 lower)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with No stent before SWL	Risk difference with Stent (95% CI)
Readmission	42 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1 due to risk of bias	Peto OR 0.09 (0.01 to 0.71)	Moderate	
				211 per 1000	187 fewer per 1000 (from 51 fewer to 208 fewer)
Ancillary procedures	42 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1 due to risk of bias	Peto OR 0.08 (0.01 to 0.38)	Moderate	
				368 per 1000	323 fewer per 1000 (from 187 fewer to 362 fewer)
Major adverse events (sepsis)	42 (1 study) time-point not reported	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision	Peto OR 0.1 (0.01 to 1.74)	Moderate	
				105 per 1000	93 fewer per 1000 (from 104 fewer to 65 more)

1 Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

See appendix F for full GRADE tables.

1.5 Economic evidence

1.5.1 Included studies

No relevant health economic studies were identified.

1.5.2 Excluded studies

One economic study relating to this review question was identified but was excluded due to methodological limitations. [29] These are listed in appendix I, with reasons for exclusion given.

See also the health economic study selection flow chart in appendix G.

1.5.3 Unit costs

Table 8: UK costs of stent (per surgery i.e. removal and insertion = cost x 2)

Parameter	Description	Unit cost
Stent removal cost	LB09D Intermediate Endoscopic Ureter Procedures, 19 years and over	£1,018

Source: NHS reference cost 2016/17 [59]

The clinical review data identified compares inserting a stent prior to SWL, and then leaving the stent in until a few weeks after the SWL then removing. This is compared to SWL with no stent inserted.

This essentially means that there are three procedures in the stent arm; stent insertion, SWL, and stent removal, and only the SWL in the no stent arm. This will create a large cost difference between the two interventions of over £2,000.

1.6 Resource costs

The recommendations made in this review are not expected to have a substantial impact on resources.

1.7 Evidence statements

1.7.1 Clinical evidence statements

Adults, ureteric, 10-20mm

One study compared stent use before SWL to SWL alone in a population of adults with 10-20mm ureteric stones. There was no clinical difference between the groups in terms of stone-free state and fever (1 study; n=60). There was a clinical benefit of SWL alone in terms of retreatment , and in terms of all stent symptoms outcomes (dysuria, microscopic haematuria, gross haematuria) (1 study, n=60). The quality of the evidence ranged from Low to Very Low. The main reasons for downgrading evidence included risk of bias and imprecision.

Adult, renal, 10-20mm

Three studies compared stent use before SWL and SWL alone in a population of adults with 10-20mm renal stones. All the studies reported stone-free state, and the evidence showed

no clinical difference between the two groups (3 studies; n=258). Evidence from single studies showed no clinical difference for the outcomes clinically insignificant fragments, clinically significant fragments, ancillary procedures and retreatment (1 study; n=58-120). Evidence from two studies also showed no clinical difference in terms of readmission (2 studies; n=200). In terms of adverse events, evidence demonstrated no clinical difference in terms of UTI and in terms of fever (1-2 studies; n=58-138). In terms of stent symptoms, there was no clinical difference between groups for the outcome haematuria (3 studies; n=258). There was a clinical benefit of SWL alone in terms of all other stent symptom outcomes (urgency, frequency, dysuria, nocturia) (1 study; n=80). The quality of the evidence ranged from Moderate to Very Low. The main reasons for downgrading evidence included risk of bias, imprecision and in some cases, inconsistency.

Adults, renal, >20mm

One study compared stent use before SWL to SWL alone in a population of adults with renal stones >20mm. There was no clinical difference between the groups in terms of stone-free state, fever and failed technology (1 study; n=38-400). There was a clinical benefit of stent before SWL in terms of retreatment (1 study, n=38). The quality of the evidence ranged from Moderate to Very Low. The main reasons for downgrading evidence included risk of bias, imprecision and in some cases, indirectness.

Children, renal, 10-20mm

One non-randomised study compared stent use before SWL to SWL alone in a population of children with 10-20mm renal stones. The evidence demonstrated a clinical benefit of stent before SWL in terms of stone-free state, retreatment, ancillary procedures, and dysuria (1 study, n=20). For the outcome haematuria, there was a clinical benefit of SWL alone (1 study; n=20). The quality of the evidence was Very Low. The main reasons for downgrading evidence included risk of bias and imprecision.

Children, renal, 10-20mm

One non-randomised study compared stent use before SWL to SWL alone in a population of children with staghorn renal stones. The evidence demonstrated a no clinical difference between the groups in terms of stone-free state (1 study; n=42). There was a clinical benefit of stent before SWL in terms of readmission, ancillary procedures, length of stay and major adverse events (sepsis) (1 study, n=42). The quality of the evidence was Very Low. The main reasons for downgrading evidence included risk of bias and imprecision.

1.7.2 Health economic evidence statements

- No relevant economic evaluations were identified.

1.8 The committee's discussion of the evidence

1.8.1 Interpreting the evidence

1.8.1.1 The outcomes that matter most

The committee agreed that stone-free state, recurrence rate, use of healthcare services, kidney function, quality of life, failed technology, major adverse events, minor adverse events and stent symptoms were the outcomes that were critical for decision making. Pain was also considered as an important outcome.

Evidence was reported for stone-free state, recurrence rate, use of healthcare services, failed technology, major adverse events, minor adverse events and stent symptoms. There was no evidence for the critical outcomes of quality of life or kidney function, or for the important outcome pain.

No evidence was found that compared stent use to no stent for the surgery modalities of URS or PCNL. The only evidence found for inclusion used SWL as the treatment modality.

1.8.1.2 The quality of the evidence

For the majority of evidence in this review, the quality ranged from a GRADE rating of moderate to very low. This was due to a lack of blinding, presence of selection bias in terms of a lack of adequate randomisation and allocation concealment, resulting in a high risk of bias rating. Evidence was further downgraded due to the presence of imprecision for many of the outcomes, and inconsistency for one outcome. No outcomes were given a high quality rating.

1.8.1.3 Benefits and harms

Evidence for people with both symptomatic and asymptomatic stones was searched for; however no evidence was identified for the asymptomatic population. The committee therefore agreed that the recommendations should only apply to those with symptomatic stones.

Adults, ureteric, 10 to 20 mm

The committee considered very low to low quality evidence from one study with 60 participants and noted that there was no difference between the two groups, or a clinical benefit of no stent. There was no evidence of a clinical benefit of stent for any outcomes. The committee agreed that this demonstrated that there was no evidence that stents improve outcomes for participants, and may actually impede beneficial outcomes, demonstrated by more retreatments, and more stent related adverse events and symptoms. Having a stent in place during SWL may prevent the shocks reaching the stone and consequently more retreatments may be required. The committee therefore agreed that stenting should not be recommended for ureteric stones of 10-20mm. The committee's opinion was that ureteric stones need to be treated more urgently compared to renal stones as large ureteric stones can block the kidney and can lead to obstructive uropathy within 2-6 weeks, therefore treatment needs to be completed within this time frame. The committee considered that in cases where SWL could not be done in a timely fashion, the use of a stent may be considered appropriate in individual circumstances.

Adults, renal, 10 to 20 mm

The committee considered very low to moderate quality evidence from three studies and noted that there was no clinical difference between those who had had a stent before SWL and those who had not for any outcomes apart from the stent symptoms outcomes. The committee agreed that this demonstrated that there was no benefit of stenting before SWL over not stenting, and discussed that given that stenting is associated with a number of stent related adverse events and symptoms, stenting should not be offered for this group of people.

Adults, renal, greater than 20 mm

The committee considered the evidence from one study of very low to moderate quality and noted that there was no difference between the groups for the stone-free state, minor adverse events and failed technology outcomes. There was a clinical benefit for the stent group in terms of retreatment rate, however the committee noted that this evidence was from a single study and was very imprecise. The committee further noted several concerns regarding the validity and applicability of this study. For instance, it was noted that it is unusual practice to perform SWL for renal stones of this size, and that this would not be done in the UK. The committee also noted that the number of shocks given per session was above the recommended limit, which also does not reflect UK practice. It was further noted that in order to tolerate this level of shocks, it is likely that this would have been performed under

general anaesthesia, which is also a deviation from standard practice in the UK. Therefore, the committee agreed that this study does not reflect UK current practice and therefore may not be applicable to a UK population. It was also noted that following the surgical interventions review, there is no recommendation for SWL for this group of people.

There was no evidence for ureteric or renal stones less than 10 mm, and no evidence for ureteric stones greater than 20 mm. The committee agreed that stone size should not be specified in the recommendation for a number of reasons;

- For small renal stones, current standard practice is not to stent pre-treatment.
- For small ureteric stones, stenting is sometimes used in current practice for a variety of reasons (ongoing pain, obstruction, lack of access to emergency definite treatment), however as shown in the timing of surgery review, there is clinical benefit to primary intervention within 48 hours, therefore avoiding the use of stents. The committee wanted to further encourage best practice of treating with primary treatment rather than temporising with a stent.
- Ureteric stones greater than 20 mm are unlikely to be treated with SWL and therefore the recommendation would not apply to this group.

Overall, the committee agreed that although the evidence had been reviewed and presented by strata, the results demonstrated that the same recommendation should be made for all adults with either ureteric or renal stones of all sizes. This is because the recommendation would only apply to where SWL is being used anyway (which generally precludes large stones; >20mm), and would reinforce current or best practice in other groups (stents before surgery are not generally used in small renal stones, and treatment within 48 hours would preclude the use of stents before SWL). Therefore adding a size into the recommendation was not felt to be necessary. The committee agreed no evidence had been presented that would warrant recommending the use of stents prior to SWL for any of the strata.

Children and young people, renal, less than 10 mm

One small non-randomised comparative study of very low quality was identified. Although this evidence demonstrated potential clinical benefit of stenting before SWL in terms of stone-free state, retreatment rate, ancillary procedures the committee noted that there was very high risk of bias and serious and very serious imprecision in the outcomes. The committee noted that this was likely due to the unequal distribution of lower pole stones in each arm (3/10 lower pole stones in stent group versus 7/10 lower pole stones non-stented group). These stones are more difficult to treat, and therefore the committee agreed that the differences between groups in stone-free state, retreatment rate and ancillary procedures are likely to be due to this difference in stone location. The committee were also aware that although the mean stone size of the participants was less than 10mm, the maximum stone size was 16mm and so some of this evidence included participants in the 10-20mm population. The committee further noted that this evidence was not consistent with clinical experience as stents would not normally inserted before SWL in this population. Therefore, the committee did not have confidence in the evidence and decided not to make a recommendation for this stratum.

Children and young people, renal, staghorn

Evidence from one non-randomised comparative study demonstrated a clinical benefit of stenting before SWL in terms of readmission, ancillary procedures, length of stay and sepsis, and no clinical difference between groups in terms of stone-free state. The committee considered that the maximum number of shockwaves per session used in this study was high compared to standard practice in the UK, but noted that it was unclear how many participants received the maximum number of shocks. The committee noted that the

evidence came from a single study of very low quality. However, it was noted that the reduction in readmission and ancillary procedures were of particular benefit for the paediatric population. Based on this evidence, clinical experience and expertise of the committee, the consensus of the committee was that children with staghorn stones would generally derive benefit from having a stent and this would reflect usual practice, therefore it was agreed that stenting before SWL should be considered for children with a staghorn stone. The committee also noted that although SWL monotherapy is an option for paediatric staghorn calculi, many centres utilise PCNL as first line treatment for children with this type of stone.

No evidence was found for ureteric stones or for renal stones greater than 10 mm for children. The committee agreed that standard practice for children and young people is varied and so agreed that a consensus recommendation could not be made.

1.8.2 Cost effectiveness and resource use

One economic evaluation was identified but excluded because it was based on retrospective data and therefore considered to have very serious limitations, as this is not in keeping with the clinical review (for adults).

All the clinical review data identified compares inserting a stent prior to SWL, and then leaving the stent in until a few weeks after the SWL, then removing. This is compared to SWL with no stent inserted. This essentially means there are 3 procedures in the stent arm; stent insertion, SWL, and stent removal, and only the SWL in the no stent arm. This will create a large cost difference between the two interventions of over £2,000, as inserting or removing a stent comes under the same procedure code which has a cost of £1,018.

There were more stent symptoms with a stent which is to be expected. This will involve resource use such as patients possibly seeking healthcare advice such as GP time or hospital attendances, and being given pain relief and/or other drug treatments. For most outcomes there was no difference. Most outcomes are informed by only one study so it is difficult to have confidence in the results. However in general, if stents are a more expensive strategy and it is uncertain if there is any benefit but they do have more adverse events, then no stents are likely to be a dominant option if cheaper and equally effective.

The committee felt that there are two aspects to using stents; 1) if having an SWL, then does a stent stop the fragments getting stuck?, and 2) if there is an obstruction, should a stent be used to delay surgery?. It's possible that this review can answer the first nuance, but not necessarily the second.

In the data identified for an adult ureteric population, there was a clinical benefit for no stent for retreatment, and also for stent symptoms. The committee thought that the stent may be impeding stone passage, which can sometimes happen, and might explain why more people needed retreatment in the stent group. This would lead to additional resource use of more interventions in the stent group, as well as more stent symptoms. The committee concluded that there was no convincing benefit to using stents and is also likely to be more costly.

In the adult renal stones population, data was identified for two strata; 10-20cm and >20cm. in the smaller stone group, the only outcome where there was a clinical benefit was of stent symptoms, again signalling that there is no benefit to stents but possible increased costs and quality of life impact. In the larger renal stone group, the committee had concerns about the quality of the paper with regards to the high frequency of shockwaves, and also that using SWL for this size stones was not in keeping with UK practice. There was only a clinical benefit of retreatment favouring the stent arm. This is in contrast to the result of the ureteric study where no stent led to lower retreatments. Perhaps with a larger stone the stent is helping the fragments to pass, or the increase in shockwave frequency compared to other studies has resulted in smaller fragments which can pass despite the stent. The study did not define the time frame it was reporting which may impact on outcomes such as retreatments. The committee did not feel confident making a recommendation based on this study.

The committee decided to make recommendations against using stents prior to SWL for both the ureteric and renal groups. As only data prior to SWL was identified, nothing can be said about stenting prior to other types of intervention. Kidney function can deteriorate irreversibly if left for up to 6 weeks with an obstruction, and so it is only safe to stent if treatment with SWL is available in a timely manner. In some areas, where a fixed site lithotripter is not available and patients have to wait for a mobile lithotripter, then it is a clinical decision whether the patient can safely wait for that period of time. If they cannot, then SWL is unlikely to be the appropriate intervention and surgery should be planned as soon as possible. Hence the population that cannot safely wait for SWL is a separate population that is not the intended population for these recommendations.

Stenting before SWL is not particularly common in UK practice at the moment (around 5% based on a recent UK audit (Doherty et al, 2017), however in areas where it might be, these recommendations are likely to be cost saving.

In children, only non-randomised evidence was identified. One study in children with renal stones had differing baseline characteristics which were thought to explain the results. One study relating to staghorn stones demonstrated that stenting pre SWL had a benefit with respect to readmission, ancillary procedures, and major adverse events. Readmission and ancillary procedures lead to higher resource use. The shockwave dose was thought to be high in this study. SWL monotherapy is an option for children with this type of stone. The committee reached a consensus that a consider recommendation should be made for stents in this group. A consider recommendation allows an element of clinician judgement. This population is small and therefore is unlikely to reach the resource impact threshold, even with full uptake.

1.8.3 Other factors the committee took into account

The only evidence available was for stenting pre SWL. The committee considered the availability of SWL and noted that most urology departments in the UK have access to SWL, but the majority use a mobile machine on a sessional basis. Therefore, the use of SWL for treatment of patients presenting acutely and within a timely fashion of that admission is mainly limited to units with a fixed site facility. For this reason, SWL is more routinely used for renal stones, where time to treatment is less critical.

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Appendices

Appendix A: Review protocols

Table 9: Review protocol: Is inserting a stent clinically and cost-effective before surgical treatment in people with renal or ureteric stones?

Field	Content
Review question	Is inserting a stent clinically and cost-effective before surgical treatment in people with renal or ureteric stones?
Type of review question	Intervention review A review of health economic evidence related to the same review question was conducted in parallel with this review. For details see the health economic review protocol for this NICE guideline.
Objective of the review	To find whether inserting a stent before a surgical procedure leads to better outcomes in people with renal and ureteric stones.
Eligibility criteria – population / disease / condition / issue / domain	People (adults, children and young people) with symptomatic and asymptomatic renal or ureteric stones
Eligibility criteria – intervention(s) / exposure(s) / prognostic factor(s)	Insertion of a stent followed by a surgical procedure (SWL, or UTS/RIRS or PCNL) *Concomitant treatment, such as pain medication, not part of inclusion/exclusion criteria for intervention or comparator*
Eligibility criteria – comparator(s) / control or reference (gold) standard	Surgical procedure (SWL, or URS/RIRS or PCNL) alone
Outcomes and prioritisation	Critical outcomes: • Stone-free state (including residual fragment) • Recurrence • Use of healthcare services (length of stay, readmission, retreatment or ancillary procedure) • Kidney function • Quality of life • Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) • Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) • Failure to treat (inaccessible stone, stone not seen/reached) • Stent symptoms Important outcomes: • Pain intensity (visual analogue scale)
Eligibility criteria – study design	Randomised controlled trials (RCTs) If no RCT evidence for children is available, cohort studies will be considered.
Other inclusion exclusion criteria	Exclude: Bladder stones Open surgery for renal (kidney and ureteric) stones Laparoscopic nephrolithotomy and pyelolithotomy Non-English language studies

Proposed sensitivity / subgroup analysis, or meta-regression	Strata:
	• Population
	  ○ Adults (≥16 years)
	  ○ Children and young people (<16 years)
	• Stone size:
	  ○ <1 cm
	  ○ 1-2 cm
	  ○ >2 cm
	  ○ staghorn
	• Stone site (not lower/upper pole):
	  ○ Renal stone
	  ○ Ureteric stone
	Subgroups:
	• Symptomatic/ Asymptomatic
	• Pregnant women
	• Lower/non-lower kidney pole
	• Upper/lower ureteric stones
	• Stone composition/hounsfield units
	• Obesity /skin-to-stone distance
	• Neuropathic/ cerebral-palsy /immobility

Selection process – duplicate screening / selection / analysis	Studies are sifted by title and abstract. Potentially significant publications obtained in full text are then assessed against the inclusion criteria specified in this protocol.
Data management (software)	• Pairwise meta-analyses performed using Cochrane Review Manager (RevMan5). • GRADEpro used to assess the quality of evidence for each outcome • Endnote for bibliography, citations, sifting and reference management • Data extractions performed using EviBase, a platform designed and maintained by the National Guideline Centre (NGC)
Information sources – databases and dates	Clinical search databases to be used: Medline, Embase, Cochrane Library Date: all years Health economics search databases to be used: Medline, Embase, NHSEED, HTA Date: Medline, Embase from 2014 NHSEED, HTA – all years Language: Restrict to English only Supplementary search techniques: backward citation searching Key papers: Not known
Identify if an update	Not applicable
Author contacts	https://www.nice.org.uk/guidance/indevelopment/gid-ng10033
Highlight if amendment to previous protocol	For details please see section 4.5 of Developing NICE guidelines: the manual.
Search strategy – for one database	For details please see appendix B
Data collection process – forms / duplicate	A standardised evidence table format will be used, and published as appendix D of the evidence report.

Data items – define all variables to be collected	For details please see evidence tables in Appendix D (clinical evidence tables) or H (health economic evidence tables).
Methods for assessing bias at outcome / study level	Standard study checklists were used to critically appraise individual studies. For details please see section 6.2 of Developing NICE guidelines: the manual The risk of bias across all available evidence was evaluated for each outcome using an adaptation of the 'Grading of Recommendations Assessment, Development and Evaluation (GRADE) toolbox' developed by the international GRADE working group http://www.gradeworkinggroup.org/
Criteria for quantitative synthesis	For details please see section 6.4 of Developing NICE guidelines: the manual.
Methods for quantitative analysis – combining studies and exploring (in)consistency	For details please see the separate Methods report for this guideline.
Meta-bias assessment – publication bias, selective reporting bias	For details please see section 6.2 of Developing NICE guidelines: the manual. [Consider exploring publication bias for review questions where it may be more common, such as pharmacological questions, certain disease areas, etc. Describe any steps taken to mitigate against publication bias, such as examining trial registries.]
Confidence in cumulative evidence	For details please see sections 6.4 and 9.1 of Developing NICE guidelines: the manual.
Rationale / context – what is known	For details please see the introduction to the evidence review.
Describe contributions of authors and guarantor	A multidisciplinary committee developed the evidence review. The committee was convened by the National Guideline Centre (NGC) and chaired by Andrew Dickinson in line with section 3 of Developing NICE guidelines: the manual. Staff from NGC undertook systematic literature searches, appraised the evidence, conducted meta-analysis and cost-effectiveness analysis where appropriate, and drafted the evidence review in collaboration with the committee. For details please see Developing NICE guidelines: the manual.
Sources of funding / support	NGC is funded by NICE and hosted by the Royal College of Physicians.
Name of sponsor	NGC is funded by NICE and hosted by the Royal College of Physicians.
Roles of sponsor	NICE funds NGC to develop guidelines for those working in the NHS, public health and social care in England.
PROSPERO registration number	Not registered

Table 10: Health economic review protocol

Review question	**All questions – health economic evidence**
Objectives	To identify economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the individual review protocol above. • Studies must be of a relevant economic study design (cost-utility analysis, cost-effectiveness analysis, cost-benefit analysis, cost-consequences analysis, comparative cost analysis).

	• Studies must not be a letter, editorial or commentary, or a review of economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	An economic study search will be undertaken using population-specific terms and an economic study filter – see Appendix G *[in the Full guideline]*.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2002, abstract-only studies and studies from non-OECD countries or the USA will also be excluded. Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in Appendix G of the 2014 NICE guidelines manual.[57] **Inclusion and exclusion criteria** • If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. An economic evidence table will be completed and it will be included in the economic evidence profile. • If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded then an economic evidence table will not be completed and it will not be included in the economic evidence profile. • If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included. **Where there is discretion** The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the Committee if required. The ultimate aim is to include economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the Committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation as excluded economic studies in Appendix M. The health economist will be guided by the following hierarchies. *Setting:* • UK NHS (most applicable). • OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden). • OECD countries with predominantly private health insurance systems (for example, Switzerland). • Studies set in non-OECD countries or in the USA will have been excluded before being assessed for applicability and methodological limitations. *Economic study type:* • Cost-utility analysis (most applicable). • Other type of full economic evaluation (cost-benefit analysis, cost-effectiveness analysis, cost-consequences analysis). • Comparative cost analysis. • Non-comparative cost analyses including cost-of-illness studies will have been excluded before being assessed for applicability and methodological limitations.

	Year of analysis: • The more recent the study, the more applicable it will be. • Studies published in 2002 or later but that depend on unit costs and resource data entirely or predominantly from before 2002 will be rated as 'Not applicable'. • Studies published before 2002 will have been excluded before being assessed for applicability and methodological limitations. *Quality and relevance of effectiveness data used in the economic analysis:* • The more closely the clinical effectiveness data used in the economic analysis matches with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual 2014, updated 2017 https://www.nice.org.uk/guidance/pmg20/resources/developing-nice-guidelines-the-manual-pdf-72286708700869

For more detailed information, please see the Methodology Review. [Add cross reference]

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 11: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 12 September 2017	Exclusions Randomised controlled trials Systematic review studies Observational studies
Embase (OVID)	1974 – 12 September 2017	Exclusions Randomised controlled trials Systematic review studies Observational studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2017 Issue 9 of 12 CENTRAL to 2017 Issue 8 of 12 DARE, and NHSEED to 2015 Issue 2 of 4 HTA to 2016 Issue 4 of 4	None

Medline (Ovid) search terms

1.	exp urolithiasis/
2.	(nephrolitiasis or nephrolith or nephroliths or urolithias?s or ureterolithias?s).ti,ab.
3.	((renal or kidney* or urinary or ureter* or urethra*) adj3 (stone* or calculi or calculus or calculosis or lithiasis or c?olic*)).ti,ab.
4.	stone disease*.ti,ab.

5.	((calculi or calculus or calcium oxalate or cystine) adj3 (crystal* or stone* or lithiasis)).ti,ab.
6.	or/1-5
7.	letter/
8.	editorial/
9.	news/
10.	exp historical article/
11.	Anecdotes as Topic/
12.	comment/
13.	case report/
14.	(letter or comment*).ti.
15.	or/7-14
16.	randomized controlled trial/ or random*.ti,ab.
17.	15 not 16
18.	animals/ not humans/
19.	exp Animals, Laboratory/
20.	exp Animal Experimentation/
21.	exp Models, Animal/
22.	exp Rodentia/
23.	(rat or rats or mouse or mice).ti.
24.	or/17-23
25.	6 not 24
26.	limit 25 to English language
27.	exp Stents/
28.	stent*.ti,ab.
29.	exp Catheters/ or exp Cannula/
30.	(catheter* or cannul*).ti,ab.
31.	or/27-30
32.	26 and 31
33.	randomized controlled trial.pt.
34.	controlled clinical trial.pt.
35.	randomi#ed.ti,ab.
36.	placebo.ab.
37.	randomly.ti,ab.
38.	Clinical Trials as topic.sh.
39.	trial.ti.
40.	or/33-39
41.	Meta-Analysis/
42.	exp Meta-Analysis as Topic/
43.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
44.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
45.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
46.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
47.	(search* adj4 literature).ab.

48.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
49.	cochrane.jw.
50.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
51.	or/41-50
52.	Epidemiologic studies/
53.	Observational study/
54.	exp Cohort studies/
55.	(cohort adj (study or studies or analys* or data)).ti,ab.
56.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
57.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
58.	Controlled Before-After Studies/
59.	Historically Controlled Study/
60.	Interrupted Time Series Analysis/
61.	(before adj2 after adj2 (study or studies or data)).ti,ab.
62.	or/52-61
63.	exp case control study/
64.	case control*.ti,ab.
65.	or/63-64
66.	62 or 65
67.	Cross-sectional studies/
68.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
69.	or/67-68
70.	62 or 69
71.	62 or 65 or 69
72.	32 and 40
73.	32 and 51
74.	72 or 73
75.	32 and 71
76.	75 not 74

Embase (Ovid) search terms

1.	exp urolithiasis/
2.	(nephrolitiasis or nephrolith or nephroliths or urolithias?s or ureterolithias?s).ti,ab.
3.	((renal or kidney* or urinary or ureter* or urethra*) adj3 (stone* or calculi or calculus or calculosis or lithiasis or c?olic*)).ti,ab.
4.	stone disease*.ti,ab.
5.	((calculi or calculus or calcium oxalate or cystine) adj3 (crystal* or stone* or lithiasis)).ti,ab.
6.	or/1-5
7.	letter.pt. or letter/
8.	note.pt.
9.	editorial.pt.
10.	case report/ or case study/
11.	(letter or comment*).ti.

12.	or/7-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animal/ not human/
16.	nonhuman/
17.	exp Animal Experiment/
18.	exp Experimental Animal/
19.	animal model/
20.	exp Rodent/
21.	(rat or rats or mouse or mice).ti.
22.	or/14-21
23.	6 not 22
24.	limit 23 to English language
25.	exp stent/
26.	stent*.ti,ab.
27.	exp catheter/ or exp cannula/
28.	(catheter* or cannul*).ti,ab.
29.	or/25-28
30.	24 and 29
31.	random*.ti,ab.
32.	factorial*.ti,ab.
33.	(crossover* or cross over*).ti,ab.
34.	((doubl* or singl*) adj blind*).ti,ab.
35.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
36.	crossover procedure/
37.	single blind procedure/
38.	randomized controlled trial/
39.	double blind procedure/
40.	or/31-39
41.	systematic review/
42.	meta-analysis/
43.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
44.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
45.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
46.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
47.	(search* adj4 literature).ab.
48.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
49.	cochrane.jw.
50.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
51.	or/41-50
52.	Clinical study/
53.	Observational study/
54.	family study/

55.	longitudinal study/
56.	retrospective study/
57.	prospective study/
58.	cohort analysis/
59.	follow-up/
60.	cohort*.ti,ab.
61.	59 and 60
62.	(cohort adj (study or studies or analys* or data)).ti,ab.
63.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
64.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
65.	(before adj2 after adj2 (study or studies or data)).ti,ab.
66.	or/52-58,61-65
67.	exp case control study/
68.	case control*.ti,ab.
69.	or/67-68
70.	66 or 69
71.	cross-sectional study/
72.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
73.	or/71-72
74.	66 or 73
75.	66 or 69 or 73
76.	30 and 40
77.	30 and 51
78.	76 or 77
79.	30 and 75
80.	79 not 78

Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Urolithiasis] explode all trees
#2.	(nephrolitiasis or nephrolith or nephroliths or urolithias?s or ureterolithias?s):ti,ab
#3.	((renal or kidney* or urinary or ureter* or urethra*) near/3 (stone* or calculi or calculus or calculosis or lithiasis or c?olic*)):ti,ab
#4.	stone disease*:ti,ab
#5.	((calculi or calculus or calcium oxalate or cystine) near/3 (crystal* or stone* or lithiasis)):ti,ab
#6.	(or #1-#5)
#7.	MeSH descriptor: [Stents] explode all trees
#8.	stent*:ti,ab
#9.	MeSH descriptor: [Catheters] explode all trees
#10.	MeSH descriptor: [Cannula] explode all trees
#11.	catheter*:ti,ab
#12.	cannul*:ti,ab
#13.	(or #7-#12)
#14.	#6 and #13

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to renal and ureteric stones population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional searches were run on Medline and Embase for health economics studies.

Table 12: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	For health economics 2014 – 9 March 2018	Exclusions Health economics studies
Embase	For health economics 2014 – 9 March 2018	Exclusions Health economics studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 9 March 2018 NHSEED - Inception to March 2015	None

Medline (Ovid) search terms

1.	exp urolithiasis/
2.	(nephrolitiasis or nephrolith or nephroliths or urolithias?s or ureterolithias?s).ti,ab.
3.	((renal or kidney* or urinary or ureter* or urethra*) adj3 (stone* or calculi or calculus or calculosis or lithiasis or c?olic*)).ti,ab.
4.	stone disease*.ti,ab.
5.	((calculi or calculus or calcium oxalate or cystine) adj3 (crystal* or stone* or lithiasis)).ti,ab.
6.	or/1-5
7.	letter/
8.	editorial/
9.	news/
10.	exp historical article/
11.	Anecdotes as Topic/
12.	comment/
13.	case report/
14.	(letter or comment*).ti.
15.	or/7-14
16.	randomized controlled trial/ or random*.ti,ab.
17.	15 not 16
18.	animals/ not humans/
19.	exp Animals, Laboratory/
20.	exp Animal Experimentation/
21.	exp Models, Animal/
22.	exp Rodentia/
23.	(rat or rats or mouse or mice).ti.
24.	or/17-23
25.	6 not 24

26.	limit 25 to English language
27.	Economics/
28.	Value of life/
29.	exp "Costs and Cost Analysis"/
30.	exp Economics, Hospital/
31.	exp Economics, Medical/
32.	Economics, Nursing/
33.	Economics, Pharmaceutical/
34.	exp "Fees and Charges"/
35.	exp Budgets/
36.	budget*.ti,ab.
37.	cost*.ti.
38.	(economic* or pharmaco?economic*).ti.
39.	(price* or pricing*).ti,ab.
40.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
41.	(financ* or fee or fees).ti,ab.
42.	(value adj2 (money or monetary)).ti,ab.
43.	or/27-42
44.	26 and 43

Embase (Ovid) search terms

1.	exp urolithiasis/
2.	(nephrolitiasis or nephrolith or nephroliths or urolithias?s or ureterolithias?s).ti,ab.
3.	((renal or kidney* or urinary or ureter* or urethra*) adj3 (stone* or calculi or calculus or calculosis or lithiasis or c?olic*)).ti,ab.
4.	stone disease*.ti,ab.
5.	((calculi or calculus or calcium oxalate or cystine) adj3 (crystal* or stone* or lithiasis)).ti,ab.
6.	or/1-5
7.	letter.pt. or letter/
8.	note.pt.
9.	editorial.pt.
10.	case report/ or case study/
11.	(letter or comment*).ti.
12.	or/7-11
13.	randomized controlled trial/ or random*.ti,ab.
14.	12 not 13
15.	animal/ not human/
16.	nonhuman/
17.	exp Animal Experiment/
18.	exp Experimental Animal/
19.	animal model/
20.	exp Rodent/

21.	(rat or rats or mouse or mice).ti.
22.	or/14-21
23.	6 not 22
24.	limit 23 to English language
25.	health economics/
26.	exp economic evaluation/
27.	exp health care cost/
28.	exp fee/
29.	budget/
30.	funding/
31.	budget*.ti,ab.
32.	cost*.ti.
33.	(economic* or pharmaco?economic*).ti.
34.	(price* or pricing*).ti,ab.
35.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
36.	(financ* or fee or fees).ti,ab.
37.	(value adj2 (money or monetary)).ti,ab.
38.	or/25-37
39.	24 and 38

NHS EED and HTA (CRD) search terms

#1.	MeSH DESCRIPTOR urolithiasis EXPLODE ALL TREES
#2.	(((nephrolitiasis or nephrolith or urolithiasis)))
#3.	((((renal or kidney or urinary or ureteric or ureteral or ureter or urethra*) adj2 (stone* or calculi or calculus or calculosis or lithiasis or colic))))
#4.	((stone disease*))
#5.	((((calculi or calculus) adj2 (stone* or lithiasis))))
#6.	(#1 OR #2 OR #3 OR #4 OR #5)

Appendix C: Clinical evidence selection

Figure 1: Flow chart of clinical study selection for the review of Is inserting a stent clinically and cost-effective before surgical treatment in people with renal or ureteric stones?

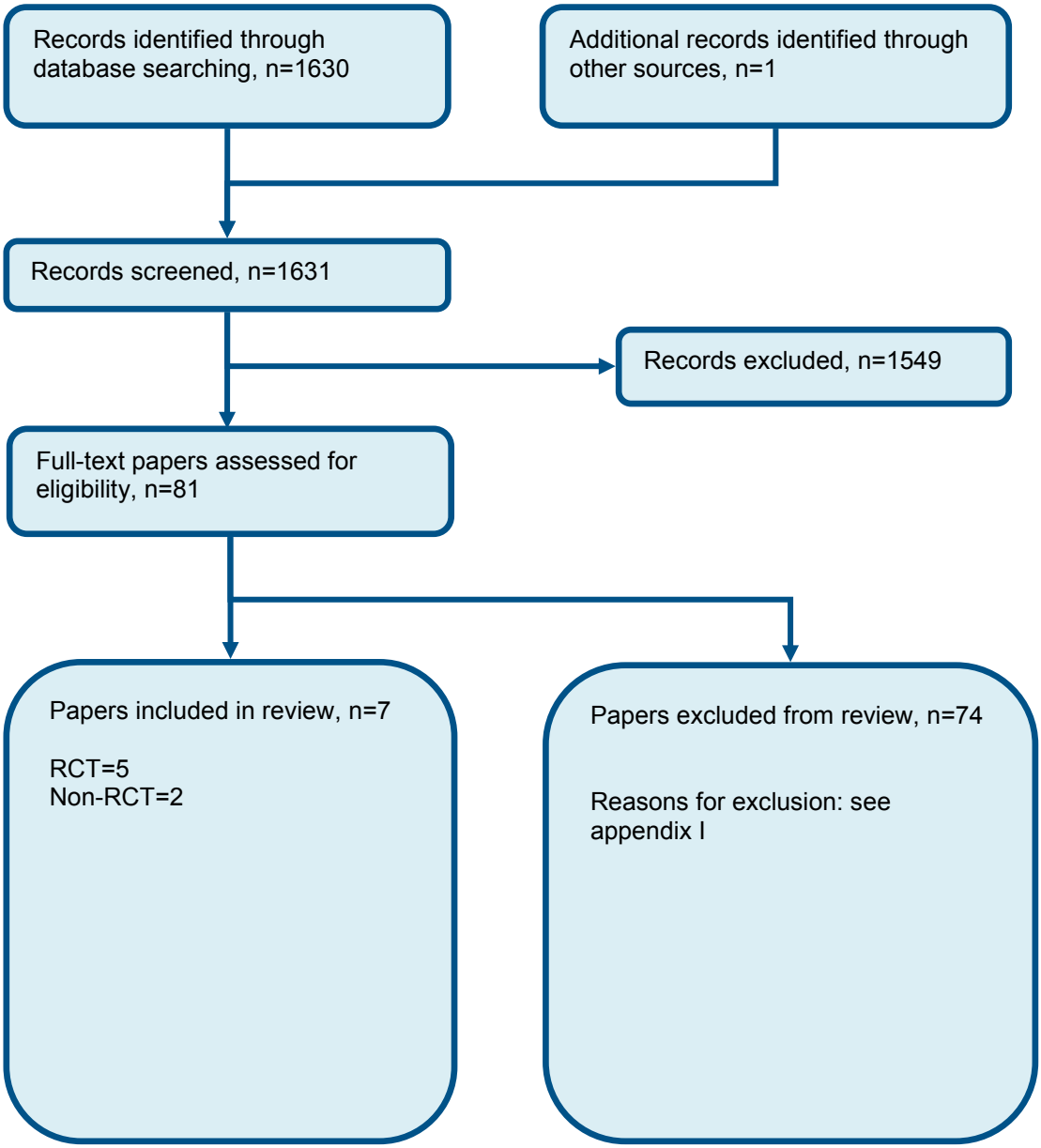
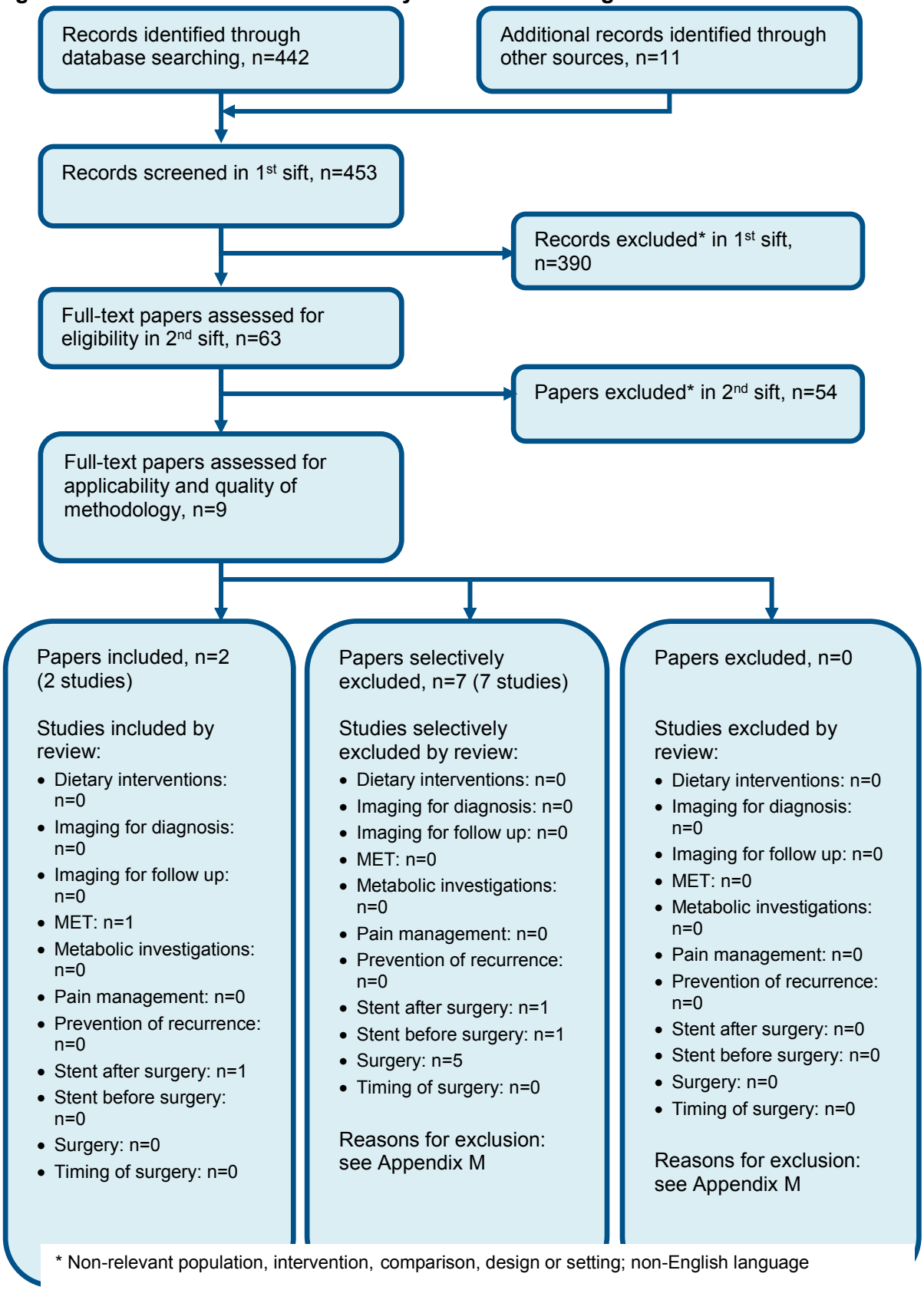


Figure 2: Flow chart of economic study selection for the guideline



Appendix D: Clinical evidence tables

Study	Al-awadi 1999[2]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=400)
Countries and setting	Conducted in Kuwait; Setting: Stone Centre
Line of therapy	Unclear
Duration of study	Unclear
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Adults, renal, >20mm: Mean diameter
Subgroup analysis within study	Post-hoc subgroup analysis: The effect of stone size on the incidence of steinstrasse in the presence or absence of J stents
Inclusion criteria	Patients with unilateral renal calculi (mean diameter 1.5-3.5cm); normal renal function, sterile urine on culture; unilateral stone disease and IVU showing no evidence of PUJ or ureteric obstruction
Exclusion criteria	Not reported
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): 43 (18.7). Gender (M:F): 337/63. Ethnicity: Not reported
Further population details	1. Kidney pole: Not stated / Unclear 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Not stated / Unclear 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Not stated / Unclear 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=200) Intervention 1: Stent followed by surgery - SWL followed by stent. J stents (Cook Urological, USA) inserted were 4-8F and 20-28cm long, depending on body build. The stents were removed within a week of the patients becoming stone-free. Patients underwent SWL using the Siemens LithoStar 2-Plus machine (1993 model, Siemens GmbH, Erlangen, Germany). The standard treatment protocol involved giving 6000 shocks per stone per session. All the patients underwent lithotripsy by one of three operators who had at least 10 years' experience using various models of lithotripters. The shock waves were delivered initially to the most dependent part of the calculi to ensure that parts of the calculi fragmented could pass into the ureter and be voided. SWL was repeated weekly until the patients became stone-free.. Duration Not applicable. Concurrent medication/care: Not applicable. Indirectness: No indirectness Comments: Stent followed by SWL

	(n=200) Intervention 2: Surgery alone - SWL. Same procedure as stent group, but no stent was placed before SWL. Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SWL FOLLOWED BY STENT versus SWL

Protocol outcome 1: Stone-free state at Define
- Actual outcome for Adults, renal, >20mm: Stone clearance at Not reported; Group 1: 172/200, Group 2: 174/200
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - High, Crossover - Low; Indirectness of outcome: Serious indirectness, Comments: Distinction between stone-free and residual stone not defined; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 2: Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define
- Actual outcome for Adults, renal, >20mm: Retreatment (ESWL leading to fragmentation) at Not reported; Group 1: 1/12, Group 2: 4/26
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low; Indirectness of outcome: Serious indirectness, Comments: Subgroup of patients with steinstrasse; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 3: Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define
- Actual outcome for Adults, renal, >20mm: Fever (with steinstrasse) at Not reported; Group 1: 2/12, Group 2: 4/26
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High, Crossover - Low; Indirectness of outcome: Serious indirectness, Comments: Subgroup of patients with steinstrasse; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcome 4: Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define
- Actual outcome for Adults, renal, >20mm: Failure to treat at Not reported; Group 1: 3/200, Group 2: 0/200; Comments: Coils of the J stent prevented adequate fragmentation of the calculi because they were in the path of the shock waves; this problem was solved by removing the stent
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - High, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 0; Group 2 Number missing: 0

Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality)

	at Define; Pain intensity at Define; Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define; Reccurence at Define
Study	**Al-busaidy 2003[4]**
Study type	Non-randomised
Number of studies (number of participants)	1 (n=42)
Countries and setting	Conducted in Oman; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: Mean follow up of 47 months (range 9 to 102)
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Children, renal, >20mm
Subgroup analysis within study	Post-hoc subgroup analysis: Partial staghorn calculi (occupying the renal pelvis and at least 2 calices) and complete staghorn calculi (occupying the renal pelvis and all calices)
Inclusion criteria	Children with staghorn calculi
Exclusion criteria	Not reported
Recruitment/selection of patients	Patients recruited between June 1992 and January 2001.
Age, gender and ethnicity	Age - Mean (SD): 5.7 (3.6 years); 6.3 (3.5 years). Gender (M:F): 29/13. Ethnicity: Not reported
Further population details	1. Kidney pole: Not stated / Unclear 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Not stated / Unclear 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Other (Partial staghorn calculi (occupying the renal pelvis and at least 2 calices) and complete staghorn calculi (occupying the renal pelvis and all calices)). 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=23) Intervention 1: Stent followed by surgery - SWL followed by stent. The children were admitted to hospital 1 day before treatment. In 35 patients 10 years and younger, SWL was performed under general anaesthesia. Lithotripsy was attempted (using a Piezolith lithotriptor) under intravenous sedation using 2 to 2.5µg.kg fentanyl and 0.15mg/kg midazolam in 7 children older than 10 years, although 4 who were unable to tolerate the pain required general anaesthesia. A Double-J ureteral stent was inserted immediately before SWL. In infants and children under 5 years or younger, a 4Fr, 8 to 10cm ureteral stent was inserted; in older children, a 4Fr, 12 to 16cm stent was inserted. SWL treatment involved delivering a maximum of 4000 shocks to the renal stone per session. Shock wave intensity was set at level 3 (35MPa) in children 3 years or younger and level 5 (65MPa) in older children. To avoid significant steinstrasse, a fractionated disintegration technique was used, in which the pelvic component of the staghorn was initially fragmented, followed by

	sequential fragmentation of the upper, mid and lower calceal components. The ureteral stent was removed 3 weeks after the last SWL session with the patient under general anaesthesia.. Duration Not reported. Concurrent medication/care: Children with a proved urinary tract infection received antiobiotic treatment before and after SWL, while those with sterile urine were given 1 dose of gentamycin intravenously before the procedure. Patients were usually hospitalised for 48 hours after each SWL session. If further SWL sessions were required, these were scheduled at 3-week intervals. In the event of absent fragmentation after the first SWL session, lithotripsy was discontinued and open nephrolithotomy was performed. Children with adequate stone fragmentation were followed with plain abdominal x-ray and renal ultrasound at 3-week interval until the fragments were completely cleared.. Indirectness: No indirectness Comments: Stent followed by SWL (n=19) Intervention 2: Surgery alone - SWL. Same procedure as stent group, but no stent placed before SWL.. Duration Not reported. Concurrent medication/care: Children with a proved urinary tract infection received antiobiotic treatment before and after SWL, while those with sterile urine were given 1 dose of gentamycin intravenously before the procedure. Patients were usually hospitalised for 48 hours after each SWL session. If further SWL sessions were required, these were scheduled at 3-week intervals. In the event of absent fragmentation after the first SWL session, lithotripsy was discontinued and open nephrolithotomy was performed. Children with adequate stone fragmentation were followed with plain abdominal x-ray and renal ultrasound at 3-week interval until the fragments were completely cleared.. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SWL FOLLOWED BY STENT versus SWL

Protocol outcome 1: Stone-free state at Define
- Actual outcome for Children, renal, >20mm: Stone-free (complete absence of residual stone fragments of any size on plain x-ray and renal ultrasound) at 3 months after the last SWL session; Group 1: 18/23, Group 2: 15/19
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Subgroups - High; Indirectness of outcome: No indirectness ; Baseline details: Reported as comparable for age, stone size, number of shock waves and SWL sessions; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define
- Actual outcome for Children, renal, >20mm: Post-SWL ancillary procedures - ureteroscopy; percutaneous nephrostomy; in-situ SWL at Not reported; Group 1: 0/23, Group 2: 7/19
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported as comparable for age, stone size, number of shock waves and SWL sessions; Group 1 Number missing: ; Group 2 Number missing:

- Actual outcome for Children, renal, >20mm: Mean hospital length of stay at Not reported; Group 1: mean 4.6 days (SD 1.5); n=23, Group 2: mean 6.4 days (SD 3.2); n=19; Comments: P-value reported as 0.022 (mann-Whitney test), significant Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported as comparable for age, stone size, number of shock waves and SWL sessions; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome for Children, renal, >20mm: Retreatment - mean number of SWL sessions at Not reported; Group 1: mean 2.6 (SD 0.9); n=23, Group 2: mean 2.5 (SD 0.7); n=19; Comments: P-value reported as 0.891 (Mann-Whitney test), not significant Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported as comparable for age, stone size, number of shock waves and SWL sessions; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome for Children, renal, >20mm: Readmission at Not reported; Group 1: 0/23, Group 2: 4/19 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported as comparable for age, stone size, number of shock waves and SWL sessions;\\ Protocol outcome 3: Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality at Define - Actual outcome for Children, renal, >20mm: Complete ureteral obstruction and sepsis after SWL (major complication) at Not reported; Group 1: 0/23, Group 2: 2/19 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Reported as comparable for age, stone size, number of shock waves and SWL sessions; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define; Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define; Pain intensity at Define; Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define; Reccurence at Define

Study	Ghoneim 2010[35]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=60)
Countries and setting	Conducted in Egypt; Setting: Not reported
Line of therapy	Unclear
Duration of study	Unclear
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Adults, ureteric, 10-20mm: Mean length 10.00 (0.43); 10.23 (0.38)
Subgroup analysis within study	Not applicable:
Inclusion criteria	A solitary, radio-opaque, impacted upper ureteral stone, of size less than or equal to 2cm
Exclusion criteria	Radiolucent stones; patients with bleeding disorders, congenital renal abnormalities, and residual renal or ureteral fragments after previous ESWL, open surgery, or endoscopy
Recruitment/selection of patients	Patients were selected between June 2007 and June 2008.
Age, gender and ethnicity	Age - Mean (SD): 43.10 (11.505); 40.73 (10.638). Gender (M:F): 39/21. Ethnicity: Not reported
Further population details	1. Kidney pole: Not stated / Unclear 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Not stated / Unclear 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Not stated / Unclear 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not stated / Unclear
Extra comments	. The stone was considered impacted if it caused moderate to severe hydronephrosis above its level, with a non-visualised ureter below it on excretory urography
Indirectness of population	No indirectness
Interventions	(n=30) Intervention 1: Stent followed by surgery - SWL followed by stent. A single silicone 6F JJ stent (Rusch International, Kernen, Germany) was fixed 1 week before ESWL. Patients were treated with SWL using the Dornier Doli S lithotriptor (Dornier MedTech, GmbH, Germany). All patients received intravenous analgesia in the form of 1 mg/kg meripidine hydrochloride and/or 1.5 microgram/kg fentanyl. Intravenous fluids were given to all patients throughout the procedure. Patients were treated in the supine position using an ungated technique. Fluoroscopy was used for stone localisation. SWL started at a lower power of 14kV, which was then gradually increased to 24kV. A total of 4000 shocks were planned for each session. The session was terminated if complete stone fragmentation, as judged by still images during fluoroscopy, was noted. . Duration Not applicable. Concurrent medication/care: On discharge, patients were instructed to drink plenty of fluids and to check for expected hematuria, passage of stone fragments, and fever. Oral analgesics were prescribed and stented patients also received a prescription for anticholinergics. Indirectness: No indirectness

	Comments: Stent followed by SWL (n=30) Intervention 2: Surgery alone - SWL. Same procedure as stent group, but no stent was placed before SWL and no prescription given for anticholinergics. Duration Not applicable. Concurrent medication/care: On discharge, patients were instructed to drink plenty of fluids and to check for expected hematuria, passage of stone fragments, and fever. Oral analgesics were prescribed.. Indirectness: No indirectness
Funding	Funding not stated (3 months)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SWL FOLLOWED BY STENT versus SWL

Protocol outcome 1: Stone-free state at Define
- Actual outcome for Adults, ureteric, 10-20mm: Stone free at 3 months; Group 1: 27/30, Group 2: 26/30
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-values given for age, sex, stone side, stone recurrence, surgical history, stone length and stone width ; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define
- Actual outcome for Adults, ureteric, 10-20mm: Retreatment at Not reported; Group 1: 23/30, Group 2: 20/30
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-values given for age, sex, stone side, stone recurrence, surgical history, stone length and stone width ; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define
- Actual outcome for Adults, ureteric, 10-20mm: Dysuria at 3 months; Group 1: 18/30, Group 2: 7/30
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-values given for age, sex, stone side, stone recurrence, surgical history, stone length and stone width ; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, ureteric, 10-20mm: Haematuria (Gross) at 3 months; Group 1: 4/30, Group 2: 1/30
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-values given for age, sex, stone side, stone recurrence, surgical history, stone length and stone width ; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, ureteric, 10-20mm: Haematuria (Microscopic) at 3 months; Group 1: 23/30, Group 2: 8/30
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-values given for age, sex, stone side, stone recurrence, surgical history, stone length and stone width ; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define - Actual outcome for Adults, ureteric, 10-20mm: Self-limited fever (<38.5'C) at 3 months; Group 1: 1/30, Group 2: 2/30 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-values given for age, sex, stone side, stone recurrence, surgical history, stone length and stone width ; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) at Define; Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define; Pain intensity at Define; Reccurence at Define

Study	Gunduz 2017[38]
Study type	Non-randomised
Number of studies (number of participants)	1 (n=20)
Countries and setting	Conducted in Turkey; Setting: Department of Pediatric Surgery for renal stones
Line of therapy	Unclear
Duration of study	Unclear
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Children, renal, <10mm
Subgroup analysis within study	Not applicable
Inclusion criteria	Children with renal calculi
Exclusion criteria	Not reported
Recruitment/selection of patients	Patients admitted between June 2012 and June 2014 were evaluated retrospectively
Age, gender and ethnicity	Age - Median (range): 4.5 (2-12 years); 4 (3-5 years). Gender (M:F): 7/13. Ethnicity: Not reported
Further population details	1. Kidney pole: Not stated / Unclear 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Not stated / Unclear 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Not stated / Unclear 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=10) Intervention 1: Stent followed by surgery - SWL followed by stent. Before SWL treatment, 3 Fr 16 cm JJ stents were inserted under general anaesthesia. Patients received antiobiotic prophylaxis, and SWL was performed under general anaesthesia. An Elmed Complit System (Elmed Medical Systems, Ankara, Turkey) was used with 11-13kV, 60 frequency, and 1000-1200 shots in patients 2-4 years old; 11-14kV, 70 frequency, and 1000-1500 shots in patients over 4 years old. If the patient had a stone-free status, the JJ catheters were removed under general anaesthesia. However, if stone clearance was not determined, SWL was performed 1 week later up to 2 times.. Duration Not reported. Concurrent medication/care: All patients were discharged the same day. Anaesthesia and operative time were decided based on the frequency and number of shots as determined in all age groups. . Indirectness: No indirectness Comments: Stent followed by SWL (n=10) Intervention 2: Surgery alone - SWL. Same procedure as stent group, but no stent placed before SWL.. Duration Not reported. Concurrent medication/care: All patients were discharged the same day. Anaesthesia and operative time were decided based on the frequency and number of shots as determined in

	all age groups. . Indirectness: No indirectness
Funding	No funding (There is no disclosure from the authors of any having received any funding.)

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SWL FOLLOWED BY STENT versus SWL

Protocol outcome 1: Stone-free state at Define
- Actual outcome for Children, renal, <10mm: Stone-free at Not reported; Group 1: 10/10, Group 2: 8/10
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - High; Indirectness of outcome: No indirectness ; Baseline details: It is reported that statistically there were no differences in age, gender, stone size, stone location, and number of sessions.; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define
- Actual outcome for Children, renal, <10mm: Ancillary procedure - retrograde intrarenal surgery (RIRS) at Not reported; Group 1: 0/10, Group 2: 1/10
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: It is reported that statistically there were no differences in age, gender, stone size, stone location, and number of sessions.; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define
- Actual outcome for Children, renal, <10mm: Haematuria at Not reported; Group 1: 3/10, Group 2: 1/10
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: It is reported that statistically there were no differences in age, gender, stone size, stone location, and number of sessions.; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Children, renal, <10mm: Dysuria at Not reported; Group 1: 1/10, Group 2: 2/10
Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - High, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: It is reported that statistically there were no differences in age, gender, stone size, stone location, and number of sessions.; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) at Define; Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define; Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define; Pain intensity at Define; Reccurence at Define

Study	Mohayuddin 2009[50]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=80)
Countries and setting	Conducted in Pakistan; Setting: Sindh Institute of Urology and Transplantation (SIUT)
Line of therapy	Unclear
Duration of study	Intervention + follow up: Not reported
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Adults, renal, 10-20mm
Subgroup analysis within study	Not applicable
Inclusion criteria	Adult patients with normal renal function; aged between 16 and 70 years old; normal ureter on IVU e.g. no PUJO or ureteric orifice obstruction with a stone measuring 20 (2mm)
Exclusion criteria	Patients with a history of previous renal surgery or SWL or with comorbid conditions such as diabetes mellitus, hypertension or renal failure.
Recruitment/selection of patients	Patients were selected between January 2007 and January 2008
Age, gender and ethnicity	Age - Mean (SD): 32.13 (11.5); 34.3 (11.35). Gender (M:F): 31/9. Ethnicity: Not reported
Further population details	1. Kidney pole: Not stated / Unclear 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Not stated / Unclear 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Not stated / Unclear 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=40) Intervention 1: Stent followed by surgery - SWL followed by stent. In the patients selected for JJ placement, a prophylactic injection of gentamycin 80mg/i/m was given and a 4.8 fr JJ percuflex plus (made of propriety Olefenic block co-polymer developed by Boston Scientific Corporation) was placed under local or general anaesthesia before SWL under fluoroscopic control. SWL was given via an SLX F2 electromagnetic SWL machine. The stone was localised using fluoroscopy. 3000 shockwaves were given and the energy was kept between 4 and 6 and the shockwave rate was 70 per minute.. Duration Not applicable . Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Stent followed by SWL (n=40) Intervention 2: Surgery alone - SWL. Same procedure as stent group, but no placement of stent before SWL.. Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness

Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SWL FOLLOWED BY STENT versus SWL

Protocol outcome 1: Stone-free state at Define
- Actual outcome for Adults, renal, 10-20mm: Stone clearance at Not reported; Group 1: 31/40, Group 2: 33/40
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define
- Actual outcome for Adults, renal, 10-20mm: Hospital admissions at Not reported; Group 1: 1/40, Group 2: 3/40
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, renal, 10-20mm: Ancillary procedures (percutaneous nephrostomy or ureteronoscopy) at Not reported; Group 1: 1/40, Group 2: 1/40; Comments: The auxillary procedure performed in both groups was percutaneous nephrostomy.
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 3: Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define
- Actual outcome for Adults, renal, 10-20mm: Fever (or high grade fever and sepsis) at Not reported; Group 1: 3/40, Group 2: 1/40
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 4: Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define
- Actual outcome for Adults, renal, 10-20mm: Dysuria at Not reported; Group 1: 23/40, Group 2: 6/40
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, renal, 10-20mm: Urgency at Not reported; Group 1: 19/40, Group 2: 4/40
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, renal, 10-20mm: Frequency at Not reported; Group 1: 18/40, Group 2: 3/40

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing: - Actual outcome for Adults, renal, 10-20mm: Hematuria at Not reported; Group 1: 37/40, Group 2: 27/40 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: P-value reported for mean age (P = 0.392); Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) at Define; Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define; Pain intensity at Define; Reccurence at Define

Study	Musa 2008[53]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=120)
Countries and setting	Conducted in Yemen; Setting: Not reported
Line of therapy	Unclear
Duration of study	Intervention + follow up: 3 months
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Adults, renal, 10-20mm
Subgroup analysis within study	Not applicable
Inclusion criteria	Patients with renal calculi
Exclusion criteria	Patients with renal stones less than 1 cm or more than 2 cm were not included.
Recruitment/selection of patients	Not reported
Age, gender and ethnicity	Age - Mean (SD): Stent group 39; unstented group 37.5 (SD not reported). Gender (M:F): 78:42. Ethnicity: Not reported
Further population details	1. Kidney pole: Not stated / Unclear 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Not stated / Unclear 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Not stated / Unclear 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not applicable
Indirectness of population	No indirectness
Interventions	(n=60) Intervention 1: Stent followed by surgery - SWL followed by stent. Patients in the stent group were stented by using 5 Fr DJ stents prior to the procedure. All patients were treated on electrohydrolic spark gap lithotripter (Medlith—India) under general anesthesia at KV ranges between 14 and 22 and shockwave rate of 75/min. Stent was removed endoscopically after 2 weeks of insertion.. Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness (n=60) Intervention 2: Surgery alone - SWL. Same procedure as stent group, but no stent was placed before SWL. Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	Funding not stated
RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: STENT FOLLOWED BY SWL versus SWL Protocol outcome 1: Stone-free state at Define	

- Actual outcome for Adults, renal, 10-20mm: Stone-free state at 3 months; Group 1: 53/60, Group 2: 55/60 Risk of bias: All domain - High, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - High; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing: Protocol outcome 2: Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define - Actual outcome for Adults, renal, 10-20mm: Readmission at Not reported; Group 1: 3/60, Group 2: 1/60 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome for Adults, renal, 10-20mm: Retreatment at Not reported; Group 1: 5/60, Group 2: 3/60 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing: Protocol outcome 3: Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define - Actual outcome for Adults, renal, 10-20mm: Transient hematuria at 48 hours; Group 1: 15/60, Group 2: 19/60 Risk of bias: All domain - Very high, Selection - Very high, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) at Define; Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define; Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define; Pain intensity at Define; Reccurence at Define

Study	Sharma 2017[70]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=88)
Countries and setting	Conducted in India; Setting: Single centre
Line of therapy	Unclear
Duration of study	Intervention + follow up: Not reported
Method of assessment of guideline condition	Unclear method of assessment/diagnosis
Stratum	Adults, renal, 10-20mm
Subgroup analysis within study	Post-hoc subgroup analysis: Not reported
Inclusion criteria	Adult patients with stone size between 15 and 20mm
Exclusion criteria	Patients with elevated creatinine (15mg% or 132.6 µmol/L); unresolved UTI; hydromephrosis; coagulopathy; morbid obesity (body mass index [BMI] >40kg/m²); pregnancy; urinary tract anomolies; stones elsewhere in the urinary tract
Recruitment/selection of patients	Patients were selected between February 2013 and December 2015
Age, gender and ethnicity	Age - Mean (SD): 32.8 (8.4); 40.4 (12.7); 39.8 (9.5). Gender (M:F): 11/16; 15:16; 21:9. Ethnicity: Not reported
Further population details	1. Kidney pole: Lower (Lower and nonlower pole subgroups). 2. Neuropathic/ cerebral-palsy /immobility: Not stated / Unclear 3. Obesity: Non obese (Normal and overweight subgroups (BMI range of 18.5 to 28.0 kg/m2)). 4. Pregnancy: Not stated / Unclear 5. Stone composition/hounsfield units: Other (Stone density categorised into three subgroups: <800 Hounsfield units (HU); 800-1200 HU and >1200 HU). 6. Symptomatic/asymptomatic: Not stated / Unclear 7. Ureteric: Not stated / Unclear
Indirectness of population	No indirectness
Interventions	(n=31) Intervention 1: Stent followed by surgery - SWL followed by stent. DJ stenting was done 1 week before SWL and the procedure was accomplished with the DJ stent in situ. The stent was kept until the completion of 3 sittings, done 4 weeks apart, or it was removed earlier upon clearance of the stones. Dornier compact sigma under fluoroscopic guidance was utilised for lithotripsy. Voltage ramping was utilised in all cases. Follow-up KUB X-rays were done every 4 weeks after the session. A repeat session was given in case of persistent calculi, at 4-week intervals and to a maximum of 3 sessions. . Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Stent followed by SWL (n=30) Intervention 2: Stent followed by surgery - SWL followed by stent. In a second stent group, DJ

	stenting was done 1 week before SWL and the stent was removed on the morning of the day of the procedure. Dornier compact sigma under fluoroscopic guidance was utilised for lithotripsy. Voltage ramping was utilised in all cases. Follow-up KUB X-rays were done every 4 weeks after the session. A repeat session was given in case of persistent calculi, at 4-week intervals and to a maximum of 3 sessions.. Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness Comments: Stent followed by SWL (n=27) Intervention 3: Surgery alone - SWL. Same procedure as stent groups, but no stent placed before SWL.. Duration Not applicable. Concurrent medication/care: Not reported. Indirectness: No indirectness
Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: SWL FOLLOWED BY STENT versus SWL

Protocol outcome 1: Stone-free state at Define
- Actual outcome for Adults, renal, 10-20mm: Stone clearance (complete and clinically insignificant residual fragment <4mm) at 4 weeks ; Group 1: 20/31, Group 2: 17/27
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Subgroups - High; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, renal, 10-20mm: Complete stone fragmentation (<4mm) at 4 weeks ; Group 1: 5/31, Group 2: 5/27
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Subgroups - High; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, renal, 10-20mm: significant residual fragments at 4 weeks ; Group 1: 11/31, Group 2: 10/27
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Subgroups - High; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing:
- Actual outcome for Adults, renal, 10-20mm: insignificant residual fragments at 4 weeks ; Group 1: 16/31, Group 2: 14/27
Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Subgroups - High; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing:

Protocol outcome 2: Minor adverse events (infective complications [UTI, fever, infection], ureteric injury [extravasation, submucosal dissection], haemorrhage [any bleeding, transfusion]) at Define
- Actual outcome for Adults, renal, 10-20mm: Fever at Not reported; Group 1: 2/31, Group 2: 0/27

Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing: - Actual outcome for Adults, renal, 10-20mm: Urinary tract infection at Not reported; Group 1: 1/31, Group 2: 2/27 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing: Protocol outcome 3: Stent symptoms (irritative symptoms, dysuria, urgency, frequency, haematuria) at Define at Define - Actual outcome for Adults, renal, 10-20mm: haematuria at Not reported; Group 1: 0/31, Group 2: 1/27 Risk of bias: All domain - High, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - High, Measurement - Low; Indirectness of outcome: No indirectness ; Baseline details: Symptom prevalence, sex ratio, BMI, and stone parameters were reported as comparable; Group 1 Number missing: ; Group 2 Number missing:	
Protocol outcomes not reported by the study	Quality of life at Define; Kidney function at Define; Major adverse events (infective complications [sepsis, obstructive pyelonephritis], ureteric injury [ureteral damage, ureteral perforation, ureteral stricture], mortality) at Define; Failed technology (failure to treat, inaccessible stone, stone not seen/reached) at Define; Pain intensity at Define; Use of healthcare services (length of stay, readmission, retreatment, ancillary procedures) at Define; Reccurence at Define

Appendix E: Forest plots

E.1 Adults, ureteric, 10-20mm

E.1.1 Stent followed by SWL versus SWL alone

Figure 3: Stone-free state

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Ghoneim 2010	27	30	26	30	1.04 [0.86, 1.25]

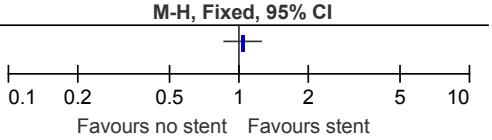


Figure 4: Retreatment

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Ghoneim 2010	23	30	20	30	1.15 [0.83, 1.59]

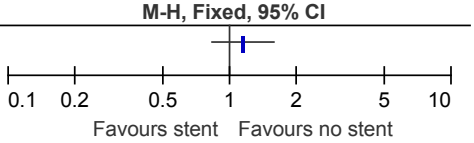


Figure 5: Minor adverse events (fever)

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Ghoneim 2010	1	30	2	30	0.50 [0.05, 5.22]

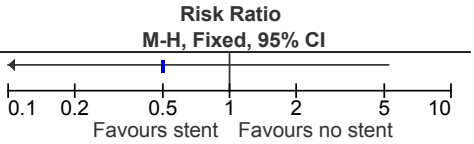


Figure 6: Stent symptoms (dysuria)

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Ghoneim 2010	18	30	7	30	2.57 [1.26, 5.24]

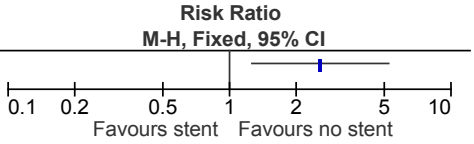
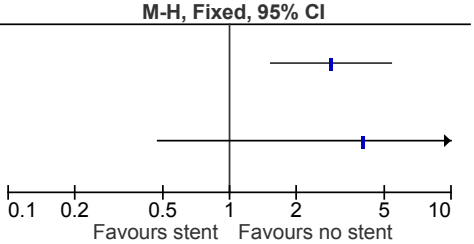


Figure 7: Stent symptoms (haematuria)

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
5.13.1 Microscopic					
Ghoneim 2010	23	30	8	30	2.88 [1.54, 5.37]
5.13.2 Gross					
Ghoneim 2010	4	30	1	30	4.00 [0.47, 33.73]



E.2 Adults, renal, 10-20mm

E.2.1 Stent followed by SWL versus SWL alone

Figure 8: Stone-free state

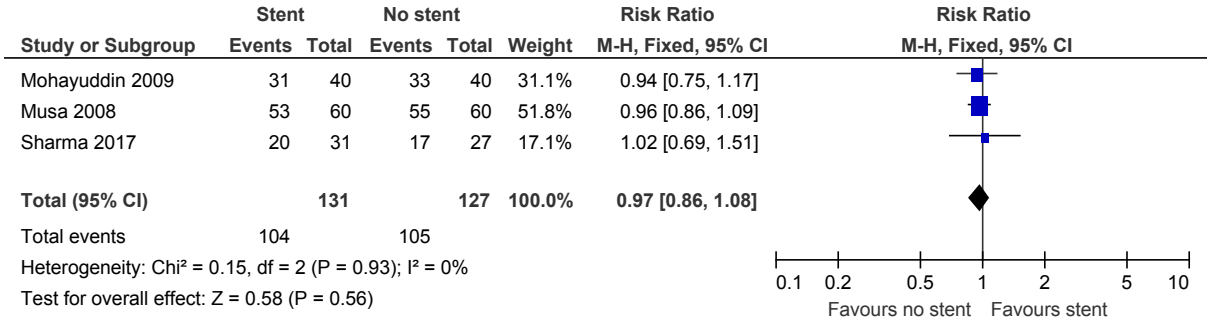


Figure 9: Clinically insignificant residual fragments

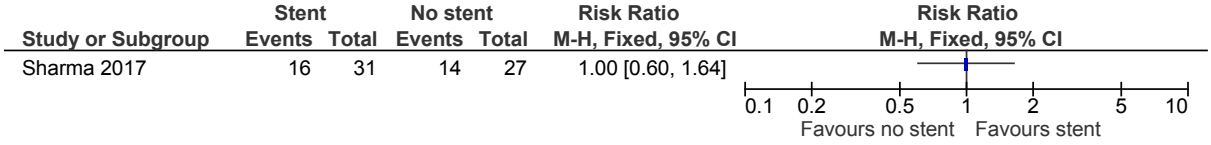


Figure 10: Clinically significant residual fragments

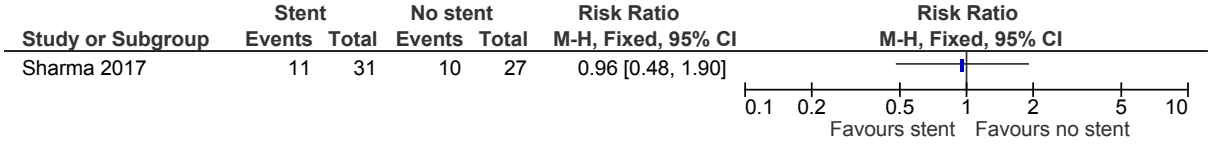


Figure 11: Readmission to hospital

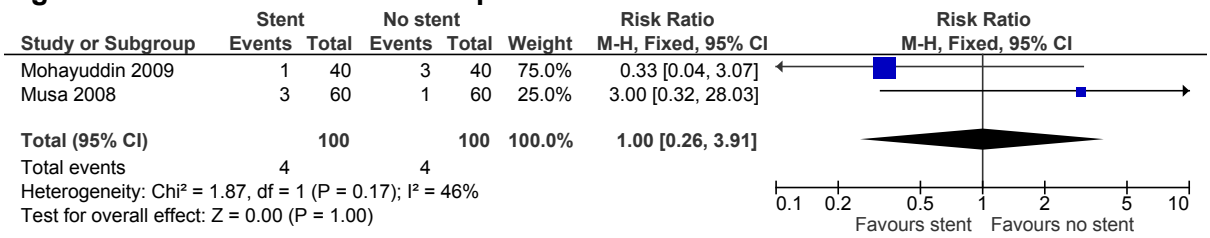


Figure 12: Retreatment rate

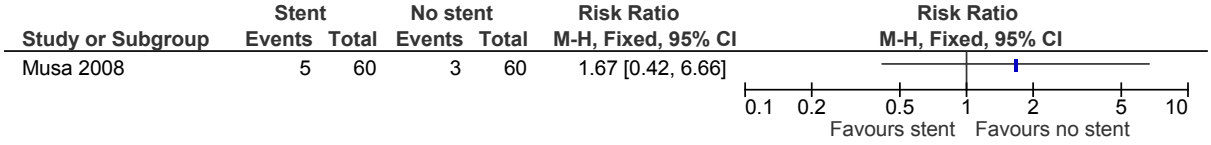


Figure 13: Ancillary procedures

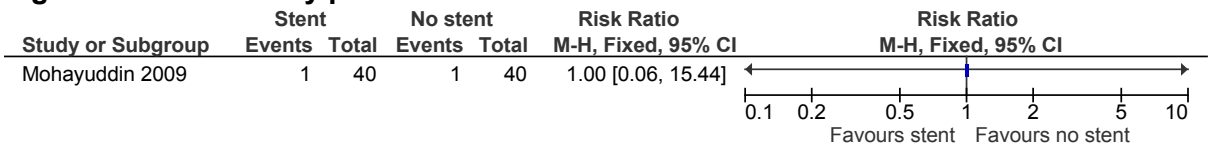


Figure 14: Minor adverse events (UTI)

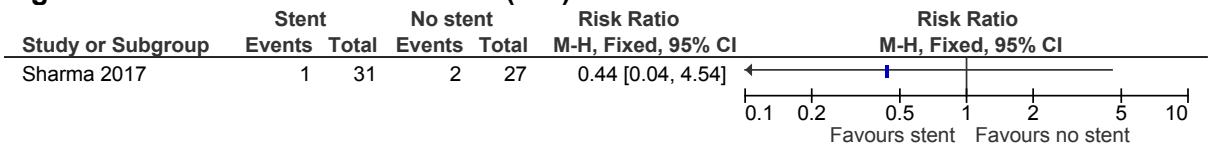


Figure 15: Minor adverse events (fever)

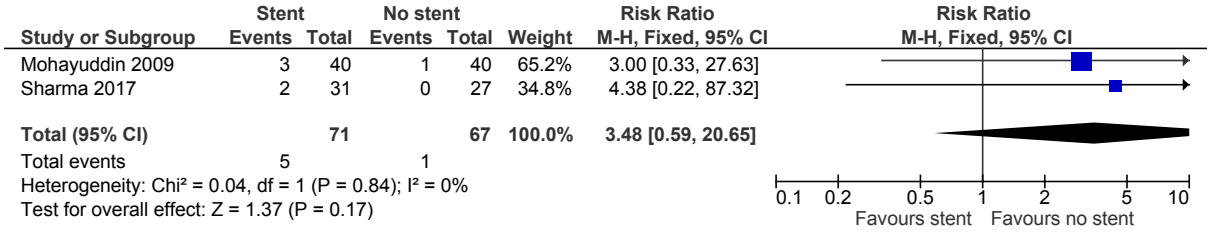


Figure 16: Stent symptoms (urgency)

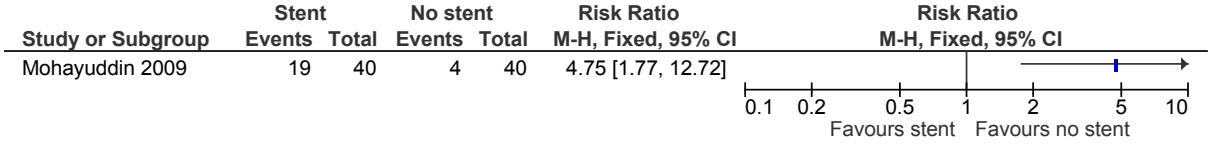


Figure 17: Stent symptoms (frequency)

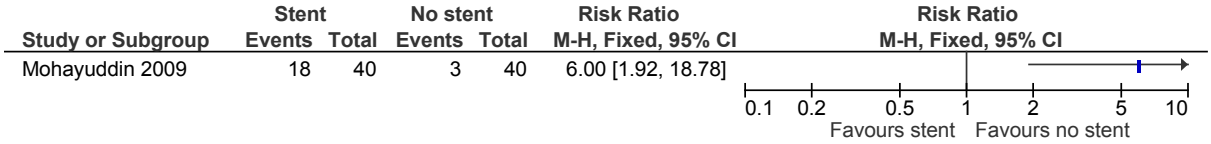


Figure 18: Stent symptoms (haematuria)

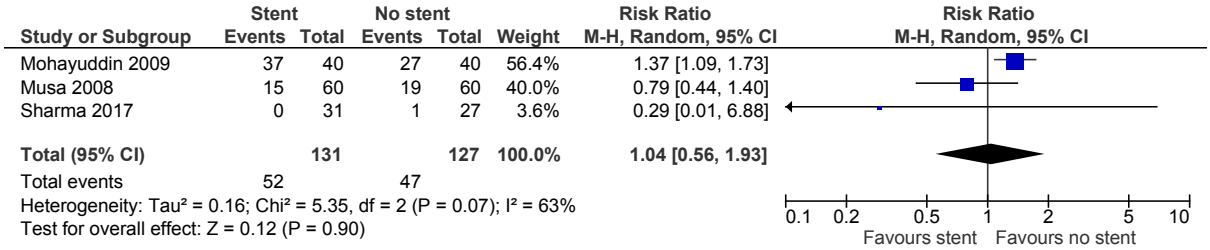


Figure 19: Stent symptoms (dysuria)

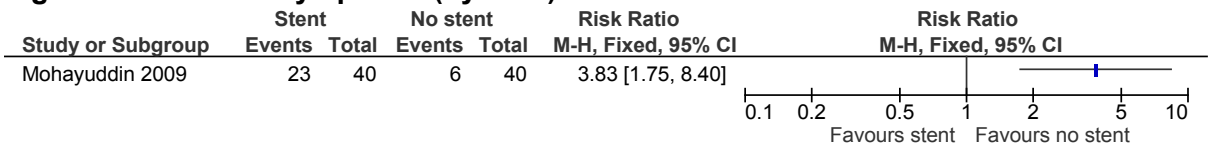
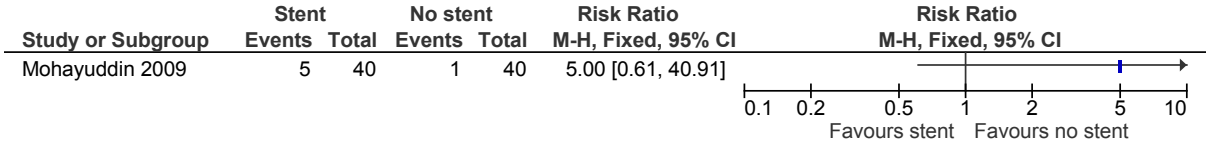


Figure 20: Stent symptoms (nocturia)



E.3 Adults, renal, >20mm

E.3.1 Stent followed by SWL versus SWL alone

Figure 21: Stone-free state

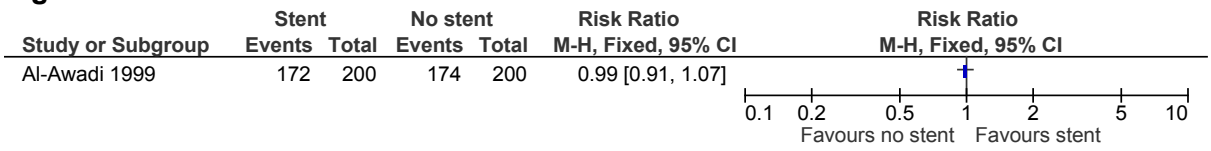


Figure 22: Minor adverse events (fever)

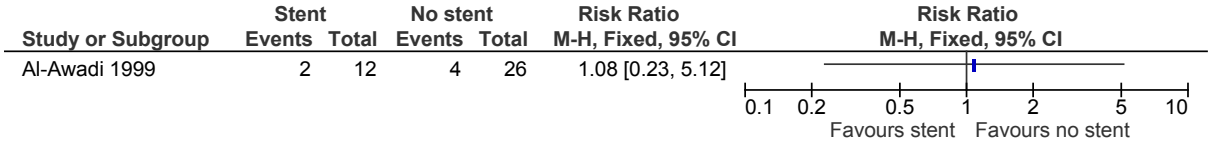


Figure 23: Retreatment (ESWL leading to fragmentation)

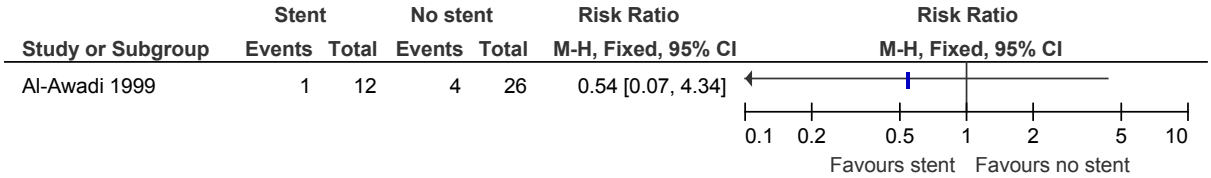
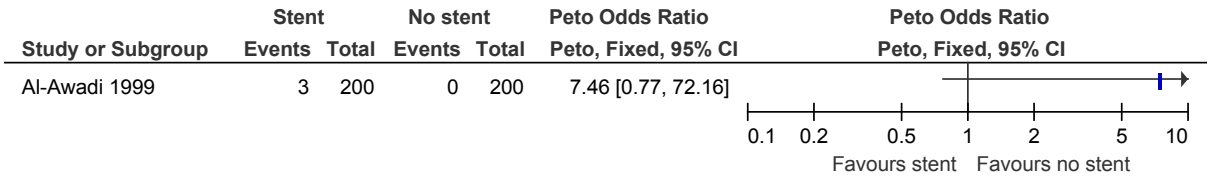


Figure 24: Failed technology



E.4 Children, renal, <10mm (non-randomised studies)

E.4.1 Stent followed by SWL versus SWL alone

Figure 25: Stone-free state

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Gunduz 2017	10	10	8	10	1.24 [0.87, 1.75]

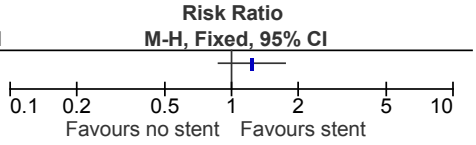


Figure 26: Retreatment

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Gunduz 2017	4	10	6	10	0.67 [0.27, 1.66]

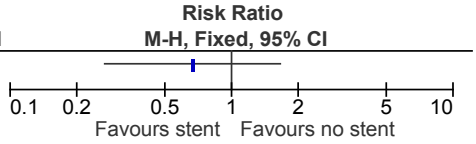


Figure 27: Ancillary procedures

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Peto Odds Ratio Peto, Fixed, 95% CI
Gunduz 2017	0	10	1	10	0.14 [0.00, 6.82]

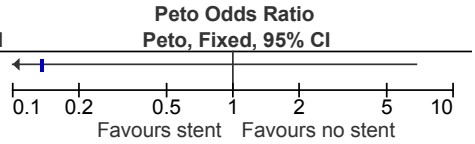


Figure 28: Stent symptoms (dysuria)

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Gunduz 2017	1	10	2	10	0.50 [0.05, 4.67]

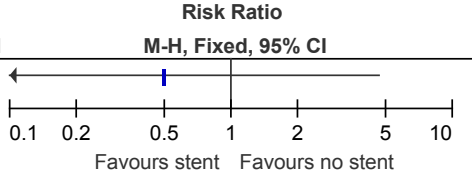
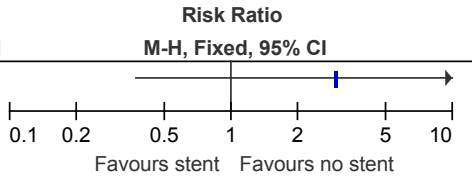


Figure 29: Stent symptoms (hematuria)

Study or Subgroup	Stent Events	Stent Total	No stent Events	No stent Total	Risk Ratio M-H, Fixed, 95% CI
Gunduz 2017	3	10	1	10	3.00 [0.37, 24.17]



E.5 Children, renal, staghorn (non-randomised studies)

E.5.1 Stent followed by SWL versus SWL alone

Figure 30: Stone-free state

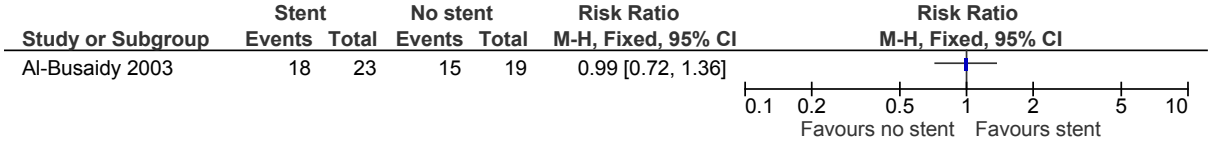


Figure 31: Length of stay (days)

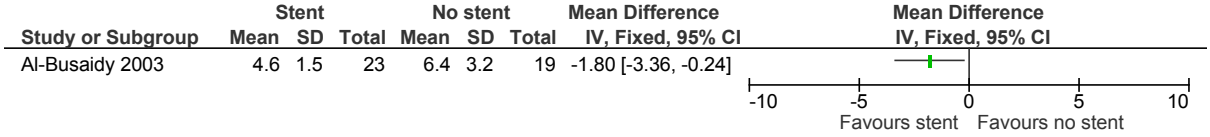


Figure 32: Readmission

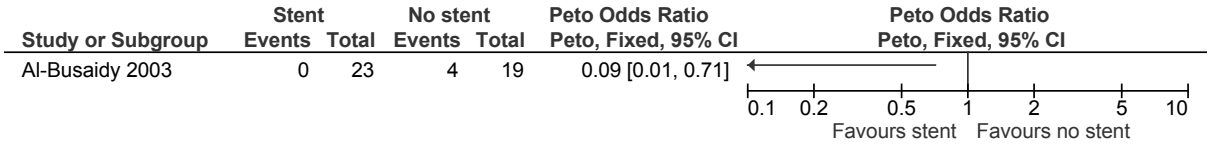


Figure 33: Ancillary procedures

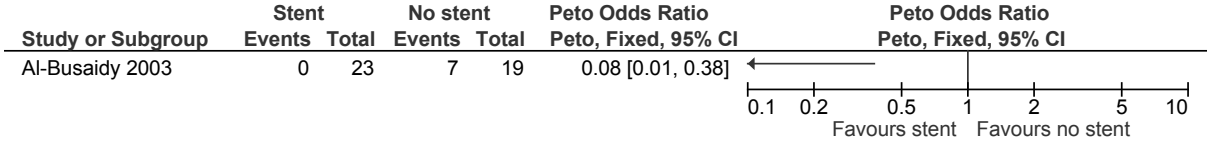
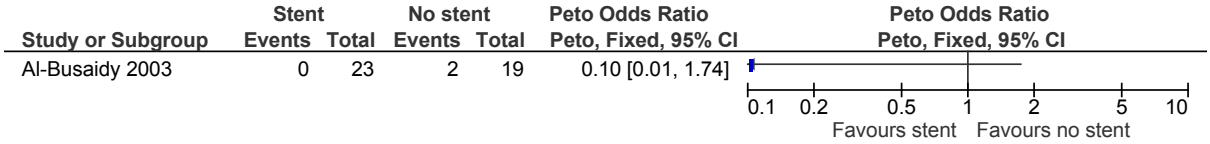


Figure 34: Major adverse events (sepsis)



Appendix F: GRADE tables

F.1 Adults, ureteric, 10-20mm

Table 13: Clinical evidence profile: Stent followed by SWL versus SWL alone

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Stent	No stent before SWL	Relative (95% CI)	Absolute		
Stone free state (follow-up 3-6 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	27/30 (90%)	26/30 (86.7%)	RR 1.04 (0.86 to 1.25)	35 more per 1000 (from 121 fewer to 217 more)	⊕⊕OO LOW	CRITICAL
Retreatment (follow-up 3-6 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[3]	none	23/30 (76.7%)	20/30 (66.7%)	RR 1.15 (0.83 to 1.59)	100 more per 1000 (from 113 fewer to 394 more)	⊕OOO VERY LOW	CRITICAL
Minor adverse events (fever) (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	1/30 (3.3%)	2/30 (6.7%)	RR 0.5 (0.05 to 5.22)	34 fewer per 1000 (from 64 fewer to 283 more)	⊕OOO VERY LOW	CRITICAL
Stent symptoms (dysuria) (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	18/30 (60%)	7/30 (23.3%)	RR 2.57 (1.26 to 5.24)	366 more per 1000 (from 61 more to 988 more)	⊕⊕OO LOW	CRITICAL
Stent symptoms (haematuria) - Microscopic (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	23/30 (76.7%)	8/30 (26.7%)	RR 2.88 (1.54 to 5.37)	502 more per 1000 (from 144 more to 1000 more)	⊕⊕OO LOW	CRITICAL
Stent symptoms (haematuria) - Gross (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[3]	none	4/30 (13.3%)	1/30 (3.3%)	RR 4 (0.47 to 33.73)	99 more per 1000 (from 17 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 or 2 increments because heterogeneity, I2=83%, p= > 0.1, unexplained by subgroup analysis
[3] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
[4] Risk difference calculated in Review Manager

[5] Downgraded by 1 increment if the outcome definition reported did not meet definition of outcome in protocol

F.2 Adults, renal, 10-20mm

Table 14: Clinical evidence profile: Stent followed by SWL versus SWL alone

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Stent	No stent before SWL	Relative (95% CI)	Absolute		
Stone free state (follow-up 1-3 months)												
3	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	104/131 (79.4%)	105/127 (82.7%)	RR 0.97 (0.86 to 1.08)	25 fewer per 1000 (from 116 fewer to 66 more)	⊕⊕OO LOW	CRITICAL
Clinically insignificant residual fragment (follow-up 4 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	16/31 (51.6%)	14/27 (51.9%)	RR 1 (0.6 to 1.64)	0 fewer per 1000 (from 207 fewer to 332 more)	⊕OOO VERY LOW	CRITICAL
Clinically significant residual fragment (follow-up 4 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	11/31 (35.5%)	10/27 (37%)	RR 0.96 (0.48 to 1.9)	15 fewer per 1000 (from 193 fewer to 333 more)	⊕OOO VERY LOW	CRITICAL
Ancillary procedure (follow-up 3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/40 (2.5%)	1/40 (2.5%)	RR 1 (0.06 to 15.44)	0 fewer per 1000 (from 24 fewer to 361 more)	⊕OOO VERY LOW	CRITICAL
Retreatment (follow-up 3 months)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5/60 (8.3%)	3/60 (5%)	RR 1.67 (0.42 to 6.66)	33 more per 1000 (from 29 fewer to 283 more)	⊕OOO VERY LOW	CRITICAL
Readmission (follow-up 3 months)												

2	randomised trials	serious[1]	no serious inconsistency	serious[3]	very serious[2]	none	4/100 (4%)	4/100 (4%)	RR 1 (0.26 to 3.91)	0 fewer per 1000 (from 30 fewer to 116 more)	⊕OOO VERY LOW	CRITICAL
Minor adverse events (UTI) (follow-up 4 weeks)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/31 (3.2%)	2/27 (7.4%)	RR 0.44 (0.04 to 4.54)	41 fewer per 1000 (from 71 fewer to 262 more)	⊕OOO VERY LOW	CRITICAL
Minor adverse events (fever) (follow-up 1-3 months)												
2	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5/71 (7%)	1/67 (1.5%)	RR 3.48 (0.59 to 20.65)	32 more per 1000 (from 5 fewer to 255 more)	⊕OOO VERY LOW	CRITICAL
Stent symptoms (urgency) (follow-up 3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	19/40 (47.5%)	4/40 (10%)	RR 4.75 (1.77 to 12.72)	375 more per 1000 (from 77 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL
Stent symptoms (frequency) (follow-up 3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	18/40 (45%)	3/40 (7.5%)	RR 6 (1.92 to 18.78)	375 more per 1000 (from 69 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL
Stent symptoms (haematuria) (follow-up 48 hours - 3 months)												
3	randomised trials	serious[1]	serious[4]	no serious indirectness	very serious[2]	none	52/131 (39.7%)	47/127 (37%)	RR 1.04 (0.56 to 1.93)	13 more per 1000 (from 139 fewer to 295 more)	⊕OOO VERY LOW	CRITICAL
Stent symptoms (dysuria) (follow-up 3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	23/40 (57.5%)	6/40 (15%)	RR 3.83 (1.75 to 8.4)	425 more per 1000 (from 113 more to 1000 more)	⊕⊕⊕O MODERATE	CRITICAL
Stent symptoms (nocturia) (follow-up 3 months)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	5/40 (12.5%)	1/40 (2.5%)	RR 5.00 (0.61 to 40.91)	100 more per 1000 (from 10 fewer to 998 more)	⊕OOO VERY LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.
[3] Downgraded by 1 increment if the outcome definition reported did not meet definition of outcome in protocol
[4] Downgraded by 1 or 2 increments because heterogeneity, I2= 63%, p= > 0.1, unexplained by subgroup analysis

F.3 Adults, renal, >20mm

Table 15: Clinical evidence profile: Stent followed by SWL versus SWL alone

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Stent	No stent before SWL	Relative (95% CI)	Absolute		
Stone free state (follow-up time-point not reported)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	172/200 (86%)	174/200 (87%)	RR 0.99 (0.91 to 1.07)	9 fewer per 1000 (from 78 fewer to 61 more)	⊕⊕⊕O MODERATE	CRITICAL
Retreatment (follow-up time-point not reported)												
1	randomised trials	serious[1]	no serious inconsistency	serious[3]	very serious[2]	none	1/12 (8.3%)	4/26 (15.4%)	RR 0.54 (0.07 to 4.34)	71 fewer per 1000 (from 143 fewer to 514 more)	⊕OOO VERY LOW	CRITICAL
Minor adverse events (fever) (follow-up time-point not reported)												
1	randomised trials	serious[1]	no serious inconsistency	serious[3]	very serious[2]	none	2/12 (16.7%)	4/26 (15.4%)	RR 1.08 (0.23 to 5.12)	12 more per 1000 (from 119 fewer to 634 more)	⊕OOO VERY LOW	CRITICAL
Failed technology (follow-up time-point not reported)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	3/200 (1.5%)	0/200 (0%)	OR 7.46 (0.77 to 72.16)	15 more per 1000 (from 4 fewer to 34 more)[4]	⊕OOO VERY LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

[3] Downgraded by 1 increment if the outcome definition reported did not meet definition of outcome in protocol
[4] Risk difference calculated in Review Manager

F.4 Children, renal, 10-20mm

Table 16: Clinical evidence profile (non-randomised studies): Stent followed by SWL versus SWL alone

Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Stent	No stent before SWL	Relative (95% CI)	Absolute		
Stone free state (follow-up time-point not reported)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	10/10 (100%)	8/10 (80%)	RR 1.24 (0.87 to 1.75)	192 more per 1000 (from 104 fewer to 600 more)	⊕OOO VERY LOW	CRITICAL
Retreatment (follow-up time-point not reported)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	4/10 (40%)	6/10 (60%)	RR 0.67 (0.27 to 1.66)	198 fewer per 1000 (from 438 fewer to 396 more)	⊕OOO VERY LOW	CRITICAL
Ancillary procedures (follow-up time-point not reported)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	0/10 (0%)	1/10 (10%)	OR 0.14 (0 to 6.82)	85 fewer per 1000 (from 100 fewer to 331 more)	⊕OOO VERY LOW	CRITICAL
Stent symptoms (dysuria)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	1/10 (10%)	2/10 (20%)	RR 0.5 (0.05 to 4.67)	100 fewer per 1000 (from 190 fewer to 734 more)	⊕OOO VERY LOW	CRITICAL
Stent symptoms (hematuria)												

1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	3/10 (30%)	1/10 (10%)	RR 3.0 (0.37 to 24.17)	200 more per 1000 (from 63 fewer to 1000 more)	⊕OOO VERY LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

F.5 Children, renal, staghorn

Table 17: Clinical evidence profile (non-randomised studies): Stent followed by SWL versus SWL alone

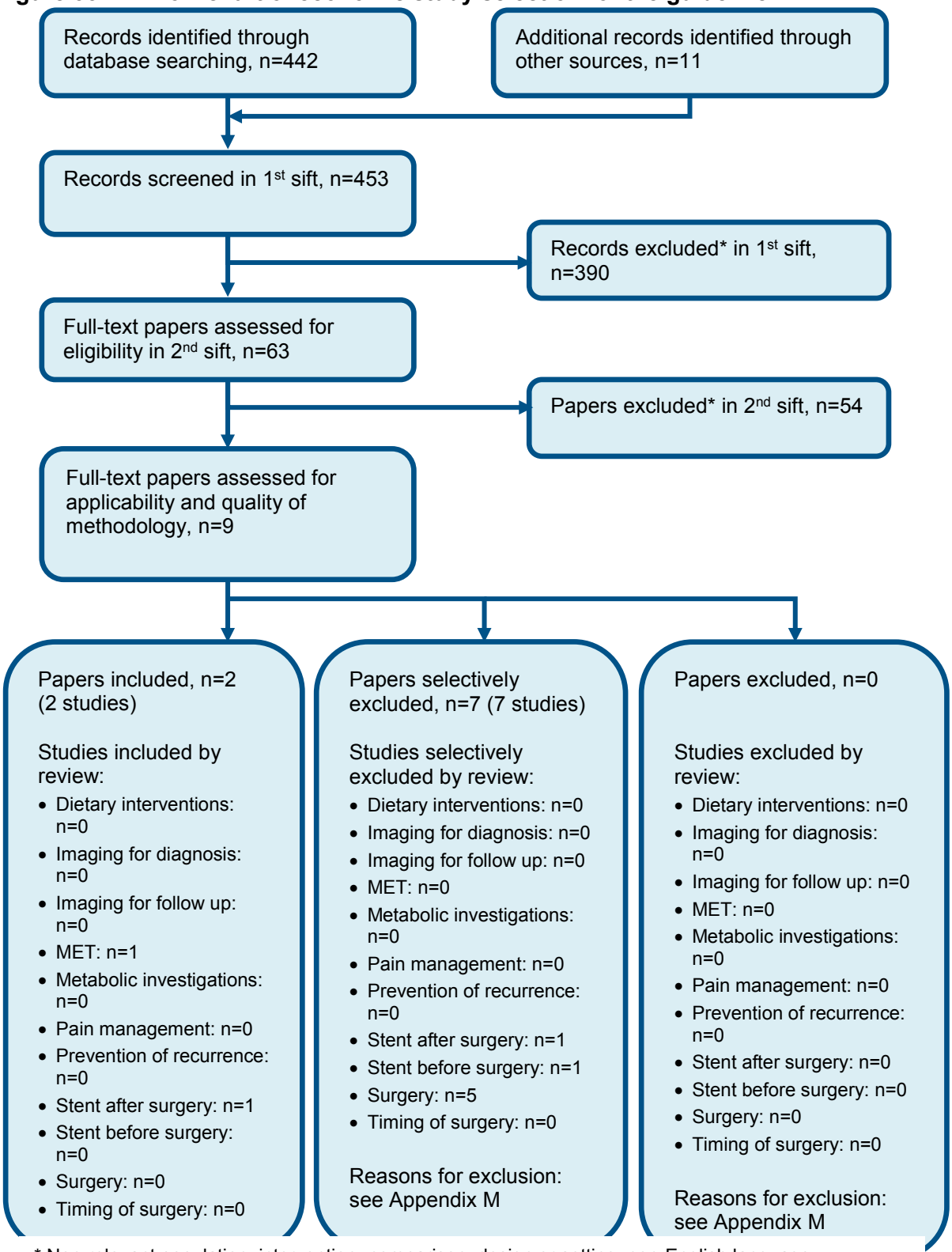
Quality assessment							No of patients		Effect		Quality	Importance
No of studies	**Design**	**Risk of bias**	**Inconsistency**	**Indirectness**	**Imprecision**	**Other considerations**	**Stent**	**No stent before SWL**	**Relative (95% CI)**	**Absolute**		
Stone free state (follow-up 3 months)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	18/23 (78.3%)	15/19 (78.9%)	RR 0.99 (0.72 to 1.36)	8 fewer per 1000 (from 221 fewer to 284 more)	⊕OOO VERY LOW	CRITICAL
Readmission (follow-up time-point not reported)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/23 (0%)	4/19 (21.1%)	OR 0.09 (0.01 to 0.71)	187 fewer per 1000 (from 51 fewer to 208 fewer)	⊕OOO VERY LOW	CRITICAL
Ancillary procedures (follow-up time-point not reported)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	none	0/23 (0%)	7/19 (36.8%)	OR 0.08 (0.01 to 0.38)	323 fewer per 1000 (from 187 fewer to 362 fewer)	⊕OOO VERY LOW	CRITICAL
Length of stay (days) (follow-up time-point not reported; Better indicated by lower values)												
1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	none	23	19	-	MD 1.8 lower (3.36 to 0.24 lower)	⊕OOO VERY LOW	CRITICAL
Major adverse events (sepsis) (follow-up time-point not reported)												

1	observational studies	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	none	0/23 (0%)	2/19 (10.5%)	OR 0.10 (0.01 to 1.74)	93 fewer per 1000 (from 104 fewer to 65 more)	⊕OOO VERY LOW	CRITICAL

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs.

Appendix G: Health economic evidence selection

Figure 35: Flow chart of economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language

Appendix H: Health economic evidence tables

None

Appendix I: Excluded studies

I.1 Excluded clinical studies

Table 18: Studies excluded from the clinical review

Study	Exclusion reason
Aghamir 2008[1]	No outcomes
Al-Ba'adani 2006[3]	Incorrect interventions
Ali 2001[5]	Incorrect study design
Ali 2004[6]	Incorrect study design
Barnes 2014[7]	Incorrect interventions
Baseskioglu 2011[8]	Incorrect interventions
Bierkens 1991[9]	Stone size not reported
Borboroglu 2001[10]	Incorrect interventions
Byrne 2002[11]	Mixed renal and ureteric stones
Castagnetti 2010[12]	Incorrect study design
Cevik 2010[13]	Incorrect interventions
Chang 1993[16]	Incorrect interventions
Chander 2010[14]	Laparoscopic nephrolithotomy and pyelolithotomy
Chandhoke 2002[15]	Mixed renal and ureteral stones
Chauhan 2015[17]	Incorrect interventions
Chen 1993[18]	Incorrect study design
Chen 2002[19]	Incorrect interventions
Cheung 2000 [21]	Incorrect study design
Cheung 2003 [20]	Incorrect interventions
Chew 2004[22]	Incorrect study design
Clayman 2005[23]	Incorrect study design
Corcoran 2008 [24]	Incorrect comparison
Crook 2008[25]	Incorrect interventions
Damiano 2004[27]	Incorrect interventions
Damiano 2005[26]	Not available
Danuser 2014[28]	Not guideline condition
Denstedt 2001[30]	Incorrect interventions
Dudek 2013[31]	Paper not available
Elgammal 2014 [33]	Incorrect comparison
El Harrech 2014[32]	Incorrect interventions
Elsheemy 2015[34]	Incorrect interventions
Gou 2010[36]	Paper not available
Grossi 2006[37]	No outcomes
Gunlusoy 2008[39]	Incorrect interventions
Haleblian 2008[40]	Incorrect study design
Hammady 2011[41]	Incorrect interventions
Hussein 2006[42]	Incorrect interventions

Study	Exclusion reason
Ibrahim 2008[43]	Incorrect interventions
Jeong 2004[44]	No outcomes
Ji 2012[45]	Incorrect study design
Kenan 2008[46]	Incorrect interventions
Marcovich 2004[47]	Incorrect interventions
Mercado 2013[48]	Incorrect interventions
Minevich 2005 [49]	Incorrect study design
Mokhmalji 2001[51]	Incorrect interventions
Moon 2011[52]	Incorrect interventions
Mustafa 2007[54]	No outcomes
Mustafa 2009[55]	No outcomes
Nabi 2007[56]	Incorrect study design
Netto 2001 [58]	Overall stone size not reported
Noh 2002[60]	Not in English
Okada 2014[61]	Citation only
Ordonez 2017[62]	Incorrect study design
Ozkan, 2015 [63]	Incorrect study design
Pais 2016[64]	Incorrect study design
Pengfei 2011[65]	Incorrect study design
Prasanchaimontri 2017[66]	Incorrect interventions
Pryor 1990[67]	Mixed renal and ureteric stones
Shao 2008[68]	Incorrect interventions
Shao 2010[69]	Paper not available
Shen 2011[71]	Incorrect study design
Singh 2008[72]	Incorrect interventions
Sofimajidpour 2016[74]	Paper not available
Sofimajidpour 2016[73]	Incorrect interventions
Song 2012[75]	Incorrect study design
Srivastava 2003[76]	Incorrect interventions
Telha 2010[77]	Incorrect interventions
Wang 2009[78]	Incorrect interventions
Wang 2017[79]	Incorrect study design
Xu 2009[80]	Incorrect interventions
Younesi Rostami, 2012[81]	Incorrect study design
Zaki 2011[82]	Incorrect interventions
Zhao 2016[83]	Incorrect interventions. Stone size not reported
Zhou 2017[84]	Incorrect interventions

I.2 Excluded health economic studies

Table 19: Studies excluded from the health economic review

Reference	Reason for exclusion
Darrad 2017[29]	This study was assessed as partially applicable with very serious limitations due to the clinical data being retrospective and not from an RCT, therefore not in keeping with the guideline clinical review.