Use of Ureteral Stent in Extracorporeal Shock Wave Lithotripsy for Upper Urinary Calculi: A Systematic Review and Meta-Analysis

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Abbreviations and Acronyms

D-J stent = Double-J® stent

ESWL® = extracorporeal shock wave lithotripsy

LUTS = lower urinary tract symptoms

RCTs = randomized controlled trials

UTI = urinary tract infection

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Purpose: This systematic review was performed to assess the necessity and complications of stenting before extracorporeal shock wave lithotripsy in the management of upper urinary stones.

Materials and Methods: A systematic research of PubMed®, EMBASE® and the Cochrane Library was performed to identify all randomized controlled trials. The comparisons were about the outcomes and complications of extracorporeal shock wave lithotripsy in the management of upper urinary stones with or without Double-J stenting before extracorporeal shock wave lithotripsy, including stone-free rate, Steinstrasse, lower urinary tract symptoms, hematuria, fever, urinary tract infection, pain and analgesia, auxiliary treatment, and nausea and vomiting. We used the Cochrane Collaboration's Review Manager (RevMan) 5.0.2 software for statistical analysis.

Results: Eight randomized controlled trials were included in analysis that reported 876 patients in total, divided into the stented group of 453 and the stentless group of 423. All studies recorded the stone-free rate and the results of the meta-analysis showed no difference between the groups (RR 0.97, 95% CI 0.91–1.03, p = 0.27). The total incidence of Steinstrasse in the stented group was similar to that of the stentless group with the exception of 1 study. However, the incidence of lower urinary tract symptoms was significantly higher in the stented group than in the stentless group (RR 4.10, 95% CI 2.21–7.61, p <0.00001). Significant differences could not be found in hematuria, fever, urinary tract infection, pain and analgesia, auxiliary treatment, or nausea and vomiting between the groups.

Conclusions: The systematic review suggested significant advantages of stenting before extracorporeal shock wave lithotripsy compared to in situ extracorporeal shock wave lithotripsy in terms of Steinstrasse. However, stenting did not benefit stone-free rate and auxiliary treatment after extracorporeal shock wave lithotripsy, and it induced more lower urinary tract symptoms. More high quality, randomized controlled trials are needed to address this issue.

Key Words: kidney calculi, ureteral calculi, lithotripsy, stents, randomized controlled trial

UROLITHIASIS is one of the most prevalent urological disorders[1] and the prevalence of urinary stones has increased in most countries. In the United Kingdom at least 1 renal stone will form in approximately 8% of male and 4% of

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female patients, and in the United States the male lifetime prevalence has increased to 15%.[2] The management of urinary calculi was revolutionized by the introduction of extracorporeal shockwave lithotripsy in 1980. ESWL is a safe, effective and minimally invasive method, and is now the first choice of treatment for most upper urinary calculi.[3,4] Most fragments pass uneventfully through the urinary tract after ESWL.

However, fragments may obstruct the ureter, thus leading to post-ESWL complications such as acute renal pain, hydronephrosis, infection and renal failure.[5] Success rates and complications are determined by the size, location and composition of the stone in the urinary tract, the type of lithotripter, shock wave energy and rate, and anatomical characteristics.[4] Fragments may become impacted in the ureter and form Steinstrasse after ESWL, but no agreement has yet been reached that ureteral stenting could be used to prevent Steinstrasse and other post-ESWL complications.[6] The European Association of Urology (2010) recommends pre-ESWL stenting for renal stones with a diameter greater than 20 mm (approximately 300 mm^2), and a D-J stent to reduce obstructive and infective complications after the use of ESWL.[7] However, stenting is considered a relatively invasive procedure and several studies have reported that D-J stent insertion does not improve ESWL results.[8] Stents are associated with significant symptoms of discomfort such as urinary frequency, urgency, dysuria, hematuria etc. Joshi et al suggested that indwelling ureteral stents resulted in a negative functional capacity and utility values, and a decreased quality of life in up to 80% of patients.[9] Whether stents should be considered routinely before ESWL for treating upper urinary calculi is still controversial.

We conducted this systematic review to assess the necessity and complications of pre-ESWL stenting in the management of urinary stones, and to verify whether stenting would influence the effectiveness of therapy by collecting all published RCTs. To our knowledge this is the first systematic review of pre-ESWL stenting in the management of upper urinary calculi.

METHODS

Search Strategy

We searched the databases PubMed (from 1980 to December 2010), EMBASE (from 1980 to December 2010), the Cochrane Central Register of Controlled Trials and the Cochrane Database of Systematic Reviews. The search process was initially designed to find all trials involving the terms "renal calculi," "ureteral calculi," "extracorporeal shock wave lithotripsy," "ESWL," "double-J stent," "ureteral stent" and "randomized controlled trial" (and multiple synonyms for each term). Reference lists from retrieved documents were also searched. Computer searches were supplemented with a manual search. Two authors (SP, YJ) independently screened all citations and abstracts selected by the search strategy to identify potentially eligible studies.

Participants

The inclusion criteria were adult patients (male or female) who had renal calculi or ureteral calculi with normal serum creatinine. All patients were suitable for ESWL and stone size varied with the criteria of each included trial. Patients with radiolucent stones, bleeding disorders, congenital renal abnormalities, increased serum creatinine, metabolic abnormalities, symptomatic urinary tract infection, unilateral stone disease, excretory urogram showing evidence of ureteropelvic junction obstruction and residual fragments after previous ESWL, open surgery or endoscopy were excluded from these RCTs.

Interventions

All patients were treated with ESWL, and were divided into the 2 groups of stented and stentless. Each group included 3 subgroups of renal stone, ureteral stone, or renal or ureteral stone subgroup. Comparisons were made regarding outcomes and complications of ESWL in the management of upper urinary stones with or without D-J stent before ESWL.

Outcome Measures

Several outcomes and complications were measured in this review, including stone-free rate, Steinstrasse, LUTS (urinary frequency, urgency, dysuria, nocturia, incontinence), hematuria (microscopic hematuria, gross hematuria, transient hematuria), fever, UTI (pyuria, pyelonephritis and others), pain (suprapubic pain, loin pain, flank pain, bladder pain and penile pain) and need for analgesia, nausea and vomiting, and auxiliary treatment. According to the included trials, objective followup data were obtained by sending a questionnaire or other ways in the clinic and followup was at least 3 months. The interval of each followup was determined by the researchers. Stone clearance was defined as the absence of residual stones by plain radiographic film, ultrasonography or excretory urography after ESWL. Cases needing an auxiliary procedure were considered treatment failures.

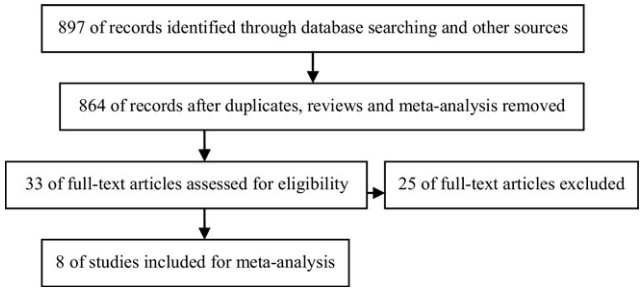

Figure 1. Flow diagram of systematic review

Data Extraction

Data were extracted independently by both authors using a pre-designed data extraction form. Data extraction included data source, eligibility, methods, participant characteristics, interventions and results. The 2 authors then met to synthesize their findings and the information subsequently was entered into RevMan 5.0.2. Any discrepancies among the extracted data were resolved by discussion, and if the disagreements could not be resolved by discussion they were resolved in consultation with another author (WJ).

Quality Assessment

The quality of included studies was assessed by 2 authors according to the Cochrane Collaboration reviewers' handbook and the QUOROM (Quality of Reporting of Meta-analyses) guidelines.[10,11] The quality items were composed of generation of randomization sequences, allocation conceal-

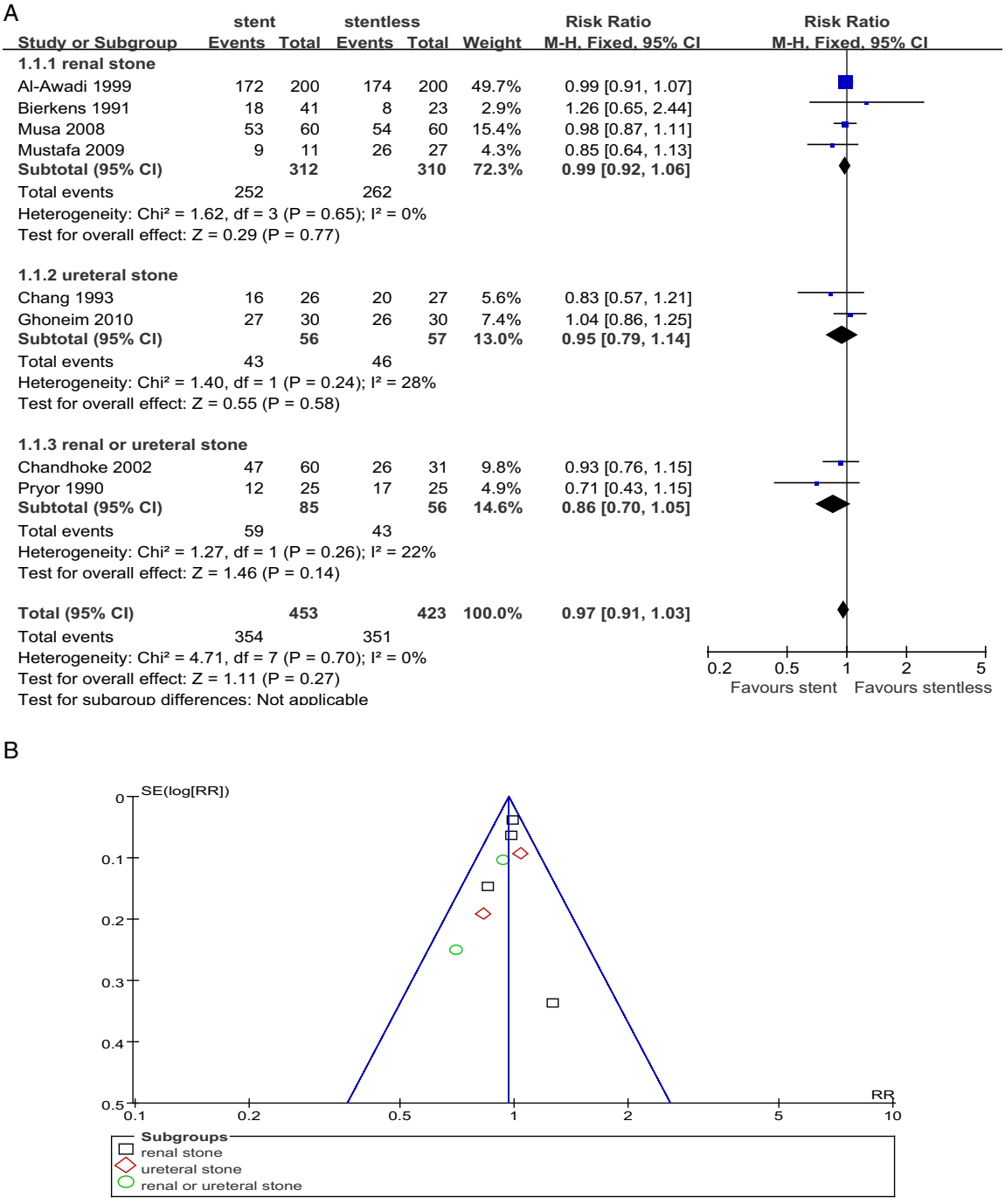

Figure 2. Stone-free rate in patients with and without stent before ESWL (*A*), and funnel plot of all included studies on stone-free rate (*B*)

ment, description of withdrawals and dropouts, intent to treat analysis, and baseline assessed by adequate, unclear or not used/reported. The blinding method was not analyzed in this review because it was not suitable for surgical clinical trials.

Data Analysis

Data analysis was performed using RevMan 5.0.2. For all eligible studies dichotomous data were presented as relative risk with 95% CI. Meta-analysis was performed using fixed effects or random effects methods depending on the presence or absence of significant heterogeneity. Statistical heterogeneity among trials was evaluated by the I-square test with significance set at $p < 0.05$. In the absence of statistically significant heterogeneity the fixed effects method was used to combine the results. Otherwise the random effects method was used. Additionally, sensitivity analysis was performed if low quality trials were included. All data analysis was directed by a statistical specialist (JM).

RESULTS

Description of Studies

A total of 897 reports were identified by the researchers. By scanning titles and abstracts 889 redundant publications, reviews and meta-analyses were excluded from study. After referring to full texts 8 studies were left for analysis involving 876 patients in total,[6,12–18] of whom 453 were designated the stented group and 423 the stentless group. All trials were published in English. The systematic review study characteristics, types of outcome measurement, quality of included trials and 4-phase search flow diagram are presented in figure 1.

Stone-Free Rate

The stone-free rate data were available from all included clinical trials. The total stone-free rate was 78.1% (354 of 453) in the stented group and 83.0% (351 of 423) in the stentless group. There was no significant difference in stone-free rate between the groups (RR 0.97, 95% CI 0.91–1.03, p = 0.27, fig.2).

Steinstrasse

Steinstrasse was reported in 5 (62.5%) studies. Al-Awadi et al treated renal stones (15 to 35 mm) with ESWL and most cases involved Steinstrasse in this review.[15] However, the authors did not report the number of subgroups so this study was analyzed as a subgroup for this outcome. There was no signifi-

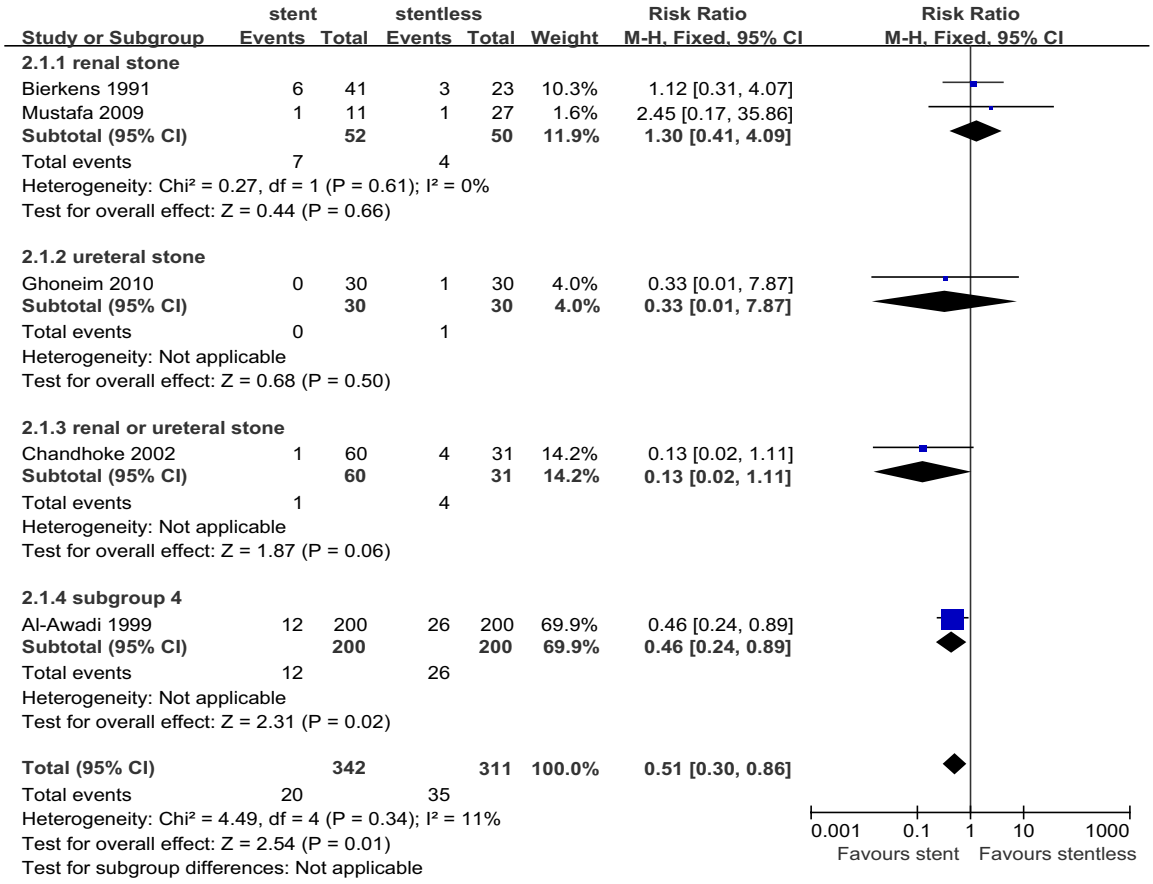

Figure 3. Steinstrasse in patients with and without stent before ESWL

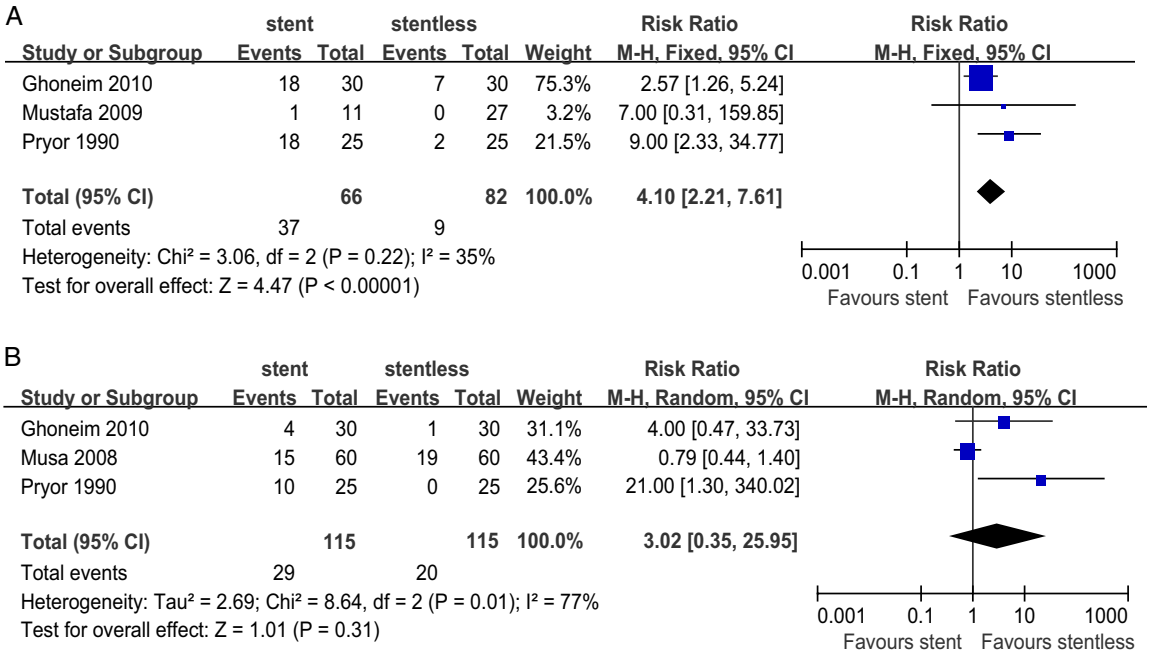

Figure 4. LUTS (*A*) and hematuria (*B*) in patients with and without stent before ESWL

cant difference in Steintrasse incidence between the stented group and the stentless group in other subgroup analyses (p = 0.66, 0.50 and 0.06, respectively). However, there was a significant difference in the study by Al-Awadi et al (RR 0.46, 95% CI 0.24–0.89, p = 0.02, fig. 3).

LUTS and Hematuria

LUTS include storage, voiding and post-micturition symptoms affecting the lower urinary tract, and they can significantly reduce quality of life. In the review 3 (37.5%) studies recorded LUTS including urinary frequency, urgency, dysuria, nocturia and

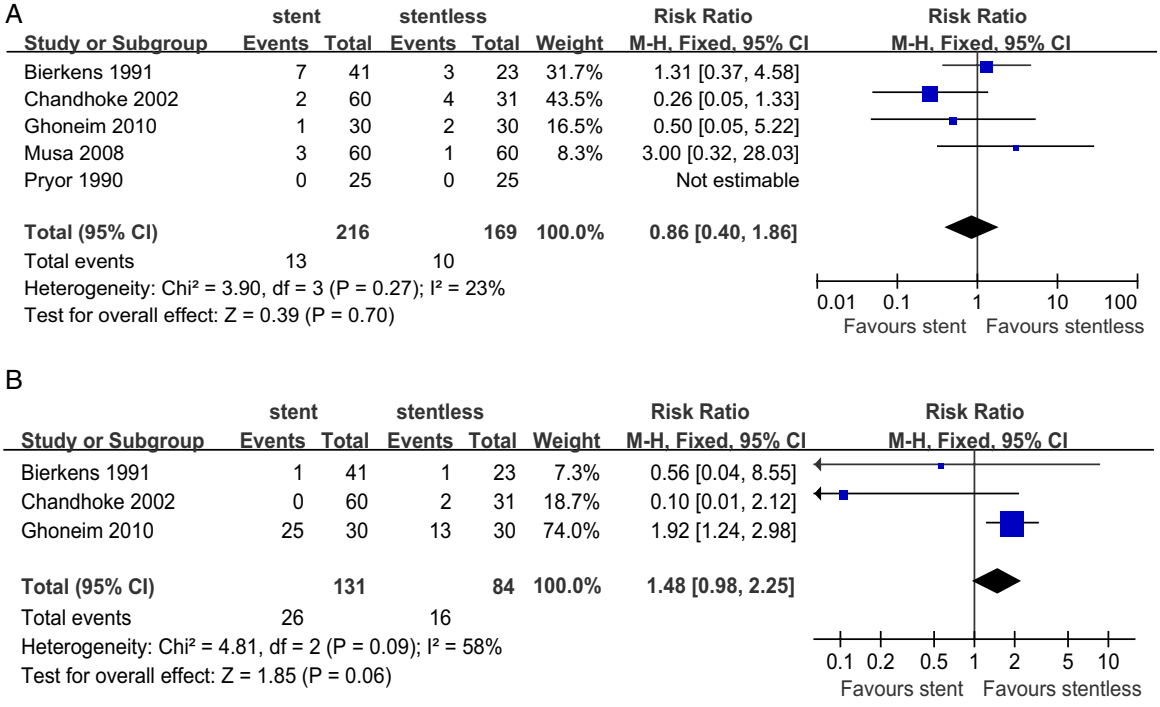

Figure 5. Fever (*A*) and UTI (*B*) in patients with and without stent before ESWL

incontinence. There was a significant difference in LUTS between the 2 groups (RR 4.10, 95% CI 2.21–7.61, p <0.00001). The major LUTS recorded in studies by Pryor and Jenkins[12] and Mustafa and Ali-El-Dein[18] were urinary frequency and urgency, but the symptom reported by Ghoneim et al was dysuria (fig. 4, *A*).[6] Hematuria was also a common symptom after ESWL, and 3 (37.5%) trials in this review reported data on microscopic hematuria, gross hematuria and transient hematuria. There was no statistically significant difference in the incidence of hematuria after ESWL between the stented and stentless group (RR 3.02, 95% CI 0.35–25.95, p = 0.31, fig. 4, *B*).

Fever and UTI

Fever was reported in 4 (50.0%) studies and no patients had a fever in the study by Pryor and Jenkins.[12] The difference in fever incidence between the stented group and the stentless group was not significant (RR 0.86, 95% CI 0.40–1.86, p = 0.70, fig. 5, *A*). UTI, including pyelonephritis and pyuria, was recorded in 3 (37.5%) studies. There was no statistically significant difference in UTI incidence after ESWL between the stented and stentless group (RR 1.48, 95% CI 0.98–2.25, p = 0.06, fig. 5, *B*).

Additional Complications

Pain (suprapubic, loin, flank, bladder and penile pain) was reported in 5 (62.5%) studies and the need for analgesia was reported in 3. Mustafa and Ali-El-Dein did not record the number of patients experiencing pain but they reported no patients needed analgesia.[18] The difference in pain between the groups was not statistically significant (RR 1.37, 95% CI 0.90–2.07, p = 0.14). Only 1 study showed that patients needed analgesia after ESWL but the difference was not significant (RR 0.75, 95% CI 0.39–1.45, p = 0.39, fig. 6, *A*).[17] There were 3 (37.5%) studies that reported nausea and vomiting after ESWL, and the difference was not statisti-

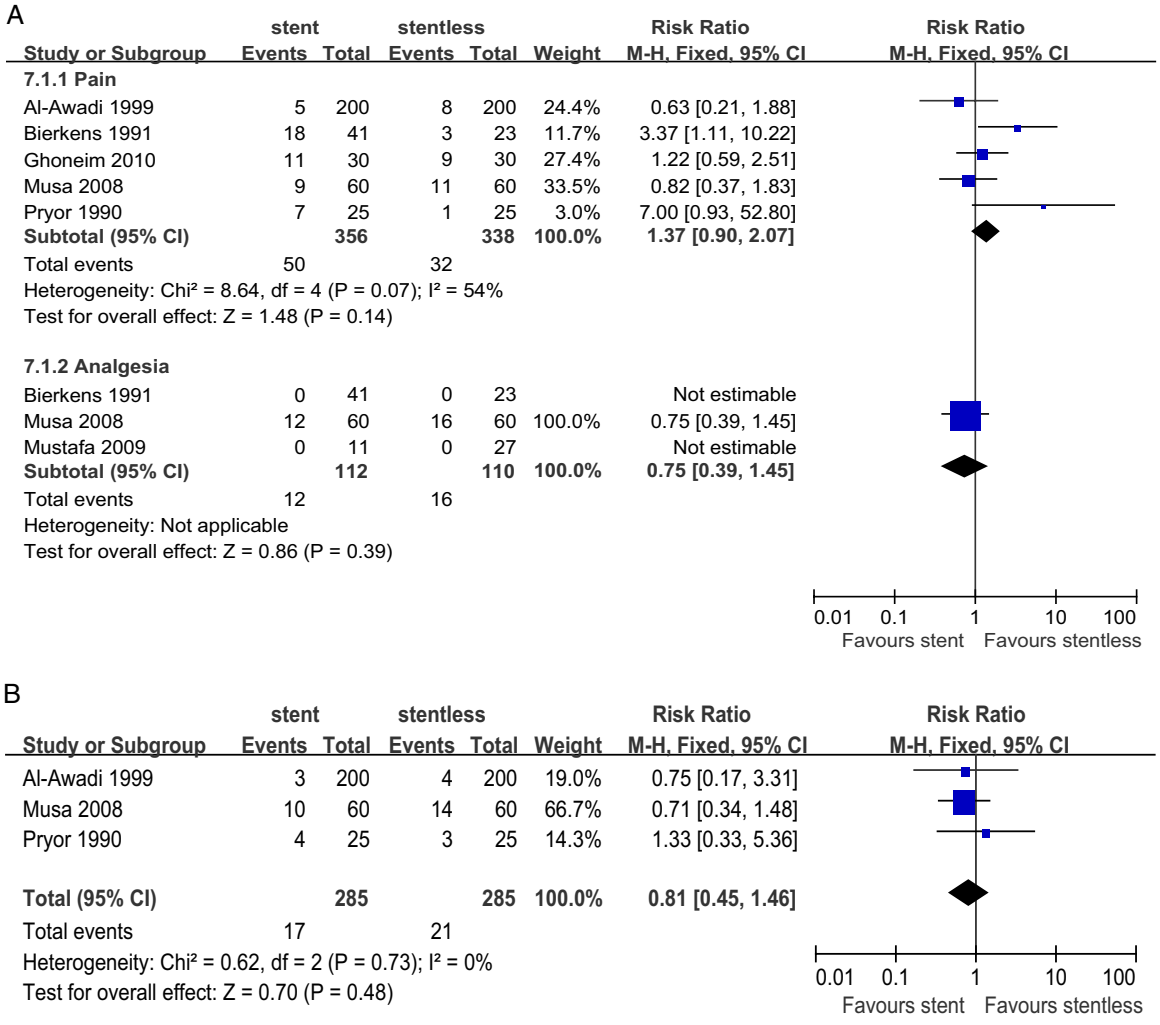

Figure 6. Pain and analgesia (*A*), and nausea and vomiting (*B*) in patients with and without stent before ESWL

cally significant (RR 0.81, 95% CI 0.45–1.46, p = 0.48, fig. 6, *B*).

Auxiliary Treatment

Auxiliary treatment included ureteroscopy, ureterolithotomy, nephrectomy and percutaneous nephrostomy. There were 6 (75.0%) trials that recorded information about auxiliary treatment after ESWL. Ghoneim et al[6] and Mustafa and Ali-El-Dein[18] reported no patients received further treatment after ESWL. There was no statistically significant difference between the groups in terms of total incidence of auxiliary treatment (RR 1.43, 95% CI 0.70–2.92, p = 0.33, fig. 7).

DISCUSSION

Most guidelines recommend ESWL as the first line treatment for ureteral and renal calculi smaller than 20 mm.[7,19] Successful stone-free rates with ESWL were reported by several authors.[20,21] The evaluation of success after ESWL implies not only the complete disintegration of the calculus but also the subsequent spontaneous passage of the fragments. Therefore, the success of ESWL is closely related to the problem of residual fragments after ESWL. Steinstrasse is possible and may constitute a potentially serious complication if not investigated carefully. The methods of reducing residual fragments after ESWL are strongly influenced by the decisions of the urologist.[22,23] In the last few years several centers have investigated the effects of ureteral stenting before ESWL on Steinstrasse and other post-ESWL complications.[6,17]

However, according to the results of this review D-J stenting before ESWL provided no additional benefit compared to in situ ESWL. Stenting did not improve the stone-free rate. The results of our subgroup analysis show that the incidence of Steinstrasse in the stented group was similar to that in the stentless group. We could not conclude that D-J stenting before ESWL had an advantage compared to another group because most patients with Steinstrasse were reported in the study by Al-Awadi et al and the stone size was larger than 20 mm.[15] These data may introduce bias and influence the results of our review. In conjunction with ESWL most urologists prefer to use a stent for stones larger than 20 mm to prevent the risk of Steinstrasse.[24,25]

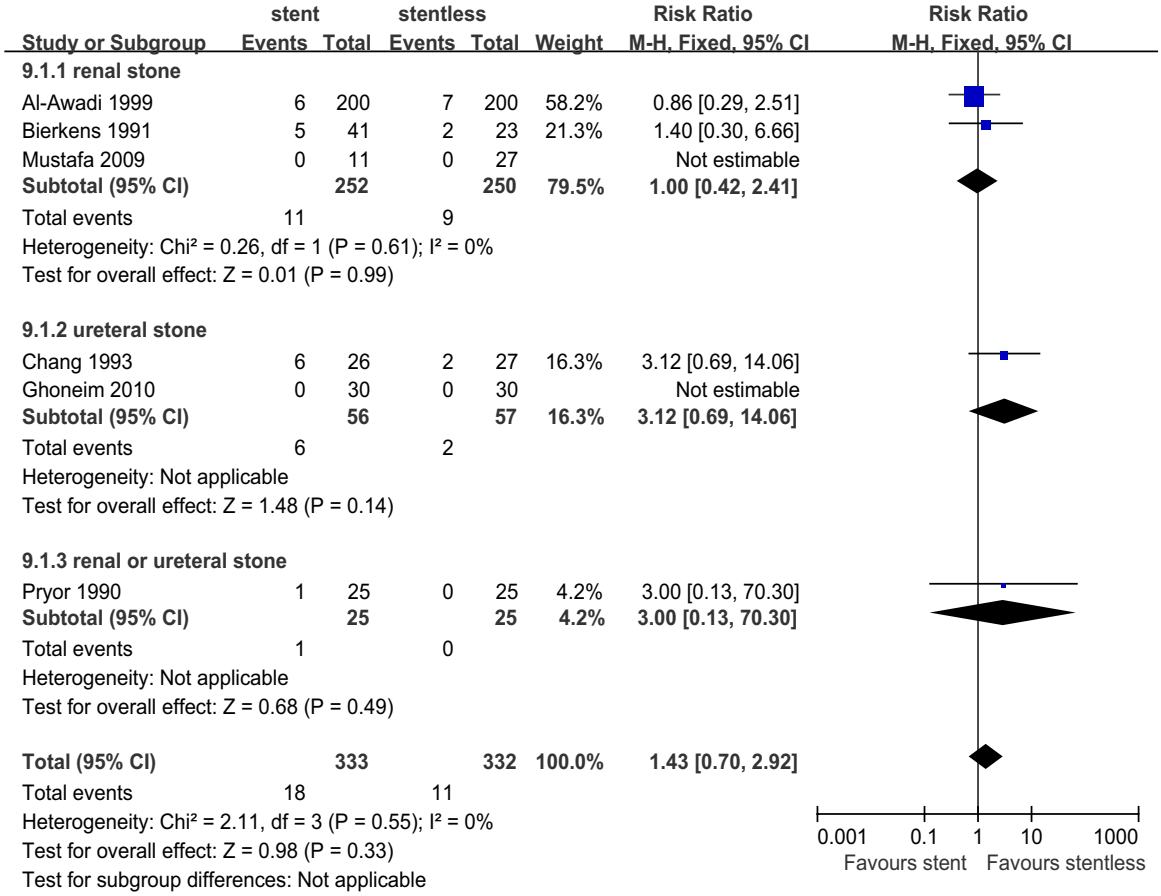

Figure 7. Auxiliary treatment in patients with and without stent before ESWL

Moreover in our review the incidence of LUTS was significantly higher in the stented group than in the nonstented group. Thus, patients with a D-J stent have frequent and evident LUTS which may be attributed to bladder irritation by the stent itself acting as a foreign body. Furthermore, these symptoms may be sufficiently severe to affect patient quality of life. In this review significant differences were not found in hematuria, fever, urinary tract infection, pain and analgesia, auxiliary treatment, and nausea and vomiting between the 2 groups. Some of the included trials reported that patients may be prescribed an antibiotic for UTI before ESWL or routinely prescribed analgesics after ESWL.[6,18] However, these data would influence our results.

We searched the literature in electronic databases without language restrictions but we could not find RCTs concerning ESWL in languages other than English. As studies with large samples and positive results are more easily reported in English than those with small samples and negative results, this might have introduced language bias and publication bias.

CONCLUSIONS

The randomized controlled clinical trials in this systematic review suggested significant advantages of pre-ESWL stenting compared to in situ ESWL in terms of Steinstrasse, but stenting did not improve the stone-free rate and auxiliary treatment after ESWL. In addition, stenting before ESWL could induce more LUTS. Whether ureteral stents should be used in ESWL remains controversial. More high quality, well designed, randomized, controlled multicenter trials that are adequately powered are needed to address this issue.

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