Effect of Silicone versus Polyurethane Ureteral Double J Stent on the Quality of Life in Extracorporeal Shock Wave Lithotripsy (SWL)Patients

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Abstract

Background: During the last few decades, ureteral stents have been widely utilized as a measure for temporary or permanent drainage of the occluded upper urinary tract. The underlying rationale is to allow the urinary flow to bypass internal obstruction which impairs its drainage. **Objectives:** To compare between the silicon and polyurethane ureteral Double J stents effect on the quality of life of patients who undergo Extra Corporeal Shock Wave Lithotripsy (ESWL) for treatment of renal or upper ureteric stones. **Patients and Methods:** This study was conducted in a prospective randomized fashion on 50 patients suffered from renal or upper ureteric stones from February 2020 to October 2020 at AL-Zahraa university hospital and managed by double-j fixation as a plan of treatment with extracorporeal shock wave lithotripsy (ESWL). Patients were then divided into two groups: group A (n = 25) – patients with polyurethane stents and group B (n = 25) – patients with silicone stents,in All patients managed with 6 Fr double-j stents. Those patients were asked to complete the Arabic translated ureteral stent symptom questionnaire (USSQ) Each participant completed a survey 1, 2, 4 weeks with the stent in situ, and after stent removal noting stent related symptoms (SRS) in each group. **Results:** the patients age range between 20 and 45 years. The analysis of data showed that the unpleasant symptoms caused by stent were encountered more frequently at 7 days after stent insertion, in terms of urinary frequency, dysuria, urgency and macroscopic hematuria, the difference in stent related symptoms between the two groups was statistically significant ($p<0.05$). After analysis the responses to USSQ questionnaire, at 1,2,4 weeks after stent placement, mean scores showed a clear reduction in the QoL of those patients, in all cases the standard deviation being at a great value, indicating a high variability of responses. **Conclusion:**this study showed Silicone ureteral stents were associated with lower Urinary symptoms and impaired QoL in comparison with polyurethane ureteral stents.

KeyWords: Ureteral stent, Silicone, Polyurethane, Stent-related symptoms, Quality of life.

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Introduction:

During the last few decades, ureteral stents have been widely utilized as a measure for temporary or permanent drainage of the occluded upper urinary tract. The underlying rationale is to allow the urinary flow to bypass internal obstruction which impairs its drainage (1).

Nonetheless, there are few side effects associated with stents that complicate their use and management, particularly when deployed as a long-term treatment option. Bacterial colonization and encrustation over the stent surface are two of the most common causes of stent-related infections and obstruction, potentially resulting in its functional failure. Given that these issues profoundly affect the therapeutic outcome, patient's quality of life and associated costs for healthcare providers, further efforts should be put in place to address them effectively (2).

Over the last few years, engineers and scientists have worked on identifying optimal constitutive materials for ureteral stents, focusing specifically on mechanical strength, flexibility, biocompatibility, surface roughness and cost-effectiveness. There are two main

types of biocompatible materials that are generally used for manufacturing ureteral stents; polymers and metals. The first ureteral stents were constituted of polyethylene, a synthetic polymer. However, rigidity and tendency to break limited their usage in the clinical setting. To overcome these limitations introduced a mixture of polyethylene and polyurethane as a more resistant material option against encrustation (3).

Silicone is widely employed for manufacturing ureteral stents, thanks to its flexibility against bending and lubricious properties. However, the rigidity of this material can potentially become a disadvantage during the insertion of the stent over a guidewire. Different polymeric materials also present a variable tendency to encrustation (4).

Aim of the Work

This study aims to compare between the silicon and polyurethane ureteral Double J stents effect on the quality of life of patients who undergo Extra Corporeal Shock Wave Lithotripsy (ESWL) for treatment of renal or upper ureteric stones.

Patients and Methods

This study was conducted in a prospective randomized fashion on 50 patients who suffered from renal or upper ureteric stones from February 2020 till October 2020 at Al-Zahraa university hospital. And managed by double-j fixation as a plan of treatment with extracorporeal shock wave lithotripsy (ESWL). With inclusion criteria: 20_45 years old patients,With renal or Upper ureteric stone,Radio-opaque stone and Stone size from 1_2 cm. exclusion criteria: Pregnant females,Patients with uncorrected bleeding disorders,Patients with aortic aneurysm, morbid obesity and patients who received medications as muscarinic antagonists or alpha blockers.Patients were then divided into two groups: group A (n = 25) – patients with polyurethane stents and group B (n = 25) – patients with silicone stents. in All patients 6 Fr, 26 cm and 6 fr, 28 cm ureteral stents were inserted via cystoscopy and X-ray guided fluoroscopy under spinal anesthesia. Stent indwelling time lasted for (4 to 8) weeks during which each patient underwent a follow-up assessment one, two and four weeks after insertion, during ESWL, and after stent removal. The aim of this study was the assessment of severity of Frequency, Urgency, Urge incontinence, Nocturia, Flank pain, and Hematuria, urinary tract infection, fever, encrustation, obstruction by stent itself. The Arabic translated ureteral stent symptom questionnaire (USSQ), which is considered as a gold standard for evaluation of stent related symptoms (SRS) (23) . at1, 2 and 4 weeks with the stent in situ, and after stent removal. The questionnaire evaluated the impact of stents on the domains of urinary symptoms, body pain, general health, work performance and sexual function as well as any additional stent related problems faced by the patients. All patients subjected to Pre-Procedure assessment including full history taking, complete physical examination, laboratory and radiological investigations.

Full history taking after ureteric stent fixation. any associated symptoms such as frequency, nocturia, urgency, and dysuria. Subjective data were collected from answers to Arabic translated ureteral stent symptom questionnaire. Patients were also asked about any medications used for some time as muscarinic antagonists or alpha blockers.

Each patient was investigated by: Urine analysis and culture when indicated: Positive urine cultures were treated with culture specific antibiotics, urea, creatinine, ALT, AST, fasting blood sugar, Complete blood picture and Bleeding profile evaluation: included prothrombin time and concentration, partial thromboplastin time; bleeding and clotting time were done. Radiological assessment Include Pelvi-abdominal ultrasonography: All patients were examined by ultrasonography to evaluate the upper and lower urinary tract, measure stone size and presence of hydronephrosis or not, Plain X-ray on urinary tract (KUB) and Non contrast pelvi-abdominal computed tomography scan (NCCT). Once diagnosis and evaluation had been completed, the disease and different lines of treatment were explained to the patient. If he had chosen the (ESWL) option, he underwent double-J fixation, Those patients were asked to complete the USSQ Each participant completed a survey1, 2 , 4 weeks with the stent in situ, and after stent removal noting stent related symptoms (SRS) within each group.

$$t\,(df) = \frac{X - Y}{SDp\,\sqrt{1/nX + 1/nY}}$$

Statistical Analysis

Data was analyzed by Microsoft Office 2010 (excel) and Statistical Package for Social Science (SPSS) version 20.

- *Where, **t (df):** value at the degrees of freedom.*
  - ***df:** degrees of freedom.*
  - ***SDp:** pooled SD (SD of both samples).*
  - Mean = $\Sigma x / n$
- Where Σ= sum & n = number of observations.
- ***Standard Deviation [SD]:***
  - SD $\sqrt{\Sigma|x-x|^2/n-1}$
- **P value > 0.05** is considered non-significant.
- **P value < 0.05** is considered significant.

P value < 0.01 is considered highly significant

Results

A total of 50 patients underwent stent insertion and were stratified as follows: group (A) 25 patients with polyurethane stents and group (B) 25 patients with silicone stents. Their demographic and clinical data were displayed, Both groups were statistically homogeneous. There were no statistical significant differences between two groups as regard of age, BMI and duration of stay of stent (p- value was 0.473, 0.432 and 0.034) as showed **in table (1).**

Table (1): showed demographic data of patients in both groups:

	Polyurethane		Silicone		Paired *t* test.	
	Mean	SD	Mean	SD	T	Sig.
Age (years)	29.73	6.357	30.28	7.756	1.023	0.437
Range	20 – 45		20 – 45			
Gender						
Male	14(56%)		13(52%)		0.624	0. 513
Female	11(44%)		12(48%)		0.583	0.533
BMI	26.40	1.25	27.23	1.58	0.756	0.432
Duration of stay of the stent (W)	34.682	4.389	37.343	5.643	1.962	0.034

P < 0.05: Significant P > 0.05: not Significant

One week after stent fixation patients reporting some urinary symptoms, the difference in stent related symptoms between the two groups was ststistically insignificant. As showed **in table (2).**

Table (2): showed the urinary symptoms after 7 days of stent fixation in both groups.

	after 7 days of stent fixation		Paired *t* test.	
	Polyurethane	Silicone	T	Sig.
Urinary frequency	0.35%	0.41%	0981	0.968
Dysuria	2.15%	2.31%	0.973	0.824
Suprapubic pain	5.67 %	8.75%	1.365	0.513
Urgency	1.58%	2.68%	0.835	0.862
Lumbar pain	13.5%	14.98%	0.894	0.984
Macroscopic hematuria	1.82%	2.13%	0.785	0.672
Persistent Macroscopic hematuria	1.31%	1.5%	0.987	0.874

P < 0.05: Significant P > 0.05: not Significant

Two weeks after stent fixation the percentage of patients reporting various urinary symptoms. A high proportion of patients with stents reported frequency, urgency, dysuria, lumber pain, suprapubic pain and hematuria, which interfered with daily activities with less incidence in group B silicone ureteral stents (p-value was 0.003, 0.041, 0.003, 0.002,0,042 and 0.003 respectively) as showed **in table (3).**

Table (3): showed the urinary symptoms after two weeks of stent fixation in both groups.

	Two weeks after fixation		Paired *t* test.	
	Polyurethane	Silicone	T	Sig.
Urinary frequency	52.13%	42.61%	2.364	0.003
Dysuria	50.36%	46.26%	1.976	0.041
Suprapubic pain	24.25%	30.82%	2.345	0.003
Urgency	52.83%	40.15%	2.836	0.002
Lumbar pain	16.32%	22.14%	1.894	0.042
Macroscopic hematuria	55.31%	39.42%	2.735	0.003
Persistent Macroscopic hematuria	23.14%	15.83%	2.437	0.003

P < 0.05: Significant P > 0.05: not Significant

There was significant increase of urinary symptoms after four weeks of stent fixation with less incidence in group B silicone ureteral stents. High proportion of patients with stents reported more frequency, urgency, dysuria, lumber pain, suprapubic pain and hematuria, which interfered with daily activities (p-value was 0.000, 0.031, 0.044, 0.003,0,032 and 0.003 respectively) as showed **in table (4).**

Comparison of pain and lower urinary tract symptoms (LUTS) in the middle of the stent dwelling period and before stent removal demonstrated significant differences between mean values of pain at 2 weeks and before stent removal with less incidence in group B (silicone ureteral stents).

Table (4): Showed the urinary symptoms after four weeks of stent fixation in both groups.

	After the indwelling of stent (4W)		Paired *t* test.	
	Polyurethane	Silicone	T	Sig.
Urinary frequency	64.34%	45.61%	3.296	0.000
Dysuria	58.64%	54.94%	1.874	0.031
Suprapubic pain	31.15%	35.48%	1.675	0.044
Urgency	59.21%	44.5%	2.831	0.003
Lumbar pain	20.12%	25.36%	2.235	0.032
Macroscopic hematuria	62.8%	45.31%	2.931	0.003
Persistent Macroscopic hematuria	30.18%	20.34%	2.876	0.003
Unplanned visits			34	0.042
No	21 (84%)	23 (92%)		
Yes	4 (16%)	2 (8%)		
Encrustation			55	0.492
No	20 (80%)	24 (96%)		
Yes	5 (20%)	1 (4%)		

P < 0.05: Significant P > 0.05: not Significant

The differences between the prevalence of urinary symptoms associated with stents as well as their

impact on quality of life compared to post-stent status had reached statistical significance (p.0.01) as shown**in table (5).**

Table (5): showed the urinary symptoms after removal of stent in both groups.

	After removal of the stent		Paired *t* test.	
	Polyurethane	Silicone	T	Sig.
Urinary frequency	11.65%	4.81%	3.182	0.000
Dysuria	20.53%	7.11%	3.271	0.000
Suprapubic pain	4.13%	1.65%	1.372	0.421
Urgency	9.98%	7.52%	1.133	0.442
Lumbar pain	1.34%	2.45%	0.824	0.642
Macroscopic hematuria	6.84%	4.85%	0.966	0.843

P < 0.05: Significant P > 0.05: not Significant

As shown**in table (6):** revealed that in approximately 80% of cases the stent caused a degree of pain that affected the daily activities, including work capacity.

Table (6): showed the effect of double J on quality of life in both groups.

	After one week of the stent		Paired *t* test.	
	Polyurethane	Silicone	T	Sig.
Reduced wok hours	9.35%	6.21%	2.162	0.003
Feeling tired	12.53%	8.31%	2.471	0.001
Analgesics	5.23%	2.45%	1.872	0.021
Sleep disturbance	8.68%	4.56%	1.933	0.012

P < 0.05: Significant P > 0.05: not Significant

selective alpha-1-blocker tamsulosin once daily improved urinary symptoms, flank pain and pain during voiding. In addition, improved urinary symptoms and QoL as showed **in table (7).**

Table (7): showed number of cases with severe symptoms who received alpha blockers in both groups.

	Treatment				Paired *t* test.	
	Polyurethane (n=10)		Silicone (n=10)			
	N	%	N	%	t	Sig.
Alpha lockers	8 cases	80%	2 cases	20%	4.483	0.000

Discussion

Ureteral double pigtail stents are now widely used for the treatment of numerous urological pathologies and, as the indications for their use have expanded during the last few years, the frequency of complications reported has, therefore, increased compared to the past. Side effects are frequently reported (5).

Silicone is widely employed for manufacturing ureteral stents, thanks to its flexibility against bending and lubricious properties. However, the rigidity of this material can potentially become a disadvantage during the insertion of the stent within a guidewire. Different polymeric materials also present a variable tendency to encrustation (4).

In a study conducted by **Lennon et al.** (6) they concluded that the softness of the ureteral stentdirectly influenced patients' tolerability; stents made from softer material correlated with less incidence of dysuria and pain.

Additionally, in a recent study done by **Wiseman et al.** found that silicone ureteral stents were associated with less patient discomfort at day 20 postoperative. Therefore, in order to further reduce SRS, alterations to stent composition could be a solution (7).

Joshi et al. (8) using the validated questionnaire USSQ, revealed that in approximately 80% of cases the stent caused a degree of pain that affected the daily activities, including work capacity.

In this study early urinary symptoms encountered during the first two weeks after stent insertion, frequency, urgency, dysuria, lumber pain, suprapubic pain and hematuria have significant difference between two groups which interfered with daily activities with less symptoms in silicone ureteral stents.

Miyaokaet al. reported that dysuria seems to be more common when using stents with excessive length, in this study dysuria appeared in statistically significant proportion (p<0.05) at 7 days after stent insertion and remained after its removal, but without statistical significance in this case. Suprapubic pain is caused by direct irritation of the bladder mucosa by stent, but can be exacerbated in the case of secondary infection or stones in the distal end (9).

Gadzhiev and colleagues in contradiction to our results revealed that there is no statistical significant difference between two groups at first week after insertion (10).this difference may be due to long time follow up with their study.

Scarneciu et al. (11) study on 2200 case reported similar results to our study: Urinary frequency and urgency are symptoms directly caused by mechanical factor. The majority of patients complain of these symptoms increased significantly during the day, highlighting the dependency of physical activity. Bladder muscle over activity is clearly enhanced by the presence of DJS. The urinary frequency and urgency were present in statistically significant percentage 7 days after the stent placement (p <0.05) (9).

Patients who complained of flank pain which caused by vesicoureteral reflux, being secondary to

the temporary cancellation of the intramural anti reflux mechanism were advised to urinate in a sitting position, avoiding any increase in abdominal pressure that may cause reflux. In cases of high fever and flank pain a urethral catheter was inserted for a week to drain urine and avoid reflux (12).

Similar to study conducted by **Gadzhiev et al.** (10) the intensity of SRS in traditional polyurethane ureteral stents and modern silicone ureteral stents were compared. From the data, use of the OAB awareness tool proved unfit to accurately assess patient QoL. However, visual active scale of pain (VASP) data concluded that patients who received silicone ureteral stents had a significantly better QoL in the middle of the stent indwelling period and immediately prior to stent removal compared to those who received polyurethane ureteral stents (10).

Many authors note such side effects that persist throughout all the stenting time. Ullah et al. showed urinary frequency and urgency in 68% of cases, dysuria in 70% of patients, hematuria in 53.4% and lumbar pain in at least one third of cases (13).

There are authors who have shown different results: **Damiano et al.** reported irritative symptoms in 37% of patients and macroscopic hematuria in 18%, far less frequently than those highlighted from the analysis of data (14).

In these results there was Insignificant difference between both groups after stent removal as regard lower urinary symptoms and effect on quality of life.

Gadzhiev and his colleagues had got the same result as ours, that is no statistical difference between both groups (10).

Different complications may occur with short- or long term use of indwelling ureteral stents. These complications vary from minor side effects to major complications (15).

The most common complication involving patients with indwelling stents is patient discomfort due to associated irritative voiding symptoms, flank, abdominal discomfort and hematuria. Most patients experience bothersome urinary symptoms that interfere with daily activities and result in reduced quality of life in up to 80% of patients (8).

In this study comparing stent-related complications such as fever and urinary tract infection from both Group A and Group B, no significant difference was observed. (p-value was 0.640 and 0.731 respectively) there was no significant difference in the stent encrustation rate. This could have been due to the small sample size used and short duration of the study limited to 4 weeks in every case. A larger sample size and longer study duration should be used to accurately determine if stent encrustation would differ between polyurethane and silicone ureteral stents.

Similar to this study: Comparing stent-related complications from both Group A and Group B, no significant difference was observed. These results speak to the overall safety of silicone ureteral stents. Originally, silicone ureteral stents were replaced with polyurethane ureteral stents due to low tensile strength which limited the internal diameter and aperture of side holes. Additionally, silicone ureteral stents proved more difficult to place due to a high volume of friction and were more expensive to produce leading to the switch to polyurethane ureteral stents. Because of recent technological advancements, silicone stents are beginning to become more similar to traditional polyurethane ureteral stents in both size and safety (16).

During stenting period of time **Leibovici et al.** show a significant percentage of sleep disorders, anxiety, decreased of libido and other sexual dysfunction, 45% of patients reporting reduced quality of life (17).

Ureteral stents impaired the quality of sexual life in male and female subjects, **Joshi et al.** (8) found that as many as 40% of patients experienced sexual dysfunction. In men the most important distress was in regard to erectile function, probably related to lower urinary tract symptoms.

Deliveliotis et al. (18), in a prospective randomized study concluded that; Alfuzosin, 10 mg once a day, improved a subset of stent-related urinary symptoms and pain, and the patients receiving alfuzosin had their sexual function and general health better preserved. Similar to our study in some cases with severe urinary symptoms which improved with alpha blockers (tamsulosin).

Wang et al. (19) suggested that the selective alpha-1-blocker tamsulosin improved urinary symptoms, flank pain and pain during voiding. In addition, **Damiano et al.** (20) reported that the administration of tamsulosin improved urinary symptoms and QoL.

Lim et al. (21) reported that combination therapy with tamsulosin 0.2 and solifenacin 5 mg improved

obstructive and irritative symptoms and QoL.

Some studies have found a correlation between stent material composition and patient QoL. (22) this study has some limitations: it was a small sample size which may have affected our study results. Further research is recommended to confirm the results of our study.

Conclusion

this study showed that Silicone ureteral stents were associated with less Urinary symptoms and impaired QoL in comparison with polyurethane ureteral stents.Our study, that was conducted on a small number of patients, Further research with larger sample size is recommended to confirm the results of our study.

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