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Original Research Article

A STUDY ON CORRELATION OF MICROBIAL CULTURE OF STENT AND SYMPTOMATOLOGY IN PATIENTS WITH LOWER URINARY TRACT SYMPTOMS (LUTS) AFTER DJ STENTING

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Abstract

Background: To compare the microbial culture of DJ stents to that of symptomatology, in patients having lower urinary tract symptoms after DJ stenting. **Materials and Methods:** Patients who were admitted to undergone DJ stenting following which they developed significant lower urinary tract symptoms were included in the study. 45 patients were followed up prospectively and were observed and assessed for severity of stent related lower urinary tract symptoms using IPSS questionnaire. Vesical end of DJ stent was subjected to microbial culture and sensitivity. The result of microbial culture positivity of DJ stent was correlated to IPSS score, status of urine microbial culture, the relevance to timing of stent removal and other parameters. **Results:** The mean age of the study group was 30.71 years. 28 were males and 17 were females.16 patients had stent on the right side and 25 had on the left side. 4 patients had bilateral stenting. The mean IPSS score was 20.25. Dysuria was predominant in 66.4%, frequency in 22.7% and urgency in 7.2 %. Female patients had more incidences of severe IPSS. Moderate IPSS (8-19) noted predominantly in 26-30 years.in the group 31-35 years it was predominantly severe (IPSS 20-35).62.2% gave Quality of Life score of 4. 15.5% had a score of 5. 8 patients gave the score as 3 and 2 patients gave a score 6. Adjusted to bilaterality, DJ stent culture was most commonly E. coli followed by kelbsiella, pseudomonas, enterococcus. The same pattern of hierarchy noted in urine culture. When analysed with SPSS v2 software, age and sex were not significant determinant of positive stent culture, nor they predicted severe IPSS score. IPSS score correlated positively with DJ stent culture. Statistical significance was seen when IPSS was tested against combine positivity of DJ and urine culture (P value 0.001). Urine culture in predicting positive stent culture had 48.3% accuracy. Stent removal was early in patients with severe IPSS and was statistically significant when correlated to combined microbial positive culture (P value 0.003). **Conclusion:** Stent related symptoms are a significant problem and the prevalence is common. Age and sex of the patient does not predict severity of stent related symptoms nor they are linked to positive stent culture. The quality of life based on IPSS questionnaire shows that majority of the patients are unhappy with the bothersome nature of stent related symptoms. Early stent removal was statistically associated with positive microbial culture (DJ stent, urine and combined) and severity of IPSS. Urine culture is not a strongly predictive variable for positive DJ stent culture.

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INTRODUCTION

By definition, the double-J or pigtail stent is a tube placed within the ureteral lumen in a retrograde or antegrade fashion in order to maintain its patency. The double-J ureteral stent had been widely applied during the endourologic surgery to relieve or prevent ureteral obstruction. Stent-related morbidities, such as lower urinary tract symptoms (LUTS), stent-related body pain and hematuria, are bothersome and might have a negative impact on quality of life (QoL) and sexual performance for both genders. Stent discomfort can vary from one patient to another in an idiosyncratic manner, but is believed to affect over 80% of patients. The prevalence hence is significant and geographic,[4] variance might exist. This makes this issue an important health problem and indirectly serves as a scale for quality of healthcare delivery to the public. The pathophysiology of stent-related symptoms remains unclear. However, the pain and LUTS caused by stent placement has been attributed lower ureter and bladder spasm due to local irritation of the stent. Studies utilizing pharmaco therapeutic agents like Tamsulosin and other antimuscarinics and α -blockers were shown to improve symptoms but the benefit is obtained by preventing unwarranted bladder,[5] contractility or other unknown mechanism (in case of α-blockers). In all these studies the primary problem is not addressed and remains unknown. Patients who fail to respond to such pharmacotherapy are left with limited options or else removal of the stent (irrespective of the consequence). Also, attempt to modify the design of bladder end of the stent was studied. The results showed no significant difference among the groups. A complete understanding of the pathogenesis of stent-related symptoms is limited by the lack of systematic analysis of the same. The role of micro-organisms (pathogenic/opportunistic) in this scenario is less investigated and reported.

An important problem here is to develop a validated, reliable and simple tool for symptom analysis. Ureteral Stent Symptoms Questionnaire (USSQ) is a very useful standard tool for such analysis. USSQ consists of 38 items and 6 subdivisions: overall general health, pain, work performance, voiding symptoms, sexual matters, and additional problems. USSQ is a lengthy and complicated instrument. Its very complexity poses problem when it is applied to large population. Furthermore, it has been shown that such complex questionnaire requires certain minimum comprehensive capacity on the patient part which is of definite concern in reference to our society, as well as in other developing nations. IPSS scores over USSQ in its relative simplicity. The real need is development and validation of an ideal research tool that should first address the needs of our society, which is ironically lacking till date. This study in part tries to address some of the questions raised above. To compare the microbial culture of DJ stents to that of symptomatology, in patients having lower urinary tract symptoms after DJ stenting.

MATERIALS AND METHODS

Prospective clinical study done in Kamineni Academy of Medical Sciences and Research Centre, Hyderabad. Telangana in Department of urology in Patients who were admitted to undergone DJ stenting for a period of one year following which they developed significant lower urinary tract symptoms were included in the study. Patient who had underwent DJ stenting with postoperative lower urinary tract symptoms were evaluated with a validated symptom specific questionnaire (International Prostate Symptom Score (I-PSS)). Patients with moderate to severe symptom score (8 and above) are studied. Stent was subjected to microbial culture at removal.

Inclusion Criteria

Patients age between 20 to 40 years who underwent DJ stenting (unilateral or bilateral) after intracorporeal lithotripsy for ureteric calculi. Patients undergoing ureteric stenting for the first time, IPSS score 8 or above after DJ stenting

Exclusion Criteria

History of severe lower urinary tract symptoms prior to DJ stenting, Gross haematuria, Associated bladder outlet obstruction, History of tuberculosis/Diabetes mellitus/medications for chronic ailment, Urine microbial culture positive at the time of DJ stenting, Cystoscopy revealing Urinary bladder abnormality, Residual stone in post-operative X ray KUBU, Lower coil of DJ stent crossing the midline, Suspected stent migration and Benign Prostatic Enlargement

The study was approved by the institutional ethical committee. In our study the complete clinical information is documented which includes age, sex, place of living, present and past clinical history, personal habits etc. Presence of co-morbid illness and use of any medications were sought for and recorded. The reason for DJ stenting and the operative records were obtained. Patients were individually assessed for their presenting symptoms. IPSS questionnaire was used and patient was offered help only if there was any difficulty in comprehension of the question. The primal focus was on ensuring patient understanding of the question. No part of the question was modified. The results recorded. Patient underwent routine urological and basic biochemical investigations. A urine culture and sensitivity was done. A plain xray KUBU and USG examination were done in all these patients to look for any significant residual calculi. All these patients were subjected to stent removal observing maximum sterile precautions. The procedure was noted and any difficulty in removal of stent was recorded. The stent was received in a sterile culture tube and the distal end (vesical end) was cut with sterile scissors and sent for culture. The stent was processed in the microbiology department. It was initially cultured in

Brain Heart Infusion broth (BHI) as soon as it is received in the department. Then isolates are cultured in McConkey agar and Blood agar. Sensitivity for antibiotics was done subsequently.

Statistical Analysis

Data were analyzed using the statistical analysis package SPSS version 20 for Windows and Medcal software. Three analyses were undertaken: 1) univariate analyses of the association of each variable with Stent culture 2) multivariable logistic regression to predict outcome of DJ stent related symptoms.3) multivariable logistic regression to predict outcome of DJ stent related symptoms and microbial culture of DJ stent (with or without culture of urine). In the univariate analysis, Chi-square test and Fisher's Exact Test was used for categorical variables and Student's t-test or Mann-Whitney test was used for continuous variables. All testing was two-sided. Univariate relative risk ratios and multivariable analyses were done by assigning the continuous variables into discrete variables, based on their being above or below a set value. The Multivariable logistic analysis was done in a stepwise manner. One variable was entered at a time into the classification equation. The variables were tested individually one at a time and the results looked for. If significant it is tested in combination with additional variable and the statistically appropriate test done. Finally, association between multiple variable was assessed.

The mean IPSS was 20.25. The most common bothersome symptom (using IPSS) was dysuria (66.4%) followed by frequency (22.7%) and urgency (7.2%). 31 (68%)patients had IPSS corresponding to 'severe' category (IPSS 20-35). 14 (32%) patients had IPSS corresponding to 'moderate' category (IPSS 8-19).

RESULTS

In our study the mean age of the patients is 30.711 years. The age limit of the study population is between 20 -40 years. When correlated to age groups, the dominant group was between 26-30 years. 28 were male patients and 17 were female patients. 16 had stent on right side, 25 had stent on left side and4 had bilateral stents.

The symptom was subclassified and plotted for sex distribution. When analysed for correlation with sex severe females reported more of severe IPSS 70%.

IPSS was also correlated to the age group. The moderate symptoms (IPSS 8- 19) predominated in the age group 26-30 years. IPSS severe symptoms (20-35) existed in the age group 31-35 years

IPSS severity(mean)correlated to age groups

IPSS Quality of Life

All patients responded with the minimum score of 3(mixed feel regarding spending the rest of life with existing symptoms).28 patients (62.22%) had given a score of '4' corresponding to 'mostly dissatisfied'. 7 patients (15.55%) had reported IPSS QoL 5 corresponding to 'Unhappy'. 8 patients (17.77%)

reported IPSS QoL 6 corresponding to 'terrible', if they were to continue with existing symptoms. [Table 1].

Microbial culture of urine was done as a part of routine urological workup. Upon removal of DJ stent, it was cultured as described previously. 46specimens had growth of microorganism positive on the DJ stent (93.87%). When corrected for bilaterality the percentage was 93.33%. 20patients had positive urine culture (44.44%). All four patients with bilateral stents had the same organism grown in culture. The most common organism grown was E. coli in both DJ stent (48.8%) and urine culture (28.8%). The second most common organism was Klebsiella, followed by pseudomonas. Other organisms were Enterococcus, Proteus, Acinetobactor and Staph. aureus. The positive cultures were predominantly unimicrobial [Table 2].

The IPSS score was categorized according to moderate (IPSS 8-19) or sever (IPSS 20-35). It was correlated with the age group.

The dominant age group (26-30 years) was tested for significance. Results showed no significant association (P value 0.68) [Table 2].

Result showed no significant association (p=0.913).

$r = 0.017, p = 0.913$

The major group, which comprised the male population was analysed for association with severity of IPSS. Analysis made with Chi square test and result tabulated. Result showed no statistical significance (P value = 0.168).

IPSS score

IPSS severity VS early stent removal:

This was tested in two parts. The variables were IPSS score (either moderate or

severe) and postoperative day of stent removal. Fisher exact test was applied

In the moderate IPSS group (IPSS 8-19), when tested for relevance using Fisher exact, there was no significant association (Fisher 0.72 Pvalue 0.396)

In the severe group (IPSS 20-35) after regression analysis showed statistically significant association (Pvalue 0.002)

$r = -0.454, p = 0.002$

Days

IPSS severity and Positive microbial culture:

IPSS severity was analysed for linkage with positive microbial culture. This was

done in four settings. First the analysis for done to test IPSS score to that of positive microbial of DJ stents. Then the test repeated for positive microbial culture of urine. In the third time it was tested for combined positive urine and stent culture. Finally the relevance for IPSS group moderate (IPSS 8-19) and severe (IPSS 20-35) was analysed.

The relationship between stent culture and IPSS score was tested. And the result was no statistically significant association (P value 0.26).

The relationship between urine culture and IPSS score was tested. The result was not statistically significant (Pvalue 0.27).

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The analysis was done for combined (DJ stent and urine) positive microbial culture. IPSS score correlated to severity of combined microbial culture. The result was statistically significant with P value 0.001 [Table 3].

The results of urine culture were correlated with the results of stent culture. The result was sought for the sensitivity, specificity, positive predictive value and accuracy. The results were tabulated as below [Table 4].

Sensitivity – 42.1%

Specificity – 100%

Positive predictive value – 100%

Negative predictive value – 21.4% % of false negatives – 57.9%

% of false positives – 0% Accuracy – 48.3%. [Table 5].

The significance of positive microbial culture (of DJ stent, urine and combination of both) and the predictability of early stent removal was analysed. Timing of standard stent removal (3 weeks) was initially tested. Then the patient group was divided arbitrarily in to two. One group with stent removal early than 10 days and other after 10 days. The results were analysed.

In the first group, the timing of standard stent removal at 3 weeks was tested with population having positive combined microbial culture, was tested for statistical significance, there was no statistical significance (P value 0.247) [Table 6].

When the test was applied to the arbitrary division of groups based on 10 days as early and beyond 10 days as late, the result was found to be statistically significant (P value = 0.003) [Table 7].

Table 1: Microorgansism grown in DJstent culture

Organism	DJ stent culture (Adjusted to bilaterality)	Urine culture
E. coli	22	13
Klebsiella	7	3
Acinetobactor	1	
Proteus	2	1
Pseudomonas	5	2
Enterococcus	4	1
Staph. aureus	1	
No growth	3	25

Table 2: The age group were analysed for association with severity of symptoms scaled with IPSS

Age group	Severity score		Chi square	P value
	Moderate	Severe		
20 – 25	5	4		
26 – 30	10	6	1.51	0.68
31 – 35	4	6		
36 – 40	6	4		

Table 3: Relation of sex and severity of IPSS

Gender	Severity score		Chi square	P value
	Moderate	Severe		
Male	19	9	1.90	0.168
Female	7	10		

Table 4: IPSS severity and combined positive microbial culture

Severity	Combined positive culture		Chi square	P value
	Yes	No		
Moderate	4	21	10.37	0.001
Severe	13	7		

Table 5: Predictive value of urine culture

Urine culture	Stent culture		Total
	Positive	Negative	
Positive	20	0	17
Negative	22	3	28
Total	42	3	45

Table 6: Combined positive microbial culture Vs early stent removal (standard timing)

Combined positivity	Stent removal		Fisher	P value
	Early	Late		
Yes	16	1	1.84	0.247
No	25	3		

Table 7: Combined positivity microbial culture and early stent removal (with redefined variable)

Combined positivity	Stent removal		Chi square	P value
	≤ 10 days	>10 days		
Yes	13	4	8.85	0.003
No	8	20		

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DISCUSSION

Insertion of ureteral stent is a common procedure in modern urology. It is a simple and effective method to ensure obstruction free flow of urine from the renal pelvis to the bladder. Ureteral stents are commonly used while management of stone disease. Ureteroscopy is a common procedure done for ureteric calculus causing obstruction. Intracorporeal lithotripsy is done to fragment the stone during such procedure. This procedure is usually followed by the insertion of DJ stent. In our hospital we experience patients coming for followup with lower urinary tract symptoms appearing for the first time after undergoing aforementioned procedure. Evaluation of these patients revealed absence of any calculi and most of them can be attributed to the DJ stent itself. This is an established and well documented observation in various publications. It is also true that the exact cause and mechanism for this stent related lower urinary tract symptoms are still unknown. Furthermore, the correlation of DJ stent culture to that of these stent related symptoms are the least evaluated.[6]

We accrued 45 patients based on our selection criteria. The age limit was from 20 – 40 years. This was to eliminate the possible sampling error that occurs in old age where LUTS is more common. Patients are restricted to the age group to minimize the possibility of bias that could arise in higher age. Established facts indicate both IPSS and incidence of infection are influenced by age, the most skewed at the extremes. Hence we excluded paediatric population and upper age limit in this study is 40 years. Though the primary aim is to identify microorganism on DJ stent and not to identify urinary tract infection, the restriction of age group soundly ensures exclusion of unnecessary bias. It has also been ensured that the standard deviation is well within the confines necessary for drawing meaningful conclusions. In our study the standard deviation of age is 5.47 years.

The patient in this study group is a mixed group containing both outpatients and inpatients. The patients in the study group are treated initially as follows for their symptoms. Following DJ stenting we have standardly prescribed Paracetamol tablets and flouroquinolone (mostly Ciprofloxacin) for 3 days. Those patients who have persistent symptoms were subjected to urine routine analysis and culture sensitivity and treated accordingly. None of the patients in this study group were prescribed any α blockers or anticholinergics by us. This we have not prescribed primarily because 1) There is still no consistent evidence testifying the effectiveness of these agents. 2) The hypothesis proposed for this study suspects infection as a cause of LUTS after DJ stenting. Hence it is irrelevant if any drug other than antibiotics (based on appropriate supportive evidence in the form of culture & sensitivity) should be prescribed. This contradicts the purpose of the study.

Also if infection is suspected any drug that will hinder bladder emptying (like anti-cholinergics) and prolonging urine stasis is dangerous and unethical (based on the proposed hypothesis). However whether some patients in our study group has undergone treatment with various available pharmacological agents either by themselves or upon prescription by someone else (other than those involved in the study) could not be completely ruled out. The medication that they could have taken is so diverse that complete documentation and analysis is technically not possible. This could be due to concealment of facts. Could be in part due to poor documentation of medicines taken by these patients. Even if it is narrowed down to one single agent, the diversity of available brands complicates the issue further. One thing was very certain. None of them reported increase in symptom 'out of proportion'. In this minor group of patients, they had no benefit by taking these drugs. This is evident by the very fact that they have come to the hospital for the symptoms. This again strongly supports our hypothesis that the real cause is definitely unknown and is not amenable to these pharmaco- therapeutic agents (either α blockers or anti-cholinergics etc.) and most importantly, infection as a potential cause cannot be ruled out.[6,7]

To definitely establish an association with these pharmaco-therapeutic agents will require a randomized control trial with much larger population. Investigating along these lines is beyond the scope of this study. The concern that this population might skew the results is unwarranted. This is because; the accrual of the study group is by random selection. Hence there is every chance that this group too is evenly distributed in the population proportion of this study. In such case they will not statistically influence the results. In fact, the very existence of this minor group of patients adds strength to the study by being a representation of the general population. This allows us to extrapolate the results with high degree of confidence.

IPSS is a validated questionnaire for LUTS assessment. We utilised IPSS in all our patients and their response was documented. IPSS has 7 items and one separate for Quality of Life. IPSS has a possible score between 0-35. Among them patients with score from 0-7 are taken to have mild symptoms. Patients with score 9-18 are taken to have moderate symptoms. Score from 20-35 are considered severe. In our study the mean IPSS score was 20.25. This value is categorized under severe symptoms, indicating that most of the patients are suffering significantly due to stent related symptoms. An analysis of this further revealed that female patients tend to have more severe stent related symptoms. Symptom severity tends to occur in certain group, with moderate symptoms more common in 26-30 years and severe symptoms more common in 31-35 years. This appears as though supporting the previous theory that Lower urinary tract symptoms are sever as the age increases. We did a test for statistical

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significance and found the P-value 0.913 (not significant). Hence in our study IPSS was not influenced by age probably due to our restricted inclusion criteria.[8]

In our analysis we found that female patients tend to have more severe LUTS. We could propose explanation for this based on social stratification, psychological health and other factors. But from our analysis the cause for this prevalence among female population is unknown. One other possibility is by correlating incidence of infection in this population subgroup. It is well known that females have higher incidence of UTI than males. This study in fact has the same purpose i.e, to identify infective cause for DJ stent related symptoms. If the previous statement is true then by mathematical association, we could suspect the reason for higher incidence of severe LUTS in female patients who had undergone DJ stenting might be due to infective microbial agents. However, in our study the test for statistical significance of positive DJ stent culture to that of severity of IPSS in this female population was not significant. This could in part due to relatively small female sample size in our study group.

IPSS has in addition the ability to assess Quality of Life of patients with stent related LUTS. In our study all our patients reported a minimum of 3 (indicates mixed feeling to continue living with current LUTS). The majority of the patients gave score of 4=unhappy. This could because, the very reason patient has come to the hospital is he has bothersome symptoms related to DJ stenting. Statistical testing however revealed lack of its influence on other variables and absence of any obvious bias.[9]

In our study up to 93.33% patient had positive microbial culture on DJ stent. It is higher that currently available published reports. Here again the reason could be the inclusion criteria. We excluded IPSS of mild symptoms (IPSS 0-7). Infact this result indirectly suggests positive correlation of DJ stent culture to that of bothersome LUTS. Though a subsequent statistical analysis was required to confirm this claim. The most common organism grown in our study was E. coli in both DJ stent (48.8%) and urine culture (28.8%). This result is comparable with most other published report.[10] This in turn points out indirectly of a positive microbial culture to be associated with stent related LUTS. Proving this statistically is very difficult and may require much larger sample size.

Analysing the effect of IPSS on stent removal, we are able to observe positive linkage of early stent removal to severe IPSS. In the severe group (IPSS 20-35) after regression analysis showed statistically significant association (P-value 0.002). This is a favorable observation to prove our 'research hypothesis' and against the 'null hypothesis'. This could be substantiated if we could demonstrate positive linkage of IPSS to stent culture. Since 90% of our patient had positive microbial culture, we could conclude that the linkage is significantly strong. But still for statistical purpose we slightly

modified it as 'Combined positive microbial culture' which include positive DJ stent as well as positive urine culture. This was significantly associated with severe IPSS and early stent removal. The test was statistically significant (P value 0.001).

The predictive value of urine culture to identify coexisted positive microbial culture of DJ stent was tested. It is well known that urine culture is not so reliable. In our study we found support for this proposition. The urine culture had Sensitivity of 42.1% and Specificity of 100% for identifying coexisted DJ stent growth. It had a Positive predictive value of 100% and Negative predictive value of 21.4%. Hence its accuracy is estimated to be 48.3%. This result is comparable with that of other authors.[11,12]

Finally we tested for relation between stent culture and early stent removal. There was a positive relationship between DJ stent culture and earl stent removal (<10 days). This is more so if the patient had concurrent positive urine culture.

CONCLUSION

The prevalence of stent related symptom is significant in incidence. If the stent related symptom occurs, then mostly it is of the severe category of IPSS (score20-35). Based on the study it was found that IPSS severity was predominant in female population but was not statistically significant. IPSS severity and prevalence of stent culture are not influenced by the side of stent or bilaterality. Age of the patients does not predict IPSS severity. With reference to age the dominant group between 20 to 40 years belonged to the subgroup 31-35 years. This prevalence also was not statistically significant predictor of increased IPSS or early stent removal. When assessed with Quality of life questionnaire based on IPSS the predominant group of patient reported that stent related symptoms a score of 4 (mostly dissatisfied). E.coli was the common micro organism grown followed by Klebsiella and Pseudomonas. This pattern was the same for both DJ stent culture and Urine culture. The culture characteristics revealed a predominant unimicrobial growth pattern. Stent removal was early in patients who had positive culture of both DJ stent and urine combined. There is also a strong linkage of higher IPSS score to that of positive DJ stent culture and positive urine culture. IPSS score is a significant predictor of positive stent culture. IPSS score severity is a definite predictor of early stent removal (before 10 days). IPSS severity is a predictor of positive microbial stent culture and urine culture. IPSS severity is also conversely predictable by combined microbial culture positivity. Multivariate analysis reveals that the severe the IPSS, the higher chance of positive microbial culture (either DJ stent, urine or both), the earlier the stent removal in these patients. Urine culture has high positive predictive value for

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presence of DJ stent culture. However its accuracy from this study is only 48.3%.

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