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Urology, Nephrology and Andrology International

Volume 6 Number 2
July - December 2021

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Original Article

Urology, Nephrology and Andrology International
Volume 6 Number 2, July-December 2021
DOI: http://dx.doi.org/10.21088/unai.2456-5016.6221.4

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Spectrum of Organisms and their Antibiotic Sensitivity Studied from Rectal Swabs in the Community

Arjun N[1], Ramesh D[2]

Abstract

Aim: To study the spectrum of organisms and their antibiotic sensitivity studied from rectal swabs in the community.

***Methods*:** A 2 years prospective study in which rectal swabs were collected from patients who fulfilled the inclusion criteria. Baseline information with a detailed written informed consent was taken from each patient. Results were characterized for identification of the organisms and antimicrobial susceptibilities. The data was tabulated for evaluation on a predesigned proforma.

***Results*:** Of 373 patients, 290 patients were male and 83 female (Mean age - 62.7 +/- 18 years). The most common organism was Escherichia coli in 76.56% of cases, Klebsiella Sp in 12.5%, Proteus Sp in 1.56% and others including Enterococcus, Pseudomonas, Staphylococcus aureus contributed to 9.37%. In the antibiotic sensitivity pattern, the sensitivity of fluoroquinolones was as low as 48.43%. Nitrofurantoin showed a higher sensitivity of 83.59 % than fluoroquinolones but similar to carbapenems (88.2%) and third generation cephalosporins (78.12%).

In our study, 23 patients were planned for a TRUS guided prostate biopsy. The culture positive rate in this group was 43.47 % of which 60% of the organisms grown was Esherichia coli ($p = 0.01$) on sub group analysis. They showed a quinolone sensitivity of only 40% .

***Conclusion*:** With increasing antibiotic resistance and multi drug resistant organisms, we suggest the use of a culture based antibiotic for infections and trans rectal biopsy procedures. There is a change in antibiotic resistance pattern of organisms of the gut flora with rising pattern of fluoroquinolone resistance.

Keywords: Antibiotic sensitivity; Biopsy; E-Coli; Prostate biopsy; Rectal swab.

How to cite this article:
Arjun N, Ramesh D/ Spectrum of Organisms and their Antibiotic Sensitivity Studied from Rectal Swabs in the Community/ Urology, Nephrology and Andrology International. 2021;6(2):39-44.

Introduction

UTI is a common presentation to urologists in daily practice. The use of prophylactic antimicrobial agents lowers the incidence of infections, but little consensus exists regarding the appropriate regimens.

Fluoroquinolones are the most commonly used prophylactic antimicrobial agents for UTI. Despite this, the incidence of infectious complications is from 2.1% to 3.0%. In addition, fluoroquinolone-resistant E. coli in rectal flora are a risk factor for infectious complications after TRUS-guided biopsy. Little is known concerning fluoroquinolone resistance in rectal flora. Although UTI ranks among the most common infection in developing countries, only around 9.17% are proved by culture.

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The present study will be undertaken to investigate the spectrum of organisms and their antibiotic sensitivity studied from rectal swabs in the hospital setting and rationale for use of empirical antibiotics in the treatment of UTI.

Subjects And Methods

This was a prospective study conducted at our institution for a duration of 2 years. Baseline information and a brief clinical history was collected with a detailed written informed consent from each patient.

Patients who fulfilled the inclusion criteria were explained clearly about the purpose and nature of the study in the language they understood and a written informed consent was taken. Patient's demographics, pre-existing diseases and drug history was recorded. Also recorded were the indications for admission including patients who were proposed for undergoing a rectal biopsy of the prostate gland.

For collecting samples, the selected patients were put in a knee chest or a left lateral SIMS position after being exposed from below the waist. Using aseptic precautions, a sterile swab was inserted around 1 inch into the anal canal and slowly rotated for about 10 seconds. The swab was then put into the swab tube. Specimens were processed as close to collection as possible and no more that 4hrs post collection. Swabs were frozen within 4 hours after collection if analysis was to be delayed.

All isolates were then further characterized for identification of the organisms and antimicrobial susceptibilities. The data collected was documented and tabulated for evaluation on a predesigned proforma.

All patients more than 15 years of age from our institution either attending OPD or admitted electively were included and patients who were diagnosed with UTI, sepsis, perianal infection, immuno-compromised conditions, patients who have received antibiotic for any reason in the last two weeks prior to the rectal swab and patients with indwelling catheters and stents were excluded from the study.

The tabulated data was evaluated using the SPSS 18 statistical software for significance. Differences in the outcome indicators were tested for statistical significance through t-test/appropriate non parametric tests of significance.

Institutional Ethical Committee approval was taken before the commencement of the study.

Results

A prospective study of 2 years duration with 373 patients, majority being males (77.74%).

The mean age in this study was 62.7 years (15-95 years). The distribution of patients in this study with respect to age was similar in both males and females.

Of the 373 patients 80.6% of the patients were admitted under the department of Urology whereas the remaining 19.4% of the patients were taken from various other departments. Of the study population, 77% of the selected patients were admitted for a urological condition whereas 23% were admitted for other reasons.

There was an overall culture positive rate from the rectal swabs of only 34.3%, which is comparable to other studies. It was however interesting to note that on analysis, it was found that the culture positive rate was higher with increasing age,

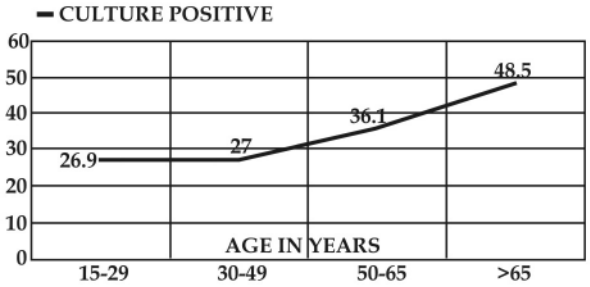

Fig. 1: Culture positivity with age.

with a significant p value on statistical analysis. (p = 0.019). Another notable factor in our study was that the men had a higher number of rectal swab cultures positive reports than women included in this study. (35.9% vs 28.9%). However, this was not statistically significant. (p = 0.24)

As seen in other studies, the most common organism grown on rectal swabs in our study was Escherichia coli (76.56%), followed by Klebsiella Sp (12.5%) and others.

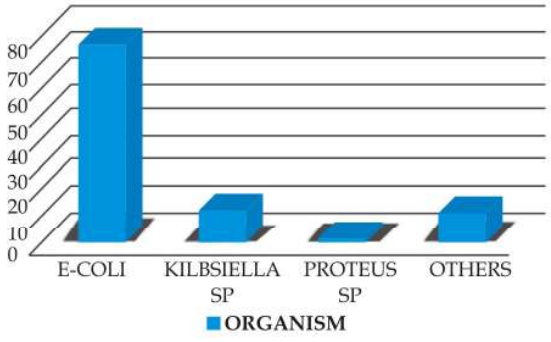

Fig. 2: Organisms grown.

In our study the antibiotic sensitivity pattern showed the organisms which were grown on culture were most resistant to fluoroquinolones among the most used antibiotics (48.43%), showing a higher rate of resistance than other studies.[1]

Table 1: Antibiotic sensitivity pattern.

Antibiotic	Sensitivity
Fluoroquinolones	48.43%
3rd Generation Cephalosporins	78.12%
Nitrofurantoin	83.59%
Carbapenems	88.28%
Amikacin	94.5%
Others	17 to 59%

Amikacin showed a high sensitivity of around 94.5% in this group. Nitrofurantoin showed a higher sensitivity of 83.59 % as compared with fluoroquinolones but resembling carbapenems and third generation cephalosporins with 88.2% and 78.12% respectively. This was found to be statistically significant with p = 0.001. Among the cephalosporins, the third generation cephalosporins showed a slightly higher sensitivity than the rest, however this was not statistically significant. Other antibiotics included ampicillin (31.25%), ceftriaxone (57.81%) etc showed varying sensitivities. Notably very low resistance was seen in the cases of colistin (96.09%) and tigicyclin (95.31%) among others. Imipenem showed a higher sensitivity than meropenem in our study. (91.4% vs 87.9%).

Similar results were seen when an independent review was done for the rectal swabs cultures positive with Escherichia coli which was the most common organism grown in the study. Among these there was a higher resistance to fluoroquinolones (58.7%) as noted in some studies, with the mention of a fluoroquinolone resistant strain.[1] The sensitivity pattern with the other antibiotics as shown

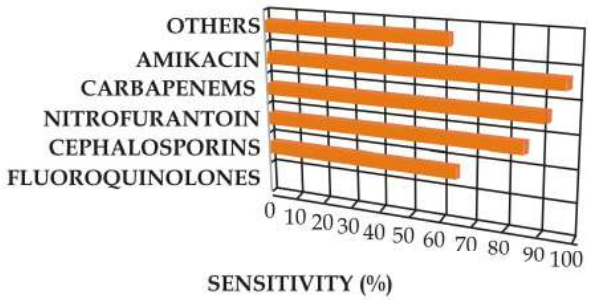

Fig. 3: Sensitivity pattern for Escherichia Coli.

was comparable as shown in Table 1. The above has an implication in cases of rectal prostate biopsy as discussed later.

In a sub group analysis, 23 patients in our study were planned for a TRUS guided prostate biopsy. The culture positive rate in this group was 43.47% of which 60% of the organisms grown was Esherichia coli.

The antibiotic sensitivity pattern was comparable to the general group, similarly showing low sensitivity to the fluoroquinolone group (40%) as compared to the others, with ceftriaxone showing 60% while amikacin, gentamycin and cephalosporins showing a higher sensitivity of 80% was noted.

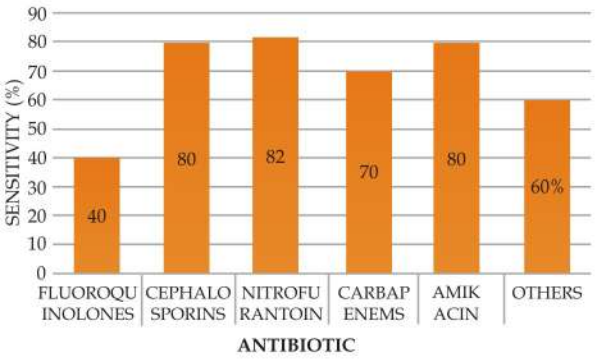

Fig. 4: Antibiotic sensitivity pattern in TRUS guided prostate biopsy group.

This is useful in the selection of a prophylactic pre procedure antibiotic in order to reduce complications associated with the procedure.

A statistically significant difference was seen when the presence of a positive rectal swab culture was made with the presence of comorbidities in the patient, either single or multiple. DM was shown to have a higher correlation with culture positivity (68.8%), than HTN (58.3%), IHD (50%) or CKD (50%). There was however a 27% of the study group who were culture positive but did not suffer from any pre-existing condition.

Discussion

We conducted a prospective study to evaluate the spectrum of organisms and their antibiotic sensitivity studied from rectal swabs in the hospital setting and to assess whether this information can be utilized in optimum treatment of patients with respect to prophylactic antibiotics and in urinary tract infections. We have also aimed to assess if the pre-existing data correlates with our findings

which we have discussed below. We selected 373 patients in our study who fulfilled the inclusion and exclusion criteria.

Of the selected patients, 290 patients were male and 83 patients were female. Age wise distribution of the selected patients showed a similar distribution in both sexes. 62.7 +/- 18 years was the mean age in our study group with a minimum age of 15 years and a maximum age of 95 years.

Majority of the patients included were in the age group of 50-65 years in our study. Females in the age group of 30 to 49 years comprised of a larger number, who were available for analysis whereas most of the males were in the age group of 50 to 65 years.

An important factor proposed to affect results in our study were the pre-existing co morbidities in our patients. 56.16% of our patients had only a single co morbidity whereas the rest presented with multiple co morbidities. Diabetes Mellitus was the predominant co morbidity accounting for 65.7% of the group followed by hypertension accounting for 45.2% and others including ischemic heart disease, chronic kidney disease etc amounting to 35.6% of the study population. On further analysis, a statistically significant difference was seen in the presence of a positive rectal swab culture and with the presence of comorbidities in the patient, either single ($p = 0.01$) or multiple ($p = 0.02$). DM has a higher correlation with culture positivity (68.8%), than HTN (58.3%), IHD (50%) or CKD (50%). We had a higher incidence of DM with a statistically significant correlation ($p < 0.01$) to positive rectal cultures in our study.

In our study the overall rate of rectal swab cultures being positive in 373 patients was only 34.3% which is comparable to other studies. A variation in rectal swab cultures is seen among various studies. In a study by B Kolator and P Rodin undertaken for the study of gonorrhea by comparision of anal and rectal swabs, showed a low positivity of these tests at 26.3% and 27.6% respectively.[2] In the study by Ebbing et al et al, sensitivity of perirectal swab compared to stool sample was 90% (95% confidence interval (CI), 70 to 99%) and the specificity was 100% (95% CI, 91 to 100%). For rectal swab, the sensitivity was 90% (95% CI, 68 to 99%) and the specificity was 100% (95% CI, 91 to 100%).[3]

Although a statistically significant point which was seen was the trend of increasing culture positivity with increasing age, with the highest culture positives seen in patients more than 60 years of age, as shown in figure 1. The increasing culture positive trend ranged from 29.9% for those aged less than 20 years to 46.5% in those aged more than 70 years, which was statistically significant. ($p < 0.019$). The importance of this however may be debatable.

Among the positive rectal swab cultures, the most common organism reported was Escherichia coli in 76.56% of the cases, followed by Klebsiella Sp in 12.5%, Proteus Sp in 1.56% and others including Enterococcus, Pseudomonas, Staphylococcus aureus together contributing to 9.37%. (FIGURE 2). The most common organism grown in rectal cultures is Escherichia coli which was also seen in studies by Gottesmann et al, where in 72 culture positive patients, Escherichia coli was seen in 97.2% of the patients. Similarly in the study by Jong et al, of the 161 bacterial isolates, 80.7% were E. coli and 9.9% were Klebsiella pneumonia. 4. This finding is uniformly seen in most studies.

In our study in the antibiotic sensitivity pattern studied in culture positive patients, the sensitivity of fluoroquinolones was as low as 48.43% of the cases. This shows the trend towards a resistance to fluoroquinolones, which are commonly used antibiotics for UTI and in prophylaxis for urological conditions and common procedures. Fluoroquinolones are the most commonly used prophylactic antimicrobial agents for TRUS guided prostate biopsy because of their broad spectrum coverage, pharmacokinetics, bioavailability, and ease of oral administration. However, despite the use of prophylactic antibiotics, the incidence of infectious complications is from 2.1% to 3.0%. Initial studies by Michael A et al showed that an overall fluoroquinolone resistance was detected in 18 of 100 patients from the first office-based rectal culture. Gottesmann et al however noted that their isolates were highly resistant with 67% displaying multidrug-resistance.[4] 33.89% of stool cultures done by Ebbing et al showed fluoroquinolone resistant Escherichia coli in the gastrointestinal tract confirmed by rectal swab cultures being positive in 90% of the patients.[3] Jong et al showed that the prevalence of quinolone resistance was 16.8% and the prevalence of extended-spectrum beta-lactamase (ESBL) positivity was 9.3%. A previous history of prostatitis was correlated with quinolone resistance and ESBL positivity in their study.5.

In our study however we have seen a higher incidence of resistance of Escherichia coli to fluoroquinolones of 51.57% than other studies, showing the need to avoid the use of these antibiotics as prophylactic drugs. The use of

a prophylactic antibiotic is known to reduce complications as bacteremia and sepsis, as well as lower the incidence of infections after a trans rectal procedure but little consensus exists regarding the most appropriate antimicrobial regimens. The percentage of fluoroquinolone resistant Escherichia coli recovered from urinary tract infections increased 4.4 folds from 2004 to 2006 in the United States. In addition, this fluoroquinolone resistant organism in rectal flora is a risk factor of infectious complications after TRUS guided biopsy.

In our study the antibiotic sensitivity pattern showed the organisms which were grown on culture were most resistant to fluoroquinolones among the most used antibiotics (48.43 %), showing a higher rate of resistance than other studies as mentioned before. When an analysis was made of the other antibiotic sensitivity pattern, a varied result was obtained. (Table 1). Amikacin showed a high sensitivity of around 94.5 % in this group. Nitrofurantoin showed a higher sensitivity of 83.59 % as compared with fluoroquinolones but resembling carbapenems and third generation cephalosporins with 88.2% and 78.12 % respectively which was statistically significant with p = 0.001. Among the cephalosporins, the third generation cephalosporins showed a slightly higher sensitivity than the rest, however this was not statistically significant. Other antibiotics included ampicillin (31.25 %), ceftriaxone (57.81 %) etc showing varying sensitivities. Notably very low resistance was seen in the cases of colistin (96.09%) and tigicyclin (95.31 %) among others. Imipenem showed a higher sensitivity than meropenem in our study. (91.4 % vs 87.9 %). p = 0.02.

Many mechanisms have been proposed for the development of fluoroquinolone resistant Escherichia coli. One of the mechanisms of fluoroquinolone resistance is the activity of ESBLs that enzymatically mediate resistance to extended spectrum third generation cephalosporins and monobactams, while not affecting carbapenems. This was seen in our study.

Jong et al noted in their study of antibiotic resistant bacteria on rectal swabs in patients undergoing a prostate biopsy that in 233 patients, 161 had positive cultures with Escherichia coli being the most organism cultured. Similarly in our study, 23 patients planned for a TRUS guided prostate biopsy. The culture positive rate in this group was 43.47 % of which 60 % of the organisms grown was Escherichia coli (p = 0.01) on sub group analysis. They showed that the prevalence of quinolone resistance was only 16.8%, but our study showed a quinolone sensitivity of only 40% showing a trend of increasing resistance to fluoroquinolones.

Furthermore, the sensitivity pattern among ceftriaxone showing 60% while amikacin, gentamycin and cephalosporins showing a higher sensitivity of 80 % was noted. (Figure 4). This is useful in the selection of a prophylactic pre procedure antibiotic in order to reduce complications associated with the procedure.[5]

Duplessis et al. showed that rectal cultures obtained before TRUS biopsy with the use of selective media to identify fluoroquinolone-resistant Enterobacteriaceae facilitate targeted antibiotic prophylaxis and appear to be highly efficacious in reducing infectious complications.[6] The above results shows the higher incidence of a quinolone resistant component and the need to consider a culture based or an alternative antibiotic as pre procedure prophylaxis in such cases.

In the times of prescription of random antibiotics for prophylactic treatment of infections, with the above we aim to aid in issuing therapeutic guidelines for empirical treatment based of the evidence shown by culture sensitivity patterns.

This study further shows the change in resistance pattern of organisms of the gut flora to antibiotics in the given setting. As an unbiased group of patients were considered, these results can be extended to the community with change in prophylactic antibiotics protocol for UTI, prostate biopsy etc prior to a culture report.

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Original Article

Urology, Nephrology and Andrology International
Volume 6 Number 2, July-December 2021
DOI: http://dx.doi.org/10.21088/unai.2456-5016.6221.5

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Management & Mortality of Emphysematous Pyelonephritis in Type 2 Diabetes Mellitus a Single Centre Experience

Mohandas M K[1], Ghasni Pasil[2]

Abstract

Emphysematous pyelonephritis (EPN) is a life threatening necrotizing infection of the kidney. It is commonly seen in diabetic patients and continuous to be a major cause for morbidity Treatment options were limited in the past and most patients were managed surgically. With newer antibiotic protocols medical management is effective in most of the cases.

Aims and Objectives: To study about the mortality with conservative medical management of Emphysematous Pyelonephritis in type 2 Diabetes Mellitus patients.

***Methods*:** Study population included type 2 Diabetes Mellitus patients with urinary tract infection (UTI) (proven by culture) and radiological evidence of Gas in the collecting system, renal parenchyma or perirenal tissue. 50 patients with EPN who were admitted in our hospital from1 October, 2010 to March 31, 2021 were included in this prospective observational study. The clinical presentation, comorbidities, baseline laboratories data and abdominal CT scan were taken. Patients were classified into four stages based on CT imaging. All the patients were started on medical management with antibiotics. Those patients not responded to medical therapy were offered surgical treatment and the outcome of management was assessed.

***Results*:** Mean age of the study group was 59.24 years. Fever was the most common presenting symptom (100%). E.Coli was the most common organism isolated from urine (75%). Patients were divided into different classes based on CT imaging and most of them belonged to class II (50%). Most of the patients managed successfully with antibiotics. Multiple factors found to influence the mortality such as shock, altered sensorium and advanced classes in CT scan.

Conclusions: Medical therapy is the corner stone of management of class I and class II EPN.

Keywords: Emphysematous Pyelonephritis; Type 2 Diabetes Mellitus.

How to cite this article:
Mohandas M K, Ghasni Pasil/Management & Mortality of Emphysematous Pyelonephritis in Type 2 Diabetes Mellitus a Single Centre Experience/Urology, Nephrology and Andrology International./2021;6(2):47-52.

Background

Type 2 Diabetes mellitus patients constitute around 15% of Kerala's population. Of them, about 30-40% develop diabetic nephropathy. About 60-70% of end stage renal disease patients in Kerala are diabetic. Acute worsening of renal function occur in Type 2 Diabetic mellitus patients due to infections like acute pyelonephritis. We have to suspect Emphysematous pyelonephritis when type 2 diabetes mellitus patients present with fever, rigor and chills, lower abdominal pain, dysuria and pyuria. Gas in the urine is also present in some cases. Longstanding uncontrolled diabetes mellitus leads to EPN. It is a severe form

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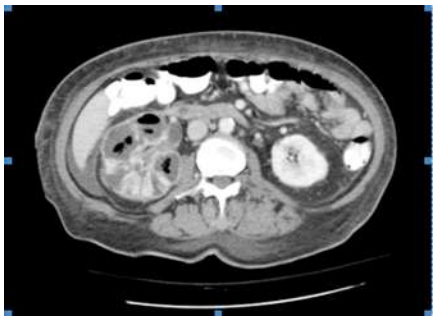
of upper UTI. EPN is a fulminant life threatening necrotizing infection of the kidney. Symptoms of EPN are characterized by gas formation within the collecting system, renal parenchyma or perirenal tissues. Most common predisposing factor for EPN is type 2 diabetes mellitus with lesser contributions from immunosuppressive conditions and urinary tract obstruction.[3,4] The presence of gas forming bacteria, impaired tissue perfusion (e.g. diabetic vasculopathy), and high levels of glucose predispose to EPN and explain the marked preponderance of diabetes in this condition. (Huang and Tseng, 2000) as well as asymptomatic bacteriuria being significantly more common in diabetics (Stapleton, 2002).

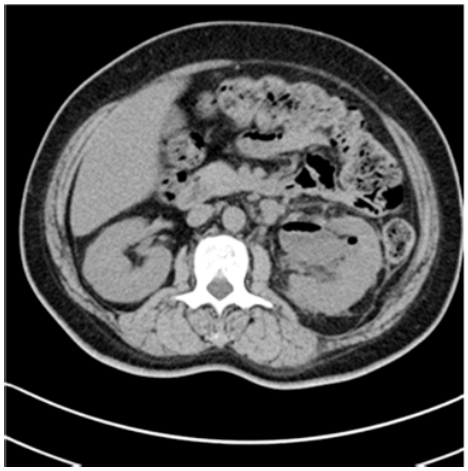
The extent of involvement ranges from inconsequential lower urinary tract colonization to cystitis, pyelonephritis and renal or perirenal abscess. EPN is an uncommon life-threatening condition, precipitated mainly by poorly controlled blood sugars and urinary tract obstruction. Prevalence of diabetes in patients with EPN ranges from 53%-90%. Nephrectomy was the treatment of choice for most patients with EPN in the past.[5] With the advent of newer antibiotics, medical management is found to be effective. Conventional treatment of EPN is parenteral antibiotics with percutaneous or open surgical drainage and/or nephrectomy. There is no current consensus on management of EPN as to whether present day antibiotics alone good enough or is surgical intervention necessary and if surgical intervention required when should one go for nephrectomy.

Diagnosis is confirmed through radiology. Abdominal x-ray can identify tissue gas distributed in the parenchyma that appears as gaseous shadows over the compromised kidney. As the infection advances, the gas extends into the perinephric space and the retroperitoneum. Ultrasound can show strong, localized echoes that suggest the presence of intraparenchymal gas. Computed tomography is the diagnostic imaging of choice for defining the extension of the emphysematous process and can aid in treatment selection. The presence of fluid in the renal or perinephric space with gas in bubbles or between the septa in the collecting system and the presence of striated or mottled gaseous patterns are associated with low mortality. The absence of fluid in the tomographic images or the presence of striated or mottled gaseous patterns with accumulated gas bubbles or septa appear to be associated with rapid destruction of the renal parenchyma and high mortality.

Since EPN is a severe life-threatening necrotizing infection of kidneys, early diagnosis and a proper management is mandatory to reduce mortality and morbidity. Treatment for patients with emphysematous pyelonephritis are Medical management (MM), MM+Endoscopic or percutaneous drainage or Emergency nephrectomy. Currently nephron sparing approach with PCD with or without elective nephrectomy at later stage is the main treatment of choice for EPN and the mortality rate is significantly low in this type of management. Nephrectomy should be reserved for extensive form of EPN with multi organ failure or for patients who show a failed response to conservative management. Conservative management is indicated in Class 1 and Class 2 EPN and early cases associated with gas in the collecting system alone, with the patient otherwise stable.



Class I: Air seen only in dilated PCS.



Class II: Air seen in PCS and Renal parenchyma.

Conservative management involves keeping the patient well hydrated and giving parenteral antibiotics. Control of blood glucose level is mandatory. In cases of urinary tract obstruction, percutaneous drainage or stent placement is indicated for relief of the obstruction. Nephrectomy is indicated in Patients who fail to respond conservative management, Situations where there

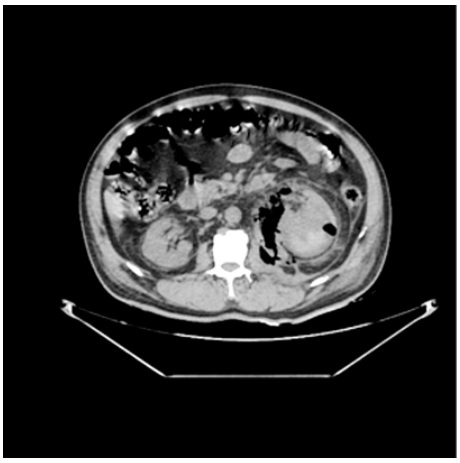
is no access to PCD/ stenting. In addition to above management options, patients might need renal supportive care like dialysis or other modes of renal replacement therapy which seems to reduce the mortality rate significantly.

Methodology

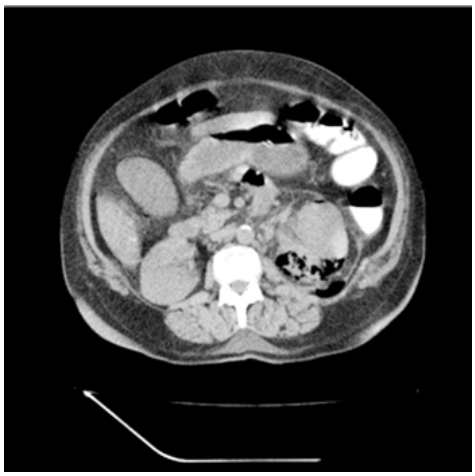
The present study was conducted between October 1, 2010 to March 31, 2021 at the Department of Nephrology, Government TD Medical College, Alappuzha, Kerala. The department cater to needs of patients from Alappuzha, Ernakulam, Kollam and Pathanamthitta districts of Southern Kerala. Inclusion Criteria used were: 1. Pyuria with culture positivity 2. Radiological evidence of gas in the collecting system, renal parenchyma, or perinephric or pararenal space. Patients who fulfilled the inclusion criteria were selected from nephrology Out Patient Department (OPD) and wards. The final sample size obtained was 50. Informed consent was taken from all the study participants. All the 50 study participants were having type 2 diabetes mellitus. Non emphysematous pyelonephritis and other UTIs were excluded from the study.

Age, sex, marital status, socioeconomic status, educational qualification and occupation were recorded. History pertaining to all co morbidities such as duration of diabetes mellitus, systemic hypertension, renal calculi, recurrent UTI, habits and additions were documented. Clinical history and physical examination were done for all patients. History of present illness such as fever, abdominal pain, dysuria, oliguria and altered sensorium were recorded.

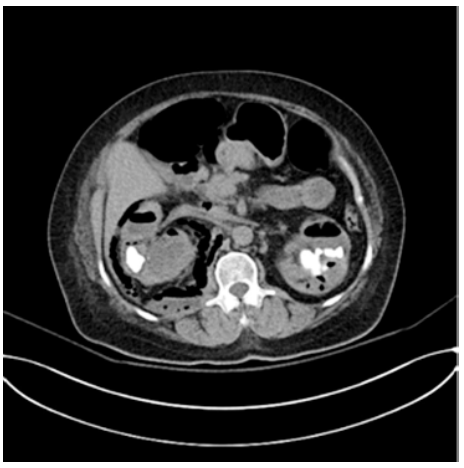
Laboratory investigations including renal function tests, routine blood examination, platelet count, coagulation profile, serum albumin, blood glucose and urine examination was done for all patients. Azotemia was defined as serum creatinine is more than 2.5mg%, thrombocytopenia as platelet count less than 1,00,000/mm3 and hypoalbuminemia as serum albumin less than 3.0gm%. Urine Culture and Sensitivity, plain X Ray abdomen, ultrasonography of kidney and urinary tract was performed at baseline. Non contrast CT was taken for all of them. Contrast enhanced computerized tomography (CECT) was performed in case of suspected renal abscess and non-recovering pyelonephritis. Staging of EPN was done using Huang et al - 2000 criteria 7- class I: gas in the collecting system only; class II: gas in the renal parenchyma without extension to the extra renal space; class III a: extension of gas or abscess to the perinephric space; class III b: extension of gas or abscess to the para renal space; class IV: bilateral EPN or solitary kidney with EPN.[1,8]



Class IIIA: Air seen extending into perinephric space.



Class IIIB: Paranephric Space.



Class IV: Air in bilateral kidney.

All patients were initiated on standard medical management with IV antibiotics for two weeks followed by oral antibiotics for two weeks and antibiotic prophylaxis thereafter. These patients were periodically followed up in nephrology OP for recurrence/complications. The outcome of management including mortality was assessed. In statistical analysis quantitative variables were summarized by mean and standard deviation, qualitative variables were described by percentage distribution.

Results

Mean age of the study group was 59.24 years (SD=7.8). Clinical features of our patients at presentation are discussed in Table 1.

Table 1: Clinical Features of Patients at Presentation.

Fever	50 (100%
Dysuria	25 (50%)
Loin Pain	20 (40%
LUTS	16 (32%)
Renal Stones	10 (20%
Oliguria	25 (50%
Altered sensorium	10 (20%)
Hematuria	25 (50%)
Shock	10 (20%)
Mortality	10 (20%)

Fever being present in all the study participants, was the most common presenting symptom followed by dysuria (50%), oliguria (50%), hematuria (50%) and altered sensorium (20%).

Regarding co-morbid illnesses while all the patients had diabetes mellitus, 30% had recurrent urinary tract infection and 20% had renal calculi. Laboratory results of patients are given in Table 2.

Table 2: Laboratory Characteristic and CT Imaging.

(HEMOGLOBIN <11 GM%)	**10(20%)**
(White cell count > 10000/mm3)	40(80%)
Thrombocytopenia	8(16%)
Urine culture	
Culture positive	90%
E. Coli	50%
K. Pnemonia	10%
Pseudomonas	10
Polymicrobial	10%
Fungal	5%
Culture negative	10%
Blood culture positive	25%
DM duration	10.7 ±5.60
HbA1C	
<7%	20%
7–8%	50%
>8%	30%
CT Classification	
Class I	10(20%)
Class II	25 (50%)
Class III a	10 (20%)
Class III b	3 (6%)
Class IV	2 (4 %)
Treatment	
IV antibiotics alone	74%
Antifungals+antibiotics	6%
IV antibiotics+PCD	20%
Nephrectomy	0%
RRT requirement	34%

Of the study participants, 20% were anemic and 80% had leucocytosis. A total of 25 patients had azotemia (50%) and out of which two patients required dialysis. On CT imaging 20% of patients belonged to class I, 50% were in class II, 20% were in class III a, 6% were in class III b and 4% belonged to class IV. Around 20% patients required surgical interventions in the form of percutaneous Nephrostomy and DJ stenting. It was done in addition to medical therapy and all of them belonged to either Class III or Class IV.

E Coli was the most common bacteria isolated from urine (75%) of the patients. Klebsiella was present in 16.7 % patients and 8.3% of patients had mixed growth on culture. All patients received I V antibiotics for two weeks followed by oral antibiotics for two weeks. One patient each in class IIIa, class IIIb, class IV underwent surgical management due to unresponsiveness with medical therapy.

One patient in class IIIa presented with shock and succumbed to death before any surgical intervention could be planned, hence the overall mortality in our study was 10%. On analysing the risk factors for mortality, we found that presence of shock, altered sensorium and class IIIb / class IV in CT scan were associated with increased mortality.

Discussion

EPN is a very rare yet life threatening medical emergency. Many factors have been implicated but most importantly high level of glucose with in the

tissue, gas forming organisms, impaired vascular supply and presence of obstruction are the culprits.[8] Vascular compromise with high glucose levels is unique to diabetic population and it explains why the condition is more common in diabetic patients. Mixed acid fermentation of glucose to produce Hydrogen (H2) and carbon dioxide (C02) is the mechanism implicated.[7,9] In our study all of the patients were diabetic further underlining the association. From literature there is preponderance of EPN in females10 and in our study the ratio was 4:1, mostly due to their increased susceptibility to urinary tract infection.[1] Clinical symptoms of EPN include fever, dysuria, hematuria, abdominal pain, vomiting depressed levels of consciousness and shock.[5,7,11] Similar to the published series, fever and dysuria were the most common symptoms in our study. Leucocytosis, and renal dysfunction were the most common laboratory findings in our study which is consistent with the reported literature.[5,8] In our study group most common organism isolated from urine was E Coli (75%) followed by Klebseilla (16.7%) similar to previous studies.[12]

Definitive diagnosis of EPN is done by CT scan and in 2000 Huang et al and Tseng put forward four radiological classifications of EPN based on the extent of gas seen on CT.[9] In our study most patients belonged to class II(50%) followed by class I and IIIa (20%). In an Indian study by Kapoor et al. altered mental status thrombocytopenia, renal failure and severe hyponatremia were predictors of higher mortality.[13] In our study, shock, altered sensorium, and class IIIb /class IV in CT scan were associated with increased mortality.

The treatment of EPN differs in the degree of urgency and that immediate nephrectomy historically has been the treatment of choice (Dutton *et al*, 2007; wong et al, 2007) The mortality of this condition has improved from 78% in the late 1970, to 13.5% (somani et al, 2008). This may be the result of earlier diagnosis with increasing use of CT scan and lesser degrees of EPN being identified earlier. It is clear that majority of patients can be treated successfully with supportive management and percutaneous drainage.[14]

EPN is often the dramatic climax to chronic subclinical UTI and as such, many patients may have received many courses of antibiotics with series risk of resistance to standard antibiotics (Soo park *et al*, 2006). The choice of treatment for EPN still continues to be a matter of debate. Most of the earlier investigations were in favour of aggressive surgical treatment.[5,14] In contrast to earlier reports recent series have voted in favour of initial conservative management with antibiotics and resorting to surgical therapy only when medial management fails.[15,16] All our patients initially. managed medically with intravenous antibiotics Overall mortality in our study was 10%.

Conclusions

EPN a life threatening infection commonly seen in diabetic patients and is responsible for significant mortality if not managed promptly. A high index of suspicion and early imaging studies are required to diagnose EPN in diabetics presenting with features of pyelonephritis, especially if blood sugars are poorly controlled CT scan is the investigation of choice, in making the correct diagnosis. Renal preservation must be the aim of treatment, but this is often associated with significant morbidity, especially in patients with extensive EPN. With a good antibiotic policy most of the patients in class I, II and IIIa were successfully managed conservatively.

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Original Article

Urology, Nephrology and Andrology International
Volume 6 Number 2, July-December 2021
DOI: http://dx.doi.org/10.21088/unai.2456-5016.6221.6

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Assessing the Role of Guys Score in the Outcome of Pcnl

SML Prakash Babu[1], Sangle Ameya Rangnath[2], Dhruva G Prakash[3]

Abstract

Urolithiasis is one of the oldest diseases and continues to be a major problem in India. PCNL continues to be the standard of care in selected cases according to the stone size, location, shape and composition of the stone. PCNL is recommended for cases with stones larger than 20mm, cases with struvite or cysteine stones, or in cases of anatomical variation. The outcomes of PCNL is interpreted in terms of success of the procedure and complication rates. Multiple factors have been investigated as predictors of success rates and complications. A quick, simple and reproducible method for the prediction of the outcomes of PCNL was proposed by Thomas et al called as the 'Guy's stone score'. The grading system mainly takes into consideration the number of stones, stone location and whether the renal anatomy is simple or abnormal. Currently there is no single agreement upon an ideal predictive model that characterizes the complexity of renal stones predicting surgical outcomes following PCNL. Hence the present study was conducted for evaluating the role of GUY's score in the outcome of PCNL.

***Materials and methods*:** Patients scheduled to undergo PCNL at Ramaiah Hospitals were assessed for eligibility for the study and those satisfying the inclusion criteria were included in the study. The stone burden was determined by radiographic studies, and stones will be classified using the GSS as Guy's I, II, III and IV. Post-operative stone clearance rate was assessed by any residual shadow in x-ray KUB in the immediate post-operative period and NCCT after 3 months and patients were followed up to note any complications in the post-operative period. And stone free status was assessed

***Results and discussion*:** 200 patients scheduled to undergo PCNL were included. Incidence of complications was more in patients with GUY'S grade IV ($P<0.01$). Incidence of relook PCNL was more in patients with GUY'S grade IV. stone free clearance was more in patients with GUY'S grade I and II, stone size <200mm^2, with essence HU <800 HU, with lower calyx puncture. We have also observed that incidence of complications pleural effusion, urine leak and bleeding was more with Guy's IV and more with superior calyx puncture.

***Conclusion*:** We conclude that GUY'S score is a useful tool in the initial evaluation to predict surgical outcomes in PCNL and can help in better pre-operative planning of the surgery.

Keywords: Guy's score; PCNL; Urolithiasis; Outcome; Prediction.

How to cite this article:
SML Prakash Babu, Sangle Ameya Rangnath, Dhruva G Prakash/Assessing the Role of Guys Score in the Outcome of Pcnl/Urology, Nephrology and Andrology International./2021;6(2):53-59.

Introduction

Urolithiasis is one of the oldest diseases known to humankind. It is noticed in Egyptian mummies. The incidence and characteristics of nephrolithiasis reflect a wide geographic variation. Stones occur at all ages without any gender predominance. Nephrolithiasis continues to be a major problem in India. It is more prevalent in northern states than in southern states of India.

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Modalities to tackle stone disease have improved vastly to ESWL and Flexible ureteroscopic surgeries, PCNL continues to be the standard of care in selected cases according to the stone size, location, shape and composition of the stone. The European Association of urologists have advocated the use of PCNL as first option for large, multiple or inferior calyx stones. Open stone surgery has been replaced by endoscopic procedures because of their lower post-operative complications, lower morbidity, shorter operative time and cost effectiveness. PCNL is recommended for cases with stones larger than 20mm, cases with struvite or cysteine stones, or in cases of anatomical variation.[1] There is no uniformity in methods for clinical and academic characterization of nephrolithiasis and for the evaluation of surgical outcomes.[2] The outcomes of PCNL is interpreted in terms of success of the procedure and complication rates. "Success" is often defined as the absence of residual stone fragments under conventional X-ray or computed tomography (CT) or when clinically insignificant residual fragments (CIRF) are observed.[3]

Multiple factors such as stone size and configuration, percutaneous access sheath size, location, renal access puncture performed by radiologist or urologist, presence of hydronephrosis have been investigated as predictors of success rates and complications. Attempts to identify the associated variables showed variations among the results which has made it difficult to classify the patients so that the stone free rate (SFR) or complications can be predicted. A quick, simple and reproducible method for the prediction of the outcomes of PCNL was proposed by Thomas *et al*[4] called as the 'Guy's stone score'. The grading system mainly takes into consideration the number of stones, stone location and whether the renal anatomy is simple or abnormal. In this scoring system, calyceal diverticulum stones, staghorn stones and any stone in a patient with a spina bifida or spinal injury are the special circumstances that effect the grading of the stone. The score is based not just on the stones targeted for treatment in the particular procedure but on all of the stones and abnormal anatomy defines an abnormal renal anatomy, an abnormal collecting system or a patient with an ileal conduit (i.e. cases where the operating surgeon believes access may be difficult).[5]

Large-series PCNL results are available in the literature. Currently there is no single agreement upon an ideal predictive model that characterizes the complexity of renal stones predicting surgical outcomes following PCNL. Hence the present study was conducted for evaluating the role of GUY's score in the outcome of PCNL.

Objective

The objective is to assess and study the predicting factors which alter the outcome of PCNL.

Materials and Methods

This is a prospective study conducted in MS Ramaiah Hospital from November 2016 to June 2018. Inclusion criteria: Patients of all age groups diagnosed to have renal stones and undergoing PCNL Exclusion criteria: 1.Stone in the diverticulum; 2. renal anomalies; 3. chronic kidney disease patients.

Patients scheduled to undergo PCNL at Ramaiah Hospitals were assessed for eligibility for the study and those satisfying the inclusion criteria were included in the study. After the approval by the Institutional Ethical Committee, written informed consent was obtained from the patients prior to intervention.

The stone burden was determined by radio-graphic studies, and stones will be classified using the GSS as Guy's I, II, III and IV.

The score is classified into four grades:

Grade I - Solitary stone in mid/lower pole or solitary stone in the pelvis with simple anatomy.

Grade II - Solitary stone in the upper pole or multiple stones in a patient with simple anatomy or a solitary stone in a patient with abnormal anatomy.

Grade III - Multiple stones in a patient with abnormal anatomy or stones in a calyceal diverticulum or partial staghorn calculus.

Grade IV - Staghorn calculus or any stone in a patient with spina bifida or spinal injury.

Post-operative stone clearance rate was assessed by any residual shadow in x-ray KUB in the immediate post-operative period and NCCT after 3 months and patients were followed up to note any complications in the post-operative period. And stone free status was assessed.

Stastical Analysis

***Statistical software*:** The Statistical software namely SPSS 18.0, and R environment ver.3.2.2

were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs, tables etc.

Results

In the present study 200 patients scheduled to undergo PCNL were included. Complete data was obtained from all study participants and were included for data analysis. The following observations were made.

Table 1 shows the GUY'S Score distribution, it was Grade I in 38 patients (19%), Grade II in 60 patients (30%), Grade III in 29 patients (14.5%) and Grade IV in 73 patients (36.5%).

Table 1: Guys Score distribution of patients studied.

Guys Score	No. of patients	%
Grade I	38	19.0
Grade II	60	30.0
Grade III	29	14.5
Grade IV	73	36.5
Total	200	100.0

Correlation of the various predictive factors

Table 2 shows the correlation of age, gender, prior history of renal calculus and prior treatment to GUY's score which was statistically not significant,

Chi-Square/Fisher Exact Test

Table 2: Correlation of clinical variables in relation to Guys Score of patients studied.

Variables	Guys Score				Total (n=200)	P value
	Grade I (n=38)	Grade II (n=60)	Grade III (n=29)	Grade IV (n=73)		
Age in years						
18-20	0(0%)	2(3.3%)	0(0%)	2(2.7%)	4(2%)	0.612
21-30	2(5.3%)	7(11.7%)	2(6.9%)	11(15.1%)	22(11%)	
31-40	17(44.7%)	16(26.7%)	8(27.6%)	18(24.7%)	42(21%)	
41-50	7(18.4%)	14(23.3%)	7(24.1%)	14(19.2%)	59(29.5%)	
51-60	6(15.8%)	11(18.3%)	8(27.6%)	14(19.2%)	39(19.5%)	
61-70	6(15.8%)	6(10%)	3(10.3%)	13(17.8%)	28(14%)	
71-80	0(0%)	2(3.3%)	1(3.4%)	1(1.4%)	4(2%)	
>80	0(0%)	2(3.3%)	0(0%)	0(0%)	2(1%)	
Gender						
Female	7(18.4%)	25(41.7%)	7(24.1%)	28(38.4%)	67(33.5%)	0.055+
Male	31(81.6%)	35(58.3%)	22(75.9%)	45(61.6%)	133(66.5%)	
H/O renal calculus						
No	25(65.8%)	40(66.7%)	17(58.6%)	53(72.6%)	135(67.5%)	0.577
Yes	13(34.2%)	20(33.3%)	12(41.4%)	20(27.4%)	65(32.5%)	

Table 3 shows the stone related details co-related with GUY'S score. Maximum number of patients

Table 3: Stone related details in relation to Guys Score of patients studied.

Variables	Guys Score				Total (n=200)	P value
	Grade I (n=38)	Grade II (n=60)	Grade III (n=29)	Grade IV (n=73)		
Stone Laterality						
Left	26(68.4%)	28(46.7%)	27(93.1%)	37(50.7%)	118(59%)	<0.001**
Right	12(31.6%)	32(53.3%)	2(6.9%)	36(49.3%)	82(41%)	
Stone Count						
Single	25(65.8%)	28(46.7%)	15(51.7%)	7(9.6%)	75(37.5%)	<0.001**
Multiple	13(34.2%)	32(53.3%)	14(48.3%)	66(90.4%)	125(62.5%)	
Stone Size						
<200 sq.mm.	20(52.6%)	15(25%)	7(24.1%)	7(9.6%)	49(24.5%)	<0.001**
200-800	18(47.4%)	45(75%)	22(75.9%)	37(50.7%)	122(61%)	
>800	0(0%)	0(0%)	0(0%)	29(39.7%)	29(14.5%)	

Chi-Square/Fisher Exact Test

Table 4: Essence HU distribution in relation to Guys Score of patients studied.

Essence HU	Guys Score				Total
	Grade I	Grade II	Grade III	Grade IV	
<800	6(15.8%)	19(31.7%)	20(69%)	15(20.5%)	60(30%)
800-1200	0(0%)	21(35%)	0(0%)	17(23.3%)	38(19%)
>1200	32(84.2%)	20(33.3%)	9(31%)	41(56.2%)	102(51%)
Total	38(100%)	60(100%)	29(100%)	73(100%)	200(100%)

P<0.001, Significant, Chi-Square Test**

Table 5 shows the tract size in patients and majority of the patients had tract size of 30 and majority of the patients in this group belongs to GUY'S grade IV.

Table 5: Tract Size distribution in relation to Guys Score of patients studied.

Tract Size	Guys Score				Total
	Grade I	Grade II	Grade III	Grade IV	
24	11(28.9%)	8(13.3%)	3(10.3%)	0(0%)	22(11%)
28	17(44.7%)	24(40%)	10(34.5%)	9(12.3%)	60(30%)
30	10(26.3%)	28(46.7%)	15(51.7%)	53(72.6%)	106(53%)
32	0(0%)	0(0%)	1(3.4%)	11(15.1%)	12(6%)
Total	38(100%)	60(100%)	29(100%)	73(100%)	200(100%)

P<0.001, Significant, Chi-Square Test Figure 20: Tract size in relation to GUY'S score.**

Table 22 shows the stone free status distribution in relation to Guy's score. And according to the present study stone free status of more than 90% was significantly high in Guy's stone grade III. 28 patients had stone free status of more than 90% and only 1 patient had stone free clearance of less than 90%.

Table 6: Stone free Status distribution in relation to Guys Score of patients studied.

Stone free Status	Guys Score				Total
	Grade I	Grade II	Grade III	Grade IV	
<90	6(15.8%)	8(13.3%)	1(3.4%)	21(28.8%)	36(18%)
90-100	32(84.2%)	52(86.7%)	28(96.6%)	52(71.2%)	164(82%)
Total	38(100%)	60(100%)	29(100%)	73(100%)	200(100%)

P=0.012*, Significant, Chi-Square Test.

Table 23 shows the co-relation of complications in relation to GUY'S score and according to the present study complications were more in GUY'S score grade IV. Out of 13 patients with decrease in haemoglobin to less than 8 g/dl requiring blood transfusion 11 patients belong to GUY'S grade IV, Out of 30 patients who had urine leak 22 patients belong to grade IV. And as well the incidence of relook PCNL was high in GUY'S grade IV. And the result was statistically significant.

Table 7: Complications and incidence of relook PCNL distribution in relation to Guys Score of patients studied.

Variables	Guys Score				Total (n=200)	P value
	Grade I (n=38)	Grade II (n=60)	Grade III (n=29)	Grade IV (n=73)		
Decrease HB						
No	38(100%)	58(96.7%)	29(100%)	62(84.9%)	187(93.5%)	0.002**
Yes	0(0%)	2(3.3%)	0(0%)	11(15.1%)	13(6.5%)	

Table Cont.....

Requiring blood transfusion						
No	38(100%)	58(96.7%)	29(100%)	62(84.9%)	187(93.5%)	0.002**
Yes	0(0%)	2(3.3%)	0(0%)	11(15.1%)	13(6.5%)	
Urine Leak						
No	36(94.74%)	58(97%)	29(100%)	57(69.9%)	180(78.09%)	<0.001**
Yes	2(5.26%)	2(3%)	0(0%)	16(30.1%)	20(21.91%)	
Relook PCNL						
No	38(100%)	60(100%)	29(100%)	65(89%)	192(96%)	0.003**
Yes	0(0%)	0(0%)	0(0%)	8(11%)	8(4%)	

Chi-Square/Fisher Exact Test

Discussion

For large and complex kidney stones PCNL is an important surgical intervention, and its success depends on several variables. Some of these can be predicted before surgery, i.e., stone burden and upper tract anatomy, but success also depends on surgical experience.[3] Several scoring systems have been developed for predicting the SFS after shock-wave lithotripsy, retrograde intrarenal surgery and PCNL. The Guy's stone score (GSS) includes stone number, location, presence of staghorn stones and abnormal anatomy to determine different grades, and it was reported that the SFS declined with increasing grades of complexity.[3]

The present study included 67 females and 133 males.

Stone distribution

PCNL is considered the first line recommended procedure for renal calculus. But patients with complex multiple renal calculi pose a special challenge for PCNL as these patients have high chances of incomplete stone clearance.

When stone related characteristics were compared with the GUY'S score, more stones with left side laterality in GUY'S grade III ($p<0.01$), Multiple stones were more compared to single stones and maximum belongs to GUY'S grade IV ($p<0.01$), Stone size of 200-800 mm2 in maximum number of patients more in GUY'S grade II and III. Essence HU of >1200 in maximum number of patients more in GUY'S grade IV ($p<0.01$), with tract size of 30 in maximum number of patients more in GUY'S grade IV ($p<0.01$).

On correlating the stone free status with the stone characteristics stone free status was >90% in 100% of patients with solitary stone in upper calyx, lower calyx, mid-calyx and it was 93.5% in patients with stone in renal pelvis. Whereas the stone free status of >90% was achieved in 61.5% patients with staghorn calculus and 77.5% patients in patients with stone at multiple calyces. And the result was statistically significant ($p<0.01$).

GUY'S Score and stone free status

External validation in several series demonstrated that GSS effectively predicted SFS. There are limitations to this system. First, it fails to account for important variables such as calyceal involvement, stone size, density, and composition. These variables determine technical difficulty of PCNL and thus have important implications for procedural success.

Table 8: Stone free status in various studies in relation to Guy's score.

Study	Pre-operative imaging	Post-operative imaging	Definition of stone free	Clearance by stone complexity
Thomas K et al.,4	CT, radiograph, IVU	KUB radiograph	4-mm fragments	Overall, 62% Grade 1, 81% Grade 2, 72.4% Grade 3, 35% Grade 4, 29%
Mandal S et al.,6	Radiograph, IVU, USS, noncontrast	KUB radiograph CT	Complete absence of stones	Overall, 76.1% Grade 1, 100% Grade 2, 74% Grade 3, 56% Grade 4, 0%

Table Cont.....

Vicentini FC et al.,7	Noncontrast CT		Asymptomatic fragments n 4 mm	Overall, 71.6% Grade 1, 95.2% Grade 2, 79.5% Grade 2, 79.5% Grade 3, 59.5% Grade 4, 40.7%
Ingimarsson JP et al.,8	Noncontrast CT		No fragments/no fragments. 2 mm/ no fragments. 4 mm	Overall, 90% Grade 1, 95% Grade 2, 97% Grade 3, 95% Grade 4, 75%
Labadie K et al.,9	CT scan	Unclear	Not defined	Overall, 56% Grade 1, 70.2% Grade 2, 65.4% Grade 3, 48.1% Grade 4, 35.9%
Noureldin YA et al.,10	Unclear	Plain radiographs or noncontrast CT	Asymptomatic residual fragments n 4 mm residual	Overall, 71.9% Grade 1, 91.5% Grade 2, 80% Grade 3, 47.6% Grade 4, 43.2%
Bozkurt IH et al.,11	CT scan KUB radiograph (unless CT; which is reserved for only symptomatic patients)		Asymptomatic residual fragments n 4 mm	Overall, 75% Grade 1, 92.8% Grade 2, 72.4% Grade 3, 68.5% Grade 4, 47.4%

In the present study GUY'S score of I, II, III and IV in 38,60,29 and 73 patients respectively. The stone free success rate of >90% was achieved in 84.2% in GUY'S grade I, 86.7% in GUY'S grade II, 96.6% in GUY'S grade III, 71.2% in GUY'S grade IV. Although the stone free status was more in GUY'S grade III and it was comparatively equal in GUY'S grade I and II and more compared to GUY'S grade IV. But the result statistically not significant.

Complications

According to the present study there was high incidence of complications and Relook PCNL in GUY'S grade IV. Categorizing of patients according to Guys stone score (I-IV) helps urologist appropriately counsel patients regarding their likely postoperative clinical outcome and, in complex scenarios, refer patients to tertiary centers.

Conclusion

Incidence of complications was more in patients with GUY'S grade IV (P<0.01).

Incidence of relook PCNL was more in patients with GUY'S grade IV.

We have also observed in our study that stone free clearance was more in patients with GUY'S grade I and II, stone size <200mm2, with essence HU <800 HU, with lower calyx puncture,

We have also observed that incidence of complications pleural effusion, urine leak and bleeding was more with Guy's IV and more with superior calyx puncture.

We conclude that GUY'S score is a useful tool in the initial evaluation to predict surgical outcomes in PCNL and can help in better pre-operative planning of the surgery.

Conflict of interest: None

***Support / Grant*:** None

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Original Article

Urology, Nephrology and Andrology International
Volume 6 Number 2, July-December 2021
DOI: http://dx.doi.org/10.21088/unai.2456-5016.6221.7

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Prevalence of Secondary Hyperparathyroidism in Patients with Stage 5 Chronic Kidney Disease on Maintenance Hemodialysis

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Abstract

Context: Disturbances in mineral metabolism are commonly seen in patients with chronic renal failure.But there are very few studies on their prevalence in Indian dialysis population.

Aim: To know the prevalence of secondary hyperparathyroidism in patients with stage 5 chronic kidney disease on maintenance hemodialysis.

***Settings and Design*:** Hospital based cross sectional study.

Methods and Material: This study was done on 85 patients undergoing maintenance hemodialysis for ≥ six months and data was collected between January 2018 and December 2018, for a period of one year. Patients were examined for clinical features of secondary hyperparathyroidism and serum calcium, phosphorus, alkaline phosphatase, 25 hydroxy vitamin D and intact parathyroid hormone levels were measured.

Statistical analysis used: The data was analysed with SPSS using Descriptive statistics, Chi-square testand significance by p value.

Results: Various mineral, bone abnormalities in our study population were as follows-hypercalcemia (5.88%), hypocalcemia (36.47%), hyperphosphatemia (30.59%), hypophosphatemia (28.24%), hyperparathyroidism (36.48%), hypoparathyroidism (10.59%), deficiency of vitamin D(52.94%) and insufficiency of vitamin D (20%).

Conclusions: Prevalence rate of secondary hyperparathyroidism was 36% in our study and 40% had oversuppresion of iPTH levels. One third of our patients had a risk of adynamic bone disease.

Keywords: Chronic kidney disease; Secondary hyperparathyroidism; hemodialysis.

How to cite this article:
Soumya NS, Suresh U Kadli, Kiran Kumd CK et. al/ Prevalence of Secondary Hyperparathyroidism in Patients with Stage 5 Chronic Kidney Disease on Maintenance Hemodialysis/Urology, Nephrology and Andrology International./2021;6(2):61-65.

Introduction

CKD stage 5 is loss of renal function requiring renal replacement therapy,with significant complications and its prevalence has increased imposing burden for health care system.[1]

Secondary hyperparathyroidism (SHPT represents alteration in bone, mineral metabolism caused by reduced kidney function with increased mortality.[2] It is important to diagnose SHPT, as its

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early treatment slows the progression of bone and cardiac complications and to know its prevalence in this dialysis population to adopt appropriate health policies. Hence this study was done to know the prevalence, biochemical and clinical profile of secondary hyperparathyroidism in chronic hemodialysis patients.

Materials and Methods

This was a cross sectional study, done on 85 Chronic Kidney Disease stage 5 patients of 18 years and above, on maintenance hemodialysis for ≥ 6months in KLE's Dr Prabhakar Kore Hospital and Medical Research Center, Belagavi, willing to participate in the study. Patients on glucocorticoids, bisphosphanates, nonsteroidal anti-inflammatory drugs, phenytoin or warfarin, patients with rheumatologic disease, primary parathyroid disorder, patients with history of liver disease, bone fracture in last six months prior to enrollment, were excluded from study.Institutional ethical clearance and informed consent from each individual participant was obtained.

- Stage of Chronic kidney disease was defined according to K/DOQI criteria.[3] eGFR was calculated by using Cockcroft-Gault formula. After taking informed consent, patient's details and a detailed clinical history was obtained for symptoms suggestive of secondary hyperparathyroidism.
- All patients were clinically examined including general physical examination, careful examination of the Joints, examination of cardiovascular system, respiratory system, per abdomen and nervous system for the signs of secondary hyperparathyroidism.
- After taking the informed consent, about 6ml of blood was drawn at start of hemodialysis session to measure serum calcium, phosphorus, alkaline phosphatase, calcitriol and intact Parathyroid hormone, creatinine and albumin.
- Serum intact parathyroid hormone was measured by electrochemiluminescence immunoassay, but not the fragments of it, which will also be increased in renal failure.
- Serum calcitriol was measured by chemiluminescence immunoassay, Alkaline phosphatase by King and Amstrong method, serum calcium by 5-nitro -5 methyl BAPTA method and serum phosphorus by phosphomolybdate UV Kinetic method.

Statistics: The information collected from the patients was noted in master chart. Analysis of data was done using statistical software version SPSS 20.00, Descriptive statistics including frequency, percentage, mean and SD, Chi-square for independence, Karl Pearson's correlationcoefficient for relationship were used and statistical significance was set at 5% level with $p<0.05$ considering significant.

Results: A total of 85 patients underwent maintenance hemodialysis for an average of 24 ± 13 months and 9.27 hours per week, Diabetes Mellitus was major cause of CKD in 49.41 % of patients.

Table 1: Distribution of subjects based on the age groups.

Age Group	No. of Patients	%
20 to 40	14	16.47
41 to 60	40	47.05
61 to 80	31	36.47
>80	0	0
Total	85	100

MEAN ± SD = 54.68± 12.46

The mean age of the study population was 54.68 ±12.46 years and ranged from 23 years to 76 years, majority being in the age group of 41- 60 years(47.05%).

Table 2: Distribution of Subjects by Gender.

Gender	Number	Percentage
Female	17	20
Male	68	80
Total	85	100.00

Males formed majority with 80 % of the study population as compared to females (20%)

Table 3: Distribution of subjects based on value of serum corrected calcium.

Corrected Calcium (in mg/dl)	Number	Percentage
<8.4	31	36.47
8.4-9.5	40	47.06
9.6-10.2	9	10.59
>10.2	**5**	**5.88**
Total	85	100

MEAN ±SD= 8.71 ± 1.09

47.06 % of patients had acceptable levels of serum corrected calcium (8.4 - 9.5 mg/dl), 36.47 % of

patients had values below and 16.47% of patients above theaccepted range. 5.88% of patients had hypercalcemia (> 10.2mg/dl).

Table 4: Distribution of subjects based on serum phosphorus levels.

Phosphorus (in mg/dl)	Number	Percentage
<3.5	24	28.24
3.5-5.5	35	41.18
>5.5	26	30.59
Total	85	100

MEAN ±SD= 4.50± 2.16

24 out of 85 patients had serum phosphorus value of < 3.5 mg/dl, 35 of them had value between 3.5mg/dl and 5.5mg/dl and in 26 patients value was > 5.5mg/dl.

Table 5: Distribution of subjects based on intact Parathyroid hormone levels.

iPTH (in pg/ml)	Number	Percentage
<100	26	30.59
100-150	9	10.59
150-300	19	22.35
300-600	24	28.24
>600	7	8.24
Total	85	100

MEAN ±SD=255.12±231.75pg/ml

Mean level of iPTH was 255.12±231.75 pg/ml with a range from 4.3 to 987.60pg/l. 36.48% of patients had intact PTH levels above 300pg/ml suggesting hyperparathyroidism as per K/DOQI guidelines. 22.35% of patients hadaccepted range (150-300 pg/ml) and 41.18% of patients had levels below 150pg/ml. 8.24% of patients had iPTH values > 600pg/ml and 30.59% of patients had iPTH levels less than 100pg/ml.

Table 6: Distribution of subjects based on 25OH vitamin D levels.

25 OH Vitamin D(ng/ml)	Number	Percentage
≤20	45	52.94
21-29	17	20.00
≥30	23	27.06
Total	85	100.00

MEAN ±SD = 25.83±19.52

27.06 % of the patients had 25OH vitamin D levels of ≥ 30ng/ml, 52.94% of patients had vitamin D deficiency(≤20ng/ml) and 20% of patients had vitamin D insufficiency(21-29ng/ml).

Table 7: Distribution of Subjects Based on serum Alkaline Phosphatase Levels.

Alkaline Phosphatase (U/L)	Number	Percentage
<120	32	37.65
≥120	53	62.35
Total	85	100

MEAN±SD=137.79±59.34

62.35 % had ALP value of ≥120U/L.

Table 8: Distribution of subjects based on the presence of Bone Mineral Disorders.

Disorders	Number	Percentage
Hypercalcemia (>10.2mg/dl)	5	5.88
Hypocalcemia (<8.4 mg/dl)	31	36.47
Hyperphosphatemia (>5.5mg/dl)	26	30.59
Hypophosphatemia (<3.5mg/dl)	24	28.24
Hyperparathyroidism (>300pg/ml)	31	36.48
Hypoparat-hyroidism (<150pg/ml)	9	10.59
Patients with iPTH<100pg/ml	26	30.59
Patients with iPTH>600pg/ml	7	8.24
Serum alkaline phosphatase >120U/L	53	62.35
Vitamin D deficiency (≤ 20ng/ml)	45	52.94
Vitamin D insufficiency (21-29ng/ml)	17	20.00

The most was common mineral bone disorder was elevated serum alkaline phosphatase levels in 62.35% of patients, followed by vitamin D deficiency in 52.94%, hyperparathyroidism in 36.48%, hypocalcemia in 36.47%, hyperphosphatemia in 30.59% of patients. iPTH levels were < 100pg/ml in 30.59% of our patients.

Discussion

In our study the mean levels of serum corrected calcium was 8.71±1.09mg/dl. In a study by Ghosh et al., mean serum corrected calcium was 8.24 ± 1.26mg/dl.[4] The results of our study showed that only 47.06 % of patients had acceptable levels of serum corrected calcium, 36.47% had below and 16.47% had values above the acceptable levels. In the study done by Fatemeh Hayati et al., 55.4% had acceptable levels (8.4-9.5mg/dl), while 7.1%

had above and 37.5% had values below acceptable levels, which is similar to our study.[1]

41.18% of patients in our study had acceptable levels of serum phosphorus between 3.5-5.5 mg/dl. Majority of patients had the values outside the acceptable levels, with 28.24% below and 30.59% above the acceptable levels. In the study by FatemehHayati et al., all the patients had serum phosphorus levels >5.5 mg/dl.[1]

In our study mean iPTH value was 255.12 ± 231.75mg/dl.In Suresh Sankarasubbaiyyan et al.study, iPTH level was 124.6 ± 174.9 pg/ml.[5] In Walter G. et al. study, mean levels of iPTH was 529±567pg/ml.[2]

41.8% of our patients had intact PTH levels <150pg/ml, 22.35% had between 150 to 300pg/ml and 36.48% of patients had more than 300pg/ml. Majority of our patients (77.66%) had iPTH levels outside the acceptable levels. In Study by Sanjay Vikrant et al., 53.1% of patients had hyperparathyroidism with iPTH levels >300pg/ml.[6] In our study 30.59% of patients had serum iPTH levels <100pg/ml which is similar to study done by Salim Lim et al., in which 30% of patients had iPTH<100pg/ml.[7]

In our study, majority of patients (52%) had vitamin D deficiency. The study by Sanjay Vikrant et al., showed that 87% of patients had vitamin D deficiency.[6] The mean level of serum alkaline phosphatase in our study was 137.79 ± 59.34 U/L. In Ghosh et al. study, mean levels of alkaline phosphatase were about 180U/L.[4]

A high prevalence of biochemical abnormalities of bone mineral metabolism was found in our study. 62.35% of patients had elevated alkaline phosphatase levels, 52.94% of patients had vitamin D deficiency, 41.18% of patients had iPTH levels <150pg/ml, 36.48% of patients had Secondary hyperparathyroidism with iPTH > 300pg/ml, 36.47% of patients had hypocalcemia, 30.59% of patients had iPTH levels <100pg/ml, 30.59% of patients had hyperphosphatemia, 5.88% of patients had hypercalcemia.

Agarwal et al. found hypocalcemia in 49.6% of patients.[8] Prevalence of secondary hyperparathyroidism in our study was 36.48%. Agarwal et al. found hyperparathyroidism in 39.4% of patients similar to our study.[8]30.59% of our patients had iPTH < 100pg/ml with more predilection for adynamic bone disease. In Suresh Sankarasubbaiyyan et al., study, 69.5% of patients had iPTH levels less than twice the normal range (<130pg/ml).[5]

Limitations of our study include the small sample size, cross-sectional methodology, overrepresentation of male patients. In addition, there was no documentation of dialysis adequacy in the study population and other markers of bone disease like bone histology.

To conclude, our study found a spectrum of mineral and bone disorders in patients with chronic kidney disease stage 5 on maintenance hemodialysis. Mean levels of phosphate, corrected calcium and calcium phosphorus product were in the acceptable levels in our study population. We also found many patients with vitamin D deficiency, secondary hyperparathyroidism, oversupression of iPTH, hypocalcemia, hyperphosphatemia in our dialysis patients.

Two fifth of patients (40%) had over-suppression of iPTH levels and a third of our patients on maintenance hemodialysis were at risk of developing adynamic bone disease.

We found a lower prevalence rate (36%) of secondary hyperparathyroidism in our study population.

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