

# Study of Clinical Profile and Management of Nephrolithiasis at Tertiary Care Rural Hospital of Central India.

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Study Protocol

Conflict of Interest: None

## ABSTRACT

**Background** :Renal stones are a major and a very common problem in today's world. They occur in every age group but the peak is seen in individuals aged between 20–49 years and more commonly among males. In developing countries, upper urinary tract stones have a less common incidence than compared to bladder calculi, while the opposite holds true for developed countries. With increasing prevalence renal stones are causing a significant burden on the economy of both developed and developing countries. Several studies have noted that nephrolithiasis are commonly seen in association with various non communicable diseases like type 2 DM , hypertension and obesity. It is also observed that certain lifestyle and environmental factors also contribute greatly in renal stones formation.

**Methodology**:A total of 40 patients of either sex , who are willing to undergo this observational study, will be enrolled in the study. Firstly, the patient's thorough history will be taken which includes his chief complaints. Athrough general examination of the patient will be done, followed by a detailed clinical examination. Patients will be first subjected to routine investigations like HB, TLC, DLC, PLATELETS, LFT, KFT, Blood sugar, Urine routine and microscopy then followed by special investigations like serum calcium, serum phosphate, Venous Blood Gas and bicarbonate. Patient will also be subjected to radiological investigation like X-ray KUB and ultrasonography of abdomen and pelvis, CECT KUB or IVP (depending on KFT).And depending on the condition of the patient the modality of management will be selected. If a patient undergoes surgical mode treatment then the stone will be sent for chemical analysis to find the Composition of stone.

**Conclusion** :Will be drawn after the study.

**Keywords** :Nephrolithiasis, renal stones, systemic diseases, lifestyle factors, chemical composition.

## INTRODUCTION :

Renal stones or Nephrolithiasis with its increasing prevalence has become a common problem worldwide. And thus imposing a significant burden on the economy of both

developing and developed nations. Several studies have noted that nephrolithiasis is commonly seen in association with various non communicable diseases like Type 2 DM , obesity, and hypertension.[1] It is also observed that various other factors like Lifestyle and environmental factors also make significant impact in their incidence . Renal colic usually has acute presentation therefore treatment is not delayed. More than 50% renal stones reoccur if no preventive measures are taken.[2]

Biochemical evaluation should be offered to every patient who has renal stones, in those without any positive familial history of renal stones and any other underlying biochemical abnormalities may be exceptions.[3] Biochemical evaluation helps us to decide the mode of management, drug of choices and their dosage. As many renal stones can be managed by fluid therapy alone. Significant biochemical abnormality is commonly seen in patients with either uric acid stones or cysteine stones.[4] Biochemical evaluation is must among those with a calcium stone, amongst those who have a history recurrent stones and those who have multiple or bilateral stones at their first presentation. It is often challenging to treat nephrolithiasis associated with obesity. Thus, to reduce the chance of any future surgical intervention in such challenging patients, biochemical evaluation is must as it may be helpful in preventing stone recurrence. Biochemical evaluation is also must in young patients with colic history as correctable abnormality is often found in these patients.[5]

## **EPIDEMIOLOGY**

Renal stones occur in every age group but the peak is seen in individuals aged between 20–49 years and more commonly among males than compared to females. Renal stones have a prevalence of 4-20% in developed nations and is estimated to increase to 56% by the year 2050 due the effects of global warming. In developing countries, upper urinary tract stones have a less common incidence than compared to bladder calculi, while the opposite holds true for developed countries.

Individuals with diabetes and obesity are more prone to suffer from renal stones. Nephrolithiasis has a very high relapse rate of about 50% within 5 years from the development of a primary stone. The underlying factors which determine the accelerated pace of stone formation in recurrent stone formers are not well known. Thus one cannot predict which patient might relapse in a single stone former. However in a patient with recurrent stone will require much more careful diagnostic evaluation and early treatment.[6]

## **PATHOPHYSIOLOGY**

Insoluble salts present in the urine act as a platform or a base for the formation of renal stones. There are two basic mechanisms by which they are formed and they are as follows

The salts present in urine precipitate and result in crystals formation which aggregate with protein or the matrix which is the non-crystalline part. The salts that are present in urine crystallize later aggregate and form a mass which then grows further to cause symptoms.[7]

The other mechanism is mostly responsible for formation of calcium oxalate stones, here the stone materials deposits form a plaque known as Randall's plaque. Though they are made up of different substances, the majority of stones are composed mostly of calcium salts. Cystine, struvite stones composed of magnesium ammonium phosphate, Uric acid, contribute to rest all stones.[8]

Renal stones can be divided into various types depending the substance of which they are composed of :

- Calcium oxalate stones
- Calcium phosphate stones
- Uric acid stones
- Struvite stones
- Cystine stones

A patient with nephrolithiasis presents with various symptoms but most common and classical symptomatology includes

- Loin pain
- Burning micturition
- Fever with chills and rigors
- Haematuria

#### SIGNS IN A PATIENT OF NEPHROLITHIASIS.

Renal angle tenderness is an very important sign of renal colic

**RATIONALE :**The principle goal behind this study is to understand the clinical profile of patients with nephrolithiasis there by estimating prevalence of different types of stones in various age groups,sex and to also understand which modality of treatment is best for them.

### AIM AND OBJECTIVES

#### AIM

To study the clinical profile and management of nephrolithiasis at tertiary care rural hospital of central India.

#### OBJECTIVES

Primary objectives

1. To study the demographic profile of patients of nephrolithiasis.
2. To study the clinical presentation.
3. To study the radiological findings and biochemical parameters.
4. To study the treatment modalities in patients of nephrolithiasis.

Secondary objective

1. To study the biochemical composition of stone in operated patients of nephrolithiasis.

### MATERIALS AND METHODS

Study design:

1. Study period : September 2020 to October 2022
2. Study area : department of General Surgery JNMC &AVBRH.
3. Study design : prospective observational study.
4. Study population: Patients, 20-60yrs of age of either gender.

### **Study Settings:**

After the approval of the ethics and screening committee of Jawaharlal Nehru Medical College, DMIMS (DU), Acharya Vinoba Bhave Rural Hospital (AVBRH), Datta Meghe Institute of Medical Sciences, Sawangi (M), Wardha. This study will be conducted on 40 individuals.

Written and informed consent will be obtained from all the patients prior to study.

### **PARTICIPANTS**

#### **Inclusion Criteria:**

- All patients of renal calculi included.

#### **Exclusion Criteria:**

Patients not willing to participate in the study

### **DATA SOURCE AND MEASUREMENTS:**

DATA SOURCE : AVBRH, Sawangi Meghe, Wardha

DATA MEASUREMENTS: HB, TLC, DLC, PLATELETS, LFT, KFT, Blood sugar, Urine routine and microscopy.

Serum calcium, serum phosphorus, Venous Blood Gas and bicarbonate.

Radiological investigation - X-ray KUB and ultrasonography of abdomen and pelvis, CECT KUB or IVP (depending on KFT).

stone will be sent for chemical analysis .

Sample Size: 40

Sample size formula with desired error of margin

$$n = \frac{Z^2 \alpha/2 p (1-p)}{d^2}$$

Where

Z  $\alpha/2$  is a level of significance at 5% i.e.

95% confidence interval – 1.96

p = Prevalence = 25.8% / lakh population

= 0.058/1000 population = 0.0258

d = Desired error of margin = 5% = 0.05

$$n = \frac{1.96^2 \times 0.0258 \times (1-0.0258)}{0.05^2}$$

= 38.62

□ n = 40 patients need in the study

Materials (Study Subjects): In the present study patients coming to OPD/IPD with symptoms or signs suggestive of nephrolithiasis will be included in the study.

## **METHODOLOGY :**

A total of 40 patients of either sex , who are willing to undergo this observational study, will be enrolled in the study. After obtaining written in- formed consent,

Firstly, the patient's thorough history will be taken which includes his chief complaints such as loin pain, burning micturition , fever with chills if any episodes present and hematuria , history of the presenting illness, past history, if any existing comorbidities are present, any familial history with similar complaints are present, personal history and medication history will be noted. A through general examination of the patient will be done, followed by a detailed clinical examination.

Patients will be first subjected to routine investigations like HB, TLC, DLC, PLATELETS, LFT, KFT, Blood sugar, Urine routine and microscopy then followed by special investigations like serum calcium, serum phosphate, Venous Blood Gas and bicarbonate. Patient will also be subjected to radiological investigation like X-ray KUB and ultrasonography of abdomen and pelvis, CECT KUB or IVP (depending on KFT)

And depending on the condition of the patient the modality of management will be selected. If a patient undergoes surgical mode treatment then the stone will be sent for chemical analysis to find the Composition of stone.

## **STATISTICAL METHODS:**

Analysis will be done with intention to treat principles. All participants with available data at baseline and follow up visits will be included. The impact of missing values will be explored in sensitivity analysis. The data will be entered into the Excel spread sheets and statistical analyses will be conducted using SPSS software. Descriptive analyses of age, sex, and treatment compliance will be performed. The histogram will be plotted to observe the distribution of all the variables and continuous variables which are normally distributed will be described using mean and standard error. The effect size will be expressed in terms of relative risk and risk difference along with their 95% confidence interval

**EXPECTED OUTCOME:** Will be assessed after the study.

## **DISCUSSION:**

Prakash Mathiyalagen et al [9] conducted a case control study in coastal regions of India to study the effects of certain biological and environmental factors like sex, literacy, BMI, water consumed daily in the formation of renal stones. Their study showed significant co relation between renal stones formation and various biological and environmental factors such as female sex, illiteracy, body mass index greater than 25, less than 1.5 l/day of water is consumed and family history of renal stones. They concluded that in the areas selected for their studies i.e. coastal parts of India, there is a significant increase in the risk of developing renal stone disease amongst female gender, illiterate, individuals with high BMI, those who consume inadequate water, and in those with a familial history of renal stones.

Trinchieri A. Et al [10] conducted a study over a period of ten years to know the cause of increased prevalence of symptomatic urinary tract stones. They have observed that the prevalence of upper urinary tract stones has shown a continuous increase throughout the 20th

century, but they also observed that there was a considerable difference amongst various countries and also within the same country. They carried out this study in Italy over a two time periods between 1986 and 1998. The study population was asked various questions about previous history of kidney stones in their lifetime. The results of this study was such that The overall prevalence of stone formers among males was 6.8% in 1986 and 10.1% in 1998; that among females was 4.9% in 1986 and 5.8% in 1998. In all age groups. The stone prevalence had shown a significant increase in 1998 than compared to 1986. The yearly incidence was estimated at 0.4%, with 0.6 and 0.18% in men and women, respectively. This study concluded that the significant increase in prevalence of renal stones might be due to environmental factors. Dietary habits and changing lifestyles of individuals. They also concluded that there is a great significant positive association between Dietary habits such as animal protein consumption and stone formation.

G C Curhan et al [11] conducted a study in 1997 to identify how one's positive family history of renal stones increased their own risk of developing renal calculi. Kidney stones are seen to develop more frequently in those persons with positive familial history of renal calculi than compared to those without any positive familial history. However very little information is available about this pattern of increased prevalence ie. based on familial history. Is it attributable to genetic factors, environmental exposures and any other possible cause or exposure. In this report, the relation between family history and risk of kidney stone formation was studied on 37,999 male participants in the Health Professionals Follow-up Study. During their study period of 8 years around 800 cases were documented. After adjusting various other factors Information about any positive family history of kidney stone formation, the relative risk of incident stone formation in men with a positive family history, compared with those without, was 2.57 (95% CI, 2.19 to 3.02). From their observational study they have concluded that a positive family history significantly increased the incidence of renal stones. In addition they have also observed that dietary calcium restriction may increase the risk of stone formation, even among individuals with a family history of kidney stones. Many interesting studies related to chronic kidney diseases were reported by Balwaniet. al. [12-16]. Other related studies were reviewed [17-20].

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