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"A Clinical Study to Evaluate Efficacy of CAP . Ashma - 6 Hypothetical and Varunadi Kashya in the Management of Mootra Ashmari W.S.R.To Urolithiasis "-A Research Article

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Abstract: Mutrasmari is one of the most common urinary disorders . Acharya Susruta , the pioneer in the art and science of surgery has described widely and comprehensively About Mutrasmari along with its classification , symptomatology , etiology , pathology , complications and its management.³ Formation of urinary calculi is described in Ayurvedika scriptures Mutrasmari . The diagnostic part in case of calculi by ancient Acharya seems to be true even at present . Formation ofMutrasmari , according to Susruta , is due to SrotoVaigunya resulting from DusitaKapha localized in Basti , in conjunction with PradusitaVata and Pitta . Mootraashmari or urinary stone is a most painful & common disease in our country & pain due to kidney stone is known as worse condition than that of labour pain It is the third most common disease of the urinary tract . Mootraashmari is very high incidence occurring due to the high mineral content of water and hot climate.
Key points: Asmari, Ashma -6 , Varunadi kashya,

I. INTRODUCTION

Ayurveda is the most to enhance the perception of Ayurveda towards humanity ancient of all medical sciences . Ayurveda ,the system of Indian medicine and science of life deals with the wellbeing of mankind . The three great authors namely ***Caraka*** , ***Susruta*** and ***Vaghhara*** followed the scientific methods of study Calculi is known to mankind since times immemorial . Clinical features of the disease are described even in Veda , the oldest repositories of human knowledge . ***Susruta*** the father of surgery explained urinary calculus under the heading of Asmari in details including etiological factors , classification , symptomatology , pathology , complications and its management in a most scientific manner . This disease is dreadful and hence considered one of the " Mahagada ' by Susruta , may be owing to its potentiality to disturb the anatomy and physiology of urinary system | 3

Mutrasmari is one of the most common urinary disorders . ***Acharya Susruta ,*** the pioneer in the art and science of surgery has described widely and comprehensively About Mutrasmari along with its classification , symptomatology . etiology , pathology , complications and its management Formation of urinary calculi is described in Ayurvedika scriptures Mutrasmari . The diagnostic part in case of calculi by ancient Acharya seems to be true even at present . Formation ofMutrasmari , according to ***Susruta*** , is due to SrotoVaigunya resulting from DusitaKapha localized in Basti , in conjunction with PradusitaVata and Pitta Mootraashmari or urinary stone is a most painful & common disease in our country & pain due to kidney stone is known as worse condition than that of labour pain It is the third most common disease of the urinary tract . Mootraashmari is very high incidence occurring due to the high mineral content of water and hot climate.

About 30 % patients of urinary disorders are found suffering from urolithiasis . In India approximately 5-7 million patients suffer from mutraashmari& at least 1/1000 of Indian population need to hospitalization due to kidney stone disease . The process of urinary stone formation as described by Sushruta is as follows.

In Asanshodhanasheela persons , one who does not follows Shodhana (purification) treatment and who is Apathyakaari (uses un whole some items) . ShleshmaDosha gets aggravated , and saturates the urine in system . This saturated urine (ShleshmaYuktaMootra) is the material (cementing substance) which causes urinary stone formation . Through urine different stone forming Doshas - like Vaata , Pitta &Kapha come from the system and along with the cementing substances they ! form urinary stone of particular Dosha involved .

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Modern science consider the involvement of various type factors like heredity , age , sex , metabolic disorders , sedentary life style , hydration status , mineral content of water nutritional deficiency . etc for urinary stone formation . Urolithiasis typically occurs in middle age 30-45

1) Management of various types of Ashmari has been described in ***Sushruta Samhita*** in view of the fatality of the disease . Treatment has been advised to be three types of calculi undertaken in the early stages of the disease . Ghrita recipes have been mentioned along with indication of appropriate food , drinks and other measures . Indication for the surgical management has been given along with a note of caution regarding its dangers and doubtful chances of success . It was to be undertaken only on failure of conservative treatment and when death was inevitable if not treated surgically .
2) Western medical field also did a lot of research work in the field of urinary calculi and even in surgical line of treatment for the same .
3) However these therapies are curative treatment of urolithiasis but cannot avoid thepathogenesis behind the formation of stone . So recurrence of stone even after removal is becoming a great problem and constant efforts are being made to evolve an effective treatment as well as prevention of recurrence of the disease . There are various useful management and herbal treatments for urolithiasis
4) These factors invite the need of an effective medicinal treatment for urolithiasis with least chances of recurrence .
5) Urolithiasis is one of the most common among Mootraashmari and very well explained in ayurvedic texts .
6) Thus in order to prove the significance of ayurvedic system of medicine inmootraashmari the present study " A CLINICAL STUDY TO EVALUATE EFFICACY OF CAP . ASHMA - 6 HYPOTHETICAL AND VARUNADI KASHYA IN THE MANAGEMENT OF MOOTRA ASHMARI W.S.R.TO UROLITHIASIS " hasbeenplanned and carried out with the following aims and objectives .

II. AIMS & OBJECTIVES

To study the etiopathogenesis of Mootraashmari in detail according to Ayurveda and modern. 2.To evaluate the efficacy of cap . ashma - 6 &varunadikashya and in the management of mootraashmari .

A. Etiopathogenetic

The manifestation of any disease is described in five steps in Ayurveda that are Nidana , Purvarupa , Rupa . Upashaya and Samprapti . These are the five steps which helps the physician / surgeon to reach at a proper diagnosis .
Nidana includes all the etiological factors . The knowledge of Nidana is helpful for the proper diagnosis , prevention of disease and treatment , According to Ayurveda AaharaVihara and Manasika Bhava are considered as Nidama for the manifestation of a disease .
Acharya Sushruta has described the causative factors of Mutrashmari separately , while Charaka and Kashyapa included under Mutrakrichchhra.
In those patients , who do not undergo Shodhana therapy and in those who are indiscrete regarding their dietary habits or one who takes unwholesome food.
AcharyanSushruta , Charaka and Vagbhatta have similarly explained the process of Ashmari formation by citing different examples viz–

B. Sushruta's View

Either Tridosha or Kapha gets aggravated in the persons who do not undergoes Shodhana procedures and uses unwholesome diet and mixes with Mutra , enters into Basti and takes the shape of an Ashmari.
As clear water kept in a new pitcher gets muddy in due course of time . similarly calculus is formed in Basti.
Acharya Sushruta has given another example to explain the Ashmari formation . The way in which the air and electricity produced by thunders during rain freezes the water , similarly Pitta located in the bladder , in conjugation of Payaw consolidates Kapha (to form Ashmariy.
The Pitta and Kapha produced in excess by their specific Naidanika factors combines with each other and localized in the urinary system and get precipitate specially at bladder neck and obstructs the bladder outlet.
In the classical texts , many preparations have been mentioned for the treatment of Mutrashmari (urolithiasis) , out of which for the present study two compound drugs are used for the clinical trial .

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They are-

1) *Cap . ASHM -6 (HYPOTHETICAL)*

Cap . Ashma - 6 contains the following drugs :

S.N	Drug name	Botanical name	Part used	Quantity
1.	Tila	Sesamumindicum	Panchang	1 part
2.	Apamarg	Achyranthesaspera	Panchang	1 part
3.	Kadali	Musa aradisiaca	Moola	1 part
4	Palash	Butea monosperma	Panchang	1 part
5.	Amalaki	Emblicaofficinalis	Panchang	1 part
6.	Yava	Hordeumvulgare	Panchang	6 part

2) *Varunadi Kashay*

Contains the following drugs

S.n	Drug name	Botanical name	Part used	Quantity
1.	Varuna	Crataevareligiosa	Bark	1 part
2.	Paashanbhed	Berginialigulata	Leaf	1 part
3.	Sunthi	Zingiberofficinale	Kand	1 part
4.	Gokshur	Tributes terrestris	Moola	1 part
5.	Yavakshara	KOH		0.25 part

3) *Clinical Study*

III. MATERIALS AND METHODS :

A. *Selection Of Patients*

1) The patients attending O.P.D. & I.P.D. of Govt . M.M.M. hospital Udaipur were selected for the present clinical study single Centre or Multiple center.
2) All the patients in the present study were selected irrespective to age , sex , Clinical Study religion , occupation etc.

B. *Inclusion Criteria*

1) Age between 18 to 70 years
2) Ultra sonological evidence of single calculus / multiple calculi 10 mm , present in kidney (s) / ureter (s) / urinary bladder .
3) Willing and able to participate for study .
4) Patients with signs and symptoms of Mutrashmari will be included in the study

C. *Exclusion Criteria*

1) Age less than 18 years and more than 70 years .
2) Patients with obstructive uropathy .
3) Patients suffering from any major systemic diseases like Diabetes Mellitus , Hypertension , Renal failure etc.
4) Altered Renal functions.

D. *Criteria For Withdrawal*

1) If any serious condition or any serious adverse effects appear during the course of study which requires urgent treatment .
2) If patient wants to withdraw him / herself from the clinical study .

E. *Sampling Technique*

A total number of 30 patients with signs and symptoms of Mutrashmari were registered treated with Cap . ASHMA - 6 & VARUNADI KASHAY .

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Drugs and posology

Drugs	Ashma-6	Varunadikashaya
Content	Tila,apamarg,kadali,Palash amalaki,yavakshara	Varun,paasanbhed, Shunthi,gokshura
Dose	500 mg. B.d	20 ml b.d
Duration	45 days	45 days
Sahapna	Luke water	---------

F. Plan Of Work

The study was carried out as follows –

1) Performa

A special perform was prepared on the basis of signs and symptoms of Mutrashmari and Urolithiasis described in Ayurvedic and modern text respectively to maintain the records of all findings regarding the patients .

2) Informed Consent

Written informed consent was taken from each patient before starting thestudy .

Following investigations had been performed according to the requirement .

■Urine routine and microscopic ■X - ray KUB

■ U.S.G. KUB ■ C.B.C ■ E.S.R

■Sr. albumin ■Sr . Uric acid ■ Sr. urea

■Routine Urine Examination ■ IV.P (if needed)

3) Assessment

The observations were noted down regularly on 15th and 30 thday.

4) Follow up

Every 15 day for further 45 day .

G. Criteria for Assessment

Most of the sign.s and symptoms of Mutrashmari described in Ayurveda are subjective in nature , to give the results objectively and for statistical analysis multidimensional scoring system have been adopted . The symptoms score obtained after treatment , statistical analysis and percentage relief was taken to know the efficacy of therapy . Score was given according to severity of symptoms .

H. Subjective Criteria

Assessment of the therapy was done according to the relief observed in the signs and symptoms , with the help of scoring pattern .

The details of the scores adopted for the chief signs and symptoms in the present study were as follows –

1) Pain

- No pain - 0
- Occasional pain which require no treatment - 1
- Occasional pain requiring treatment - 2
- Constant dull pain requiring treatment - 4
- Constant severe pain , not relieved even after treatment - 5

2) Burning Micturition

- No burning micturition - 0
- Occasional burning micturition which require no treatment - 1
- Occasional burning micturition requiring treatment -2
- Constant burning micturition requiring treatment -3
- Constant severe burning micturition not relieved even after treatment - 4

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3) Dysuria

- No dysuria - 0
- Occasional dysuria which require no treatment - 1
- Occasional dysuria requiring treatment - 2
- Constant dysuria requiring treatment - 3
- Constant severe dysuria not relieved even after treatment -4

4) Tenderness Inrenalangle

- No tenderness - 0
- Mild tenderness - 1
- Moderate TENDERNESS - 2
- Severe tenderness -3

5) Hematuria : On The Basis Of Microscopic Urinalysis

- No RBC / Hpf - 0
- 1 – 5 RBC / Hpf - 1
- 6 – 10 RBC / Hpf - 2
- 11- 15 RBC / Hpf - 3
- > 15 RBC / Hpf - 4

6) Pus Cells : On Basis Of Microscopic Urine Analysis

- **No**puscell /Hpf - 0
- **0**- 5 pus cell / Hpf - 1
- 6- 10 pus cell / Hpf - 2
- 11 – 15 pus cell / Hpf - 3
- > 16 pus cell /Hpf - 4

7) Size of Calculus - On the Basis of USG KUB

In case of multiple calculi maximum size of Calculus has been considered as size of Calculus for statistical analysis.

No change 0

Decrease 1.5 – 2.5 1
2.6 to 3.5 2
3.6 to 4.5 3
4.6 to above 4

8) Statistical Analysis

The information gathered on the basis of various parameters was subjected to statistical analysis in term of meaning, standard deviation and standard error. Wilcoxon matched-pairs signed – ranks test was carried out within the group. The obtained results were interpreted as –

P value	Wording	Summary
< 0.0001	Extremely significant	****E.S
0.0001 to 0.001	Extremely significant	*** E.S
0.001 to 0.01	Very significant	** V.S
.01 to 0.05	significant	*S
>0.05	Not significant	N.S

I. Criteria For Result

For the assessment of the total effect of the therapy following four categories were taken into considerations by comparing assessment done on 1 day with the assessment done on 45th day.

- Good response : 75 % and above relief in presenting signs and symptoms of the disease.
- Fair response : 50 % to 74 % relief in presenting signs and symptoms of the disease.
- Poor response : < 50 % relief in presenting signs and symptoms of the disease .
- No response :- No relief in presenting signs and symptoms of the disease .

IV. OBSERVATIONS AND RESULTS

A. Effect Of Therapies

30 patients included in present study . In this part , the effect of therapies on cardinal sign & symptoms has been assessed by giving a specific gradation to these symptoms which has been made by applying appropriate statistical test .

1) Subjective parameters : The result were assessed by applying (Mann - Whitney test) .

2) The various laboratory investigation before & after the treatment were assessed statistically . Unpaired T - test applied for assessment of data according to that , result have been made .

For calculation of statistical values in the following tables , following abbreviation is being used:

- H.S.= Highly significant
- V.S. = Very significant
- N.S.= Not significant
- S. = significant

B. Effect of Therapy on General Symptoms

It has been explained in the criteria of assessment that the effect of therapy will be evaluated on clinical features by adopting score system which is described in the criteria of assessment . These symptoms were pain , (Nabhivedana , bastivedna , sevanivedna , mehanavedna) , burning urination , tenderness in renal angle , dysuria , frequency of micturition , haematuria , pus cell in urine , Stone size reduction , Each of these symptoms was assessed before the start of treatment as well as after the completion of treatment Relief in the symptoms score calculated with the help of percentage described .

It could be comprehended that more percentage of relief in the symptomsscore was observed in the symptoms .

V. RESULT

All the Results are calculated by using Software : Graph pad in stat 3 ....

For Nonparametric Data Mann - Whitney Test is used while for Parametric Data Paired ' Test is used and results Calculated.

Tables showing the effect of clinical recovery of subjective parameters in 30 patients in Mutrasmari .

Table - 15 : Effect of therapy on subjective criteria in 30 patients of Mutrashmari

variables	Mean			% Relif	±S.D	SE	P	Sig.
	B.T	A.T	Diff.					
Pain	1.56	0.466	1.100	70.21	0.069	0.0111	<0.001	H.S
Burning urination	0.73	0.133	0.6	81	0.394	0.0718	<0.001	H.S
Dysuria	0.73	0.233	0.533	72	0.25	0.455	<0.001	V.S
Tendernss in renal angle	1.20	0.333	0.866	72.22	0.0047	0.0008	<0.001	H.S
Frequency of micturation	0.93	0.400	0.533	57.12	0.22	0.041	<0.001	H.S

1. The data reveals that maximum relief in pain was found in the patients of 70.21 % , there was highly significant . Mann - Whitney U - statistic = 98.00 , P value < 0.0001
2. The data reveals that maximum relief in burning micturition was found in the patients of 81 % , there was highly significant . Mann - Whitney U - statistic = 234.00 . P value < 0.0002 .
3. The data reveals that maximum relief in Dysuria as found in the patients of 72 % , there was very significant . Mann - Whitney U - statistic = 256.00 , P value < 0.0011 .
4. The data reveals that maximum relief in Tenderness in renal angle was found in the patients of 72.22 % , there was highly significant . Mann - Whitney U - statistic = 130.00 , P value < 0,0001
5. The data reveals that maximum relief in Frequency of micturition was found in the patients of 72.22 % , there was highly significant . Mann - Whitney U - statistic 273.00 . P value = < 0.0018

Table - 16 : Effect of therapy on objective criteria (Non parametric data) in 30 patients of Mutrashmari

Variables	Mean			%Relief	±SD	SE	P	Sig.
	B.T	A.T	Diff.					
Stone size reduction	3.5	1.75	1.8	51.42	1.02	0.189	<0.001	H.S
Haematuria	0.57	0.100	0.46	80.70	0.47	0.422	<0.002	V.S
Pus cell in urin	1.16	0.53	0.63	54.24	0.33	0.06	<0.008	V.S

The data reveals that maximum relief in Stone size reduction was found in the patients of 51.42 % , there was highly significant . Mann - Whitney U - statistic 196 , P value < 0.001 .

2. The data reveals that maximum relief in Haematuria was found in the patients of 80.70 % , there was very significant . Mann - Whitney U - statistic 307.50 , P value < 0.028 .

3. The data reveals that maximum relief in pus cell in urine was found in the patients of 54.24 % , there was very significant . Mann - Whitney U - statistic = 299.50 , P value < 0.008 .

Table -17: Effect of therapy on objective criteria (parametric data)in 30 patients of

Variables	Mean			% Relif	±SD	SE	T	P	Sig.
	B.T	A.T	Diff.						
Serum creatinine	0.91	0.62	0.3	32.96	0.23	0.04	7.17	<0.001	H.S
Effect on Hb	12.58	12.56	0.017	0.017	0.85	0.15	0.107	0.46	N.S
Effect on TLC	6943	6790	144.67	2.08	359.94	65.71	2.20	0.017	S
Effet on ESR	25.53	22.83	2.70	10.57	2.40	0.43	6.13	<0.001	H.S
Effect on uric acid	4.26	3.77	0.49	11.50	0.319	0.058	8.43	<0.001	H.S
Effect on calcium	9.27	8.38	0.89	9.6	0.4925	0.089	9.58	<0.000	H.S
Effect on albumin	4.73	4.41	0.32	6.76	0.229	0.041	7.65	0.001	H.S

Mutrashmari-

4. The data reveals that maximum relief in serum creatinine was found in the patients of 32.96 % , there was highly significant . Paired T test , P value < 0.0001 , T value = 7.17 .

5. The data reveals that maximum relief in Haemoglobin was found in the patients of 0.14 % , there was no significant . Paired T test , P value < 0.46 , T value = 0.107 .

6. The data reveals that maximum relief in TLC was found in the patients of 2.08 % , there was significant . Paired T test , P value < 0.017 , T value = 2.20 .

7. The data reveals that maximum relief in ESR was found in the patients of 10.57 % , there was Highly significant . Paired T test , P value < 0.001 , T value = 6.139

8. The data reveals that maximum relief in Uric acid was found in the patients of 0.14 % , there was Highly significant . Paired T test , P value < 0.001 , T value = 8.43 .

9. The data reveals that maximum relief in Serum calcium was found in the patients of 9.6 % , there was highly significant . Paired T test , P value < 0.0001 . T value = 9.58 .

10. The data reveals that maximum relief in Albumin was found in the patients of 6.76 % , there was highly significant . Paired T test , P value < 0.46 , T value = 7.65 .

Table : 18 Overall effect of therapy on 30 patients of Mutrashmari

Results	Number of patients	⁒ Relief
Cured	15	50
Moderate improment	03	10
Mild improment	09	30
No changed	03	10

- Cured : Complete relief in signs and symptoms along with expulsion and disintegration of Mutrashmari.
- Moderate Improvement : 51-75 % relief in signs and symptoms along with disintegration of Mutrashmari .
- Mild Improvement : Up to 50 % relief in signs and symptoms along with disintegration of Mutrashmari .
- Unchanged: no change

The data of the present study shows that 15 patients (50 %) showed cured , 03 patients (10 %) showed Moderate improvement , 09 patients (30 %) showed Mild improvement and 03 patient (10 %) showed no response .

VI. DISCUSSION

The urological problems form an important part of medical deliberations . Perhaps , this can be the reason for detailed description of the urinary system related disease i.e. Mutrashmari - Urolithiasis in our Ayurvedic texts . Old literature gives a clear idea of disease that ithas come into existence from the very beginning. The clear cut cause of the disease is still unknown . But in Ayurveda , Kaphadosha in increased quantity has been accepted as the main reason for the formation of Mutrashmari . Where as in Modern Science they have considered so many causative factors for the stone formation , but stone has been seen even in those patients also , where those factors were not present . So in total , the etiology of the disease is still unknown . The frequency of occurrence of acute and chronic renal disorders has increased significantly in recent years due to changes in the environmental condition and dietary habits . Medical treatment is not satisfactory in many of the cases . Hence it would be highly desirable to have nephroprotective drugs in the therapeutic armamentarium . Although many advances have been made in this identification of risk factors for stone formation , there is as yet proven preventive or medical treatment . If we find out indigenous medicine that simply dissolve or expel the stone , it will be great achievement for a country like India .

So this problem was selected for the present study taking all these points into effective consideration .

A. Discussion on Clinical Study

In the present clinical study , 30 patients of Mutrashmuri was studies treated by

1) Cap . ASHMA - 6

2) VARUNADI KASHYA.

B. Discussion on Results

◇Effect of therapy on subjective criteria :

Effect of therapy in : (EFFICACY OF CAP . ASHMA - 6 & VARUNADI KASHYA) provided highly significant relief in pain 70.21 % & burning micturition 81 % , tenderness in renal angle 72.22 % , frequency of micturition 72.22 % relief .

VII. CONCLUSION

At this particular moment the fruitful conclusions which have automatically emerged through the discussion of the available concepts and obtained data are being presented below:

1) From the study of ancient surgical treatise , it becomes evident that the urological problems form an important part of medical deliberations . The concepts of Mutrashmari , its classification , symptomatology , etiological factors , pathology , complications and management have been dealt with both medico - surgical procedures .

2) The study suggests that Mutrashmari occurs in both sexes but most commonly observed in the male in between 31-40 years age group .

3) Higher incidence of Mutrashmari is observed in Hindu religion .

4) Middle class and sedentary life style of persons were more prone to the disease .

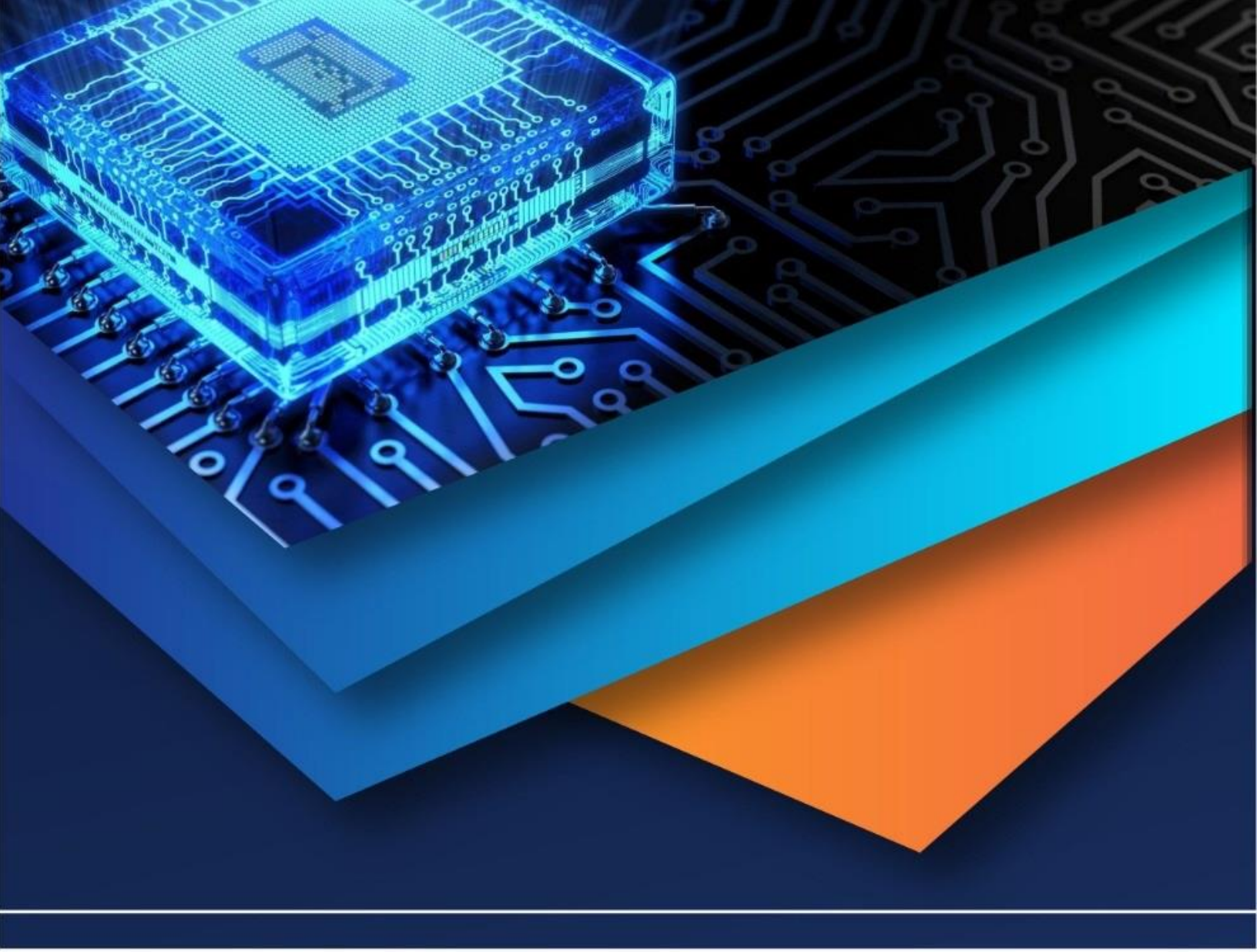
5) Maximum number of patients observed with Multiple renal calculus of size between 4.6-10 mm .

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