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# Controlled Trial in 100 Cases with Nephro-Uretero-Lithiasis by Cystone - An Indigenous Drug and Other Advocated Methods

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## INTRODUCTION

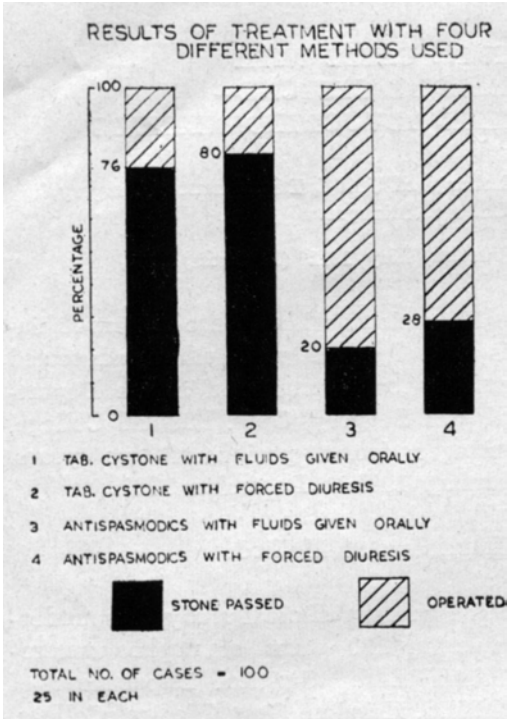
Frere Jacques, that famous lithotomist of middle ages, used to say, "I have removed the stone, but God will cure the patient" (Bailey and Love, 1976). With the advance of knowledge, however, the subject of nephrolithiasis has become a complicated one, as regards its aetiology and treatment. Current opinion about its aetiology is varied *viz.* Dietetic, altered urinary solutes and colloids, decreased urinary output of citrate, renal infection, inadequate urinary drainage, prolonged immobilization, hyperparathyroidism and Randall's plaque microliths. Again, during treatment the clinician is often faced with the problem, "How to treat a patient with small renal calculi and ureteric calculus -conservatively or surgically?"

Small renal calculi and in many cases ureteric calculi are known to pass spontaneously, however, a good number of cases require surgery. Antispasmodics, used for the relief of ureteric colic to facilitate the passage of calculi, have a limited scope. "Forced Diuresis" to assist the passage of small, renal and ureteric calculi has remained under clinical trial for the last few years and the result claimed are controversial.

However, an indigenous drug, Cystone has proved a promising means of medical treatment for eliminating renal calculi and ureteric calculi. In order to evaluate the efficacy of Cystone, "A controlled trial in 100 patients with nephro-uretero-lithiasis by Cystone and other advocated methods", was conducted in the Department of Surgery, Govt. Medical College, Srinagar for a period of two years, January 1979 to December 1980.

## MATERIAL AND METHODS

The present clinical study was undertaken on 100 cases of nephro-uretero-lithiasis in the Surgical Department of S.M.H.S. Hospital, Govt. Medical College, Srinagar from 1st January 1979 to 31st December 1980. Patients of all ages and both sexes were selected for the study. A detailed history and thorough clinical examination was done in all the cases. The diagnosis of nephro-uretero-lithiasis was made by doing KUB and IVP studies of these patients.




These 100 cases of nephro-uretero-lithiasis were divided into four equal groups of 25 cases each for the purpose of treatment and to evaluate the effectiveness of these four methods in the treatment of small renal calculi and ureteric calculi.

Group -I cases (25) were given tablet Cystone in the dosage of 2 tablets 3 times a day for a period of 2 to 6 months. These patients were also encouraged to take

plenty of fluids by mouth.

Group - II cases (25) were given tablet Cystone in the dosage of 2 tablets 3 times a day for a period of 2 to 6 months. These patients were also put on forced diuresis (Fluids viz. 5% dextrose and dextrose saline and frusemide intermittently during this period).

Group - III cases (25) were given antispasmodics (tablets in mild cases and parenteral injections in cases of severe colic). These patients were also encouraged to drink plenty of fluids. The cases were followed up for the period of one year.

Group - IV cases (25) were put on antispasmodics (tablets in mild cases and parenteral injections in cases of severe colic). These patients were also put on forced diuresis (I.V. Fluids viz. 5% dextrose and dextrose saline and I.V. frusemide intermittently). The cases were followed up for the period of one year.

Repeated X-rays (KUB and IVP in suitable cases) were taken in these 100 cases at intervals of 4 weeks during the follow-up studies to compare the effectiveness of each method used in the expulsion of small renal calculi and ureteric calculi.

*Each tablet of Cystone contains*:

| | |
|---|---|
| Exts: Didymocarpus pedicellata | 65 mg |
| Saxifraga ligulata | 49 mg |
| Rubia cordifolia | 16 mg |
| Cyperus scariosus | 16 mg |
| Achyranthes aspera | 16 mg |
| Onosma bracteatum | 16 mg |
| Vernonia cinerea | 16 mg |
| Shilajeet (Purified) | 13 mg |
| Hajrul yahood bhasma | 16 mg |

Hajrul yahood bhasma is prepared with Ocimum basilicum, Tribulus terrestris, Mimosa pudica, Dolichos biflorus, Pavonia odorata, Equisetum arvense, Tectona grandis seed.

**OBSERVATIONS**

The age and sex distribution are shown in Tables I and II.

**Table I: Age distribution**

| Age group (in years) | No. of cases | Percentage |
|---|---|---|
| 10 – 20 | 21 | 21.0 |
| 21 – 30 | 33 | 33.0 |
| 31 – 40 | 20 | 20.0 |
| 41 – 50 | 16 | 16.0 |
| 51 – 60 | 10 | 10.0 |
| Total | 100 | 100.0 |

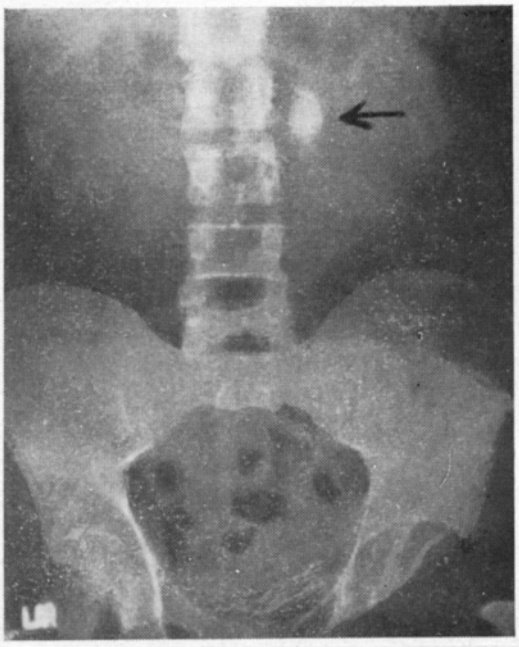


*Fig. I A*
Left ureteric calculus before Cystone therapy.



*Fig. I B*
Post-Cystone skiagram, showing that the stone has been expelled.

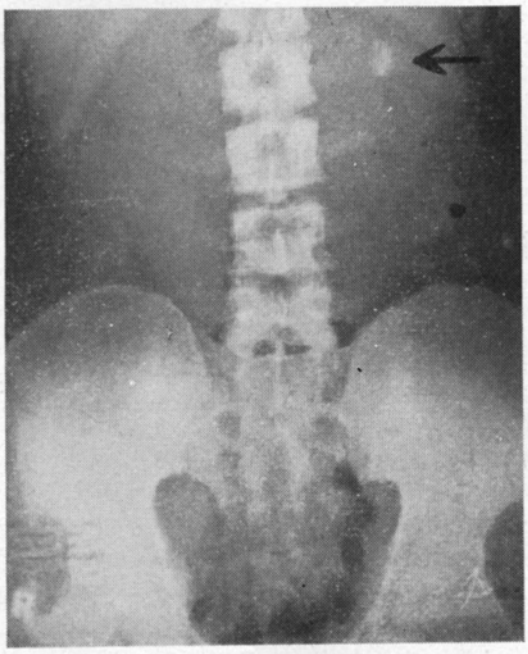


*Fig. II A*
Calculus at the (L) pelvic-ureteric junction before Cystone therapy.



*Fig. II B*
Post-Cystone skiagram, revealing the results of therapy (stone passed out).

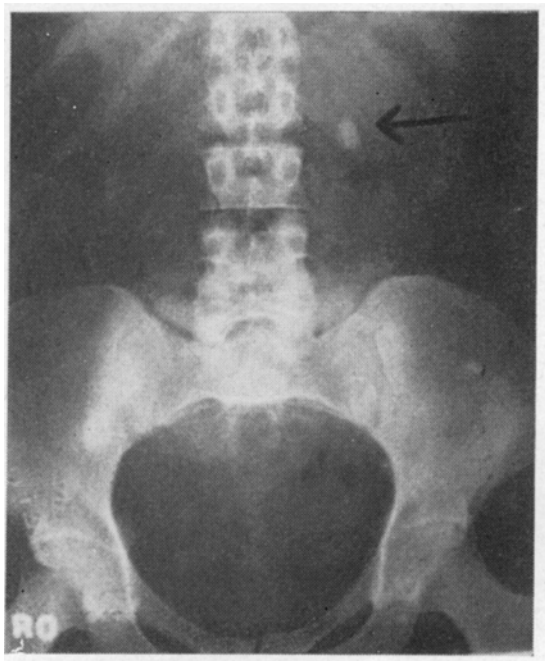


*Fig. III A*
(L) ureteric calculus (mid-ureter) before Cystone therapy.



*Fig. III B*
Post-Cystone skiagram, showing that stone has been passed out.

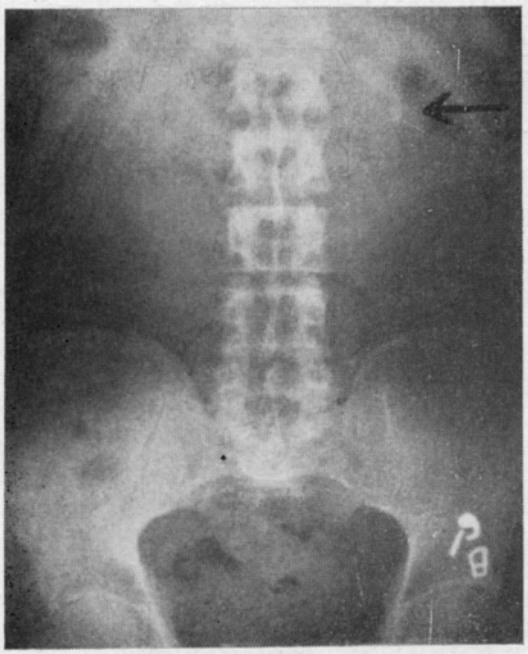


*Fig. IV A*
Pre-Cystone skiagram, with two small renal calculi (L) side.

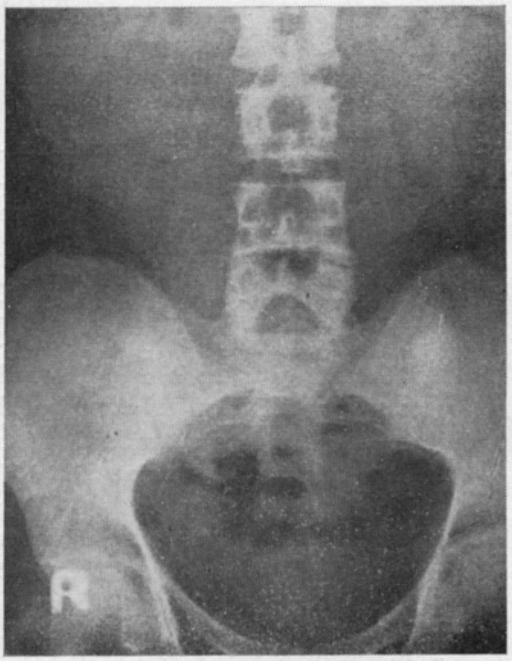


*Fig. IV B*
Post-Cystone skiagram, revealing a normal study (stones passed out).

| Table II: Sex distribution | | |
|---|---|---|
| Sex | No. of cases | Percentage |
| Male | 68 | 68.0 |
| Female | 32 | 32.0 |
| Total | 100 | 100.0 |

The sites of stone in the kidney and ureter are detailed in Table III.

| Table III: Site of calculus in the kidney and ureter | | | |
|---|---|---|---|
| | Site | No. of cases | Percentage |
| I | Kidney | 10 | 10.0 |
| II | Ureter | 90 | 90.0 |
| | a. Pelvic-ureteric junction | 64 | 71.1 |
| | b. Crossing the left iliac artery | 5 | 5.5 |
| | c. Juxtaposition of vas deferens or broad ligament | 7 | 7.8 |
| | d. Entering bladder wall | 8 | 8.9 |
| | e. Ureteric orifice | 6 | 6.7 |

Hundred cases of nephro-uretero-lithiasis treated with the four different methods of treatment during the period of two years from 1st January 1979 to 31st December 1980 revealed the results tabulated in Table IV.

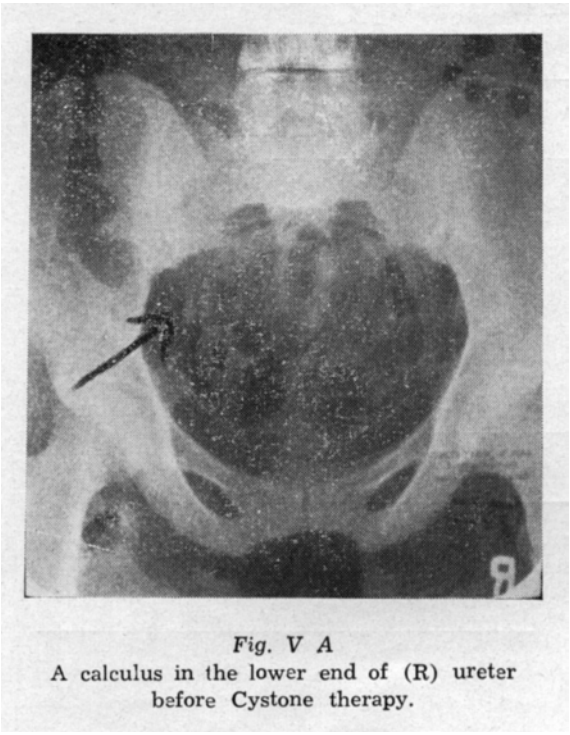


*Fig. V A*
A calculus in the lower end of (R) ureter before Cystone therapy.

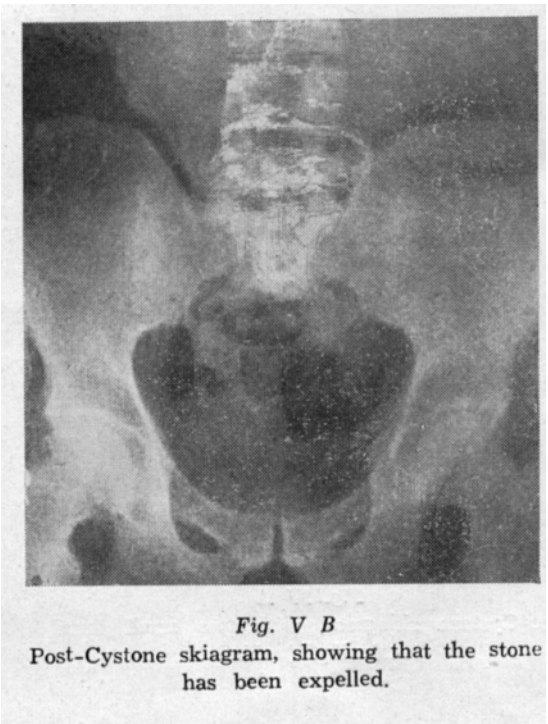


*Fig. V B*
Post-Cystone skiagram, showing that the stone has been expelled.

| Table IV: Results of treatment with 4 different methods used | | | | | | |
|---|---|---|---|---|---|---|
| | Method used | No. of cases | Stone passed | % | Operated | % |
| 1. | Tablet Cystone and fluids orally | 25* | 19 | 76.0 | 6 | 24.0 |
| 2. | Tablet Cystone and forced diuresis | 25• | 20 | 80.0 | 5 | 20.0 |
| 3. | Antispasmodics and fluids orally | 25 | 5 | 20.0 | 20 | 80.0 |
| 4. | Antispasmodics and forced diuresis | 25 | 7 | 28.0 | 18 | 72.0 |
| | Total | 100 | 51 | 51.0 | 49 | 49.0 |
| * Included 5 cases of small renal calculi and 20 cases of ureteric calculi.<br>• Inlucded 5 cases of small renal calculi and 20 cases of ureteric calculi. | | | | | | |

In Group I, 25 cases of nephro-uretero-lithiasis including 20 cases of single ureteric calculus and 5 cases of multiple renal calculi were given Cystone tablets in the dosage of 2 tablets 3 times a day with plenty of fluids by mouth for a period of 2 months to 6 months. Nineteen cases (76%) including 16 cases of ureteric calculus and three cases of small renal calculi showed good response to treatment with Cystone and thereby could avert an operation. Six cases (24%) did not respond to therapy and underwent surgery. In 16 cases (64%) out of 19 cases who passed out their stones, the stones were expelled between 4-8 weeks. Two cases (8%) expelled the stone at the end of 12 weeks of therapy with Cystone and in one case (4%) the stone passed out at the end of 6 months. All the 19 cases who responded to treatment with Cystone observed remarkable relief in the burning sensation during micturition.

In Group II, 25 cases of nephro-uretero-lithiasis including 20 cases of single ureteric calculus and 5 cases of small renal calculi, were put on intermittent forced diuresis in addition to Cystone tablets. Twenty cases (80%) showed good response and expelled the stones and 5 cases (20%) were put to surgery. Eighteen cases (72%) passed out the stones at the end of 8 weeks and 2 cases (8%) passed out the stone at the end of 16 and 24 weeks respectively.

In Group III, 25 cases of nephro-uretero-lithiasis who were given antispasmodics and fluids orally, only 5 cases (20%) passed out the stones and 20 cases (80%) had to undergo surgery.

In Group IV, 25 cases of nephro-uretero-lithiasis who were given antispasmodics and forced diuresis, only 7 cases (28%) responded to the treatment and 18 cases (72%) had to undergo surgery.

Patients in Groups I and II who were treated with Cystone tablets for 2 to 6 months, tolerated the therapy very well, without any adverse side-effects.

## DISCUSSION

One hundred cases of nephro-uretero-lithiasis were treated with four different combinations outlined in Table IV. The object of the study was to determine the comparative efficacy of Cystone tablets in nephro-urethero-lithiasis. The therapy with Cystone tablets and fluids given orally revealed 76% positive results whereas the therapy with Cystone tablets combined with forced diuresis revealed 80% positive results. The slight difference (4%) was probably due to forced diuresis but it has to be viewed against the possible side-effects of forced diuresis e.g. hypovolaemia, fluid and electrolytic imbalance. Whereas antispasmodics combined with fluids given orally showed 20% positive results, 80% of cases had to undergo operation. Therapy with antispasmodics in combination with forced diuresis showed 28% positive results and 72% of cases had to undergo operation. Thus forced diuresis alone is not as effective as the therapy with Cystone alone in the treatment of nephro-uretero-lithiasis.

Gupta and Singh (1976) reported good results with Cystone tablets and showed that they are effective in propelling urinary stones of less than 0.5 cm in diameter from the kidney to the ureter, down to bladder and then expel them per urethra.

Phukan *et al* (1977) had studied the effect of Cystone tablets in experimental animals and demonstrated diuretic activity, changes in the electrolyte excretion and spasmolytic effect on the smooth muscles of the animals. Significantly, lower levels of serum proteins in these animals were also demonstrated.

The mechanism of action of Cystone tablets is not as yet clearly known but the excellent results observed in our series could be attributed to:

(1) diuretic activity
(2) effect on crystalloid and colloid balance
(3) relaxation of smooth muscles
(4) its disintegrating action on the mucin in the calculi.

**SUMMARY AND CONCLUSION**

Of the four different methods tried in the treatment of nephro-uretero-lithiasis, Cystone tablets (The Himalaya Drug Company) gave excellent results (76%) as compared to other methods (20-28%). The mechanism of action of Cystone could be attributed to its diuretic and spasmolytic action, effect on crystalloid and colloid balance and its disintegrating action on the Binding mucin. As Cystone contains no toxic ingredients, no side effects were observed even on prolonged therapy for six months. The present study thus establishes that Cystone has a potent role in early cases of nephro-uretero-lithiasis and should therefore be used in every such case before resorting to surgical intervention.

**REFERENCES**

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2. Gupta, P.D. and Singh, L.M., A Clinical Trial of Cystone tablets in the Treatment of Various Urinary Disorders. *Probe* (1976): 2, 108.

3. Phukan, D.P., *et al.,* Pharmacological and Clinical Study on Cystone, *Probe* (1977): 1, 25.