



A COMPARATIVE STUDY OF PHENAZOPYRIDINE (PYRIDIDIUM) AND CYSTONE AS SHORT-TERM ANALGESIC IN UNCOMPLICATED URINARY TRACT INFECTION

DR. DEEPALATHA.C, DR. NARAYAN DESHPANDE

Received: 17 Sep 2010, Revised and Accepted: 18 Oct 2010

ABSTRACT

It is a randomized, open label comparative study between Pyridium and Cystone to assess the analgesic efficacy in treating burning micturition & pain during voiding of urine within 48 hours of diagnosis of uncomplicated urinary tract infection. **Materials and methods:** The study comprises 80 patients divided into 3 groups. Patients in first group (Pyridium alone) –treated with dose of 200 mg tid over 48 hrs period beginning at the time of diagnosis. Total dose of 1200 mg of pyridium is administered in the first group. In the second group (Pyridium + antibiotics) (ciprofloxacin,doxycycline) --- were administered. In the third group two tablets of Cystone were administered tid for a period of 48 hrs. **Results:** Satisfactory response is seen in pyridium with antibiotic group showing 91% reduction in burning micturition and 89% reduction in pain during voiding of urine as compared to cystone. **Conclusion:** Pyridium when administered with antibiotics is efficacious as short term analgesic in treatment of uncomplicated urinary tract infections.

Keywords: Phenazopyridine, Cystone, Urinary tract infection

INTRODUCTION

Urinary tract infections are quite common in clinical practice. The associated symptoms are burning micturition, pain during voiding and increased frequency of urination. Phenazopyridine (Pyridium) acts as urinary tract analgesic. It has mostly been studied in animal models, but they may not be very representative of humans^[1]. Rat models have shown its half-life to be 7.35 hours^[2] and that it is excreted 40% hepatically^[2]. It is known that the chemical has a direct topical analgesic effect on the mucosa lining of the urinary tract. It is rapidly excreted by the kidneys directly into the urine^[1]. Hydroxylation is the major form of metabolism in humans,^[1] and the azo ring is usually not cleaved.^[1] On the order of 65% of an oral dose will be secreted directly into the urine chemically unchanged.

Side effects of Phenazopyridine

This drug frequently causes a distinct color change in the urine, typically to a dark orange to reddish color. Other such side effects include fever, confusion, shortness of breath, and swelling of the face, fingers, feet, or legs. Long-term use may cause yellowing of nails^[9]. Phenazopyridine should be avoided by people with glucose 6 phosphate dehydrogenase deficiency^[4] ^[5] ^[6] because it can cause hemolysis (destruction of red blood cells) due to oxidative stress^[7]. Since phenazopyridine discolors the urine, it interferes with the standard urine dipstick test done in a physician's office, especially the leukocyte esterase parameter^[8].

Cystone

It is an herbal formulation which maintains composition of urine and is used to treat burning micturition, recurrence of urinary tract infections^[9].

Cystone causes disintegration of the calculi and the crystals by acting on the mucin which binds particles together. Cystone's antimicrobial activity is beneficial in the prevention of urinary tract infections associated with urinary stones and crystalluria. Cystone's antispasmodic and anti-inflammatory activities relieve ureteric colic and alleviate symptoms of painful and burning micturition.

Contraindications - There are no contraindications for the use of Cystone

Special precautions - Special precautions are to be exercised in patients with kidney liver & heart impairment.

Side effects - Cystone does not produce any side effects, if taken as per the prescribed dosage.

Drug interactions - No clinically or biochemically significant drug interactions have been reported with use of cystone.

MATERIALS AND METHODS

Present study was conducted on 80 patients of uncomplicated urinary tract infection who attended out patient department (Rural health center, Bhaskar General hospital, Moinabad), during the period of September 2008 to March 2010.

Inclusion criteria

Male, female patients above 18 years. Patients able to give informed consent. Patients of uncomplicated UTI (must have either cystitis or urethritis). Patients with positive urine dip stick test showing nitrates and leucocyte esterase. Patients must have pain and burning sensation.

Exclusion criteria

Any diagnosis that is not an uncomplicated UTI. Patients sensitive to these drugs on prior use. Patients of child bearing age, pregnant women, lactating women. Subjects unable to comprehend informed consent. Patients with G6PD deficiency and hemolytic anemias.

Study design: 80 patients both male and female of uncomplicated UTIs were randomly enrolled into the study for a period of 48 hrs. The patients had burning micturition and pain during voiding of urine as chief complaints. These patients were divided into three groups. Phenazopyridine group (comprising 35 patients), Phenazopyridine with antibiotic (comprising 25 patients), Appropriate antibiotics like Doxycycline, Ciprofloxacin are administered. Cystone group (comprising 20 patients). Thorough investigations were done on the patients and baseline recording of symptom assessment questionnaire was taken from the patients before administering the drugs.

Dosage regimen: In the first and second group 200mg of phenazopyridine was administered tid over 48 hrs period beginning at the time of diagnosis. Total dose of 1200 mg is administered. In the second group antibiotics are added. In the third group two tablets of Cystone were administered tid for a period of 48 hrs. Symptom assessment questionnaire was taken from patients at baseline (before drug administration) and were repeated at 24 and 48 hrs and results were compared.

Investigations: Urine dipstick test for nitrates and leucocyte esterases.

Complete urine examination.

Complete Blood picture
Blood Urea Nitrogen.
Serum creatinine.
ECG

The patients are asked to circle the score while recording. Out of 60 patients of pyridium group 35 patients were in pyridium alone, group-1, 25 were in pyridium with antibiotic group-2 & 20 in cystone group group -3. All were suffering with moderate to severe symptoms at the beginning of therapy.

The patients are asked to fill the following questionnaire

Please indicate the following	Did not have	Mild	Moderate	Severe
Burning sensation	0	1	2	3
Pain during voiding	0	1	2	3
Frequency of urination	0	1	2	3
Low back pain	0	1	2	3

Baseline score

	Pyridium alone Number of patients 35 (Group-1)	Pyridium with antibiotic (Group-2)	Number of patients 25	Cystone Number of patients 20 (Group-3)
Burning sensation	Score 2&3	Score 2&3		Score 2&3
Pain during voiding	Score 3	Score 3		Score 3
Frequency of urination	Score 2&3	Score 2&3		Score 2&3
Low back pain	Score 2&3	Score 2&3		Score 2&3

Values at 24 hrs - % cured

	Pyridium alone Out of (35) patients (Group-1)	Pyridium with antibiotic (25) (Group-2)	Cystone (20) (Group-3)
Burning sensation	30%	51%	nil
Pain during voiding	60%	63%	2%
Frequency of urination	50%	52%	3%
Low back pain	30%	40%	nil

Values at 48 hrs - % cured

	Pyridium alone Out of 35 pts (Group1)	Pyridium with Antibiotic out of 25 pts (Group2)	Cystone Out of 20pts (Group3)
Burning sensation	73%	91%	53%
Pain during voiding	80%	89%	44%
Frequency of urination	66%	83%	51%
Low back pain	70%	80%	30%

Statistical data

P" VALUE significant

Positive correlation seen with P <0.05 in group 1&2.

Positive correlation seen with P <0.05 in group 2&3.

Observation

Out of 60 patients on pyridium therapy 43 were female & 17 were male. 35 patients were on pyridium alone and 25 patients on pyridium with antibiotic, after 48hrs 73% (n=25 patients) reduction is seen case of burning micturition in group-1 and 91% (n=23 patients) in group-2. Patients on cystone therapy group-3 had relief of symptoms of burning micturition by 53% (n=10 patients.) Reduction in pain during voiding was seen by 89% in group-2, Frequency of burning micturition 83% group-2. Lowback pain 80% in group-2. Group 2 shows high reduction in symptoms compared to group1 & 3. No adverse effects were reported during the study.

RESULTS

Our study shows that marked reduction in urinary symptoms of burning micturition & pain is seen in pyridium group with antibiotic when compared to pyridium group alone & cystone group.

CONCLUSION

As we see satisfactory response, Pyridium is very useful as adjuvant to antimicrobial therapy in uncomplicated urinary tract infection. Highly efficacious as short term analgesic to relieve pain &

burning micturition as compared to cystone in uncomplicated urinary tract infections.

ACKNOWLEDGEMENT

I heartfully thank my seniors and my colleague Dr. Nagaveni in helping me to conduct this study. I thank medical officer Dr. Raja vikram Prasad of rural health centre for supplying the study material.

REFERENCES

1. Thomas BH, Whitehouse LW, Solomonraj G, Paul CJ (Apr 1990). "Excretion of phenazopyridine and its metabolites in the urine of humans, rats, mice, and guinea pigs". *Journal of Pharm Sci* 79 (4): 321-5
2. Jurima-Romet M, Thomas BH, Solomonraj G, Paul CJ, Huang H (Mar 1993). "Metabolism of phenazopyridine by isolated rat hepatocytes". *Biopharm Drug Dispos* 14 (2): 171-9.
3. Amit, G; Halkin, A (15 Dec 1997). "Lemon-yellow nails and long-term phenazopyridine use" (letter). *Annals of Internal Medicine* 127 (12): 1137.
4. Ishler, M; Abramov, A (1983). "Phenazopyridine-induced hemolytic anemia in a patient with G6PD deficiency". *Acta Haematol* 70 (3): 208-9.
5. Galun E, Oren R, Glikson M, Friedlander M, Heyman A (Nov 1987). "Phenazopyridine-induced hemolytic anemia in G-6-PD deficiency". *Drug Intell Clin Pharm* 21 (11): 921-.
6. Mercieca JE, Clarke MF, Phillips ME, Curtis JR (4 Sep 1982). "Acute hemolytic anaemia due to phenazopyridine

- hydrochloride in G-6-PD deficient subject". *Lancet* 2 (8297): 564
7. Fank JE (October 2005).Diagnosis and management of G6PD deficiency America family of physicians 72 7 -1277-82.
 8. Mae Nolan,shuster BL Inteference phenazopyridine with leucocyte esterase dipstick test.Journal of american medical association 238-89 .
 9. Cystone in burning micturition Garg & singh ,LLRMmedical college ,meerut.19885XXIV ,2,119.