

A COMPARATIVE ANALYSIS OF EFFICACY OF MEDICAL EXPULSIVE THERAPY IN MID URETERIC AND LOWER URETERIC CALCULUS

Ravikumar Banavase Ramesha¹, Dhayanand G. S², Madappa K. M³, Girish T. D⁴, Amruthraj G. Gowda⁵, Prashanth Darakh⁶

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ABSTRACT: BACKGROUND: Medical expulsive therapy has been proven to enhance stone expulsion rate, decrease stone expulsion time and decrease the use of analgesics in lower ureteric calculus. But adequate data is not available on the efficacy of medical expulsive therapy for mid ureteric calculus. Hence we have studied the efficacy of medical expulsive therapy in patients with mid ureteric calculi in this study. **PURPOSE:** To determine the efficacy of medical expulsive therapy in mid ureteric calculi of up to 10 mm in size and Comparing the results with Placebo and lower ureteric calculi. **MATERIAL AND METHODS:** It was a prospective randomized study conducted between September 2011 to march 2013. 60 patients with mid ureteric calculi of ≤ 10 mm and 60 patients with lower ureteric calculi of ≤ 10 mm were randomly selected for the study. Patients in the study group received 0.4 mg of Tamsulosin and Aceclofenac 100 mg SOS, whereas the control group received only analgesics. Statistical methods used: All the data was collected and analyzed using SPSS 16.0 (2007) software. **RESULTS:** The stone expulsion rate was higher for patients with mid ureteric calculi who received medical expulsive therapy compared to controls (56.6% Vs. 20%). The stone expulsion rate was higher for patients with lower ureteric calculi compared to patients with mid ureteric calculi (93.3% Vs. 56.6%). **CONCLUSION:** Medical expulsive therapy can be used with success in patients with mid ureteric calculi up to 10 mm in size. Medical expulsive therapy is more beneficial in patients with lower ureteric calculi as compared to patients with mid ureteric calculi. **KEYWORDS:** CT KUB, Expulsion, Medical expulsive therapy, Pain, tamsulosin.

INTRODUCTION: Urolithiasis is one of the three most common urological diseases and has become a worldwide health problem.¹ The life time risk of stone formation varies from 5 – 12% in Europe and in United States the risk is 13% and 7% in men and women respectively.¹

Over the past 2 decades the prevalence of stones has increased by 37%.² 50% of these stone formers will go on to have recurrence within 5 years of their first episode.³ Stone formation is affected by gender, age, and geography.

Men are more likely to form stones than women. However, the ratio has decreased from a 3:1 male to female predominance to less than 1.3:1.⁴ Stone prevalence increases with age in both men and women, with the highest prevalence in the 4th and 5th decades. Lifestyle and diet may play a more significant role in stone formation than ethnicity.

Geography also seems to be a significant risk factor, with a higher prevalence of stone disease in hot, arid, or dry climates.⁵

Of all urinary tract stones 20% are ureteral stones, of which 70% are found in the lower third of the ureter.⁶ The consequences of urinary stone disease are not only health related but economic as

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well. Total costs arising from urinary stone disease diagnosis, treatment and lost wages total more than \$2 billion annually in the united states.⁷

Minimally invasive therapies such as extracorporeal shock wave lithotripsy, ureteroscopy, and percutaneous nephrolithotomy have revolutionized the treatment of ureteric calculi, altering surgical treatment dramatically for ureteric calculi. Although efficacious, these techniques are not without morbidity (7% rate of significant complications) and are quite costly.^{8,9} In light of these data, researchers recently have sought out pharmacologic means of increasing rates of stone passage and reducing both surgical intervention and financial costs.

Thus a cost-effective strategy, Medical Expulsive Therapy (MET), for distal ureteral stones has been developed in the last few years.⁴ There are not many studies and not enough data available in the literature to study the efficacy of medical expulsive therapy in patients with mid-ureteric calculi. This study aims at studying the feasibility of using medical expulsive therapy in patients with mid ureteric calculi of up to 10 mm in size and comparing the results with lower ureteric calculi.

MATERIALS AND METHODS: It was a prospective randomized study done between September 2011 to march 2013. Recruitment of the patients was done at JSS Hospital Mysore, Karnataka, India. Consent was obtained from all the patients before inclusion in the study. Ethical clearance was obtained from the Ethical committee of the hospital.

Patients attending the out-patient department with clinical features suggestive of ureteric colic were evaluated. Thorough history was taken and relevant clinical examinations were done. Urine microscopy and serum creatinine estimation was done for all the patients. Ultrasound-KUB and Plain X-ray KUB was done for all the patients. Spiral CT-KUB was done for patients where calculus was not visible in Plain X-ray KUB.

INCLUSION CRITERIA:

1. Ureteric Calculus in the mid and lower ureter.
2. Stone size less than or equal to 10 mm in transverse axis.
3. Solitary stone.
4. Short duration of pain- < 1 week.

EXCLUSION CRITERIA:

1. Fever/ UTI.
2. Raised serum creatinine - >1.4 mg/dl.
3. Multiple stones.
4. Solitary kidney.
5. Pregnancy.
6. Pediatric patients < 16 yrs of age.
7. Severe pain refractory to analgesics.
8. Abnormal renal/ureteric anatomy.
9. High risk occupation.
10. Poor glycemic control and immuno-compromised patients.
11. H/o previous surgeries on the ureter.
12. H/o hypersensitivity reaction to tamsulosin.

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13. Patients on medications containing Calcium channel blockers or alpha-1 adrenoceptor antagonists.
14. Patients who refused to take part in the study.

Before patient recruitment, the sample size needed in each group was calculated on the basis of previous studies that estimated stone expulsion rate to be 90% and 65% in patients with and without tamsulosin respectively with a difference of 25%. A sample size of 60 in each arm was found to give a power of 80% with type II statistical error <20% and type I <5%.^{10, 11, 12} 60 patients with mid-ureteric calculi and 60 patients with lower ureteric calculi who met the inclusion criteria were selected for the study.

The mid ureter was defined as the part of the ureter that overlies the bony pelvis, i.e., the position of the ureter that corresponds to the sacroiliac joint. The upper ureter is above and the lower ureter is below.¹³ The patients were randomly divided into 4 equal groups of 30 patients each. (Table 1) All the patients were explained about the study and the possible complications of conservative treatment, side effects of the drugs used and the need for surgical intervention if the therapy fails.

Patient's details such as name, age, sex and hospital number were recorded in a pre-formed Proforma. Stone size, location and laterality were recorded. Stone size was measured along the transverse axis as seen in the Plain X-ray KUB and Spiral CT- KUB. The pain score was recorded for all the patients on the basis of 10 point visual analogue scale before starting the treatment. All the patients were given a proforma to record the daily pain score, Number of analgesics consumed, fluid intake, side effects of the drug and any other complications such as fever. Patients were instructed to drink 2-3 liters of fluid daily.

All the patients were given 100 mg of Aceclofenac and were instructed to take the tablet only if required (due to ureteric colic) and number of analgesics consumed by the patient in the study period was recorded. 0.4 mg of Tamsulosin was given to the study population (Group I and III). Patients were instructed to take the tablet at bed time to avoid postural hypotension and to record any side effects of the drug and to report immediately in case of any complications. Placebo was given to control group (Group II and IV).

All the patients were evaluated at the end of 1 week. History was taken for any episode of fever, severity of pain and for side effects of drugs. Ultrasound KUB, plain X-ray KUB and serum creatinine were repeated for the patients. Patients who were pain free and ultrasound KUB and plain X-ray KUB not showing any evidence of ureteric calculus, were declared stone free and the data was recorded. Spiral CT-KUB was done in patients with equivocal findings in the above investigations and in patients who continued to have pain despite the ultrasound evidence of expulsion of calculus.

Patients with persistent calculus and symptomatic improvement were advised to continue the same medications for another week. Patients who had worsening of pain, complications or side effects of the drug were discontinued from the study and subjected for ureteroscopy and stone removal.

All the patients who continued the study were evaluated at the end of 2nd week of the study in a similar manner and the data was recorded. Patients with persistent calculus underwent ureteroscopy and stone removal. Following Variables were recorded and analyzed- Age, Gender, Stone location, Stone size, Serum creatinine, Stone expulsion & Time to stone expulsion.

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RESULTS: The mean age of patients in our study was 35.88 years. The youngest patient was 18 years of age and the oldest patient was 66 years of age. (Table 2)

In our study 75% of the patients were males and 25% were females, with a male to female ratio of 3:1. (Table 2)

Right sided ureteric calculi were more common in the all the groups except in group III in which it was equally distributed. Overall 56.6% of the patients had right sided calculi and 43.4% of the patients had left sided calculi. (Table 2)

The mean serum creatinine was 1.06 mg/dl in group I, 1.18 mg/dl in group II, 1.04 mg/dl in group III and 1.10 mg/dl in group IV. The overall mean serum creatinine was 1.09 mg/dl. (Table 2)

The average stone size was 7.15 mm in group I patients, 7.33 mm in group II, 7.25 mm in group III and & 7.82 in group IV. The mean stone size in our study was 7.38 mm. The smallest calculus was 3 mm in size, whereas the largest calculus was 10 mm in size. (Table 2 & Fig 1)

STONE EXPULSION RATE: Stone expulsion rate was 56.6% in group I, 20% in group II, 93.3% in group III and 43.3% in group IV. (Table 3 & Fig. 2).

The difference in stone expulsion rate was statistically significant between groups I & II, groups III & IV and groups I & III, whereas it was not significant for groups II & IV. (Table 4).

TIME TAKEN FOR STONE EXPULSION: Stone expulsion rate was 11.5 days for group I, 12.8 days for group II, 10.75 days for group III and 12.3 days for group IV Mean stone expulsion rate was 11.8 days. (Table 5 & Fig. 3).

DISCUSSION: Urolithiasis is one of the three most common urological diseases and has become a worldwide health problem.¹

The consequences of urinary stone disease are not only health related but economic as well.

Minimally invasive therapies such as extracorporeal shock wave lithotripsy, ureteroscopy and Percutaneous nephrolithotomy have revolutionized the treatment of ureteric calculi, altering surgical treatment dramatically for ureteric calculi.

Although efficacious, these techniques are not without morbidity (7% rate of significant complications) and are quite costly.^{8,9}

In light of these data, researchers recently have sought out pharmacologic means of increasing rates of ureteral stone passage and reducing both surgical intervention and financial costs. Thus a cost-effective strategy, Medical Expulsive Therapy (MET), for distal ureteral stones has been developed in the last few years.⁴

In the combined AUA and EAU guidelines for the management of ureteral calculi, it is recommended that, in a patient who has a newly diagnosed ureteral stone <10 mm and whose symptoms are controlled, observation with periodic evaluation is an option for initial treatment. Such patients may be offered an appropriate medical therapy to facilitate stone passage during the observation period.

Patients should be followed with periodic imaging studies to monitor stone position and to assess for hydronephrosis. Stone removal is indicated in the presence of persistent obstruction, failure of stone progression, or in the presence of increasing or unremitting colic.^{14,15}

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There is level I evidence available for efficacy of MET for distal ureteric calculi of less than 10 mm. It has been proved in various randomized controlled trials that medical expulsive therapy is beneficial in lower ureteric calculi.^{13,16,17}

Various drugs studied in MET are alpha-1 receptor antagonists, calcium channel blockers, corticosteroids and hormones.

Alpha-1 receptor antagonists proved to be superior compared to other drugs in medical expulsive therapy in various studies.^{14,15,17}

Even though there are many studies available to study the efficacy of MET in lower ureteric calculi, there are not many studies and not enough data available in the literature to study the efficacy of medical expulsive therapy in patients with mid-ureteric calculi.

Majority of the studies divided the ureter into 2 parts i.e. upper and lower ureter, the dividing line being crossing of iliac vessels. Hence they have combined patients with mid and upper ureteric calculus into one group. There is no data available regarding the efficacy of medical expulsive therapy for mid-ureteric calculi alone.

In a study by Chau LH, Tai DC in 2011, MET using alfuzocin increased the stone expulsion rate of upper ureteric calculi by 51.3% in 2 weeks. The overall stone expulsion rate was 31.8%.¹⁸

In a study by Micali S et al. in 2007, nifedipine was used as a medical expulsive agent for upper and mid-ureteric calculi after ESWL. The stone clearance rate was 85.7% in their study after 1 month of ESWL.

In our study we have divided the ureter into 3 parts- upper, mid and lower ureter. The mid-ureter is the part of the ureter from the upper border of SI joint to the lower border. The upper ureter is above and lower ureter is below this part of the ureter. This division is based on literature support from many anatomy, radiology and urology literature.¹⁹

Our study aims at studying the feasibility of using medical expulsive therapy in patients with mid ureteric calculi of up to 10 mm and comparing the results with lower ureteric calculi.

We have used tamsulosin 0.4 mg at night time daily as a medical expulsive agent along with the analgesics (Aceclofenac 100mg orally) for the study group. Placebo was used for the control group.

The study period in our study was 2 weeks. This is in accordance with many studies, in which the study period was 10-14 days.^{20,21} The MET was given for up to 4 weeks and 8 weeks in some studies. But the majority of stones are expelled by 2 weeks as seen by many studies. Hence they found that continuing the treatment for longer period was not effective in increasing the stone expulsion rate and leads to increased complications and renal damage.

In our study, all the patients in group I and III (patients who received MET) completed the study, whereas 2 patients in group II (mid-ureteric calculi without MET) and 1 patient in group IV (lower ureteric calculi without MET) were withdrawn from the study because of severe pain and underwent ureteroscopy. The overall study completion rate was 97.5%. The increased compliance in patients receiving medical expulsive therapy may be attributed to decrease in pain because of alpha blockers in these patients.

The stone size is an important predictor of stone expulsion in patients with ureteric calculi. It also helps in deciding the best treatment option for a particular patient. The stone size may vary from 2 mm to several centimeters depending on ureteric diameter and various other factors. Medical expulsive therapy is usually prescribed for patients with stone size of 10 mm or less.

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The average stone size in our study was 7.38 mm. The smallest calculus was 3 mm in size, whereas the largest calculus was 10 mm in size. There was no difference in stone size between different groups.

The rate of stone expulsion and benefit of MET depends largely on stone location as well. The distal the stone, higher is the probability of spontaneous stone expulsion and vice-versa. Same principle applies to those patients who receive MET. This is largely because of abundance of alpha receptors in the distal ureter compared to mid and upper ureter and the less distance needed for the stone to travel to get expelled. Hence medical expulsive therapy is advocated mainly for patients with lower ureteric calculi.

In a study by M.S.Griwan et.al in 2010, the stone expulsion rate in patients with lower ureteric calculus who received MET was 87%, whereas it was 60% for the controls. In a study by Xizhao sun et.al in 2008, the stone expulsion rate was 90% in the study group and 26.7% in controls, in patients with lower ureteric calculus.

In a study by Seung ryeol Lee et.al in 2012, the stone expulsion rate in patients receiving MET for mid and upper ureteric calculi was 55.2% for calculi of ≤ 7 mm and 4% for > 7 mm calculi. The overall stone expulsion rate was 45.7% irrespective of stone size. The stone expulsion rate for lower ureteric calculi was 74.25% for calculi of ≤ 7 mm and 20% for calculi of >7 mm. The overall stone expulsion rate was 69.7%.

In our study, the rate of stone expulsion for patients with mid-ureteric calculi who received medical expulsive therapy (Group I) was 56.6%. The stone expulsion rate for patients with mid-ureteric calculi who did not receive medical expulsive therapy (group II) was 20%. The stone expulsion rate for patients with lower ureteric calculi who received medical expulsive therapy (group III) was 93.3%. The stone expulsion rate for patients with lower ureteric calculi who did not receive medical expulsive therapy (group IV) was 43.3%.

The difference in stone expulsion rate between patients with mid ureteric calculi with and without MET was 36.6%, it was statistically significant (P value- 0.049) Hence in our study medical expulsive therapy had beneficial effect on stone expulsion rate for patients with calculi in the mid ureter.

Patients with lower ureteric calculi (group III and IV) had higher stone expulsion rate compared to patients with mid- ureteric calculi (group I and II).

In patients with mid and lower ureteric calculi who did not receive medical expulsive therapy (group II and IV), there was no statistical difference in stone expulsion rate. (p value- 0.052)

The stone expulsion rate in patients who received medical expulsive therapy was higher for lower ureteric group compared to mid-ureteric group. So the medical expulsive therapy was more beneficial for patients with lower ureteric calculi compared to patients with mid-ureteric calculi.

The mean time to stone expulsion in group I, II, III and IV was 11.5 days, 12.8 days, 10.75 days and 12.3 days respectively. The difference in time to stone expulsion in patients with mid-ureteric calculi with and without MET (group I and II) and in patients with lower ureteric calculi with and without MET (group II and IV) was not statistically significant.

The difference in time to stone expulsion in patients with mid and lower ureteric calculi irrespective of MET was not statistically significant. In our study, medical expulsive therapy did not influence the time taken for stone expulsion.

CONCLUSION:

- Medical expulsive therapy is beneficial in patients with mid ureteric calculi up to 10 mm in size as compared to placebo.
- Medical expulsive therapy is effective in patients with lower ureteric calculi of ≤ 10 mm size.
- Medical expulsive therapy is more beneficial in patients with lower ureteric calculi when compared to patients with mid ureteric calculi.
- Medical expulsive therapy does not influence the time taken for stone expulsion in both mid and lower ureteric calculi.

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GROUP I (MUC+MET)	Study group	Patients with mid-ureteric calculus who received Medical expulsive therapy
GROUP II (MUC-MET)	Control group	Patients with mid-ureteric calculus who did not receive Medical expulsive therapy
GROUP III (LUC+MET)	Study group	Patients with lower-ureteric calculus who received Medical expulsive therapy
GROUP IV (LUC-MET)	Control group	Patients with lower-ureteric calculus who did not receive Medical expulsive therapy

Table 1: Division of patients into different groups

Group	Mean age (Yrs)	SEX (%)		Side of stone (%)		Mean SC (mg/dl)	Mean stone size (mm)
		M	F	Right	Left		
MUC + MET (I)	33.86	76.7	23.3	66.7	33.3	1.06	7.15
MUC - MET (II)	39.16	76.7	23.3	53.3	46.7	1.18	7.33
LUC + MET (III)	38.06	76.7	23.3	50	50	1.04	7.25
LUC - MET (IV)	32.43	73.3	26.7	56.7	43.3	1.10	7.82

Table 2: Baseline characteristics

Group	N	Stone expulsion		%
		Yes	No	
MUC + MET (I)	30	17	13	56.6
MUC - MET (II)	30	06	24	20.0
LUC + MET (III)	30	28	02	93.3
LUC - MET (IV)	30	13	17	43.3
TOTAL	120	64	56	53.3

Table 3: Stone expulsion rate

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Between groups	Odd's Ratio	P-Value
I and II	2.68 (0.86-8.33)	.049
III and IV	18.31 (3.67- 91.23)	.000
I and III	10.71 (1.91-78.65)	.001
II and IV	3.06 (0.85-11.39)	.052

Table 4: Comparison between groups in stone expulsion rate

Group	Time to expulsion	Std. Deviation
MUC + MET (I)	11.5	3.511
MUC - MET (II)	12.8	2.858
LUC + MET (III)	10.75	3.555
LUC - MET (IV)	12.3	3.070
TOTAL	11.8	3.382

Table 5: Mean time to stone expulsion (days)

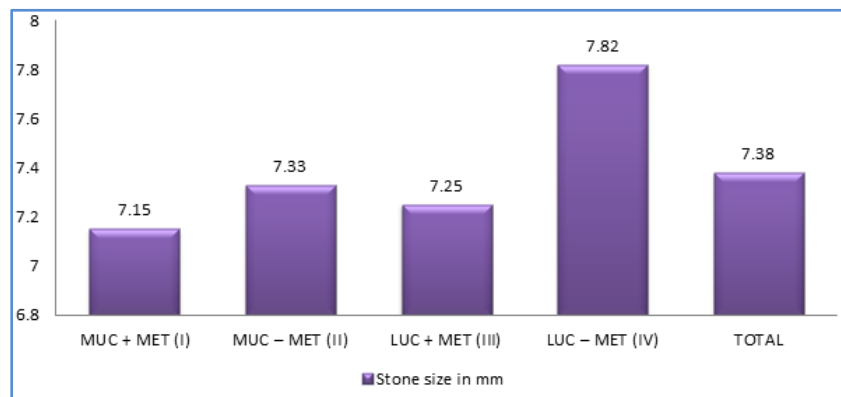


Fig. 1: Mean stone size in mm

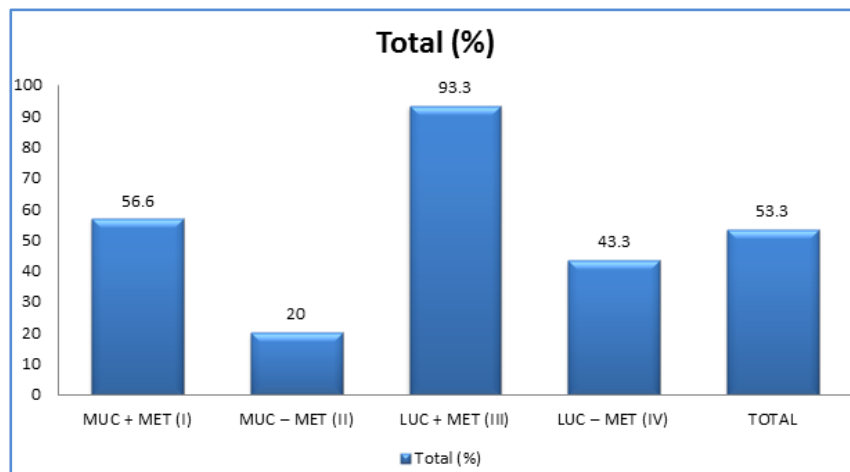


Fig. 2: Stone expulsion rate (%)

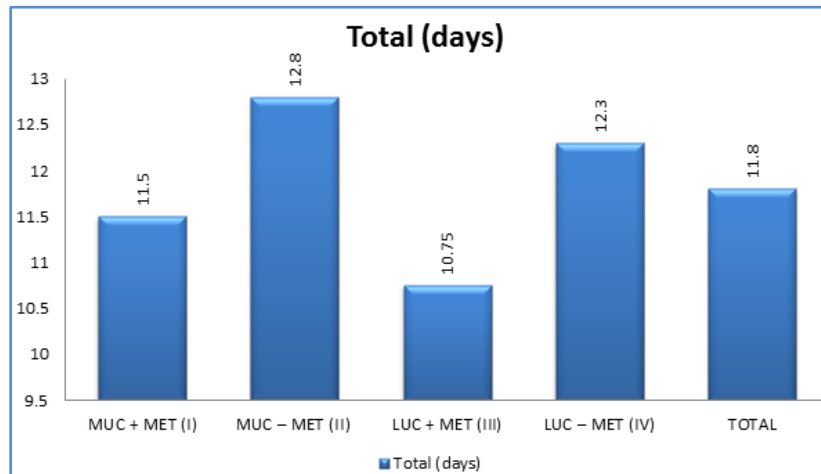


Fig. 3: Mean time to stone expulsion (Days)

AUTHORS:

1. Ravi Kumar Banavase Ramesha
2. Dhayanand G. S.
3. Madappa K. M.
4. Girish T. D.
5. Amruthraj G. Gowda
6. Prashanth Darakh

PARTICULARS OF CONTRIBUTORS:

1. Assistant Professor, Department of Urology, JSS Hospital, Mysore.
2. Assistant Professor, Department of Urology, JSS Hospital, Mysore.
3. Professor & HOD, Department of Urology, JSS Hospital, Mysore.
4. Associate Professor, Department of Urology, JSS Hospital, Mysore.

5. Professor, Department of Urology, JSS Hospital, Mysore.
6. Consultant Urologist, Mahatma Gandhi mission hospital, Aurangabad.

NAME ADDRESS EMAIL ID OF THE CORRESPONDING AUTHOR:

Dr. Ravi Kumar Banavase Ramesha,
Assistant Professor,
Department of Urology,
J.S.S. Hospital, M. G. Road,
Mysore-570004.
Karnataka, India.
Email: ravibrdoc@gmail.com

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