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Research Article

A Randomised Double Blind Placebo Controlled Trial Of Cantharis Vesicatoria In The Management Of Urinary Tract Infection

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Abstract:

Aim: A urinary tract infection (UTI) is a collective term for infections that involve any part of the urinary tract. It is one of the most common infections in local primary care. The incidence of UTIs in adult males aged less than 50 years is low, with adult women being 30 times more likely than men to develop a UTI. Appropriate classification of UTI into simple or complicated forms guides its management and the ORENUC classification can be used. Diagnosis of a UTI is based on a focused history, with appropriate investigations depending on individual risk factors. **Methods**: 30 patients in treatment group took Cantharis vesicatoria; whereas the patients in placebo group took placebo mother tincture for 6 months. The urinary tract infection of the patients was evaluated at baseline, and 6 months of the clinical trial. **Results:** The final results showed that Cantharis vesicatoria significantly p value 0.05. No serious side effect was reported for Cantharis vesicatoria administration. Therefore, Cantharis vesicatoria could be considered as a supplement for treatment of urinary tract infection.

Key words: Randomised double blind placebo controlled trial, urinary tract infection, Cantharis vesicatoria.

Introduction

Urinary tract infection (UTI) is a collective term that describes any infection involving any part of the urinary tract, namely the kidneys, ureters, bladder and urethra. The urinary tract can be divided into the upper (kidneys and ureters) and lower tract (bladder and urethra). During the first six months of life, UTIs are more common in boys[1]. The outcome is usually benign, but UTIs can progress to renal scarring in early infancy, especially when associated with congenital anomalies of the urinary tract. Renal scarring may lead to complications in adulthood including hypertension, proteinuria, renal damage and even chronic renal failure, which requires dialysis treatment[2,3]. In general, 40% of women develop a UTI at some point in their life. In Singapore, 4% of young adult women are affected and the incidence increases to 7% at 50 years of age.

Adult women are 30 times more likely than men to develop a UTI, with almost half of them experiencing at least one episode of UTI during their lifetime. It is reported that one in three women have their first episode of urinary tract infection by the age of 24 years. UTIs are most commonly seen in sexually active young women. Other susceptible adults include the elderly and patients requiring urethral catheterisation. A complicated urinary tract infection is an infection associated with a condition, such as a structural or functional abnormality of the genitourinary tract, or the presence of an underlying disease; this increases the risk of the outcome of a urinary tract infection being more serious than expected, as compared to its occurrence in individuals without any identified risk factors (i.e. uncomplicated UTI)[4]. Asymptomatic bacteriuria (ABU) does not cause renal disease or damage. Several studies involving women and the paediatric population have demonstrated that treatment for ABU increases the risk of subsequent symptomatic UTIs; hence, it is not recommended except in diagnostic and therapeutic procedures involving entry to the urinary tract with a risk of mucosal damage, such as endoscopic urological surgery and transurethral resection of the prostate[5-9].

Material and methods:

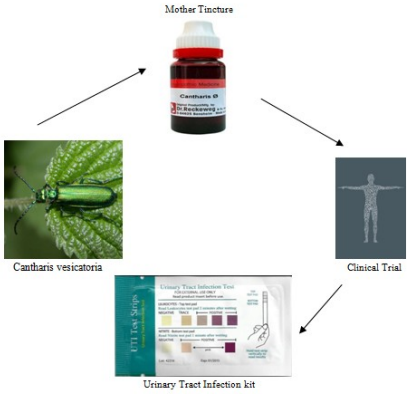
Preparation of Cantharis vesicatoria mother tincture

Cantharis vesicatoria mother tincture was obtained from Belagavi Pharmacy, Belagavi, Karnataka, India. The cantharis vesicatoria mother tincture was kept at room temperature in darkness until use.

Preparation of mother tincture bottles:

Extraction of cantharis vesicatoria mother tincture was purchased and stored as mentioned above. Cantharis vesicatoria mother tincture and placebo were prepared into bottle in Department of homoeopathy pharmacy, Bharatesh Homoeopathic Medical College, Hospital and Research Center, Belagavi, Karnataka. The cantharis vesicatoria mother tincture bottle was identified at the department of homoeopathy Pharmacy, Bharatesh Homoeopathic Medical College, Hospital and Research Center, Belagavi. The placebo mother tincture bottle was filled with neutral and inert additive substance whereas; each cantharis vesicatoria mother tincture bottle was filled with 200µl/kg body weight mother tincture (recommended dose given for rats in 20 µl/100 g body weight) & per orally in de ionized water (180 µl) as vehicle for administration. There were no in clinical studies on the anti urinary tract infection effect of cantharis vesicatoria mother tincture. In the abovementioned works, administration of cantharis vesicatoria mother tincture was safe and effective.

Figure 1. Graphical Abstract



Study design:

The randomised double blind placebo controlled trial was fully conducted in accordance with the Ethical Committee of the Bharatesh Homoeopathic Medical College, Hospital and Research Center, Karnataka and written informed consent was obtained from all patients before their inclusion in the randomised double blind placebo controlled trial. The trial was randomised double blind placebo controlled trial, three months, clinical trial which was carried out on 30 urinary tract infection outpatients of Bharatesh Homoeopathic Medical College, Hospital and Research Center, Belagavi, India. The authors applied inclusion and exclusion criteria for patients to improve the quality of the results in this trial.

Inclusion criteria: Male and female outpatients aged 25 to 65 years with urinary tract infection

Exclusion criteria: The patients who had a history of chronic or metabolic diseases such as diabetes, Ischemic heart disease, hypertension, tachycardia, peripheral vascular disease, coronary artery disease, thyroid dysfunction, hospitalized, cannot follow therapeutic lifestyle modification and pregnancy, Smoking, HTN.

Sample size

To have a power of 90%, a two sided test was used, with a significance level of 0.05, and a 20% minimum detectable mean difference changes for LDL-C and SD 20.5% between treatment and placebo group. Finally, minimum sample size of 30 patients for each arm was calculated. Because of expected dropout, we considered 15 patients in each group.

The patients were randomised double blind placebo controlled trial divided into the treatment (15 patients) treatment group and the pla-

cebo (15 patients) groups. Finally, 30 patients successfully completed a randomised double blind placebo controlled trial.

Interventions

Participants were randomised double blind placebo controlled trial to 2 intervention groups of 15 patients. The patients in the treatment group were taking cantharis vesicatoria mother tincture; whereas the patients in placebo group were taking placebo (mother tincture). Participants did not receive any other urinary tract infection drugs during the randomised double blind placebo controlled trial. The patient's compliance and medication adherence were confirmed through checking with the patient and his/her caregiver along with a mother tincture count at each visit.

Outcome measures

Urinary tract infection were measured improve, recovery and not improved treatment and placebo group.

Masking

The enrolled participants were assigned using a stratified randomization and all of them received asparagus racemosus mother tincture or placebo mother tincture, which were prepared in the same way. For randomization, a randomized code number was obtained from Microsoft Excel for each pillbox (treatment and control groups). All mother tincture bottles had similar colour, shape, size, texture and odour. The mother tincture bottles were stored in a dark container and coded by a pharmacist. The participants and those assessing outcomes were blinded until all participants finished the protocol.

Safety

The patients were requested to inform investigators about any adverse events or complaints for all illnesses, and hospitalizations that occurred during the trial. The symptoms were checked and recorded at the beginning and at each visit by general physician, cardiologist. Also, possible side effects were checked and recorded via telephone call every week and the general physician/homoeopathy physician was responsible for continuing or discontinuing the drugs.

Statistical analysis

Baseline characteristics were analyzed using independent t-test or $\chi 2$ tests.. The variables were reported as mean and standard deviation (Mean ± SD). P value less than 0.05 was considered statistically significant.

Results

Among 30 urinary tract infection patients with mean ± SD, maximum cases were in the male 13 (43.33%) and 17 (56.66%) patients were females.

Table 1. Distribution of UTI According to Sex

Sex	No. Of Cases	Percentage
Male	15	50.00%
Female	15	50.00%
Total	30	100%

We observed in age group of 25 – 35 years in 6 (20%) cases, 35 – 45 years in 16 (53.33%) cases, 45 – 55 years of age group had 8 (26.66%) cases.

Table 2. Distribution of UTI According to Age Group

Age group	No. Of Cases	Percentage (%)
25 –3 5	6	20.00%
35 – 45	16	53.33%
5 – 55	8	26.66%
Total	30	100%

Out of 30 cases 15 (50.00%) were females and 15 (50.00%) were males.

Associated symptoms were the symptoms that had no direct relation with the disease but were present in the patients of urinary tract infection. Urinary tract infection all age group Cantharis vesicatoria mother tincture were prescribed to the patients according to the symptoms similarity and the following observations were made. Cantharis vesicatoria mother tincture is the most effective medicine out of the other Homoeopathic medicines chosen for the study. It was observed that out of 30 patient, 27 (90%) patients were cured, 2 (6.66%) patients had improvement, 1 (3.33%) patients showed no response (table 3).

Table 3. Distribution of Treatment out Come in UTI

Out come to Treatment	No. Of Cases	Percentage (%)
Cured	**27**	**90%**
Improved	**2**	**6.66%**
Not improved	**1**	**3.33%**
Total	**30**	**100%**

Discussion

Urinary tract infection is the worst seen among below 15 years of age children. A repeated attack leads to chronicity and other systematic complications. The presenting complains may vary from systemic symptoms like fever, burn-

ing micturition. The study was conducted on the patients who attended the Out Patient department at Bharatesh Homoeopathic Medical College, Hospital and Research Center, Belagavi. The patients, age 25 – 65 years were selected for the study. Both sexes were included and who belong to different socio economic group was taken as per inclusion criteria. A total of 30 cases were selected. Minimum duration of study was 6 months. The statistical analysis made here is based on the data obtained from 30 cases. This study was conducted to prove the efficiency of the treatment for successful management of urinary tract infection and arrive at a constitutional Cantharis vesicatoria frequently indicated in such as a condition.

Conclusion

The research shows that Homoeopathic medicines play an important role in the treatment of urinary tract infection. The study depicts that 99% of patients got relief from the Homoeopathy medicines and this is not a small number. There were no side effective during the treatment and it can be concluded that homoeopathic medicines can be help the patient to take a new lease on life. During the study it was observed that in almost all the cases the cantharis responded well and the patient not only got rid of the main complaints of urinary tract infection but also got rid of the associated complaints with restoration of health. With the help of use of cantharis vesicatoria even antibiotics was avoided. Thus we can conclude that Cantharis vesicatoria used with holistic approach are very effective in treating the cases of urinary tract infection.

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References

1. Shah SN. API textbook of medicine. 8th ed. Mumbai: The association of physicians of India; 2009.1-7.
2. Mello JD. Efficacy of Homoeopathy in treating lower urinary tract infections. Homeo Buzz 2011 June; 7:16-19.
3. Mohan H. Textbook of pathology. 6th ed. St Louis (USA): Jaypee Brothers Medical Publishers (P) LTD; 2010.
4. Chimthanawala S, Chimthanawala F. Manual of Homoeopathic Gynecology & Obstetrics. Nagpur : Shaad Publications; 2011.
5. Ganganagar, S. A Brief Study of Efficacy of Homoeopathic Medicines in Controlling Tonsillitis in Paediatric Age Group.
6. Reddy, R., Sharma, P. K., & Praveen Raj, P. Homoeopathic treatment of intestinal. *Research Journal of Recent Sciences ISSN*, *2277*, 2502.
7. Rami, B. S. A. D. S., & Reddy, E. Utility of passiflora incarnata homoeopathic mother tincture in general anxiety disorder: A pilot study.
8. Chakraborty, P. K., Chatterjee, N., & Sharma, P. K. (2019). Effect of epigea mother tincture in nephrolithiasis.
9. Luthra N. Homoeopathy cures urinary tract infection effectively. Homoeopathy For All 2008; 9:49.