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EFFICACY AND SAFETY OF DIFFERENT DOSAGES OF FOSFOMYCIN AS ANTIMICROBIAL PROPHYLAXIS IN TRANSRECTAL BIOPSY OF THE PROSTATE: A PILOT STUDY

Hypothesis / aims of study

Prostate biopsy, the gold standard diagnostic procedure for prostate cancer diagnosis, is not free from complications, with a post biopsy prostatitis rate ranging between 1 and 5% [1].
In the recent years, especially in Europe, the incidence of bacterial strains like Escherichia coli, Klebsiella pneumoniae, Enterococci spp resistant to fluoroquinolones and cephalosporine is growing critically, leading to significative death and morbidity risk [2].
Fosfomicin, a bactericidal antibiotic produced by streptomycetes, shows a good activity against gram positive and gram negative bacteria and seems to be an attractive alternative to quinolones based prophylactic regimen for prostate biopsies, due to the promising results of Cai et al [3].
The aim of our randomized study was to evaluate efficacy and safety of a prostate biopsy phrophylaxis protocol using two VS three fosfomicine dosis, with the aim to assess the optimal timing and dosage of this antibiotic.

Study design, materials and methods

262 patients undergoing transrectal ultrasound guided prostate biopsy were prospectively evaluated between April and March 2017 in a single italian center.
All the patients were evaluated with history, comorbidity with Charlson score, complete urological examination, PSA, urine exam and urinalysis, transrectal ultrasound.
The patients were, moreover, randomized to group A (fosfomicine 3 gr within 4 hours from the procedure and after 24 hours) and group B (fosfomicine 3 gr 12 hours before the procedure, within 4 hours from the procedure and after 24 hours).
About three weeks after the procedures the patients were evaluated in our outpatients clinic.

Results

229 patients were randomized to group A (n: 135) or group B (n:127); allocation was done by date of birth.
The 2 groups were comparable with respect to age (65 VS 66 yrs, p 0.2), comorbidity (CCI 0.66 VS 0.76, p 0.5), PSA value (30.3 ng/ml VS 13.4, p 0.44), prostate volume (45.2 VS 48.7 cc, p 0.23), operative time (12.3 VS 12.3 min, p 0.99) and positive urine culture (16 VS 10, p 0.3).
26 pts had a positive urine culture (only 2 with < 100.000 UFC, no resisteant to fosfomicine; only one patient (5 -10.000 UFC E. Coli plurisensible) pts was readmitted after the procedure.
3.8% (10/262) of our patients developed fever requiring a readmission after the procedure (7 in group A and 3 in group B, p 0.33).
Four of these patients presented respectively positive urineculture (only one positive for Enterobacter cloacae resistant to fosfomicine) and two presented a positive hemoculture (only one a Klebsiella pneumoniae resistant to fosfomicine).
None of the patients developed > grade II complications.

Interpretation of results

The low readmission rate of our cohort, treated with both doses of fosfomicine, shows that this prophylaxis is safe and effective.
Moreover, the two doses (2 VS 3 doses) show an overlapping efficacy.
Our study presents, moreover, possible limitations, as the single center, multisurgeon basis and the relatively low number of patients enrolled

Concluding message

The low fever and prostatitis rate shows that fosfomicine prophylaxis is safe and efficacy; moreover, the two dosage seem to be overlapping in term of post operative outcomes.

References

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