

Session: EP192 Urinary tract infections: current issues

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Data from an ongoing clinical trial: five cases of uncomplicated LUTI caused by ESBL-producing *Escherichia coli* were successfully treated with pivmecillinam 400 mg t.i.d. for 3-5 days

Filip Jansåker*¹, Frederik B. Hertz², Sara Thønnings³, Niels Frimodt-Møller⁴, Jenny Knudsen⁵

¹*Hvidovre Hospital; Clinical Microbiology 445*

²*Herlev Hospital; Clinical Microbiology*

³*Hvidovre Hospital; Clinical Microbiology*

⁴*Rigshospitalet (Copenhagen University Hospital); Dept. of Clinical Microbiology 9301*

⁵*Hvidovre Hospital*

Background: Uncomplicated lower urinary tract infections (uLUTI) are common and one of the most frequent infections in women. We are currently conducting a randomized, double-blinded, placebo-controlled clinical phase IV study (EudraCTno.: 2014-001321-32), to compare the efficacy of pivmecillinam 400 mg *t.i.d.* in a 3-day respectively 5-day regimen, against community acquired uLUTI (terminates in May 2017). We have earlier demonstrated effective outcomes of pivmecillinam 400 mg *t.i.d.* against ESBL producing *Escherichia coli*, and here we wish to confirm those findings as part of a large clinical study with more detailed data.

Material/methods: We have to date included >220 patients (November 2016). Six of the cases were caused by ESBL-producing *E. coli*, which corresponds to the expected prevalence in the primary sector of Denmark. Patients with clinical features of uLUTI without exclusion criteria were included by collaborating general practitioners according to GCP. Cardinal symptoms of uLUTI (*i.e.* dysuria, pollakiuria and urgency) were scored from 0-3 on day 0, and a symptom load ≥ 2 was considered significant for uLUTI. The patients received a double-blinded antibiotic therapy (*i.e.* 3 or 5 day regime of pivmecillinam), questionnaires for day 0-7 and day 28. The patients answered questions on their symptom load and gave a urine sample on day 9 and day 28. Patients were followed for 6 months on our laboratory database for bacteraemia or any relapsing bacteriuria.

Results: Five patients followed up on all the questionnaires and urine samples. One patient dropped out just after inclusion. Four patients had experienced recurrent UTIs the last year prior to enrolment. Four patients informed they had travel out-side of Scandinavia within the last 6 months. All patients scored over >4 in symptom load of uLUTI on day 0.

Four patients were bacteriologically cured at the first control urine sample and with no recurrence. One patient still had asymptomatic bacteriuria in the first control urine sample, which vanished without antibiotic therapy in the second urine sample.

Four of the five patients with follow-up data informed they were clinically cured on day 2, day 7 and day 28, respectively. Only one patient did not get clinically cured within the first 7 days and one patient experienced clinical relapse within the first month.

None of the six patients had bacteraemia, or relapse bacteriuria of the ESBL-producing *E. coli*. Only two patients' had new bacteriuria (*i.e.* *E. coli* and *Enterococcus faecalis*).

Conclusions: Pivmecillinam 400 mg *t.i.d.* for 3-5 days was effective in patients with uLUTI caused by ESBL-producing *E. coli*. No patient experienced relapse. We therefore confirm that pivmecillinam, given as 400 mg *t.i.d.* is effective and a relevant option against ESBL-producing *E. coli*.