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Complicated urinary tract infections: heterogeneity among hospitals. A retrospective observational cohort study. Results of the COMBACTE-MAGNET, RESCUING study

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Background: Urinary tract infections (UTI) are highly prevalent worldwide. Complicated UTI (cUTI) is an entity defined by the FDA and EMA and serves for inclusion of patients into trials of antibiotic management, including new antibiotics. In a large multinational cohort study we aimed to examine the heterogeneity among hospitals in the characteristics and management of patients with cUTI.

Material/methods: We performed a retrospective, observational, multinational and multicenter cohort study. The study was conducted in 20 hospitals around Europe, Turkey and Israel. Approximately 50 consecutive cases of cUTI were included from each site. The study involved collection of data of hospitalised patients between 01/01/2013 and 31/12/2014. Patients with a diagnosis of cUTI as the primary cause of hospitalisation and patients who developed cUTI during their hospital stay were included. To avoid selection bias, all consecutive patients who had ICD-9 or ICD-10 CM codes were reviewed at each site. All patients who met the protocol inclusion criteria were selected for data collection.

The main outcome was treatment failure. Secondary outcomes included; time to clinical response, time to death, duration of antibiotic therapy, length of hospital stay (LOS), in-hospital mortality, 30 day mortality, hospital readmission within 60 days and adverse events related to antibiotic treatment.

Results: Overall, 989 patients with cUTI were included. The median age of the cohort was 68 (IQR 56-80). Approximately, 18% resided at long term medical facilities and 16% were bedridden patients. Patients presented with multiple comorbidities; 26.8% (275/989) had diabetes mellitus, 27.8% (275/989) had chronic kidney disease and 19.1% (189/989) had congestive heart failure.

The treatment failure rate was 26.6% (261/981) and ranged from 5% to 61.6% between hospitals. The crude 30-day-all-cause mortality rate was 8.7% (85/976) and ranged from 0 to 25.9% between hospitals. The median LOS ranged from 5.9 days to 20.7 days between hospitals and the median age ranged from 53.7 to 78.1. Further data on the differences between the hospitals can be seen in the

supplementary table. The percentage of pyelonephritis did not explain the huge heterogeneity among hospitals.

Conclusions: The large heterogeneity among hospitals raises questions and concerns regarding the cohesion of the complicated UTI definition as is often used in antibiotic clinical trial.

Descriptive statistics of main variables per hospital

Variable	minimum	25%	50%	75%	Maximum
% pyelonephritis	0	5.42	13.55	33.32	44.8
% Treatment failure	5	12.87	24.2	38.02	61.6
% 30 day mortality	0	0.82	7.8	14.75	25.9
% Male (sex)	15.4	39.1	45	54.35	66.7
% ultrasound examinations	26.7	40.7	45.85	62.35	95
% Abdominal computerized tomography scan	1.3	6.9	10.55	18.25	72
Mean Age	53.75	60.53	65.44	69.41	78.1
Mean Length of hospital stay, days	5.88	9.47	11.18	15.14	20.66