Supplementary Tables- Online Resource 2

Title:

Oral steroids for reducing renal scarring in young children with febrile urinary tract infections: the contribution of Bayesian analysis to a randomized trial not reaching its intended sample size

Authors:

Liviana Da Dalt^{a*}, Silvia Bressan^{a*}, Floriana Scozzola^b, Enrico Vidal^{a,c}, Monia Gennari^d, Claudio La Scola^e, Mauro Anselmi^f, Elisabetta Miorin^c, Pietro Zucchetta^g, Danila Azzolina^h, Dario Gregori^h, Giovanni Montini^{i,l}

Affiliations:

- ^aDepartment of Women's and Children's Health, University of Padova, Padova, Italy;
- ^b Pediatric Unit, Treviso Hospital, Treviso, Italy;
- ^c Division of Pediatrics, Department of Medicine (DAME), University Hospital of Udine, Italy;
- ^d Pediatric Emergency Unit, Department of Medical and Surgical Sciences (DIMEC), S. Orsola Hospital, Bologna, Italy;
- ^e Nephrology and Dialysis Unit, Department of Woman, Child and Urological Diseases, Azienda Ospedaliero-Universitaria Sant'Orsola-Malpighi, Bologna, Italy

^fPediatric Unit, Dolo-Mirano Hospital, Dolo, Italy;

- g Nuclear Medicine Unit, Department of Medicine DIMED, University-Hospital of Padova, Padova, Italy
- ^h Unit of Biostatistics, Epidemiology and Public Health, Department of Cardiac, Thoracic, Vascular Sciences and Public Health, University of Padova, Padova, Italy;
- ⁱ Pediatric Nephrology, Dialysis and Transplant Unit, Fondazione IRCCS Ca' Granda, Ospedale Maggiore Policlinico, Milano, Italy;
- ¹ Giuliana and Bernardo Caprotti Chair of Pediatrics, Department of Clinical Sciences and Community Health, University of Milano, Milano, Italy.

Corresponding author:

Silvia Bressan

Department of Women's and Children's Health, University of Padova

Via Giustiniani 4, 35128, Padova (Italy)

silvia.bressan.1@unipd.it; silviabress@gmail.com

Tel: +39 0498213570.

eTable 1. Comparison of baseline demographic characteristics between enrolled patients and eligible plus potentially eligible patients.

	n = 48	n = 164*	р
Age in months - median, (IQR)	8.3 (4.2-12.9)	9.1 (6.1-13.4)	0.259
Sex (females) – n (%)	29 (60%)	108 (70%)	0.231
Race (caucasian) – n (%)	40 (83%)	130 (84%)	0.924

^{*} sum of potentially eligible children (n=131, who did not undergo PCT determination or urine catheterization for urine specimen collection) and eligible children (declined consent, n=21; and not approached, n=12)

^{*} Joint first authors

eTable 2. Baseline demographic and clinical characteristics of patients who completed the follow up for the assessment of the primary outcome and those who were lost to follow up

Variables	Total randomized patients (n= 48)		
	Patients excluded after randomization (n=8§)		
	Included in the final	Lost to follow up	
	analysis		
	n= 18	n= 22	
Age in months	7.2 (3.9-15.9)	9.1 (5.3-12.6)	0.891
Sex (females)	10 (56%)	14 (64%)	0.604
Race (caucasian)	15 (83%)	20 (91%)	0.515
Urinary tract abnormalities on fetal	0 (0%)	0 (0%)	na
US			
Max body temperature in °C	39.4 (39.0-40.0)	39.7 (39.3-40.0)	0.179
Duration of fever in days	2.5 (2-4)	2.5 (2-4)	0.944
Weight in kg	8.3 (6.6-10.9)	9.0 (7.0-10.0)	0.935
Weight percentile by sex/age	50.0 (25.0-90.0)	75.0 (50.0-95.0)	0.176
Height in cm	69.0 (62.0-80.0)	70.5 (65.0-76.0)	0.860
Height percentile by sex/age	75.0 (50.0 -90.0)	75.0 (50.0 -90.0)	0.338
PCT ng/ml	2.6 (1.7-6.1)	2.8 (1.3 – 8.1)	0.891
CRP mg/L	16.75 (10.0-109)	10.2 (6.9-70.0)	0.464
Leukocytes n/mm ³	18.100 (8.680-23.650)	16.740(12.510-23.000)	0.927
Hemoglobin g/L	11.1 (10.1-11.6)	11.2 (10.7-11.7)	0.532
Urea mg/dL	13.0 (9.1-16.5)	10.6 (7.0-16.0)	0.519
Creatinine mg/dL	0.32 (0.28-0.39)	0.31 (0.26-0.36)	0.470
Leukocyturia on urine dipstick	18 (100%)	22 (100%)	na
Nitraturia on urine dipstick	15 (83%)	15 (68%)	0.271
Hospitalization	13 (72%)	15 (68%)	0.701
Antibiotics initially administered			0.781
• Oral			
 Amoxicillin –clavulanate 	7 (39%)	10 (46%)	
Parenteral	` ,		
 Ceftriaxone 	10 (56%)	10 (46%)	
 Amoxicillin –clavulanate 	0 (0%)	1 (5%)	
 Ampicillin - sulbactam 	1 (6%)	1 (5%)	
Antibiotic therapy duration in days	10 (10-10)	10 (9-10)	0.085
Renal and bladder US performed	16 (89%)	20 (91%)	1.000
Patients with abnormal findings	7 (44%)	5 (25%)	
Loss of cortico-medullary	0	1	
differentiation			
 Parenchymal thinning 	1	0	
o Parenchymal	0	1	
hyperechogenicity			
 Calyceal dilatation 	4	3	
 Pelvic dilatation 	3	3	
 Uretheral dilatation 	2	1	

^{§ 6} patients eventually had a negative urine culture, one patient withdrew consent after randomization and one had recurrent UTIs.