

Prophylactic antibiotics vs. placebo after stented hypospadias repair (PROPHY): a multicenter, randomized, double-blind trial

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Background

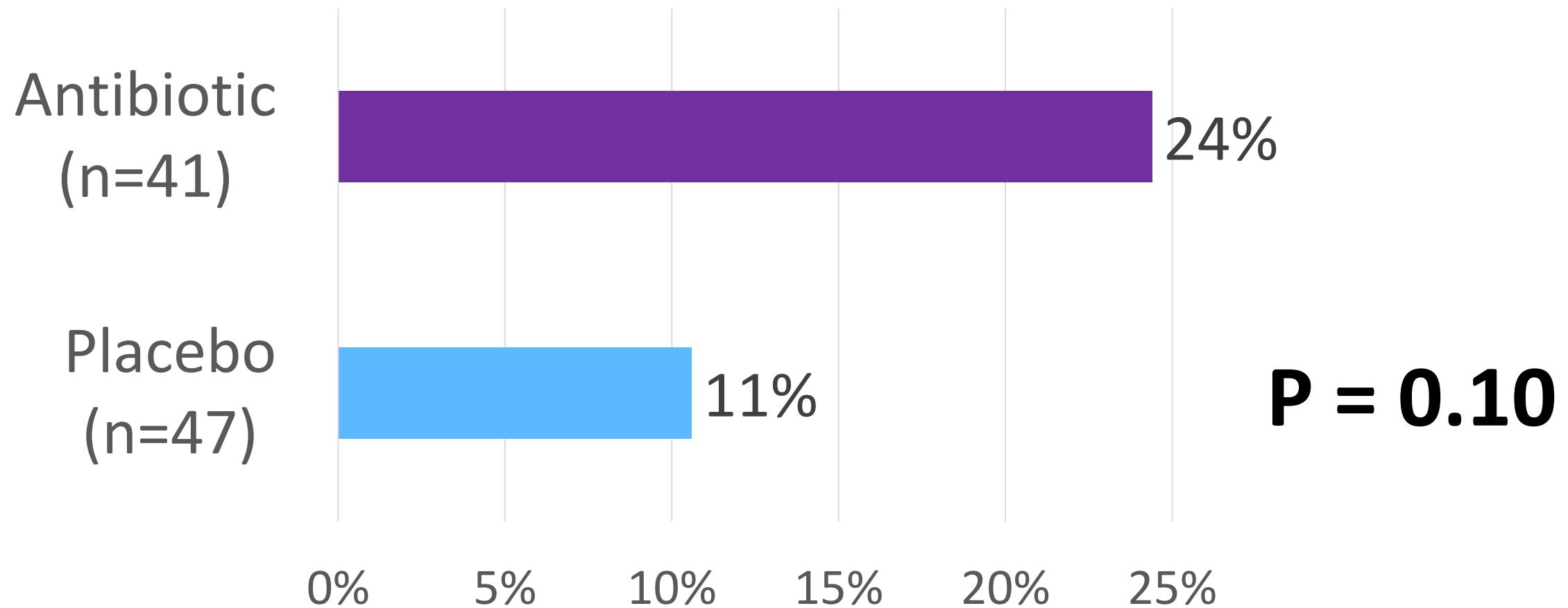
- Variable use of prophylactic antibiotics after stented hypospadias repair
 - 78% of pediatric urologists use prophylaxis “all the time”
- Previous studies have had contradictory results
 - 2 RCT's: prophylaxis reduces symptomatic UTI and fever (n=185)
 - 3 studies, including 2 RCT's: no benefits (total n=264)
- No prior placebo-controlled trials

Methods

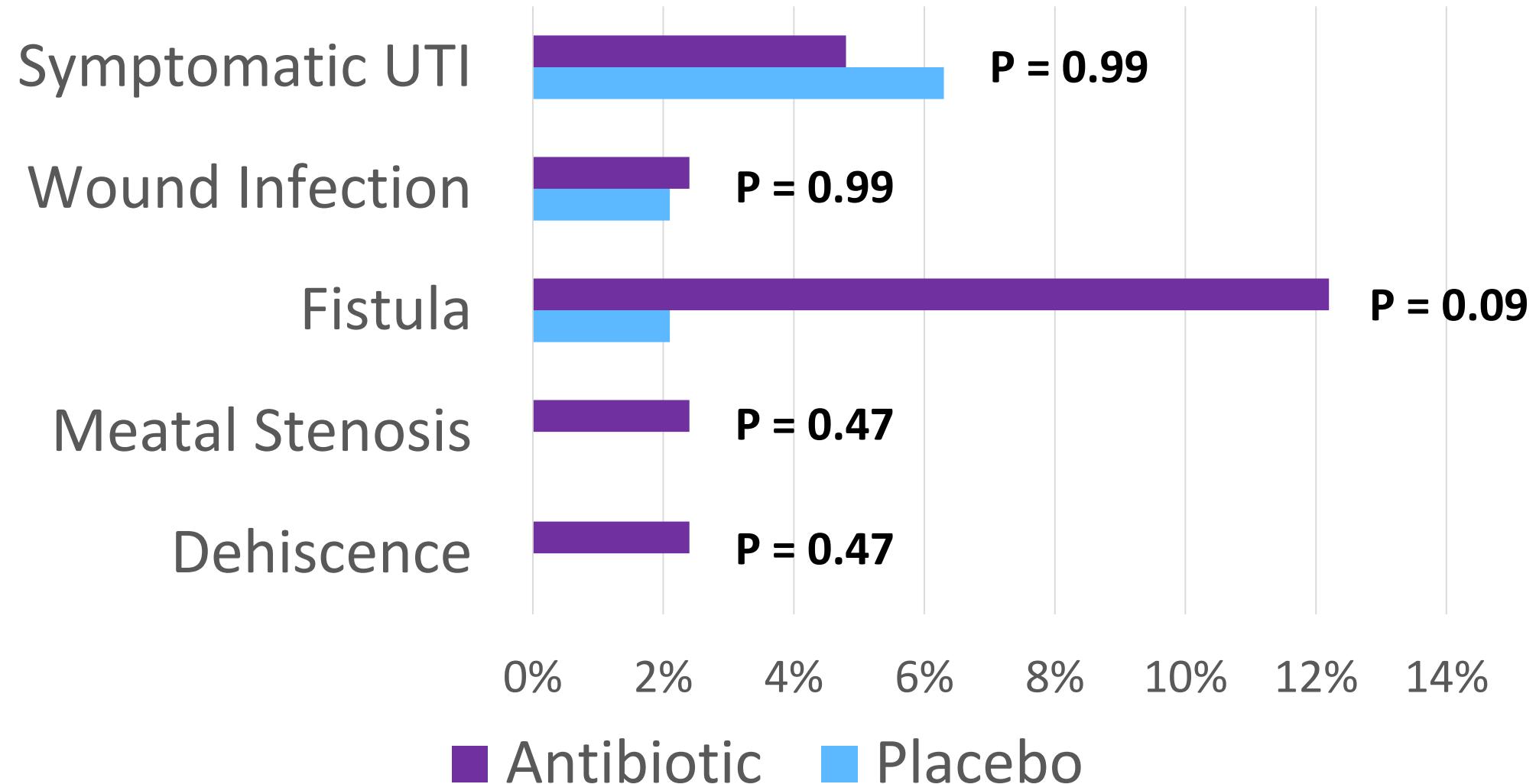
- Inclusion Criteria
 - primary, single-stage repair of mid-to-distal hypospadias
 - placement of open-drainage urethral stent for intended duration of 5-10 days
- Double-Blind Randomization
 - trimethoprim-sulfamethoxazole (TMP-SMX) x 10 days
 - placebo x 10 days
- Question: Do postoperative prophylactic antibiotics reduce complications?
- Primary Outcome: infection (symptomatic UTI, wound infection) OR wound-healing complication (fistula, etc.)

Periop Clinical Data	Antibiotic (n=43)	Placebo (n=48)
Age, mos, median (IQR)	9.7 (8.0-11.4)	9.7 (7.9-12.1)
Pre-operative Testosterone Use	8 (18.6%)	6 (12.5%)
Peri-operative IV Antibiotics	43 (100%)	48 (100%)
Locoregional Anesthesia		
Caudal Block	41 (95.4%)	43 (89.6%)
Penile Block	2 (4.7%)	4 (8.3%)
Meatal Location		
Glanular	2 (4.7%)	2 (4.2%)
Coronal	18 (41.9%)	19 (39.6%)
Distal Shaft	18 (41.9%)	22 (45.8%)
Mid-shaft	5 (11.6%)	5 (10.4%)
Length of Urethral Repair, mm	9 (7-12)	10 (8-10)

Primary Outcome (Infection OR Wound-healing Complications)



Primary Outcome Components: Breakdown



Conclusion

- Postoperative prophylactic antibiotics did not reduce complications after stented repair of mid-to-distal hypospadias
- Key Limitation: relatively small size
 - low statistical power
 - vulnerability to chance bias
- Growing body of evidence does not support use of prophylactic antibiotics in this context