Prophylactic antibiotics in urodynamics: a systematic review of effectiveness and safety

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CRD summary
The authors concluded that prophylactic antibiotics safely reduce the risk of significant bacteriuria after urodynamics, but that the effect on symptomatic urinary tract infection was unknown. The review was generally well conducted and the authors’ conclusions on efficacy appeared to be reliable. However, it is unclear whether there was sufficient evidence to support the conclusion that the intervention was safe.

Authors’ objectives
To evaluate the effectiveness and safety of prophylactic antibiotics for preventing urinary tract infection (UTI) after urodynamics (UDS).

Searching
The Specialised Register of the Cochrane Incontinence Group (June 2006), Cochrane Central Register of Controlled Trials (Issue 4, 2006), MEDLINE/PubMed, CINAHL, TRIP (all to January 2007), LILACS (to March 2007) and the National Library for Health were searched. Search terms were provided. The reference lists of relevant reviews and primary studies were handsearched, as were the proceedings of the International Urogynaecological Society and the International Continence Society (2004 to 2006). The search was not restricted by language.

Study selection
Randomised controlled trials (RCTs) of patients having urodynamics were eligible, provided they compared the use of prophylactic antibiotics versus placebo or no treatment.
The studies in the review included patients aged from 18 to 82 years, mostly female, who received UDS using standard techniques. Most studies recruited patients from urodynamics clinics. Exclusion criteria included self-catheterisation, permanent catheter in-situ, antibiotic allergy, current antibiotic therapy, existing UTI or recurrent cystitis, pregnancy, breast feeding and diabetes. A wide variety of doses, types and duration of prophylactic antibiotics was used. Regimens used included trimethoprim, nitrofurantoin, augmentin, ciprofloxacin, norfloxacin and cinoxacin, administered up to one hour before or up to one day after the intervention, as a single dose or for up to five days. Control groups received placebo or no treatment. In some studies both groups received phenazopyridine hydrochloride as a co-intervention. In all studies the primary outcome was significant bacteriuria, defined as over 100,000 bacteria per mL of clean catch urine, taken two to seven days post-UDS. Other outcomes reported were pyrexia, haematuria and dysuria. Outcomes were assessed at one day to one week after UDS.

Studies were independently selected by two reviewers.

Assessment of study quality
The following criteria were used to assess study validity: randomisation method; allocation concealment; blinding; numbers randomised, excluded or lost to follow up; use of intention to treat analysis; and use of power calculation. The validity assessment was performed independently by two reviewers using a standardised format.

Data extraction
Odds ratios (ORs) were calculated from the numbers of events in the control and intervention groups of each study, with 95% confidence intervals (CIs). Data from intention-to-treat analyses were used where possible. Data extraction was performed independently by two reviewers using a standardised format. Attempts were made to contact study authors for more information.

Methods of synthesis
Data were combined using the fixed effect Peto-modified Mantel-Haenszel method to obtain pooled ORs and 95% CIs. The number needed to treat (NNT) to avoid one case of significant bacteriuria was calculated. Heterogeneity was assessed using the $X^2$ test and $I^2$ statistic.
Results of the review
Eight RCTs were included (n=995), two of which were in abstract form. The studies were of low quality and methods were poorly described. One was double-blinded and two single-blinded, one reported adequate allocation concealment, one reported adequate randomisation method, two were analysed by intention to treat, three had at least 85 per cent follow up and three used a power calculation.

Effectiveness
Prophylactic antibiotics significantly reduced the odds of significant bacteriuria compared to placebo or no treatment (OR 0.39, 95% CI: 0.24, 0.61). Thirteen patients needed treating to avoid one episode of bacteriuria (NNT 13). No significant heterogeneity was detected for this finding (I²=33.8%).

Safety
Two adverse events were reported in the treatment group: one major anaphylactic reaction and one minor skin rash. There were few data on other safety outcomes. No Clostridium difficile infection was reported in the intervention group.

Authors’ conclusions
Prophylactic antibiotics safely reduced rates of significant bacteriuria after UDS, but the effect on symptomatic UTI was unknown.

CRD commentary
The objectives and inclusion criteria of the review were clear. Relevant sources were searched for studies, without language restriction. Steps were taken to reduce the risk of bias by having more than one reviewer independently involved in study selection, data extraction and quality assessment, although it was unclear how any disagreements were resolved. Appropriate criteria were used to assess study validity. The characteristics of included studies were reported in some detail. It was not entirely clear which studies prospectively collected data on adverse effects or whether follow up was adequate to detect any emergence of microbial resistance, so it was unclear whether there was sufficient evidence to support the authors’ conclusion that the intervention is safe. Suitable statistical methods were used to pool study data and assess for heterogeneity, but publication bias was not assessed as the authors determined that there were insufficient studies. The authors appropriately drew attention to the absence of data on symptomatic UTI and noted that asymptomatic bacteriuria is of unknown clinical significance. They also highlighted methodological problems in the primary studies (small samples, unclear allocation concealment) and heterogeneity between the studies with respect to the interventions used. The review was generally well conducted, and the authors’ conclusions on efficacy were likely to be reliable. However, it was unclear whether there was sufficient evidence to support their conclusion that the intervention is safe.

Implications of the review for practice and research
Practice: the authors stated that institutions could consider auditing rates of post-UDS de novo UTI and should instigate a prophylaxis policy if rates are high, in consultation with microbiologists.

Research: the authors stated that thorough cost-benefit analyses and better quality trials were required in this area.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.