

Preventing Ventilation Tube Otorrhea and Obstruction (PreVenTO2): A Randomized Controlled Trial

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Abstract

Objectives: To determine the effectiveness of ciprofloxacin 0.3% antibiotic eardrops in preventing clinically significant postoperative otorrhea and tube obstruction following grommet insertion in children. **Design:** 3-arm double-blinded randomized controlled trial. Randomisation in 1:1:1 ratio into two interventional and one control arm. The interventional groups received either 5 drops of topical ciprofloxacin 0.3% eardrops in each ear intraoperatively or intraoperatively and for 5 days postoperatively. The control group received no drops. Patients were assessed by blinded assessors at 6 weeks postoperatively. **Setting:** The study was conducted in a large tertiary health network in Melbourne, Australia. **Participants:** All children, 17 years and under, undergoing bilateral MEVT surgery with or without concurrent upper airway surgery for recurrent acute otitis media and chronic otitis media with effusion were approached. **Main Outcome Measures:** Presence of postoperative otorrhea and ventilation tube obstruction at 6 weeks postoperatively. **Results:** 256 pediatric patients completed the study with a median age of 4.02 years. 153 participants were male. Intraoperative antibiotics were more effective than control in preventing otorrhea (RR=0.341, 95%CI 0.158–0.738, NNT= 11.25, p=.006). Postoperative antibiotics were more effective than control in preventing ventilation tube obstruction (RR=0.424, 95%CI 0.193 to 0.930, NNT=14.7 p=.032). **Conclusion:** Intraoperative topical ciprofloxacin was effective at preventing early postoperative otorrhea and a prolonged course was effective at preventing ventilation tube obstruction. Future studies on this topic should seek to clarify whether particular subgroups of patients benefit more from prophylactic topical antibiotics and model for cost-effectiveness. **Trial Registration:** This trial was registered prospectively on the Australian New Zealand Clinical Trials Registry (ACTRN12618001082291) on the 28th of June 2018. Available at URL: <https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=375306>

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