Question: In young children with persistent otitis media with effusion, does prompt insertion of tympanostomy tubes protect against or minimise subsequent developmental impairment at 3 years of age compared with delayed insertion?

Design
Randomised (allocation concealed, blinded (outcome assessors), controlled trial with follow up to 3 years of age.

Setting
2 hospitals and 6 private paediatric group practices in Pittsburgh, Pennsylvania, USA.

Patients
Of 6350 children enrolled by age 2 months, 429 children (mean age 15 mo, 57% boys) in whom persistent otitis media with effusion developed by the age of 3 years participated. Exclusion criteria included birth weight <2270 g, small for gestational age, history of neonatal asphyxia or other serious illness, major congenital malformation or chronic illness, and multiple births, 94% completed the study.

Intervention
216 children were allocated to early (defined as “as soon as possible”) insertion of tympanostomy tubes (grommets) and 213 were allocated to late (defined as “up to 9 mo or later if effusion persisted”) insertion of tympanostomy tubes.

Main outcome measures
Developmental outcomes including speech, language, cognition, and psychosocial development (parenting stress and child behaviour) at 3 years of age.

Main results
At age 3 years no statistically significant differences existed between the treatment groups for any of the outcomes (table).

Conclusion
In young children with persistent otitis media with effusion, prompt insertion of tympanostomy tubes did not measurably improve developmental outcomes at age 3 years.

COMMENTARY
Affecting most children by 2 years of age, otitis media is the most commonly diagnosed illness, other than the common cold, in children in the US. In most children the illness resolves relatively quickly, but in many children, middle ear effusion, accompanied by hearing loss of variable degree, persists for months on end. In such children insertion of tympanostomy tubes is often done1 because of the long standing belief that the development of communication and interpersonal skills may be jeopardised by delaying the insertion of tubes in affected children.

The strengths of the study by Paradise et al lie in its randomisation of patients, blinding of outcome assessors to the timing of the procedure, and follow up to 3 years of age.

The results of Paradise et al showed that, even though children in the delayed treatment group had effusion more often during the first 24 months and had diminished hearing when they had effusion, speech, language, cognitive, and psychosocial development were not compromised by delaying the insertion of tympanostomy tubes beyond 3 years in otherwise well children.

This study is an important addition to the knowledge about otitis media and tympanostomy tube insertion. It should be remembered, however, that it relates only to children with persistent middle ear effusion and not to those with recurrent attacks of acute otitis media, in whom the advisability of surgery depends on other clinical outcomes such as severe pain and discomfort precipitated by pressure in the middle ear (and consequent loss of sleep).

Jeanette Robertson, RN, MSc
Deputy Director, Western Australian Centre for Evidence Based Nursing and Midwifery
Perth, Western Australia, Australia