National Horizon Scanning Unit
Horizon scanning prioritising summary

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EarPopper™ for the treatment of otitis media with effusion in children.

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Enquiries about the content of this summary should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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This Horizon scanning prioritising summary was prepared by Adriana Parrella, Janet Hiller and Linda Mundy from the National Horizon Scanning Unit, Adelaide Health Technology Assessment, Department of Public Health, Mail Drop 511, University of Adelaide, South Australia, 5005
NAME OF TECHNOLOGY: EARPopper™

PURPOSE AND TARGET GROUP: TREATMENT OF OTITIS MEDIA WITH EFFUSION IN CHILDREN

STAGE OF DEVELOPMENT (IN AUSTRALIA):
- ☑ Yet to emerge
- ☐ Established
- ☐ Experimental
- ☐ Established but changed indication or modification of technique
- ☐ Investigational
- ☐ Should be taken out of use
- ☐ Nearly established

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL
- ☐ Yes
- ☑ No
- ☐ Not applicable

INTERNATIONAL UTILISATION:

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>LEVEL OF USE</th>
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</thead>
<tbody>
<tr>
<td>United States</td>
<td>Trials Underway or Completed</td>
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</tbody>
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IMPACT SUMMARY:
Micromedics provides the EarPopper™ with the aim of treating otitis media with effusion (OME) in children.

BACKGROUND
OME or ‘glue ear’ is defined as the presence of fluid in the middle ear without signs or symptoms of acute ear infection (Rosenfeld et al 2004). OME is considered distinct from acute otitis media (AOM), which is defined as a history of acute onset of signs and symptoms. OME may occur spontaneously because of poor eustachian tube function, or as an inflammatory response following AOM.

The EarPopper™ is a non-invasive device for treating conditions such as otitis media with effusion, middle ear effusion, aerotitis/barotitis and eustachian tube dysfunction, without the need for surgery or antibiotics (Micromedics 2005).

The EarPopper™ device delivers a constant, regulated stream of air pressure and flow into the nasal cavity through the nostril with a 1-oz infant nasal syringe equipped with a plastic tip. During the moment of swallowing the air is diverted up the Eustachian tube clearing and ventilating the middle ear. The EarPopper™ relieves the negative ear pressure allowing any accumulated fluids to drain.
The device has two settings. Setting 1 delivers an air pressure of 5.2 psi at a volume velocity of 1,524 ml/min; setting 2 delivers an air pressure of 2.5 psi at a volume velocity of 1,690 ml/min (Arick and Silman 2005).

Figure 1. The EarPopper™ (Micromedics 2005)

CLINICAL NEED AND BURDEN OF DISEASE

OME is a very common condition in children, occurring mostly between the ages of one and three years with a prevalence of 10% to 30%, and a cumulative incidence of 80% at the age of four years (Burton et al 2005). Approximately 90% of children (80% of individual ears) have OME at some time before school age, most often between ages 6 months and 4 years (Rosenfeld et al 2004). In the first year of life, more than 50% of children will experience OME, increasing to more than 60% by age 2 years. Many episodes resolve spontaneously within 3 months, but about 30% to 40% of children have recurrent OME and 5% to 10% of episodes last 1 year or longer. Some children with OME may go on to develop chronic otitis media with structural changes (tympanic membrane retraction pockets, erosion of portions of the ossicular chain and cholesteatoma), language delays and behavioural problems.

DIFFUSION

The EarPopper™ is not currently available in Australia.

COMPARATORS

Alternative methods of managing persistent OME include observation, medical or surgical approaches. Medical approaches include administration of decongestants, antihistamines, corticosteroids, and antimicrobial agents. Surgical approaches may include myringotomy, a surgical incision into the eardrum (to relieve pressure or release pus from the middle ear) with or without tympanostomy tube placement, adenoidectomy with or without tonsillectomy; and insufflation of the middle ear using the Valsalva manoeuvre or the Politzer method.1

The efficacy of some of these methods has been questioned partly because OME resolves spontaneously in 80% to 90% of children within three months (Rosenfeld et al 2004). The benefits of antihistamines and antibiotics have also been questioned and/or not recommended

1 The two most common methods of insufflation of the eustachian tube are the Valsalva manoeuvre and the Politzer method. The Valsalva manoeuvre involves performing forced nasal expiration with the nose and lips closed. The Politzer method involves inserting the tip of a rubber air bulb into a patient's nostril, simultaneously compressing the other nostril with a finger, and having the patient swallow as the rubber bulb is compressed (Arick and Silman 2005).
for treatment (Williams et al 1993, Rosenfeld et al 2004). Potential complications of
tympanostomy tube placement include tympanic membrane retraction, foreign body reaction,
granulation, hyalinisation, tympanosclerosis, and hearing loss. Tympanostomy tubes often fall
out prematurely and there is a risk of otorrhea (discharge from external ear).

**EFFECTIVENESS AND SAFETY ISSUES**

In a recent study (level II intervention evidence) 94 children aged four to eleven years (174
ears) were randomised to treatment with the EarPopper™ in the home setting for a seven-week
period or to the control group (Arick and Silman 2005). Study criteria included a minimum
two-month history of middle ear effusion (MEE) and associated hearing loss, pure tone air-
conduction deficits, tympanometric peak pressures (TPP) of -100 decapascals (daPa) or less,
absence of large adenoids and other ear abnormalities.

Children in the control group (n=47; 86 ears) received no treatment during the seven weeks
and 47 patients (88 ears) were assigned to treatment with the EarPopper™ device for seven
weeks. Treatment with the EarPopper™ device was administered twice daily by the parent
(morning and evening) for seven weeks and compliance was monitored with a daily log. The
study group had a compliance rate of 98%. Children in the control group who had not
spontaneously recovered by the post-test were given the option of receiving treatment with
the study device upon the conclusion of their involvement in the study. Results for these
children were yet to be published at the time of writing this summary.

Audiometry (air- and bone-conduction threshold testing and tympanometry),
otoscopic examinations and otoscopy were performed at baseline and at four weeks
post study termination by investigators blinded to treatment. Treatment was temporarily
discontinued during respiratory tract infections and completed after recovery. There were no
reported difficulties in using the device.

The study reports significant improvements in mean air-conduction thresholds in the study but
not in the control group. There was a significant improvement in the TPP for the treatment
group compared to the control group ($p<0.001$). In the treatment group, comparisons of pre-
and post-test measures in each ear demonstrated a statistically significant improvement
($p<0.001$) in mean air-conduction thresholds across 4 frequency ranges in both ears. There
was no statistically significant improvement in mean air-conduction thresholds at any
frequency or in either ear in the control group ($p>0.05$). The treatment group experienced a
statistically significant improvement ($p<0.001$) in mean TPPs in both ears, while no
improvement was observed in the control group ($p>0.05$).

Hearing sensitivity returned to at least one ear in 40/47 (85%) patients in the treatment group
compared to 15/47 (32%) patients in the control group. Recovery of hearing sensitivity was
observed in 74% of treatment and 27% of control ears. At baseline, bilateral hearing loss was
present in 41/47 (87%) patients in the treatment group. Hearing was restored to normal in
37(90%) of these patients. Of these 37 patients, hearing was restored to both ears in 68% and
in one ear in 32%. Of those who achieved normal hearing sensitivity after treatment, normal
tympanic membrane mobility was seen in 75%, moderate mobility in 19%, and no mobility in
6%. The authors suggest the lack of hearing improvement in 7/47 (15%) of the treatment
group may be attributed to a deterioration developing over the four week gap between ending
treatment and audiologic evaluations (Arick and Silman 2005). These children were offered
an additional three weeks treatment with the EarPopper™. The results are yet to be published
at the time of preparing this summary.

Although the study ceased at four weeks post treatment, the authors report on 6 children who
experienced recurrent episodes of OME at different time points (three, seven, nine and 12
months) following treatment with the EarPopper™. For two of the three children who were
seen post study (one at three months and the second at seven months) a repeat treatment with the device improved hearing while the third child seen at nine months was found to have hearing within normal limits. All three children who had contact at ≥12 months reported surgical treatment for OME: two children received tympanostomy tubes (one with an adenoidectomy) and one child underwent an adenoidectomy alone. Repeat treatment with the EarPopper™ appeared to improve hearing in one child’s hearing post tube insertion (who was still experiencing OME with hearing loss). The authors do not report on the second child who received a tympanostomy tube. The child who received and adenoidectomy alone improved.

The EarPopper™ has been tested in young children and in the short-term only. The authors note that further studies of safety and effectiveness are required in children younger than four years, adolescents and adults.

**COST IMPACT**

The current cost of tube insertion including myringotomy (MBS item number 41632) is $202.65 (Medicare Benefits Schedule 2005). In 2004-05 Medicare Australia reported a total of 39,577 services for unilateral and bilateral tube insertions) performed in Australia at a total cost of $4,404,000 (Medicare Australia 2005). Of the total number of procedures 31,542 (80%) were performed in children aged 0-14 years (Medicare Australia 2005).

The cost of the EarPopper™ is $AUD400. At the time of preparing this summary there was no available data on the cost impact of the use of the EarPopper™.

**ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS**

No issues were identified/raised in the sources examined.

**OTHER ISSUES**

The authors of the above study developed the EarPopper™ device.

**CONCLUSION:**

Recurrent OME in children is a common condition with considerable burden on families in treating the condition. The evidence date suggests that the EarPopper™ may provide a safe and effective treatment option in the short term with minimal clinical impact on health practitioners as it can be used at home.

**HEALTHPACT ACTION:**

HealthPACT recommended that this technology be monitored.

**SOURCES OF FURTHER INFORMATION:**


LIST OF STUDIES INCLUDED

Total number of studies
Level II intervention evidence 1

SEARCH CRITERIA TO BE USED:

Eustachian Tube/ physiopathology
Hearing Tests
Middle Ear Ventilation
Nasal Decongestants/therapeutic use
Otitis Media with Effusion/ diagnosis/ therapy
Otitis Media with Effusion/physiopathology/prevention & control/ therapy
Otoscopy
Politzer Maneuver
Tympanic Membrane/physiopathology
Valsalva Maneuver