

What You Need to Know:

Treatment Alternative to
Costly Antibiotics and Surgery
for Common Ear Problems

A White Paper



THE EARPOPPER™ EAR PRESSURE RELIEF DEVICE — THE NEW Rx FOR COMMON EAR PROBLEMS

Otitis media with effusion (OME) is a very common condition affecting up to 90% of children, as well as many adults. Currently, OME is most often treated with prescription drugs, usually antibiotics, or ear tube surgery despite the recommended treatment guidelines. The EarPopper™ ear pressure relief device offers a third option for effective, economical, and safe treatment of OME while reducing the need for antibiotics or ear surgery.

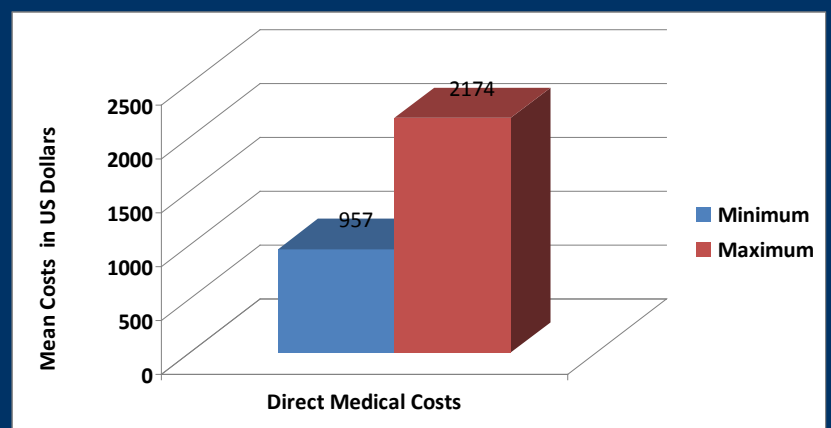
OTITIS MEDIA WITH EFFUSION (OME): FACTS AND FIGURES

- ❖ OME affects 80% of children in the US by age 4 increasing to 93% of children by age 7.^{1,2}
- ❖ This includes an estimated 2.64 million visits to Emergency Departments and almost 17 million physician visits for OME.³
- ❖ The estimated economic costs of OME range between \$3 and \$5 billion annually-- largely due to expenditures for antibiotics.³
- ❖ The proportion of OME cases treated with amoxicillin increased from 1.7% in 1996 to 41.9% in 2004.⁴
- ❖ Antibiotic resistance, which is caused by repeated and improper use of antibiotics is one of the top concerns of the US Centers for Disease Control and Prevention.⁵
- ❖ Vent tube placement is also often used to treat OME with the number of surgeries reported to have risen almost 250% in recent years, making it one of the most common surgical procedures performed for children.⁶
- ❖ Vent tubes may solve the condition for a short time but 40% fall out prematurely 4 to 7 months after surgery and 33% to 75% of children require repeat surgery to replace ear tubes.⁷

ESTIMATED COSTS OF OME

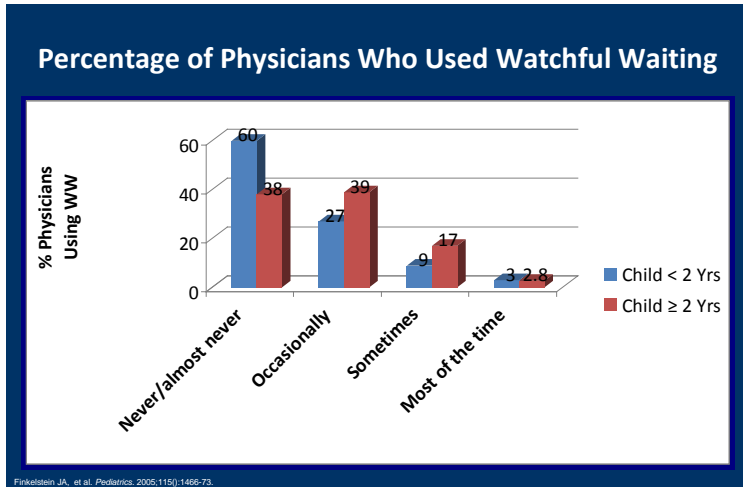
Estimated costs for medical treatment of OME range from \$947 to \$2,174 per episode.⁸ Direct medical costs include those associated with surgical insertion of ear tubes, outpatient visits to ear, nose, and throat specialists and primary care physicians, prescription medications, and other medical expenses. Indirect costs associated with OME include travel to medical appointments, non-prescription medicines, lost wages and time at work by caregivers, and home care expenses.

Estimated Direct Costs for Current Surgical or Medical Treatment of OME



RECOMMENDED TREATMENT GUIDELINES

Guidelines issued in 2004 by the American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, and the American Academy of Pediatrics recommend “watchful waiting” (WW).⁹ However, a 2006 survey revealed that only 15% of primary care physicians adhere to watchful waiting.¹⁰

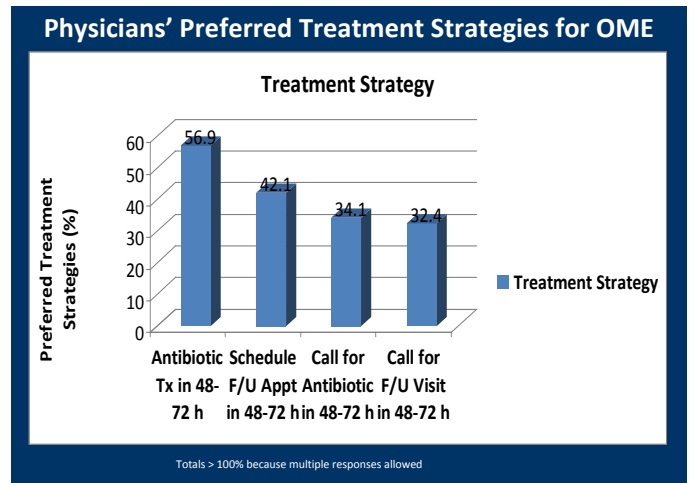


Among children under 2 years, 60% of physicians NEVER OR ALMOST NEVER use WW for initial treatment of OME and 77% of physicians report they NEVER, ALMOST NEVER, OR ONLY OCCASIONALLY use WW for children 2 or older with OME.¹¹

WHY DON'T PROVIDERS FOLLOW RECOMMENDED TREATMENT GUIDELINES?

Fifty-seven percent of physicians prefer to manage OME with an immediate prescription for antibiotics.¹⁰

Eighty percent of physicians indicate that the most important reasons they DO NOT follow recommendations for WW of OME are parental expectations, the burden of follow-up care, and concern for symptom management. Parents are concerned about their child’s pain, fever, risk of a more serious infection, hearing loss, and lost time at work and school due to the symptoms of OME.¹⁰

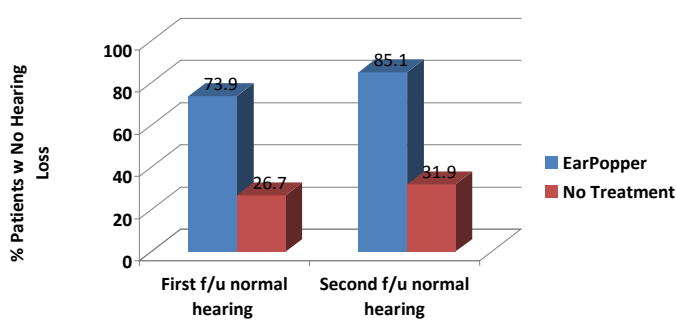


CAN PATIENTS AND PROVIDERS TREAT THE SYMPTOMS OF OME DURING WATCHFUL WAITING? YES!



There is a safe, effective, and cost-saving alternative to surgery and antibiotics for treatment of most cases of OME and other eustachian tube problems. The EarPopper, developed by an otolaryngologist and an audiologist, is a battery-powered device that safely delivers a constant, controlled stream of air pressure into the nasal cavity. This opens the eustachian tube, normalizes pressure in the ear, and eliminates symptoms of OME such as pain and hearing loss.

Efficacy of Treatment of Persistent OME and Associated Hearing Loss with the EarPopper™



STUDIES WITH CHILDREN AND ADULTS

The EarPopper has been tested in a number of studies including a 4-year study sponsored by the National Institutes of Health. 85% of children treated with the EarPopper had normal hearing at follow-up compared with only 32% of those not treated with the EarPopper.⁷

Other studies confirm that the EarPopper restores eardrum pressure to normal limits in adults treated with the device.¹² This suggests that the EarPopper can relieve the pain and discomfort of the pressure caused by OME and other eustachian tube dysfunctions.

According to Dr. Raymond Komray, West Michigan Hearing and Speech Center, "the EarPopper™ has a controlled rate of constant mild air pressure that comes in through the nostril...that opens up the Eustachian tube that goes up into the middle ear. It could minimize the need for common ear tube procedures in children, cut down on office visits, and use of antibiotics."¹³



CONCLUSIONS

Treatment of OME and other eustachian tube disorders with the EarPopper is a safe, effective method to restore normal ear pressure and hearing and reduce pain and discomfort. The EarPopper can help prevent more costly medical interventions such as insertion of tubes or treatment with antibiotics, which is expensive and can cause antibiotic resistance. The EarPopper provides patients and physicians with a reusable, simple-to-use, effective, and safe treatment for common but potentially costly conditions.

EarPopper NDC# 08564000000

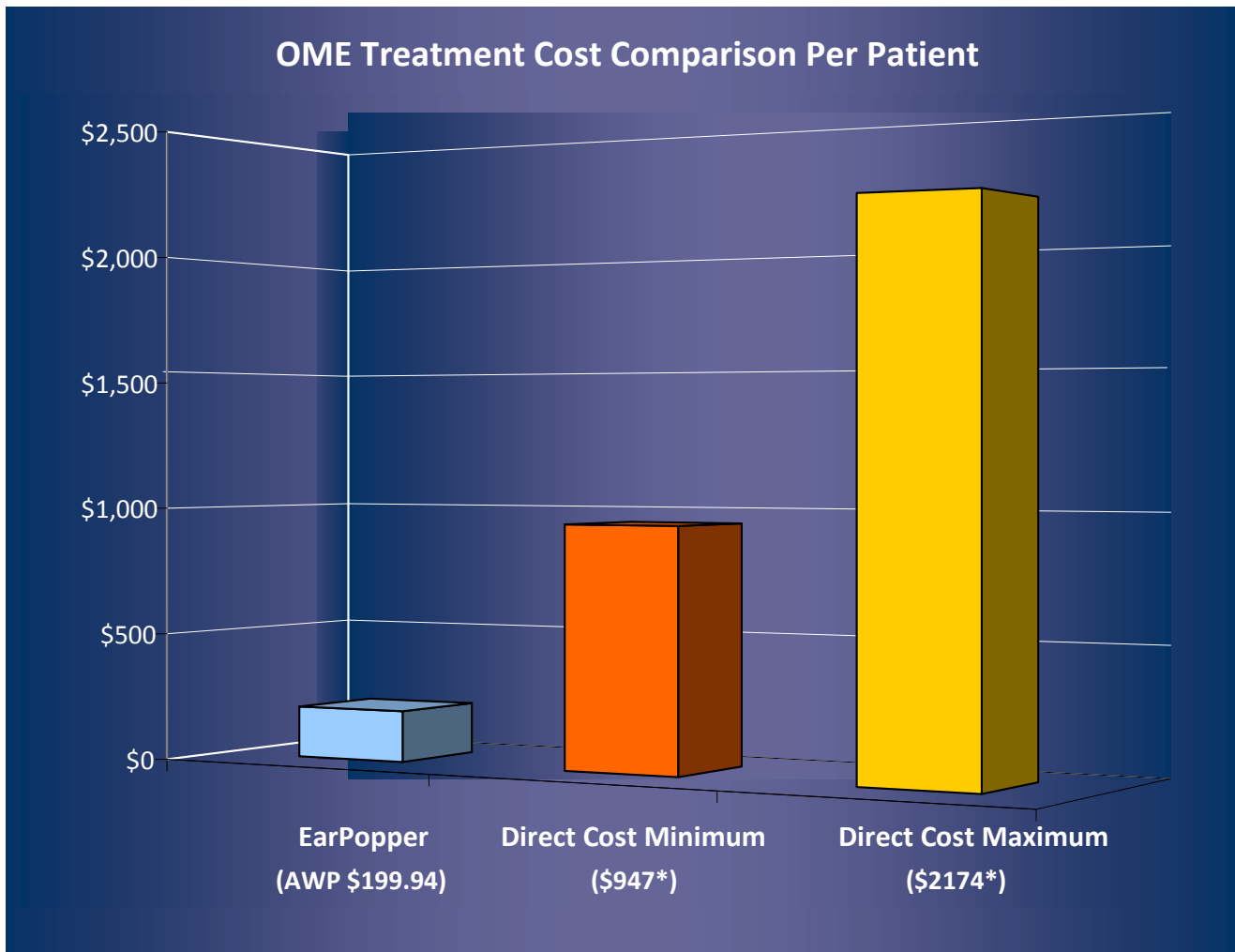
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