Serious Adverse Event Case Report

Adverse incident

Female child aged 8 years admitted John Radcliffe Oxford with suspected acute mastoiditis

Details of event

27/3/2012	Otalgia R ear. Debris in canal. Treated with Otomize spray for otitis externa.
03/4/2012	Screened and diagnosed with bilateral OME (2 B-type tympanomgrams) . Presenting symptoms of hearing loss and snoring. Randomised to the Otovent group
13/4/2012	Otalgia initially resolved but returned in last 2 days. C/o stinging when using Otovent. Otovent stopped initially. Erythromycin antibiotic given.
14/4/2012	Out of hours - R ear sticking out abnormally. Redness behind ear and mastoid area. TM not seen as debris in canal. Diagnosed R Mastoiditis and referred to John Radcliffe paediatric - Kamran's Ward. Admitting surgeon Mr Mahmood Bhutta SpR in ENT. Consultant in charge Mr Grant Bates. Mastoiditis (mild/early) confirmed and child settled quickly on iv antibiotic

Medical History

9/2010	Pneumonia
2/2011	Chest infection referred to Paediatrician due to recurrent infections
12/2/2012	LRTI with asthma symptoms treated with erythromycin

Other Medication:

Cetirazine, clotimazole cream

Summary incident details

This is the first reported association of autoinflation with acute mastoiditis as far as we are able to determine. The incidence in the trial of acute mastoiditis in the treated group is 1 in 100 and 0 in 100 in the control group. If all clinical trial evidence is included (where quality reporting of adverse events is expected-Cochrane update) then there are about 350 in the treatment group, which together with our trial data gives a rate of 1 in 450. Epidemiology of comparator background incidence is available from the GPRD and suggests a background rate of approximately 1 in 2000 cases for acute mastoiditis (where there was otitis media in the previous 3 months). Apart from trial evidence Otovent is readily available over the counter and has been for over a decade. The manufacturer has not noted any serious adverse incidents with Otovent. The case has thus far been discussed with the DMEC, the chair of the TSC, The practice, the admitting ENT surgeon, and at an Expert Otitis Media Meeting in Oxford on April 24th. All relevant regulatory bodies are being notified.

The case was reported as mild by the admitting surgeon, the child made a rapid recovery on iv antibiotics without the need for surgery. Mr Ramsden the chair of the TSC stated that the actual clinical details of the case were very typical especially in relation to the time frame of the events starting with an URTI/Otitis Media and then progressing to acute mastoiditis at about 10 days. An expert microbiologist wondered if the case was an unusual infection e.g. mycoplasma but no microbiology was available.

Ascending infections are a theoretical possibility for an association but fewer such infections were found in the only previous small trial from the UK (Blanshard and Maw). The DMEC has data of middle ear infection episodes after randomisation on our trial database.

A single previously unreported event: *acute mastoiditis* associated with autoinflation, presents us with interpretive difficulties that would be clarified had we more data (a large sample from diverse quality sources). We have not established a clear theoretical mechanism in this instance, the technique involves pressure changes in the nose akin to doing the Valsalva manoeuvre but by using a balloon. There are some interesting details in the child's individual case record that suggest that she probably has a higher than average background risk of acute upper respiratory and serious infections.

Ian Williamson Chief Investigator AIR study 26th April 2012