Atoms

Howard Bauchner, *Editor-in-Chief*

A new treatment strategy for children with gastro-oesophageal reflux

The increase in use of proton pump inhibitors (PPIs) in children of all ages is of concern. PPIs have been associated with numerous side-effects, including community and hospital acquired pneumonia and osteoporosis. There are data that they are not effective for the treatment of gastro-oesophageal reflux in infants.[1] Lee *et al* from Korea propose a different approach to management – one quite similar to how inhaled corticosteroids are used to treat patients with asthma – step-up and step-down therapy. Based upon response to 8 weeks of PPI use, patients were divided into three groups: (1) observation in patients whose symptoms had resolved; (2) continual treatment for 16 weeks in those patients with attenuated symptoms; and (3) continuous treatment in patients with persistent symptoms. This was not a randomised clinical trial and the authors provide little justification for the 8-week initial treatment period. In addition, I suspect that many patients stop taking their PPIs when they feel better. Nevertheless this 'on-demand' therapeutic approach to children with gastro-oesophageal reflux should reduce the number of patients who are exposed to long-term PPIs. ***See page 9.***

The evolving nature of research ethics

Last week I received a common inquiry – would *Archives* be interested in publishing a particular paper. This one focused on child maltreatment. The authors claimed it was an audit. Given the subject matter, I responded that the paper could be of interest however research ethics would have to be carefully described. They wrote back indicating ethical approval was not necessary because the study was an audit and that perhaps I was unfamiliar with UK law. I politely responded that I was not only quite well versed with UK law but also my responsibilities as a journal editor. They had mistakenly decided for themselves that the project was an audit and had not sought approval by a research ethics committee. I have mentioned this numerous times in Atoms, authors cannot decide for themselves what constitutes research – this decision must be made by a regulatory body with no vested interest in the study. Knowles and colleagues describe their experiences with obtaining approval for a multicentre follow-up study of children with congenital heart defects. They report that the ethic committees stipulated that they could not approach the families directly, but rather the request to participate in the study had to be sought by their general practitioners. Local study registration took 40 weeks. PD Singleton adds his voice to this discussion, describing the tension between researchers, patients and regulatory bodies. My group conducts many types of research, including clinical trials, observation cohort studies, mining of large administrative data bases, community-based research projects, gene-environmental studies (with banking of biological samples) and qualitative studies. Many of my colleagues become frustrated with our institutional review board. Obtaining approval can be a long and difficult process. A consent form that is deemed adequate at the time of initial submission can later be found inadequate. Increasingly, our ethics committee is reluctant to approve studies when some of the individuals involved in the research protocol are not our employees. My advice to our investigators – always ask an ethics committee if their project is research and governed by federal regulation. Second, learn from other investigators who have successfully submitted ethic committee applications. Although I applaud the increased attention to protecting the privacy and rights of research subjects, I fear that ethic committees are underfunded, with inadequate and often poorly trained staff. Because of national laws, many ethics committees 'go it alone,' with little cooperation between committees, frustrating investigators who are conducting multicentre trials. ***See page 14.***

Should all competitive athletes have ECGs?

There are no national cardiac screening programmes in the UK. This is a hotly debated international issue.[2] The Olympic Gods – the committee that organises the Olympics – as well as the European Society of Cardiology – recommend that all competitive athletes have resting 12-lead ECGs. Investigators from Bristol provide denominator data, the outcome of 11 elite athletes referred to a cardiology clinic because of possible cardiac symptoms. Ten of the 11 were allowed to return to sport. Rightfully the authors do not conclude that this study provides evidence of the effectiveness of a national screening programme for athletes. Whether countries should institute national screening programmes is a complicated decision, dependent upon available resources and a societies' tolerance of risk. See page 21.

Deformational plagiocephaly

Two recent articles shed some light on plagiocephaly, a consequence of the worldwide back to sleep campaign. Parents are concerned both about the cosmetic consequences of plagiocephaly as well as any potential developmental problems. This has led many parents to have their infants fitted with helmets. Hutchinson and colleagues from New Zealand describe the 'natural history' of deformational plagiocephaly or brachycephaly diagnosed during infancy in 129 4-year old children. Only 4% of the children were judged to have severe misshapen heads at follow-up and 87% of parents were no longer concerned. In a related study, Lipira *et al* found that helmets worn 23 h per day, compared to repositioning, had a significantly greater impact on asymmetry of the head as measured by three-dimensional whole-head surface scans.[3] Although both of these studies provide additional information about plagiocephaly, some basic questions remain unanswered. First, is plagiocephaly associated with any long-term developmental consequences? Second, is the use of helmets associated with improved head shape? An observational cohort study can answer the first question, but requires a carefully chosen control group. The second question can only be answered with a randomised clinical trial in which an appropriate primary outcome is defined before the study begins. ***See page 85.***

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