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Editorial

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Biological agents in chronic rhinosinusitis, simulation in ENT training and the 'fragility index' for randomised controlled trials

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We both either currently or previously worked at a hospital where in the 1970s and 1980s nasal polyp patients had badges awarded after having had a large number of nasal polyp operations (gold, silver and bronze). A patient with a history of anything between 25 and 100 operations was not unusual. Surgical polypectomy, whether in out-patients under local anaesthesia (in special 'nasal polyp lists') or in the operating theatre, was the default therapy for the patient with significant symptoms. Thankfully, this situation is now a rarity and the treatment of chronic rhinosinusitis with nasal polyps has been gradually medicalised, with many colleagues believing that it is only a matter of time before surgery becomes a relatively infrequently used treatment option. After the introduction of corticosteroids topically then systemically, we have seen macrolide antibiotics and interleukin antagonists, and now need to consider the indications for (very) expensive biological agents for patients with difficult-to-control polyps. This issue of The Journal of Laryngology & Otology has a paper of the month¹ from Liverpool (UK) which reviews the literature on the use of endoscopic sinus surgery versus a biological agent (dipulimab, an interleukin-4 and interleukin-14 inhibitor). The literature unfortunately includes no direct comparison between the two modalities of treatment, which makes comparison of complications difficult (a suggested avenue for further work). The eye-watering cost of the long-term use of this drug, as with most new 'biological' agents, allows the authors to conclude, '... cost-effectiveness, FESS is far superior to dupilumab given the high costs of this biological product. This might change after the next 10 years when the patent of this drug expires. If this drug is available at a more affordable price, it will likely revolutionise the treatment...'.

The Journal has published numerous articles on trends in education, particularly the gradual change in teaching practices in response to changes in trainees' working hours and experience in recent decades, as well as the reduction in the supply of cadaver temporal bones and other specimens for teaching.^{2,3} This issue contains two papers that examine teaching trends. The first, from York, Sheffield and Hull (UK), reviews the features of five different validated temporal bone simulation devices.⁴ The other is a Short Communication paper from Hopkins and colleagues in NHS Lothian (UK), with input from the Royal College of Surgeons of Edinburgh, that examines the efficacy of a short simulation-based course in teaching the basic skills needed for emergency ENT work. In most large hospital groups, large numbers of very junior staff need to be trained in these skills, trainees often cross-covering a variety of specialties.⁵ This latter study was precipitated by the need for accelerated learning during the coronavirus disease 2019 pandemic, but the lessons learned can be applied more widely to benefit patient safety.

Randomised controlled trials (RCTs) form the bedrock of cancer research, in head and neck cancers as with all others. This issue has a paper from Philadelphia (USA) that describes the interesting concept of the 'fragility index',⁶ which shows the number of patients needed to convert a statistically 'significant' result to an 'insignificant' result. In other words, how easily the statistical outcome of a trial can be swayed by small numbers of patients (hence they are 'fragile' conclusions). The results were disappointing for the head and neck cancer trials that the authors reviewed, with just two patients being able to alter the outcome of the trial, prompting the authors to recommend that the 'fragility index' be included in such RCT studies in future as a guide to the statistical robustness of the study in question.

References

- 1 Alshatti A, Webb C. Biologics versus functional endoscopic sinus surgery for the treatment of chronic rhinosinusitis with nasal polyps: a literature review. J Laryngol Otol 2024;138:361-6
- 2 West N, Konge L, Cayé-Thomasen P, Sørensen MS, Andersen SAW. Peak and ceiling effects in final-product analysis of mastoidectomy performance. J Laryngol Otol 2015;129:1091–6
- 3 Wijewickrema S, Zhou Y, Ioannou I, Copson B, Piromchai P, Yu C *et al*. Presentation of automated procedural guidance in surgical simulation: results of two randomised controlled trials. *J Laryngol Otol* 2018;**132**:257–63
- 4 Bolton L, Young K, Ray J, Chawdhary G. Virtual temporal bone simulators and their use in surgical training: a narrative review. J Laryngol Otol 2024;138:356–60
- 5 Hopkins ME, Li LQ, Yeo JJ, Hathorn I. Using simulation as a platform to prepare for ear, nose and throat emergencies in the coronavirus disease 2019 era and beyond. J Laryngol Otol 2024;138:466-71
- 6 Suresh NV, Go BC, Fritz CG et al. The fragility index: how robust are the outcomes of head and neck cancer randomised, controlled trials? J Laryngol Otol 2024;138:451-6

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