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Clinical Studies in Paediatric Otolaryngology Have Been Stopped and are Not Being Published

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Discontinuing and not publishing randomised controlled trials (RCTs) can waste resources, slow the progress of medical science, and weaken ethical standards across all specialties. Uncertainty persists regarding the incidence of abandoned or unreported RCTs including prevalent paediatric otolaryngology problems and treatments analysis of common paediatric otolaryngology RCTs that were completed and submitted to Clinical Trials. The registry's data were gathered, and publication status was determined. The corresponding realists were informed via email if a justification for the trial's termination or nonpublication could not be found after a thorough search. 260 RCTs remained after exclusion and were used in the study. Following analysis, it was discovered that of the 198 RCTs were abandoned. Program termination by the sponsor or management a lack of participant enrolment, difficulties in recruiting, or sluggish accrual were the most frequently cited reasons for RCT cessation. published RCTs were found. 36 (58%) of the stopped RCTs were never published, while of them did. In terms of the completed RCTs, 166 of the 198 completed trials.

Keywords: Otolaryngology consults; Otorhinolaryngology diseases; Covid-19; Epistaxis; Anticoagulation

Introduction

The development of treatment modalities and the discovery of strategies to enhance patient outcomes are both based on clinical trials. However, there are surprisingly few reports of therapy safety and efficacy in the juvenile patient group. As a result, children may receive therapies that are ineffective and have negative side effects [8]. Due to obstacles including strict criteria, a lack of research infrastructure, the relative lack of disease, and complicated ethical concerns, conducting otolaryngology clinical trials in children and adolescents is more difficult than doing so in adults. For instance found around otolaryngology clinical trials during a 3-year period, whereas estimated 122 paediatric otolaryngology clinical studies conducted over 17 years the incomplete and discontinued reporting of clinical trial data is one of these flaws. Clinical studies are frequently abandoned across a range of medical specializations and age groups **[1]**. As an illustration, Pica and Bourgeois discovered that nearly one-fifth of all paediatric clinical trials were halted discovered that 11% of trials for osteoarthritis were stopped. Particularly, in the field of otolaryngology, 39.2% of head and neck cancer clinical trials were found to have been stopped, and 40.2% were never published.

Moreover, studies have shown that surgical trials are more likely than non-surgical trials to end early and the reasons for these premature terminations are frequently avoidable. Clinical trials should never be abandoned since doing so exposes participants to possibly hazardous The Declaration of Helsinki mandates that all trial data, including unfavourable and inconclusive results, shall be made available to the public in an effort to prevent cessation and no publication. Rates and patterns of trial abandonment and non-publication, however, continue to be an issue. We wanted to assess the rate and trends of cessation and non-publication of clinical trials in prevalent paediatric otolaryngology problems and therapies in light of the considerable results of discontinuation and nonpublication in paediatric studies and other fields of otolaryngology. All patients' records who received otolaryngology consultations at a busy tertiary care hospital between April 30, 2020, and October 1, 2020, had their records examined. A record was kept of the patient's demographic data, length of stay, COVID-19 status, reason for consultation, and otolaryngology interventions **[2,3]**.

Using R software, statistical analysis was carried out. Communities and healthcare systems all around the world were ravaged by the SARS-CoV-2 (COVID-19) coronavirus pandemic, which resulted in over 449 million cumulatively confirmed cases and an estimated 5.9 million fatalities [1]. A cross-sectional multi-institutional survey of 55 otolaryngology departments across North America revealed nearly universal cancellations of elective cases at the height of the pandemic. Healthcare personnel adapted routines and procedures to protect themselves. Otolaryngology attending and residents have continued to practise medicine and accept call across the nation despite these shifts in cases and responses, with the unavoidable exposure to patients with COVID-19 who have been confirmed or are being investigated [2,3]. Despite the fact that COVID-19's otolaryngologic symptoms, such as olfactory impairment, sneezing, and nasal congestion, have thus far been well-described **[4]**.

Discussion

This single-institution study of inpatient otolaryngology consult rates according to COVID-19 status was motivated by the high rates of interventions for oropharyngeal bleeding seen in patients with severe COVID-19 infection, in light of new data challenging the benefit of therapeutic anticoagulation. We specifically wanted to know if individuals with COVID-19 would need more frequent measures to control their bleeding and if they would need an otolaryngology consultation more frequently than patients without COVID-19. From April 30, 2020, to October 1, 2020, otolaryngology was consulted on all of the patients. Patients with inpatient stays after scheduled surgeries were excluded. Test findings dated within 14 days before or after consultation were used to determine COVID-19 status. Even if their positive date was more than 14 days prior to consultation, patients were still regarded as positive if they were receiving treatment for COVID-19-related pneumonia or respiratory failure at the time **[5-7]**.

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Therapeutic anticoagulation was administered according to varying regimens set by the intensive care unit or hematology services. Usually, heparin infusions or daily enoxaparin treatment were required. Twelve categories were used to group consultations. Patients with trauma were examined for face trauma, laryngeal and temporal bone fractures, and traumatic injury to nearby structures (e.g. facial nerve, parotid duct, etc). Peritonsillar abscess, head-and-neck cellulitis, Pott's puffy tumour, epiglottitis, parotitis, and sialadenitis were among the infections. Epistaxis and oropharyngeal haemorrhage were among the bleeding. Otitis, mastoiditis, hearing loss, vertigo, and auricular infections were all evaluated with otology. Hemorrhage following a tonsillectomy, hardware loosening (such as mandibulomaxillary fixation devices), and potential surgical site infections were all discussed at post-operative consultations. Sinusitis, cerebrospinal fluid leaks, and pituitary tumours were all evaluated using rhinology. Consultations for placement, unintentional decannulation, exchanges, and bleeding from tracheostomy were all covered in the care of tracheostomies [**8-10**].

Conclusion

Consults to look into malignancy suspicions, head-and-neck cancers already known to exist, and benign endocrine masses were all considered head-and-neck masses. Consults requiring an assessment of the upper airway due to worries about airway compromise or active stridor that wasn't due to a foreign body obstruction were considered to be part of the airway evaluation. The dysphonia category covered consultations for individuals with abnormal phonation that involved an evaluation of the upper airway. If a foreign item was suspected of obstructing the airway or was known to be present, a foreign body consult included an airway assessment. Patients who were worried about aspiration or couldn't handle oral intake had consultations for dysphagia.

Acknowledgement

None

Conflict of Interest

None

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