

Determining the national fistula rate for unilateral complete cleft lip and palate repairs from the Cleft Care UK study

Principle Applicant: Bruce Richard

Scientific outline

Study Design: The study will be a retrospective analysis of data collected by the CCUK project.
Study duration: 4-6 months

Study Population: 268 five-year-old patients with nonsyndromic unilateral UCLP born between 1 April 2005 and 31 March 2007.

Ethics: The original CCUK study was designed for research purposes and obtained full ethical approval (REC reference number 10/H0107/33, South West 5 REC).³

Liaison with Bristol Cleft Collective: Through Professor Sandy and his CCUK team in Bristol, the preliminary study proposal was discussed and an invitation was extended to us to apply to become a CCUK collaborator in order to access its data and resources.

Data collection and management: Through the CCUK archive, data will be interrogated for fistulae and their anatomic locations. The fistula location will be classified using the Pittsburgh classification.⁴ All fistulae at or anterior to the incisive foramen (Pittsburgh class 5-7) will be excluded to prevent any ambiguity as to whether a fistula was intentional or not. With this we anticipate that a candid oronasal fistula rate can be obtained based on standardised cleft reporting across the UK since the implementation of CSAG recommendations.

The fistulae will be related to the cleft centres, repair techniques, and if possible the operating surgeons to analyse for statistical differences or trends. There may not be enough statistical power for all or some of these aspects to be analysed.

Who assessed the presence of fistula or not will also be noted in terms of whether it was the primary surgeon or a dental or other colleague, looking for bias in reporting.

Furthermore, the five-year functional speech outcomes (GOS.SP.ASS '97) will be analysed for patients with a fistula and compared to the rest of the CCUK subjects. An attempt will be made to perform subgroup comparisons of speech outcomes based on fistula location by Pittsburgh classification. For interest, comparisons will also be made between non-intentional fistula speech outcomes and intentional fistula speech outcomes (Pittsburgh class 5-7). This will help to assess if intentional fistulae were done in circumstances of more difficult or wider clefts as opposed to a surgeon's preference in technique.

All information will be entered on to a data protected spreadsheet or database.

Statistical Analysis: All variables will be summarised by standard descriptive statistical summary.

Study Limitations: Accuracy of data collection by CCUK. Sample size, especially for subgroup analyses.

Research Management: The investigator will perform this study based at the Birmingham Children's Hospital, UK, under the direction and supervision of Mr Bruce Richard. Results of this research will be written up as scientific papers and submitted for publication in peer-reviewed journals. The results of this study will also be disseminated by presentations at national and international meetings.

Summary: This retrospective analysis of the CCUK data aims to determine the postoperative incidence of nonintentional fistula following the repair of complete unilateral cleft lip and palate patients born between 1 April 2005 and 31 March 2007 across the UK. Fistula rates will be compared between fistula locations (by Pittsburgh classification), cleft centres, and repair techniques. Five-year functional speech outcomes (GOS.SP.ASS '97) will be analysed in relation to the presence of fistula, their locations, and compared against speech outcomes of patients with non-intentional fistulae.

Keywords: Complete unilateral cleft lip and palate, Fistula, CCUK, speech outcome