

Fistula Rate after primary palatal repair with intravelarveloplasty: a retrospective three-year audit of six units (NorCleft) in the UK

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Abstract

Our aim was to evaluate the rate of fistulation after one-stage palatal repair by intravelarveloplasty in the NorCleft Cleft Services (Scotland and Northern England), this being a primary outcome measure after repair of a cleft palate. We designed a retrospective, three-year clinical audit of six cleft units in the UK, and retrospectively reviewed the casenotes of babies with cleft palate born in 2006–2008 who were treated by intravelarveloplasty. We recorded type of cleft and procedure, including lateral relieving incisions, and our main outcome measure was the presence of a fistula behind the incisive foramen at 3 years of age, or a history of repair of a fistula. A total of 743 patients had cleft palates, but 69 (9%) were excluded (because they had not been operated on, or had not been reviewed by the age of 3 years, or their records were unavailable). A total of 626 patients had had a Sommerlad intravelarveloplasty repair, and 48 had had mixed procedures including Veau-Wardill-Kilner, Furlow, or two-stage repairs, and were not studied further. Eighty-seven (14%) who had had intravelarveloplasty had a fistula behind the incisive foramen. There was no significant difference in age at time of repair between those who developed a fistula and those who did not ($p=0.65$). The fistula rate of 14% is comparable with that of Sommerlad. The fistula rate was higher in patients who had had lateral releasing incisions (58/275, 21%) or who had bilateral cleft palate (16/63, 25%). To our knowledge this is the largest review of the fistula rate in patients who had primary palatal repair using the intravelarveloplasty technique in the UK, and shows significant correlation between lateral releasing incisions and formation of a fistula, except in the unilateral cleft lip and palate group ($p=0.12$).

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Introduction

The fistula rate is a recognised early outcome measure for repair of a cleft palate. Other measures such as speech and growth have been reported extensively, but a

considerable time elapses before results can be related back to the technique that was used to repair the cleft. Fistulation can, however, be assessed early in the clinic, and it is possible then to relate this to other outcome measures.

The radical technique of intravelarveloplasty as described by Sommerlad¹ is commonly used in both primary and secondary palatal repair in the UK, whereas other techniques such as the Furlow double opposing Z-plasty² are used, but less often.

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The reported fistula rate after primary repair of a cleft palate varies enormously. A recent worldwide systematic review with meta-analysis³ reported that oronasal fistulas develop in 8.6% of patients after repair of cleft palate, and highlighted several important reasons why the true incidence of fistula is difficult to establish. The authors discussed the problems of classification and the position of the fistula, and illustrated the lack of standardisation in the reporting of fistulas, which may lead to ambiguity and possible under-reporting.

Some authors include fistula of the primary palate and intentional, unrepaired fistulas, whereas others do not. Asymptomatic fistulas may or may not be reported, and follow up of patients can vary enormously. To confound these issues there are many other factors that must be considered including the patients, the age at the time of repair, the presence of syndromes, and the experience and skill of the operating surgeon.

A second, more recent systematic review⁴ reported the incidence of fistula to be 4.9% of 2505 patients over a two-year period. The most common site was reported as the junction of the hard and soft palate, and they identified a significant relation between Veau classification and the occurrence of a fistula, patients with a Veau IV cleft being significantly more likely to develop an oronasal fistula.

We know of only a few reports of the incidence of fistula after intravelarveloplasty worldwide. Lu et al⁵ reviewed 176 patients with non-syndromic cleft palate treated over a two-year period. At the one month follow up only 12 patients (7%) had a fistula. However, 68% of the patients were over 18 months old at the time of operation, which is older than the accepted age for repair in the UK.

In 2012 Williams et al⁶ compared von Langenbeck repair with Furlow's palatoplasty, the operations being done between 9-12 or 15-18 months of age. The 9-12 month von Langenbeck group had an overall rate of fistula of 16% in 133 patients, with the Furlow's group a significantly larger number. Kahraman et al⁷ reported that the risk of fistula after Furlow's palatoplasty was lower than that associated with the V-Y pushback technique.

Becker and Hansson⁸ reported the outcomes of 175 patients who had intravelarveloplasty, and differentiated between native and non-native patients with fistula rates of 5% and 16%, respectively.

In the UK fistula rates are often audited and presented locally at three-centre or four-centre audit groups,⁹ but these are generally small numbers as they are presented annually. The results are not widely available, and we know of few published data about fistula rates in the UK. Sommerlad reported an overall rate of 15%, with a rate of 12% for intravelarveloplasty if patients with bilateral cleft palate were excluded.¹

The NorCleft Audit Group is the forum in which the combined results from four cleft services (six units) are presented. NorCleft comprises units in the north of the United Kingdom: the Scottish Cleft Network (Edinburgh and Glasgow),

Northern and Yorkshire (Leeds and Newcastle), North West, Isle of Man, North Wales (Liverpool and Manchester), and Trent (Nottingham). At the 2011 four-centre meeting it was decided to organise a retrospective audit of fistula rates after primary palatal repair to establish baseline results before any prospective studies.

Our aim was to calculate an overall fistula rate for primary palatal repair, specifically intravelarveloplasty, in the north of the UK, by identifying and recording factors that may specifically influence the fistula rate such as operative techniques; classification of clefts; the incidence of underlying medical conditions, syndromes, and Pierre Robin Sequence; and the patient's age at the time of repair.

Methods

We retrospectively reviewed the casenotes of those born from 2006-2008. The inclusion criteria included patients who had had primary repair of a cleft palate before they were 3 years of age using the Sommerlad technique of intravelarveloplasty,¹ at one of the NorCleft units. Patients were identified from the units' databases. Data were extracted from the casenotes and recorded on a standard proforma. The presence or absence of fistula was identified at the three-year audit review.

Exclusion criteria included patients who had delayed primary repair of a cleft palate (after the age of 3 years) or a repair by an alternative surgical technique, if the operation or clinical notes were missing, and if they had not had a three-year review. They were also excluded if they were transferred to another unit and if the original operation had been done at another unit.

Data collected included year of birth, type of cleft, past medical history, syndromes, Pierre Robin Sequence, age at operation, operative techniques, and relieving incisions. Type of cleft was grouped by the LAHSHAL classification,¹⁰ and then simplified into cleft palate only, and unilateral or bilateral cleft lip and palate. If there was a separation between the palatal and lip components of the cleft (for example, an incomplete lip with a cleft of the soft palate alone), for the purposes of this study it was classified as a cleft palate alone (Table 1).¹⁰ The data were collated centrally and analysed using StatsDirect software (StatsDirect Ltd, Altrincham, Cheshire WA14 4QA, UK).

Results

Results were available for babies born during the three years 2006-8 for five units, with one unit providing results for the 2006 group alone. A further unit was unable to provide results in the format requested so was excluded.

A total of 743 patients were identified from the databases of which 69 were excluded by the criteria. Forty-eight patients did not have intravelarveloplasty so were also excluded and are not discussed further (Table 2).

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