The Hierarchy of Evidence

The Hierarchy of evidence is based on summaries from the National Health and Medical Research Council (2009), the Oxford Centre for Evidence-based Medicine Levels of Evidence (2011) and Melynyk and Fineout-Overholt (2011).

I Evidence obtained from a systematic review of all relevant randomised control trials.

II Evidence obtained from at least one well designed randomised control trial.

III Evidence obtained from well-designed controlled trials without randomisation.

IV Evidence obtained from well designed cohort studies, case control studies, interrupted time series with a control group, historically controlled studies, interrupted time series without a control group or with case-series

V Evidence obtained from systematic reviews of descriptive and qualitative studies

VI Evidence obtained from single descriptive and qualitative studies

VII Expert opinion from clinicians, authorities and/or reports of expert committees or based on physiology


Sham feeding for infants with unrepaired long-gap oesophageal atresia

<table>
<thead>
<tr>
<th>Reference (include title, author, journal title, year of publication, volume and issue, pages)</th>
<th>Evidence level (I-VII)</th>
<th>Key findings, outcomes or recommendations</th>
</tr>
</thead>
</table>
“When surgical treatment is delayed, some authors have suggested a method of "sham feeding" in which the patient is allowed to “eat” by mouth while the material swallowed is immediately aspirated from the Replogle tube; this allows the development of sucking and swallowing and a more rapid recovery of the oral feeding after correction of the atresia, but requires optimum care to prevent aspiration.” |
Feeding outcomes:
63% of the primary Foker process cases had reached full oral nutrition versus 9% of the secondary Foker process cases at follow-up (median follow-up 16 months for both cohorts). Individual times to full oral feeding data not provided. |

- IV
- 5 patients sham fed.
- Study compared sham feeding vs oral stimulation.
- Conclusion:
The sham feeding program demonstrates positive outcomes on infants’ oro-motor skills allowing earlier weaning of enteral nutrition via gastrostomy.


- IV
- Description of Foker Procedure / oesophageal elongation:
  “Pledgeted traction sutures were placed in the upper and lower esophageal segments, and for external traction, these were brought out above and below the incision. In some cases, internal tension was applied to one or both segments by anchoring the traction sutures in the prevertebral fascia. The tension on the external sutures was increased one to three times each day. Within these intervals, growth occurred and the tension on the segments lessened, requiring it to be retightened. The growth was followed by the location of clips placed on the esophageal ends by daily chest x-rays. When the growth was sufficient, the incision was simply reopened and a true primary repair performed.”


- VI
- All infants successfully completed the sham feeding protocol before undergoing delayed primary esophageal repair. After repair, they had a shortened time to full oral feeding.
  “Our ‘sham’ feeding protocol is safe and very effective in early development of oral feeding mechanisms and shortens time to complete oral feeding after delayed esophageal repair.”
IV

Key findings:

Time to full oral feeding (FOF) was significantly reduced in those 12 patients with successful sham feeding (medium FOF 75 days IQR 57-227; compared to those in the group not sham fed FOF 730 days, IQR 125-1100 vs P = 0.03).

In long gap OA, successful sham feeding improves time to full oral feeding post definitive repair and was not associated with aspiration.

Reported success with sham feeding even in patients undergoing staged repair with traction suture techniques, including in those following traction suture placement.

VI

“Infants with OA and distal TOF have a number of factors that influence the post-operative establishment of oral feeding and contribute to reliance on tube feeding at the time of discharge. These factors include associated surgical issues, postoperative complications related to TOF/OA repair, neonatal issues, associated congenital anomalies and respiratory issues.”

“The use of ‘sham’ feeding may be applicable to our population undergoing a delayed repair or replacement as this practice would support the early development of oral feeding, allowing the baby to breast or bottle feed in the first few weeks of life, thus facilitating oral feeding following OA repair.”
<table>
<thead>
<tr>
<th>Source</th>
<th>Grade</th>
<th>Summary</th>
<th>Key findings</th>
</tr>
</thead>
</table>
| Lemoine, C., Faure, C., Villeneuve, A., Barrington, K., Desrosiers, C., Thiboutot, L & Aspirot, A. (2016). P-21: Feasibility and safety of sham feeding in long gap esophageal atresia. *Diseases of the Esophagus*, Volume 29, Issue 3, 1 April 2016, Page 294, https://doi.org/10.1093/dote/29.3.294b | IV    | “27 patients were included in this study. 9 patients were offered sham feeding. Glucose water was most often offered at the time of gavage feeds. Quantities varied from 5 cc to 30 cc. Sham feeds were pursued until time of delayed primary anastomosis in 8 out of 9 patients. There were no medical contra-indications to sham feeding, as there were no complications derived from sham feeding. The two patients who benefited from the protocol seemed to have a decreased tendency to oral aversion while parents greatly appreciated the experience.” | Key findings: 
- Sham feeding is feasible and safe in LGEA.
- High parental satisfaction                                                                 |
| Sri Paran T, Decaluwe D, Corbally M, Puri P. (2007). Long-term results of delayed primary anastomosis for pure OA: a 27 –year follow-up. *Pediatric Surgery International*, 23 (7): 647-651.                                                                                         | VII   | Key findings: “At the time of this study, 15 out of the 17 survivors (88%) were on normal diet with no respiratory problems and 2 (12%) were dependent on gastrostomy feeds.”  
“The high incidence of gastroesophageal reflux and associated morbidity requires early intervention to prevent ongoing feeding problems due to oesophagitis and stricture formation.” |                                                                                                   |
Sham feeding sessions are considered if primary repair in infants with esophageal atresia is delayed to enable further growth of the infant and additional esophageal growth....Infants who are deprived of oral feeding may develop oral defensiveness or other behaviours that make the eventual transition to oral feeding difficult.

1. Ensure the Replogle tube is positioned correctly and is functioning.
2. The infant should be fed in an upright position.
3. Introduce sham feedings initially by offering a small amount of H2O, 5% dextrose/H2O or ½ strength expressed breastmilk by nipple. (To monitor infant's condition with sucking, swallowing & breathing. Some infants may require techniques to slow the flow from the nipple, i.e. Haberman feeder).
4. The Replogle tube is used to empty the esophageal pouch as the infant sucks and swallows. (Two options for retrieval of esophageal contents (milk & mucus) can be: (a) A mucus trap addition to the continuous suction set up, (b) withdrawing via a syringe attached to the Replogle tube.
5. Re-feed esophageal contents via the gastrostomy tube.
6. Increase amounts & strength of feed as per infant's tolerance. Mother can breast feed once routine is established.
https://clinicaltrials.gov/ct2/show/NCT03350022

| Further details required once study complete | Pilot study to evaluate sham feeding “to promote adequate oral skills in order to prevent oral aversion and/or poor oral skills due to the delay in oral feeds for surgical reasons. Sham feeding is intended for infants who are expected to have a prolonged course without normal enteral feeding by mouth.’ ‘Sham feeding has been shown to be safe and shorten time to oral feeding in infants with esophageal atresia with delayed esophageal repair. Anecdotal evidence from Le Bonheur suggests that sham feeding in post-operative gastroschisis patients improves parental satisfaction and engagement.” |