## The Hierarchy of Evidence

The Royal Children's Hospital Melbourne

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
- Melynyk, B. & Fineout-Overholt, E. (2011). *Evidence-based practice in nursing & healthcare: A guide to best practice (2<sup>nd</sup> ed.).* Philadelphia: Wolters Kluwer, Lippincott Williams & Wilkins.
- National Health and Medical Research Council (2009). *NHMRC levels of evidence and grades for recommendations for developers of guidelines* (2009). Australian Government: NHMRC. <u>http://www.nhmrc.gov.au/\_files\_nhmrc/file/guidelines/evidence\_statement\_form.pdf</u>
- OCEBM Levels of Evidence Working Group Oxford (2011). *The Oxford 2011 Levels of Evidence*. Oxford Centre for Evidence-Based Medicine. <u>http://www.cebm.net/index.aspx?o=1025</u>

**Replogle Tube Management** *Please note: minimal literature & evidence available on Replogle tube management.* All evidence level VII.

Further research required into this area.

Reference (include title, author, journal title, year of publication, volume and issue, pages)	Evidence level (I-VII)	Key findings, outcomes or recommendations
Alberti D, Boroni G, Corasaniti L & Torri F. 2011. "Esophageal atresia: pre and post- operative management.' <i>Journal of Maternal-Fetal and Neonatal Medicine</i> . 24 (S(1): 4-6.	VII	"A 10F Replogle tube is placed in the upper esophagus and placed in continuous suction; the double-lumen Replogle tube allows the aspiration of secretions, but limits the suction on the mucosa preventing ulcerations. Quite frequently the suction catheter becomes blocked by thick salivary secretions with a significant risk of aspiration if not recognized. Frequent irrigations with saline or infusion of 3– 5cc of air are useful to prevent blockage of the Replogle tube; sometimes the tube must be replaced."
Bairdain, S., Hamilton, T.E., Smithers, C.J., Manfredi, M., Ngo, P., & Gallagher, D., Zurakowski, D., Foker, J.E., & Jennings, R.W. (2015). Foker process for the correction of long gap esophageal atresia: Primary treatment versus secondary treatment after prior esophageal surgery. <i>Journal of Pediatric Surgery</i> , 50(6): 933-937. doi: 10.1016/j.jpedsurg.2015.03.010	IV	"The Foker process (FP) uses tension-induced growth for primary esophageal reconstruction in patients with long gap esophageal atresia."
Braithwaite, I. (2011). Continuous low suction pressure: an innovative solution to transporting patients with Replogle tubes. <i>Infant,</i> 7(4):132-133.	VII	"Replogle suggested that his design of a double lumen catheter should be used with suction pressures of -25-30mmHg, which equates to 3- 4kPa or 34-40cmH20 of negative pressure."

Cardinal Health (2020). Argyle <sup>™</sup> Replogle Suction Catheters. Accessed June 22, 2020, <u>https://www.cardinalhealth.com.au/en_au/medical-products/patient-care/obstetric-and-neonatal/neonatal-care/argyle-replogle-suction-catheters.html</u>	VII	Product description: "ARGYLE™ replogle suction catheters were specially designed for the neonate. Our replogle catheters are latex- free and are available in 6 Fr, 8 Fr and 10 Fr sizes. They feature a clear double-lumen tube, three smooth eyes and are highly X-Ray opaque. Venting action provides safe, effective drainage. The replogles are marked from 5cm to 25cm for measuring the depth of insertion."
---	-----	---

Children's Hospital Boston. 2013. The patient care manual - 'Insertion and Management of Replogle Suction Catheters.' Boston, USA.	VII	<ul> <li>Recommendations: "Insertion Precautions:</li> <li>Some medical and surgical conditions warrant special consideration before Replogle® suction catheter placement. The physician weighs the risks and benefits of Replogle® suction catheter placement for patients with these conditions. In these instances placement of Replogle® suction catheters may be restricted to physician or advanced practice nurse.</li> <li>Esophageal atresia with fistula between upper esophageal pouch and trachea.</li> <li>Growth induction sutures on proximal pouch.</li> <li>Esophageal leak.'</li> <li>'Maintain low continuous wall suction of Replogle® suction catheters at 20-40mmHg.</li> <li>Assess Replogle® suction catheter a minimum of hourly for correct insertion depth and patency.</li> <li>Gently irrigate the blue "vent" port of the Replogle® suction catheter with 1-2 ml air of normal saline every 2-4 hours as indicated</li> <li>Patients with an unrepaired fistula between the upper oesophageal pouch and trachea have Replogle® suction catheter flushed with air only.</li> <li>If the catheter not patent attempt the following:</li> <li>a. Gently flush blue "vent" port with 1-2 ml air.</li> <li>b. If not patent, gently flush blue "vent" port with 1-2ml normal saline. Saline is preferred over water in case of</li> </ul>
		with 1-2ml normal saline. Saline is preferred over water in case of inadvertent tracheal aspiration. c. If still not patent, replace Replogle® suction catheter."

Hawley, A. 2001. Long-gap Oesophageal Atresia – A Nursing Perspective. <i>Journal of Child Health Care</i> . 5 (1). Pp.19-25.	VII	Discussion included: "Problems identified with Replogle tubes: • Difficulty with correct placement
		<ul> <li>Tubes moving out of the correct position</li> <li>Trauma to the oesophageal pouch from continuous suction or misplaced tube.</li> <li>Blockage with possible aspiration</li> <li>Difficulty with size 10fg Replogle tubes in premature infants (due to the large diameter of the tube)."</li> </ul>

Hawley, AD & Harrison D. 'Suctioning Practices for the upper oesophageal pouch in infants with unrepaired oesophageal atresia in Australia and New Zealand.' P105. <i>Perinatal Society of Australia and New Zealand Annual Congress</i> March 2003, Hobart, Australia.	Л	<ul> <li>Findings:</li> <li>"A Replogle tube was used in 61% of the NICUs surveyed. A Replogle tube is double lumen tube; one lumen is for drainage of saliva and the other functions as an air vent. The Replogle tube is connected to continuous low pressure suction to aspirate saliva from the upper oeosphageal pouch."</li> <li>"Intermittent suctioning of the upper oesophageal pouch was used in 15% of NICUs. 23% of NICUs used a combination of intermittent and Replogle suction."</li> <li>"There are varied practices throughout Australian and New Zealand NICUs with regards to suctioning of the upper oesophageal pouch in infants with unrepaired oesophageal pouch in infants with unrepaired oesophageal atresia."</li> <li>"There is no evidence available in the literature outlining which method results in the best outcomes (short and long term) to infants and children with this condition."</li> <li>"Further research needs to be undertaken to establish the most appropriate method for providing suction of the proximal oesophageal pouch."</li> </ul>
--	---	---

Jawaheer G & Hocking M. 2009. 'Initial management of an infant with oesophageal atresia' Southern West Midlands Newborn Network.	VII	"The Replogle tube should be connected to low level suction with the pressure set at 5Kpa and increased as required to ensure continuous flow of secretions from the upper oesophagus (up to a maximum of 10Kpa). Patency of the Replogle tube shuld be checked every 15 minutes and the tube should be flushed via the blue side arm with 0.5ml saline if there is no movement of secretions."
Johnson PRV. 2005. 'Oesophageal atresia.' Infant. 1(5): 163-167	VII	Discussed: "Prevention of aspiration of pharyngeal secretionseither by regular intermittent suctioning or continuous aspiration of the upper pouch using a double-lumen lower pressure catheter, the Replogle tube."
Kolimarala, V., Jawaheer, G., & Reda, B. (2010). Management of the upper pouch in neonates with oesophageal atresia: National survey on use of Replogle tubes in United Kingdom (Poster). <i>Pediatric Research</i> , 68, 476. DOI: 10.1203/00006450-201011001-00954	VI	Research study involving questionnaire to obtain information relating to the use of Replogle tubes in neonates with oesophageal atresia in Neonatal units in the United Kingdom Low flow suction was used in conjunction with Replogle tubes in 87% of cases. Guidelines on the use of Replogle tubes were available in 40% of cases. The tube was flushed in 36% of cases. Variable practices & methods for managing the upper pouch were noted.

Lakkundi, A, Wake C & Ormsby J. 2010 'Management of infant with Replogle tube in NICU. ' Newcastle Children's Hospital, NSW. http://www.kaleidoscope.org.au/docs/GL/Repogle_NICU.pdf' accessed 6/9/12	VII	Guidelines support our clinical practice guideline. "The Replogle tube should then be gently passed until resistance is felt with the blind ending (atretic) upper oesophagus. Pull the Replogle tube back about 1/2cm, to prevent trauma and adherence to the oesophageal wall. Set the suction on the pump between 3.5Kpa (25-30mmHg 35-42cmH20). 0.5mls of 0.9% sodium chloride for injection should be instilled into the small lumen [Blue lumen] every 15 minutes."
Leeds Teaching Hospitals NHS Trust. (2018). Oesophageal atresia and trache- oesophageal fistula requiring a Replogle tube – Management of Infants with. Leeds Teaching Hospitals NHS Trust, Leeds, UK. Retrieved June 22, 2020 from http://lhp.leedsth.nhs.uk/detail.aspx?id=4008	VII	<ul> <li>"Replogle tube - 10Fg &gt; 1500gms</li> <li>Size 8Fg Replogle &lt;1500g, for the very premature infant."</li> <li>"Change Replogle tube every three to four days (more frequently if secretions are thick or excessive)."</li> <li>"Observe and document colour and consistency of secretions. Collect specimens of oral secretions as requested."</li> <li>"Do not include instilled volumes of sodium chloride 0.9% within fluid balance. Sodium chloride 0.9% instilled is continuously aspirated and therefore not an intake."</li> </ul>

Leung, T.S.M., & Bayston, R., & Spitz, L. (1985). Bacterial colonisation of the upper pouch in neonates with oesophageal atresia. <i>Z Kinderchirurgie</i> , 41: 78-80. DOI: <u>10.1055/s-2008-1043314</u>	VI	Described research study "the bacterial flora in the upper oesophageal pouch of forty neonates with oesophageal atresia was studied at daily intervals preoperatively. Of the twenty-nine infants whose oesophagus was anastomosed within 24 hours of admission, no organisms were isolated in sixteen, despite the fact that only nine of these patients had antibiotics. The remaining thirteen grew oropharyngeal organisms. Of eleven infants having delayed anastomosis eight received antibiotics. All eleven grew organisms in the upper pouch. Pseudomonas and serratia grew only in those receiving antibiotics. These results suggest that prophylactic antibiotics are rarely indicated. Efficient continuous aspiration of the pouch is probably more important."
Metcalfe, F. (2019). Yorkshire and Humber Neonatal ODN Setting up a Patient on a Replogle Tube. The Yorkshire and Humber Neonatal Operational Delivery Network.	VII	<ul> <li>"Recommendation for Replogle tube –</li> <li>Size 10Fg – greater than 1500g</li> <li>Size 8Fg – less than 1500g, for the very preterm infant</li> <li>Ensure secretions are draining continuously along the Replogle tube. Continuous drainage demonstrates optimum tube placement."</li> </ul>

Newborn Services Clinical Guideline: Neonatal Surgery 'Oesophageal Atresia with a distal Tracheo-oesophageal Fistula' 2012. http://www.adhb.govt.nz/newborn/guidelines/Surgery/SurgeryTOF.htm	VII	"Adequate drainage of the upper pouch is essential. This can be either by intermittent suction every 15 minutes or via insertion of a Replogle tube as far as it will go and placed on continuous low pressure suction. Flush with 0.9% NaCl usually Q15-30 minutes."
Replogle RE. 1963. 'Esophageal atresia. Plastic sump catheter for drainage of the proximal pouch.' Surgery. 54: 296-297.	VII	Recommends the use of a Replogle tube, a double lumen tube to provide continuous drainage of the upper oesophageal pouch.
Royal Hospital for Women (2014). Procedure Guideline: Set-up and insertion of Replogle tube. Retrieved November 20, 2020 from <u>https://seslhd.health.nsw.gov.au/sites/default/files/migration/RHW/Newborn_Care/Guidelines/Nursing/Replogleset.pdf</u>	VII	"A double lumen tube, where larger one is for drainage of saliva and the smaller one for instillation of 0.9% sodium chloride and serves as an air vent. Gently, insert the replogle tube via the oro- or naso-pharynx until resistance is met. Withdraw the replogle tube by 0.5 cm"
Scott, JE, Hawley, A, Brooks, J-A. (2020). Delayed diagnosis in esophageal atresia and tracheoesophageal fistula. <i>Advances in Neonatal Care.</i> doi:10.1097/ANC.0000000000000763	VII	Discusses: "Esophageal pouch suction can be done either intermittently or by insertion of a Replogle tube (10 Fr) 0.5 cm above the distal end of the esophageal pouch on continuous low pressure suction to remove saliva."
Southern West Midlands Maternity & Newborn Network. (2015). Neonatal Guidelines 2015-2017: Oesophageal Atresia. p. 231- 233. Retrieved November 20, 2020 from: http://kids.bch.nhs.uk/wp-content/uploads/2017/05/neonatal-guidelines-2015-17.pdf	VII	Recommendations: "Flush Replogle tube with 0.5 mL sodium chloride 0.9% via the sidearm every 15 min. More frequently if visible oral secretions. If no movement of secretions in Replogle tube after flushing with 0.5 mL sodium chloride 0.9% via the sidearm, change tube."

Spitz, L. 2007. 'Oesophageal atresia.' Orphanet Journal of Rare Diseases. 2: 24	VII	Recommends: "A suction catheter, preferably of the double lumen type (Replogle catheter No.10 French gauge), is placed in the upper oesophageal pouch to suction secretions and prevent aspiration occurring."
Women and Newborn Health Service Neonatal Directorate. (2019). Clinical Practice Guideline: Oesophageal atresia/tracheoesophageal fistula. Government of Western Australia, North Metropolitan Health Service. Retrieved April 20, 2020, <u>https://kemh.health.wa.gov.au/~/media/Files/Hospitals/WNHS/For%20health%20professionals/</u> <u>Clinical%20guidelines/NEO/WNHS.NEO.OesophagealAtresiTracheoesophagealFistula.pdf</u>	VII	<ul> <li>"Atrium suction control dial is set at -15cmH20 to -40cmH20 as ordered by the consultant."</li> <li>"To vent lumen of the Replogle tube is flushed every 15 minutes with 0.5mls of normal saline 0.9%."</li> <li>"To maintain patency of the Replogle tube, flush manually 2-4 hourly or more often if required with 2mls of normal saline 0.9%. Disconnect from the Atrium drain and attach a 10ml syringe, gently aspirate with syringe as you flush the saline in."</li> </ul>