Te Whatu Ora Health New Zealand

Candidates for Fetoscopic Endoluminal Tracheal Occlusion



Wāhi Rua New Zealand Maternal Fetal Medicine Network

In babies with moderate to severe Congenital Diaphragmatic Hernia (CDH), research into fetoscopic endoluminal tracheal occlusion (FETO) has been performed in order to increase the survival changes for baby. Tracheal occlusion is utilised to stimulate lung growth and has been shown a survival advantage in those with moderate to severe CDH. In the severe cases survival has shown to increase from 15 to 40% in those with severe left-sided CDH.

In Australasia this service is offered through the Mater Mothers Hospital in Brisbane, Australia. Access to this is via the High Cost Treatment Pool. Please read carefully the inclusion and exclusion criteria below.

All enquiries should be directed to Dr Glenn Gardener, Clinical Director of MFM at Mater Mothers Hospital. This should be directed by the lead Senior Medical Officer for the case. Dr Gardener can be contacted via:

Email: <u>Glenn.Gardener@mater.org.nz</u> Phone: +61 404 467 844

Once the case is considered to be a potential candidate a teleconference should be arranged to discuss the process, informed consent and for the family to ask any questions prior to transfer.

The teleconference should involve the patient and her family (whānau), clinical team (Senior Medical Officer, Fellow, Midwife co-ordinator) and the Brisbane MFM team. Other specialities that may want to be on the call include Paediatric Surgery and Neonatology.

Should the transfer to Brisbane go ahead the National Clinical Director of the NZMFMN (Dr Jay Marlow) will need to be involved for funding arrangements.

Dr Jay Marlow can be contacted by:

Email: jay.marlow@ccdhb.org.nz Phone: +64 21 924945

Inclusion Criteria

- Severe CDH
 - O/E LHR <25% irrespective of liver position
- Singleton pregnancy

Exclusion criteria

- Chromosomal defects
- Additional major structural anomaly
- Placental location limiting access

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- Technical limitations to surgery
 - o Severe maternal obesity
 - Uterine fibroids (placement)
- Elevated risk of preterm birth
 - Cervical length <15mm
 - Mullerian anomaly
 - Placenta previa
- Psychological, socioeconomic or other factors that might prevent adherence to protocol

Prerequisites

- Ability to relocate to Brisbane, Australia until the balloon reversal procedure takes place. However if there are complications may need to stay in Brisbane for the remainder of the pregnancy and postnatally
- High-cost treatment pool will pay for flights, surgery and accommodation. Food, local transport and passports are to be paid for by patient/family.
- Current passport
- Local antenatal MRI to evaluate lung volumes
- Normal microarray

Procedure

- Fetoscopic procedure which places a balloon in the trachea
- Performed at 27⁰-29⁶ weeks gestation
- Reversal at 34⁰-34⁶ weeks gestation



Maternal risks

• Minimal

Fetal risks

• Failure of balloon removal prior to birth or at the time of delivery 2%

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- Tracheomalacia 2%
- Fetal death at time of FETO (rare)
- ECMO 5%
- Preterm delivery (64-75%)
 - Average GA at delivery 34⁴ weeks.
- Preterm prelabour rupture of membranes (44-47%)

All statistics are taken from:

- Deprest JA, Nicolaides KH, Benachi A, Gratacos E, Ryan G, Persico N, Sago H, Johnson A, Wielgoś M, Berg C, Van Calster B, and Russo FM, for the TOTAL Trial for Severe Hypoplasia Investigators. Randomized Trial of Fetal Surgery for Severe Left Diaphragmatic Hernia N Engl J Med 2021;385:107-18.
- Van Calster B, Benachi A, Nicolaides KH, *et al*. The randomized Tracheal Occlusion To Accelerate Lung growth-trials on fetal surgery for congenital diaphragmatic hernia: reanalysis using pooled data. *Am J Obstet Gynecol* 2022;226:560.e1-24.

Notes:

- It is not a requirement to deliver at an ECMO centre. If this is to be considered it needs to be discussed that:
 - There is no evidence this is a survival advantage
 - There are harms related to the use of ECMO.
- AJOG: reanalysis using pooled data of moderate and severe cases
 - FETO increases survival in both moderate and severe cases. Likely better if done earlier.
 - Trade off earlier procedure with higher risk of PTB/PPROM.
- Moderate groups are not currently a criteria for international FETO until further evidence is available. There maybe consideration on a case-by-case basis.
 - o O/E LHR 25-34.9% irrespective of liver position
 - O/E LHR 35-44.9% with intra thoracic liver herniation
- Right sided CDH with <45% O/E LHR

This document was created by Dr Jay Marlow with input from members of Wāhi Rua NZMFM Network and Dr Glenn Gardener, Mater Mothers Hospital, Brisbane. Endorsed in December 2022.

The most up to date version of this document can be found on Healthpoint Wāhi Rua: New Zealand Maternal Fetal Medicine Network (NZMFM) webpages: <u>https://www.healthpoint.co.nz/public/wahi-rua-new-zealand-maternal-fetal-medicine/</u>