

Outcome after fetoscopic tracheal occlusion treatment of congenital diaphragmatic hernia



OBJECTIVE

Fetoscopic tracheal occlusion (FETO) is an experimental prenatal treatment intended to mitigate the pulmonary hypoplasia and hypertension that is a consequence of severe congenital diaphragmatic hernia (CDH). We evaluated outcome of FETO performed at our center and compared these to the largest feasibility study by Jani et al., (Ultrasound Obstet Gyneol 2009; 34:304-10).

BACKGROUND

Survival of infants with congenital diaphragmatic hernia (CDH) is dependent on the degree of pulmonary hypoplasia and hypertension that occurs as a developmental consequence of prenatal lung compression. The lowest infant survival is expected for fetuses with an observed/expected lung to head ratio (O/E LHR) <30%.

Fetoscopic tracheal occlusion (FETO), an experimental prenatal treatment intended to mitigate the pulmonary effects of severe CDH, has resulted in significantly higher than expected survival rates (Jani et al., Ultrasound Obstet Gyneol 2009; 34:304-10).

METHODS

Patients with isolated severe CDH (O/E LHR<30% by ultrasound trace method) were prospectively enrolled for FETO in an FDA monitored trial (NCT: 02710968). The prenatal and postnatal carepath was prospectively defined (figure on second page).

Procedure details, obstetric and infant outcomes until discharge were collected. Categorical outcomes were compared to study outcomes by Jani et al.

RESULTS

13/52 (25%) screened patients were enrolled between 2015-18 (11 left, 2 right CDH, median O/E LHR 23.4; range 15- 24.9%). FETO at 28+6 (27+4 - 29+6) weeks gestational age (wks GA), took 12 minutes (range 4-110) and was successful in all cases (vs 7/201 Jani et al, p1/40.9). All balloons remained in situ and contralateral lung increased by a median of 40.5% (21-83.1%, p<0.001, figure to on second page).

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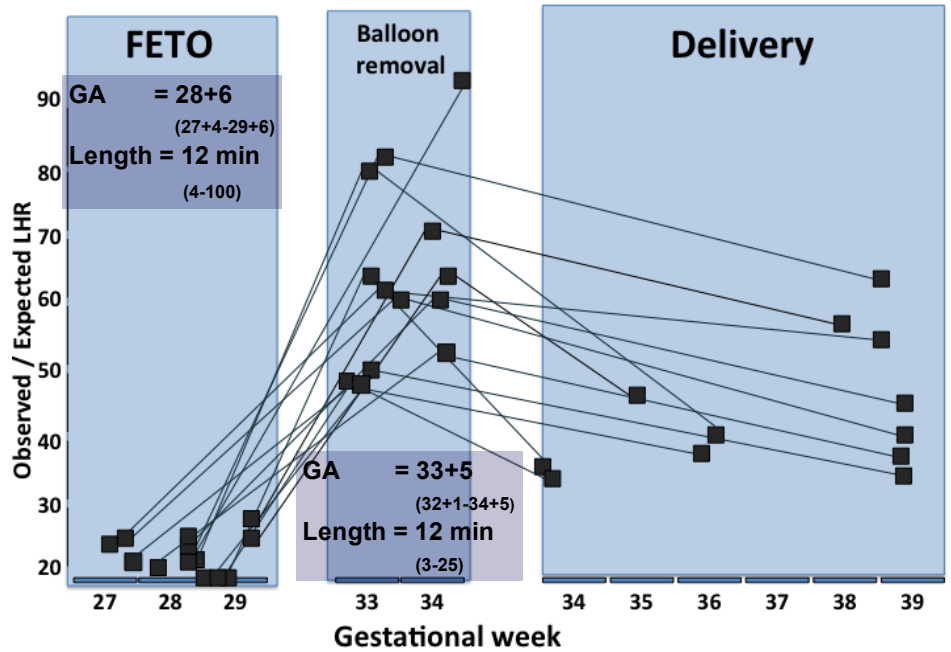
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All balloons were removed prenatally (vs. Jani: 146/194, $p < 0.05$) at 33+5 wks GA (32+1-34+5; median occlusion 33 days, range 17-44). 4 of 13 balloon removals were emergent (vs. Jani: 109/194, $p = 0.0893$) and in 7/13 by sono-guided puncture (vs. Jani, 40/146, $p = 0.0587$). Four patients had preterm membrane rupture (vs. Jani 99/210, $p = 0.3908$). 11 infants delivered to date at a median GA of 38+5 wks (33+6-39+4, vs Jani 35+3, $p < 0.001$). We observed one birth < 34 wks GA (vs. Jani 65/210, $p = 0.012$).

Patch repair was required for all 11 infants and was performed at a median of 7 days (range 2-15). Extracorporeal membrane oxygenation was required for 6/11 infants for a median duration of 7.5 days (3-19). All infants had pulmonary hypertension; requiring multiple agents. 9/11 infants delivered to date have survived until discharge (vs. Jani 98/205, $p < 0.05$).

Lung growth after fetoscopic tracheal occlusion



CONCLUSIONS

FETO performed in multidisciplinary single center setting is feasible and safe. Despite the severity of CDH we report significantly higher survival than expected in other feasibility studies. This should have a significant impact on the design of a randomized trial in the US for severe CDH. It is unclear if later gestational age at delivery, ECMO availability or standardized postnatal CDH management are the main drivers of improved survival.

	JHU N=13	Jani et al., N=210	p-value
Successful FETO	13 (100%)	7 (97%)	0.9000
Spontaneous balloon deflation	0	17 (8.1%)	0.3908
Lung size increase	40.5% (21-83%)	--	0.0001
Emergent balloon removal	4 (31%)	109 / 194 (66%)	0.0893
Balloon removal - fetoscopic	6 (46%)	106 / 146 (73%)	
- sono-guided	7 (54%)	40 / 146 (27%)	0.0587
Postnatal balloon removal	0	48 / 194 (25%)	0.0420
Removal to delivery interval (days)	30 (0-59)	--	
Delivery within 7 days of removal	3 (23%)	26 / 146 (31%)	0.4465
PPROM	4 (31%)	99 / 210 (47%)	0.3908
Delivery gestation (Week+day)	38+5 (33+6-39+4)	35+5 (25+7-41)	0.0060
Preterm birth < 34 weeks	1 (7.6%)	65 (31%)	0.0462
Delivery by - SVD	9 (69%)	--	
- Cesarean section	4 (31%)	--	
Birthweight	3060 (1920-3710)	--	
Apgar 1 / 5	3 / 6	--	
Cord pH	7.31 (7.25-7.38)	--	
1 hour pH after birth	7.15 (6.56-7.29)	--	
ECMO	7 (54%)	--	
Length of ECMO	7 (3-19)	--	
Surgical repair with patch	13 (100)	--	
- Day of repair	6 (2-15)	--	
- Repair on ECMO	4 (31%)	--	
Survival until discharge	11 (85%)	98 (47%)	0.0277

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