



Radiologic assessment of fetal tracheal balloon occlusion

Eric J. Jordan ^{a,*}, Vickie A. Feldstein ^a, Willieford Moses ^b, Andrew S. Phelps ^a

^a University of California San Francisco, Department of Radiology, United States

^b University of California San Francisco, Department of Surgery, United States

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ABSTRACT

Fetal endoscopic tracheal occlusion (FETO) is a novel technique to treat cases of isolated severe congenital diaphragmatic hernia (CDH). Although there are benefits of MRI over ultrasound in assessing lung volumes, it is unknown whether there are benefits of MRI for localizing the tracheal balloon. This is a retrospective study reviewing the imaging characteristics of FETO in patients who underwent both MRI and ultrasound exams done to localize tracheal balloons.

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1. Background

Fetal endoscopic tracheal occlusion (FETO) is a novel technique used to treat cases of isolated severe congenital diaphragmatic hernia (CDH) in both Europe and the United States. FETO is an intrauterine procedure that utilizes a percutaneous technique to place a small balloon within the fetal trachea [1]. The purpose of this intrauterine tracheal occlusion is to prevent fetal lung fluid egression, thereby increasing pulmonary pressure [2]. The increased pulmonary pressure is theorized to increase alveolar space and pneumocyte maturation, which in turn may improve pulmonary hypoplasia and pulmonary hypertension [3]. The concept for this procedure was inspired by observation of the over-expanded fluid-filled lungs in fetuses with CHAOS: congenital high airway obstruction syndrome.

Both prenatal ultrasound (US) and fetal magnetic resonance imaging (MRI) are utilized to evaluate the fetus, determine the severity of CDH and inform prognosis. Measurements from *in utero* imaging techniques include calculation of the lung-to-head ratio (LHR) with ultrasound, as well as total fetal lung volume (TFLV) and percent predicted lung volume (PPLV) with magnetic resonance imaging [4–6]. In patients who have undergone FETO, both ultrasound and MRI can be used to confirm positioning of the balloon within the trachea. In addition, ultrasound and MRI are often used to serially measure estimated size and change in lung volumes following the procedure while the balloon remains deployed [3,7]. Prior to delivery of the infant, the balloon must be removed

in one of two ways: a) second prenatal fetoscopic surgery or b) *Ex Utero* Intrapartum Treatment (EXIT) procedure *via* a planned cesarean delivery [8]. However, if on serial imaging the balloon is found to have migrated, dislodged or deflated, the mother could potentially deliver the infant without undergoing a balloon removal procedure.

This is a retrospective study reviewing FETO patients who underwent both MRI and ultrasound exams done to localize deployed tracheal balloons. Although there are reported benefits of MRI over ultrasound in assessing lung volumes in fetuses with CDH, it is unknown whether there are benefits of MRI for localizing the tracheal balloon in patients who have undergone FETO [6]. The surgical management and clinical outcomes of CDH cases treated with tracheal occlusion at our institution are being reported separately and are not included in this manuscript.

Little has been reported about imaging findings following *in utero* intervention for CDH with FETO. The purpose of this retrospective study is to describe our experience utilizing US and MRI for visualizing and localizing the fetal tracheal occlusion balloon.

2. Methods

This retrospective image and chart review study was approved by the Institutional Committee for Human Research.

Retrospective analysis of all patients who underwent FETO procedures for severe left-sided CDH performed at a single institution between January 2008 and November 2014 was conducted. This cohort of patients was part of a larger clinical/surgical FETO research project. The technical aspects and clinical outcomes in that series are being reported separately and not included in this manuscript. The study reported here addresses only the imaging aspects of post-procedure balloon

* Corresponding author at: University of California San Francisco, Department of Radiology & Biomedical Imaging, 505 Parnassus Ave, Room M-327, San Francisco, CA 94143, United States.

E-mail address: eric.jordan@ucsf.edu (E.J. Jordan).

identification and localization by targeted fetal ultrasound and MRI. The tracheal balloon specifications utilized during this time frame are: Nfocus Neuromedical (Palo Alto, CA), GVB 17 Detachable Balloon, silicone balloon with a maximal diameter of 8.5 mm and maximum length of 11.5 mm. This balloon model was the most readily available and frequently utilized in the United States during this time period. At our institution, intra-operative ultrasound is utilized to guide and then confirm placement of the fluid-filled, deployed occlusion balloon within the fetal trachea. Post-procedure sonogram is performed the next day, followed by serial studies to monitor the fetus, assess the size and echogenicity of the lungs, and demonstrate position of the tracheal balloon. Post-FETO MRI is often though not routinely performed at our institution and may be conducted in some cases specifically for confirmation of tracheal balloon position.

Inclusion criteria for this study included any patient enrolled in the aforementioned cohort study who had undergone both post-FETO US and MRI within 1 week of the other. A total of 6 potential imaging studies for each patient were reviewed, including US and MRI done at three time points: a) within 1 week prior to FETO, b) within 1 week following FETO, and c) within 1 week prior to balloon removal, EXIT procedure, or conventional delivery. All imaging studies (US and MRI) were reviewed by both a pediatric radiologist (AP) and dedicated sonologist (VAF). The reviewers were blinded to the outcome. The pediatric radiologist is fellowship trained with three years of fetal MRI experience. The dedicated sonologist is fellowship trained with over 20 years of experience. Any discrepancies between the readers were discussed further and a single consensus interpretation was reached. The US and MRI results were compared to one of three possible reference standards for outcomes: prenatal balloon removal by fetoscopic surgery, postnatal balloon removal during EXIT or postnatal imaging of the newborn. The relationship between post-FETO US and MRI was defined as concordant when both imaging studies demonstrated either a) balloon within the trachea or b) balloon not within the trachea (regardless of whether extra-tracheal balloon position could be determined). The US and MRI findings were defined as non-concordant when one modality could demonstrate the balloon within the trachea whereas the other study revealed the balloon not within the trachea. This definition was chosen due to the importance and clinical necessity of determining whether the balloon is or is not located in the fetal trachea.

2.1. Ultrasound technique

Detailed fetal sonograms were performed by sonographers, with additional targeted images obtained by sonologists (radiologists with US expertise and range of experience of 10–25 years in high risk obstetrical US). These exams included dedicated images focused upon the fetal

neck and region of the trachea. The ultrasound equipment used was Logiq E9 (General Electric) with a range of transducers (C1–6, C2–9, 9L-D, RAB 6-D).

2.2. MRI technique

All studies were performed on a 1.5 Tesla magnet (General Electric 1.5 T HD23.0 V02), with the exception of one examination that was conducted on a 3 Tesla magnet (General Electric 3.0 T Discovery750 DB24 V01). All studies included single shot fast spin echo (SSFSE) and T1 gradient sequences in multiple fetal planes.

3. Results

A total of 8 patients underwent FETO procedures between 2008 and 2014. Of these, only 6 patients underwent both post-FETO US and MRI thereby meeting inclusion criteria for this series. The indication for MRI in 4 of the 6 patients was to calculate percent predicted lung volume (PPLV); in 2 of the 6, the indication was to assess balloon position due to non-visualization by ultrasound.

At the time of FETO procedure, the mean maternal age was 32 years, mean gestational age was 27 weeks with mean lung-to-head ratio (LHR) of 0.8, and mean PPLV of 30 (Table 1). The average number of post-FETO MRI studies per patient was 1.33 (range 1–2). The average number of post-FETO US studies per patient was 6 (range 5–7). All but 1 of the paired US and MRI exams reported in this series were performed within one day of the other. There was one patient in whom the post-procedure imaging studies were conducted 5 days apart.

On US imaging, the tracheal balloon was identified as non-shadowing short linear parallel bright reflectors related to the metallic valve and/or abnormal dilatation of the fluid-filled trachea. Ring-down artifact due to the metallic valve component of the balloon was often appreciated. Dilatation of the trachea is believed to be secondary to the fluid-filled balloon contours or to retained intra-tracheal fluid obstructed by the balloon. As the metallic balloon valve is located at the proximal (upper) aspect of the detachable balloon, the parallel bright reflectors will always be cephalad to the abnormal tracheal distention (Figs. 1, 2). When the balloon is deflated and/or dislodged from the trachea, visualization of the tiny metallic valve can reveal the balloon location (Figs. 3, 4).

On MR, the tracheal balloon was identified on SSFSE imaging by abnormal dilatation of the fluid-filled trachea. T1 gradient imaging did not prove to be helpful in identifying the balloon. No susceptibility artifact from the tiny gold valve at the edge of the balloon was appreciated on T1 gradient sequences. In 1 case, punctate focus of T2 hypo-intensity

Table 1
Demographics and results of the study patients.

Maternal age (years)	Gestational age (weeks)	Lung-head ratio (LHR)	PPLV by MRI	Balloon location by US (# of exams)	Balloon location by MRI (# of exams)	Follow-up
31	26	0.9	13	Trachea (6)	Trachea (1)	Confirmed at removal
32	26	0.8	34	Trachea (6)	Trachea (1)	Confirmed at removal
30	28	0.9	54	Trachea (5)	Trachea (1)	Confirmed at removal
21	27	n/a ^a	12	Not in trachea ^b (7)	Not in trachea (2)	Confirmed by X-ray
37	27	0.9	21	Not in trachea ^c (6)	Not in trachea ^d (2)	Not identified ^e
36	27	0.5	49	Not in trachea (5)	Not in trachea (1)	Not identified ^f

Clinical and imaging findings in the 6 reported patients are summarized.

Maternal age and gestational age at the time of FETO procedure.

LHR and PPLV are calculated from imaging studies done prior to FETO.

Balloon location as shown by US and MRI exams following intervention with FETO.

Number of studies post-FETO and prior to balloon removal or delivery (in parentheses).

^a LHR could not reliably be measured.

^b Intra-abdominal location of balloon valve shown by ultrasound.

^c Balloon valve shown within the amniotic fluid by ultrasound.

^d Possible metallic susceptibility artifact due to valve within the amniotic fluid on SSFSE MR images.

^e Patient declined delivery by EXIT procedure, no balloon identified at normal vaginal delivery.

^f EXIT performed, balloon not visualized.

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