ORIGINAL ARTICLE

Development and use of a high-fidelity simulator for fetal endotracheal balloon occlusion (FETO) insertion and removal

Rory Windrim[1,2]*, Greg Ryan[1,2], Francis LeBouthillier[3], Paolo Campisi[2,4], Edmond N. Kelly[2,5], David Baud[1,2], Shi-Joon Yoo[2,6] and Jan Deprest[7]

[1]Fetal Medicine Unit, Mount Sinai Hospital, Toronto, Canada
[2]University of Toronto, Ontario, Canada
[3]Department of Sculpture, Ontario Art and Design University, Toronto, Canada
[4]Department of Otolaryngology – Head and Neck Surgery, Hospital for Sick Children, Toronto, Canada
[5]Department of Neonatology, Mount Sinai Hospital, Toronto, Canada
[6]Department of Diagnostic Imaging, Hospital for Sick Children, Toronto, Canada
[7]Fetal Medicine Unit of the Department of Obstetrics and Gynaecology, University Hospital Gasthuisberg, Leuven, Belgium
*Correspondence to: Rory Windrim. E-mail: rwindrim@mtsinai.on.ca

ABSTRACT

Objectives The objective of this article is to describe the development of an anatomically accurate simulator in order to aid the training of a perinatal team in the insertion and removal of a fetal endoscopic tracheal occlusion (FETO) balloon in the management of prenatally diagnosed congenital diaphragmatic hernia.

Methods An experienced perinatal team collaborated with a medical sculptor to design a fetal model for the FETO procedure. Measurements derived from 28-week fetal magnetic resonance imaging were used in the development of an anatomically precise simulated airway within a silicone rubber preterm fetal model. Clinician feedback was then used to guide multiple iterations of the model with serial improvements in the anatomic accuracy of the simulator airway.

Results An appropriately sized preterm fetal mannequin with a high-fidelity airway was developed. The team used this model to develop surgical skills with balloon insertion, and removal, and to prepare the team for an integrated response to unanticipated delivery with the FETO balloon still *in situ*.

Conclusions This fetal mannequin aided in the ability of a fetal therapy unit to offer the FETO procedure at their center for the first time. This model may be of benefit to other perinatal centers planning to offer this procedure.

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Conflicts of interest: Francis Lebouthillier owns a medical simulator company that sells the model described in this report.

INTRODUCTION

Congenital diaphragmatic hernia (CDH) is a fetal anomaly with mortality rates of up to 33%, despite optimal postnatal intensive care and surgical repair of the diaphragmatic defect.[1] A number of prenatal interventions have been attempted for CDH, including primary anatomical ‘patch’ repair by open fetal surgery[2] and minimally invasive fetal tracheal occlusion leading to entrapment of lung fluid with subsequent lung growth.[3,4] At present, the best studied tracheal occlusion technique is the use of an endovascular detachable latex balloon in a procedure currently referred to as fetal endotracheal balloon occlusion (FETO), in which the balloon is inserted at approximately 28 weeks’ gestation and electively removed at approximately 34 weeks.[5,6] Removal of the FETO balloon can be either at prenatal or after delivery – either by tracheoscopy while the newborn remains on placental circulation as in an EXIT procedure or, failing that, by ultrasound-guided needle puncture through the neonate’s neck immediately after vaginal delivery. In the largest FETO series available ($n=210$), there were ten deaths directly related to difficulties in postnatal removal of the balloon, often because the team was not familiar with the management of an airway with a balloon in place.[7] Therefore, any team responsible for a fetus with a balloon-obstructed airway should be prepared and trained for emergency perinatal balloon retrieval at any time.

The FETO approach is currently being evaluated against standardized postnatal management in a randomized trial ‘Tracheal Occlusion to Accelerate Lung Growth’ (TOTAL) Trial (www.totaltrial.eu).[8] To become a participating center in this trial, a unit must demonstrate appropriate experience in caring for infants with CDH, achieve appropriate FETO training for the fetal therapists, and ensure a well-developed protocol for safe and effective unplanned balloon removal. Because simulation has been employed in the past to help with surgical and multi-disciplinary team preparation for challenges similar to those encountered in the FETO procedure,[9] a high-fidelity model was developed to meet the two new challenges associated with FETO – acquisition of surgical skills and team preparation for emergency postnatal balloon removal.

MATERIALS AND METHODS

In order to develop the fetal model for the FETO procedure, the clinical team collaborated with a sculptor (FL) in the Ontario College of Art and Design University, with whom we had previously developed models for operative vaginal delivery education and a maternal model for teaching amniocentesis and other ultrasound guided invasive fetal procedures.[10]

The model's morphologic specifications were to be consistent with those of an approximately 28-week fetus and to have a high-fidelity fetal airway, from the fetal mouth to the level of the mainstem bronchi. In order to achieve anatomically correct airway dimensions for the mannequin, the model fabricator derived anatomical measurements and landmarks from a variety of reference materials.[11–15] We collaborated with the Diagnostic Imaging colleagues at the Hospital for Sick Children, Toronto, in order to obtain measurements from magnetic resonance imaging of a 28-week neonate (Figure 1). The dimensions and exact location of all landmarks, such as the mouth, pharynx, larynx, and upper airways were recorded for the sculptor. On the basis of these data, the model was then hand sculpted in order to produce an anatomically accurate and responsive fetal model in silicone rubber. Members of the surgical team, including an operator with extensive clinical experience with balloon insertion and removal (JD), serially tested a number of prototypes, providing feedback for continual model improvement. This feedback consisted primarily of subjective evaluation of the anatomic accuracy of the mannequin airway. The neck and head were remodeled to allow a flexed or extended position that could facilitate easier insertion of the fetoscope into the larynx. A range of colors were developed that represented the variations of anatomical detail, such as engorged blood vessels and cartilage, in order to increase the level of realism of the anatomical detail. We then included the epiglottis, a vocal cord system, and repositioned the neck and head, in order to reflect a more natural position of the fetus at rest *in utero*. After further testing, we refined the appearance of the tongue, raphe line, alveolar ridges, uvula, tonsillar pillars, epiglottis, vocal cords, trachea, carina, and esophagus and included a port for the induction of fluid into the primary bronchial tubes and the esophagus (Figure 2). After approximately four iterations of the prototype, a first working model was supplied to the surgical team. The team then employed this simulator as an aid for developing skills in endoscopic balloon insertion and removal. This practice augmented the clinical education that had already been undertaken, in which the most experienced fetal endoscopic surgeon in the candidate team traveled to the FETO Trial Center in order to undergo training in the operative technique, and the Trial's principal investigator traveled to the candidate site in order to mentor assist in clinical procedures locally. The FETO model was used both as a procedure practice tool for both the neonate (Figure 3) and the fetus in the maternal mannequin (Figure 4). We did not, however, objectively measure any changes in surgical skills deriving from this practice.

The second use of the FETO mannequin was preparation of the multidisciplinary perinatal team for urgent balloon removal at birth. Extensive practice was undertaken in both removal approaches: direct laryngoscopic removal and transabdominal needle under ultrasound guidance. The removal was planned as if balloon extraction would be on placental circulation in order to oxygenate the newborn as in an 'EXIT' procedure initially developed for removal of tracheal occlusion as well as airway management for other

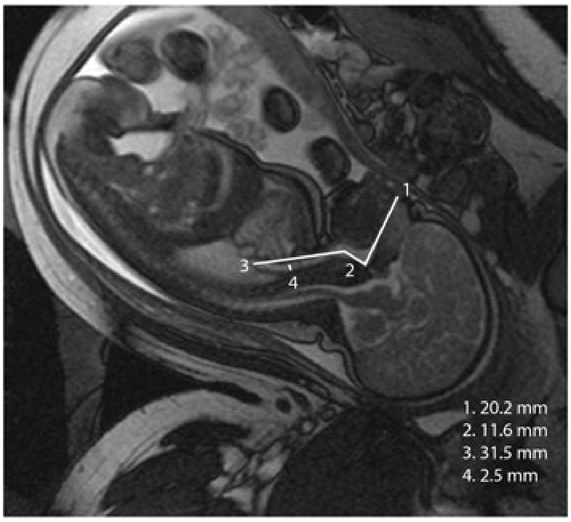

Figure 1 Magnetic resonance imaging of 28-week fetus with airway measurements

Figure 2 Model of fetal larynx

Figure 3 Practice of balloon retrieval on FETO model

Figure 4 The maternal model (1)

causes of airway obstruction, such as laryngeal teratoma, 'CHAOS' syndrome.[16]

The model was thus used as the focal point of multiple team drills in which all the decisions regarding the procedure were examined and resolved: choice of personnel, anatomic approach, newborn medications, and instruments used, and so on. Having decided on a sequence for the procedure, a checklist was developed and practiced by team members until there was consensus regarding familiarity and competence with the care plan. The team members responsible for the actual balloon removal used the model repeatedly, until they felt confident in the skills required for the balloon removal.

DISCUSSION

The FETO procedure is still investigational, and its exact place in fetal medicine can only be determined by an appropriate trial – the TOTAL trial.[8] In order for a unit to participate in this trial, it must be a large volume CDH care and fetoscopy center. Additionally, it is mandatory that it is familiar with the FETO and balloon removal procedure. The empirically determined requirement is that 15 procedures need to be performed by the candidate team prior to being authorized as a recruiting treatment center. One of the critical steps in this investigational procedure is the balloon management, both insertion and removal. This can be practiced on animal models, which is how the technique was developed.[3] The ovine model has been used extensively for studying both the physiology of CDH and the FETO procedure. However, the sheep model has a number of limitations: (1) the relationship among the decidua, membranes, and amniotic fluid volume is completely different; (2) most experiments are performed under general anesthesia; (3) the sheep neck is much longer and more mobile; and (4) there are financial, logistic, and ethical restrictions to the extensive use of animal models.

Models have been used for training for many technical procedures, including those in fetal medicine.[10,17,18] For a procedure as complex as FETO, with a critical *sine qua non* requirement of being able to offer '24/7' skill for safe balloon removal prior to, or immediately after birth, it would seem logical to train all potential surgeons as effectively as possible. As the multidisciplinary team managing the FETO patients is large, inanimate models appear to be the logical training tool to use. We have previously demonstrated the ability of a high-fidelity simulator developed at our center to improve surgical skill in perinatal procedures.[7] This maternal model allows the placement of a simulated placenta, both anterior and posterior, thereby increasing the model's fidelity. This approach has also been successfully adopted in training for fetal blood sampling in prenatal diagnosis.[17,18] When combined with the maternal model, the FETO mannequin was effective in increasing clinicians' comfort levels with balloon removal. This is of high importance, given the need for immediate removal in order to avoid the previously documented risk of neonatal neurological damage or death from airway obstruction at birth. This enhanced team comfort mirrors that found in a prior study of simulator-based training in rarely encountered procedures, where trainees not only reported higher procedural comfort levels, but also an increased willingness to perform these procedures on their own.[9] Other factors in favor of the use of the FETO simulator that were reported in feedback comments from team members were the ability to rehearse the procedure in a controlled setting with no patient risk; the ability to work through various scenarios in order to minimize the risk of unexpected events; the ability to perform analysis for areas of potential error – and to design steps to minimize the risk of error. These and other factors have previously been extensively reviewed in the simulation literature and simulation-based preparation for surgical procedures has been demonstrated to improve clinical skills compared with traditional training.[19,20] Because simulation-based training has also been shown to improve patients' confidence and preparedness to permit surgical procedures to be carried out by less experienced trainees,[21] we included details of our preparation when counseling parents in our early cases.

The level of evidence that simulator-based training improves clinical performance was previously low. However, randomized evidence for the benefit of simulation is beginning to emerge for both enhancement of team responses to obstetric emergencies such as shoulder dystocia[22] and for improvement of laparoscopic surgical skills.[23] Although there are few randomized controlled trial's of the effectiveness of simulation-based training, we agree with the comment of Gaba from more than 20 years ago that 'no industry in which human lives depend on skilled performance has waited for unequivocal proof of the benefits of simulation before embracing it'.[24]

Our finding that the use of a simulator was a useful focal point for promoting team interaction is at odds with previous opinion in this area[25] and one that we feel deserves further research. Additionally, during drilling with the mannequin, we found that when repeated attempts at balloon removal were observed by the entire multidisciplinary team, a tension regarding success or failure developed in practitioners. This tension served to mitigate two previously reported limitations implicit in simulator-based training: the artificial nature of the simulated procedure[26] and the absence of negative consequences when failure or error occurs.[27]

There are limitations with this report. The enhanced comfort levels reported after use of the mannequin are all subjective, with no objective measurements of individual learning curves or team performance. One of the coauthors (FL) has a stated financial interest in this project as he now manufactures the FETO model for commercial sale.[28] Despite these limitations and the general limitations of simulation-based training discussed earlier, we feel that this report warrants attention primarily because of the team's perception of the model's utility when preparing for this high-stake time-sensitive procedure, where failure in our first *in vivo* removal would likely have resulted in immediate iatrogenic neonatal demise. There was a strong feeling within our group that the availability of the high-fidelity mannequin was central to the development of the processes required to confidently begin FETO at our unit and to help complete the number of FETO procedures required to become a fully participating center in the TOTAL Trial.

A number of other international centers that are working to develop FETO competence, two in Europe and four in the United States, have also acquired this model in order to advance their competence in a similar manner. If there is a positive result in the TOTAL Trial and FETO becomes part of standard CDH care, these learning challenges will likely be mirrored in many other centers worldwide. The future utility of this, or a similar, model is therefore potentially quite significant. With regard to procedures other than FETO, this model may also be of benefit. A full EXIT procedure, with general anesthesia and complete uterine relaxation, is not required for FETO, given the predictable nature and location of the airway obstruction. However, the model described here could be utilized in the training of the large number of specialists in a formal EXIT team as it prepares for the birth of neonates with other airway complications. Similarly, the model could be used as a training mannequin when teaching intubation of preterm neonates to neonatology and respiratory therapy trainees.

CONCLUSIONS

We have reported the development of a high-fidelity fetal simulator used to improve surgical skills and team coordination in a new and complex perinatal challenge. These benefits were felt to be central to the ability of our center to offer this intervention. We believe that this simulation-based approach to the introduction of novel procedures warrants further consideration and research in order to further evaluate whether simulation-based training improves surgical skills and team performance.

WHAT'S ALREADY KNOWN ABOUT THIS TOPIC?

- There is no published report of a fetal simulator for fetal airway therapy. There is no information regarding whether or not a simulator will aid the development in surgical skill with fetal endotracheal balloon occlusion and removal.

WHAT DOES THIS STUDY ADD?

- This study reports the development of a high-fidelity simulator for fetal endotracheal balloon occlusion and high approval with its use by a training team.

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