Ongoing development of a new device for fetal endoscopic tracheal occlusion

Sananes N, Favre R, Debry C

Strasbourg University Hospital, Strasbourg, France

Objective

Fetal endoscopic tracheal occlusion (FETO) improves survival of fetuses with severe congenital diaphragmatic hernia (CDH). However, several serious issues relate to in utero removal of the balloon: frequent emergency setting, need for advanced expertise, iatrogenic preterm delivery, and fetal mortality. Our aim is to develop a new device for FETO, which allows an easy, non-invasive, and remotely activated reversal of the fetal tracheal occlusion.

Methods

We brainstormed in collaboration with engineers and a technology transfer company. Intellectual property, regulatory environment, and market context were addressed. Given these constraints, our strategy was therefore to develop the simplest possible technology.

Results

We designed a balloon addressing the specifications that were previously defined. It requires limited developments from the existing balloon currently used for FETO. A system of magnetic valve allows the deflation of the balloon when exposed to an external magnetic field. A proof of concept has been achieved using a prototype scale 1: 1.

Conclusion

This new device addresses the issues of balloon removal in case of CDH managed by FETO. Further tests regarding operation, biocompatibility, and safety of the device are needed.