KU LEUVEN

Symposium n.a.v. de toelating tot het emeritaat van

Valedictory for

Prof Dr Frank Van Calenbergh

Neurochirurg – Neurosurgeon

UZ KU Leuven, Leuven, Belgium

Friday 26 January 2024

with symposium

Prenatal Management of Spina Bifida Aperta

SCAN ME

Symposium

Prenatal Management of Spina Bifida Aperta

Program

9:30-11:30	Yada Kunpalin, KUL & UCL	Public defense of doctoral thesis: Novel tools to fetal surgery for spina bifida

11:30-12:45		**Registration & light lunch (for registered participants)**
12:45	**Johannes van Loon, Leuven**	**Welcome to friends & colleagues of Frank Van Calenbergh**
	Gert Van Assche, CMO UZ Leuven	**Thank you to Frank Van Calenbergh**
Chair		Luc De Catte, Leuven Katrien Jansen, Leuven
12:50	**Jute Richter, Leuven**	**First trimester diagnosis spina bifida: clinical reality?**
13:05	**Michael Aertsen, Leuven**	**The spectrum of brain changes in spina bifida on fetal MRI**
13:20	**Nicole Ochsenbein, Zurich**	**Criteria for fetal spina bifida surgery: life after the MOMS trial**
13:35	**Jean-Marie Jouannic, Paris**	**Limited dorsal myeloschisis**
13:50	**Francesca Russo, Leuven**	**Prenatal Prediction of Motor Function**
14:05	**Tim Van Mieghem, Toronto**	**Prenatal Predictors of Treatment of Hydrocephalus**
14:30		**Pause – Break (coffee/tea)**
Chair		Roland Devlieger, Leuven Philippe De Vloo, Leuven
14:50	**Jan Deprest, Leuven**	**From open to fetoscopic repair: maternal arguments and prematurity**
15:05	**Paolo De Coppi, London**	**Fetoscopic neurosurgery: more than one way to skin a cat**
15:20	**Dominic Thompson, London**	**Should we revisit the outcome measures in spina bifida repair ?**
15:35	**Darach Crimmins, Dublin**	**Surgical management of the very large defect**
15:50	**Jochem Spoor, Rotterdam**	**Meta-analysis postnatal outcomes of pre- or postnatal spina bifida repair**
16:05	**Bernie Stocks, London**	**NHS England's commissioning of treatment of rare diseases through the highly specialised portfolio – how, why, who**
16:20	**Neeltje Crombag, Leuven & Utrecht**	**The patient voice (interview via teleconference)**

17:00	Simen Vergote, KUL	Public defense of doctoral thesis: Fetal surgery: current implementation and ongoing innovation

Speakers and chairs:

***J van Loon**, UZ Leuven, Neurosurgery, Leuven, Belgium*
***L De Catte**, UZ Leuven, Fetal Medicine, Leuven, Belgium*
***R Devlieger**, UZ Leuven, Fetal Medicine, Leuven, Belgium*
***K Jansen**, UZ Leuven, Pediatric Neurology, Leuven, Belgium*
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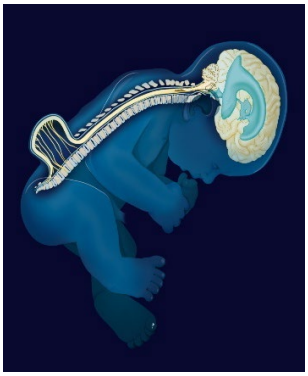
***F Russo**, UZ Leuven, Fetal Medicine, Leuven, Belgium*
***T Van Mieghem**, Mount Sinai Hospital, Fetal Medicine, Toronto, Canada*
***J Deprest**, UZ Leuven & UCL Hospital, Leuven & London, Belgium & UK*
***P De Coppi**, Great Ormond Street Hospital, Pediatric Surgery, London, UK*
***D Thompson**, Great Ormond Street Hospital, Pediatric Neurosurgery, London, UK*
***D Crimmins**, Children's Health Ireland, Neurosurgery, Dublin, Eire*
***J Spoor**, Sophia Children's Hospital, Neurosurgery, Rotterdam, the Netherlands*
***B Stocks**, National Health Service England, Highly Specialised Services, London, UK*
N Crombag, KU Leuven, Woman and Child, Leuven, Belgium



About this symposium:

Organised by "My FetUZ", the research group on fetal therapy,
Department Development and Regeneration, Biomedical Sciences, KU Leuven
on the occasion of 10 years service of Prof Van Calenbergh
in the prenatal spina bifida repair program.

For Belgian : accreditation has been granted
Ethics & economy accreditation has also been requested.
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*Painting by **Jonas Balduyck**, resident in training Obstetrics and Gynaecology KU Leuven*

Extended Summary Doctoral Thesis Mrs Yada KUNPALIN, MD

THE DEVELOPMENT OF NOVEL TOOLS FOR FETAL SURGERY IN SPINA BIFIDA APERTA

A TRANSLATIONAL AND CLINICAL INVESTIGATION

Since the publication of the Management of Myelomeningocele study (MOMs), open fetal surgery has become one of the gold standards for treating isolated spina bifida aperta (SBA). Fetal surgery significantly reduces the necessity for cerebrospinal fluid (CSF) diversion surgery, enhances lower motor function, and improves the overall quality of life for affected children when compared to those undergoing postnatal surgery. While the benefits of the surgery are clearly evident, numerous unresolved questions persist concerning perioperative management. These include the incidence of brain changes detected preoperatively that were related to SBA, the potential application of regenerative medicine such as stem cells, and the establishment of a follow-up protocol for decentralised perioperative management. The overall objectives of this doctoral thesis are to address these outstanding questions and contribute to the advancement of prenatal treatment for SBA.

To comprehensively document detectable brain changes on ultrasound prior to fetal surgery for SBA, a systematic review was conducted to determine the incidence of such alterations. Approximately one-third of these changes are part of the Chiari II malformation (CIIM) spectrum including funnelling of the posterior fossa, a small trans-cerebellar diameter, a banana-shaped cerebellum, a beaked tectum and the 'lemon' sign. Other cranial findings include a small head size, an abnormal corpus callosum (CC) and abnormalities of the brain parenchyma including periventricular nodular heterotopia, gyration disorder, ventriculomegaly, pointed occipital horns of the lateral ventricle and thin occipital lobe, and the presence of an interhemispheric cyst (1).

A retrospective study within our cohorts revealed that nearly three-quarters of eligible fetuses for fetal surgery exhibit an abnormal CC, without a single case of complete agenesis. The CC dimensions are generally smaller, except for a thicker body part, when compared to normal fetuses. Partial agenesis is predominantly observed in the splenium and the rostrum. Common patterns of CC abnormalities include a shortened CC and a thicker body part. Fetuses with severe ventriculomegaly were more likely to exhibit partial agenesis of the CC (2).

To investigate the potential application of regenerative medicine, specifically focusing on the use of stem cells in SBA fetal surgery, we conducted a systematic review to consolidate findings regarding the efficacy and safety of in utero stem cells application in preclinical animal models with SBA. We document that a variety of stem cell types, delivery techniques and animal models had been used. The collective results indicate positive outcomes, demonstrating the benefits of stem cells in terms of animal survival, defect coverage and spinal cord function (3). Additionally, we undertook a characterization analyses of amniotic fluid stem cells obtained from fetuses with SBA; however, these specific findings are not included in this thesis.

While the use of dural patches has become commonplace in fetal SBA surgery across multiple centres, the local host response elicited by these patches has not been thoroughly examined. Utilising a fetal rabbit SBA model, we observe that a watertight repair with either Duragen or Durepair yield no difference in motor neuron density compared to the non-operated control fetuses. In other words, there are no histologic indications of motor neurodegeneration, a contrast to SBA fetuses that did not undergo fetal repair. Despite the absence of differences in motor neuron density, the repair groups exhibit a significantly increase in local neuroinflammatory response. It is noteworthy, however, that this inflammation is considerably less than what is observed in the unrepaired fetuses (4).

Lastly, with a decentralised fetal surgery service, we conducted an assessment to gauge the extent to which short- and long-term maternal and paediatric outcomes were spontaneously reported by the postnatal management centres. Additionally, we explored the role patients could play in enhancing the return of outcome data. Our findings underscore that patient involvement significantly boosts data acquisition. This

approach not only serves as a means of engaging patients in research but also transitions them from a passive to a more active role promoting patient empowerment with respect to their own care and facilitating health care data auditing (5).

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Prof. Paolo De Coppi, UCL, KU Leuven

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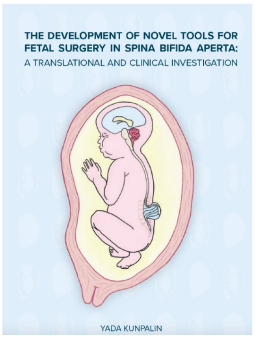
Prof. Liesbeth Lewi, KU Leuven (thesis advisory committee)
Prof. Frank Van Calenbergh, KU Leuven (thesis advisory committee)
Prof. Tim Van Mieghem, University of Toronto, Canada
Prof. Jean-Marie Jouannic, Sorbonne University Paris, France
Mr. Dominic Thompson, UCL, U.K.

Ceremonial chair: Prof. Annick Bogaerts, KU Leuven



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Extended Summary Doctoral Thesis Mr Simen VERGOTE, MD

FETAL SURGERY IMPLEMENTATION AND INNOVATION

Prenatal interventions are undertaken when they can improve outcomes in fetuses with predicted poor outcome. Fetoscopic endoluminal tracheal occlusion (FETO) for congenital diaphragmatic hernia (CDH) improves survival, while prenatal repair of spina bifida aperta (SBA) reduces the requirement of a shunt and improves motor function. These operations are now increasingly wider embraced, and our center has been offering both procedures for a long time yet. Whereas FETO outcomes in a randomized trial only became available in the course of this doctoral project, spina bifida repair had already been introduced a decade ago. We aimed to benchmark our outcomes and contribute to a wider aim, i.e. introduce and use standardized reporting of future fetal surgeries.

Despite level I evidence, implementing these surgeries remains challenging because of the associated risks and long-term outcomes of both conditions. These and all prenatal surgeries are associated with an increased risk of membrane rupture and prematurity, and in case of ”open” fetal surgery, with uterine scar related complications. Efforts to modify techniques are ongoing to mitigate these risks. Iatrogenic preterm premature rupture of membranes (PPROM) remains a major matter of concern, requiring further investigation into the biomechanical properties of preterm membranes.

In the first part, we conducted a knowledge, attitude, and practice (KAP) survey among fetal medicine specialists to assess their perspectives on the risk-benefit balance of FETO for CDH and how they perceived the need of a randomized trial.[1] We did so prior to the conclusion of the TOTAL trial when there was a divide in the fetal medicine community. We observed that most specialists were in equipoise. Interestingly, despite doubts about the reliability of prenatal prediction of neonatal survival, the majority of specialists performed severity assessments, counseled patients likewise and even referred patients for FETO, suggestive of discrepancy between their beliefs and practice. Following the completion of the TOTAL trial, only a minority found the risk-benefit ratio of FETO for left-sided CDH still unclear.[2] Also, the majority was now convinced that mid-gestation survival predictions were reliable. These findings suggest that the TOTAL trial results enhanced specialists' confidence in outcome prediction and in the effectiveness of FETO. The survey also demonstrated that robust non-randomized trials impact the practice of fetal medicine specialists too, given that a majority offers FETO for severe right-sided CDH, although there is no level I evidence for the benefits of FETO in this group.

We also conducted an audit of the first 100 consecutive patients who underwent open spina bifida repair at our center.[3] As we refer our patients after surgery to their local tertiary units, we depend on these centers for feedback on outcomes. The spontaneous return of outcomes was in our experience dramatically low. We discovered that involving women in data collection on their own situation, aided enormously to complete missing outcomes, and promoted patient empowerment as they became active participants in the research process.

To classify complications collected through this audit, we implemented a novel complication rating system called the Maternal Fetal Adverse Event Terminology (MFAET). This system enables the classification of pregnancy-related complications on a scale from grade 1 (mild) to grade 5 (death). Between fetal surgery and delivery, there was a 7% severe (grade ≥3) maternal complication rate and a 18% fetal complication rate. These numbers are consistent with findings from the Management of Myelomeningocele Study and other larger cohorts. We also identified long-term outcomes and noted one uterine rupture and one instance of placenta accreta in 16 subsequent pregnancies.[4] Remarkably, three out of four mothers reported psychological problems. These findings highlight the importance of informing women about potential procedure-related complications and the necessity of systematic, rather than opportunistic, long-term psychological support.

In an experimental study we evaluated two modifications of fetoscopic spina bifida repair, currently promoted by two surgical teams.[5] We compared fetoscopic repair through two or three cannulas, the former being more complex and time consuming. Previous concerns revolved around the potential impact of surgery duration on the central nervous system. Our study in fetal lambs revealed no differences in brain neurohistology or volumetry measured by MRI between both methods, despite the 2-port technique requiring a 40% longer operation time.

To investigate potential causes of iatrogenic PPROM further, we embarked on a biomechanical study of preterm and term membranes, together with experts in the biomechanical study of fetal membranes.[6] Fracture testing showed that preterm amnion and chorion have greater resilience to deformation compared to term membranes. Suture testing also found that suturing the membranes within specific limitations can be done safely. Additionally, the preterm chorion demonstrated greater strength and resilience than term membranes, which may suggest its role in maintaining the structural integrity of the fetal membrane.

In the final section, we addressed the problem of high variability in outcome reporting in fetal medicine, and in particular in CDH. To address this, we developed a core outcome set (COS) to establish standardized reporting for perinatal interventions in CDH using robust methodology.[7,8] The COS was created in the middle of the COVID pandemia through a consensus-building method involving international stakeholders. This process included a Delphi survey, online breakout meetings, eventually a post-pandemic in-person consensus meeting, and a series of meetings to define each outcome. Importantly, patients and patient representatives were actively involved in the development of the COS to ensure their perspectives were integrated.

In conclusion, this work investigated the implementation and ongoing advancements in perinatal interventions. The TOTAL trial had a positive impact on specialists' perspectives, leading to consistent offering of FETO for CDH. Short- and long-term complications of open SBA in our hands were documented, comparing favorably to the benchmark. Iatrogenic PPROM remains a frequent complication of prenatal interventions but does not appear to be solely attributable to biomechanical factors. Finally, a core outcome set (COS) was developed to standardize outcomes and allow comparison, facilitating the clinical implementation of future modifications.

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Dr. Johannes van der Merwe, KU Leuven

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Prof. Maissa Rayyan, KU Leuven (thesis advisory committee)
Prof. Philippe Devloo, KU Leuven (thesis advisory committee)
Prof. Tim Van Mieghem, University of Toronto, Canada
Prof. Nicole Ochsenbein-Kölble, University of Zürich, Switzerland
Prof. Dominic Thompson, UCL, U.K.

Ceremonial chair:
Prof. Dirk Timmerman, KU Leuven

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For more work from Simen Vergote
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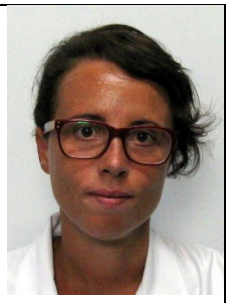
The fetal spina bifida surgery team of the University Hospitals Leuven thanks you for attending this symposium in honour of Prof Van Calenbergh, emeritus professor at the KU Leuven, Belgium.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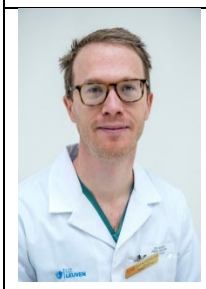					
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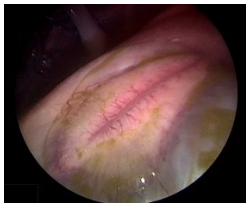

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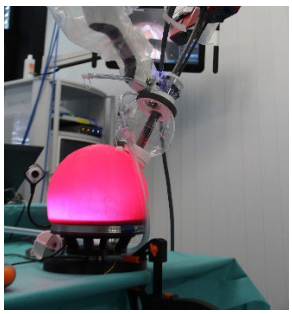

On 19 February 2024 at 14:00 Mr Mirza Awais Ahmad will defend his thesis

“Single Orifice and Robot Solutions for Fetal Surgery”

This is an Erasmus Mundi joint thesis
KU Leuven (Promoters: J Deprest, E Van der Poorten, T Vercauteren) and
University of Barcelona (Promoters: E Eixarch and M Ballester)

You are welcome for this public defense in auditorium Hergé, UZ Leuven

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2019

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