



Australian Government
Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon Scanning Technology Prioritising Summary

Fetoscopic tracheal occlusion using a detachable balloon

February 2005

(Updated March 2006)



ASERNIP/S

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**



**Royal Australasian
College of Surgeons**

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The production of this Horizon scanning prioritising summary was overseen by the Health Policy Advisory Committee on Technology (HealthPACT), a sub-committee of the Medical Services Advisory Committee (MSAC). HealthPACT comprises representatives from health departments in all states and territories, the Australia and New Zealand governments; MSAC and ASERNIP-S. The Australian Health Ministers' Advisory Council (AHMAC) supports HealthPACT through funding.

This Horizon scanning prioritising summary was prepared by staff from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

Name of Technology:

Fetoscopic tracheal occlusion using a detachable balloon

Purpose and Target Group:

Occlusion of the foetal trachea inhibits foetal lung fluid egression, stimulating the growth of hypoplastic lungs. This procedure may therefore be applicable for foetuses with diaphragmatic hernia.

Stage of Development (in Australia): Not yet emerged

- Experimental
- Investigational
- Nearly established
- Established
- Established but changed indication or modification of technique
- Should be taken out of use

International Utilisation:

COUNTRY	LEVEL OF USE		
	Trials underway	Limited use	Widely Diffused
United States	✓		
United Kingdom	✓		

Impact Summary:***Background***

Congenital diaphragmatic hernia is created when the diaphragm (a wide, flat muscle that separates the chest and abdominal cavities) is absent or incompletely formed, leaving a hole. The hole allows the contents of the abdomen including the stomach, intestine, liver, spleen and kidneys to migrate up into the chest. The presence of these organs in the chest cavity then prevents one or both lungs from growing to normal size – pulmonary hypoplasia (Fetal treatment, 2002). Whilst in the uterus the foetus does not need its lungs to breathe. However, if the baby is born with hypoplastic lungs, the baby will have insufficient oxygen to survive (Fetal treatment, 2002). Foetuses with severe congenital diaphragmatic hernia (CDH), evidenced by the migration of the liver into the chest cavity and a low lung to head ratio (LHR), have a very poor prognosis (Neonatal Handbook, 2004). Approximately 50 to 60% of foetuses with CDH do not survive after birth (Neonatal handbook, 2004).

The development of various prenatal evaluation techniques such as Level II ultrasound, foetal magnetic resonance imaging (MRI), foetal chromosome studies and foetal echocardiogram, now enables the severity of the hernia to be determined prior to birth, along with any comorbidities (Neonatal Handbook, 2004). With adequate counselling, families are then able to choose whether to terminate the pregnancy, undergo fetoscopic

tracheal occlusion (FETO) or carry to term for postnatal management (Fetal Diagnoses, 2004). Postnatal management strategies include planned delivery, immediate stabilisation, and immediate access to specialised ventilation techniques such as nitric oxide and ex utero intrapartum treatment (EXIT) (Fetal Diagnoses, 2004). Treatment and survival varies depending on the size and timing of the hernia. Late herniation after 25 weeks' gestation can usually be adequately managed postnatally. However, liver herniation into the chest prior to 25 weeks gestation usually results in poor survival.

Temporary tracheal occlusion is a technique which prevents the normal efflux of foetal lung fluid, which enhances positive pressure in the growing lungs and promotes lung growth (Harrison *et al.* 2003). Originally, occlusion occurred by placement of an occlusion clip around the trachea via open hysterotomy. However, due to the high rate of preterm delivery and irreversible damage to the laryngeal nerve and trachea, and difficulty for reversal, fetoscopic tracheal occlusion using a detachable balloon has been developed (Harrison *et al.* 1998). The detachable balloon can be placed via one fetobronchoscopic port and deflation at birth aids an easier reversal. This minimally invasive technique may improve postnatal survival in patients with severe CDH and may be used in conjunction with postnatal management strategies.

Clinical Need and Burden of Disease

In the United States, CDH occurs in approximately one out of every 2000 to 4000 live births and accounts for 8% of all major congenital anomalies (Hekmatnia *et al.* 2003). Median overall mortality for patients with CDH is 58% (interquartile range (IQR), 43-65%) if diagnosed in utero, 48% (IQR, 35-55%) if born alive, and 33% (IQR, 18-54%) postoperatively (Beresford *et al.* 2000). Diagnosis prior to 25 weeks' gestation does not always result in a poor prognosis (40% survival rate) (Beresford *et al.* 2000).

Although the impact of CDH on the Australian population is unknown, 15 to 25 cases are reported in Victoria each year, corresponding to an incidence of 1 in every 3000 live births (Neonatal Handbook, 2004).

Estimated Speed, Geographic and Practitioner Use Patterns of Diffusion in the Health System

A comparative study performed by Harrison *et al.* (1998) in the United States reported performing foetal tracheal occlusion using a Fetendo clip via an open hysterotomy since 1994. However, in 1996 they began offering fetoscopically delivered temporary tracheal occlusion. Flake *et al.* (2000), also of the United States, reported a case series using haemoclips for fetoscopic temporary tracheal occlusion. Two case series, one a multicentre trial involving sites in the United Kingdom, Belgium and Spain and the other conducted in the United States, have both reported fetoscopic temporary tracheal occlusion by detachable balloon (Deprest *et al.* 2004, Harrison *et al.* 2001).

Existing Comparators (apart from medication)

- Temporary fetoscopic tracheal occlusion with clips
- Tracheal occlusion via open procedure
- Postnatal management

Estimated Cost Impact

The costs associated with this new product are not available. The cost of surgery involving fetal tracheal occlusion in Australia is also not available. However, reimbursement fees for repair of congenital diaphragmatic hernia repair by thoracic or abdominal approach as stated in the Medicare Benefits Schedule (Item numbers 43837 (for diagnosis confirmed in the first 24 hours of life), 43840 (for diagnosis after the first day of life but before 20 days of age)) is \$1179.35 and \$1022.10 respectively. According to the Health Insurance Commission a total of 13 claims were processed between July 2003 and June 2004 for item numbers 43837 and 43840 (Health Insurance Commission, 2004).

Efficacy and Safety Issues

List of Studies Found

Total number of studies	2
Case series studies	1
Case report	1

The studies included in this summary are highlighted in bold in the reference list.

Correct placement of the balloon at the first tracheoscopy was reported in 16/21 (76.2%) patients, 4/21 (19%) patients had misplaced balloons but they were removed and corrected during the same operation and 1/21 (4.7%) patient had the balloon inflated in the right main stem bronchus, which caused laceration (Deprest *et al.* 2004). The balloon was withdrawn and the procedure successfully completed two weeks later (Deprest *et al.* 2004).

Postoperatively, Deprest *et al.* (2004) reported no maternal complications and no patients required additional tocolysis. However, 11/21 (52.4%) patients experienced postoperative prelabour amniorrhexis, within two weeks in five patients and after two weeks in six patients. The neonatal outcome reported by Deprest *et al.* (2004) showed the median gestational age at delivery was 34 weeks (range 27 to 38). Nine of the 21 (42.8%) babies died in the neonatal period due to complications from pulmonary hypoplasia and a further two following surgery to repair the hernia, one of which was due to liver failure. Harrison *et al.* (2001) reported no airway-related morbidities, and both babies were alive at 21 and 19 months respectively. Deprest *et al.* (2004) later retrospectively evaluated 12 liveborn babies who met the criteria but were denied fetoscopic tracheal occlusion.

Median gestation at FETO was 26 weeks (range 25 to 33) (Deprest *et al.* 2004). Harrison *et al.* (2001) reported that one patient was referred for prenatal evaluation tests at 26 weeks' gestation and the other patient at 24 weeks' gestation. One patient had a low lung/head ratio (LHR) of 0.52 but an LHR could not be calculated in the other patient due to a large amount of pleural fluid (Harrison *et al.* 2001). Procedure time was reported inconsistently between

studies with Deprest *et al.* (2004) reporting a mean time for endotracheal placement of the balloon of 20 minutes (range 5 to 54) compared to Harrison *et al.* (2001) reporting a total operating time of 145 minutes for patient 1 and 125 minutes for patient 2. Deprest *et al.* (2004) reported that ultrasound scans after FETO demonstrated an increase in the echogenicity of the lungs within 48 hours and an improvement in the LHR from a median of 0.7 (range 0.4 to 0.9) before FETO to 1.8 (range 1.1 to 2.9) within two weeks of after surgery.. Eleven of the 12 (91.6%) babies died in the neonatal period due to pulmonary hypoplasia and hypertension and only 1/12 (8.3%) baby survived.

There is limited safety and efficacy data available on fetoscopic tracheal occlusion using a detachable balloon. However, results suggest fetoscopic tracheal occlusion may increase survival of patients with severe CDH.

2006 update

A search of relevant databases, online journals and the internet was conducted in February 2006, following the recommendation in February 2005 that fetoscopic tracheal occlusion using a detachable balloon be monitored for assessment in 12 months time. No new evidence on the safety and efficacy of this technique on treating congenital diaphragmatic hernia was retrieved.

Based on the limited evidence available, it is recommended that this procedure be archived.

Ethical Issues:

Families where abnormal prenatal evaluations are found require adequate professional counselling. These families should be informed of all options available to them.

Cultural or Religious Considerations:

Under some circumstances, abortion may be recommended as an option for severe CDH especially in the presence of additional comorbidities. Abortion can have cultural or religious implications. If the FETO procedure is effective, families may have other options besides abortion.

Other Issues:

No other issues were identified from the retrieved material.

Recommendation:

Limited evidence exists on the safety and efficacy of fetoscopic tracheal occlusion. Long-term safety and efficacy data from randomised controlled trials may be required before this procedure can be widely accepted. Due to the limited evidence available on this procedure, it is recommended that the following be conducted:

- Horizon Scanning Report Full Health Technology Assessment
- Monitor Archive

References:

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Further Information:

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Search Criteria:

A search of MEDLINE, PubMed and Cochrane Library, Current Controlled Trials metaRegister, UK National Research Register, International Network for Agencies for Health Technology Assessments, relevant online journals and the Internet was conducted in October 2004.

Search terms used were: 'Fetoscopic tracheal occlusion' 'congenital diaphragmatic hernia and tracheal occlusion' and 'balloon and tracheal occlusion'.

This Horizon Scanning Prioritising Summary was prepared by Ms Lynette Cufone from the NET-S Project, ASERNIP-S for the Health Policy Advisory Committee on Technology (Health PACT), on behalf of the Medical Services Advisory Committee (MSAC) and the Australian Health Ministers' Advisory Council (AHMAC).