



Australian Government
Department of Health and Ageing



Horizon Scanning Technology Prioritising Summary

Modification of the Tan-Bianchi procedure for infantile hypertrophic pyloric stenosis

June 2004



**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:**

Modification of the Tan-Bianchi procedure.

PURPOSE & TARGET GROUP:

This new technique may become an alternative treatment for infantile hypertrophic pyloric stenosis (HPS), particularly when the pyloric hypertrophic muscle is large.

STAGE OF DEVELOPMENT (IN AUSTRALIA): Yet to emerge in Australia

- 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
Italy		✓	

IMPACT SUMMARY**Background:**

This procedure involves a right semicircular umbilical skin fold incision. The anterior rectus abdominal muscle sheath is incised vertically all around the umbilicus leaving a two to three millimetre edge on the umbilical side. The muscle is displaced laterally and its posterior sheath and the peritoneal cavity entered in the same line. With two retractors placed on both edges, the abdominal cavity is opened and the stomach and pylorus are grasped gently and entered into the wound. With large hypertrophic pyloric muscles, the subcutaneous tissues can be undermined in a cephalad direction, and the rectus abdominis muscle sheath incision extended up along the linea alba without enlarging the skin incision. A routine pyloromyotomy is then performed.¹

Clinical need and burden of disease:

Infantile hypertrophic pyloric stenosis is a condition caused by thickening of the muscles of the pylorus channel, preventing the stomach from emptying into the small intestine. This can lead to vomiting, dehydration, weight loss and severe hypochloremic metabolic alkalosis. The cause of the thickening is unknown; gender, ethnic origin and genetic factors may play a role. Internationally, this condition affects approximately two infants in 1,000 between the ages of three and ten weeks, and is associated with a 4-6:1 male-to-female ratio. The condition appears to be more common in infants of Caucasian descent and is rare in Asian children and patients older than six months.^{2,3}

Estimated speed, geographic and practitioner use patterns of diffusion in the health system:



The Tan-Bianchi procedure for treatment of HPS was first described in 1986; this new modification was developed by researchers in Italy. Results for 25 patients treated by this new procedure were published in 2004.¹

Existing comparators:

The open Ramstedt extramucosal pyloromyotomy, first described in 1912⁴, is the main surgical treatment for HPS and involves incision into the patient's abdomen. A small cut is made into the thickened pyloric muscle down to the mucosa and spread apart; the passage can then be widened without removal of any tissue. After surgery the pylorus heals itself, the thickening reduces over time and the passage resumes a normal shape. Complications such as prolonged postoperative emesis, wound infection and duodenal perforation can occur. In addition, surgery leaves a permanent scar.^{2,3}

There are several modifications to the Ramstedt pyloromyotomy, but it is difficult to determine which of the treatments are most effective for treatment of HPS. Such techniques include the Tan-Bianchi⁵ operation which involves a circumbilical incision. This offers better cosmetic results, but infection, incisional hernia and prolonged gastroparesis can occur. Laparoscopic approaches are purported to reduce operative time and tissue trauma and offer better cosmetic results. Other techniques include V-Y plasty,⁶ traumamyoplasty⁷, right-sided lateral⁸ and omega-shaped⁹ wound extension modifications.

Estimated cost impact:

The cost of a pyloromyotomy for HPS in Australia is not available. The Medicare Benefits Schedule reimbursement fee for pyloromyotomy (procedure only) would be approximately A\$370.¹⁰ The costs associated with this new procedure are not available.

Efficacy and safety issues:

Short-term safety and efficacy data exist from one case series.¹

Twenty-five children were treated for HPS by this new procedure. No wound infections were reported, large pyloric muscles were all easily delivered into the wound and 'excellent' cosmetic results were reported with little evidence of scarring at one year follow-up.

Ethical issues:

Not applicable.

Cultural or religious considerations:

Not applicable.

Other issues:

The authors have reported the following benefits of this new technique.

- opening of the abdominal cavity may be easier as all incisions lie in the same axis



- the rectus muscles fibres are not severed, which may reduce the risk of haematoma formation
- the presence of a medial edge of rectus muscle sheath may assist with closure, lowering the risk of incisional hernia
- the use of a subcuticular drain may not be required unlike the Ramstedt procedure and its modifications.

Conclusion:

Limited evidence exists on the safety and efficacy of this procedure for treatment of infantile hypertrophic pyloric stenosis. As there are many modifications to the original surgery (Ramstedt pyloromyotomy), it is difficult to determine how effective this procedure would be as an alternative treatment for HPS.

HealthPACT decision:

- | | |
|---|--|
| <input checked="" type="checkbox"/> Horizon Scanning Report | <input type="checkbox"/> Full Health Technology Assessment |
| <input type="checkbox"/> Monitor | <input type="checkbox"/> Archive |

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**SOURCES OF 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 January 2004.

Search terms used were: Tan Bianchi pyloric, hypertrophic pyloric stenosis, pyloromyotomy, Ramstedt pyloromyotomy.