New and Emerging Techniques - Surgical

Horizon Scanning Report

The Tan-Bianchi Procedure and Modifications

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New and Emerging Techniques – Surgical

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Royal Australasian College of Surgeons

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Introduction

The Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S) in conjunction with the Royal Australasian College of Surgeons has undertaken a Horizon Scanning Report to provide advice on the state of play of the introduction and use of the Tan–Bianchi procedure and subsequent modifications.

The Tan–Bianchi procedure is a circumumbilical incision which provides access to the pyloric muscle for Ramstedt pyloromyotomy among patients with infantile hypertrophic pyloric stenosis. It is an alternative to the traditional right upper quadrant (RUQ) open abdominal surgery, performed to provide access to the muscle.

This Horizon Scanning Report is intended for the use of health planners and policy makers. It provides an assessment of the current state of development of the Tan-Bianchi procedure, its present use, the potential future application of the technology, and its likely impact on the Australian health care system.

This Horizon Scanning Report is a preliminary statement of the safety, effectiveness, cost-effectiveness and ethical considerations associated with the Tan-Bianchi procedure and subsequent modifications of the original procedure.

Background

Background to the Condition

Infantile hypertrophic pyloric stenosis (IHPS) commonly leads to gastric obstruction which is characterised by a narrowing of the pyloric muscle at the base of the stomach (International Paediatric Endosurgery Group 2004). Under normal conditions the pyloric muscle regulates the passage of food from the stomach into the duodenum. When the pyloric muscle is contracted it inhibits the premature escape of food before adequate digestion by stomach acids. When the food is adequately digested the pylorus relaxes, the stomach contracts and subsequently food enters the duodenum for further digestion. When hypertrophy of the pyloric muscle occurs, despite muscle relaxation, the pylorus remains closed. Thus, contraction of the stomach muscle subsequently results in food passing back up the gullet causing vomiting (Medicodirect 2004).

The aetiology of IHPS is unknown and symptoms usually present before the infant is three months of age. Babies with pyloric stenosis can begin to occasionally 'spit-up' food as early as one week after birth. As it progresses, vomiting becomes more frequent until it eventually follows every feeding and turns into a forceful, projectile vomiting. The baby then becomes irritable because of hunger and may become dehydrated if little fluid is kept down. Deaths resulting from IHPS tend to be rare; however, morbidity tends to be linked directly to the duration and frequency of vomiting. Continual vomiting causes a

loss of essential nutrients and electrolytes, which results in dehydration and metabolic alkalosis (International Pediatric Endosurgery Group 2004).

When the diagnosis of pyloric stenosis is confirmed and resuscitation occurs to compensate for any dehydration, the infant can undergo surgery. IHPS is the most common indicator for infantile surgery. The gold standard operation, Ramstedt's pyloromyotomy, is performed under general anaesthesia and may be via open abdominal surgery, laparoscopic surgery or circumumbilical incision (International Pediatric Endosurgery Group 2004). However, the traditional open Ramstedt's pyloromyotomy procedure results in an abdominal scar. Circumumbilical incision was introduced in 1986 by Tan and Bianchi (Tan & Bianchi 1986), hence it is referred to as the Tan-Bianchi procedure, designed to camouflage the scar within the natural umbilical skin folds. The procedure is increasing in use among surgeons as the umbilical skin-fold incision permits access to the pylorus for pyloromyotomy, whilst leaving an almost undetectable scar.

Description of the Technology

The Procedure

This report covers the Tan-Bianchi and subsequent procedure modifications. The technique involves thoroughly cleaning the umbilicus with a spirit solution. A three-quarter circle incision is performed supra-umbilically in the natural skin fold following the curve of the umbilicus. The epigastric skin is elevated and the peritoneal cavity opened in the midline through the linea alba and to the right of the umbilical vein. Following pylorotomy, the abdomen is closed in layers with continuous sutures. The optional extension of the fascial incision, by a small transverse skin extension at the angles of the wound, was designed to allow easy delivery of a large pyloric mass. This optional extension is often reported as the omega-shaped modification and has proven to be quite popular. The Tan-Bianchi technique was developed with the intention of producing a long-term cosmetically superior appearance in comparison with the open abdominal approach. The incision is well placed within the natural umbilical creases, resulting in an almost undetectable scar. However, as the procedure has become more widely used, some surgeons have reported difficulty in delivering a large pyloric tumour into the wound to perform the pyloromyotomy due to the small incision. Subsequently many technical variants of the Tan–Bianchi procedure have been proposed to overcome the difficulty experienced in delivering a large pyloric mass.

Variations to allow greater access to larger pyloric masses have been made to either the location of skin incisions or modification to subcutaneous procedures. A skin incision variation often referred to as Y-V closure plasty has been utilised by two separate groups, Besson *et al.* (1997) and Poli-Merol *et al.* (1996). This variation involved the initial incision in the upper half of the circumference of the umbilicus, accompanied with a second skin incision at the midline that joins to the top of the first incision. In both publications the technique is similar except in Besson *et al.* (1997), where three parts of the incision are

equal compared to Poli-Merol *et al.* (1996), where the longitudinal upper umbilical incision is stated to be over 1 cm in length.

Other variations to the skin incision to allow better access to the pylorus include:

- Replacement of the small transverse extensions at the angle of the wound with bilateral skin incisions of 0.5 to 1 cm, made 0.5 cm above the two ends of the semicircular incision (Khan & Al Bassam 2000).
- A supra-circumumbilical skin incision skirting half the circumference of the umbilicus accompanied with a 0.5 to 1 cm extension to the right side. The wedge of skin on the right, excised on closing, facilitates the scarring to remain inside the umbilicus folds (Misra & Mushtaq 1998).
- A right semicircular skin fold incision, enabling all the incisions to lie on the same axis, and thus facilitating access to the pylorus and lateral displacement, rather than severing of the rectus muscle fibres (Alberti *et al.* 2004).

Subcutaneous variations have also been used in many studies, where access is increased but scarring is hidden under the original skin incision. These include:

- Karri *et al.* (2003) who developed a variation in the position of the original circumumbilical incision. The division of subcutaneous tissue is as described in Tan *et al.* (1986); however, a 3 cm midline vertical incision in the linea alba is accompanied by a transverse incision made to intersect the caudal end to form an 'inverted T'.
- Another often used modification is the undermining of the epigastric skin once the original incision is made (De Caluwe *et al.* 1998; Horwitz & Lally 1996; Shankar *et al.* 2001).
- Lambert *et al.* (2002) and Huddart *et al.* (1993) developed a simple modification after the original incision, involving a curved incision into the linea alba.

Intended Purpose

Currently the Tan–Bianchi procedure and its subsequent modifications are being used as an alternative to the open abdominal approach in infants with hypertrophic pyloric stenosis. The procedure allows access to the pylorus for pyloromyotomy whilst effectively hiding the scar within the naturally occurring umbilical folds. Modifications to the technique have been designed in an attempt to optimise the efficient removal of larger pyloric masses.

Contraindications

The Tan-Bianchi procedure and its subsequent modifications may be complicated by patients with very large pyloric masses or masses that lie outside the incisional window. Difficult tumour delivery appears to result in increased operating time and more gastric manipulation. Hence these patients tend to show an increase in complications such as wound infection rates (Khan & Al Bassam 2000), muscle ischaemia and haematoma

formation (Karri *et al.* 2003). These complications can be overcome by extending the incision to allow better access and avoid excessive traction of retractors.

Clinical Need and Burden of Disease

In the USA, infantile hypertrophic pyloric stenosis is the most common cause of infantile surgery affecting 1 to 3 of every 1000 live births, with a predominately higher incidence in male than female infants (http://www.ipeg.org). Pyloric stenosis also appears to be more common in Caucasian infants compared to Asian infants (Ordorica-Flores *et al.* 2001). Symptoms usually appear between 1 and 12 weeks of age, but rare cases have occurred up to 6 months of age. The phenotypic vomiting associated with the disorder causes dehydration, weight loss and electrolyte abnormalities such as hypokalaemia and hypochloremic metabolic alkalosis. The disorder can ultimately be fatal if not promptly treated. The development of abdominal ultrasounds, radiographs and serum electrolyte imbalance tests has enabled early diagnosis of the disorder reducing the frequency and severity of the associated morbidities (International Pediatric Endosurgery Group 2004).

Pyloromyotomy is the treatment required for IHPS. The traditional open abdominal access for pyloromyotomy has tended to result in unsightly abdominal scarring, potentially impacting on the psychological well-being of the patient, particularly during adolescence. Circumumbilical incisions for pyloromyotomy tend to result in an almost undetectable scar potentially reducing the long-term psychological impact of the treatment for the disorder.

In Australia, during 2003, there were 97 requested Medicare services processed for pyloromyotomy (Medicare Benefits Schedule item number 43930) by the Health Insurance Commission (http://www.hic.gov.au) for the private health sector. Ninety two of the ninety seven (95%) claims were for patients in the age group of 0 to 4 years of age, 12/92 (13%) patients were female compared to 78/92 (85%) patients who were male. This is an approximate 6:1 male to female ratio, consistent with the predominate prevalence of the disorder in males. Whether access for the pyloromyotomy was via open abdominal, laparoscopic or circumumbilical incision can not be determined.

Stage of Development

The original Tan–Bianchi procedure for treatment of IHPS was developed in the United Kingdom and first described in 1986 (Tan & Bianchi 1986). Since then eight additional studies have reported using the original Tan-Bianchi procedure. These studies include four comparative studies conducted in Saudi Arabia (Khan & Al Bassam 2000), United States (Leinwand *et al.* 1999), France (Podevin *et al.* 1997) and Canada (Fitzgerald *et al.* 1990) and four case series conducted in Japan (Takamizawa *et al.* 2004), Italy (Franchella & Sicilia 1997), France (Besson *et al.*1997) and Jordan (Ali Gharaibeh *et al.* 1992). Technical variations to the Tan–Bianchi have also been described in 11 studies; three comparative studies (Huddart *et al.* 1993; Khan & Al Bassam 2000; Poli-Merol *et al.* 1996) and eight case series (Alberti *et al.* 2004; Besson *et al.* 1997; De Caluwe *et al.* 1998;

Horwitz & Lally 1996; Karri *et al.* 2003; Lambert et al. 2002; Misra & Mushtaq 1998; Shankar *et al.* 2001).

The Tan-Bianchi procedure and subsequent modifications are recommended for the indication of IHPS and hence users of the technology are paediatric surgeons. The surgical treatment of pyloromyotomy for hypertrophic pyloric stenosis is also performed in older children/adults; however, the Tan-Bianchi procedure does not appear to be used for these patients. The Tan-Bianchi procedure is designed to leave an almost undetectable scar, and subsequent modifications designed to enable adequate access to the pylorus, potentially making this technique widely adoptable by paediatric surgeons.

Treatment Alternatives

Existing Comparators

The RUQ Ramstedt extramucosal pyloromyotomy, first described in 1912 (Ramstedt 1912), is the main surgical treatment for IHPS. It involves an abdominal incision. A small cut is then 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.

There are several modifications to the Ramstedt pyloromyotomy, but it is difficult to determine which of the treatments are most effective for the treatment of IHPS. The Tan–Bianchi operation offers a better cosmetic result than open Ramstedt pyloromyotomy, but infection, mucosal perforation and prolonged gastroparesis can occur. Laparoscopic approaches are reported to reduce operating time and tissue trauma and offer a better cosmetic result compared to open abdominal access, but scarring is still greater than when using the Tan-Bianchi.

Clinical Outcomes

This report assesses the effectiveness and safety of the original Tan-Bianchi procedure and each subsequent variation. The original Tan-Bianchi includes the omega-shaped extension. Modifications of the Tan-Bianchi include: Y-V closure plasty, lateral extension of the omega-shaped incision, right lateral extension, right semi-circular incision, Tan-Bianchi with subcutaneous 'inverted T' incision, undermining of the epigastric skin and Tan-Bianchi with curved linea alba incision.

Effectiveness

Tan-Bianchi Procedure (Includes Omega-Shaped Modification)

The original circumumbilical incision, including the original omega-shaped extension has been reported for 502 patients across nine studies.

Incision

Of the nine studies that used the Tan–Bianchi procedure, two (Besson *et al.* 1997; Podevin *et al.* 1997) reported difficulties in delivery of large pyloric masses. Podevin *et al.* (1997) reported that when it was noted, delivery was difficult in 34.5% of Tan–Bianchi patients compared with 8.3% in patients who underwent RUQ incision. Besson *et al.* (1997) reported 1/32 (3.1%) patient was converted to a right-sided transverse incision as the Tan–Bianchi procedure (without omega modification) could not support delivery of a very large pyloric mass.

Operating Time

Podevin *et al.* (1997) reported that mean operating times were longer in patients who received the Tan- Bianchi (52 [14] mins; n=118) compared to patients who underwent the RUQ incision (38 [14] mins; n=121) (p<0.001). However, comparative studies by Khan & Al Bassam (2000) (n=39) and Fitzgerald *et al.* (1990) (n=100) both reported that there was no significant difference in operating time between the Tan–Bianchi procedure and RUQ.

Hospital Stay

The length of hospital stay tended to vary between studies, ranging anywhere from 2.2 [1.2] days (Fitzgerald *et al.* 1990; n=100) to 7.2 [2.1] days (Podevin *et al.* 1997; n= 239). A comparative study by Podevin *et al.* (1997) reported hospital stay to be significantly decreased for patients who received the Tan-Bianchi (7.2 [2.1] days; n=118) compared to those who received RUQ (7.8 [1.9] days; n=121) (p=0.04). However, two comparative studies (Fitzgerald *et al.*1990; Leinwand *et al.* 1999) with a total of 444 patients reported the length of hospital stay to be similar between patients who received the Tan–Bianchi procedure and those who received RUQ.

Feeding

Three comparative studies (378 patients) showed no statistical difference in postoperative feeding tolerance between Tan–Bianchi patients and RUQ patients (Fitzgerald *et al.* 1990; Khan & Al Bassam 2000; Podevin *et al.* 1997).

Scar

Studies conducted by Fitzgerald *et al.* (1990) and Podevin *et al.* (1997) both reported that patients who underwent the Tan–Bianchi procedure had almost undetectable scars (n=168) in comparison to patients who underwent RUQ incisions (n=171). The

comparative study by Khan & Al Bassam (2000) showed that the Tan–Bianchi without lateral extension (21/33) resulted in a scar barely visible, where as patients who received the lateral extension tended to have small scars at the umbilicus (12/33). Four case series (Ali Gharaibeh *et al.* 1992; Besson *et al.* 1997; Franchella & Sicilia 1997; Tan & Bianchi 1986) also report almost undetectable scars in Tan–Bianchi patients (n=127).

Y-V Closure Plasty Modification

The Y-V closure plasty modification of the Tan–Bianchi procedure has been reported for 51 patients.

Operating Time

Poli-Merol *et al.* (1996) reported the same mean operating time of 28 minutes for patients who received the modified Tan–Bianchi approach (40/80) and those who received the classic transrectus approach (40/80).

Hospital Stay

Poli-Merol *et al.* (1996) reported patients who received the Tan-Bianchi (40/80) and patients that received the classic transrectus approach (40/80) had a similar mean five day hospital stay.

Feeding

Postoperative feeding tolerance was similar between the modified Tan–Bianchi and transrectus approach (Poli-Merol *et al.* 1996; n=80).

Scar

The 51 patients who received the modified Tan–Bianchi approach all resulted in an almost undetectable scar, which was well incorporated into the umbilicus (Besson *et al.* 1997; Poli-Merol *et al.* 1996).

Lateral Extensions of the Omega-Shaped Incision (Modified Upward 0.5 – 1.0 cm)

This modification has been reported for 9 patients.

Operating Time

Operating times were comparable between patients who received this modification of the Tan-Bianchi procedure (9/39) and patients who underwent the original Tan-Bianchi procedure (24/39) or RUQ (6/39) (Khan & Al Bassam 2000).

Feeding

Feeding tolerance was comparable between patients who received this modification of the Tan-Bianchi procedure (6/39) and patients who underwent the original Tan-Bianchi procedure (24/39) or RUQ (6/39) (Khan & Al Bassam 2000).

Scar

The scarring from this modification (9/39) was similar to that of patients who underwent the original Tan-Bianchi without the omega-shaped modification (21/39), although ruffled in appearance. The scarring was less noticeable on patients who received the modification (9/39) than those that received the omega-shaped procedure (3/39) (Khan & Al Bassam 2000).

Right Lateral Extension

This procedure has been reported for 30 patients.

Incision

This modification allowed delivery of the pylorus to the surface in all 30 patients (Misra & Mushtaq 1998).

Scar

All 30 patients who received this modification reported scarring which was barely visible (Misra & Mushtaq 1998).

Right Semi-Circular Incision

This procedure has been reported for 25 patients.

Scar

Alberti *et al.* (2004) reported excellent cosmetic results for all 25 patients, with barely visible scars.

Tan-Bianchi Incision with Subcutaneous 'Inverted T' Incision in Linea Alba

This procedure has been performed on 51 patients.

Incision

No patient of the 51 patients who received this modification needed conversion to the right hypochondrium approach for better access (Karri *et al.*2003).

Operating Time

Mean operating time was 31.4 minutes (Karri *et al.* 2003).

Hospital Stay

Mean post operative hospital stay was 2 to 3 days (Karri *et al.* 2003).

Tan-Bianchi Incision with Undermining of Epigastric Skin

The three included studies are not identical in method but the undermining of the epigastric skin is the common feature to all. The modified Tan-Bianchi procedure has been reported for a total of 133 patients.

Incision

None of the 133 patients in total who received this modification required conversion to a RUQ incision.

Operating Time

Shankar *et al.* (2001) reported a mean operating time of 30 minutes for this procedure (n=86), which is similar to the mean 32.4 [7.7] minutes reported by Horwitz *et al.* (1996) (n=18).

Hospital Stay

Shankar *et al.* (2001) reported an average hospital stay of 58 hours post procedure (n=86) which is consistent with the median 2.5 days reported by De Caluwe *et al.* (1998) (n=29).

Scar

Two of the three studies reported barely visible scars, healing as quickly as 1 week or as late as 6 weeks post procedure (Horwitz & Lally 1996; Shankar *et al.* 2001) (n=104).

Tan-Bianchi Procedure with Curved Linea Alba Incision

This procedure has been reported for 236 patients.

Hospital Stay

Huddart *et al.* (1992) reported that the length of hospital stay was similar between the 138 patients that received the modified circumumbilical incision (mean 4.4 days) and the 182 patients that received the open procedure (4.1 days).

Lambert *et al.* (2002) reported that patients were discharged after a median 46 [22] hours (n=98).

Safety

Tan-Bianchi Procedure (Includes Omega-Shaped Modification)

Wound Infection

For patients who underwent the Tan-Bianchi procedure, a median wound infection rate of 4.1% (range 3% to 6.7%) was reported compared to 1.8% (range 1.2% to 16.6%) for patients who received RUQ (Fitzgerald *et al.* 1990; Khan *et al.* 2000; Leinwand *et al.* 1999; Podevin *et al.*1997). It must be noted that Khan *et al.* (2000) used the Tan-Bianchi and a modified version. It was not reported to which group patients with wound infection belonged.

Patients reported in case series using the Tan-Bianchi had median wound infection rates of 13.6% (range 0% to 20%) (Ali Gharaibeh *et al.* 1992; Besson *et al.* 1997; Franchella *et al.* 1997; Takamizawa *et al.* 2004; Tan *et al.* 1986). It must be noted that Besson *et al.*

(1997) used the Tan-Bianchi and Y-V closure plasty. It was not reported to which group patients with wound infection belonged.

Mucosal Perforation

For patients who underwent the Tan-Bianchi procedure, a median mucosal perforation rate of 6.15% (range 0% to 10%) was reported compared to 1.6% (range 0% to 4%) for patients who received RUQ (Khan *et al.* 2000; Podevin *et al.* 1997; Fitzgerald *et al.* 1990; Leinwand *et al.* 1999).

Patients reported in cases series using the Tan-Bianchi had a median mucosal perforation rate of 5.2% (range 0% to 9.5%) (Ali Gharaibeh *et al.* 1992; Besson *et al.* (1997); Franchella *et al.* 1997; Takamizawa *et* al. 2004).

Wound Dehiscence

Patients reported in case series using the Tan-Bianchi had a median wound dehiscence rate of 2.5% (range 0% to 4.5%) (Ali Gharaibeh *et al.* 1992; Franchella *et al.* 1997; Tan *et al.* 1986).

Abscesses

A comparative study by Fitzgerald *et al.* (1990) reported minor stitch abscesses in 6% of Tan-Bianchi patients compared to 2% of RUQ patients.

Besson *et al.* (1997) reported that abscesses occurred in 6/32 (18.7%) patients; however, both the Tan-Bianchi procedure and Y-V closure plasty were used and it was not reported to which group patients with abscesses belonged. Franchella *et al.* (1997) reported no operative or postoperative complications.

Postoperative Vomiting

Fitzgerald *et al.* (1990) reported 38/50 (76%) RUQ patients had postoperative vomiting compared to 36/50 (72%) who underwent the Tan-Bianchi. In comparing time to last vomiting episode, no significant difference was detected between groups. Khan *et al.* (2000) reported 6/33 (18.2%) of Tan-Bianchi patients had postoperative vomiting for 1-6 days. A further 3/33 (9.1%) Tan-Bianchi patients had gastro-oesophageal reflux requiring medical treatment. It should be noted that Khan *et al.* (1990) used not only the Tan-Bianchi but also a modified version. It was not reported to which group patients with postoperative vomiting belonged.

Case series using the Tan-Bianchi by Franchella *et al.* (1990) reported no postoperative complications amongst any patient.

Y-V Closure Plasty Modification

Wound Infection

Poli-Merol *et al.* (1996) reported wound infection in 1/40 (2.5%) patient who underwent pyloromyotomy using the transrectus approach. No wound infections were reported in patients who underwent the Tan-Bianchi.

Mucosal Perforation

Poli-Merol *et al.* (1996) reported a duodenal mucosal wound, which was immediately sutured in 1/40 (2.5%) patient who underwent the Tan-Bianchi. No patients who underwent the transrectus approach were reported to have mucosal perforation.

One of eleven patients who underwent Y-V closure plasty in a case series by Besson *et al.* (1997) reported mucosal perforation.

Wound Dehiscence

One of 40 patients (2.5%) who underwent Y-V closure plasty reported postoperative wound dehiscence compared to zero patients reported who underwent the transrectus approach. At follow-up no patient in either group reported abdominal wall dehiscence (Poli-Merol *et al.* 1996).

Lateral Extensions of the Omega-Shaped Incision

Published safety data for this modification was grouped with the patients that received the original Tan-Bianchi procedure. As only 9/33 patients received the modified procedure, the data has been included under the original Tan-Bianchi.

Tan-Bianchi with Right Lateral Extension

No complications were reported for this modification (Misra & Mushtaq 1998).

Right Semicircular Incision

No complications were reported for this modification (Alberti *et al.* 2004).

Tan-Bianchi Incision with Subcutaneous 'Inverted T' Incision in Linea Alba

Wound Infection

Wound infection occurred in 2/51 (3.9%) patients who underwent the Tan-Bianchi with subcutaneous 'inverted T' incision (Karri *et al.* 2003).

Mucosal Perforation

One of fifty one patients (2%) patients who underwent the Tan-Bianchi with subcutaneous 'inverted T' incision reported mucosal perforation (Karri *et al.* 2003).

Tan-Bianchi incision with undermining of epigastric skin

Wound Infection

For patients that underwent the Tan-Bianchi incision with undermining of epigastric skin, no study reported wound infection.

Mucosal Perforation

For patients that underwent the Tan-Bianchi incision with undermining of epigastric skin, mucosal perforation rates of 6.9%, 0% and 0% (De Caluwe *et al.*1998, Horwitz *et al.* 1995 and Shankar *et al.* 2001, respectively) were reported.

Abscesses

One of twenty nine patients (3.4%) presented 13 days postoperatively with a small wound abscess that was locally drained (De Caluwe *et al.* 1998).

Tan-Bianchi Procedure with Curved Linea Alba Incision

Mortality

One in 321 patients (0.3%) died preoperatively due to severe dehydration. Treatment allocation for this patient was not stated.

Wound Infection

Huddart *et al.* (1992) reported that wound infection rates were higher in patients who received the Tan-Bianchi with curved linea alba incision (22/138, 15.8%) compared to those who received RUQ (10/182, 5.4%).

Mucosal Perforation

Lambert *et al.* (2002) reported a mucosal breach occurring in 3/98 (3%) patients who underwent the Tan-Bianchi procedure with curved linea alba incision. The breach was recognised and repaired at the time of original surgery.

Potential Cost Impact

Cost Analysis

The Tan-Bianchi procedure and its modifications have been designed to be a safe alternative to the traditional RUQ pyloromyotomy. The procedure is performed under the same conditions as for the open abdominal procedure with operating time and hospital stay reportedly similar to the open abdominal procedure. This potentially makes the cost of the Tan-Bianchi procedure (including modifications) similar to that of the traditional open abdominal procedure. However, the costs for the Tan–Bianchi procedure or its modifications were not currently available. The Medicare Benefits Schedule reimbursement fee for standard pyloromyotomy, procedure only, (Medicare Benefits Schedule item number 43930) is approximately A$370.00 (http://www.hic.gov.au).

The reduced incidence of scarring that accompanies the Tan-Bianchi procedure could potentially have reduced long-term cost impacts by decreasing patient psychological

issues, reducing the potential cost to the mental health system and antidepressant medications.

Ethical Considerations

Informed Consent

With the initial development of the Tan–Bianchi procedure in 1986, the procedure has reportedly become the standard technique for access to the pylorus in some institutions. Participants in research studies are required to provide informed consent prior to their involvement in the study. As this procedure is performed on patients under 18 years of age, informed consent is provided by parents/guardians. It is apparent in some, but not all, of the reported studies that informed consent was received.

Access Issues

As the Tan-Bianchi procedure requires no additional equipment to that used to perform the RUQ pyloromyotomy, the procedure is able to be performed at institutions that currently perform RUQ pyloromyotomy.

Training and Accreditation

Training

No information could be found on the training required to perform circumumbilical pyloromyotomy in addition to the standard training required for RUQ pyloromyotomy.

Clinical Guidelines

No clinical guidelines could be found for circumumbilical pyloromyotomy.

Limitations of the Assessment

Methodological issues and the relevance or currency of information provided over time are paramount in any assessment carried out in the early life of a technology.

Horizon scanning forms an integral component of Health Technology Assessment. However, it is a specialised and quite distinct activity conducted for an entirely different purpose. The rapid evolution of technological advances can in some cases overtake the speed at which trials or other reviews are conducted. In many cases, by the time a study

or review has been completed, the technology may have evolved to a higher level leaving the technology under investigation obsolete and replaced.

A Horizon Scanning Report maintains a predictive or speculative focus, often based on low level evidence, and is aimed at informing policy and decision makers. It is not a definitive assessment of the safety, effectiveness, ethical considerations and cost effectiveness of a technology.

In the context of a rapidly evolving technology, a Horizon Scanning Report is a 'state of play' assessment that presents a trade-off between the value of early, uncertain information, versus the value of certain, but late information that may be of limited relevance to policy and decision makers.

This report provides an assessment of the current state of development of the Tan–Bianchi procedure and subsequent modifications, its present and potential use in the Australian public health system, and future implications for the use of this technology.

Search Strategy Used for Report

A systematic search of MEDLINE, PubMed, Cochrane Library and Science Citation index using Boolean search terms was conducted, from the inception of the databases until April 2004. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, national Research Register, relevant online journals and the internet were also searched in April 2004. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on the Tan–Bianchi procedure and any subsequent modifications of the procedure in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were included if they contained relevant safety and efficacy data. In the case of duplicate publications, the latest, most complete study was included. Articles were excluded for reporting no clinical outcomes, being review articles without data or involving techniques other than the Tan–Bianchi or modified procedure.

Articles were grouped for reporting similar procedures:
- Tan–Bianchi procedure (including omega-shaped modification)
  (Ali Gharaibeh *et al.* 1992; Besson *et al.* 1997; Fitzgerald *et al.* 1990; Franchella & Sicilia 1997; Khan & Al Bassam 2000; Leinwand *et al.* 1999; Podevin *et al.* 1997; Takamizawa *et al.* 2004; Tan & Bianchi 1986)

- Y-V closure plasty modification
  (Besson *et al.*1997; Poli-Merol *et al.* 1996)

- Lateral extensions of the omega-shaped incision, modified upward 0.5 – 1.0 cm
  (Khan & Al Bassam 2000)

- Right lateral extension
  (Misra & Mushtaq 1998)

- Right semi–circular incision
  (Alberti *et al.* 2004)

- Tan–Bianchi incision with subcutaneous 'inverted T' incision in linea alba
  (Karri *et al.* 2003)

- Tan–Bianchi incision with undermining of epigastric skin
  (De Caluwe *et al.* 1998; Horwitz & Lally 1996; Shankar *et al.* 2001)

- Tan–Bianchi procedure with curved linea alba incision
  (Huddart *et al.* 1993; Lambert *et al.* 2002)

Availability and Level of Evidence

Total Number of studies:	18
Non-randomised comparative studies	6
Case series	12

Sources of Further Information

There were no other sources of further information.

Impact Summary

Hypertrophic pyloric stenosis is the most common indication for infantile surgery. Traditionally an open approach allows access to the pylorus, resulting in a life-long abdominal scar. However, the development of the circumumbilical incision has resulted in an almost unnoticeable scar, hidden within the naturally occurring umbilical skin folds. The Tan–Bianchi procedure results in a similar operating time, feeding tolerance and hospital stay duration as the traditional RUQ incision.

Commonly reported complications of the Tan–Bianchi procedure have been wound infection, mucosal perforation and postoperative vomiting. The data on wound infection rates varies with some studies reporting an increased incidence of wound infection from circumumbilical incision and others reporting wound infection rates to be comparable with that of RUQ or even non-existent with adequate cleansing prior to the procedure. Mucosal perforation appears to have an increase in incidence in Tan–Bianchi procedures compared to RUQ.

With an array of Tan–Bianchi modifications developed, the adoption of the optimal extension is imperative to minimise complications. However, due to limited studies and small patient numbers it is difficult to determine which technique is superior in cosmetic result whilst minimising complications. The original Tan-Bianchi including the omega–shaped extension (n=502) has the most extensive range of studies compared to other

variants, and has effectively shown to minimise scarring. However, the benefit of the cosmetically favourable scar needs to be assessed against the increased risk of wound infection and mucosal perforation compared to RUQ.

Conclusions

The Tan–Bianchi procedure allows access to the pylorus, whilst resulting in a cosmetically favourable scar nestled within the umbilical skin folds. Reports suggest the Tan–Bianchi does not allow delivery of a large pyloric mass; however, modifications such as the omega-shaped extension, have shown to minimise the need for conversion to an open procedure. The original Tan-Bianchi including the omega–shaped extension appears to be quite popular amongst surgeons, with favourable cosmetic results and fewer serious complications.

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Appendix A: Table of Key Efficacy and Safety Findings - Comparative Studies

Author, Date, Location, Number of Patients, Length of Follow-up, Selection Criteria	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Fitzgerald et al. 1990, Canada Retrospective historical comparative study 100 patients Follow-up: Ranged from 1 week to 12 months. *Comparison:* Group 1 – right upper quadrant incision (n=50) Group 2 – Circumbilical incision (n=50) *Selection Criteria:* Not stated. *Exclusion Criteria:* Patients with a history of prior operative procedures or significant medical illness.	Mean operating time: Mean operating time was 33 [9] minutes for group 1 compared to 35 [12] minutes for group 2. Feeding: There was no significant difference in postoperative feeding tolerance. Mean hospital stay: Length of postoperative hospital stay was similar for both groups (group 1 – 2.3 [1.3] days, group 2 – 2.2 [1.2] days). Scar: The group 1 patients had a visible but acceptable scar, whereas group 2 patients had an almost undetectable scar which became well incorporated into the umbilicus.	Mucosal Perforation: Intraoperative complications in group 1 patients consisted of one mucosal perforation and one minor serosal tear. Intraoperative complications in group 2 patients consisted of two mucosal perforations and three minor serosal tears. Post-operative vomiting: 38/50 (76%) patients in group 1 had postoperative vomiting compared to 36/50 (72%) patients in group 2. In comparing time to last vomiting episode no significant difference was detected between the groups. Wound complications: Complication / Group 1 (n=50) / Group 2 (n=50) Infection — 1/50 (2%) / 2/50 (4%) Minor stitch abscesses — 1/50 (2%) / 3/50 (6%) Hypertrophic scar — 1/50 (2%) / 1/50 (2%) Haematoma — 1/50 (2%) / 0/50 (0%) None of the wound infections required drainage. 1/50 (2%) patients in group 2 who developed a wound infection received antibiotics. 14/50 (28%) patients in group 2 received preoperative dose of intravenous antibiotics.	*Procedure:* Original Tan-Bianchi procedure.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Huddart *et al.* 1992, United Kingdom Retrospective comparative study 320 patients Follow-up: 6 weeks Median age: 4.9 weeks (range 2 to 10 weeks) Comparison: Group 1 – transverse right hypochondrial incision (n=182) Group 2 – circumumbilical incision (n=138)	Mean hospital stay: The average length of hospital stay was similar between the group 1 (4.1 days) and group 2 (4.4 days) patients. Scar: At follow-up strong well healed scars occurred in all patients except those that had incisional hernia. The 1/138 (0.7%) group 2 patient healed well with conservative management. 2/5 (40%) of group 1 patients who developed incisional hernia required operative repair.	Mortality: One of the 321 patients (0.3%) died preoperatively (not reported which group they were to be assigned) from cardiac arrest whilst being resuscitated for severe dehydration. Wound infection: Wound infection rates were higher in group 1 (22/138, 15.8%) patients compared to group 2 (10/182, 5.4%) patients. Hernia: Postoperative incisional hernia was greater in group 1 patients (5/182, 2.7%) compared to group 2 patients (1/138, 0.7%).	*Procedure:* Tan-Bianchi with curved linea alba incision. The umbilicus is cleaned thoroughly. The umbilical skin is incised for 50%-75% of its circumference. Entry into the peritoneum however is via a curved incision into the linea alba, rather than the midline approach. Where the pyloric mass was large incision was extended laterally into the rectus sheath.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Khan & Al Bassam 2000, Saudi Arabia 39 patients Follow-up: 8 weeks Male/female ratio: 5.4:1 Mean age: 35 days Mean weight: 3.56 kg *Comparison:* Group 1- Right upper Quadrant (RUQ) incision (n=6) Group 2 – Circumumbilical (CUI) incision (n=33) Incisions: Without lateral extension (n=21) Omega-shaped (n=3) New modification (n=9) *Selection Criteria:* Not stated	Incision: No patient in group 2 required conversion to RUQ incision or reoperation due to inadequate exposure. Mean operating time: Mean operating time for all cases was 28 mins (range 20 to 66) (n=39). Feeding: All patients commenced feeding within 6 to 12 hours (n=39). Weight: At follow-up all patients had gained considerable weight (n=39). Scar: Group 2 patients who underwent CUI without lateral extension (21/39) or the new modification (9/39) had a "ruffled up" appearance of the wound but wound scar was barely visible Group 2 patients that underwent omega-shaped incision (3/39) had small, visible scars at the umbilicus.	Mucosal perforation No patient had mucosal perforation Postoperative vomiting: 6/33 (18.2%) group 2 patients had postoperative vomiting for 1-6 days 3/33 (9.1%) group 2 patients had gastro-oesophageal reflux on contrast meal and were medically treated. Wound infection: 2/39 (5.1%) patients had wound infection (1 patient was from group 1 and 1 patient from group 2). Both were treated with antibiotics.	*Procedure:* Lateral extension of omega-shaped incision. The modification involved making bilateral (0.5 to 1 cm) skin incisions 0.5 cm above the two ends of the semicircular incision normally performed during the Tan-Bianchi procedure with no midline deep fascial incision. 39 consecutive pyloromyotomies performed. 16 operations performed under supervision of consultants.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments

Leinwand et al. 1999 United States
 	
 Retrospective analysis
 	
 344 patients
 	
 Comparison:
 Group 1 – right upper Quadrant incision (RUQ) (n=254)
 Group 2 – circumumbilical incision (UMB) (n=90)
 	
 Selection criteria:
 Not stated
	Mean hospital stay:
	 Length of hospital stay was similar between groups, 2.7 [1.5] for group 1 compared to 2.6 [1.12] for group 2 (p=0.35).
		Wound complications:
		 Intraoperative complication rate was 2.8% in group 1 compared to 13.3% in group 2 (p=0.001).
		
		 Complication Group 1 Group 2
		   (n=254) (n=90)
		 Mucosal 4/254 8/90
		 perforation 1.6% 8.9%
		 Serosal tear 3/254 4/90
		   1.2% 4.4%
		
		 Mucosal perforation:
		 Mucosal perforation increased mean hospital stay in group 2 (n=90) patients from 2.4 [1.1] to 3.9 [0.8] days.
		
		 Post operative complication rate was 1.6% (4/254) in group 1 patients compared to 7.8% (7/90) in group 2 patients.
		
		 Wound infection:
		 Wound infection rate was 1.2% (3/254) in group 1 patients compared to 6.7% (6/90) in group 2 (p=0.01)
			Procedure:
			 Original Tan-Bianchi procedure.
			
			 Antibiotic prophylaxis decreased wound infection rates eliminating the statistical difference between groups.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Podevin *et al.* 1997, France Retrospective historical comparison 239 patients *Comparison:* Group 1 – right upper quadrant incision (RUQ) (n=121) Group 2 – umbilical incision (UMB) (n=118) *Inclusion criteria:* Not stated. *Exclusion criteria:* Cases with prior history of operative procedures or with unhealed umbilicus at the time of pyloromyotomy were excluded.	Incision: When it was noted, pyloric exteriorisation was difficult for 3/36 (8.3%) group 1 patients compared to 10/29 (34.5%) group 2 patients. Mean operating time; The mean operating time was longer in group 2 patients (52 [14] mins) than in group 1 patients (38 [14] mins) (p<0.001). Feeding: Postoperative feeding tolerance was similar for both groups. Mean hospital stay: Postoperative hospital stay tended to be shorter in the group 2 patients (7.2 [2.1] days) (n=118) compared to group 1 patients (7.8 [1.9] days) (n=121) (p=0.04). Scar: In comparison to group 1 patients (n=121), group 2 (n=118) patients had an almost undetectable scar incorporated in the umbilicus.	Mucosal perforation: Intraoperative mucosal perforation occurred in 2/121 (1.6%) patients in group 1 compared to 4/118 (3.4%) patients in group 2. Postoperative complications: Complication Group 1 Group 2 (n=121) (n=118) Wound 2/121 5/118 infections (1.6%) (4.2%) Wound 0/121 0/118 dehiscence (0%) (0%) Stenosis 0/121 1/118 relapse (0%) (1%) Ventral 0/121 0/118 hernia (0%) (0%) The overall morbidity rate (intraoperative and postoperative) was 3.3% (4/121) in group 1 patients compared to 8.5% (10/118) in group 2 patients.	*Procedure:* Original Tan–Bianchi procedure. 118 consecutive pyloromyotomies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Poli-Merol et al. 1996, France 80 patients Follow-up: 10 months to 3 years *Comparison:* Group 1 – classic trans-rectus approach (n=40) Group 2 – Circumumbilical incision (n=40) *Selection Criteria:* Not stated	<u>Mean operating time:</u> The mean operating time was 28 minutes in each group (n=80). <u>Feeding:</u> The mean time for resumption of feeding was 4.5 hours (range 1.5 to 12 hours) in group 1 (40/80) and 5.75 (range 2 to 20 hours) in group 2 (40/80). <u>Mean hospital stay:</u> The mean hospital stay was similar for both groups at 5 days (n=80). <u>Scar:</u> The cosmetic appearance of the seam was judged better in group 2 (40/80, 50%) by both family members and surgeons. The Circumumbilical scar was well masked by the umbilicus fold.	<u>Wound infection:</u> 1/ 40 (2.5%) in group 1 presented a wound suppuration which was surgically treated four days post-operatively. <u>Wound dehiscence:</u> In group 2, 1/40 (2.5%) patients had wound dehiscence which was reoperated 3 days post-operatively and 1/40 (2.5%) had a duodenal mucosal wound which was immediately sutured. At follow-up no patient in either group had abdominal wall dehiscence or presented hypertrophic scar.	*Procedure:* Y-V closure plasty Group 2 patients had a semi-circular incision in the superior umbilical fold with longitudinal upper umbilical skin incision over 1 cm. Subcutaneous dissection was done above the umbilical ring. The linea alba was opened longitudinally and pyloromyotomy was performed.

Appendix A: Table of Key Efficacy and Safety Findings – Case Series Studies

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Alberti *et al.* 2004, Italy 25 patients *Selection Criteria:* Patients with infantile hypertrophic pyloric stenosis (IHPS)	Scar: Study reported excellent cosmetic results, right lateral umbilical skin fold does not grow with age; scar was hardly visible.	Complications: No complications or wound infections occurred in any patient.	*Procedure:* Tan-Bianchi procedure – right semicircular incision. The procedure involved a right semicircular incision is performed at umbilical skin fold. The subcutaneous tissue underlying the skin incision in undermined to expose the anterior rectus abdominis muscle sheath, which is incised all around and next to the umbilicus leaving a 2 to 3 mm edge. *Incision:* All incisions in this procedure lay in the same axis. This enabled abdominal cavity to be easily opened with two retractors. Rectus muscle fibres are only laterally displaced and not severed as with other modifications of technique Presence of medial edge of rectus muscle sheath assures strong fascial closure, lowering risk of incisional hernia.

Study Details	Key Efficacy Findings	Key Safety Findings		Appraisals/Comments
Ali Gharaibeh et al. 1992, Jordan 22 patients Follow-up: ranged from 2 to 48 months. Mean age: 33 days (range 18 to 60 days) *Selection criteria:* Not stated	<u>Mean hospital stay</u>: The mean duration of hospital stay was 4 days (range 3 to 6 days). <u>Incision:</u> No patient revealed incisional hernia at follow-up. <u>Scar:</u> Scars were barely visible in 20/22 (90.9%) patients. 2/22 (9.1%) patients without neat scars were the patients which developed wound dehiscence and stitch sinus. Twenty one patients of 22 (95.4%) had strong abdominal wall healing except 1/22 (4.5%) who had incisional hernia.	<u>Wound complications:</u> Complication Mucosal perforation Wound infection Wound dehiscence Stitch sinus Incisional hernia	Patient Number (n=22) 2/22 (9.1%) 3/22 (13.6%) 1/22 (4.5%) 1/22 (4.5%) 1/22 (4.5%)	*Procedure:* The original Tan Bianchi procedure The high rate of wound infection suggested to be due to the fact Jordan is a poorer country with less hygiene facilities.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisals/Comments
Besson *et al.* 1997, France 32 patients Follow-up: 1.5 to 2 months Age: 16 to 91 days *Selection criteria:* Not stated	Scar: The final cosmetic results were very good without any cases of eventration.	Incision: One patient who underwent Tan-Bianchi procedure needed a right-sided transverse incision because delivery of a very large pyloric mass (before modification was used). Wound infection: Six of 32 (18.7%) patients developed wound infections, was not reported which groups patients were from. Mucosal perforation: Three of 32 (9.4%) patients had incidental mucosal perforation preoperatively that was immediately sutured. (2 patients from Tan-Bianchi group, 1 patient from modified procedure group). Abscesses Five of 32 (15.6%) patients had minor stitch abscesses and 1/32 (3.1%) had true wound abscess with purulent discharge.	*Procedure:* 21 patients had original Tan – Bianchi procedure. 11 patients had Y-V closure plasty. The procedure involved an incision in the skin fold of the upper half of the circumference of the umbilicus, with a second incision at the midline joining the first one at the top. The three parts of the incision are all equal in length. The subcutaneous tissue is divided over the alba linea, which is split longitudinally and the peritoneal cavity is opened.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
De Caluwe *et al.* 1998, Belgium 29 patients Follow-up: 10 days postoperatively Median age: 30 days (range 17 to 70 days) Median weight: 3.72 kg (range 2.8 to 4.8 kg) *Selection Criteria:* Not stated.	Mean hospital stay: The median hospital stay of the 29 patients was 2.5 days	Mucosal perforation: In two patients, a small mucosal perforation occurred intraoperatively, which was repaired with one or two stitches Abscesses: One patient presented 13 days postoperatively with a small wound abscess that was locally drained	*Procedure:* Tan-Bianchi procedure with undermining if epigastric skin. Procedure involved a hemicircumferential upper periumbilical skin incision, the supraumbilical skin undermined on 1 to 2 cm above the umbilical ring. The supraumbilical rectus muscle sheath was incised transversely to the right of the umbilical vein and the rectus muscle split vertically to facilitate optimal exposure to the suspended pyloric muscle.
Franchella *et al.* 1997, Italy 33 patients Follow-up: 1 month Mean age: 32.6 days (range 15 to 52 days) *Selection criteria:* Not stated	Mean operating time: Operating time was similar to that required for transverse right incision. Hospital stay: Mean hospital stay was 4 days. Scar: Surgeons reported satisfying cosmetic result.	Wound infection: No wound infections reported. Complications: No operative or postoperative complications were reported.	*Procedure:* Original Tan-Bianchi procedure. Information from abstract, article in Italian.

Study Details	Key Efficacy Findings	Key Safety	Appraisal/Comments
Horwitz _et al._ 1995, USA 18 patients Follow-up period: 1 to 10 months Mean age: 4.52 [2.3] weeks Mean weight: 3.73 [0.7] kg _Selection criteria:_ Not stated	<u>Incision:</u> No patient required conversion to a right upper-quadrant (RUQ) incision due to inadequate exposure. No patient required reoperation due to inadequate pyloromyotomy. <u>Mean operating time:</u> The mean operating time for all 18 patients was 32.4 [7.7] minutes. <u>Scar:</u> By 6 weeks after surgery, skin incisions were barely visible within the natural umbilical skin.	<u>Complications</u>: There were no reported intraoperative complications or postoperative wound complications during follow-up period.	_Procedure:_ Tan-Bianchi procedure with undermining of epigastric skin. The procedure involved transverse incision made within the supraumbilical skin fold and carried down to the abdominal wall fascia. The midline fascia was exposed in a cephalad direction by undermining the epigastric skin. The peritoneal cavity was entered via the midline and the pylorus was delivered into the incision.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Karri *et al.* 2003, Norfolk & Norwich 51 patients Follow-up: 3 months Mean age: 4.7 weeks (range 2 to 10 weeks) *Selection Criteria:* Selection criteria was not stated	Incision: Extension of the skin incision or conversion to the right hypochondrium approach was not required for 0/50 (0%) patient. Mean operating time: Mean operating time was 31.4 minutes (range 15 to 70 mins) (n=51). Mean hospital stay: The mean post-operative hospital stay was 2 to 3 days (n=51).	Wound infection: Wound infection occurred in 2/51 (3.9%) patients, resolved by antibiotic treatment. Mucosal perforation: Mucosal perforation occurred in 1/51 (2%) patient and was responsible for the longest operating time of 70 minutes. Hernia: No incision hernia was detected at the 3 month follow-up in any patient.	*Procedure:* Tan-Bianchi with curved linea alba incision. The procedure involved a circumumbilical skin incision and division of subcutaneous tissue performed as in the Tan-Bianchi procedure, a 3cm vertical midline incision is made into the linea alba. Subsequent transverse incision is made to intersect the claudal end to form an 'inverted T' with the right limb approximately double the length of the left.
Lambert *et al.* 2002, United Kingdom 98 patients Mean age: 6 weeks (range 2 to 22 weeks) *Selection Criteria:* Selection criteria was not stated	Mean hospital stay: Patients were discharged mean 46 [22] hours postoperatively.	Mucosal perforation: A mucosal breach occurred in 3/98 (3%) patients which was recognised and repaired at the time of the original surgery. Complications: There were 3/98 major and 2/98 minor wound complications (overall 5.1%), independent of antibiotic prophylaxis.	*Procedure:* Tan-Bianchi procedure with curved linea alba incision. *Patients:* Consecutive recruitment Prophylactic antibiotics was given to 64/98 (65%) patients.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Misra *et al.* 1998, United Kingdom 30 patients *Selection criteria:* Not stated	Incision: Incision allowed delivery of the pylorus to the surface in all 30 patients. Scar: The reported cosmetic result is excellent and parents were pleased with the barely visible scar (n=30).	Complications: No complications reported	*Procedure:* Tan-Bianchi with right lateral extension. A supra-circumumbilical skin incision is made. On the right hand side, a 0.5-1cm lateral extension is made. The underlying muscles are divided transversely, involving division of the linea alba and partial division of the right rectus muscle. The pylorus is delivered to the surface. Consecutive patients.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Shankar *et al.* 2001, United Kingdom 86 patients Median age: 43 days (range 10 to 61 days) *Inclusion Criteria:* Patients with infantile hypertrophic pyloric stenosis (IHPS)	Mean operating time: Mean operating time was 30 minutes (n=86). Mean hospital stay: Patients went home an average 58 hours post surgery (n=86). Scar: Umbilical scar was barely visible at 1 week postoperatively in the majority of patients (n=86).	Complications: No complications reported.	*Procedure:* Tan-Bianchi with undermining of epigastric skin. The procedure involved circumferential skin crease incision created deep in the umbilical fold. The skin was undermined in a cephalad direction and the linea alba exposed. The linea was incised vertically and the peritoneal cavity entered, exposing the pyloric tumour. The cephalad incision in the linear alba, 'hidden' under the umbilical scar.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Takamizawa *et al.* 2004, Japan 104 patients *Comparison:* Group 1 - Intracorporeal approach (ICP) (n=75) Group 2 - Extracorporeal approach (ECP) (n=29) *Inclusion Criteria:* Patients with IHPS diagnosed by ultrasound to have pyloric muscle thickness of 3mm of greater.	Mean operating time: Operating time in group 1 patients (56.4 [13.6] min) was significantly longer than in group 2 patients (48.7 [16.3] min), (p=0.004). Feeding: The average time to full feeding (160 ml/kg/day) without vomiting was significantly shorter in group 1 patients (2.1 [1.6] days) compared to group 2 patients (2.9 [1.9] days), (p=0.002). Weight: All patients gained weight postoperatively without any further gastrointestinal problems (n=104).	Incision*:* Extension of the skin and/or fascial incision was required in 2/75 (2.6%) group 1 patients compared to 11/29 (37.9) group 2 patients (p<0.0001). Mucosal perforation*:* 1/ 75 (1.3%) patients in group 1 had a mucosal perforation that was detected during the operation and repaired without requiring extension of the fascia or skin incisions. Wound infection: Postoperative wound infection occurred in 4/75 (5.3%) of group 1 patients and 2/29 (6.9%) of group 2 patients. All were treated by drainage only.	*Procedure:* Original Tan-Bianchi procedure The procedure involved a supraumbilical skin crease incision, with the abdomen entered via a longitudinal incision on the linea alba. For ICP, an incision through the supraumbilical window into muscle fibres of the pylorus was made. Fibres were then spread until the submucosal layer bulged out. For ECP, the hypertrophied pylorus was delivered manually through the incision and pyloromyotomy occurred as in Ramstedt pyloromyotomy. As the procedure is Tan-Bianchi and the modification is of pyloromyotomy technique, the results of this study are all integrated into Tan-Bianchi.

Study Details	Key Efficacy Findings	Key Safety Findings	Appraisal/Comments
Tan *et al.* 1986, United Kingdom 40 patients follow-up range: 6 to 10 weeks Age range: three to eight weeks *Selection criteria:* Not stated	Incision: 39/40 (97.5%) patients the pylorus was easily accessible with standard procedure, 1/40 (2.5%) patients required modification of the procedure as outlined in comments column to allow greater access for a very large pyloric mass. All 40 patient wounds healed primarily. Mean operating time: Operating time was not increased when compared to open pyloromyotomy. Scar: Six to ten weeks postoperatively revealed a well healed strong abdominal wall in 39/40 (97.5%) patients. Skin incisions were hardly visible, integrating well with the natural umbilical scar.	Wound dehiscence: 1/40 (2.5%) patients had wound dehiscence at fascial level. Wound infection: 7/40 (17.5%) patients had a slight cellulitic flare around the wound leading to antibiotic treatment. 1/40 (2.5%) patients had marked infection in the subcutaneous pocket with purulent discharge. Following drainage the wound healed primarily. Hernia: 1/40 (2.5%) patients developed incisional hernia.	*Procedure:* Original Tan-Bianchi procedure. The procedure involved a three-quarter circle incision is placed supraumbilically in the natural skin fold, following the curvature of the umbilicus. Epigastric skin is elevated and peritoneal cavity opened in the midline through the linea alba and to the right of the umbilical vein. Greater access can be obtained by extending the fascial incision and by small traverse skin extensions at the angles of the wound.