Health Policy Advisory Committee on Technology

Technology Brief

Endoscopic pancreatic stenting for prophylaxis of pancreatic fistula after distal pancreatectomy

May 2013
Pancreatic stenting for prophylaxis after distal pancreatectomy:

Technology, Company and Licensing

Register ID  WP161
Technology name  Prophylactic endoscopic pancreatic stenting
Patient indication  For use in patients who are scheduled to undergo distal pancreatectomy

Description of the technology

Endoscopic pancreatic stenting is a prophylactic measure aimed to reduce the development of postoperative pancreatic fistula (POPF) following distal pancreatectomy.¹ These stents (Figure 1) may be helpful by facilitating the flow of pancreatic juice through the sphincter of Oddi, thereby reducing the secretory pressure on the surgical closure.² This should be associated with a reduction in the pressure gradient between the main pancreatic duct and the duodenum.¹

Prophylactic endoscopic pancreatic stenting is designed to occur approximately six days before the distal pancreatectomy. Patients are consciously sedated and a guidewire is endoscopically inserted into the main pancreatic duct under fluoroscopic guidance. A sphincterotomy is then performed followed by the insertion of a pancreatic stent over the guidewire. To minimise the risk of spontaneous stent dislocation, the stent must be as long as possible but its distal tip must not surpass the planned transection plane for the distal pancreatectomy.³ Consequently, 3-7cm, five or seven French stents are recommended. It should be noted that there is no correlation between stent size and risk of POPF.² The stent should be removed one to two weeks after the distal pancreatectomy to prevent any alterations to the pancreatic duct.⁴,⁵

Figure 1  Geenen® Pancreatic Stent used in Abe et al. (2006) study of prophylactic endoscopic pancreatic stenting in preventing pancreatic fistulas⁶
Company or developer

Three pancreatic stents designed to drain obstructed pancreatic ducts have been identified on the Australian Register of Therapeutic Goods (ARTG) (Table 1). All the stents are produced by William A Cook Australia Pty Ltd (Brisbane, Australia).

Reason for assessment

Postoperative pancreatic fistula is a common complication following distal pancreatectomy with no effective strategies preventing its development.

Stage of development in Australia

- ☒ Yet to emerge
- ☐ Established
- ☐ Experimental
- ☐ Established but changed indication or modification of technique
- ☐ Investigational
- ☐ Should be taken out of use
- ☐ Nearly established

Licensing, reimbursement and other approval

Prophylactic endoscopic pancreatic stenting is not presently listed on the Medicare Benefits Schedule (MBS).

Three pancreatic stents were identified on the ARTG (Table 1). However, it is unclear whether these items would be suitable for endoscopic pancreatic stenting.

Table 1  ARTG listings for pancreatic stent sets

<table>
<thead>
<tr>
<th>ARTG number</th>
<th>Description</th>
<th>Sponsor</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>101016</td>
<td>Pancreatic Stent Sets - Prosthesis, internal, stent, pancreatic</td>
<td>William A Cook Australia Pty Ltd</td>
<td>Medical device class IIb</td>
</tr>
<tr>
<td>142998</td>
<td>Pancreatic Stent Sets - Prosthesis, internal, stent, pancreatic</td>
<td>William A Cook Australia Pty Ltd</td>
<td>Medical device class IIb</td>
</tr>
<tr>
<td>142999</td>
<td>Pancreatic Stent Sets - Prosthesis, internal, stent, pancreatic</td>
<td>William A Cook Australia Pty Ltd</td>
<td>Medical device class IIb</td>
</tr>
</tbody>
</table>

Australian Therapeutic Goods Administration approval

- ☒ Yes  ARTG numbers: 101016, 142998, 142999
- ☐ No
- ☐ Not applicable

Technology type  Procedure

Technology use  Preventative
**Patient Indication and Setting**

**Disease description and associated mortality and morbidity**

Distal pancreatectomy involves surgical resection of pancreatic tissue to the left of the superior mesenteric artery and vein. Indications for distal pancreatectomy include:

- Benign;
  - chronic pancreatitis
  - pseudocysts
  - trauma associated with the main duct

- Malignant and premalignant diseases;
  - pancreatic adenocarcinoma
  - pancreatic cystic neoplasms
  - neuroendocrine tumours.

Although the mortality rate associated with distal pancreatectomy is low - approximately three per cent, morbidity remains high. This is due, in part, to the exocrine function of the pancreas, which often results in pancreatic leakage following surgery. The standard surgical procedure to prevent leakage of pancreatic fluid from the resected plane after distal pancreatectomy is ligation of the main duct, suturing the pancreatic remnant and placement of at least one intra-abdominal drainage tube. However, the pancreatic duct has up to five small diameter side-branches which are difficult to identify and ligate during resection. Leakage from the side branches may cause the development of postoperative pancreatic fistulas.

Postoperative pancreatic fistulas result from failure of the pancreatic closure to correctly heal and seal the pancreatic ducts that are exposed on the raw pancreatic surface. Postoperative pancreatic fistulas are divided into three distinct grades dependent upon its severity and deviation from the normal clinical management.

Grade A pancreatic fistulas are the most common. It is a transient fistula requiring little to no deviation from the normal clinical pathway. Patients remain clinically well and do not require antibiotics or somastatin analogues. They are managed by slow removal of the intra-abdominal drains.

Grade B is a more severe form of pancreatic fistula which requires deviations from the normal clinical pathway. Patients are not fed orally and the pancreatic drains are maintained in place. If the fistula results in abdominal pain, fever or leukocytosis, antibiotics and somatostatin analogues are required. Grade B POPFs are associated with a prolonged hospital stay.

Grade C fistulas are the most severe form of pancreatic fistula and require major changes to the normal clinical pathway. Patient stability may be borderline and will often require
reoperation. Grade C fistulas are associated with an increased risk of mortality and prolonged hospitalisation.\textsuperscript{10}

The main risks associated with grade B and C postoperative pancreatic fistulas are intraperitoneal abscess, sepsis, haemorrhage and death.\textsuperscript{1}

It is difficult to determine who will develop postoperative pancreatic fistulas. However, a number of patient related risk factors have been identified such as: <65 years old\textsuperscript{11}, body mass index >25, higher American society of anaesthesiologist score and decreased albumin level.\textsuperscript{8} Operative risk factors include, not ligating the main pancreatic duct\textsuperscript{11}, concomitant splenectomy, soft texture of the pancreas\textsuperscript{12} and an operating time greater than 480 minutes.\textsuperscript{13}

**Number of patients**

Pancreatic fistula is the most common complication following distal pancreatectomy. The incidence varies (5 to 60%) depending on the criteria and method used to diagnose fistula.\textsuperscript{14,15} A meta-analysis of 479 distal pancreatectomy patients, determined the incidence of postoperative pancreatic fistulas was 31 per cent.\textsuperscript{16}

Within Australia, information regarding POPF is limited. A case study of 46 patients undergoing laparoscopic distal pancreatectomy determined postoperative pancreatic fistulas occurred at a rate of 15 per cent.\textsuperscript{17} All fistulas resolved after a median of six weeks without reoperation (grades A and B). Applying this statistic to the 2011-2012 MBS claims for distal pancreatectomy, at least 25 patients may have developed POPF (Table 2).

### Table 2  
**Utilisation of MBS items for relating to distal pancreatectomy from July 2011 to June 2012**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Description</th>
<th>Fee</th>
<th>Number of Claims (July 2011 to June 2012)</th>
</tr>
</thead>
<tbody>
<tr>
<td>30583</td>
<td>Distal pancreatectomy</td>
<td>$1,194.25 (Benefit 75% = $995.70)</td>
<td>167</td>
</tr>
<tr>
<td>30491</td>
<td>Bile duct, endoscopic stenting of (including endoscopy and dilatation)</td>
<td>$555.35 (Benefit 75% = $416.55, 85% = $480.85)</td>
<td>2,726</td>
</tr>
</tbody>
</table>

MBS, Medicare Benefits Schedule.

**Speciality**  
Gastrointestinal, pancreatic and liver disease

**Technology setting**  
General Hospital

**Impact**

**Alternative and/or complementary technology**

Prophylactic endoscopic pancreatic stenting is an additional procedure occurring before distal pancreatectomy.

Attempted alternative prophylactic strategies include, surgical techniques such as pancreatic transection with an automatic stapler or ultrasonic dissector, fibrin glue sealing
of the pancreatic stump and octreotide. These strategies however, do not completely prevent the development of postoperative pancreatic fistula.\(^1\)

**Current technology**

Ligation of the main pancreatic duct, suturing the pancreatic remnant and placement of at least one intra-abdominal drainage tube is the current standard surgical technique designed to prevent postoperative pancreatic fistulas.\(^3\)

**Diffusion of technology in Australia**

The diffusion of prophylactic endoscopic pancreatic stenting within Australia was unable to be determined through review of the published literature. Correspondence with a clinical expert revealed it is unlikely that there are Australian groups conducting clinical trials on the use of pancreatic stents to reduce the risk of postoperative fistulae.

**International utilisation**

Prophylactic pancreatic stenting has been utilised in Japan\(^1\), Germany\(^3\) and Sweden\(^2\) with ongoing clinical trials reported in the United States of America.

<table>
<thead>
<tr>
<th>Country</th>
<th>Level of Use</th>
<th>Trials underway or completed</th>
<th>Limited use</th>
<th>Widely diffused</th>
</tr>
</thead>
<tbody>
<tr>
<td>Germany</td>
<td></td>
<td>✓</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Japan</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>United States of America</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Cost infrastructure and economic consequences**

Prophylactic endoscopic pancreatic stenting is an additional procedure to distal pancreatectomy. Increased costs associated with the procedure include, an endoscope, pancreatic stent, guidewire, imaging systems – fluoroscopy or CT scans, consumables, additional hospital stay, specialist and support staff.

The cost of the William A Cook Australia Pty Ltd Geenen\(^\circ\) pancreatic stents is $85.\(^{18}\) Currently, endoscopic pancreatic stenting is not listed on the MBS. However, a procedure of similar time and complexity, endoscopic stenting of the bile duct, costs $555.35 (Table 2).

**Ethical, cultural or religious considerations**

No ethical, cultural or religious considerations where identified in the published literature.
Evidence and Policy

Safety and effectiveness

One randomised controlled trial (RCT) (level II intervention evidence), one non-randomised comparative study (level III intervention evidence) and one case series (level IV intervention evidence) were included in the Technology Brief. The case study retrospectively analysed the rate of postoperative pancreatic fistulas in nine patients who underwent prophylactic endoscopic pancreatic stenting. The RCT and the nonrandomised comparative study compared prophylactic endoscopic pancreatic stenting prior to distal pancreatectomy to distal pancreatectomy without endoscopic pancreatic stenting. The safety and effectiveness of endoscopic pancreatic stenting was assessed in a total of 61 patients with the occurrence of pancreatic fistula assessed across all three studies. A summary of the details of the included studies is outlined in Table 3.

Table 3 Summary of details of the included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Level of evidence</th>
<th>Number of patients</th>
<th>Patient details</th>
<th>Comparative treatment</th>
<th>Comparison of patient populations</th>
<th>Randomisation</th>
<th>Intervention</th>
<th>Follow-up</th>
<th>Conflict of interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abe et al. 20061</td>
<td>IV</td>
<td>9</td>
<td>Scheduled for distal pancreatectomy</td>
<td>Distal pancreatectomy</td>
<td>No significant differences</td>
<td>No</td>
<td>Endoscopic pancreatic stenting</td>
<td>Not reported</td>
<td>Not reported</td>
</tr>
<tr>
<td>Rieder et al. 20102</td>
<td>III</td>
<td>48</td>
<td>Scheduled for distal pancreatectomy</td>
<td>Distal pancreatectomy</td>
<td>No significant differences</td>
<td>No</td>
<td>Endoscopic pancreatic sphincterotomy and stenting</td>
<td>Not reported</td>
<td>None</td>
</tr>
<tr>
<td>Frozanpor et al. 20123</td>
<td>II</td>
<td>53</td>
<td>Scheduled for distal pancreatectomy</td>
<td>Distal pancreatectomy</td>
<td>No significant differences</td>
<td>Computer-generated randomised numbers allocated to a group</td>
<td>Endoscopic pancreatic sphincterotomy and stenting</td>
<td>3-4 weeks</td>
<td>None</td>
</tr>
</tbody>
</table>

Frozanpor et al. 20122

A randomised controlled trial (level II intervention evidence) was conducted at the Karolinska University Hospital in Sweden by Frozanpor et al. Sixty-four non-consecutive patients with planned distal pancreatectomy surgery were recruited for the study and a total number of 53 were included in the analysis (11 excluded). Patients were excluded if transpapillary cannulation was not feasible and if the indication for pancreatic resection was trauma. Patients were treated in the following way. Using opaque sealed envelopes with computer-generated random number in blocks of 10 (5:5) patients were randomised to one of two groups – those receiving endoscopic pancreatic sphincterotomy with stenting.
followed by distal pancreatectomy and those receiving only distal pancreatectomy. All patients received a follow-up three to four weeks after discharge from the hospital. Of the included patients 51 per cent were female with 41 per cent of all patients over the age of 65. Additionally, 58 per cent of patients reported a body mass index (BMI) greater than 25. The causes for distal pancreatectomy included adenocarcinoma (n=15), benign cyst (n=8), mucinous cyst (n=3), intraductal papillary mucinous neoplasm (n=4), neuroendocrine tumour (n=11), chronic pancreatitis (n=5), renal cancer metastases (n=4) and pseudopapillary tumour (n=3). At baseline, there were no significant differences reported in patient characteristics.

**Safety**

This RCT reported no deaths in either treatment group following endoscopic pancreatic stenting. Endoscopic retrograde cholangiopancreatography-related complications occurred in three patients in the intervention group (11%). Following distal pancreatectomy (DP), 81.4 and 18.5 per cent of the control group experienced minor complications (Clavian gradings I-II) and major complications (Clavian gradings ≥IIIa), respectively. Although the intervention (DP + stent) group had a higher rate of major complications (42.3%) and consequently a lower rate of minor complications (57.7%), this difference between the two groups was not statistically significant.

Eleven patients from the intervention group (42.3%) developed an intra-abdominal abscess compared to five patients in the control group (18.5%).

**Effectiveness**

Overall, endoscopic placement of the pancreatic stent was successful in 92 per cent of all patients. The main pancreatic duct could not be cannulated in two patients. At the time of the follow-up six of the stents had spontaneously dislocated.

Post-operative pancreatic fistula (POPF) developed in eight (37.0%) and 13 (50.0%) patients in the control and intervention group, respectively (p=0.122). Although there was a trend of towards more clinically significant fistula’s (grades B and C) in the intervention group (42 vs. 22%), this was not significant (p=0.14). Of those patients who developed a POPF, four control (14.8%) and 10 (38.5%) intervention patients developed an intra-abdominal abscess (OR: 3.59, 95% CI [0.96, 13.50]; p = 0.058). There was a trend of increased operation time in

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1 Clavien classification of surgical complications: Grade I Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions; Grade II Requiring pharmacological treatment with drug other than such allowed for Grade I complications; Grade III Requiring surgical, endoscopic or radiological intervention; Grade IIIa Intervention not under general anaesthesia; Grade IIIb Intervention under general anaesthesia; Grade IV Life-threatening complication; Grade IVa Single organ dysfunction; Grade IVb Multiorgan dysfunction; Grade V Death of a patient.

the experimental group compared to the control – 284 ± 131.9 and 218.8 ± 94.1 minutes respectively (p=0.052). Similarly, the experimental group tended to have prolonged hospital stays compared to the controls – 19.4 ± 14.4 vs. 13.4 ± 6.4 days (p=0.071) respectively.

Rieder et al. 2010

A non-randomised cohort study with a retrospective control group (level III-3 intervention evidence) was conducted at an academic teaching hospital in Germany by Rieder et al. Forty-eight consecutive patients scheduled to undergo distal pancreatectomy between January 2001 and October 2008, were recruited for this study. The study consisted of two arms - a retrospective control group (n=25) (January 2001 to March 2004) and an experimental group (n=23) (July 2004 to October 2008). The exclusion criterion was not reported. The patients in the intervention group were treated in the following way – six days (range 1 – 18 days) prior to the planned surgical resection, an endoscopic pancreatic sphincterotomy with stenting was performed. Distal pancreatectomy with or without splenectomy was then performed by the same surgeon. The stent was removed eight weeks postoperatively. The retrospective control group underwent distal pancreatectomy with or without splenectomy. These patients however, did not receive a preoperative pancreatic stent. All patients were scheduled for endoscopy eight weeks postoperatively. Stent removal was performed without repeated pancreaticography. There was no systematic follow-up after stent removal. Of the included patients 43 per cent were female, with a mean age of 65 (36-84) and 68 (40-81) for the control and experimental group respectively. Forty-one per cent of all participants were over the age of 65. The mean BMI for the control and stenting groups were 23.5 kg/m² (18–36) and 23.9 kg/m² (17.7–30.9) respectively. Thirty three per cent of all patients reported a BMI greater than 25. The indications for distal pancreatectomy included adenocarcinoma (n=26), neuroendocrine tumour (n=7), intraductal papillary mucinous tumour (n=3), cystadenoma (n=4) and focal pancreatitis or pancreatic pseudocyst (n=8). At baseline, there were no significant differences reported in patient characteristics.

Safety

There were no reported deaths from preoperative endoscopic pancreatic stenting. Mild pancreatitis, a major complication was reported in four per cent of all patients undergoing stenting – all of whom had intraductual papillary mucinous tumours. Minor complications such as bleeding or perforation did not occur. No deaths occurred following distal pancreatectomy. However, major complications – intra-abdominal bleeding, pneumonia, acute coronary syndrome or enterocutaneous fistula, occurred in 12 and 16 per cent of the control and experimental groups respectively. However, this was not statistically significant. Minor complications were not reported.

Effectiveness
Overall, the endoscopic pancreatic sphincterotomy with stenting was successfully performed in 92 per cent of all patients. The guide wire could not be passed after cannulation of the pancreatic duct in two patients. Spontaneous stent dislocation had occurred in five patients by the eight week follow-up.

Post-operative pancreatic fistula developed in 22 per cent of patients in the control group (2 grade A’s, 1 grade B and 2 grade C’s). The fistula spontaneously resolved in two patients however, three patients required additional surgery – either percutaneous drainage, surgical resection or therapeutic endoscopic drainage. By comparison, there were no reported cases of pancreatic fistula in the intervention group (p=0.02). Five patients were required to prevent one pancreatic fistula. To prevent a pancreatic fistula that required deviation from normal clinical management, the number needed to treat was eight.

The operating time was significantly less in the intervention group compared to the control – 205 minutes (150-395) vs. 255 minutes (193-505) (p=0.017). The length of hospital stay was similar between both groups (mean =15 days). However, it was noted patients who required additional surgery had prolonged hospital stay - up to 91 days.

Abe et al. 2006

A case series was conducted at single centre in Japan by Abe et al. Between August 2000 and February 2003, nine patients underwent preoperative endoscopic pancreatic stenting prior to distal pancreatectomy (level IV intervention evidence). The exclusion criterion was not reported. Patients were treated in the following way – one to six days prior to distal pancreatectomy with concomitant splenectomy, an endoscopic transpapillary pancreatic stent was placed. Eight to 28 days postoperatively, the stent was removed. The duration of follow-up was not reported. Of the included patients 44 per cent were female with a mean patient age of 57 years (range 27 to 80 years). The causes for distal pancreatectomy included ductal adenocarcinoma (n=3), intraductal papillary mucinous tumour (n=3), ductal adenocarcinoma concomitant with intraductal papillary-mucinous tumour (n=1) and mucinous cystic tumour of the pancreas (n=2). Additional baseline patient characteristics were not reported.

Safety

This case series reported no deaths from preoperative endoscopic pancreatic stenting. Mild acute pancreatitis - a major complication, was reported in 22 per cent of the patients following endoscopic pancreatic stenting. All pancreatitis patients had intraductual papillary mucinous tumours. Minor complications were not reported. There were no deaths or any major or minor complications following distal pancreatectomy.

Effectiveness

No pancreatic fistulas were reported in any of the nine patients postoperatively. No pancreatic stent occlusion was found following macroscopic observation of the stent lumen.
There was no reported spontaneous stent dislocation and it was successfully removed eight to 28 days post-operatively.

**Economic evaluation**

No economic evaluations regarding the cost effectiveness of prophylactic endoscopic pancreatic stenting were identified in the literature.

In 2006, a decision analytic evaluating a hypothetical intervention to reduce the complication rate of distal pancreatectomy by one third determined it would be financially justifiable up to a cost of $1,418 (US dollars) per patient.  

**Ongoing research**

One clinical trial, currently underway, was identified from searches of www.clinicaltrials.gov and the Australian and New Zealand Clinical Trials Register (ANZCTR) (Error! Reference source not found.).

**NCT00671463 – Pancreatic stent to prevent leak after distal pancreatectomy (LEAPS)**

A randomised control trial investigating preoperative pancreatic duct stenting is described at clinicaltrials.gov. The trial is currently inviting participants (n=80) at the Massachusetts General Hospital in Boston. The trial consists of two study arms, (1) preoperative pancreatic duct stenting prior to distal pancreatectomy or (2) no preoperative pancreatic duct stenting prior to distal pancreatectomy. The primary endpoint is examining pancreatic leak, with peritoneal fluid analysis, serum biochemical analysis and clinical outcomes as secondary endpoints. The study was expected to be completed in April 2010.

**Other issues**

Several issues were identified with prophylactic endoscopic pancreatic stenting, including the suggestion that patients with intraductal papillary mucinous tumour do not tolerate stenting well. Abe et al. suggests the large amounts of mucin associated with this tumour may result in the stagnation of pancreatic juice in the stent resulting in pancreatitis.  

An editorial discussing Reider et al. article identified four aspects which limit the study:

- The pancreatic texture was not assessed preoperatively, which is a risk factor known associated with POPF.
- The operation duration was significantly shorter in the intervention group compared to the control group. Long operation times are a risk factor associated with POPF. The decreased POPF seen in the intervention group may be due to the surgeons increased experience.
- The definition used to diagnose the presence of POPF is the subject of criticism. Dumonceau et al. notes if they used an alternative definition the difference between the intervention and the control group may not have been as significant.
• The overall morbidity was similar between the intervention and the control group.

A case study of five patients undergoing preoperative endoscopic transpapillary stenting followed by pancreatic head resection was examined in Japan. Stenting was successful in all five patients, none of whom developed grade C fistulas. If the stent is not correctly placed, endoscopic manipulation may increase the risk of pancreatitis.

**Summary of findings**

Pancreatic fistula is a common postoperative complication following distal pancreatectomy with no effective strategies preventing its development. The current Technology Brief, utilised one RCT, a nonrandomised controlled trial and a case series to assess whether prophylactic endoscopic pancreatic stenting would prevent the occurrence of postoperative pancreatic fistulas. In addition to the small number of studies available, there are several limitations to the studies included for assessment. For example, the International Study Groups definition of POPF was released after Abe et al completed their study. As a result, the definition of POPF used by Abe et al differs from those used in Reider et al and Frozanpor et al. Furthermore, all three studies inserted and removed the stents at different time points. It is presently unknown whether this would affect the development of postoperative pancreatic fistulas. It has been suggested that prolonged pancreatic stenting may induce changes to the pancreatic duct which mimic those seen in chronic pancreatitis. Finally, an important risk factor for the development of pancreatic fistulas, the texture of the pancreas, was not reported in any of the studies.

In the included studies, rates of post-operative pancreatic fistulas ranged from 0 to 50 per cent in stented patients, compared to rates ranging from 22 to 37 per cent in control patients. However, the highest quality study, the RCT by Frozanpor et al, reported no significant difference in the rate of POPF between patients who underwent stenting and controls, despite a trend towards a higher rate in the intervention group. While the analysed literature suggests the endoscopic placement of the pancreatic stent is fairly well tolerated among patients, from the three studies described, 15 of the 58 patients who underwent prophylactic pancreatic stenting developed major complications - intra-abdominal bleeding, pneumonia, acute coronary syndrome and entercutaneous fistula. By contrast, only eight patients from the control group reported major complications. In addition, discordant findings in terms of operating time were reported by the RCT (an increase) and the nonrandomised controlled trial (a decrease).

**HealthPACT assessment**

There is conjecture in the literature whether prophylactic endoscopic pancreatic stenting reduces the development of post-operative pancreatic fistula. The nonrandomised control trial favours the use of pancreatic stenting however the RCT demonstrates a higher albeit
non-significant trend to developing more major complications and pancreatic fistulas following distal pancreatectomy. At present, the small body of evidence cannot be used to make an informed decision regarding the use of prophylactic endoscopic pancreatic stenting.

It is recommended that this technology be archived. However, the HealthPACT secretariat will monitor the progress of the ongoing RCT and report on its results when they become available in the peer-reviewed literature.

**Number of studies included**

All evidence included for assessment in this Technology Brief has been assessed according to the revised NHMRC levels of evidence. A document summarising these levels may be accessed via the HealthPACT web site.

<table>
<thead>
<tr>
<th>Total number of studies</th>
<th>3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of Level II studies</td>
<td>1</td>
</tr>
<tr>
<td>Total number of Level III studies</td>
<td>1</td>
</tr>
<tr>
<td>Total number of Level IV studies</td>
<td>1</td>
</tr>
</tbody>
</table>

**References**


8. Goh BK, Tan YM, Chung YF, Cheow PC, Ong HS, Chan WH, et al. Critical appraisal of 232 consecutive distal pancreatectomies with emphasis on risk factors, outcome,


18. Tammita A. Cook pancreatic stents. ASERNIP-S. 2013 Apr 12 ['cited' 2013 Apr 12]


Search criteria to be used (MeSH terms)

MeSH: Pancreatectomy AND Stents

Text: distal pancreatectomy, pancreatectomy, pancreatic resection, stent and stents