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Australia and New Zealand Horizon Scanning Network

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TERRITORY GOVERNMENTS OF AUSTRALIA
AND THE GOVERNMENT OF NEW ZEALAND

Horizon scanning technology prioritising summary

Single incision laparoscopic surgery (SILS) for appendectomy and nephrectomy

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**Australian
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Enquiries about the content of the report should be directed to:

HealthPACT Secretariat
Department of Health and Ageing
MDP 106
GPO Box 9848
Canberra ACT 2606
AUSTRALIA

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

PRIORITISING SUMMARY

REGISTER ID S000111

NAME OF TECHNOLOGY SINGLE INCISION LAPAROSCOPIC SURGERY (SILS)
FOR APPENDECTOMY AND NEPHRECTOMY

PURPOSE AND TARGET GROUP TREATMENT OF PATIENTS WITH ACUTE
APPENDICITIS OR PATIENTS UNDERGOING
NEPHRECTOMY DUE TO BENIGN OR MALIGNANT
KIDNEY DISEASE OR AS LIVE DONORS FOR RENAL
TRANSPLANTATION

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|---|--|
| <input checked="" type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input type="checkbox"/> Experimental | <input type="checkbox"/> Established <i>but</i> changed indication
or modification of technique |
| <input type="checkbox"/> Investigational | <input type="checkbox"/> Should be taken out of use |
| <input type="checkbox"/> Nearly established | |

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- Yes
- No
- Not applicable

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	Limited Use	Widely Diffused
United Kingdom	✓		
United States	✓		
South Korea	✓		
India	✓		

IMPACT SUMMARY

Single incision laparoscopic surgery (SILS) is a new technique where laparoscopic surgery takes place through a single umbilical incision, without the need for additional laparoscopic ports. This new method has been used for a variety of procedures including appendectomy and nephrectomy. Several manufacturers provide devices that can be used in SILS appendectomy and nephrectomy. This technology includes the SILS™ Port (Covidien, Mansfield, MA, USA), the TriPort Laparoscopic Access Device

(Advanced Surgical Concepts, Bray, County Wicklow, Ireland), the R-Port Laparoscopic Access Device (Advanced Surgical Concepts, Bray, County Wicklow, Ireland), the Uni-X™ Single Port Laparoscopic System (Pnavel Systems, Brooklyn, NY, USA) and the GelPort Single Incision Access System (Applied Medical Resources Corporation, Rancho Santa Margarita, CA, USA).

BACKGROUND

The increased interest in minimally invasive surgical approaches has been driven largely by the need to reduce patient morbidity following surgery, and thus increase postoperative recovery rates and shorten the length of stay in hospital.

Of particular concern is the morbidity associated with surgical wounds, as each incision carries the potential risk of complications such as hernia, internal organ damage, pain, bleeding and poor cosmesis (Lowry et al 2003; Marcovici 2001). The issue of cosmesis in particular is becoming an increasingly important factor in surgical procedures involving paediatric, as well as adult patients (Dunker et al 1998). The development of laparoscopic surgical techniques, which are now routinely used for the treatment of a wide variety of elective and acute surgical conditions, has led to a considerable reduction in postoperative pain and length of hospital stay, as well as a faster recuperation and return to normal function, compared with open surgical approaches (Lowry et al 2003). However, laparoscopic surgical techniques still necessitate a number of incisions of at least 1 to 2 cm in length to be made.

In recent years, surgeons have developed a minimally invasive approach to surgery known as natural orifice transluminal endoscopic surgery (NOTES). It has been suggested that this approach, where access to the peritoneal cavity is gained through the mouth, anus, vagina or urethra, may reduce many of the complications associated with conventional surgical approaches, including hernias, wound infections and postoperative abdominal wall pain (Wagh and Thompson, 2007), as well as promote better cosmesis with the promise of potentially “scarless” surgery. However, despite these potential benefits, there may still be significant risks associated with NOTES as it requires puncture of the intraabdominal viscus (Chow et al 2009).

More recently, another minimally invasive surgical approach known as single-incision laparoscopic surgery (SILS) has emerged. SILS is also known as single port access (SPA) surgery, laparoendoscopic single-site surgery (LESS), one port umbilical surgery (OPUS), single port incisionless conventional equipment-utilising surgery (SPICES), natural orifice transumbilical surgery (NOTUS) or embryonic natural orifice transumbilical surgery (E-NOTES). In this technique, the peritoneal cavity is accessed through a single transumbilical incision, following which the surgeon is able to perform the operation in the same way as a standard laparoscopic procedure (Chow et al 2009). As the only incision is through the umbilicus, a number of potential advantages of SILS compared with conventional laparoscopic surgical techniques have been identified, including:

- Better cosmesis (no visible scars)
- Less postoperative pain and decreased need for analgesics
- Faster recovery from surgery

- Faster return to normal activities
- Reduced wound-related complications (1 incision rather than 4 incisions)

SILS has been used in humans to perform a wide variety of surgical procedures, including cholecystectomy, hysterectomy, oophorectomy, tubal ligation, splenectomy, sleeve gastrectomy, colectomy, gastric bypass surgery, Nissen fundoplication, hernia repair and liver resection. The purpose of this summary is to establish the feasibility, safety and efficacy of SILS for patients undergoing (1) appendectomy for acute appendicitis and (2) nephrectomy due to benign or malignant kidney disease or as live donors for renal transplantation.

CLINICAL NEED AND BURDEN OF DISEASE

Appendectomy

Acute appendicitis is among the most common causes of surgical abdominal disease worldwide (Davies et al 2004). In 1997, appendicitis-related hospitalisations accounted for 0.6% of all hospitalisations in the United States, resulting in approximately one million hospital days and US\$3 billion in hospital charges (Davies et al 2004). In Australia, there were 17,477 hospital separations for acute appendicitis in 2006-2007; 14,756 of these were in public hospitals (AIHW, 2008). The average length of stay in hospital for patients suffering from acute appendicitis was 3.4 days (AIHW, 2008). Based on Medicare Benefits Schedule (MBS) data on services performed by a registered provider (not including services provided to public patients in a public hospital), laparoscopic procedures were performed more commonly than open procedures, with 5,102 claims for laparoscopic appendectomy (Item number 30572) and 1,604 claims for open appendectomy (Item numbers 30571 and 30574) between 2008 and 2009 (Medicare Australia, 2010).

Nephrectomy

Nephrectomy is indicated for both malignant (renal cell carcinoma) and benign kidney disease, and live donor renal transplantation. Chronic kidney disease is a significant contributor of morbidity and mortality in the Australian population, particularly among Indigenous Australians (AIHW, 2009). One in seven Australian adults over the age of 25 years had some degree of chronic kidney disease in 1999-2000, while chronic kidney disease contributed to approximately 10% of all deaths in 2006 and over 1.1 million hospitalisations in 2006-2007 (AIHW, 2009). In addition, the rate of people with a kidney transplant rose by 34% between 2000 and 2007 (AIHW, 2009). Based on MBS data on services performed by a registered provider, there were 1,515 claims for nephrectomy procedures (Item numbers 36516, 36519, 36522, 36525, 36526, 36527, 36528) between 2008 and 2009 (Medicare Australia, 2010); however it is unclear from this data how many of these procedures were performed using the laparoscopic approach and how many were open procedures. Data from the Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database (2007-2008) indicated that laparoscopic nephrectomy procedures were performed less frequently than open procedures (AIHW, 2010).

DIFFUSION

Several single-port access systems have been developed for use during SILS procedures, including appendectomy and nephrectomy. Some of these devices have received US Food and Drug Administration (FDA) approval. FDA 510(k) clearance has been granted for the SILS™ Port (November 2008), the TriPort Laparoscopic Access Device (January 2008), the R-Port Laparoscopic Access Device (August 2007) and the GelPort Single Incision Access System (February 2009) (US FDA, 2010). The Uni-X™ Single Port Laparoscopic System has yet to be approved by the FDA. In Australia, none of these devices are currently listed on the Australian Register of Therapeutic Goods (ARTG) (TGA, 2010), and there is no evidence that SILS appendectomy and nephrectomy have been widely adopted within the healthcare system.

Studies using SILS appendectomy and nephrectomy have been performed in several countries including the United Kingdom, United States, South Korea and India. Further trials are currently underway, including randomised controlled trials in the United States, Hong Kong, and South Korea comparing SILS appendectomy with conventional laparoscopic appendectomy (ClinicalTrials.gov identifiers NCT00997516, NCT00981136, NCT01024439, NCT01007318) and single arm trials in the United States and Canada examining SILS appendectomy (ClinicalTrials.gov identifiers NCT00616616, NCT00925145) (ClinicalTrials.gov, 2010).

COMPARATORS

Appendectomy

The comparator procedures for SILS appendectomy are:

- Conventional laparoscopic appendectomy
- Open appendectomy

Nephrectomy

The comparator procedures for SILS nephrectomy are:

- Conventional laparoscopic nephrectomy
- Open nephrectomy

SAFETY AND EFFECTIVENESS ISSUES

Study description

Appendectomy

Two case series studies describing SILS appendectomy for the treatment of patients with acute appendicitis were included in this summary.

A case series study by Hong et al (2009) described the use of transumbilical single-port laparoscopic appendectomy (TUSPLA) for patients with presumed appendicitis. TUSPLA was undertaken in 33 patients (11 males and 22 females). The average age and body mass index (BMI) of patients was 31.2 years (range, 14 to 73 years) and 22.8

kg/m² (range, 16.8 to 35.8 kg/m²), respectively. Pathologic examinations demonstrated acute appendicitis in 23 of the 33 patients (69.6%), gangrenous appendicitis in 3 patients (9.0%), and perforated appendicitis with a local abscess in 4 patients (12.1%). Three of the 33 patients (9.0%) had a normal appendix, with the diagnosis of mesenteric lymphadenitis.

Chow et al (2009) reported on the use of SILS for appendectomy and cholecystectomy, however only data relating to appendectomy is reported here. SILS appendectomy was performed in a total of 12 patients (7 male and 5 female) with a diagnosis of acute appendicitis, between May and December 2008. The average age of patients was 28.7 years (range, 12 to 42 years). None of the patients had undergone previous abdominal surgery. All procedures were carried out by the same surgeon and data were prospectively collected, and retrospectively re-reviewed from patient notes as well as an operating theatre electronic database. Patient follow-up took place six to eight weeks after surgery in the outpatient department.

Nephrectomy

Two studies, one case-control study and one case series study, describing SILS nephrectomy for the treatment of patients with benign or malignant kidney disease, or for patients acting as live donors for renal transplantation, were included in this summary.

A retrospective case-control study by Raman et al (2009) compared a single surgeon's experience with SILS nephrectomy and conventional laparoscopic nephrectomy. A total of 11 patients (2 males and 9 females) underwent SILS nephrectomy between August 2007 and March 2008, while 22 patients (13 males and 9 females) underwent conventional laparoscopic nephrectomy between September 2004 and August 2007. The mean patient age for both groups was 53 years (range, 19 to 83 years). All conventional laparoscopic nephrectomy patients were specifically matched in a 2:1 ratio to SILS nephrectomy patients with respect to age, surgical indication (benign vs malignant), and tumour size. In 15 of the 33 patients in this study, nephrectomy was conducted for non-functional kidneys where pathology was consistent with chronic pyelonephritis and interstitial fibrosis without evidence of malignancy. The remaining 18 patients underwent radical nephrectomy for enhancing renal masses with a median tumour size of 5.5 cm (range, 3 to 7 cm).

Ganpule et al (2009) reported on the use of laparoendoscopic single-site (LESS) donor nephrectomy for renal transplantation. A total of 13 patients (5 males and 8 females) underwent LESS donor nephrectomy between August 2008 and January 2009. All procedures were performed by a team of experts experienced in conventional laparoscopic donor nephrectomy. The average age and BMI of patients was 46.61 years (range, 35 to 58 years) and 22.18 kg/m² (range, 17.9 to 29.78 kg/m²), respectively.

Safety

Appendectomy

The case series by Hong et al (2009) reported that no intraoperative complications were observed; however, postoperative complications were observed in three of the 33 patients (9.6%). This included two cases of localised pericecal abscess and one case of omphalitis. All complications were successfully treated with conservative measures.

Chow et al (2009) reported that no intraoperative or early postoperative complications were observed in any of the 12 patients, including no postoperative wound complications. One of the 12 patients was readmitted to hospital with abdominal pain one week after discharge. However no evidence of haematoma or pelvic collection was observed following CT scan and ultrasound, and the symptoms resolved spontaneously. No postoperative complications such as port-site herniation were observed at six to eight weeks follow-up.

Nephrectomy

In the study by Raman et al (2009) the rate of both major and minor perioperative complications, defined as those occurring within the first month of the procedure, was not significantly different for SILS nephrectomy compared with conventional laparoscopic nephrectomy (0% for both).

Ganpule et al (2009) reported that two renal units had upper pole abrasion, which did not require any intervention.

Efficacy

Appendectomy

Hong et al (2009) reported that TUSPLA was successfully completed in 31 of the 33 patients (93.9%). The procedure was converted to the conventional three-port laparoscopic appendectomy in two of the 33 patients (6.0%). In one patient this was due to a gangrenous change at the base of the appendix, which was dealt with by applying an intracorporeal suture after appendix removal. In the other patient, this was due to perforated appendicitis containing a local abscess, which left a shaggy, granulating cavity after appendix removal, and was addressed by inserting a closed-suction drain. None of the procedures were converted to open surgery. The mean operative time and postoperative hospital stay were 40.8 minutes (range, 15 to 90 minutes) and 2.5 days (range, 1 to 11 days), respectively.

The study by Chow et al (2009) reported that the procedure was successful in all 12 patients. The mean operative time and postoperative length of stay and were 61.3 minutes (range, 24 to 86 minutes) and 1.1 days (range, 1 to 2 days), respectively.

Nephrectomy

Raman et al (2009) reported no significant differences in median operative time (122 minutes vs 125 minutes, $P=0.78$), analgesic use (8 morphine equivalents vs 15 morphine equivalents, $P=0.69$), and length of stay (49 hours vs 53 hours, $P=0.44$) between SILS and conventional laparoscopy patients. However, the median estimated blood loss was significantly lower in SILS patients compared with conventional

laparoscopy patients (20 ml vs 100 ml, $P=0.001$), although no patient from either group required a blood transfusion. No significant differences were observed in the absolute decrease (1.8 mg/dl vs 2.3 mg/dl, $P=0.20$) or percent decrease (14.1% vs 15.8%, $P=0.52$) from preoperative haemoglobin to postoperative day 1 measurements, in SILS patients compared with conventional laparoscopy patients. In addition, no patients in either group demonstrated a delay in initiating oral intake or a regular diet.

In the case series by Ganpule et al (2009), nephrectomy was successfully completed in all 13 patients, each of whom demonstrated prompt urine output following the procedure. The mean operative time, estimated blood loss, warm ischemia time, and hospital stay were 176.9 ± 42.47 minutes (range, 90 to 240 minutes), 158 ± 78 mL (range, 50 to 300 mL), 6.79 ± 1.7 minutes (range, 4 to 10 minutes), and 3 ± 0.45 days (range, 2 to 5 days), respectively. Graft artery, vein, and ureteral length was 3.8 ± 0.4 cm (range, 3 to 4.3 cm), 4 ± 0.12 cm (range, 3.8 to 4.2 cm), and 14.54 ± 0.82 cm (range, 13 to 16 cm), respectively. The mean haemoglobin drop was 1.8 g %, while the recipient nadir serum creatinine was 1.14 ± 0.23 mg % (range, 0.9 to 1.5 mg %) three days after surgery. The average visual analogue pain score (VAS) for patients was 2/10 on discharge and 0/10 two weeks after surgery, while cosmesis was rated as excellent, with an average incision length of 5.23 ± 0.96 cm (range, 4 to 7 cm).

COST IMPACT

There are no cost-effectiveness studies on the use of single incision laparoscopic surgery (SILS) for appendectomy or nephrectomy and none of the four studies included in this summary discussed cost issues. As SILS procedures require the use of specialised equipment, including single-port access systems and articulated surgical instruments, it is likely that these procedures will be more costly than conventional laparoscopic procedures. However, these additional costs may be offset by the potential reduced length of hospital stay following SILS procedures compared with conventional laparoscopic procedures. Attempts to retrieve cost information on single-port access systems from the manufacturers were unsuccessful.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

Studies have acknowledged that there are a number of technical issues that will need to be addressed before SILS can be used routinely in clinical practice. The use of crossed-over instruments has been identified as one of the major drawbacks of SILS procedures, as this requires the surgeon to “reprogram” his hand-eye coordination because his right hand will be moving the left-sided instrument and the left hand the right-sided instrument on screen (Chow et al 2009). In addition, the normal triangulation of instrumentation that is allowed with conventional laparoscopic procedures is not possible with the SILS approach, and this may change the view and the depth of perception and thus hinder the progress of the operation (Chow et al 2009). The clashing of instruments is another difficulty associated with the SILS approach, as all instruments pass through the same incision. However, the development of more

streamlined instruments designed specifically for SILS may help overcome many of these technical challenges in the future. Given the challenges associated with this approach, it is important that surgeons performing SILS procedures have significant experience with conventional laparoscopic surgery, as well as access to an experienced and appropriately trained surgical team for assistance (Ganpule et al 2009).

SUMMARY OF FINDINGS

There is a lack of high quality evidence on SILS for appendectomy and nephrectomy, with the majority of the available studies limited to case series. Three of the four studies included in this summary reported that no intraoperative or postoperative complications were observed following SILS appendectomy or nephrectomy. One study reported a postoperative complication rate of 9.6% following SILS appendectomy, however all complications were treated successfully with conservative management. Importantly, one study which compared SILS nephrectomy with conventional laparoscopic nephrectomy reported no difference in the rate of major or minor perioperative complications between the two procedures. The success rate of SILS procedures ranged from 94% to 100% in the three studies which reported this outcome. One study reported that VAS pain scores were low at discharge and two weeks after SILS nephrectomy, while another study reported no significant difference in analgesic use following SILS nephrectomy compared with conventional laparoscopic nephrectomy. Similarly, operating time and length of hospital stay were not significantly different following SILS nephrectomy compared with conventional laparoscopic nephrectomy, however estimated blood loss during SILS was significantly lower. Cosmesis following SILS was only reported in one study, where it was rated as excellent.

In summary, based on the findings of three case series studies and one case control study, it appears that SILS is a feasible, safe and effective approach for patients undergoing appendectomy and nephrectomy. However, further prospective randomised controlled trials are required in order to substantiate the benefits of the SILS technique beyond cosmesis.

HEALTHPACT ASSESSMENT

The available evidence on SILS continues to grow substantially, however most of these are limited to small case series studies or case reports. Although patient outcomes were generally positive, larger comparative studies are necessary to determine the learning curve, technical issues (crossed-over instruments, clashing etc) and long-term cost effectiveness. Due to the limited evidence available to date, SILS will be noted but no further assessment by HealthPACT is necessary at this time.

NUMBER OF STUDIES INCLUDED

Total number of studies	4
Level IV intervention evidence	3
Level III-2 intervention evidence	1

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SEARCH CRITERIA TO BE USED

Single incision laparoscopic surgery

SILS

Nephrectomy

Appendectomy

Appendicectomy