Australian Government

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Australia and New Zealand Horizon Scanning Network

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Horizon scanning technology prioritising summary

Single-incision laparoscopic cholecystectomy

August 2009

ASERNIP-S

Australian Safety and Efficacy Register of New Interventional Procedures - Surgical

Royal Australasian College of Surgeons

ISBN
Publications Approval Number:

Electronic copies can be obtained from http://www.horizonscanning.gov.au

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

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PRIORITISING SUMMARY

REGISTER ID **S000097**

NAME OF TECHNOLOGY **SINGLE-INCISION LAPAROSCOPIC CHOLECYSTECTOMY**

PURPOSE AND TARGET GROUP **PATIENTS REQUIRING CHOLECYSTECTOMY**

STAGE OF DEVELOPMENT (IN AUSTRALIA)

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

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION APPROVAL

- ☐ Yes
- ☑ No
- ☐ Not applicable

INTERNATIONAL UTILISATION

COUNTRY	LEVEL OF USE		
	Trials Underway or Completed	**Limited Use**	**Widely Diffused**
China	✓		
Germany	✓		
India	✓		
Italy	✓		
South Korea	✓		
The Netherlands	✓		
Turkey	✓		
USA	✓		

IMPACT SUMMARY

Single-incision laparoscopic cholocystectomy allows the removal of the gallbladder through a single skin incision in the umbilicus. Several manufacturers provide devices that can be used in single-incision laparoscopic cholocystectomy. 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, Inc., Brooklyn, NY, USA), and the GelPort Single Incision Access System (Applied Medical Resources Corporation, Rancho Santa Margarita, CA, USA).

BACKGROUND

Bile, a liquid that aids in the digestion of fats, is made in the liver and enters into the small intestine via the common bile duct. Excess bile is stored in the gallbladder, a small muscular sack located behind the liver. Bile comprises a variety of substances including cholesterol, lecithin, calcium, bile salts and acids (Heuman et al 2006). Gallstones can form when certain substances in the bile, such as cholesterol, are present in concentrations that approach the limits of solubility (Heuman et al 2006). The excess solutes precipitate to form microcrystals, which aggregate to form gallstones (Shaffer 2007). In the Western world, the majority of gallstones contain cholesterol as their main component (Heuman et al 2006).

As gallstones are often asymptomatic, they can be present in the gallbladder for decades without causing any adverse effects (Heuman et al 2006). The symptoms of gallstones can range from biliary colic (pain due to gallstones temporarily obstructing the cystic duct of the gallbladder during a contraction) to acute cholecystitis (inflammation and infection of the gall bladder due to persistent stone impaction in the cystic duct). Chronic gallstones may cause progressive scarring of the gallbladder wall and loss of gallbladder function (chronic cholecystitis) (Heuman et al 2006).

Cholecystectomy, the surgical removal of the gallbladder, is the main treatment for symptomatic cholelithiasis (gallstones). When surgery is not immediately feasible, small stones may be dissolved through ingestion of bile acid (ursodeoxycholic acid). For critically ill patients, drainage of pus from the gallbladder (cholecystostomy) may be used to stabilise the patient before cholecystectomy is performed (Heuman et al 2006). Asymptomatic gallstones are managed expectantly (Heuman et al 2006; Shaffer 2007).

Surgical treatment was initially conducted via open cholecystectomy, which was developed in the 1880s and typically involved a 10 to 18 cm incision (Keus et al 2009). However, since the 1970s small-incision cholecystectomy has been used where the incision is typically less than 8 cm (Keus et al 2009). The first laparoscopic cholecystectomy was performed in 1985. It is now the standard procedure for gallbladder removal and the most commonly performed laparoscopic surgical procedure in the world (Chamberlain & Sakpal 2009). Conventional laparoscopic (keyhole) surgery typically uses three or four small incisions to allow the insertion of operating ports through which a camera and instruments are fed (Keus et al 2009).

Several new techniques have been developed to further minimize the number and size of the incisions used during cholecystectomy, reduce postoperative pain and recovery time, and improve cosmetic outcomes (Chamberlain & Sakpal 2009). One such technique is

natural orifice transluminal endoscopic surgery (NOTES), which eliminates skin incisions by using natural body openings. The NOTES technique has been used to perform a cholecystectomy via a transvaginal approach, but the drawbacks included difficulties with access, orientation and closure, a lack of appropriate instrumentation, and the risk of infection (Ersin et al 2009).

Another recently developed technique is single-incision laparoscopic cholecystectomy, where the gallbladder is removed through the belly button (umbilicus) using a laparoscopic camera and instruments. This technique aims to provide the benefits of NOTES, such as fewer incisions and less visible scarring, without requiring additional specialist training beyond that required for standard laparoscopic cholecystectomy (Hodgett et al 2009).

The first attempts at single-incision laparoscopic cholecystectomy were performed by Navarra et al (1997) and Piskun & Rajpal (1999). A single incision was made through the umbilicus and two trocars or ports were inserted through the opening with a bridge of fascia (soft connective tissue) between them (Navarra et al 1997; Piskun & Rajpal 1999). Subsequent studies using single umbilical skin incision laparoscopic cholocystectomy have altered the technique, with some using multiple fascial punctures to insert multiple ports in the same incision and others using single-port access systems that allow multiple instruments to be inserted through the same port without clashing. An alternative technique of transumbilical endoscopic cholcystectomy has also been reported which uses a second abdominal skin incision for inserting an instrument to grasp the gallbladder, but this is not strictly a single-incision technique (Zhu et al 2009).

CLINICAL NEED AND BURDEN OF DISEASE

Gallstones are a major cause of morbidity in Western countries. In the USA, the estimated incidence of symptomatic cholelithiasis is 2.2 per 1000 individuals, with more than 500,000 cholecystectomies being performed each year (Keus et al 2009). In Australia, cholecystectomy is one of the most common hospital procedures, with 47,331 hospital separations for cholecystectomy occurring in 2006–2007; 52% of these were public hospital patients (AIHW 2008). Based on Medicare Benefits Schedule claims for services that are performed by a registered provider, but not including services provided by hospital doctors to public patients in public hospitals, laparoscopic procedures were performed more commonly than open procedures, with 19207 claims for laparoscopic cholecystectomy (item number 30445) and 1026 claims for open cholecystectomy (item number 1026) between 2007 and 2008 (Medicare Australia 2009). The average length of hospital stay for public or private hospital patients undergoing laparoscopic cholecystectomy (without closed common duct exploration or catastrophic or severe complications or comorbidities) was 1.8 days (AIHW 2008).

DIFFUSION

Several single-port access systems have been developed to for use during single-incision laparoscopic cholocystectomy, some of which have 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 2009). The Uni-X Single Port Laparoscopic System has yet to be approved by the FDA (US FDA 2009). None of these devices are listed on the Australian Register of Therapeutic Goods (TGA 2009).

Studies using single-incision laparoscopic cholocystectomy have been performed in several countries, including China, Germany, India, Italy, South Korea, The Netherlands, Turkey, and the USA. Further trials are currently underway, including several randomized controlled trials in the USA, Greece and Switzerland that are comparing single-incision laparoscopic cholecystectomy with conventional four-port laparoscopic cholecystectomy (ClinicalTrials.gov identifiers NCT00832767, NCT00892879, NCT00872287, NCT00904865) (Clinical Trials 2009).

COMPARATORS

For symptomatic gallstones, where surgery is feasible, the comparative procedures for single-incision laparoscopic cholecystectomy are:

- open cholecystectomy (now reserved for special situations only);
- small-incision open cholecystectomy;
- conventional laparoscopic cholecystectomy;
- NOTES.

A recent systematic review evaluated studies on open, small-incision and laparoscopic cholecystectomy in patients with symptomatic cholelithiasis and found no significant differences in mortality or complications between the three techniques. Patients undergoing either small-incision or laparoscopic cholecystectomy had a shorter convalescence than those undergoing the open technique, but there were no clear differences between small-incision and laparoscopic cholecystectomy in terms of patient outcomes (Keus et al 2009).

SAFETY AND EFFECTIVENESS ISSUES

Study description

One non-randomised prospective comparative study was identified on single-incision laparoscopic cholecystectomy (Hodgett et al 2009), which compared this technique with conventional multi-port, multi-incision laparoscopic cholecystectomy. Fifteen case-series were also identified, as well as several case reports. The most recent case-series (published in the last two years), with the largest patient cohorts ($n \geq 20$), were included (Ersin et al 2009; Merchant et al 2009; Rao et al 2008).

Hodgett et al (2009) performed single-incision laparoscopic cholecystectomy on 29 consecutive patients between 2007 and 2008 in a procedure they termed laparoendoscopic single site cholecystectomy (LESS). This procedure used two ports inserted in the same incision. There were 6 males and 23 females, with a median age of 51 years (mean 50 years, standard deviation [SD] 16.2). The gallbladder pathology was

chronic cholecystitis in 76% of the patients. The concurrent comparative group consisted of 28 patients who underwent conventional multi-incision laparoscopic cholecystectomy. There were 9 males and 19 females, with a median age of 46 years (mean 48 years, SD 16.7). Seventy-two percent of patients in this group had chronic cholecystitis. The same surgeon performed all operations for both groups. There were no significant differences between the groups in terms of age, sex, body mass index, or gallbladder pathology. Length of follow-up was not reported (Hodgett et al 2009).

In the prospective case-series by Ersin et al (2009), single-incision laparoscopic surgery (which they termed SILS) was performed using three trocars in the same incision. Between 2008 and 2009, SILS was used on 20 patients (2 males, 18 females) with a mean age of 44.9 years (range 18 – 82 years). All patients had a previous diagnosis of symptomatic gallstones but with no acute attacks of inflammation. Patients were followed-up 7 days' postoperatively. In the case-series by Merchant et al (2009), the technique performed was also termed SILS; however, in this study the GelPort device was used to establish single-port access. This study reported results for 21 cholecystectomy patients, although patient details were not reported. The longest follow-up was 6 months. Another prospective case-series by Rao et al (2008) used the R-port device to perform single-incision, single-port laparoscopic cholecystectomy in 2007 on 20 patients (4 males. 16 females) with symptomatic cholelithiasis who were aged between 23 and 67 years. Length of follow-up was not reported.

Efficacy

In the non-randomised comparative study by Hodgett et al (2009), two patients undergoing LESS cholecystectomy required placement of additional trocars away from the umbilicus to facilitate exposure, but were still considered to have undergone the LESS procedure for the purpose of comparison. None of the patients required conversion to an open operation. The median operative time was 72 minutes (mean 74 minutes, SD 17.3) for the LESS cholecystectomy patients, and 66 minutes (mean 71 minutes, SD 16.3) for the conventional laparoscopic cholecystectomy patients (P=0.46). All patients in both groups had less than 100 cc of estimated blood loss. The median length of hospital stay was 1 day (mean 1±SD0.61 days) for the LESS cholecystectomy patients, and 1 day (mean 1±SD0.51 days) for the conventional cholecystectomy patients (P=0.81) (Hodgett et al 2009).

In the case-series by Ersin et al (2009), 19 of 20 patients successfully underwent the SILS procedure; the remaining patient required conversion to the conventional laparoscopic technique due to a failure in trocar insertion. The mean operative time for the SILS procedure was 94 minutes. All patients were discharged the day after the procedure. The authors reported that there were no patient complaints about the operation at 7 days' follow up (Ersin et al 2009).

Merchant et al (2009) reported that the operative time for the 21 SILS cholecystectomy patients ranged from 45 to 90 minutes. Two procedures were performed for acute cholecystitis, with one of these patients requiring an additional port for dissection. All

patients were discharged on the same day of surgery with minimal narcotic requirements (Merchant et al 2009).

Rao et al (2008) successfully performed single-port laparoscopic cholecystectomy procedure on 17 of 20 patients. In ten of these patients no additional ports or instrumentation were needed, while in seven a port closure needle was required to retract the fundus (bottom) of the gallbladder. The remaining three patients required a second port; for two patients this port was used to perform an additional procedure of common bile duct stone removal, while the third patient required conversion to two-port cholecystectomy during the procedure. There were no conversions to three-port, four-port or open surgery. The mean operative time was 40 minutes (range 19 to 100 minutes). Blood loss ranged from 50 to 100 cm^3. The patients required 50 mg of diclofenac three times a day for 48 to 72 hours after the procedure. All cholecystectomy patients were discharged on the same day. It was reported that the scars receded into the umbilicus and were hardly visible (Rao et al 2008).

Safety

Hodgett et al (2009) reported that no biliary injuries or major postoperative complications occurred in any patients. Two patients in the LESS group required extended post-operative stays for pain control, and one patient in the LESS group required catheter insertion for urinary retention. There were no reported complications in the conventional multi-incision laparoscopic cholecystectomy group (Hodgett et al 2009).

Ersin et al (2009) reported that there were no complications involving the intraumbilical incision and that the postoperative course of all patients up to 7 days' follow up was uneventful. Merchant et al (2009) reported that the main complaint from patients was pain from the umbilical wound site. However, there were no wound complications such as surgical site infections or hernias (Merchant et al 2009). There were no wound infections and no deaths in the case-series by Rao et al (2008).

COST IMPACT

No cost effectiveness studies are currently available on single-incision laparoscopic cholecystectomy. The comparative study by Hodgett et al (2009) suggested that this procedure may not incur the cost of increased operative time and can be performed with existing equipment. However, if one of the available disposable devices (e.g. R-Port) is utilised to assist with single-incision laparoscopic cholecystectomy, it is reasonable to expect some increase in total cost. Nevertheless, one manufacturer has claimed that the use of these devices reduces surgeon fatigue by eliminating the need for surgeons to work through separately spaced long, narrow channels (Advanced Surgical Concepts 2007). 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

No issues were identified from the retrieved material.

SUMMARY OF FINDINGS

The sole comparative study found single-incision laparoscopic cholecystectomy to be as effective as conventional laparoscopic cholecystectomy, with comparable results for operative time, blood loss, and length of hospital stay. There were several minor complications reported in the single-incision group only, but no major complications in either group. The included case-series reported few conversions to alternative techniques, short hospital stays, and no major complications. It is unclear from the limited evidence whether the single-port access systems provides any substantial clinical benefits over the multiple port method of performing single-incision laparoscopic cholocystectomy.

HEALTHPACT ACTION

There is insufficient comparative evidence currently available to establish any substantial clinical benefits of single-incision laparoscopic cholocystectomy over the conventional laparoscopic technique. However, given the fact that a number of new randomised studies are currently being conducted on single-incision laparoscopic cholecystectomy, this technique will be monitored for further developments and reassessed in 12 months.

NUMBER OF STUDIES INCLUDED

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

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

Cholecystectomy AND ((Single incision laparoscopic) OR (Single-incision laparoscopic) OR SILS OR (Transumbilical endoscopic surgery) OR TUES OR (Laparoendoscopic single site surgery) OR (Laparoendoscopic single-site surgery) OR (Natural orifice transumbilical surgery) OR NOTUS OR (Single laparoscopic incision transabdominal surgery) OR SLIT)