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Department of Health and Ageing



Australia and New Zealand Horizon Scanning Network

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Horizon Scanning Technology Prioritising Summary

SpyGlass® Direct Visualization System



September 2010

**Australian
Safety
and Efficacy
Register
of New
Interventional
Procedures -
Surgical**

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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 and Ms Deanne Leopardi from the Australian Safety and Efficacy Register of New Interventional Procedures – Surgical (ASERNIP-S).

PRIORITISING SUMMARY

REGISTER ID S000119

NAME OF TECHNOLOGY SPYGLASS® DIRECT VISUALIZATION SYSTEM

PURPOSE AND TARGET GROUP SPYGLASS® PROVIDES DIRECT VISUALISATION FOR DIAGNOSTIC AND THERAPEUTIC APPLICATIONS DURING ENDOSCOPIC PROCEDURES IN PATIENTS WITH BILIARY AND PANCREATIC DISEASES

STAGE OF DEVELOPMENT (IN AUSTRALIA)

- | | |
|--|---|
| <input type="checkbox"/> Yet to emerge | <input type="checkbox"/> Established |
| <input checked="" 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
Japan	✓		
USA		✓	
Spain	✓		

IMPACT SUMMARY

SpyGlass® offers direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system, including the hepatic ducts, in patients with biliary and pancreatic diseases.

BACKGROUND

Until recently, direct visualisation of the pancreatobiliary system for the diagnosis and treatment of lesions in the biliary and pancreatic ducts has been limited by the technical challenges associated with developing a scope capable of allowing direct visualisation of

these ducts. A number of limitations of traditional cholangioscopy systems have been identified, including (Chathadi and Chen 2009):

- Suboptimal functionality and lack of user-friendliness. For example, there is a need for two trained operators, one physician to handle the ‘mother’ duodenoscope, and another to manoeuvre the ‘daughter’ cholangioscope.
- A limited field of view due to the fact the scope is only capable of two-way steering.
- Damage to the scope was common after just a few uses, due to thin steering cables and a fragile fiberoptic bundle which increase the susceptibility to rupture of the scope’s outer sheath, particularly at the bending section.
- Costly repairs, ranging from 35% to 50% of the original cost of the scope.
- Sharp angulations, which often prevent access into intrahepatic ducts, the cystic duct, and the pancreatic duct.

In the past, conventional endoscopic retrograde cholangiopancreatography (ERCP), an indirect radiographic imaging technique, has been used for guidance; however, this procedure can lead to an inaccurate or inconclusive clinical diagnosis, which in turn necessitates additional testing (Reavis and Melvin 2008). More recently, the SpyGlass direct visualization system (Boston Scientific, Natick, MA, USA) has been developed to provide direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in the pancreaticobiliary system. This system is a mother–daughter scope system and consists of a monitor, light source, camera, and cart; a 10 French single-use access and delivery catheter (SpyScope) with a 1.2 mm working channel; a reusable 0.77 mm-diameter fibre optic visualisation probe attached to the camera head; and disposable biopsy forceps (Reavis and Melvin 2008). The visualisation probe is inserted through the single-use access and delivery catheter via the 1.2-mm working channel, which allows for four-directional steering to access and examine all parts of the area under investigation (Paul 2006).

The SpyGlass direct visualization system has a number of advantages over traditional cholangioscopy systems. Firstly, procedures can be performed by a single operator, as the endoscopist can operate the controls of both the duodenoscope and the SpyScope with one hand, therefore eliminating the need for two operators (Judah et al 2008). In addition, this system utilises 4-way tip deflection, which enables improved access of the tertiary ducts.

Intraductal endoscopy using the SpyGlass direct visualization system can be used for a variety of diagnostic and therapeutic indications. Diagnostic indications include the detection of occult stones, evaluation of equivocal fluoroscopy findings, and characterisation and directed tissue sampling of strictures (including determination of morphologic features and extent of cholangiocarcinoma) (Chathadi and Chen 2009). Therapeutic indications include treatment of biliary stones, palliative therapy of biliary malignancies, and facilitation of selective guide wire access to the gallbladder or intrahepatic ducts (Chathadi and Chen 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). Common bile duct stones (CBDS) may occur in up to 3%-14.7% of all patients for whom cholecystectomy is performed (Shojaiefard et al 2009). Patients presenting with CBDS have symptoms including biliary colic, jaundice, cholangitis, pancreatitis or may be asymptomatic, and CBDS can be caused either by primary bile duct stones that originate in the bile duct or by secondary bile duct stones that have descended from the gallbladder (Shojaiefard et al 2009). In addition, cholecystectomy at a young age leads to common bile duct dilatation and is another acquired risk factor for CBDS. Based on AIHW National Hospital Morbidity Database data, there were 88,529 hospital separations attributed to disorders of the gallbladder, biliary tract and pancreas in 2007-2008 in Australian hospitals (AIHW 2008). 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).

DIFFUSION

The SpyGlass Direct Visualization Probe received US Food and Drug Administration (FDA) 510(K) approval on 24 August 2005 (510(K) number: K052194) (FDA 2005). The SpyGlass Direct Visualization Probe was approved by the FDA to be used through the SpyScope Access and Delivery Catheter (510(K) approval date: 16 June 2005; 510(K) number: KO51504) which provides stability for steering the device. SpyScope is inserted into the working channel of a duodenoscope for entry into the duodenum for access to the indicated site. The intended use of the SpyGlass Direct Visualization Probe is to provide direct visualisation for diagnostic and therapeutic applications during endoscopic procedures in the pancreatobiliary system including the hepatic ducts (FDA 2005).

COMPARATORS

Two procedures that enable the optical examination of the ductal systems have been identified as comparators for the SpyGlass direct visualisation system:

- Percutaneous choledochoscopy
- Laparoscopic choledochoscopy

Percutaneous choledochoscopy can be used for a number of the diagnostic and therapeutic interventions that the SpyGlass direct visualisation system is used for, including management of stones with lithotripsy and targeted biopsy (Judah et al 2008). This procedure is generally used if the SpyGlass direct visualisation system has failed or is unavailable, rather than as a first line treatment option, due to its more invasive nature.

Laparoscopic choledochoscopy has been shown to be one of the safest and most effective procedures for exploring the common bile duct, and has been frequently used during laparoscopic cholecystectomy when retained stones have been indicated on the intraoperative cholangiogram (Judah et al 2008).

SAFETY AND EFFECTIVENESS ISSUES

Two case series studies were retrieved for inclusion in this summary. One of these studies evaluated SpyGlass for its performance, feasibility and safety in the management of pancreaticobiliary disease (Fishman et al 2009) and the other evaluated the clinical utility and safety of the SpyGlass system for diagnostic and therapeutic endoscopic procedures in bile ducts specifically (Chen and Pleskow 2007).

Fishman et al (2009) conducted a multicentre retrospective analysis of 128 patients with various pancreaticobiliary disorders. Seventy-one patients were male and 57 were female, with a mean age of 57.6 years. Forty-four percent (n=56) of SpyGlass procedures were undertaken for diagnostic purposes, for indications including abnormal serum liver tests (n=15), abnormal imaging studies (n=38) and cholangiocarcinoma staging (n=3), and 56% (n=72) were for therapeutic indications including choledocholithiasis (n=41), pancreaticolithiasis (n=6) and biliary strictures (n=25). The majority of SpyGlass procedures were performed per-orally (n=121) and the remaining procedures were performed percutaneously (n=7).

The second included case series study by Chen and Pleskow (2007) was a multicentre prospective observational clinical study where 35 consecutive patients underwent (per-oral) SpyGlass evaluation. Of these patients, 13 were male and 22 female, with a mean age of 63 years (standard deviation, 16 years). Study inclusion criteria were either the need to answer biliary diagnostic questions unresolved by previous cholangiopancreatography or to perform biliary therapeutic interventions that were failed during previous cholangiopancreatography. Specific indications for SpyGlass examination included indeterminate stricture (n=22), indeterminate filling defect (n=5), stone therapy (n=5), cystic lesion (n=2) or gallbladder stent placement to treat symptomatic gallstone disease in patient with pretransplant cirrhosis (n=1). Procedural success rate was defined as the proportion of SpyGlass procedures in which the diagnostic/therapeutic objectives of the procedure was achieved. Where evaluation of indeterminate strictures or filling defects, with the intent of ruling out malignancy, was the objective success was judged by the ability to visualise the stricture and obtain adequate biopsy tissue from the target lesion. The success of stone therapy was measured by the visualisation and clearance of the stones.

Safety

Fishman et al (2009) reported that there was no morbidity or mortality associated with the use of SpyGlass SpyScope for the diagnosis of malignant/benign biliary stricture or for the treatment of stone disease.

Chen and Pleskow (2007) reported procedure-related complications in only 6% (2/35) of patients. One patient experienced ascending cholangitis, marked by jaundice without fever, white blood cell elevation and positive blood cultures, which developed 3 weeks after SpyGlass examination, during which the patient was diagnosed with intraductal papillary mucinous neoplasm. A biliary stent was not placed at the time of the original procedure which may have allowed ductal occlusion by viscous mucin, contributing to the occurrence of cholangitis. Repeat cholangiopancreatography revealed purulent

material coming from the biliary orifice and treatment consisted of placement of a plastic stent and intravenous antibiotics. This patient was hospitalised for 4 days and recovered uneventfully. The second complication (ascending cholangitis and right lobe intrahepatic abscess) occurred in another patient with pre-existing cholangitis 11 days after the SpyGlass examination. This patient was treated with CT-guided percutaneous drainage of the infected fluid, was hospitalised for 7 days and recovered without further sequelae.

Effectiveness

In the study by Fishman et al (2009), 29 patients underwent SpyGlass procedures to determine the behaviour of their bile duct strictures (for diagnostic purposes). Of these patients, 20 had their diagnosis modified postoperatively as a result of SpyGlass findings. Of the 23 patients with preoperative diagnoses of malignant strictures, only 10 were confirmed to be malignant by SpyGlass, and of the 17 patients with unknown biliary stricture diagnoses preoperatively, 9 were found to have malignant strictures and 8 were found to have benign strictures, according to SpyGlass.

Fishman et al (2009) also reported the use of SpyGlass to facilitate the treatment of biliary stone disease (for therapeutic purposes) by electrohydraulic lithotripsy (EHL) or holmium laser fragmentation of the stone, in 41 patients. Lithotripsy was successful in 37 out of 41 patients. The manoeuvrability of the SpyGlass device was superior if the guide wire was removed from the working channel. Intrahepatic peroral advancement occurred without difficulty in 80% (8/10) of cases, percutaneous advancement occurred in 100% (6/6) of cases and holmium laser usage was achievable in 100% (3/3) of cases. Poor targeting of the lesion with EHL occurred in 10% (4/41) of patients and EHL was unable to be advanced in 7% (3/41) of patients. Visualisation was considered to be good in 31 cases, fair in six cases and poor in four cases; however, the criteria on which visualisation was measured was not reported.

Overall, SpyGlass modified the preoperative diagnosis of 66% of patients, prevented unnecessary surgery in two patients with cholangiocarcinoma, changed the diagnosis of malignant to benign disease in 45% of patients with biliary stricture and provided successful therapy in 87% of patients with stone disease.

Chen and Pleskow (2007) carried out the following procedures at the time of SpyGlass examination: biopsy (n=20), stent placement (n=13), balloon dilation (n=9), stone removal (n=9), sphincterotomy (n=8), brushing cytology (n=7), EHL (n=5) or sphincterotomy extension (n=1). No additional procedures were carried out in 4 patients. The diagnostic and therapeutic objectives of the SpyGlass procedure were achieved in 32 patients; therefore, the procedural success rate of SpyGlass was 91% (95% confidence interval, 77-98%). In the three patients where objectives were not met, access to the area of interest was precluded by small intrahepatic duct size (n=2) and suboptimal visualisation of a short presphincteric stricture was apparent (n=1). Technical difficulties were encountered in 12.5% (4/32) of successful SpyGlass procedures, and included trouble advancing the SpyBite Biopsy Forceps (n=1), clearing stone fragments during EHL (n=1), orienting the forceps within the left hepatic duct (n=1), and maintaining the desired position of the SpyScope for biopsies (n=1).

The preliminary sensitivity and specificity of SpyGlass visual diagnosis were 100% (7/7) and 77% (10/13), respectively. Three false-positive visual findings occurred in patients with primary sclerosing cholangitis (PSC). The preliminary sensitivity and specificity of SpyGlass biopsy diagnosis were 71% (5/7) and 100% (13/13), respectively. One false-negative result was obtained due to difficulties maintaining the desired SpyScope position for biopsy of the prespincteric target lesion in the distal common bile duct. A second false-negative occurred in a patient with confirmed unresectable pancreatic adenocarcinoma. True-negative biopsy results were obtained in the three patients with PSC; hence the concordance between SpyGlass visual examination and SpyGlass-directed biopsy was 75% (15/20).

SpyGlass-directed EHL was successful in all of the five patients who underwent stone therapy. Complete stone clearance was achieved without the need for further intervention in two patients, and following repeat SpyGlass-directed EHL (n=2) or cholangiopancreatography (n=1). Four additional patients underwent SpyGlass-directed stone removal without EHL. Cystic dilation was successfully evaluated by SpyGlass examination in two patients and SpyGlass-directed stent placement was performed in a patient with pretransplant cirrhosis and symptomatic cholelithiasis resulting in relief from gallbladder disease symptoms.

COST IMPACT

There were no cost analysis studies identified from the retrieved material. Contact with the manufacturer of the SpyGlass system was made in regards to the current cost of the device (awaiting response).

The SpyGlass Direct Visualization System is designed to accelerate diagnostic accuracy during cholangiopancreatography. The SpyGlass System is a single-operator system developed to overcome the hurdles of traditional cholangioscopy systems and reduce the need for exploratory surgery. The proposed benefits of SpyGlass over conventional visualisation may translate into cost reductions as a result of reduced time in the operating theatre, the need for only one trained endoscopist to use the device, and the elimination of unnecessary exploratory surgeries. Further research evaluating the effects of SpyGlass on cost are required to support these assumptions.

The current equipment cost (in an Australian clinical setting) of Spyglass is likely to range from \$120,000 to \$125,000. Similarly the cost of procedural consumables is likely to be in the range of \$3,000 to \$3,500.

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

There were no issues identified from the retrieved literature.

OTHER ISSUES

Both authors of the included case series study published in 2007 (Chen and Pleskow) were reported to be consultants to the Boston Scientific Corporation (the manufacturer of

the SpyGlass system) and grant support was provided by Microvasive Endoscopy, Boston Scientific Corporation.

In addition to this, it is important to note that the SpyGlass direct Visualization system is likely to undergo design refinements to improve its capabilities in the near future, with particular emphasis on improvements in image quality (Chathadi and Chen 2009). Currently, SpyGlass produces fiberoptic images which are inferior in quality to digital images (acquired in the gastrointestinal tract with standard video endoscopes) (Chathadi and Chen 2009). At this point in time fiberoptic images are acceptable for recognising and delivering therapy to target sites within pancreatic/biliary ducts; however, in order to differentiate between benign and malignant lesions higher-quality images are required (Chathadi and Chen 2009).

SUMMARY OF FINDINGS

SpyGlass appears to be clinically feasible and safe. In general, the SpyGlass device was not associated with significant complications. As well as this, the procedural success rate of SpyGlass was reported as 91% in one of the included case series studies. Narrow ducts impeded the advancement of the SpyGlass device in a small proportion of patients and suboptimal visualisation occurred at times; these technical difficulties resulted in failed SpyGlass interventions in some patients. The most recently published included study noted that improvements in the optical quality, catheter size and manoeuvrability of SpyGlass were anticipated.

HEALTHPACT ASSESSMENT

Based on the unlikelihood of additional high-quality comparative studies reporting the use of SpyGlass being published in the near future, it is recommended that no further assessment of this technology be undertaken at this time.

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

HEALTHPACT ACTION

NUMBER OF STUDIES INCLUDED

Total number of studies	2
Level IV evidence	2

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SOURCES OF FURTHER INFORMATION

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SEARCH CRITERIA TO BE USED

SpyGlass OR SpyGlass Direct Visualization

HEALTH PACT DECISION

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

PRIORITY RATING

- High** **Medium** **Low**