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Australia and New Zealand Horizon Scanning Network

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Horizon scanning technology prioritising summary

Robot-assisted endoscopic thyroidectomy

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**Australian
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PRIORITISING SUMMARY

REGISTER ID S000103

NAME OF TECHNOLOGY ROBOT-ASSISTED ENDOSCOPIC THYROIDECTOMY

PURPOSE AND TARGET GROUP PATIENTS WITH CANCEROUS OR BENIGN THYROID DISEASE

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

- | | |
|-----------------------------------------|---------------------------------------------|
| <input checked="" type="checkbox"/> Yes | ARTG number: 97348 (Class IIb) ¹ |
| <input type="checkbox"/> No | |
| <input type="checkbox"/> Not applicable | |

INTERNATIONAL UTILISATION

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

IMPACT SUMMARY

It has been suggested that robot-assisted thyroidectomy addresses the limitations of conventional endoscopic surgery, as it allows for haptic feedback, three-dimensional optics and utilises flexible endoscopic instruments. This is expected to improve patient outcomes while simultaneously reducing operator stress due to better instrumentation and ergonomics.

¹ ARTG ID number for the Da Vinci surgical system.

BACKGROUND

Thyroidectomy is the surgical removal of all or part of the thyroid gland and is often performed to treat thyroid cancer and other conditions such as hyperthyroidism. It is a commonly performed procedure and has a low morbidity when conducted by skilled surgical teams (Manolidis et al 2001). Recent advances in surgical techniques have led to the development of various minimally invasive approaches, with the main aim of improving cosmetic outcomes. Since the use of endoscopy for neck surgery was first performed by Gagner in 1996, various endoscopic techniques have been introduced. Furthermore, there is strong patient preference for scarless neck procedures, particularly due to the fact that thyroid disease is more prevalent in women (Shimizu et al 2006, Ikeda et al 2000). Recent research has demonstrated that endoscopic thyroidectomy is as an acceptable technique for the excision of benign thyroid tumours (Kang et al 2009a). In addition, the feasibility of endoscopic thyroidectomy for the treatment of thyroid cancer has been investigated in a limited number of studies (Chung et al 2007, Lombardi et al 2007).

Despite the advantages of endoscopic surgery, there are some inherent limitations to this technique, including limited visualisation and difficulty with the precision of instruments. These limitations are the direct result of utilising two-dimensional images to guide the procedure and the rigidity of instruments commonly utilised for these procedures. The da Vinci® robotic surgical system was developed to address the limitations of endoscopic surgery and has been utilised in abdominal and thoracic surgery. The da Vinci system allows for operational manipulations through a three-dimensional magnified field of view, multi-articulated instruments and an ergonomic workspace. The use of the da Vinci system for endoscopic thyroidectomy did not occur until recently, due to the lack of a pre-existing workplace, relatively bulky robotic arms in deep/narrow operative fields and the hypervascularities of target organs which are surrounded by critical nerves and major vessels (Kang et al 2009b). Despite the relatively slow adoption of robotics within the field of otolaryngology, some researchers have suggested that the use of robot-assisted endoscopic thyroidectomy may reduce morbidity, improve postoperative recovery times and achieve better cosmetic results.

CLINICAL NEED AND BURDEN OF DISEASE

A United States study conducted in 2000 reported that the overall prevalence of thyroid disease in a population of Colorado residents (health fair participants; n=25,862) was 11.7% (Canaris et al 2000). However, it is important to note that this study was conducted in a select non-randomised population group and may have overstated the prevalence of the disease. In Australia, thyroid diseases affect approximately 850,000 individuals, approximately 7.5% of women and 1.5% of men (ABC Health 2009). A large majority of these cases can be managed with medical treatment.

The Australian Institute of Health and Welfare reported a total of 3,653 separations for malignant neoplasm of the thyroid gland from 2007 to 2008. Meanwhile, data from

public hospitals indicates that 8,671 total and 580 subtotal thyroidectomies were performed from 2007 to 2008 (Australian Institute of Health and Welfare 2009).

DIFFUSION

As indicated previously, endoscopic thyroidectomy is a relatively new technique and has only recently been accepted by some clinicians as a viable procedure for the excision of benign thyroid tumours. Robot-assisted endoscopic thyroidectomy is a recent attempt to overcome the limitations of endoscopic surgery and presumably enhance the feasibility of this surgical technique. To date, human studies on robot-assisted thyroidectomy have been conducted in the United States (Lee et al 2009) and South Korea (Kang et al 2009a, Kang et al 2009b).

The da Vinci Surgical System was first approved by the United States Food and Drug Administration (FDA) in 2000 for general laparoscopic procedures such as gall bladder removal (FDA 2005). In recent years, the system has diffused worldwide and the FDA has approved the use of the da Vinci system for a wide variety of surgical procedures, including prostatectomy, hysterectomy, myomectomy, mitral valve repair and coronary artery bypass surgery. In Australia, the da Vinci surgical robotic system is listed on the Therapeutic Goods Administration (TGA) Australian Register of Therapeutic Goods (ARTG) (Class IIb) and is distributed in Australia by Device Technologies Australia, P/L.

COMPARATORS

The main comparator to robot-assisted endoscopic thyroidectomy is conventional open thyroidectomy. Endoscopic thyroidectomy itself is not an established procedure and trials on its safety and effectiveness are currently ongoing. Another emerging alternative to open thyroidectomy is minimally invasive video-assisted thyroidectomy (MIVAT), a relatively new procedure that has been suggested to be safe and is thought to confer several advantages, including less postoperative pain and scarring (Sgourakis et al 2008).

SAFETY AND EFFECTIVENESS ISSUES

Study description

Our searches identified a total of 5 published papers on robot-assisted endoscopic thyroidectomy, all of which utilised the da Vinci system. From this, a total of three papers were selected for inclusion in this summary based on quality and the size of the patient cohort. There is substantial patient overlap for two papers that were published by the same research group (Kang et al 2009a, Kang et al 2009b). However, the older study (Kang et al 2009a) will be included for discussion, as the authors presented additional data to compare outcomes with patients that underwent conventional open thyroidectomy.

The first study by Kang et al (2009a) reported on their experience with robot-assisted endoscopic thyroidectomy from October 2007 to March 2008. During this period, a total

of 100 consecutive patients (95 female; mean age: 39.9 ± 8.9 years) with diagnosed thyroid papillary cancer underwent the gasless transaxillary approach performed with the da Vinci system. The outcomes of 80 of these patients were compared with historical data of 224 patients who underwent conventional open thyroidectomy for papillary thyroid microcarcinoma. Selection criteria for tumour size required that the tumour should not be larger than 2cm when visualised with ultrasound. Patients with definite extrathyroidal tumour invasion, multiple lateral neck node metastases or perinodal infiltration of the metastatic lymph nodes or distant metastasis, were excluded. In addition, patients in whom the lesion was located in the posterior capsule area of the thyroid were also excluded, in order to prevent injury to the trachea, oesophagus or recurrent laryngeal nerve (RLN). Mean follow up duration was 188.5 days (range: 120-280 days) (Kang et al 2009a).

A more recent paper by Kang et al (2009b) presented the results of 200 consecutive patients (192 female; mean age: 40.3 ± 9.5 years [mean \pm standard deviation]) diagnosed with papillary thyroid carcinoma and treated with robot-assisted thyroidectomy from October 2007 to July 2008. Patients underwent robot-assisted endoscopic thyroidectomy using a gasless transaxillary approach and were considered eligible if they had well-differentiated thyroid carcinoma and a tumour size of ≤ 2 cm. Patients were excluded if they had definite extrathyroidal tumour invasion, multiple lateral neck node metastases, perinodal infiltration at a metastatic lymph node, or distant metastasis or a lesion located in the thyroid dorsal area. A total of 155 patients underwent partial thyroidectomy and the remaining 45 had total thyroidectomies. Mean follow up duration was 328.3 days (range: 206-485 days) (Kang et al 2009b).

The second study was conducted by Lee et al (2009) between March and May 2008. A total of 15 patients (13 female; mean age: 44 ± 9 years; range: 24-58 years) with papillary thyroid cancer underwent robot-assisted endoscopic thyroidectomy with the bilateral axillary breast approach (BABA). All but one of these patients underwent total thyroidectomy with this technique. Patients were selected to undergo robot-assisted surgery utilising the same inclusion criteria for conventional endoscopic thyroidectomy within the author's institution: papillary thyroid cancers with low risk patients, defined by tumour size not exceeding 1cm in preoperation ultrasonography and no evidence of lateral lymph node metastasis or local invasion on preoperative ultrasonography and computed tomography (Lee et al 2009). No follow-up data beyond hospital stay was presented.

Safety and Effectiveness

Kang et al (2009a) reported that compared with open thyroidectomy, patients who underwent robot-assisted endoscopic thyroidectomy had significantly longer operation times (136.5 ± 36.6 minutes vs. 105.5 ± 41.6 minutes; $p=0.000$). For the robotic group, operation time consisted of working space time², docking time³ and console time⁴. Mean

² Flap dissection from the axillary to anterior neck and connection of retractor to external lifting system.

³ Placement of robotic arms

working, docking and console time were 20.9 ± 8.4 minutes, 6.8 ± 3.1 minutes and 59.9 ± 25.9 minutes, respectively. Postoperative hospital stay was slightly shorter for the robotic group (3.0 ± 0.45 days) relative to the open surgery group (3.3 ± 1.7 days), but did not achieve statistical significance ($p=0.066$). Mean postoperative analgesic use was comparable, with 0.75 ± 0.82 for the robotic group and 0.88 ± 0.89 for the open surgery group. Postoperative complications within the robotic group were minor, and included one case of transient hypocalcaemia and two cases of transient hoarseness. Complications observed in patients who underwent open surgery experienced temporary hypocalcaemia (45/117, 38.5%), temporary hoarseness (5 patients, 2.2%), seroma (1 patient, 0.4%) and haematoma (2 patients, 0.9%). Patients who experienced hypocalcaemia or hoarseness recovered within 1 month and there were no cases of permanent hypocalcaemia or RLN palsy in either group (Kang et al 2009a).

Kang et al (2009b) reported that there were no conversions to open surgery and the mean total operative time was 141.1 ± 38.8 minutes. Postoperative complications included transient hypocalcaemia (6%, 12 patients), transient hoarseness (4%, 8 patients), seroma (1%, 2 patients) and permanent RLN palsy (0.5%, 1 patient). The patient with RLN palsy did not recover vocal cord movement. In patients who experienced transient hypocalcaemia, serum parathyroid hormone levels reduced slightly during the immediate postoperative period (up to 7 days). In most patients, calcium and parathyroid hormone levels normalised within 1 month after surgery. The investigators reported that 38/45 patients who underwent bilateral total thyroidectomy (7 low risk patients excluded) underwent radioactive iodine (RAI) ablation 4 to 6 weeks postsurgery and iodine¹³¹ whole body scans 2 days after RAI ablation. No patient had abnormal RAI uptake. At 4 months postsurgery, the investigators reported that serum thyroglobulin was <1 ng/mL in 42 patients (93.3%) and was >1 ng/mL in the remaining three patients (6.7%). There were no signs of local recurrence throughout the follow up period (mean: 328.3 days).

Lee et al (2009) reported that the mean operative time was 218 ± 28.7 minutes (range: 155-285 minutes). The authors noted that the total operative and console time improved steadily over time. Operative blood loss was minimal, however no specific data was provided. There were no conversions to open surgery or conventional endoscopic surgery. In addition, there were no cases of complications such as bleeding, RLN injury (transient or permanent) or hypocalcaemia. Mean hospital stay was 3.5 days (range: 3-5 days). Postsurgery questionnaires indicated that patients rated the cosmetic results as excellent; however, no specific data was presented. The authors suggested that the robotic system provided good visualisation of the operative field and vital structures, which may have contributed to the low morbidity rate observed in this cohort.

COST IMPACT

Despite the purported advantages of robot-assisted endoscopic thyroidectomy, the technique may prove to be cost prohibitive when factors such as the general cost, fees of disposables and equipment maintenance are considered. In addition, the large space requirement for the da Vinci system may inhibit the adoption of this technology in certain

⁴ Actual time for thyroid surgery

hospitals. When compared with conventional endoscopic surgery, robot-assisted endoscopic thyroidectomy is substantially more time-consuming. However, there is evidence that improved proficiency over time will decrease the total operative time.

The actual cost of the da Vinci system in Australia is unclear. Other studies have reported that the cost of the da Vinci Robotic Surgical System with the 4-arm system and software upgrades is approximately \$USD1.5 million (Weinstein et al 2007).

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 evidence available to date indicates that robot-assisted endoscopic thyroidectomy is feasible and appears to be relatively safe. The procedure is substantially more time consuming compared with open surgery; however, there is some evidence that overall procedure time will decrease with experience. It is important to note that long-term data on recurrence rates for patients treated for thyroid cancer is lacking and most trials to date are limited to case series studies. Considering the fact that the da Vinci system is gaining acceptance within the field of otolaryngology, it is likely that more studies on this procedure will be published in the near future. Additional research on the various approaches that can be used (transaxillary, BABA etc.) is also required.

HEALTHPACT ACTION

Based on the limited evidence available, robot-assisted endoscopic thyroidectomy should be attempted in a clinical trial setting with a select patient group. Additional long-term studies are warranted, as robotic surgery continues to diffuse widely across various surgical specialties. It is recommended that robot-assisted endoscopic thyroidectomy be monitored for 12 months for additional evidence of its long-term effectiveness.

NUMBER OF STUDIES INCLUDED

Total number of studies	2
Level IV intervention evidence	3

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SEARCH CRITERIA TO BE USED

Robot* AND thyroidectomy, Thyroidectomy/methods*, Robotics*.

PRIORITISING SUMMARY (UPDATE 2010)

NAME OF TECHNOLOGY	ROBOT-ASSISTED ENDOSCOPIC THYROIDECTOMY
PURPOSE AND TARGET GROUP	PATIENTS WITH CANCEROUS OR BENIGN THYROID DISEASE

2010 SAFETY AND EFFECTIVENESS ISSUES

Study description

Two studies were eligible for inclusion in this update based on the quality of the study and its cohort size. Both of these were nonrandomised comparative studies comparing the safety and efficacy of robot-assisted thyroidectomies with open thyroidectomies (Lee et al 2010; Tae et al 2010). In both of the included studies, operations were performed using a gasless transaxillary approach with the da Vinci surgical system.

The comparative study published by Lee et al (2010) analysed the outcomes of 84 patients who underwent either robotic thyroidectomy (the 'robot group', n=41) or conventional open thyroidectomy (the 'open' group, n=43) between April and October 2009. Inclusion criteria consisted of patients between 21-65 years of age who possessed either a minimally invasive follicular thyroid carcinoma ≤ 4 cm in diameter or a papillary thyroid carcinoma ≤ 2 cm in diameter. Patients were given the choice between robot-assisted and open thyroidectomy procedures. The mean patient age [\pm Standard Deviation] was 39 ± 7.0 [SD] years for the robot group and 37.7 ± 6.5 [SD] years for the open group. All patients were followed up for at least 3 months; videolaryngostroboscopic examinations were performed preoperatively, 1 week postoperatively and 3 months postoperatively.

The study published by Tae et al (2010) detailed the outcomes of 41 robot-assisted endoscopic thyroidectomies and compared these with the outcomes of 167 open thyroidectomies which occurred during the same period of time in the same institution. To be eligible for robot-assisted thyroidectomies, patients required the presence of follicular adenoma or benign thyroid nodules < 5 cm in diameter or papillary thyroid carcinoma < 2 cm at its largest diameter. Exclusion criteria included cases of papillary thyroid carcinoma with definitive extrathyroidal extensions, multiple cervical lymph node metastases in the lateral neck or central compartment, the presence of distant metastases, and patients with a history of previous neck, thyroid, or breast surgery and irradiation. In comparison, the group undergoing open thyroidectomies excluded patients with previous papillary thyroid carcinoma that required lateral neck lymph node dissection. Mean ages were 39.2 ± 10 [SD] years and 51.7 ± 12.4 [SD] years for the robot group and open group, respectively ($P < 0.001$). Significant gender differences were also apparent, with males making up 4.9% (2/41) of the robot-assisted group and 27.6% (45/163) of the open group ($P = 0.001$). Postoperative pain was measured at 1 week, 1 month and 3 months in both

robot-assisted (32/41) and open thyroidectomy (89/163) patients by means of questionnaires.

Safety and Effectiveness

Lee et al (2010) reported postoperative complications in 19.5% (8/41) and 16.3% (7/43) of patients experiencing robotic or open thyroidectomy, respectively ($P=0.395$). Of these, transient hypocalcemia in total thyroidectomy patients resulted from 19.2% (5/26) of robotic operations and 15.4% (4/26) of open operations. The remainder of postoperative complications consisted of transient hoarseness ($n=1$), and seroma ($n=2$) for the robot group, and flap haematoma ($n=1$) and seroma ($n=2$) from the open group. The mean operative time for the robot group was 128.6 ± 36.3 [SD] minutes compared with 98.0 ± 22.2 [SD] minutes for the open group, an average of 30.6 minutes longer ($P = 0.001$). The mean number of dissected central lymph nodes was 4.4 ± 2.1 [SD] in the robot group and 4.3 ± 2.9 [SD] in the open group. Central lymph node metastasis was observed in 43.9% (18/41) of robot group patients and 44.2% (19/43) of open patients, with a mean number of metastatic lymph nodes of 1.8 ± 0.7 [SD] in the robot group and 1.3 ± 0.9 [SD] in the open group. Mean postoperative hospital stay was 2.5 ± 1.2 [SD] days for the robot group and 3.2 ± 1.8 [SD] days for the open group ($P=0.196$).

Incidence of hyperesthesia and paresthesia in the neck were reported in 36.6% (15/41) of patients 1 week after surgery and 9.8% (4/41) of patients 3 months after surgery in the robot group, compared with 95.3% (41/43) of patients 1 week after surgery ($P = 0.010$) and 65.1% (28/43) of patients 3 months after surgery in the open group ($P=0.002$). However, a far higher incidence of hyperesthesia and paresthesia was reported in the anterior chest of robot group patients compared with the open group, with 46.3% (19/41) of patients experiencing hyperesthesia after 1 week and 19.5% (8/41) after 3 months, compared with 2.4% (1/43) after 1 week and none after 3 months in the open group.

In the study presented by Tae et al (2010), no conversions to open surgery were required in the 41 patients undergoing robot-assisted thyroidectomies. Five and 56 postoperative complications occurred in the robot and open groups, respectively; however, this figure may not reflect the number of patients for whom complications occurred as one patient may have experienced more than one complication. Of these, transient hypothyroidism in total thyroidectomy patients resulted from 20% (2/10) of robotic thyroidectomy procedures and 30.1% (34/113) of open thyroidectomy procedures. Permanent hypothyroidism occurred in 3.1% (5/113) of patients in the open group. No incidence of permanent hypothyroidism occurred in the robot group. The remainder of postoperative complications consisted of transient RLN palsy ($n=1$) and seroma ($n=2$) in the robot group, and transient RLN palsy ($n=4$), permanent RLN palsy ($n=1$), postoperative haematoma ($n=5$), seroma ($n=6$) and chyle leakage ($n=1$) in the open group.

The mean operative times were 179.0 ± 12.5 [SD] minutes (range: 112-295 min) in the robot group and 131.0 ± 47 [SD] minutes (range: 85-290 min) in the open group ($P < 0.001$). The number of nodes removed between the two groups differed significantly, with a mean of 4.78 ± 1.99 [SD] (range: 2-8) lymph nodes removed in the robot group

compared with 9.61 ± 6.8 [SD] (range: 1-31) lymph nodes removed in the open group ($P < 0.01$). Mean patient discharge times were 6.4 ± 1.6 [SD] days and 6.1 ± 2.1 [SD] days in the robot and open groups, respectively. On a scale of 1-5, patients receiving robot-assisted thyroidectomies had a higher anterior chest pain score 1 week postoperatively compared with the open group (2.0 ± 0.8 [SD] for the robot group compared with 1.2 ± 0.5 [SD] for the open group, $P < 0.001$). There were no other differences with regards to postoperative neck or anterior chest pain at 1 week, 1 month and 3 months following surgery. Cosmetic satisfaction was significantly higher at 1 week, and 1 and 3 months follow-up in the open group ($P < 0.001$).

ETHICAL, CULTURAL OR RELIGIOUS CONSIDERATIONS

No issues were identified from the retrieved material.

OTHER ISSUES

A large case series study (n=644) was recently published by Lee et al (2010)^b, however there is significant overlap with one of the studies included in this update (Lee et al, 2010). This study assessed the learning curve involved in performing robotic thyroidectomies by comparing operational variants/factors/statistics between a surgeon experienced in the robotic thyroid surgery (ES) and three novice surgeons who had no prior experience with robotic thyroid surgery (NS). This study concluded that the learning curve for total and subtotal thyroidectomies was 50 procedures and 40 procedures, respectively. Operation times were $132.8 \pm [SD]28.8$ minutes for ES compared with 181.5 ± 78.2 minutes for NS. Other factors, such as major complication rate and blood loss were also lower in the ES group than the NS group (data not shown).

A recent study by Kang et al (2009c) reported the outcomes of 338 patients who underwent robotic thyroidectomies between October 2007 and November 2008, however this study was omitted from the report due to a significant overlap with two studies presented in the original summary (Kang et al 2009a & Kang et al 2009b).

2010 SUMMARY OF FINDINGS

Early operative outcomes, such as perioperative complications, postoperative hospital stay and pain levels are similar between robotic and open thyroidectomies. Furthermore, the study by Lee et al (2010)^b demonstrates that operational times for robotic thyroidectomies can be reduced significantly with increased surgeon experience, making them comparable to open surgery. However, many problems still need to be addressed before robotic thyroidectomies can replace open thyroidectomies as the preferred method of thyroid cancer removal. Of high importance, more prospective controlled studies are required that include an assessment of long term oncologic safety of robotic thyroidectomies. Furthermore, the cost involved in purchasing and maintaining a da Vinci surgical system may prove prohibitive, requiring a very high case load in order to cover this cost. Based on the included studies, the only statistically significant benefit of robotic surgery over open surgery appears to be cosmetic.

HEALTHPACT ACTION

2010 STUDIES INCLUDED

Total number of studies	2
Level III-1 interventional evidence	1
Level III-2 interventional evidence	1

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