A Comparison of the Bilateral Axillo-breast Approach (BABA) Robotic and Open Thyroidectomy for Papillary Thyroid Cancer After Propensity Score Matching

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Background: We aimed to investigate the potential advantages of bilateral axillo-breast approach (BABA) robotic thyroidectomy over conventional open surgery and to determine whether it is a safe and complete surgical procedure compared with open surgery in patients with papillary thyroid cancer.

Patients and Methods: We retrospectively reviewed the records of 315 consecutive patients (robotic, n = 54; open, n = 261) who underwent total thyroidectomy and central neck dissection for papillary thyroid cancer from March 2013 to June 2014. Postoperative complication rate and surgical completeness were analyzed between patients who underwent BABA robotic thyroidectomy (robotic group) and those who chose open thyroidectomy (open group) after propensity score matching according to age, sex, body mass index, tumor size, extrathyroidal extension, and lymph node (LN) metastasis.

Results: Transient hypoparathyroidism was higher in the open group than in the robotic group (13.0% vs. 1.9%; $P = 0.029$). No difference was observed in the mean number of retrieved LNs and metastatic LNs. The mean level of stimulated thyroglobulin was acceptably low in both groups, and there was no difference in the proportion of patients who had stimulated thyroglobulin levels <1 ng/mL between the groups ($P = 0.543$).

Conclusions: Our results show that the outcomes of BABA robotic thyroidectomy may be comparable to those of conventional open thyroidectomy, with possibly better preservation of blood supply to the parathyroid glands, without sacrificing surgical completeness.

Key Words: bilateral axillo-breast approach, complication, surgical completeness, da Vinci, thyroidectomy

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Since its initial reports in 2009,[1,2] robotic thyroidectomy has gained popularity as a treatment for thyroid tumors and has become a good surgical alternative.[3–5] Robotic thyroidectomy has some potential technical advantages over conventional open thyroidectomy and these include improved access to the narrow space, magnified 3-dimensional imaging, improvement in fine motor control during instrumentation, better ergonomics for surgeons, and even lower surgical stress.[6–10]

According to recent systematic reviews of robotic thyroidectomy,[5,11–13] there are no significant differences between robotic and open thyroidectomy in terms of complication rates or postoperative thyroglobulin (Tg) levels, which is a surrogate marker of surgical completeness. Open thyroidectomy has a low morbidity rate with excellent surgical outcomes, whereas robotic thyroidectomy only showed cosmetic benefits.[11–13] However, more experienced surgeons may have reduced complication rates and improved surgical completeness compared with those of the earlier robotic cases.[14] Therefore, this study investigated whether robotic thyroidectomy could be performed more safely in papillary thyroid cancer (PTC) patients, without sacrificing surgical completeness.

In this context, we compared the complication rates and surgical completeness of patients with thyroid cancer who underwent bilateral axillo-breast approach (BABA) robotic surgery with those of patients who underwent open thyroidectomy. To reduce potential confounding effects and treatment selection bias [young women with low body mass index (BMI) who have early thyroid cancer may be selected for the robotic procedure], we conducted propensity score matching. The aim of this study was to investigate the safety and completeness of BABA robotic thyroidectomy in patients with PTC and to investigate the potential advantages of robotic thyroidectomy.

PATIENTS AND METHODS

Patients

The records of 315 consecutive adult (over the age of 18 y) patients who underwent total thyroidectomy and central neck dissection (CND) for PTC, between June 2013 and June 2014, were retrospectively reviewed. A single surgeon who experienced more than 100 cases of robotic thyroidectomy during 4.5 years performed all conventional open and robotic thyroidectomies. Postoperative complications (eg, recurrent laryngeal nerve injury, hypocalcemia, postoperative bleeding, chyle leakage, and wound infection) and surgical completeness were compared between robotic (54 cases) and open (261 cases) surgery groups. The protocol of this retrospective study was approved by the relevant institutional review board. All methods were performed in accordance with the relevant guidelines and regulations. The surgical indications for robotic thyroidectomy in our institution were as follows: tumor size <4 cm, no significant tracheal or esophageal invasion, and no great vessel invasion. Patients who underwent modified radical neck dissection for lateral neck lymph node (LN) metastasis were not included in this study.

All patients were offered the option of choosing open or robotic procedures preoperatively after an explanation of the pros, cons, and contraindications (beyond lateral neck

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metastasis) of robotic operation, and they chose based on their preference.

Surgical Method for Robotic Thyroidectomy and CND

All enrolled patients underwent total thyroidectomy and routine prophylactic unilateral CND at the tumoral side. A bilateral CND was performed in cases in which both lobes presented with PTC. For robotic thyroidectomy, we used the Si da Vinci surgical system (Intuitive Surgical Inc., Sunnyvale, CA), and intraoperative neuromonitoring using the NIM-Response 3.0 System (Medtronic Xomed, Jacksonville, FL) was routinely performed. BABA using a verticalizing maneuver was used in all robotic cases for better access to the lower part of the neck (Fig. 1).

Surgical Outcome Parameters

Postoperative complications (eg, recurrent laryngeal nerve injury, hypoparathyroidism, postoperative bleeding, chyle leak, or wound infection) and surgical completeness (eg, mean number of retrieved LNs, median levels of stimulated Tg, and the proportion of patients with stimulated Tg levels <1 ng/mL) were compared between the open and robotic groups. All patients underwent postoperatively vocal cord examination through laryngoscopy, and vocal cord palsy lasting more than 6 months was defined as permanent. When the patient felt hoarseness or vocal core movement disorder, then positive vocal paralysis was recorded. Postoperative hypoparathyroidism was defined as the presence of any symptom of hypocalcemia with decreased serum calcium level (< 8.0 mg/dL) or ionized calcium (< 1.00 mmol/L), intact parathyroid hormone (iPTH) level (< 15 pg/ml). Permanent hypoparathyroidism was defined as hypoparathyroidism requiring calcium medication for more than 12 months post surgery. Radioactive iodine (RAI) therapy was administered to patients with extrathyroidal extension, primary tumor size of > 4 cm, or LN metastases. Stimulated Tg was measured on the day of RAI treatment after 28 days of levothyroxine withdrawal or of recombinant human thyroid-stimulating hormone (Thyrogen, Genzyme, Cambridge, MA) injection for thyroid-stimulating hormone stimulation. The ablation was considered successful when serum Tg was < 1.0 ng/ml.

Statistical Analysis

To reduce the potential confounding effects and treatment selection bias, we conducted propensity score matching. We selected 6 factors that could affect the operative outcomes: age, sex, BMI, size, extrathyroidal extension, and LN metastasis. Finally, 54 matched pairs were obtained after propensity score matching. Paired *t* tests and the McNemar test were used to assess the differences between the paired 2 groups. *P*-values <0.05 were considered statistically significant. All statistical analyses were performed using the SPSS software suite (version 20.0; SPSS Inc., Chicago, IL).

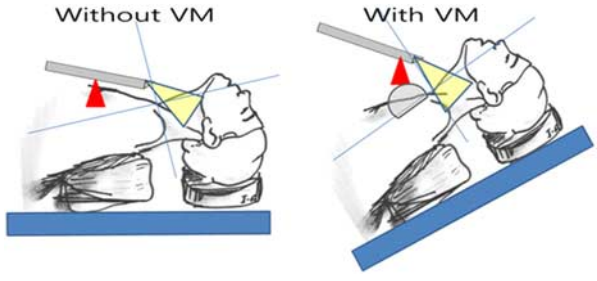

FIGURE 1. Verticalizing maneuver (which might enable more meticulous central neck dissection). VM indicates verticalizing maneuver.

TABLE 1. Clinicopathologic Characteristics of the Patients

Variables	Open Group (n = 261)	Robotic Group (n = 54)	*P*
Mean age, y	47.7 ± 10.8	37.2 ± 9.2	< 0.001
Sex [male:female (F %)]	64:197 (75.5%)	6:48 (88.9%)	0.001
BMI (kg/m^2)	24.3 ± 3.9	23.0 ± 3.1	0.024
Mean tumor size, cm	0.82 ± 0.63	0.80 ± 0.61	0.826
Presence of extrathyroidal extension	51.7%	46.3%	0.394
Size			0.201
≤ 1 cm	61.3%	65.4%	—
< 1 cm and ≤ 2 cm	24.0%	17.3%	—
> 2 cm	14.7%	17.3%	—
Presence of LN metastasis	46.0%	51.9%	0.433

BMI indicates body mass index; LN,lymph node.

RESULTS

Characteristics of the Study Populations Before Matching

The baseline characteristics of the 315 patients in the robotic (54) and open (261) groups are summarized in Table 1. Patients in the robotic group were younger (37.2 ± 9.2 vs. 47.7 ± 10.8 y; $P < 0.001$) and had a lower BMI (23.0 ± 3.1 vs. 24.3 ± 3.9; $P = 0.024$). There were more women in the robotic group than in the open group (88.9% vs. 75.5%; $P = 0.001$). The mean tumor size, presence of extrathyroidal extension, T-stage tumors, and the presence of LN metastasis are presented in Table 1. No significant differences were observed between the 2 groups ($P > 0.05$).

The data presented in Table 2 represent the surgical outcomes of robotic and open surgery. Transient hypoparathyroidism occurred in only 1.9% (1/54) of patients in the robotic group, and the mean iPTH level on postoperative day 1 was higher in the robotic group (43.1 vs. 32.4 pg/mL, $P = 0.035$). Less transient vocal cord palsy occurred in the robotic group, but this difference was not statistically significant ($P = 0.376$). Permanent vocal cord palsy was observed in 2 patients in the open group in whom cancer had significantly invaded the recurrent laryngeal nerve. There were no differences in the incidence of postoperative bleeding, wound infection, or chyle leakage ($P > 0.05$).

The mean number of retrieved LNs was 8.04 ± 5.02 in the open group and 8.09 ± 4.61 in the robotic group. The mean number of metastatic LNs was 1.27 ± 2.10 in the open group and 1.59 ± 2.14 in the robotic group. There were no statistically significant differences in the numbers of retrieved and metastatic LNs between the 2 groups ($P = 0.942$ and 0.304, respectively). RAI treatment was administered to 159 (60.1%) open group patients and 30 (55.6%) robotic group patients. The mean levels of stimulated Tg at RAI treatment were relatively low in both groups: 0.85 ng/mL in the open group and 0.77 ng/mL in the robotic group ($P = 0.774$). There was no difference in the

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TABLE 2. Comparison of Surgical Outcomes Between the Robotic and Open Thyroidectomy Groups

Variables	Open Group (n = 261)	Robotic Group (n = 54)	*P*
Mean operation time (min)	112.8 ± 32.0	185.2 ± 38.1	0.001
Transient hypoparathyroidism	24 (9.2%)	1 (1.9%)	0.007
Postoperative mean iPTH level, pg/ml	32.4 ± 20.23	43.1 ± 32.17	0.035
Permanent hypoparathyroidism	0	0	NA
Transient VC palsy	22 (8.4%)	3 (5.6%)	0.376
Permanent VC palsy	2 (0.8%)	0	0.520
Postoperative bleeding	0	0	NA
Wound infection	1 (0.4%)	0	0.520
Chyle leakage	0	0	NA
Mean number of retrieved LNs	8.04 ± 5.02	8.09 ± 4.61	0.942
Mean number of metastatic LNs	1.27 ± 2.10	1.59 ± 2.14	0.304
Proportion of metastatic LNs ≦1	73.1%	59.3%	—
Proportion of metastatic LNs 1 < and ≦3	16.9%	26.0%	—
Proportion of metastatic LNs > 3	12.3%	14.8%	—
Stimulated Tg level, ng/mL (mean)	0.85 ± 1.31	0.77 ± 1.27	0.774
Proportion of stimulated Tg <1.0 ng/mL	132/158 (83.5%)	23/30 (76.7%)	0.718

iPTH indicates intact parathyroid hormone; LN, lymph node; NA, not applicable; Tg, thyroglobulin; VC, vocal cord

proportion of patients with stimulated Tg levels of <1 ng/ml between the groups (open vs. robotic group: 83.5% vs. 76.7%; $P = 0.718$).

Outcomes of Matched Cohorts

Propensity score matching of the 54 BABA robotic thyroidectomy and 261 open thyroidectomy patients yielded 54 matched pairs of patients (Table 3). The matched cohorts did not differ in age, sex, BMI, tumor size, extrathyroidal extension, and LN metastasis using appropriate statistical methods. Transient hypoparathyroidism occurred in 1.9% (1/54) of patients in the robotic group, and the mean iPTH level on postoperative day 1 was higher in the robotic group (43.12 vs. 29.19 pg/mL, $P = 0.020$). Less transient vocal cord palsy also occurred in patients in the robotic group, although this difference was not statistically significant ($P = 0.467$). There were no differences in the incidence of postoperative bleeding, chyle leaks, or wound infection ($P > 0.05$) between the groups. The mean number of retrieved LNs was 9.11 ± 5.93 in the open group and 8.09 ± 4.61 in the robotic group. The mean number of metastatic LNs was 1.63 ± 2.82 in the open group and 1.59 ± 2.14 in the robotic group. There were no statistically significant differences in the numbers of retrieved and metastatic LNs between the 2 groups ($P = 0.321$ and 0.939, respectively).

RAI treatment was administered to 34 (63.0%) patients in the open group and 30 (55.6%) patients in the robotic group. The mean values of stimulated Tg levels at RAI treatment were relatively low in both groups: 0.86 ng/mL in the open group and 0.77 ng/mL in the robotic group ($P = 0.779$). There was no difference in the proportion of patients who had stimulated Tg levels <1 ng/ml between the groups (70.6% open vs. 76.7% robotic, $P = 0.543$).

DISCUSSION

In the present study, we investigated the postoperative complications and surgical completeness of robotic thyroidectomy. Previous studies have reported no significant differences in complication rates or postoperative Tg levels between robotic and open thyroidectomy[8,15–17]; this may have been due to the insufficient experience of the surgeons in the use of a robot during surgery. However, surgeons have continued to use and gain experience in robotic thyroidectomy, which could lead to reduced complication rates

TABLE 3. Comparison of Surgical Outcomes Between the Robotic and Open Thyroidectomy Groups After Propensity Score Matching

Variables	Open Group (n = 54)	Robotic Group (n = 54)	*P*
Mean operation time (min)	115.5 ± 18.2	192.8 ± 32.1	0.001
Transient hypoparathyroidism	7 (13.0%)	1 (1.9%)	0.029
Postoperative mean iPTH level, pg/mL	29.19 ± 16.49	43.12 ± 32.17	0.020
Permanent hypoparathyroidism	0	0	NA
Transient VC palsy	5 (9.3%)	3 (5.6%)	0.467
Permanent VC palsy	0	0	NA
Postoperative bleeding	0	0	NA
Wound infection	1 (1.9%)	0	0.322
Chyle leakage	0	0	NA
Mean number of retrieved LNs	9.11 ± 5.93	8.09 ± 4.61	0.321
Mean number of metastatic LNs	1.63 ± 2.82	1.59 ± 2.14	0.939
Proportion of metastatic LNs ≤ 1	70.4%	59.3%	—
Proportion of metastatic LNs 1 < and ≤ 3	16.7%	26.0%	—
Proportion of metastatic LNs > 3	13.0%	14.8%	—
Stimulated Tg level, ng/mL (mean)	0.86 ± 1.19	0.77 ± 1.27	0.779
Proportion of stimulated Tg <1.0 ng/mL	24/34 (70.6%)	23/30 (76.7%)	0.543

iPTH indicates intact parathyroid hormone; LN, lymph node; NA, not applicable; Tg, thyroglobulin; VC, vocal node.

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and improved surgical completeness compared with the earlier robotic thyroidectomy cases. In this regard, we have recently reported the possibility of better preservation of blood supply to the parathyroid glands using robotic surgery.[14]

Regarding the clinicopathologic features of the patients represented in the present study, patients who selected robotic thyroidectomy compared with the other group were young women with lower BMI, who were more concerned about the cosmetic outcome. Performing this surgery on male patients might be more difficult than it was on female patients, and the difference in the ratio of men to women between the groups might have influenced the better outcomes in the robotic group. We selected 6 factors that could affect operative outcomes, which were age, sex, BMI, size, extrathyroidal extension, and LN metastasis.[16,18–21] The mean tumor size, the presence of extrathyroidal extension, and the presence of LN metastasis may also affect the surgical outcomes of robotic thyroidectomy,[18–21] though these factors were not significantly different between the 2 groups in the present study. Our matched cohorts did not differ in any of these clinicopathological parameters, and thus, surgical outcome parameters are likely to be unaffected.

Transient hypoparathyroidism occurred in only 1.9% of patients in the robotic group, and the mean iPTH level on postoperative day 1 was higher in the robotic group ($P = 0.020$). Less transient vocal cord palsy also occurred in the robotic group patients, although this difference was not statistically significant. Several factors may be responsible for the reduction of transient hypoparathyroidism in robotic thyroidectomy seen in the current study: one of these is surgical expertise in robotic thyroidectomy. A surgeon, though he could be considered experienced in robotic and open thyroidectomy, may be more experienced now in robotic thyroidectomy compared with earlier case studies. Furthermore, there are many benefits of robotic thyroidectomy. The magnification (15 times) may help surgeons identify and avoid microvascular structures around the parathyroid glands.[14,17] In addition, previously, surgeons used a monopolar hook, whereas hot shears are now being used. Adopting this sharp instrument enables more delicate manipulation. There were no differences in the incidences of other complication parameters.

For the assessment of surgical completeness, the most reliable parameters were the number of retrieved LNs and serum-stimulated Tg levels.[4,16] In a previous study, we reported that a less extensive CND was achieved with BABA robotic thyroidectomy compared with an open procedure.[19] Therefore, we have modified the BABA procedure for better access to the lower part of the neck (verticalizing maneuver,[19,22,23] Fig. 1), allowing complete CND with similar surgical completeness. In the present study, there was no difference in these parameters and also there was no difference in the proportion of patients who had stimulated Tg levels <1 ng/ml between the groups ($P = 0.543$). Robotic thyroidectomy can be performed successfully, without sacrificing the completeness of thyroid surgery.

The present study has some limitations, including its single-institution and nonrandomized design. Cost and whether patients are in private insurance coverage can be a factor, also. We performed propensity score matching to overcome selection bias. However, regarding the cost, especially in Korea, not only the wellness of the patients but whether they are in the private insurance coverage influenced much more (the majority of patients had casually chosen robotic operations when private insurance covers the cost of the robotic surgery). Therefore, we thought cost issues cannot be assessed directly. There may be other sources of unassessed nonuniformity, such as body habitus and comorbidities, that may have been neglected between the robotic and open cohorts. Unilateral and bilateral CND rates can also affect the rate of hypoparathyroidism, though our data on CND rates were not significantly different (about half of the patients in both groups underwent bilateral CND). Moreover, the sample size was relatively small and all data were obtained from a single surgeon. Long-term multicenter studies using validated instruments will be essential.

In conclusion, the outcomes of robotic thyroidectomy were similar to those of conventional thyroidectomy, with possible better preservation of blood supply to the parathyroid glands. Using the da Vinci robot in thyroid surgery may help experienced thyroid surgeons to reduce the prevalence of transient hypoparathyroidism without sacrificing the completeness of thyroid surgery.

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