Original Article

Harmonic versus LigaSure for Flap Creation in Bilateral Axillary Breast Approach Thyroid Surgery

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Conflict of Interest

No potential conflict of interest relevant to this article was reported.

ABSTRACT

Purpose: The bilateral axillary breast approach (BABA) is frequently utilized for remote access thyroid surgery. The first step in this surgical approach is to make a subcutaneous flap from the axilla to the neck, usually using a Harmonic ACE. Our institution has utilized LigaSure to create these flaps. This study reports comparative results with these 2 energy devices.

Methods: Medical data and video clips from 73 patients who underwent robotic BABA thyroid surgery were retrospectively reviewed. Flaps for BABA were created by first and second year endocrine fellows under the guidance of an experienced endocrine surgeon. There were no criteria for allocation to energy devices.

Results: Of the 73 patients, 31 and 42 underwent flap creation with the Harmonic ACE and LigaSure devices, respectively. Demographic characteristics were similar in the 2 groups. Mean time for flap creation was significantly shorter (33.46 ± 8.33 vs. 38.27 ± 7.14 min, $P=0.012$), and mean number of camera cleanings significantly lower (4.21 ± 2.53 vs. 10.45 ± 4.95 , $P<0.001$), in the LigaSure group. Surgical site pain on day 2 was significantly lower in the LigaSure group. Postoperative bleeding and skin burn occurred only in patients in the Harmonic group.

Conclusion: LigaSure showed better performance than the Harmonic ACE device for BABA flap creation, as shown by time for flap creation, postoperative pain scores, and complications. Because this study was a small sized retrospective comparison, large randomized controlled trials are needed to confirm these results.

Keywords: Thyroid neoplasms; Robotic surgical procedures; Surgical flap; Electrosurgery

INTRODUCTION

National cancer statistics showed that thyroid cancer was the third most common cancer in South Korea in 2016, as well as being the second most common cancer in women, especially in those aged 15–34 years (1). Because thyroid cancer is common in young women, various surgical methods have been developed to hide surgical scars at sites removed from the visible anterior neck. The bilateral axillo-breast approach (BABA) was first introduced in South Korea in 2004 using an endoscopic device (2) and later expanded for use with the da-Vinci

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robotic system in 2008 (3). This surgical approach has since become a standardized method for robotic thyroid surgery.

The BABA requires 4 incision sites, one in each areola and one in each axillary area, with the working space provided by creating a flap. The borders of the flap are from the bilateral axillae and breasts to the anterior neck up to the thyroid cartilage superiorly and the medial border of the sternocleidomastoid (SCM) muscle laterally (4). The mean time required to create a BABA flap has been reported to range from 30 to 40 minutes (5-7), accounting for a large portion of the operation time required for thyroid surgery using BABA (8). Thus, creation of a proper BABA flap is important for the success of BABA thyroid surgery, whether performed endoscopically or robotically.

The Harmonic ACE (Ethicon Endo-Surgery Inc., Cincinnati, OH, USA) is an advanced energy blade that uses ultrasonic-based hypervibration (2,9,10) as an alternative to traditional diathermy for safe bleeding control and tissue dissection during BABA flap creation. Although the Harmonic ACE device provides faster and safer tissue dissection than traditional electrocoagulation devices (11-13), it has several disadvantages, including fluid splash during the firing and burn injury caused by the high temperature of the blade tip (200°C) (12). As an alternative to the Harmonic ACE device, our institution has used the LigaSure for BABA flap dissection since 2018 (14). The LigaSure (Valley Lab, Boulder, CO, USA) is an advanced bipolar electrosurgical device. Vessel sealing is achieved by bipolar energy between 2 jaws and cutting is achieved by cutter inside the jaw. LigaSure has a reduced lateral energy spread profile under 2 cm, with decreased risk of injury to adjacent structures (12,15).

To our knowledge, no study to date has compared the Harmonic and LigaSure devices for BABA flap creation. The present study therefore compared outcomes in patients who underwent BABA flap creation using the LigaSure and conventional Harmonic ACE devices.

MATERIALS AND METHODS

1. Data collection and analysis

From December 2018 to May 2019, 73 patients in our institution underwent robotic BABA thyroid surgeries performed by a single experienced endocrine surgeon. We reviewed those patients' medical records and surgical videoclips retrospectively. BABA flaps were created by 2 endocrine fellows, a second-year fellow (surgeon A) and a first-year fellow (surgeon B), under the guidance of the experienced endocrine surgeon.

The electronic medical records of these patients were analyzed to determine their clinical characteristics and postoperative outcomes. Intraoperative video clips were reviewed by the 2 fellows to measure the time required for and the camera cleaning frequency during BABA flap creation. Postoperative pain scores were assessed every day at 6:00 am using a visual analog scale ranging from 0 to 10, as a routine postoperative patient assessment in our hospital. Drainage volume from the flap was recorded daily for the first 3 postoperative days and totaled. BABA flap-related complications, such as seroma formation, bleeding, or skin burn, were recorded. Surgery-related variables were separately analyzed for surgeon A and surgeon B.

The study protocol was approved by the institutional review board of our hospital (IRB number: 2020-04-033). Statistical analyses were performed using IBM SPSS version 19.0

software (IBM Corp., Armonk, NY, USA). Continuous variables were compared by Student's t-tests and categorical variables by the chi-square or Fisher exact tests. Differences were considered significant when $P < 0.05$.

2. Steps for BABA flap

Steps for BABA flap creation have been standardized at our hospital (**Figs. 1 and 2**). Following hydrodissection, in which saline containing 1:200,000 epinephrine was injected subcutaneously, blunt subcutaneous dissection was started from the right (point ① in **Fig. 1**) to the left (point ② in **Fig. 1**) axilla. The axillary trocars were installed in both axillary areas, and a camera was inserted through the right axillary port. The space around the anterior chest area was widened using an energy device (**Fig. 2A and B**). The anterior chest wall flap was completed, and breast ports were inserted into the right (point ③ in **Fig. 1**) and left (point ④ in **Fig. 1**) areolae. After installation of all 4 trocars, the flap was expanded to the neck space, including the layer between the platysma and strap muscle (**Fig. 2C and D**). The camera used the right breast trocar and the energy device used the left breast trocar (point ⑤ in **Fig. 1**). The superior border of flap consisted of the thyroid cartilage and lateral borders were the bilateral SCM muscles (**Fig. 2E and F**).

3. Energy devices

The 2 types of energy devices used for BABA flap creation were the Harmonic ACE® 7+ Laparoscopic Shears 36 cm with Advanced Hemostasis (Ethicon US, LLC) and the LigaSure™ Maryland Jaw Laparoscopic Sealer/Divider 37 cm (Medtronic, Minneapolis, MN, USA). There were no selection criteria for energy device allocation. Rather, the energy device used was based on the supply of surgical instruments in the hospital's operating theatre. Surgical videos were reviewed and patients were assigned to 2 groups, a Harmonic and a LigaSure group, depending on the type of energy device used.

Fig. 1. Standard order of BABA flap creation in the authors' institution.

BABA flap starts from the right axilla ① to the left axilla ② by blunt hydro-dissection and the insertion of 8 mm robot trocars. A space was created around the sternal area using the energy device, and the 8 mm breast ports were inserted in the right ③ and left ④ areolae. After installation of all 4 trocars, the flap was extended to the strap muscle of the neck ⑤.

BABA = bilateral axillary breast approach.

Fig. 2. Comparative view of flap creation using the Harmonic (left column) and LigaSure (right column) energy devices.

A space was made in the anterior chest area using the Harmonic (A) or LigaSure (B) energy device. A camera was inserted through the right axillary port and the energy device through the left axillary port. Subsequently, the camera was moved to the right breast port and the Harmonic (C) or LigaSure (D) energy device to the left breast port. The neck area flap was subsequently created above the strap muscle using the Harmonic (E) or LigaSure (F) device.

RESULTS

During the study period, 73 patients underwent robotic BABA thyroid surgery. Of these, 31 (4 males and 27 females) underwent flap creation using the Harmonic device and 42 (7 males and 35 females) using the LigaSure device. Surgeon A created flaps in 45 patients, 21 using the Harmonic and 24 using the LigaSure device, whereas Surgeon B created flaps in 28 patients, 10 using the Harmonic and 18 using the LigaSure device. **Table 1** shows the demographic and pathological characteristics of the included patients. There were no significant between-group differences in gender, age, body mass index (BMI), tumor location, tumor size, multiplicity, and retrieved and metastatic lymph nodes. The proportion of patients with papillary thyroid carcinoma was higher in the LigaSure than in the Harmonic group (90.5% vs. 71.0%). In addition, 4 patients in the LigaSure group and 6 in the Harmonic

Table 1. Demographic and clinical characteristics of the patients included in this study

Variables	Harmonic (n=31)	LigaSure (n=42)	P value
Gender			0.75
Male	4 (12.9)	7 (16.7)	
Female	27 (87.1)	35 (83.3)	
Age (yr)	41.52±11.9	45.95±10.15	0.09
BMI (kg/m ²)	23.07±6.08	24.87±4.07	0.13
Tumor location			0.35
Right	12 (38.7)	23 (54.8)	
Left	16 (51.6)	17 (40.5)	
Bilateral	3 (9.7)	2 (4.8)	
Pathologic diagnosis			0.031
PTC	22 (71.0)	38 (90.5)	
Others	9 (29.0)	4 (9.5)	
Size, mm	0.75±1.27	0.27±0.76	0.07
Multiplicity	1.51±0.77	1.67±1.16	0.53
LN metastasis	0.32±0.98	0.93±2.18	0.15
LN retrieved	2.39±2.60	2.14±3.18	0.28

Results are reported as mean±standard deviation or as number (%).

BMI = body mass index; PTC = papillary thyroid carcinoma; LN = lymph node.

group had nodular hyperplasia, and one patient each in the Harmonic group had follicular adenoma and follicular carcinoma.

Table 2 shows the surgical variables associated with BABA flap creation. Although total operation time, including flap and console time, was similar in the LigaSure and Harmonic groups (160.6±38.7 vs. 169.3±29.8 minutes, $P=0.28$), flap creation time was significantly shorter in the LigaSure than in the Harmonic group (33.46±8.33 vs. 38.27±7.14 minutes, $P=0.012$). When individual surgeons were analyzed, Surgeon A showed significantly shorter flap creation time when using the LigaSure (32.54±6.36 vs. 39.03±7.74 minutes, $P=0.004$). Although Surgeon B also showed shorter flap creation time using LigaSure, the difference was not statistically significant (34.68±10.47 vs. 36.67±5.70 minutes, $P=0.584$). Frequency of camera wiping was significantly lower in the LigaSure than the Harmonic group (4.21±2.53 vs. 10.45±4.95 times, $P<0.001$), with Surgeons A (4.63±2.81 vs. 10.62±5.23 times, $P<0.001$) and B (3.67±2.06 vs. 10.10±4.56 times, $P<0.001$) showing similar results.

Postoperative outcomes associated with BABA flap creation are shown in **Table 3**. Although surgical site pain scores did not differ significantly in the 2 groups, pain scores on the second postoperative day were significantly lower in the LigaSure than in the Harmonic group (2.48±0.67 vs. 2.81±0.40, $P=0.01$), and in patients who underwent flap creation by Surgeon A (2.46±0.59 vs. 2.81±0.40, $P=0.02$). Total drainage amount from the flap tended to be lower in the LigaSure group (132.12±42.29 vs. 144.23±50.60 mL, $P=0.23$). Three patients in each group

Table 2. Flap-related surgical variables according to energy devices

Variables	Harmonic (n=31)	LigaSure (n=42)	P value
Total operation time (min)	160.6±38.7	169.3±29.8	0.280
Flap time (min)			
Total	38.27±7.14	33.46±8.33	0.012
Surgeon A	39.03±7.74	32.54±6.36	0.004
Surgeon B	36.67±5.70	34.68±10.47	0.584
Camera wiping frequency			
Total	10.45±4.95	4.21±2.53	<0.001
Surgeon A	10.62±5.23	4.63±2.81	<0.001
Surgeon B	10.10±4.56	3.67±2.06	<0.001

Results reported as mean±standard deviation.

Table 3. Postoperative outcomes associated with flap area

Variables	Harmonic (n=31)	LigaSure (n=42)	P value
Pain score (VAS*, range 0 to 10)			
Day 1			
Total	2.97±0.18	2.79±0.61	0.07
Surgeon A	3.00±0.00	2.83±0.83	0.10
Surgeon B	2.90±0.32	2.72±0.75	0.49
Day 2			
Total	2.81±0.40	2.48±0.67	0.01
Surgeon A	2.81±0.40	2.46±0.59	0.02
Surgeon B	2.80±0.42	2.50±0.79	0.28
Day 3			
Total	2.08±0.57	2.07±0.69	0.97
Surgeon A	2.13±0.62	2.09±0.60	0.85
Surgeon B	2.00±0.50	2.06±0.86	0.83
Drainage, mL			
Total	144.23±50.60	132.12±42.29	0.23
Surgeon A	154.52±52.65	127.71±42.42	0.07
Surgeon B	122.60±40.10	135.67±42.89	0.44
Flap related complications			
Seroma under the flap	3 (9.7)	3 (7.1)	0.69
Postop bleeding from flap	1 (3.2)	0 (0)	0.43
Skin burn	1 (3.2)	0 (0)	0.18

Results are reported as mean±standard deviation or as number (%).

*VAS indicates visual analog scale; ranges 0 (no pain) to 10 (worst pain).

developed seromas under the flap after discharge from the ward. Skin burn and postoperative bleeding from the flap site were observed only in the Harmonic group.

DISCUSSION

Robotic BABA thyroid surgery has been performed for over 15 years, both endoscopically and robotically (2,3,5,16). This approach provides not only excellent cosmetic outcomes but favorable oncologic outcomes (4,17-20). However, the BABA method requires a wider subcutaneous flap, extending from the axillae and breasts to the superior neck, than other methods of remote access thyroid surgery, such as the transaxillary, retroauricular, and transoral approaches. This may result in increased postoperative pain from the chest and clavicular areas (10,21), as well as unexpected flap-related complications, such as skin burns or perforation by the energy devices, as well as seromas or adhesions. Difficulties in flap creation may prevent surgeons from performing BABA surgery (4). Many studies have described BABA methods, including how to make the BABA flap (2-4,10). BABA flap creation generally requires 30–40 minutes, increasing total operation time (5-8). Appropriate training for BABA flap creation is very important for the successful implementation of BABA surgery. Because most steps in BABA flap creation are performed by energy devices, surgical skills are very important, with most previous studies of BABA flap focusing on postoperative pain around the flap area (9,10,21,22).

To our knowledge, no previous study has compared energy devices used for BABA flap creation, making this the first study to compare outcomes of BABA flap creation using 2 different energy platforms, ultrasonic-based Harmonic ACE and bipolar-based LigaSure. This study found that the time required to create the BABA flap was significantly lower using the LigaSure, probably because the need for a camera was significantly lower using this device. Due to the high frequency of ultrasound vibrations, fluid scattering to adjacent

areas is high and jaw temperature can increase to over 200°C with the Harmonic ACE device (12). These factors can cause deposition of liquid onto the camera or blurring of the field of view, requiring the camera to be wiped more than 10 times during the flap creation. The LigaSure device utilizes electrical energy between the 2 jaws, with each jaw fully sealed by the insulator. This can reduce fluid scattering when compared with the non-insulated activation blade of the Harmonic ACE device.

The more skilled second year endocrine fellow required less time for flap formation, with less postoperative pain, using the LigaSure than the Harmonic device. This finding suggests that increased surgical skill increases the accuracy and effectiveness of the LigaSure for flap layer dissection, without unwanted damage to surrounding tissue. Total fluid drainage volume tended to be lower in the LigaSure group, but the difference was not statistically significant. This was particularly noticeable during flap creation by Surgeon A, with mean fluid drainage using the Harmonic and LigaSure devices being 154.52 and 127.71 mL, respectively, suggesting that tissue damage can be reduced when a skilled surgeon uses the LigaSure device.

BABA flap-related surgical complications, including postoperative bleeding from the flap and skin burn, were observed only in the Harmonic group. The difference in skin burn rate may be due to a difference in jaw temperature, which has been reported to be higher using the Harmonic (195.9°C) than the LigaSure (96.4°C) (12). In addition, the Harmonic device is insulated on only one side, whereas both blades of the LigaSure device are insulated. Activating the blade of the Harmonic device can damage surrounding tissue due to residual heat immediately after use. Thus, accidental touching of the flap by the Harmonic device can burn the subcutaneous area. Studies comparing the Harmonic and LigaSure devices for open thyroidectomy found no significant differences in hemostasis and complications (23,24). The differences observed in the present study may be due to the creation of subcutaneous flaps during remote access thyroidectomy. Our experience suggests that creation of a BABA flap is safer using the LigaSure than the Harmonic device (2,9,10).

To our knowledge, this study is the first to compare surgical outcomes for BABA flap creation using 2 different energy devices. Compared with the traditionally used Harmonic ACE, the LigaSure device was faster and safer. Furthermore, as trainee surgeons accumulate more surgical experience for BABA flap creation, using the LigaSure may reduce flap creation time while increasing safety. Although the learning curve for BABA flap creation has not been determined, statistical analysis of the learning curve should be done later.

This study has some limitations. This was a retrospective study, in which patients were not randomized to the Harmonic ACE or LigaSure device. Thus, the results may have been affected by bias. In addition, the number of patients and the number of surgeons were not sufficient for adequate comparisons. Randomized controlled trials with larger numbers of patients and operations performed by larger numbers of surgeons are needed to confirm these findings.

CONCLUSION

In this study, we found that LigaSure energy device showed faster time to create BABA flap than traditional Harmonic ACE, without significant flap related complications. It suggested that LigaSure may be a good alternative energy device for BABA flap creation. Due to this

study is small retrospective analysis, prospective large volume study should be proceeded to consolidate our suggestion.

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