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Safety and Performance of Harmonic® HD 1000i Shears in Thoracoscopic Procedures: A Retrospective Study

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Abstract

Background: Ultrasonic energy devices are utilized for transection, incision, and hemostasis in traditional open and laparoscopic procedures. The Harmonic HD 1000i Shears, designed to deliver a precise amount of thermal energy during tissue transection and vessel sealing, has been utilized in many specialties. This study aimed to confirm real-world safety and performance of the Harmonic device in two thoracoscopic procedures: lobectomy and segmentectomy. **Methods:** The primary endpoint of this retrospective, observational, single-arm study was rate of post-operative blood transfusions related to study device or procedure. Secondary endpoints included occurrence of intra- and post-operative adverse events (AEs) or complications device- or procedure-related, and rate of required additional hemostatic measures. Adults included those who underwent thoracoscopic lobectomy or segmentectomy where HD 1000i shears were used while excluding those where additional advanced energy devices were used. The study was conducted at Severance Hospital, Yonsei University Health System, South Korea from May 1, 2018, to November 30, 2020. **Results:** Subjects included n = 766 lobectomies (mean age 63.79, 52% male) and n = 215 segmentectomies (mean age 63.19, 54% male). Estimated blood loss was 50 mL (0 min, 3200 max) and 20 mL (0 min, 800 max), intraoperative transfusion rate 0.001% and 0%, intraoperative complication/AE rate 1% and 2%, and post-operative complication/AE rate 9% and 4% in the lobectomy and segmentectomy groups, respectively. Median

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operative times were 108 min. (35 min, 395 max) for lobectomies and 105 min. (32 min, 574 max) for segmentectomies. **Conclusion:** Given the low rate of blood loss and intra- and post-operative complication/AE rates, HD 1000i can be used confidently for thoracoscopic pulmonary resection in adults.

Keywords

Harmonic HD 1000i Shears, Lobectomy, Segmentectomy, Ultrasonic Energy Device

1. Introduction

Ultrasonic energy devices are employed in many surgical specialties for tissue cutting and coagulation. They continue to undergo development and refinement to maintain clinical utility for increasingly complex open and minimally invasive procedures. Advantages of ultrasonic instruments compared to conventional electrosurgery have included improved hemostasis, less thermal damage, combined vessel sealing and tissue dissection capability, and reduced surgical smoke production [1] [2] [3] [4]. The ability of ultrasonic energy to be adjusted for tissue tension, power settings, and activation times has contributed to safety and favorable clinical outcomes when the device is used near vital organs [5]. In addition, modern ultrasonic devices such as the Harmonic shears (Ethicon, Inc.) can seal vessels through 7 mm in diameter, which may help to reduce the number instrument changes required for hemostatic tissue dissection and transection of larger vessels in complex procedures.

In the context of cardiothoracic surgery, ultrasonic energy has been effectively utilized in variety of applications. Harmonic ACE+ 7 shears were noted to be safe and effective for sealing of pulmonary artery branches in clinical trials of video-assisted thoracoscopic and robotic lobectomy [6], and open lung resection [7]. Together, these studies included over 250 pulmonary artery branches ≤7 mm in diameter that were divided with the Harmonic device. No postoperative bleeding was noted for vessels sealed with Harmonic shears. Other reported lobectomy applications of Harmonic shears were anatomical vascular dissection, lymphadenectomy, and bronchial dissection [8] [9] [10]. Otsuka *et al*. noted successful use of Harmonic in minimally invasive esophagectomy [11], and Harmonic shears were useful in harvesting internal thoracic arteries for grafting in coronary artery bypass procedures [12] [13].

The current generation of Harmonic shears (HD 1000i) consists of multifunctional devices that can be used for dissection, coaptation, coagulation and transection during laparoscopic or open surgical procedures. The Adaptive Tissue Technology system found in HD 1000i shears was designed to deliver a precise amount of thermal energy during tissue transection and vessel sealing. Multiple clinical studies have demonstrated effective use of Harmonic HD 1000i Shears in various specialties such as pancreatectomy [14], breast reconstruction capsu-

lectomy [15], laparoscopic hysterectomy [16], and esophagectomy [11]. In addition, several clinical meta-analyses have indicated that Harmonic devices were associated with significant reductions in operating time [17] [18] [19], blood loss [17] [19] [20], post-operative pain [19], complications [21], length of hospital stay [17] [21], and costs [21]. The objective for the current study was to evaluate Harmonic HD 1000i Shears for use in thoracoscopic procedures in adult subjects using a retrospective medical chart analysis.

2. Methods

2.1. Study Design and Subject Population

This retrospective study was carried out on adult patients who underwent thoracic surgery in which the Harmonic HD 1000i shears (Ethicon-Endo Surgery, Puerto Rico, USA; product codes HARHD20 and HARHD36) were used from May 1, 2018, to November 30, 2020, at Severance Hospital (Yonsei University Health System, South Korea). The ethics review board provided approval of the protocol prior to study onset and the study was carried out following the Declaration of Helsinki and local regulations. Due to the retrospective study design, informed consent was waived.

Subject inclusion criteria included individuals older than 18 years of age who underwent a thoracoscopic lobectomy or segmentectomy using the HD 1000i shears. Exclusion criteria included the use of any additional advanced energy device (such as ultrasonic, bipolar, or laser) in the same procedure and any subject with a missing value (e.g., hemoglobin level). The HD 1000i shears were utilized intraoperatively specifically to dissect, cut, and seal vessels in lobectomies and segmentectomies.

2.2. Study Objective and Endpoints

The objective of the study was to evaluate the safety and performance of the HD 1000i shears in thoracic procedures. The primary endpoint of this study was the rate of post-operative transfusions that were related to the study device (Harmonic HD 1000i) or the procedure. Secondary endpoints included the occurrence of intra-operative or post-operative adverse events or complications possibly device- or procedure-related, and the rate of any additional hemostatic measures required (e.g., hemoclips, staples, sutures, topical hemostats).

2.2.1. Data Collection and Study Variables

Designated study personnel reviewed electronic medical records and identified adult subjects for inclusion in the study. Subject data was de-identified and stored in a secure database for analysis. Study variables collected included basic subject demographic information (age and gender), BMI, pre-operative hemoglobin levels, and the primary indication for surgery. Procedural details included the type of operation, study device information (*i.e.*, product code and number), and surgical approach. Adverse events were chronicled as was operative time, estimated blood loss and transfusion data, and any concomitant procedures

performed. Post-operative details included length of stay (LOS), adverse events (AEs), re-operation or re-admission associated with the primary procedure, blood transfusion, and morality occurring that period. The interval window was defined as a short-term postoperative follow-up period (up to 30 days) or for the duration of post-surgical follow-up if fistula formation was present.

2.2.2. Statistical Methods

All data analysis was performed with R Data Analysis (R Foundation for Statistical Computing, Vienna, Austria). A minimum sample size of 234 was determined based upon an internal study using the Premier Healthcare Database showing that the risk of blood transfusion in thoracic surgeries utilizing the HD 1000i shears was 4.9%. The calculated sample size provided greater than 80% power to rule out a doubling of the reference rate of 4.9% with a one-sided significance level of 0.025.

Descriptive analyses included summarization of categorical variables with frequencies and associated percentages, determination of means, standard deviations, and medians and ranges for continuous variables. Confidence intervals were provided for procedure-related variables. Secondary endpoints including adverse events/complications and additional hemostatic interventions were summarized with counts and percentages. Only observed data were summarized with no imputation for missing data performed.

Confidence intervals were calculated for the primary endpoints observed in the study. A null hypothesis (H_0) was defined as: $p \geq 9.8\%$, where p = the observed rate of transfusions in the study and 9.8% is the doubling of the reference rate. The null hypothesis was rejected if the upper bound of the 95% confidence interval was strictly less than 9.8; *i.e.*, the alternative hypothesis (H_a) was $p < 9.8\%$.

3. Results

Of the total 1370 subjects found in the database, 389 were excluded: n = 34 were open procedures, 327 were thoracic cases other than lobectomies or segmentectomies, and the remainder did not have complete medical records (**Figure 1**). Finally, 981 subjects were included (n = 766 lobectomies; n = 215 segmentectomies) with the mean age being 63.79 ± 10.23 years and 63.19 ± 11.55 years and 52% and 54% being male, respectively. The main surgical indications were primary lung cancer (93% lobectomy, 76% segmentectomy), metastatic lung cancer (3% lobectomy, 17% segmentectomy), and benign lung disease (4% lobectomy, 7% segmentectomy) as shown in **Table 1**.

The incidence of intraoperative blood transfusion was 0.001% in the lobectomy group and 0% in the segmentectomy group. Mean pre-operative hemoglobin levels were 13.28 g/dl (lobectomy) and 13.31 g/dL (segmentectomy) compared with 11.36 g/dL (lobectomy) and 11.31 g/dL (segmentectomy) post-operatively (**Table 2**). Reported post-operative complications and AEs were 9% and 4% (lobectomy and segmentectomy, respectively) none of which were deemed device

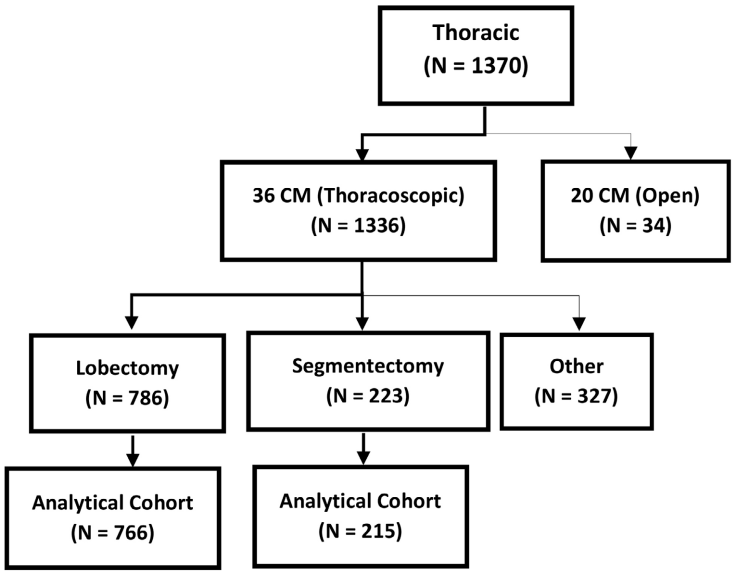

Figure 1. Patient disposition. Of the 1370 thoracic cases found, 389 Subjects excluded: 34 were open; 327 surgeries other than lobectomy or segmentectomy; 28 did not have complete electronic medical records.

Table 1. Pre-operative demographic and surgical characteristics.

		Lobectomy		Segmentectomy	
		N	%	N	%
Cohort size		766		215	
Age (years)	Mean ± SD	63.79 ± 10.23		63.19 ± 11.55	
BMI (kg/m²)	Mean ± SD	24.21 ± 3.36		24.24 ± 2.70	
Gender	Female	365	48%	100	47%
	Male	401	52%	115	54%
Indication	Primary lung cancer	713	93%	163	76%
	Metastatic lung cancer	24	3%	36	17%
	Benign lung disease	29	4%	16	7%

Table 2. Comparison of pre- and post-operative hemoglobin levels. Values are given as number ± standard deviation.

	Lobectomy	Segmentectomy
Cohort Size	766	215
Pre-operative hemoglobin level (g/dl)	13.28 ± 1.58	13.31 ± 1.53
Date difference (days)	−0.48 ± 2.07	−0.59 ± 2.45
Post-operative hemoglobin level (g/dl)	11.36 ± 1.36	11.31 ± 1.32
Date difference (days)	4.24 ± 2.20	3.83 ± 1.97
Hemoglobin differences (Post - Pre)	−1.92 ± 1.14	−2.00 ± 1.12

related. The median operative times were 108 min. (35min, 395 max) for lobectomies and 105 min. (32 min, 574 max) for segmentectomies. Estimated blood loss was 50 mL (0 min, 3200 max) and 20 mL (0 min, 800 max), concomitant operative procedures 0.0003% and 1%, and intraoperative AE or complication rate of 1% and 2% for lobectomy and segmentectomy, respectively (Table 3). Specifically, intra-operative AEs/complications occurred in 14 subjects (9 lobectomy; 5 segmentectomy) of which 13 were deemed to be device-related, with one surgical complication (bleeding) occurring. Of the 13 device-related complaints, 10 were deemed "mild" and 3 "moderate" in severity. The designation of mild indicated that the complaint did not negatively affect the device user's normal activities and caused a minimal inconvenience, while moderate indicated an inconvenience that might have significantly hindered the user's normal activities. The 13 AEs/complications were device-related complaints and mechanical in nature. Due to the retrospective nature of the study, specific device complaints could not be identified in all cases but causes for device failure included foreign matter present in device, pad melting, failure to conduct, misfire, and device error messages.

Re-admission rates were 0.001% and 0% in the lobectomy and segmentectomy groups, respectively. Table 4 shows the post-operative AEs based upon the coded system class. A total of 7 patients died during the study period none of which were deemed device related (n = 6 lobectomy; n = 1 segmentectomy) (Table 5). The rate of hemostatic agents utilized was not analyzed given the difficulty in reliably compiling this variable from the electronic medical records.

4. Discussion

HD 1000i was introduced in 2017 as an ultrasonic shears device that could seal vessels up to and including 7 mm in diameter, similar to its precursor, the Harmonic ACE+7, but with superior dissecting capabilities [22]. The jaws of HD

Table 3. Intra-operative characteristics.

		Lobectomy		Segmentectomy	
		N	%	N	%
Cohort size	**N**	**766**		**215**	
Operative time (min)	Mean ± SD Median (min, max)	117.18 ± 42.4 108 (35, 395)		111.35 ± 48.6 105 (32, 574)	
Estimated blood loss (ml)	Mean ± SD Median (min, max)	75.16 ± 192.85 50 (0, 3200)		42.35 ± 75.82 20 (0, 800)	
Concomitant surgical procedure	N	3	0.003%	2	1%
Intra-operative complaint/adverse event/complication	N	9	1%	5	2%

Table 4. Summary of coded post-operative adverse events/complications based on system organ classes.

System Organ Class	Subjects (#)	Events (#)
Cardiac	5	5
Infections & infestations	16	16
Injury, poisoning, procedural	4	4
Nervous system	2	2
Renal/urinary	1	1
Respiratory, thoracic, mediastinal	50	56
Surgical/medical	2	2
Other	7	7

Table 5. Post-operative clinical characteristics for thoracic patients.

		Lobectomy		Segmentectomy	
		N	%	N	%
Cohort size	**N**	**766**		**215**	
Length of hospital stay (days)	Mean ± SD Median (min, max)	8.97 ± 12.84 7 (4, 208)		7.52 ± 10.82 6 (4, 158)	
Re-operation	N	1	0.001%	0	0%
Re-admission	N	22	3%	3	1%
Mortality	N	6	1%	1	1%
Post-op adverse event/complication	N	65	9%	8	4%

1000i are longer and designed to mimic the profile of a Maryland dissector. Lengthening the jaw necessitated decreasing the resonant frequency of HD 1000i to approximately 50 kHz, which had the propitious side effect of producing even stronger seals in less time.

A review of studies performed since its launch [23] has shown the benefits of HD 1000i in a variety of procedures, including pancreatectomy, breast reconstruction, capsulectomy, laparoscopic hysterectomy, and esophagectomy. As early as 1997, the superior dissecting skills of Harmonic technology was recognized in thoracic procedures such as artery harvesting [24], and continual improvements in the technology keeps Harmonic at the forefront of thoracic dissection today [25]. Recent advances in the understanding of device-tissue interactions has now permitted the use of certain Harmonic devices in sealing vessels as large as 7 mm in diameter, and the first of these devices, the Harmonic ACE+7, has been successfully used to seal pulmonary artery branch vessels in a large international study of pulmonary lobectomy [6].

While HD 1000i is designed to be superior to its previous incarnation in terms

of dissection, and hence should be highly suitable for thoracic applications, there has been only one VATS study published to-date, in which post-thoracotomy pain was evaluated [26]. In this study we assessed use of HD 1000i in thoracoscopic applications, specifically pulmonary lobectomy and segmentectomy, in a large cohort of male and female adult subjects. Our primary endpoint, the rate of transfusion, was low for both intra-operative and post-operative transfusion and significantly below our pre-determined success criterion, demonstrating effective hemostasis. Based upon pre-operative and post-operative hemoglobin level measurements, there was no clinically significant change post-surgery although a slight decrease was observed. Only one subject was reported to have had intra-operative bleeding though it is not clear the outcome of that event due to the retrospective design of this study.

Most of the intra-operative device complaints were related to tissue build-up on the jaws and were resolved without consequence or impact to the patient. Two devices experienced slight jaw pad melting, which did not otherwise affect the surgical procedure. This occasional melting results from maintaining the device activated for too long, and has been rectified in a modified design that limits the maximum temperature of the device [23]. There were no post-operative adverse events/complaints related to the HD 1000i device. Morbidity/mortality occurrences were related to the severity of the disease, principally primary lung cancer, and not deemed to be related to the device.

A limitation of this single-arm study was that no direct comparison could be made to other hemostatic approaches. Additionally, it was difficult to accurately ascertain the rate of additional required hemostats given the retrospective nature of the study. While the number of complaints and AEs/complications were collected, it was difficult to determine if they were possibly related to the study device due to the presence of other complex factors including the patient's general condition, underlying disease, and disease severity.

5. Conclusion

In conclusion, the low rate of bleeding, demonstrates that HD 1000i can be used confidently for thoracoscopic pulmonary resection in adults. Future work should focus on examining the differences between HD 1000i and other advanced energy devices to show where the application of Harmonic H1000i provides the largest benefit.

Conflicts of Interest

JRW, PPV and GAT are employees of Ethicon Inc.

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