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Safety and Performance of the HD1000i Shears in Urologic Procedures: A Retrospective Review

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Abstract: *Background:* Ultrasonic devices including the Harmonic HD1000i Shears are utilized for incision, dissection, and separation and division of tissues to achieve hemostatic transection of vessels in a wide range of procedures. This study was conducted to further evaluate the safety and performance of the HD1000i in a clinical setting use during urologic procedures. *Methods*: The primary endpoint of this retrospective, observational, single-arm study was intra- and post-operative transfusions deemed related to study device. Secondary endpoints were occurrences of intra-operative and post-operative adverse events (AEs) or complications possibly related to the procedure or device. Adult patients who underwent open cystectomy (OC), or laparoscopic (LN) or open nephrectomy (ON) from May 1, 2018 to November 30, 2020 at Severance Hospital (South Korea) where the device had been utilized (without the use of alternative advanced energy device used) were included in this study. *Results*: One-hundred and five subjects met inclusion criteria: 48 in OC, 18 in ON, and 39 in LN. Overall blood transfusion rates were 52.1% (25/48), 38.9% (7/18), and 5.1% (2/39) for the OC, ON, an LN groups, respectively, and 32.4% (34/105) overall. AE's/complications were reported in 2.9% of subjects: one in the ON group (6%) and 2 in the LN subset (5%). *Conclusion*: Analysis of a single institution's experience with the Harmonic HD1000i device in urologic surgery demonstrates acceptable safety and efficacy comparable to the published literature.

Keywords: Urologic Surgery, HD1000i Shears, Safety, Performance, Ultrasonic Shears

1. Introduction

Bleeding control and prevention in surgery relies on a succession of tasks including safely identifying, dissecting, ligating/sealing, and dividing vessels to minimize intra- and post-operative risk of hemorrhage. [1] Mechanical and energy-based modalities are commonly used for ligation and sealing of vessels. The most frequently employed energy-based tools employ radiofrequency electrosurgery and/or ultrasonic energy. [2-5] Ultrasonic energy devices convert electrical energy into mechanical energy, providing a rapid motion, to first seal and then transect vessels. These various devices have partially addressed risks and complications which are frequently observed during electrosurgery including bleeding and localized thermal injuries. [6. 7] Ultrasonic devices are frequently utilized beyond hemostasis for incision, dissection, separation and division of tissues in a wide range of procedures and specialties. [8, 9] Benefits for

their use include improved vessel sealing, tissue dissection, minimized impact on tissue, decreased surgical time, lowered risk of adhesion formation post-operatively, and decreased surgical smoke creation. [10-12] Part of a consistent evolution towards refined performance and safety, an earlier generation of ultrasonic device, the Harmonic ACE®+7 (Ethicon, Inc, Cincinnati OH), brought an advanced algorithm which assesses tissue within the device jaws and responds accordingly to alter energy based upon tissue type and thickness. [13] This allowed the device to seal vessels up to and including 7mm.

The use of a contemporary device reported on in this study, the Harmonic HD1000i Shears (Ethicon, Inc., Cincinnati OH), is an iterative device based upon the Harmonic ACE®+7 Shears. The HD1000i shears simultaneously divides and coagulates tissue by use of its titanium blade vibrating at 49-50,000 Hz while preventing bleeding and is particularly useful for soft tissue dissection when minimization of bleeding and thermal injury is required. Harmonic devices allow surgeons to both incise paucivascular tissues and achieve hemostatic transection of larger blood vessels. While early iterations of ultrasonic devices could transect vessels up to 5 mm in diameter, the Harmonic ACE+7 and HD1000i Shears allow for dissection and sealing of vessels with a diameter up to 7 mm allowing for a reduction in instrument changes which are often necessitated in complicated surgical interventions. [14, 15] There are two available shaft lengths of the HD1000i Shears primarily designed for open or minimally invasive procedures (20 cm and 36 cm). [16] Devices of both lengths have been effectively utilized in a wide variety of surgical specialties and distinct procedures, including esophagectomy [17], hysterectomy [12], breast reconstruction capsulectomy [18], adrenalectomy [19], and pancreatectomy [20]. Ota et al. reported its successful use on a chest wall desmoplastic fibroblastoma [21]. Post market clinical follow-up data, though, on its use is lacking in the field of urologic surgery. It is in this context that this retrospective study was conducted with the aim of further evaluating the safety and performance of the HD1000i Shears in real world use in the adult population during urologic surgical procedures.

2. Methods

2.1. Study Design and Subject Population

This was a retrospective, observational, single-arm study conducted at a single Medical Center in Korea. Adult patients who underwent urologic surgery in which the Harmonic HD1000i Shears (product codes HARHD20 and HARHD36, Ethicon, Inc., Cincinnati OH) were used at Severance Hospital (Yonsei University Health System, South Korea) from May 1, 2018 to November 30, 2020 were screened for inclusion. Institutional Review Board (IRB) approval was obtained prior to study onset and informed consent was waived due to the study's retrospective design. Subject inclusion criteria were patients 18 years of age or older who had undergone a clinically prescribed urologic procedure (cystectomy or nephrectomy) during which the HD1000i Shears were used. Exclusion criteria included the use of any other advanced energy device (i.e., ultrasonic, bipolar, or laser) in addition to the HD1000i Shears during the same procedure. There were no prior or concomitant therapy restrictions of subjects. The objective of the study was to further evaluate real-world safety and performance of the HD1000i shears in adult patients undergoing urologic operations.

2.2. Study Endpoints

The primary endpoint of this study was the rate of intra- and post-operative (collectively "perioperative") transfusions performed that were deemed related to the study device or procedure. An internal study utilizing hospital billing records contained in the Premier Healthcare Database (PHD) [22] indicated that the risk of blood transfusion in urologic procedures where the HD1000i Shears device was used was 9.9%. The following hypothesis was tested: H_0: $p \geq 19.8\%$ vs. H_1: $p < 19.8\%$, where p represents the true rate of intra-operative or post-operative transfusions performed that are possibly related to the study device or procedure. The value of 19.8% here represents a doubling of the reference rates from the PHD review. A 95% confidence interval was calculated for the rate of the primary endpoint observed in this study and the null hypothesis was to be rejected if the upper bound of that confidence interval was less than 19.8%. A sample size of 101 subjects provided greater than 80% power for ruling out a doubling of the reference rate of 9.9%. Secondary endpoints included the occurrence of intra- or post-operative adverse events (AEs) or complications possibly related to the procedure or device tracked up to 30 days out.

2.3. Data Collection and Study Endpoints

Designated study personnel reviewed electronic medical records from Severance Hospital and identified and screened adult subjects for inclusion in the study. Data from medical records were collected and recorded to a source worksheet, and subsequently uploaded into the Research Warehouse Database for analysis. Subjects' demographic information, medical history, procedural details, and postoperative course were collected. Specifically, baseline data collected included age, gender, and primary indication for surgery. Operative details collected were primary surgical procedure performed, any concomitant procedures performed, study device utilized (product code and number), surgical approach (open, laparoscopic, or robotic), intraoperative AEs/complications, device malfunctions, and any blood transfusions. Postoperatively transfusions and AEs/complications through 30 days were captured. All subject protected health information was maintained and research performed in accordance with the ethical standards of the IRB and Declaration of Helsinki.

2.4. Statistical Methods

Data analysis was performed with R Data Analysis (R Foundation for Statistical Computing, Vienna, Austria). 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. Subset analyses were additionally performed, dividing the patients into three groups: open cystectomy (OC), open nephrectomy (ON), and laparoscopic nephrectomy (LN).

3. Results

A total of 105 patients who met criteria were included: 48 in OC, 18 in ON, and 39 in LN. There was no significant difference in demographic composition of the three groups in terms of patient sex (p=0.10), age (p=0.20), or BMI (p=0.15). The most common primary indications for surgery were bladder cancer, renal cell cancer, and ureter cancer (Table 1).

The overall blood transfusion rates were 52.1%, 38.9%, and 5.1% for the OC, ON, and LN groups, respectively, and an overall rate of 32.4% (Table 2). Only the upper 95% CI for laparoscopic nephrectomy was below the hypothesis criterion of 19.8%. Intra-operatively there were 32 transfusions, 24 for OC, 6 for ON and 2 for LN. Postoperatively, 25 OC, 7 ON, and 1 LN subjects received blood transfusions. Of the 33 patients who received post-operative transfusions, 18 subjects were had also required transfusions intra-operatively. Among these, 14 subjects were in the OC group, 3 in the ON group, and 1 patient in the LN group. Two re-admissions occurred, both in the OC group, neither of which required transfusions during the readmission.

Mean operative times were 223±74 min, 200±114 min, and 153±65 min for OC, ON, and LN groups, respectively (Table 3). Mean blood loss was 921±549 mL for the OC group, 938±1362 mL for the ON group, and 196±353 mL for the LN group. AEs/complications were reported intraoperatively in 2.9% of subjects: one in the ON group (6%) and 2 in the LN subset (5%). All three of these AEs were bleeding, and therefore determined to be possibly related to the study device. In the post-operative period, 13 AEs were reported, only 4 of which were bleeding and therefore deemed possibly related to the study device (2 in group OC, 2 in group ON). The remaining unrelated AEs were atelectasis (4), ileus (4), and fever (1). One subject in the ON group experienced both an intra-operative and post-operative AE of bleeding, but no re-operations were required in any group during the study period. There were no reported deaths.

Concomitant procedures occurred in 22% in the ON group and 8% of the OC group, while no concomitant procedures were performed in the LN group. These procedures included exploratory laparotomy, distal pancreatectomy, primary repair of perforated mesentery and intestine, Hartmann's operation, repair of rectum, adhesiolysis, resection of jejunum, and diverting ileostomy. Mean pre-operative hemoglobin levels were 11.5±2.2 g/dL, 11. 9±3.0 g/dL, and 12.4±2.0 g/dL in the OC, ON, and LN groups, respectively. Mean post-operative hemoglobin levels were 10.0±1.2 g/dL, 10.4±2.2 g/dL, and 11.2±1.7 g/dL in the OC, ON, and LN groups, respectively (Table 4).

Mean length of stay was 24.0±21.2, 11.4±5.8, and 8.3±4.5 days for the OC, ON, and LN groups, respectively (Table 5). No re-operations were performed during the study. There were no reported deaths. While there were 13 post-operative AEs/complications (17%, 17%, and 5% in the OC, ON, and LN groups, respectively). AEs/complications were comprised of bleeding (n=4), ileus (n=4), atelectasis (n=4), and fever (n=1).

Table 1. *Demographic and surgical characteristics.*

		Open Cystectomy		Open Nephrectomy		Laparoscopic Nephrectomy	
		N	%	N	%	N	%
Cohort size		48		18		39	
Age (years)	Mean±SD	67.0±14.6		60.7±16.6		62.0±13.6	
BMI (kg/m^2)	Mean±SD	22.5±3.0		23.7±4.3		23. 9±3.7	
Gender	Female	9	19%	8	44%	12	31%
	Male	39	81%	10	56%	27	69%
Indication	Bladder cancer	44	92%	0	0%	0	0%
	Renal cell cancer	0	0%	14	78%	15	39%
	Renal pelvis cancer	0	0%	0	0%	8	21%
	Ureter cancer	2	4%	3	17%	11	28%
	Other	2	4%	1	6%	5	13%

Table 2. *Overall Rates of Transfusion.*

Procedure	Transfusions	N	Rate	95% CI	p-value
Cystectomy (open)	25	48	52.1%	0.0-64.6%	1.000
Nephrectomy (open)	7	18	38.9%	0.0-38.9%	0.985
Nephrectomy (laparoscopic)	2	39	5.1%	0.0-15.3%	0.010
Total (open & laparoscopic)	34	105	32.4%	0.0-40.7%	0.999

Table 3. *Intra-operative characteristics.*

		Open Cystectomy		Open Nephrectomy		Laparoscopic Nephrectomy	
		N	%	N	%	N	%
Cohort size	N	48		18		39	
Operative time (min)	Mean±SD	223±74		200±114		153±65	
Estimated blood loss (mL) [max, min]	Mean±SD [Median]	921±549 [850]		938±1362 [425]		196±353 [100]	
Concomitant surgical procedures	N	4	8%	4	22%	0	0%
*Intra-operative AEs / complications	N	0	0%	1	6%	2	5%

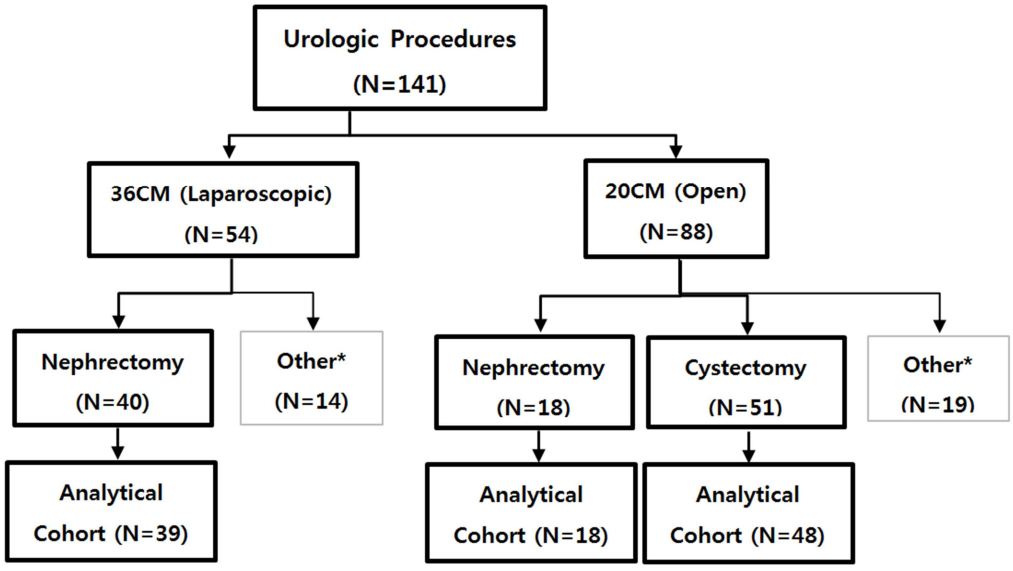
Table 4. *Comparison of pre- and post-operative hemoglobin levels.*

	Open Cystectomy	Open Nephrectomy	Laparoscopic Nephrectomy
Cohort size (N)	5	18	39
Pre-operative hemoglobin level (g/dl) [Mean±SD]	11.5 ± 2.3	11.9 ± 3.0	12.4 ± 2.0
Post-operative hemoglobin level (g/dl) [Mean ± SD]	10.0 ± 1.2	10.4 ± 2.2	11.2 ± 1.7
Hemoglobin differences *(Post - Pre)*	-1.53 (1.98)	-1.52 (2.02)	-1.19 (1.21)

Table 5. *Post-operative characteristics.*

		Open Cystectomy		Open Nephrectomy		Laparoscopic Nephrectomy	
		N	%	N	%	N	%
Cohort size	N	48		18		39	
Length of hospital stay (days)	Mean±SD (Median)	24.0±21.2 (16.0)		11.4±5.8 (9.5)		8.3±4.5 (7.0)	
Re-operation	N	0	0%	0	0%	0	0%
Re-admission	N	2	2%	0	0%	0	0%
Mortality	N	0	0%	0	0%	0	0%
*Post-operative AEs/complications	N	8	17%	3	17%	2	5%

*The N values in 'Post-operative adverse event/complication' do not include complaints/malfunctions.



*Excluded from study

Figure 1. *Patient disposition.*

4. Discussion

Various ultrasonic surgical energy devices have demonstrated safety and efficacy in a variety of procedures. [9-12] This post-market study demonstrates the safety of the Harmonic HD1000i. The primary endpoint of this study for intraoperative and postoperative blood transfusions was a rate of 32.4%, which was substantially higher than the rate anticipated from the PHD review of 9.9%. In fact, only the rate for laparoscopic nephrectomy of 5.2% (upper 95% CI: 15.3%) met the hypothesis criterion. The rate of 9.9% was determined by using results for HD1000i in urology procedures. Since HD1000i is designed for laparoscopic surgery, the results from the PHD review primarily represent laparoscopic procedures.

A review of the literature shows that transfusion rates are substantially higher for open procedures. For open cystectomy, where we observed a rate of 52.1%, the literature reports rates ranging from 38% to 60%. [23-27] For open nephrectomy, where we observed a rate 38.9%, transfusion rates in the literature range from 21.4% to 45.5%. [28-31]

For laparoscopic nephrectomy, where we observed a rate of only 5.1%, the literature has rates of 9% [29] and 11.1% [32], similar to our anticipated rate from the PHD review of 9.9%. The transfusion rate for all three procedures for HD1000i was within or below the range of rates that have been historically observed.

Using average values from the literature, i.e., 50.5% for cystectomy, 32.8% for open nephrectomy, and 10.1% for laparoscopic nephrectomy, and using the same weighting by procedure as our study, the overall transfusion rate would be estimated to be 32.5%, nearly identical to our observed value of 32.4%. While there is an indication that HD1000i may be superior to the standard of care for laparoscopic procedures, it appears to be similar to conventional methods when both open and laparoscopic approaches are included. Moreover, there are no signs indicating that transfusions were device related.

Adverse events also occurred at an acceptable rate as compared to previously published studies. Of the 105 total subjects, 15 experienced an AE (14.3%), compared with 17-29% in the literature [33, 34] (one patient experienced two AEs, intra- and post-operative bleeding). Furthermore, only seven of the 16 AEs were deemed possibly related to study device use. Importantly, no re-operation was performed, only two readmissions occurred, and no deaths were observed. Unfortunately, it was impossible to ascertain whether some of the intra- and post-operative AEs were device related.

This study does have several limitations. Initial study design was intended to produce adequate sample sizes to achieve statistically significant non-inferiority of primary endpoint occurrence rates at 80% power compared to baseline occurrence in PHD data. However, significant heterogeneity between procedure sub-groups makes it impossible to designate an accurate pooled baseline rate. For example, cystectomy is a surgery with inherently more average blood loss than nephrectomy regardless of operative approach, and subsequently higher need for blood transfusions. [26, 35] Furthermore, a number of patients in the open procedures groups underwent multiple procedures at once (upwards of 22% in the ON group), including several major procedures that would have undoubtedly impacted the blood loss and overall risk of primary and secondary endpoints. However, due to the retrospective nature of this study these details were not able to be further investigated.

Additionally, due to the retrospective nature of this study, some specifics were not able to be precisely resolved. For instance, transfusion protocols might have been different between the United States (source for the PHD data) and Korea, and this might have inflated the transfusion rates observed in this analysis. Moreover, there was little available data to determine whether some of the AEs during surgery or the post-operative period possibly were device related. Any possible relationships were therefore necessarily inferred from AE type, but it is conceivable that a bleeding event or transfusion requirement was caused by something other than use of the study device.

5. Conclusion

Analysis of a single institution's experience with the Harmonic HD1000i device in urologic surgery demonstrates acceptable safety and efficacy as compared with expected rates.

Conflict of Interests

MS, JW, PG, PV. and GT are employees of Ethicon, Inc. The other authors declare that they have no competing interests.

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