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RESEARCH PAPER

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Complications associated with energy-based devices during thyroidectomy from 2010–2020

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Abstract

Objective: Harmonic Focus (Ethicon, Johnson and Johnson, Cincinnati, OH, USA), LigaSure Small Jaw (Medtronic, Covidien Products, Minneapolis, MN, USA), and Thunderbeat Open Fine Jaw (Olympus, Japan) are electrosurgical instruments used widely in head and neck surgery. The study aims to compare device malfunctions, adverse events to patients, operative injuries, and interventions related to Harmonic, LigaSure, and Thunderbeat use during thyroidectomy.

Methods: The US Food and Drug Administration's Manufacture and User Facility Device Experience (MAUDE) database was queried for adverse events associated with Harmonic, LigaSure, and Thunderbeat from January 2005 to August 2020. Data were extracted from reports pertaining to thyroidectomy.

Results: Of the 620 adverse events extracted, 394 (63.5%) involved Harmonic, 134 (21.6%) LigaSure, and 92 (14.8%) Thunderbeat. The reported device malfunctions most frequently associated with Harmonic was damage to the blade (110 (27.9%)), LigaSure was inappropriate function (47 (43.1%)), Thunderbeat was damage to the tissue or Teflon pad (27 (30.7%)), respectively. Burn injury and incomplete hemostasis were the most commonly reported adverse events. The operative injury reported most frequently when using Harmonic and LigaSure was burn injury. No operator injuries were reported with Thunderbeat use.

Conclusion: The most frequently reported device malfunctions were damage to the blade, inappropriate function, and damage to the tissue or Teflon pad. The most frequently reported adverse events to patients was a burn injury and incomplete hemostasis. Interventions aimed at improving physician education may help reduce adverse events attributed to improper use.

KEYWORDS

Adverse events, Harmonic, LigaSure, Manufacture and User Facility Device Experience, Patient safety, Quality, Thunderbeat, Thyroidectomy

INTRODUCTION

Within the United States, approximately 130,000 thyroidectomies are currently performed annually.[1,2] Recognizing the thyroid as a highly vascular gland, early surgeons utilized ligatures, cautery, and caustic substances to control hemorrhage, until the introduction of the first effective hemostatic forceps in 1874.[3] Suture ligature and/or hemostatic clips became a mainstay of thyroid surgery up until the 1980s. With the continued advancement of surgical device development, various energy-based devices (EBD) were introduced over a decade ago, and have demonstrated utility in thyroidectomy.[4,5] The Harmonic Focus (Ethicon, Johnson and Johnson, Cincinnati, OH, USA), LigaSure Small Jaw (Medtronic, Covidien Products, Minneapolis, MN, USA), and Thunderbeat Open Fine Jaw (Olympus, Japan) are among the most commonly used.[6] Recent studies have shown EBD to be used in 58.3% to 65.7% of thyroidectomy cases[7,8] with significantly reduced operative time and intraoperative blood loss.[7]

The Harmonic Focus utilizes ultrasonic energy to simultaneously cut and coagulate, boasting precision and strong vessel sealing at lower temperatures when compared to electrosurgery.[9] In contrast, LigaSure uses bipolar energy to fuse vessels up to 7 mm in diameter using the body's own collagen and elastin, claiming to decrease operative blood loss and procedure time.[10] Thunderbeat is the first device to synergistically use both ultrasonic as well as advanced bipolar energy, allowing quick and precise dissection along with effective vessel sealing.[11] A number of studies have previously investigated the advantages and disadvantages of these energy-based devices for a variety of surgical procedures.[6,12] Within thyroid surgery, these devices have been compared to conventional hemostatic techniques such as clamp-and-tie vessel ligature, and have been shown to decrease operative time and intraoperative bleeding.[13] While a systematic review comparing energy-based devices to conventional hemostatic techniques found no difference in the rate of postoperative hematoma following total thyroidectomy,[14] these devices continue to be preferred for other benefits such as reduced operative time.

While informative, the above studies have largely been limited to the experiences of single institutions. To our knowledge, complications associated with the use of energy-based devices in thyroid surgery have not yet been studied at the national level. The U.S. Food and Drug Administration's (FDA) Manufacturer and User Facility Device Experience (MAUDE) database compile adverse events involving medical devices. Medical device reports (MDRs) include suspected device-associated malfunctions, injuries, and deaths. The database is populated by mandatory (manufacturers, importers, and device user facilities) and voluntary reporters (health care professionals, patients, and consumers). Thus, the MAUDE database is a passive surveillance system limited by potentially incomplete, inaccurate, or biased data, and the database should not be used to determine incidence or prevalence.

Nevertheless, the MAUDE database represents a valuable resource for the surveillance of medical devices and may supplement current literature. Within otolaryngology, MAUDE has been used to examine complications associated with multiple devices including hypoglossal nerve stimulators, tracheoesophageal prosthesis, implantable microvascular dopplers, as well as airway laser use.[15–18] The purpose of this study was to explore adverse events associated with Harmonic, LigaSure, and Thunderbeat use during thyroidectomy, as well as to examine their consequences and potential causes, using a national adverse event reporting database.

METHODS

The MAUDE database was queried using a simple search strategy to identify reports involving Harmonic, LigaSure, or Thunderbeat during thyroidectomy, submitted from January 2005 to August 2020. Exclusion criteria included duplicate reports, cases based on publications in the literature, insufficient information, and procedures other than thyroidectomy. Variables extracted from MDRs included device malfunctions, adverse events to patients, operative injuries, type of surgery, root cause of the events, interventions required during the procedure, resultant patient injury, and timing of the event.

Device malfunction was defined as any event in which the device did not perform as expected during the surgery. Device malfunctions were categorized into six categories: dislodgement of a device component, damaged device component, peeled or delaminated component, temperature problem, activation problem, and functional problem. Dislodgments were further categorized based on the device component involved, including blade, tissue or Teflon pad, clamp arm, and jaw or probe tip. Similarly, the damage was further categorized based on the device component involved, including blade, tissue or Teflon pad, clamp arm, packaging, and peeled or delaminated. Peeled or delaminated components were further categorized based on the device component involved, separating the tip or jaw from the handpiece. Temperature problems were further categorized as overheating, melting, or ignition.

The activation problems were further categorized into unable to activate, unable to inactivate, auto-activation, error message, and incorrect setting. Lastly, functional problems were further categorized into inappropriate function or failure to function. Inappropriate function is defined as the components of the device functioning differently from its primary purposes. Failure to function is defined as the components of the device failing to carry out its primary purposes. Examples include handpiece or button switch malfunction, mechanical jam, or retraction problem. Adverse event to the patient was defined as any event having the potential to harm the patient. Based on event descriptions, the following adverse events to patients were recorded: burn injury, incomplete hemostasis, unintentional tissue damage, and vocal cord injury. Adverse event to the operator was defined as any event having the potential to harm the operator. Based on event descriptions, the following adverse event to the operator was recorded: burn injury.

In some cases, both an adverse event to patient and a device malfunction were extracted from the same MDR. For example, an

MDR describing an event in which device overheating resulted in a patient burn would be extracted as two adverse events: one device malfunction and one adverse event to patient. Furthermore, some MDRs included more than one adverse event to patient or multiple device malfunctions. For example, an MDR describing both blade damage and dislodgment of the blade would be extracted as two device malfunctions. Thus, the total number of adverse events is greater than the number of reports extracted from the MAUDE database. Each MDR was also categorized based on the type of thyroidectomy performed: open, robotic, or endoscopic. If not explicitly specified, the categorization was deduced from the event description when possible.

If explicitly stated, the root cause of device malfunctions, adverse events to patients, and operative injuries were categorized as operator error or defective device. Interventions required during the procedure were likewise recorded if specified in the event description. Interventions following device malfunctions included switching to a replica of the same device or to an alternative device. Medical interventions following adverse events to patients or operators were recorded. Device malfunctions leading to adverse events to patients were also recorded. The timing of adverse events to patients or operators was categorized as intraoperative or postoperative.

This study met exemption criteria established by the Institutional Review Board from the George Washington School of Medicine and Health Sciences.

RESULTS

A total of 659 MDRs occurring during thyroidectomy were identified, with 402 involving Harmonic, 181 LigaSure, and 76 Thunderbeat. After excluding 27 duplicates, 118 based on publications in the literature, and 31 with insufficient information, 483 MDRs were included in this study. From these 483 MDRs, a total of 620 adverse events were extracted.

Table 1 summarizes adverse events by category for Harmonic, LigaSure, and Thunderbeat. Of the 620 adverse events, 394 (63.5%) involved Harmonic, 134 (21.6%) LigaSure, and 92 (14.8%) Thunderbeat. Of the 394 events involving Harmonic, 349 (88.6%) were device malfunctions, 42 (10.7%) were adverse events to patients, and 3 (0.8%) were operative injuries. Of the 134 events involving LigaSure, 109(81.3%) were device malfunctions and 25 (18.7%)? were adverse events to patients; no operative injuries were reported. Of the 92 events involving Thunderbeat, 88 (95.7%) were device malfunctions, 2 (2.2%) were adverse events to patients, and 2 (2.2%) were operative injuries.

The most common device malfunction associated with Harmonic was damaged blade (111 (31.8%)), followed by dislodgment of blade (82 (23.5%)). Of adverse events to patients, incomplete hemostasis (23 (54.8%)) was the most common, followed by burn injury (13 (31.0%)). With LigaSure, the most common device malfunction was an inappropriate function (47 (43.1%)), followed by a peeled or

TABLE 1 Adverse Events by Category(n = 620, n(%))

Adverse events	Harmonic (*n* = 394)	Ligasure (*n* = 134)	Thunderbeat (*n* = 92)
Device Malfunction			
Dislodgment of device components	111 (31.8)	6 (5.5)	33 (37.5)
Blade	82 (23.5)	0 (0)	0 (0)
Tissue pad or teflon pad	21 (6.0)	0 (0)	23 (26.1)
Clamp arm	8 (2.3)	0 (0)	0 (0)
Jaw or probe tip	0 (0)	6 (5.5)	10 (11.4)
Damaged device components	119 (34.1)	0 (0)	27 (30.7)
Blade	110 (31.5)	0 (0)	0 (0)
Tissue pad or teflon pad	6 (1.7)	0 (0)	27 (30.7)
Clamp arm	2 (0.6)	0 (0)	0 (0)
Packaging	1 (0.3)	0 (0)	0 (0)
Peeled or delaminated components	3 (0.9)	42 (38.5)	16 (18.2)
Tip or Jaw	3 (0.9)	42 (38.5)	0 (0)
Handpiece	0 (0)	0 (0)	16 (18.2)
Temperature problem	26 (6.6)	1 (0.9)	5 (5.7)
Device overheating	12 (3.4)	0 (0)	0 (0)
Melted	13 (3.7)	0 (0)	4 (4.5)
Ignition	1 (0.3)	1 (0.9)	1 (1.1)
Activation problem	45 (12.9)	1 (0.9)	6 (6.8)
Unable to activate	19 (5.4)	0 (0)	0 (0)
Unable to inactivate	1 (0.3)	1 (0.9)	0 (0)
Auto-activation	8 (2.3)	0 (0)	0 (0)
Device displays error message	16 (4.6)	0 (0)	6 (6.8)
Incorrect control setting	1 (0.3)	0 (0)	0 (0)
Functional problem	45 (12.9)	59 (54.1)	1 (1.1)
Inappropriate function	21 (6.0)	47 (43.1)	1 (1.1)
Failure to function	24 (6.9)	12 (11.0)	0 (0)
Total	349 (88.6)	109 (81.3)	88 (95.7)
<Adverse event to patient >			
Incomplete hemostasis	23 (54.8)	17 (68.0)	0 (0.0)
Burn injury	13 (31.0)	6 (24.0)	1 (50.0)
Unintentional tissue damage	2 (4.8)	0 (0)	0 (0.0)

(Continues)

TABLE 1 (Continued)

Adverse events	Harmonic (*n* = 394)	Ligasure (*n* = 134)	Thunderbeat (*n* = 92)
Vocal cord injury	4 (9.5)	2 (8.0)	1 (50.0)
Total	42 (10.7)	25 (18.7)	2 (2.2)
<Operatory injuries >			
Inadvertent burn	3 (100.0)	0 (0)	2 (100.0)
Total	3 (0.8)	0 (0)	2 (2.2)

TABLE 2 Type of surgery

Type	*n*(%)
Open thyroidectomy	424(91.2)
Robotic	22(4.7)
Endoscopic	19(4.1)
Total	465(100.0)

delaminated tip or jaw (42 (38.5%)). Of adverse events to patients, incomplete hemostasis (17 (68.0%)) was the most common, followed by burn injury (6 (24.0%)) and vocal cord injury (2 (8.0%)). While using Thunderbeat, the most common device malfunctions were damaged tissue pad or Teflon pad (27 (30.7%)), followed by dislodgment of tissue pad or Teflon pad (23 (26.1%)). Of adverse events to patients, burn injury (1 (50.0%)) and vocal cord injury (1 (50.0%)) were reported. Adverse events occurred most commonly during open thyroidectomy (424 (91.2%)). Others occurred during robotic (22 (4.7%)) or endoscopic (19 (4.1%)) surgery. These results are summarized in Table 2.

Based on MDRs involving Harmonic that provided information as to the cause of the event, device malfunction was attributed most commonly to operator error (195 (55.9%)), followed by a defective device (27 (7.7%)). With regard to interventions required during the procedure, a new Harmonic device (204 (58.5%)) was substituted most commonly, followed by use of alternative devices (78 (22.3%)). A total of 17 (4.9%) patient injuries resulted from device malfunctions. The device malfunctions associated most commonly with patient injury were inappropriate function (9 (42.9%)), device overheating (4 (33.3%)), and auto-activation (1 (12.5%)).

With LigaSure, operator error (21 (31.3%)) was the cause of device malfunction reported most commonly; no adverse events were attributed to a defective device. With regard to interventions required during the procedure, alternative devices (45 (67.2%)) were used most commonly, followed by use of a new LigaSure (35 (52.2%)). A total of 13 (19.4%) patient injuries resulted from device malfunctions. Inappropriate function (13 (27.7%)) was the device malfunction associated most commonly with patient injury. Using Thunderbeat, operator error (80 (90.9%)) was the most common cause of device malfunction; no adverse events were attributed to a defective device. Interventions during the procedure required most commonly a replacement Thunderbeat (64 (72.7%)), followed by use of alternative devices (23 (26.1%)). No patient injuries were associated with Thunderbeat. These results are shown in Table 3.

The most common cause of patient injury while using Harmonic was operator error (6 (14.3%)). Only one event (2.4%) was attributed to a defective device. The most common patient injuries attributed to operator error included burn injury (3(23.1%)), incomplete hemostasis (2 (8.7%)), and unintentional tissue damage (1 (50.0%)). Fourteen (14 (33.3%)) patient injuries required medical intervention. Most patient injuries occurred intraoperatively (36 (85.7%)), as opposed to postoperatively (6 (14.3%)).

The most common cause of patient injury with LigaSure was operator error (2 (8.0%)); no adverse events were attributed to a defective device. The most common patient injuries attributed to operator error included burn injury (1(16.7%)) and incomplete hemostasis (1(5.9%)). 4 (16.0%) patient injuries required medical intervention. Most patient injuries occurred intraoperatively (23 (92.0%)), with a minority occurring postoperatively (2 (8.0%)).

Patient injury while using Thunderbeat was attributed most commonly to operator error (2 (100.0%)). No reports cited a defective device as the cause of an adverse event. The most common patient injuries attributed to operator error included burn injury (1 (100.0%)) and vocal cord injury (1(100.0%)). No medical intervention was reported following patient injuries associated with Thunderbeat. All patient injuries occurred intraoperatively (2 (100.0%)). These results are shown in Table 4.

The most common cause of operator injury with Harmonic was operator error (2 (66.7%)). No event was reported to be caused by a defective device. The most common operator injury was burn injury (3(100.0%)). No medical interventions were reported. All operator injuries associated with Harmonic occurred intraoperatively (3 (100.0%)). No operator injuries were associated with LigaSure. The most common cause of operator injury with Thunderbeat was operator error (1 (50.0%)). No event was reported to be caused by a defective device. The most common operator injury was burn injury (1 (50.0%)). No medical interventions were reported. All operator injuries associated with Thunderbeat occurred intraoperatively (2 (100.0%)). These results are shown in Table 5.

DISCUSSION

Investigation of the FDA's MAUDE database reveals a variety of device malfunctions, adverse events to patients, and operative injuries associated with the use of energy-based devices during thyroidectomy over a 10-year period. Although patient injuries associated with Harmonic, LigaSure, and Thunderbeat use during thyroidectomy have been reported in the literature,[6] this is the first study to explore comprehensively device malfunctions, adverse events to patients, and operative injuries at the national level.

In this study, damaged device components were the most common device malfunctions associated with both Harmonic and

TABLE 3 Causes and Sequelae of Device Malfunctions

Adverse events	Harmonic						Ligasure						Thunderbeat					
		Cause of event		Intervention		Resultant injury		Cause of event		Intervention		Resultant injury		Cause of event		Intervention		Resultant injury
		Operator error	Defective device	New same device	Another device	Patient injury		Operator error	Defective device	New same device	Another device	Patient injury		Operator error	Defective device	New same device	Another device	Patient injury
	Total, n	*n*(%)	n(%)	n(%)	n(%)	n(%)	Total, n	n(%)	n(%)	n(%)	n(%)	n(%)	Total, n	n(%)	n(%)	n(%)	n n(%)	n(%)
Dislodgment of device components	111						6						33					
Blade	82	50(61.0)	3(3.7)	41(50.0)	29(35.4)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Tissue pad or teflon pad	21	7(33.3)	0(0)	14(66.7)	3(14.3)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	23	21(91.3)	0(0)	17(73.9)	6(26.1)	0(0)
Clamp arm	8	8(100.0)	0(0)	8(100.0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Jaw or probe tip	0	0(0)	0(0)	0(0)	0(0)	0(0)	6	0(0)	0(0)	2(33.3)	2(33.3)	0(0)	10	8(80.0)	0(0)	7(70.0)	2(20.0)	0(0)
Damaged device components	119						0						27					
Blade	110	89(80.9)	4(3.6)	61(55.5)	31(28.2)	2(1.8)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Tissue pad or teflon pad	6	3(50.0)	0(0)	4(66.7)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	27	25(92.6)	0(0)	22(81.5)	5(18.5)	0(0)
Clamp arm	2	2(100.0)	0(0)	2(100.0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Packaging	1	0(0)	1(100.0)	1(100.0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Peeled or delaminated	3						42						16					
Tip or Jaw	3	0(0)	1(33.3)	3(100.0)	0(0)	0(0)	42	17(40.5)	0(0)	12(28.6)	17(40.5)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Handpiece piece	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	16	16(100.0)	0(0)	8(50.0)	8(50.0)	0(0)

(Continues)

TABLE 3 (Continued)

	Harmonic						Ligasure						Thunderbeat					
		Cause of event		Intervention		Resultant injury		Cause of event		Intervention		Resultant injury		Cause of event		Intervention		Resultant injury
Adverse events		Operator error	Defective device	New same device	Another device	Patient injury		Operator error	Defective device	New same device	Another device	Patient injury		Operator error	Defective device	New same device	Another device	Patient injury
Temperature problem	26						1						5					
Device over-heating	12	7 (58.3)	2(16.7)	6(50.0)	1(8.3)	4(33.3)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Melted	13	6 (46.2)	0(0)	6(46.2)	4(30.8)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	4	4(100.0)	0(0)	4(100.0)	0(0)	0(0)
Ignition	1	0(0)	0(0)	1(100.0)	0(0)	0(0)	1	1(100.0)	0(0)	0(0)	1(100.0)	0(0)	1	1(100.0)	0(0)	0(0)	1(100.0)	0(0)
Activation problem	45						1						6					
Unable to activate	19	10(52.6)	3(15.8)	13(68.4)	2(10.5)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Unable to inactivat-e	1	0(0)	0(0)	1(100.0)	0(0)	0(0)	1	0(0)	0(0)	1(100.0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Auto-acti-vation	8	0(0)	1(12.5)	6(75.0)	1(12.5)	1(12.5)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Device displays error message	16	6(37.5)	4(25.0)	14(87.5)	1(6.3)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	6	5(83.3)	0(0)	6(100.0)	0(0)	0(0)
Incorrect control setting	1	0(0)	1(100.0)	1(100.0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Functional problem	45						59						1					
Inappropriate function	21	2(9.5)	1(4.8)	10(47.6)	2(9.5)	9(42.9)	47	2(4.3)	0(0)	14(29.8)	21(44.7)	13(27.7)	1	0(0)	0(0)	0(0)	1(100.0)	0(0)
Failure to function	24	5(20.8)	6(25.0)	12(50.0)	4(16.7)	1(4.2)	12	1(8.3)	0(0)	6(50.0)	4(33.3)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Total	349	195(55.9)	27(7.7)	204(58.5)	78(22.3)	17(4.9)	109	21(31.3)	0(0)	35(52.2)	45(67.2)	13(19.4)	88	80(90.9)	0(0)	64(72.7)	23(26.1)	0(0)

TABLE 4 Causes and Sequelae of Patient Injury

Adverse events	Harmonic						Ligasure						Thunderbeat					
		Cause of event		Intervention	Timing of event			Cause of event		Intervention	Timing of event			Cause of event		Intervention	Timing of event	
		Operator error	Defective device	Medical	Intraop	Postop		Operator error	Defective device	Medical	Intraop	Postop		Operator error	Defective device	Medical	Intraop	Postop
	Total, n	n(%)	n(%)	n(%)	n(%)	n(%)	Total, n	n(%)	n(%)	n(%)	n(%)	n(%)	Total, n	n(%)	n(%)	n(%)	n(%)	n(%)
Incomplete hemo-stasis	23	2(8.7)	0(0)	7(30.4)	17(73.9)	6(26.1)	17	1(5.9)	0(0)	2(11.8)	15(88.2)	2(11.8)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Burn injury	13	3(23.1)	1(7.7)	6(46.2)	13(100.0)	0(0)	6	1(16.7)	0(0)	2(33.3)	6(100.0)	0(0)	1	1(100.0)	0(0)	0(0)	1(100.0)	0(0)
Unintention-al tissue damage	2	1(50.0)	0(0)	1(50.0)	2(100.0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)
Vocal cord injury	4	0(0)	0(0)	0(0)	4(100.0)	0(0)	2	0(0)	0(0)	0(0)	2(100.0)	0(0)	1	1(100.0)	0(0)	0(0)	1(100.0)	0(0)
Total	42	6(14.3)	1(2.4)	14(33.3)	36(85.7)	6(14.3)	25	2(8.0)	0(0)	4(16.0)	23(92.0)	2(8.0)	2	2(100.0)	0(0)	0(0)	2(100.0)	0(0)

TABLE 5 Causes and Sequelae of Operatory Injury.

Adverse events	Harmonic						Ligasure						Thunderbeat					
		Cause of event		Intervention	Timing of event			Cause of event		Intervention	Timing of event			Cause of event		Intervention	Timing of event	
		Operator error	Defective device	Medical	Intraop	Postop		Operator error	Defective device	Medical	Intraop	Postop		Operator error	Defective device	Medical	Intraop	Postop
	Total, *n*	n(%)	n(%)	n(%)	n(%)	n(%)	Total, n	n(%)	n(%)	n(%)	n(%)	n(%)	Total, n	n(%)	n(%)	n(%)	n(%)	n(%)
Burn injury	3	2(66.7)	0(0)	0(0)	3(100.0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	2	1(50.0)	0(0)	0(0)	2(100.0)	0(0)
Total	3	2(66.7)	0(0)	0(0)	3(100.0)	0(0)	0	0(0)	0(0)	0(0)	0(0)	0(0)	2	1(50.0)	0(0)	0(0)	2(100.0)	0(0)

Thunderbeat. With Harmonic, the blade (110 (31.5%)) was the most commonly damaged device component; 89 (80.9%) cases were attributed to operator error, and 4 (3.6%) to defective devices. Examples of operator error included inadvertent external contact with other devices, staples, or clips during the procedure. Further investigation by the manufacturer in the report states that once minor blade damage has occurred, subsequent activation may increase the severity of the blade damage. Furthermore, a damaged blade often resulted in secondary adverse events, most commonly dislodgment of the blade (57), but also activation problems (10), displaying an alert screen (4), failure to function (2), and inappropriate function (1). Despite being the most frequent device malfunction, only 2 events (1.8%) resulted in minor burn injuries that required conservative treatment with antibiotic ointment.

With Thunderbeat, the tissue or Teflon pad (27 (30.7%)) was the most commonly damaged device component. Potential causes include mechanical or thermal damage due to the operator's technique. Further investigation by the manufacturer in the report states that the tissue or Teflon pad can be damaged when an operator continues to activate the device without contacting additional tissue, even after tissue has already been cut. This can increase the temperature of the device due to friction between the probe tip and the grasping section, subsequently leading to further damage to the tissue pad. Damage to the tissue or Teflon pad resulted most commonly in dislodgement requiring retrieval by the operator.

The Thunderbeat instruction manual contains several warning statements aimed at preventing such damage, including “Do not activate output in seal and cut mode while the grasping section is closed without contacting tissue or vessel, or ensuring that tissue is transected,” and “Do not activate output while grasping hard tissue such as bone or highly calcified tissue, or hard objects.” As an additional safety measure, the instruction manual also recommends a spare device be available during the procedure.[19] However, with the recent development of the innovative Type S coating and the revolutionary Intelligent Tissue Monitoring (ITM) safety system, a manufacturer, Olympus (Tokyo, Japan), has achieved an improvement to the temperature profile of the instrument of 26.9% and reduction in surrounding tissue damage by thermal spread. This new concept of optimal temperature control enables a targeted and efficient application of energy that has been shown to enhance the safety and speed of operation,[20] and may reduce thermal damage to the device components.

With LigaSure, the most common device malfunction was peeled or delaminated insulation coating on the jaw (17 (40.5%)). This was attributed most commonly to operator misuse. Repeated device activation at high temperatures can lead to delamination of the blue nylon insulation coating at the tip. Further investigation by the manufacturer in the report warns against using the device as a bipolar scissor, which can mimic the repeated activation and high cycle scenario. Moreover, the insulation coating can be broken by external forces, as the user inadvertently grasps a hard object. One report stated that the LigaSure was clamped on a retractor, producing excessive loading that led to mechanical damage of the insulation coating. The literature has shown insulation failure to be a main cause of endoscopic electrosurgical injuries. It is caused most commonly by excessive use of reusable instruments, especially with repetitive passage through mechanical sterilization, and activation at higher temperature that requires high concentration of electrical current.[21] Use of disposable instruments and activation of device at lower temperature may reduce the risk of insulation failure, thus reducing resultant burn injuries.[22]

As the thyroid is a highly vascularized organ, both intraoperative and postoperative bleeding have been recognized as important patient-related complications of thyroidectomy. Postoperative neck hematomas following thyroidectomy occur in up to 6.5% of cases[7] with almost all cases occurring within the first 6 hours of operation.[23] Several studies have compared the safety and effectiveness of Harmonic, LigaSure, and Thunderbeat in achieving meticulous hemostasis.[6,24,25] Our study identified incomplete hemostasis as the adverse event to patient reported most frequently with both Harmonic (23 (54.8%)) and LigaSure (17 (68.0%)). No events were reported in association with Thunderbeat use. The most common reported etiology of incomplete hemostasis with Harmonic and LigaSure was inappropriate function of the device, causing reduced coagulation.

Incomplete hemostasis was managed intraoperatively through use of a different device or new replacement of the same device. However, a few reports of uncontrolled bleeding required return to the operating room and blood transfusion. Incomplete hemostasis described among use of various electrosurgical instruments in the literature is consistent with our findings, thus the use of EBD may not necessarily increase the risk of bleeding.[23] In fact, several studies have found Harmonic, Ligasure, and Thunderbeat to have significantly reduced blood loss compared to conventional hemostasis.[26–28] A recent study has also shown that after adjusting for known risk factors for PNH, EBD use was associated with decreased risk of postoperative neck hematomas.[7]

Burn injury was the second most common adverse event to patients, again while using both Harmonic (13 (31.0%)) and LigaSure (6 (24.0%)). Thunderbeat was associated with a single report of burn injury. Burn injury can occur when an operator inadvertently places the probe tip in contact with a patient's body, as the temperature at the distal end of the device is high immediately after activation. The instruction manual warns against placing probe tips in contact with tissues other than the target tissue, leaving the device in contact with flammable objects such as a drape, or activating Thunderbeat while suctioning and/or irrigating simultaneously the surgical site, as such actions can provide a path for current to travel and cause unintended tissue burns.[11] Burn injuries result typically in first- or second-degree burns requiring conservative wound care with antibiotic ointment.

According to the Association of periOperative Registered Nurses (AORN), there are over 40,000 patient burn cases annually from electrosurgical devices and nearly $600 million paid for those injuries.[29] The cause of burn injuries identified in the literature include sparking effect at the tooltip when it comes into contact with

oxidative gases, implanted medical devices, and insulation failure.[31] Burn injury due to insulation failure is particularly important, as even a small insulation defect can lead to high current concentration resulting in fatal injury.[30] Although several events related to peeled or delaminated insulation coating were identified from our study, there was no reported burn injury. However, it is important to be aware of various mechanisms of burn injury as many are preventable events with meticulous handling of the device.

Recurrent laryngeal nerve (RLN) injury is another significant, yet preventable complication of thyroidectomy.[31] It also represents a common cause for litigation after thyroidectomy.[32] A retrospective study comparing surgical outcomes with Harmonic, LigaSure, and Thunderbeat previously identified RLN injury as a complication associated with EBD.[6] This study also identified vocal cord paralysis due to RLN injury following thyroidectomies using Harmonic (4 (9.5%)), LigaSure (2 (8.0%)), and Thunderbeat (1 (50%)). In these cases, the patients presented with postoperative hoarseness, biphasic stridor, or respiratory distress. A probable cause of operator error was given only by the report involving Thunderbeat, which has since led to the filing of a legal claim.

A total of 195 (55.9%), 21 (31.3%), and 80 (90.90%) device malfunctions with Harmonic, LigaSure, and Thunderbeat, respectively, were attributed to operator error. Similarly, 5 (25.0%), 2 (25%), and 2 (100%) patient injuries associated with Harmonic, LigaSure, and Thunderbeat, respectively, were attributed to operator error. Lastly, 2 (66.7%) operator injuries involving Harmonic and 1 (50%) involving Thunderbeat were attributed to operator error. This is of particular interest because the study reveals possible mechanisms of adverse events in which the surgeons can be aware of during its use.

Furthermore, most adverse events are largely preventable with proper use; thus it may be useful to provide operators with specific training courses such as the Basics of Electro-Surgery training (BEST). The BEST course was created to provide an effective learning environment for safe and proper use of electrosurgery. This was created to increase patient safety in the operating room.[33] Given the high incidence of events related to operator error among EBD, proper education and training courses like BEST may help reduce common adverse events as well as patient and operator injury related to these adverse events.

There are a number of limitations to this study. The MAUDE database is inherently limited by its reliance on voluntary and mandatory reporters, introducing the potential for reporting bias. This may lead to either underreporting, for example by operators reluctant to reveal details of their inadvertent error, or overreporting, for example by patients who suffer from harm who may jump to blame on operator error, of adverse events; substantial variation in the level of detail provided in each report make it difficult to estimate the overall incidence or prevalence of adverse events related to Harmonic, LigaSure, and Thunderbeat use during thyroidectomy. Moreover, three devices have been on the market for a different amount of time which lead to variation in the number of reports filed to MAUDE database. For example, newer devices such as ThunderBeat have relatively fewer overall reports over a shorter time period compared to older devices such as Harmonic. In addition, the MAUDE database is limited by inconsistent categorization of events which makes it difficult to compare directly each device. This calls for future studies using standardized reporting protocols that allow a more accurate comparison of adverse events. Despite these limitations, our data provide a relative frequency of adverse related to device malfunction, patient, and the operator. The data can be used to inform surgeons and patients regarding possible complications and provides an opportunity to develop interventions to reduce avoidable adverse events in the future.[15]

CONCLUSIONS

Harmonic, LigaSure, and Thunderbeat have demonstrated utility in thyroidectomy but are associated with adverse events. The most frequently reported device malfunctions were damage to the blade, peeled or delaminated insulation coating on the jaw, and damage to the tissue or Teflon pad. The most frequently reported adverse events to patients was a burn injury and incomplete hemostasis. The most frequently reported operative injury was a burn injury. Interventions aimed at improving physician education may help reduce adverse events related to improper use. Further study investigating proper approaches to training and education is needed. Additional studies allowing accurate estimation of the incidence of adverse events identified in this study is also needed to better inform EBD selection for thyroidectomy.

AUTHOR CONTRIBUTIONS

Esther Lee: Concept, design, acquisition, analysis, interpretation of data, Drafting of the manuscript, Critical revision of the manuscript for important intellectual content, Accountability for all aspects of the work.

Jane Tong: Concept, design, acquisition, analysis, interpretation of data, Drafting of the manuscript, Critical revision of the manuscript for important intellectual content, Accountability for all aspects of the work.

Daniel Benito: Concept, design, acquisition, analysis, interpretation of data, Drafting of the manuscript, Critical revision of the manuscript for important intellectual content, Accountability for all aspects of the work.

Luke Pasick: Concept, design, acquisition, analysis, interpretation of data, Drafting of the manuscript, Critical revision of the manuscript for important intellectual content, Accountability for all aspects of the work.

Arjun Joshi: Concept, design, accountability for all aspects of the work.

Joseph Goodman: Concept, design, accountability for all aspects of the work.

Punam Thakkar: Concept, design, accountability for all aspects of the work.

CONFLICTS OF INTEREST

None

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