

Vessel Sealing Technology For Thyroid Surgery: Current Evidence

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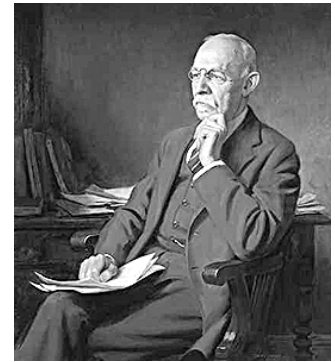
BC Cancer Agency

CARE + RESEARCH

An agency of the Provincial Health Services Authority



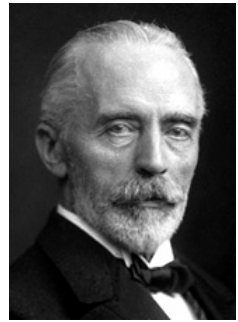
Thoughts On Thyroid Surgery



The extirpation of the thyroid gland . . . typifies, perhaps better than any operation, the supreme triumph of the surgeon's art. . . . A feat which today can be accomplished by any competent operator without danger of mishap and which was conceived more than one thousand years ago. . . . There are operations today more delicate and perhaps more difficult. . . . But is there any operative problem propounded so long ago and attacked by so many . . . which has yielded results as bountiful and so adequate?

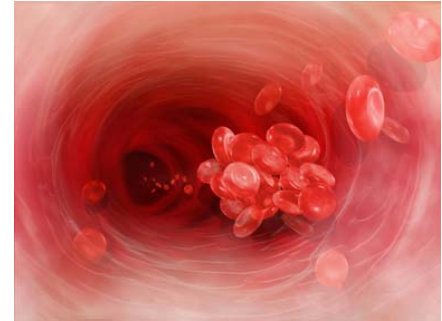
Dr. William S. Halsted, 1920

Thyroid Surgical Technique



- Current thyroid surgical technique was pioneered by Kocher that led to a reduction in mortality from 12.8% in 1883 to less than 0.5% 15 years later
- Thyroid has a rich blood supply (**5.5 mL of blood/gram of tissue/ minute**)
- Operative field for thyroidectomy is **small**, readily obscured by a small amount of blood and requires meticulous surgical technique and hemostasis
- **Recurrent laryngeal nerve and/or parathyroid injury may be a direct consequence of an obscured (bloody) operative field**
- **Postoperative hemorrhage** may arise due to inadequate surgical hemostasis and lead to airway compromise and death

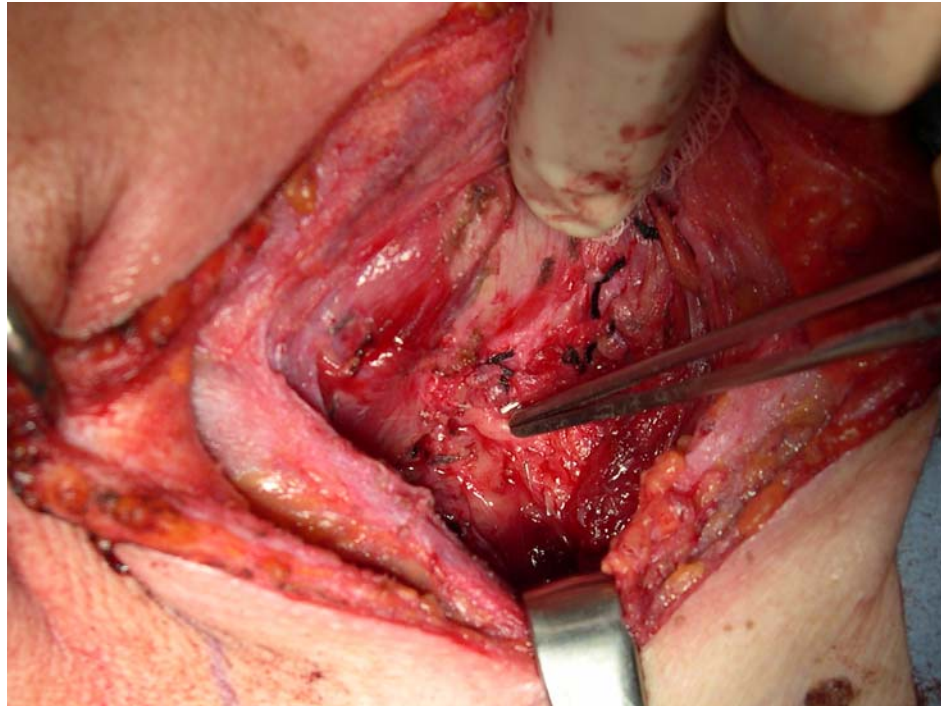
Current Options For Hemostasis During Thyroid Surgery



- Ties/Sutures/Pressure
- Electrocautery (Monopolar or Bipolar)
- Clips
- Hemostatic Agents
- Novel Hemostatic Devices
 - Electrothermal Bipolar Vessel Sealing Systems
 - Harmonic Scalpel

Ties, Sutures, Pressure

- Classic technique for hemostasis during thyroid ORs
- Clamp and tie of all named and many smaller thyroid vessels
- Advantages:
 - ‘Tested and True’
 - No current created
 - No heat created
- Disadvantages:
 - Time consuming
 - Knot slippage
 - Foreign bodies (esp silk)
 - Leave a ‘stump’



Electrocautery

- **Monopolar Cautery**

- Reliably seal vessels **2mm** in diameter
- Lateral zone of thermal injury up to **2-8mm**
- Especially useful for exposing surgical field



- **Bipolar Cautery**

- Reliably seal vessels up to **3mm** in diameter
- Lateral zone of thermal injury up to **2-8mm**
- Especially useful for small vessel hemostasis



- Tysome et al. reported a retrospective series in which bipolar cautery was compared to clamp and tie in 153 thyroid surgeries- technique of triple sealing vessels – complication rates similar and earlier d/c in the bipolar group

(Tysome et al. Eur Arch Otolary 2009;266:1781-6)

Clips & Hemostatic Agents

- Clips can seal vessels well above physiologic BP

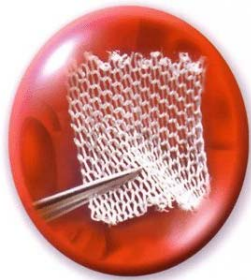
- Disadvantages

- Clip slippage or bleeding
- Foreign bodies – though absorbable clips available



- Hemostatic Agents

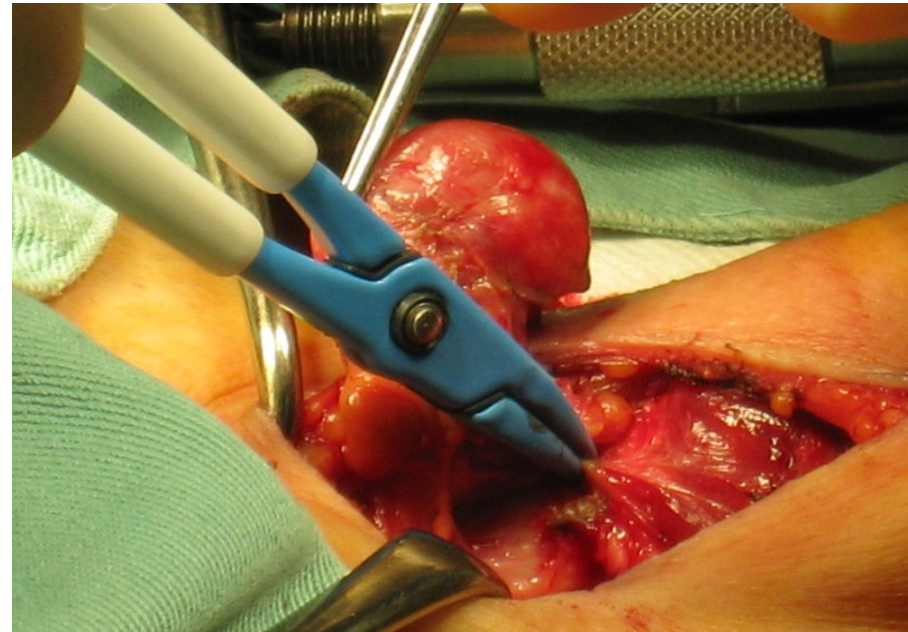
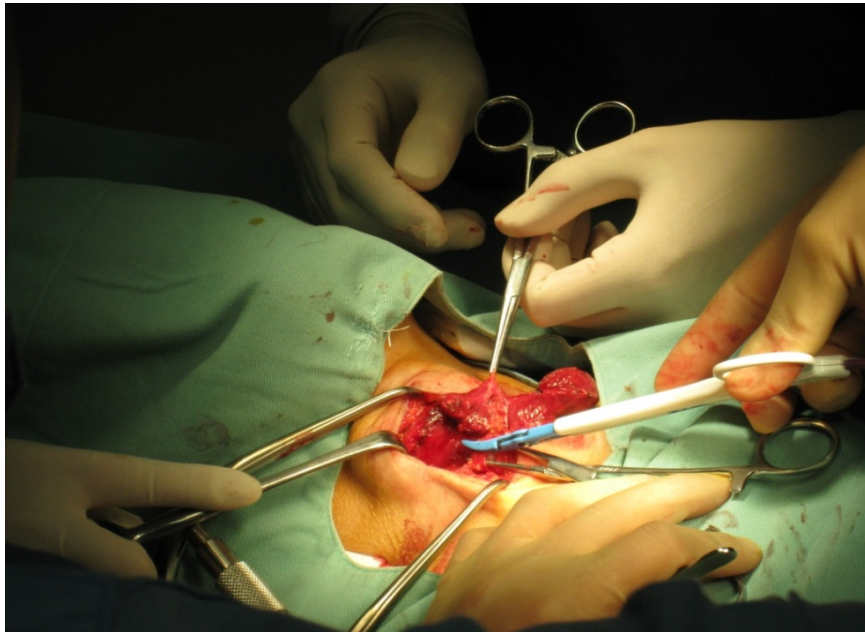
- Thrombin, fibrin glue, collagen, soluble cellulose, absorbable gelatin sponge/gauze, hemostasis paper, hemostasis foam, gold foil, absorbable cotton, enbucrylate, methyl-2, alkyl or isobutyl cyanoacrylate
- Fibrin, collagen, and fibrin and thrombin gelatin have been studied in thyroid surgery and reduce drainage volumes and hospital stay
- Especially useful for controlling capillary oozing immediately adjacent to recurrent nerve (resorbable oxidized regenerated cellulose)



Vessel Sealing For Thyroid Surgery



In The O.R. At Noguchi Hospital In Beppu Japan



(Wiseman S. Bull ACS 2008:49-53)

Limitations of Current Literature Reporting Vessel Sealing For Thyroid Surgery

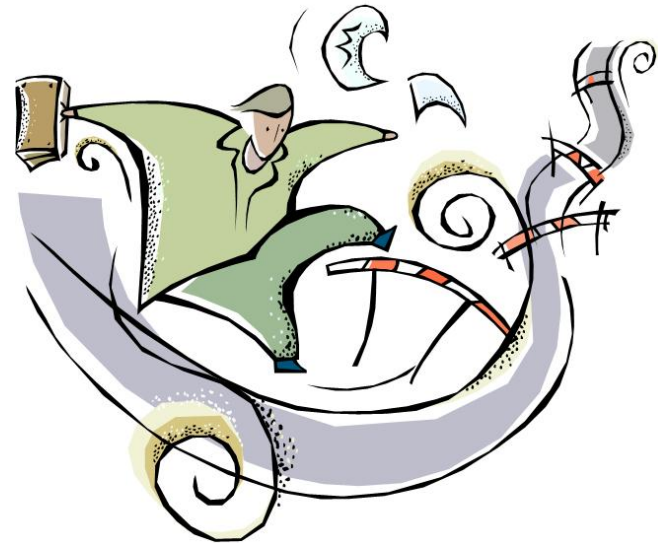


- Composed of many **small** retrospective case series
- Variable surgical **expertise**/volume/technique
- Variable patient **populations**
- Variable **instrument generations** studied
- Difficult to study **uncommon events** in thyroid surgery (ie RLN dysfunction, and hypoparathyroidism) in small studies with limited follow up
- Variable **endpoints**
- Variable **definitions** for different endpoints
- Variable **costs** from once center to another
- Instrument **learning curves** not considered

How To Overcome These Limitations?

- **Large Multicenter Prospective Randomized Controlled Trial**

- Realistic? Necessary?



- **Meta-Analysis:**

- Consolidates the results of several studies in order to address a set of related research hypotheses



Harmonic Scalpel



- Harmonic scalpel (Ethicon Endosurgery, OH, USA)
– *Harmonic FOCUS* hand piece most useful
- Uses high frequency ultrasonic energy to enable vessel and tissue **coagulation and cutting** at the precise point of impact via vibration at **55.5 kHz** while using low temperatures ranging from **50 to 100 degrees celsius**
- Controls bleeding by coaptive coagulation at lower temperatures than electrosurgery or lasers

Harmonic Scalpel

- Uses high frequency mechanical energy to coagulate and cut vessels
- **No electrical energy transferred** to or through the patient (ie. no neuromuscular stimulation)
- Vessels are tamponaded and sealed by disrupting protein structure and forming a protein coagulum



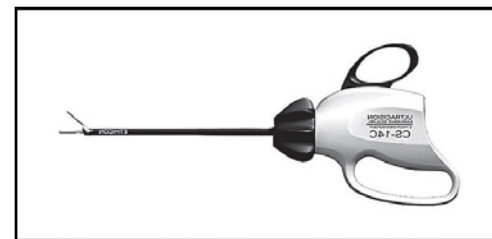
Harmonic Scalpel



- Able to seal vessels up to **5mm** in diameter to well above physiologic blood pressure levels
- Mean arterial burst strength similar to clips/ligatures and equal to the LS for vessels 0.23-3mm
- Tip of device should be carefully positioned because with activation 10-20s can reach high temperatures (**>100 degrees**)
- Thermal spread is in a zone **0-2.2mm** beyond the forceps (3-5mm safety zone recommended)

Harmonic Scalpel Application To Thyroid Surgery

- First reported for thyroidectomy in 1998 (Ultracision model)
- Currently > 80 published studies
- Harmonic Focus currently utilized
- Has been reported to:
 - Reduce operative time
 - Reduce transient hypoparathyroidism
 - Reduce intraoperative blood loss
 - Reduce postop drain output
 - Reduce postop hematoma
 - Reduce postop analgesia requirement
 - Reduce incision length
 - Reduce hospital stay
 - Reduce costs



Harmonic Scalpel Compared to Conventional Hemostasis in Thyroid Surgery: A Meta-Analysis of Randomized Clinical Trials

Adrienne L. Melck and Sam M. Wiseman

Department of Surgery, Saint Paul's Hospital, University of British Columbia, C303-1081 Burrard Street, Vancouver, BC, Canada V6Z 1Y6

Int J Surg Onc 2010;1-8

- Trials ID'd from Cochrane/MEDLINE/EMBASE/Experts/Manufacturer/Conference Proceedings (Jan 1/1995-Sept 30/2008)
- Eligibility
 - Undergoing total or subtotal thyroidectomy
 - 18 years or older
 - Only studies comparing HS to CH methods
 - VATS/ETS excluded
 - If additional procedures during OR study included if time of Thyroidectomy specified
 - Prospective, randomized clinical trials

Harmonic Scalpel Meta-Analysis

- **Primary Outcome:**

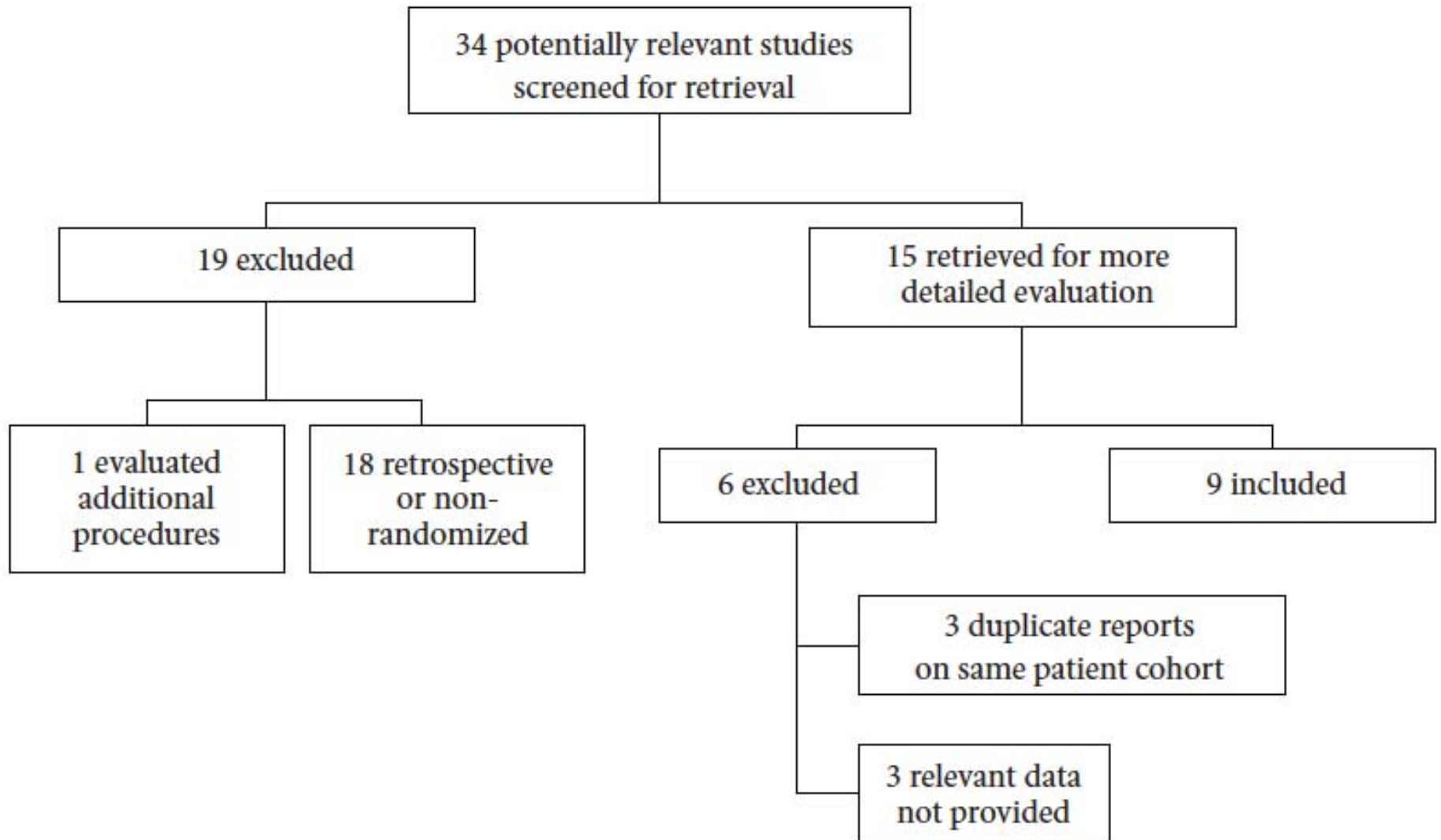
- Mean Operative Time (minutes) for total or subtotal thyroidectomy



- **Secondary Outcome:**

- Incidence of transient RLN dysfunction and transient hypocalcemia

Harmonic Scalpel Meta-Analysis: Results



Harmonic Scalpel Meta-Analysis: Results

Author	Year	Country	Industry funding	CH techniques	# patients	Mean OR					
						Time (min) for TT/ST (SD)	Transient RLND	Permanent RLND	Transient hypocalcemia	Permanent hypocalcemia	Postoperative hematoma
Hallgrímsson [11]	2008	Sweden	No	Electrocautery	CH = 24	CH = 168.8 (4.8)	CH = 1	CH = 0	CH = 7	CH = 1	CH = 0
				ligatures clips	HS = 27		HS = 4	HS = 0		HS = 5	
Lombardi [5]	2008	Italy	No	Electrocautery	CH = 100	CH = 75.2 (23.5)	CH = 1	CH = 0	CH = 29	CH = 0	CH = 1
				ligatures	HS = 100		HS = 2	HS = 0		HS = 28	
Yildirim [13]	2008	Turkey	No	Electrocautery	CH = 54	CH = 105 (16)	CH = 5	CH = 1	CH = 7	CH = 1	CH = 0
				ligatures	HS = 50		HS = 1	HS = 0		HS = 6	
Kilic [6]	2007	Turkey	No	Electrocautery	CH = 40	CH = 57.8 (12)	CH = 0	CH = 0	CH = 5	CH = 0	CH = 0
				ligatures	HS = 40		HS = 1	HS = 0		HS = 2	
Miccoli [12]	2006	Italy	Yes	Electrocautery	CH = 50	CH = 46.7 (10.8)	CH = 0	CH = 0	CH = 16	CH = 0	CH = 0
				ligatures	HS = 50		HS = 0	HS = 0		HS = 5	
Frazzetta [8]	2005	Italy	No	Electrocautery	CH = 60	CH = 96 (17)	CH = 2	CH = 0	CH = 6	CH = 0	CH = 0
				ligatures	HS = 60		HS = 1	HS = 0		HS = 4	
Cordon [9]	2005	Mexico	Yes	Electrocautery	CH = 12	CH = 136 (37)	CH = 0	CH = 0	CH = 9	CH = 0	CH = 0
				ligatures clips	HS = 7		HS = 1	HS = 0		HS = 3	
Ortega [7]	2004	Spain	No	Ligatures	CH = 57	CH = 101 (16)	CH = 1	CH = 0	CH = 6	CH = 0	CH = 2
					HS = 57		HS = 2	HS = 0		HS = 5	
Defechereux [10]	2003	Belgium	No	Electrocautery	CH = 17	CH = 96.5 (28.9)	CH = 0	CH = 0	CH = 4	CH = 0	CH = 0
				Ligatures clips	HS = 17		HS = 0	HS = 0		HS = 1	
TOTAL					CH = 414		CH = 10	CH = 1	CH = 89	CH = 2	CH = 3
					HS = 408		HS = 12	HS = 0		HS = 59	

CH: conventional hemostasis; OR: operative; HS: harmonic scalpel; TT: total thyroidectomy; ST: subtotal thyroidectomy; SD: standard deviation; RLND: recurrent laryngeal nerve dysfunction.

complications are uncommon

(Melck & Wiseman Int J Surg Onc 2010)

Results: Primary Outcome

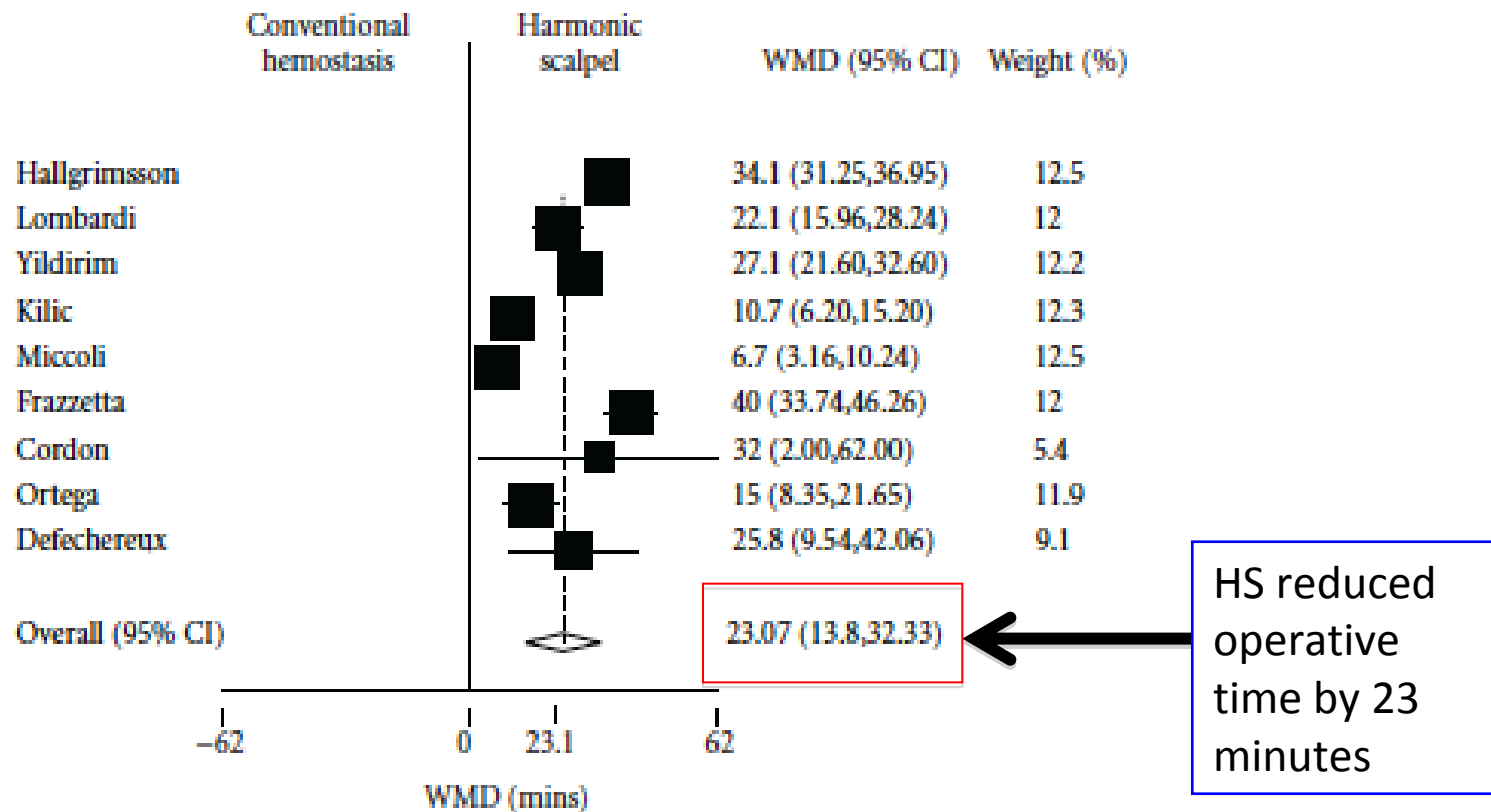
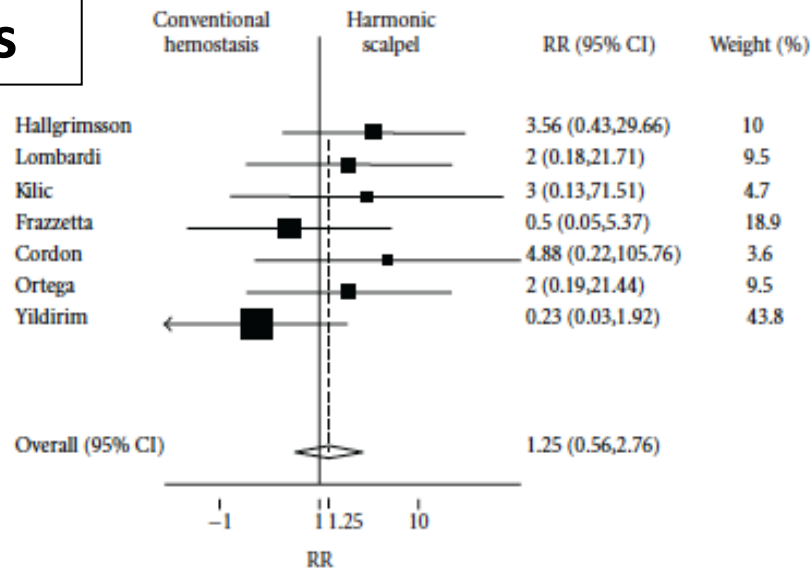


FIGURE 2: Forest plot depicting individual and pooled weighted mean difference (WMD) in operative times with 95% confidence intervals.

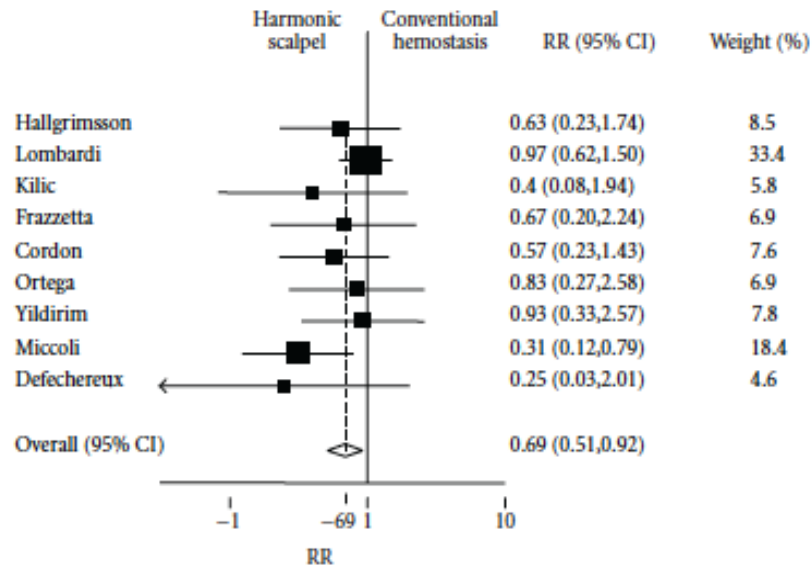
Results: Secondary Outcomes



Transient
Postoperative
Recurrent Laryngeal
Nerve Dysfunction

(22/822 (0.03%))

FIGURE 4: Forest plot depicting individual and pooled risk ratios (RRs) with 95% confidence intervals (CIs) for transient postoperative recurrent laryngeal nerve dysfunction.



Transient
Postoperative
Hypocalcemia

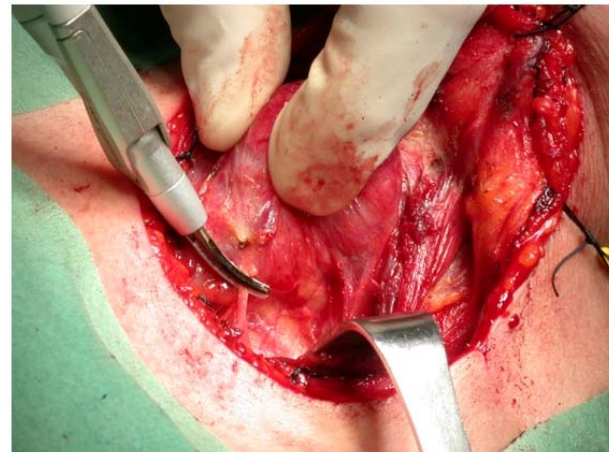
(148/822

(18%))

FIGURE 5: Forest plot depicting individual and pooled risk ratios (RRs) with 95% confidence intervals (CIs) for transient postoperative hypocalcemia. (Melck & Wiseman Int J Surg Onc 2010)

Harmonic Scalpel Meta-Analysis: Conclusions

Use of the harmonic scalpel for thyroidectomy significantly reduces operative time and is associated with a reduction in postoperative hypocalcemia compared to conventional hemostasis techniques



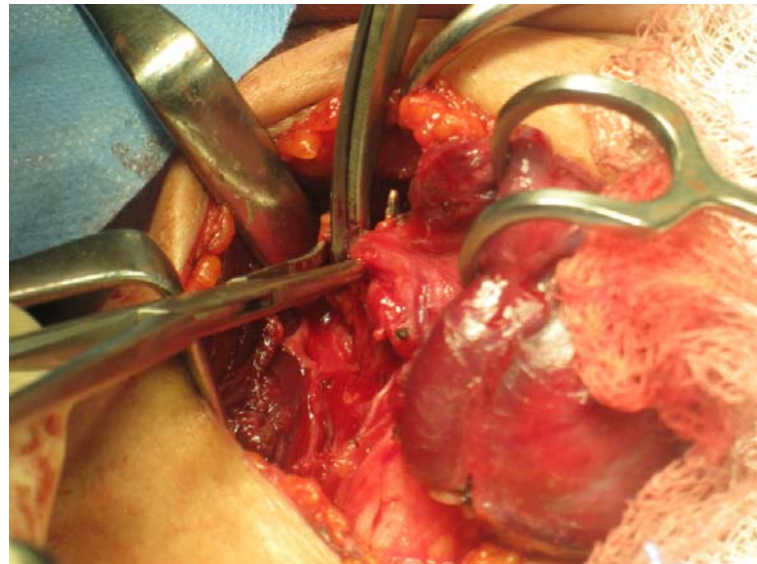
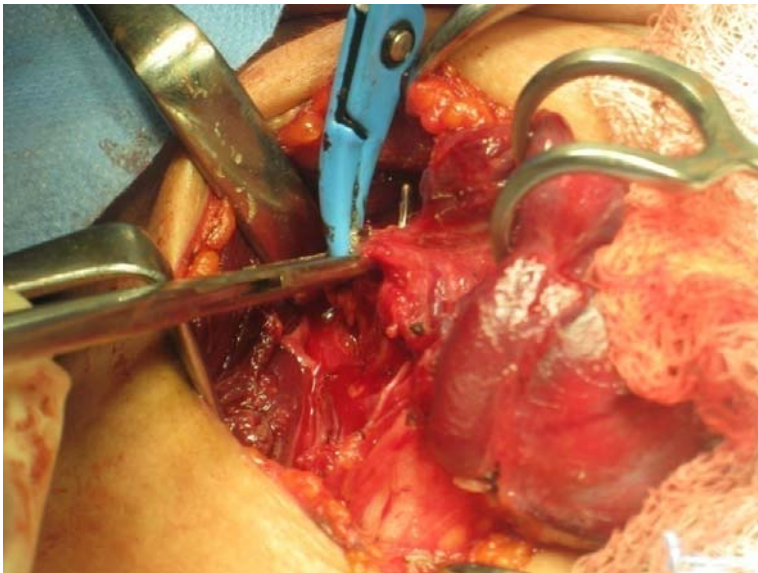
Electrothermal Bipolar Vessel Sealing Systems



- Electrothermal Bipolar Vessel Sealing System (**Ligasure** Covidien CO, USA)
- Computer controlled bipolar diathermy system that utilizes a combination of pressure and bipolar energy and incorporates impedance based feedback loops to modify bipolar energy
- During activation the response generator's computer automatically adjusts the precise amount of energy to be delivered according to the density of the grasped tissue, sensed by the generator, in order to fuse the vessel wall and create a permanent seal by denaturing collagen and elastin fibers

Electrothermal Bipolar Vessel Sealing System

- Able to seal vessels up to **7mm** in diameter to well above physiologic blood pressure levels (can tolerate up to 3x SBP)
- Mean arterial burst strength similar to clips/ligatures and higher than ultrasonic or bipolar sealed vessels when >3mm
- Thermal spread is in a zone **1.2 to 3mm** beyond the forceps (5mm safety zone recommended)



Electrothermal Bipolar Vessel Sealing System (Ligasure) Application To Thyroid Surgery

- First Reported application in 2003
- Currently > 50 published studies
- **'Precise'** and **'Small Jaw'** hand pieces
- Has been reported to:
 - Reduce operative time
 - Reduce transient hypoparathyroidism
 - Reduce intraoperative blood loss
 - Reduce postop drain output
 - Reduce postop hematomas
 - Reduce RLN palsies
 - Reduce incision length
 - Reduce hospital stay
 - Reduce the need for general anesthesia (can do under local)
 - Reduce costs



Prospective Clinical Trials of Thyroidectomy With LigaSure vs Conventional Vessel Ligation

A Systematic Review and Meta-analysis

Hou Shan Yao, MD; Qiang Wang, MD; Wei Jun Wang, MD; Can Pine Ruan, MD

Arch Surg. 2009;144(12):1167-1174

- Articles ID'd from
Cochrane/MEDLINE/EMBASE/Elsevier/Springer
Link/Ovid/Manufacturer (Jan 1/2006-July
31/2008)
- Eligibility
 - Undergoing total or subtotal
 - Only studies comparing LS to CH methods
 - Able to extract clearly complication rates for LS
and HS groups
 - Prospective, controlled design (randomized and
nonrandomized)

Ligasure Meta-Analysis

- **Primary Outcomes:**
 - Mean Operative Time (minutes)
 - Amount of intraoperative blood loss
- **Secondary Outcome:**
 - Length of hospital stay
 - Postoperative complications
 - Hypocalcemia
 - Recurrent Laryngeal Nerve lesions



Ligasure Meta-Analysis Results

- 9/27 studies met inclusion criteria (927 patients)
 - 4 randomized
 - 5 nonrandomized

Table 1. Characteristics of the 9 Clinical Trials Comparing LT and CT

Source	Design	No. of Patients		Age, Mean (SD), y		No. of Men		Type of Thyroidectomy						Pathological Diagnosis of Lesions, B/M	
		LT	CT	LT	CT	LT	CT	Total		Subtotal		Lobectomy		LT	CT
								LT	CT	LT	CT	LT	CT		
Kiriakopoulos et al, ²² 2004	Non-RCT	40	40	48.2 (7.8)	46.4 (8.2) ^a	7	9 ^a	NM	NM	NM	NM	0	0	33/7	34/6 ^a
Kirdak et al, ²³ 2005	Non-RCT	30	28	48 (13.9)	46 (12.9) ^a	6	7 ^a	8	9 ^a	14	9 ^a	8	10 ^a	28/2	25/3 ^a
Manouras et al, ²⁴ 2005	RCT	94	90	51.8 (11.6)	54 (13.3) ^b	20	10 ^a	94	90 ^a	0	0	0	0	70/24	68/22 ^a
Barbaros et al, ²⁵ 2006	Non-RCT	50	50	47 (11)	49 (13) ^a	7	8 ^a	NM	NM	NM	NM	0	0	NM	NM
Kilic et al, ²⁶ 2007	RCT	20	20	45.1 (14.3)	41.4 (12.5) ^a	3	7 ^a	0	0	20	20 ^a	0	0	20/0	20/0 ^a
Marrazzo et al, ²⁷ 2007	RCT	25	25	NM	NM	NM	NM	25	25 ^a	0	0	0	0	NM	NM
Saint Marc et al, ²⁸ 2007	RCT	100	100	49.5 (11.3)	54.1 (13.2) ^b	10	26 ^b	100	100 ^a	0	0	0	0	82/18	90/10 ^a
Cipolla et al, ²⁹ 2008	Non-RCT	53	52	50.1 (11.4)	50.5 (14.3) ^a	10	9 ^a	53	52 ^a	0	0	0	0	48/5	46/6 ^a
Youssef et al, ³⁰ 2008	Non-RCT	55	55	44 (11.4)	43.8 (10.7) ^a	12	14 ^a	15	15 ^a	30	29 ^a	10	11 ^a	51/4	52/3 ^a

Abbreviations: B, benign; CT, conventional thyroidectomy; LT, LigaSure (Valleylab, Boulder, CO) thyroidectomy; M, malignant; NM, not mentioned; RCT, randomized controlled trial.

^aNo significant difference between patients undergoing LT vs CT.

^bSignificant difference between patients undergoing LT vs CT ($P < .05$).

Ligasure Meta-Analysis Results

Table 2. Operative and Postoperative Parameters of the 9 Clinical Trials Comparing LT and CT

Source	Operative Duration, Mean (SD), min		Operative Blood Loss, Mean (SD), mL		Length of Hospital Stay, Mean (SD), d		Postoperative Complications, No. of Patients							
	LT	CT	LT	CT	LT	CT	Hypocalcemia				Nerve Lesions			
							Transient		Permanent		Transient		Permanent	
							LT	CT	LT	CT	LT	CT	LT	CT
Kiriakopoulos et al, ²² 2004	84 (6)	89 (7) ^a	30 (5)	35 (8) ^a	NM	NM	1	2 ^a	0	0 ^a	1	0 ^a	0	0 ^a
Kirdak et al, ²³ 2005	96.2 (22.2)	115.4 (19.1) ^b	NM	NM	1.4 (1.2)	1.3 (0.7) ^a	5	3 ^a	0	0	1	3 ^a	0	0
Manouras et al, ²⁴ 2005	87.3 (21.3)	101.6 (34.2) ^b	NM	NM	2.1 (1.5)	1.8 (0.9) ^a	0	0	0	0	0	0	0	0
Barbaros et al, ²⁵ 2006	58 (21)	75 (23) ^b	NM	NM	1.4 (0.1)	1.6 (0.2) ^b	2	3 ^a	0	0	0	0	0	0
Kilic et al, ²⁶ 2007	55.7 (12.7)	68.3 (19.9) ^b	NM	NM	1 (NM)	1 (NM) ^a	0	1 ^a	0	0	0	0	0	0
Marrazzo et al, ²⁷ 2007	60 (14.8)	92.4 (27.5) ^b	NM	NM	1.9 (0.4)	2.2 (0.4) ^b	3	5 ^a	0	0	1	1 ^a	0	1
Saint Marc et al, ²⁸ 2007	42.5 (11.2)	48.9 (6.8) ^b	NM	NM	1.1 (0.3)	1.1 (0.2) ^a	21	18 ^a	1	2 ^a	12	10 ^a	1	1 ^a
Cipolla et al, ²⁹ 2008	104 (12.7)	110 (15.6) ^c	58 (38.2)	61 (37.5) ^c	NM	NM	4	4 ^a	0	0	1	1 ^a	0	0
Youssef et al, ³⁰ 2008	NM	NM	65.6 (14.8)	132.7 (28.4) ^b	2 (NM)	2 (NM) ^a	2	3 ^a	0	0 ^a	2	2 ^a	0	1 ^a

Abbreviations: CT, conventional thyroidectomy; LT, LigaSure (Valleylab, Boulder, CO) thyroidectomy; NM, not mentioned.

^aNo significant difference between patients undergoing LT vs CT.

^bSignificant difference between patients undergoing LT vs CT ($P < .05$).

complications are uncommon



Ligasure Meta-Analysis Results

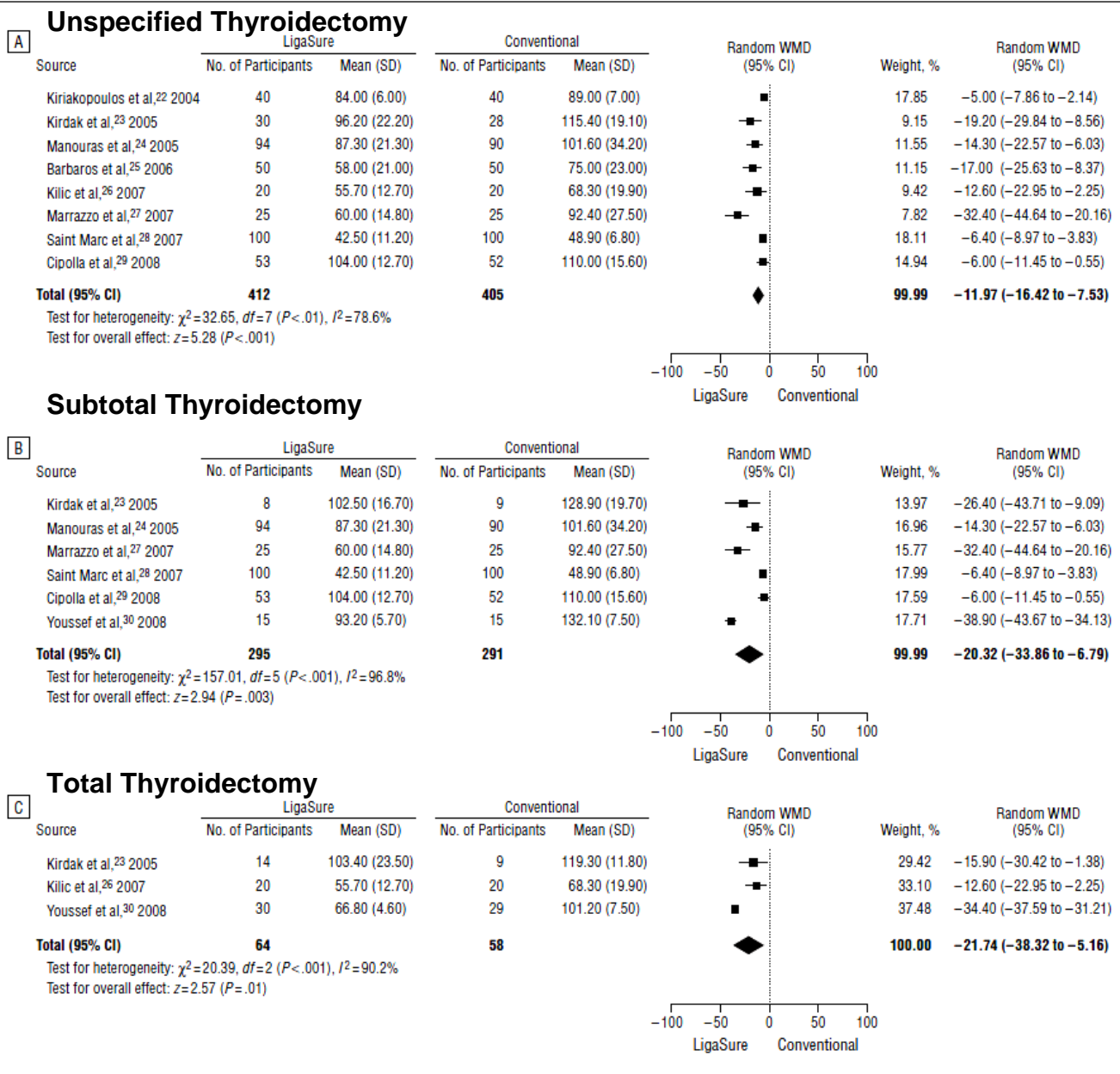


Figure 1. Forest plots for operative duration of unspecified thyroidectomy (A), total thyroidectomy (B), and subtotal thyroidectomy (C). Squares indicate the point estimates of the treatment effect (weighted mean difference [WMD]) with 95% confidence intervals (CIs) indicated by horizontal bars. Diamonds represent the summary estimate from the pooled studies with 95% CIs. Ligasure is a vessel-sealing device manufactured by Valleylab, Boulder, CO.

Ligasure Meta-Analysis Results

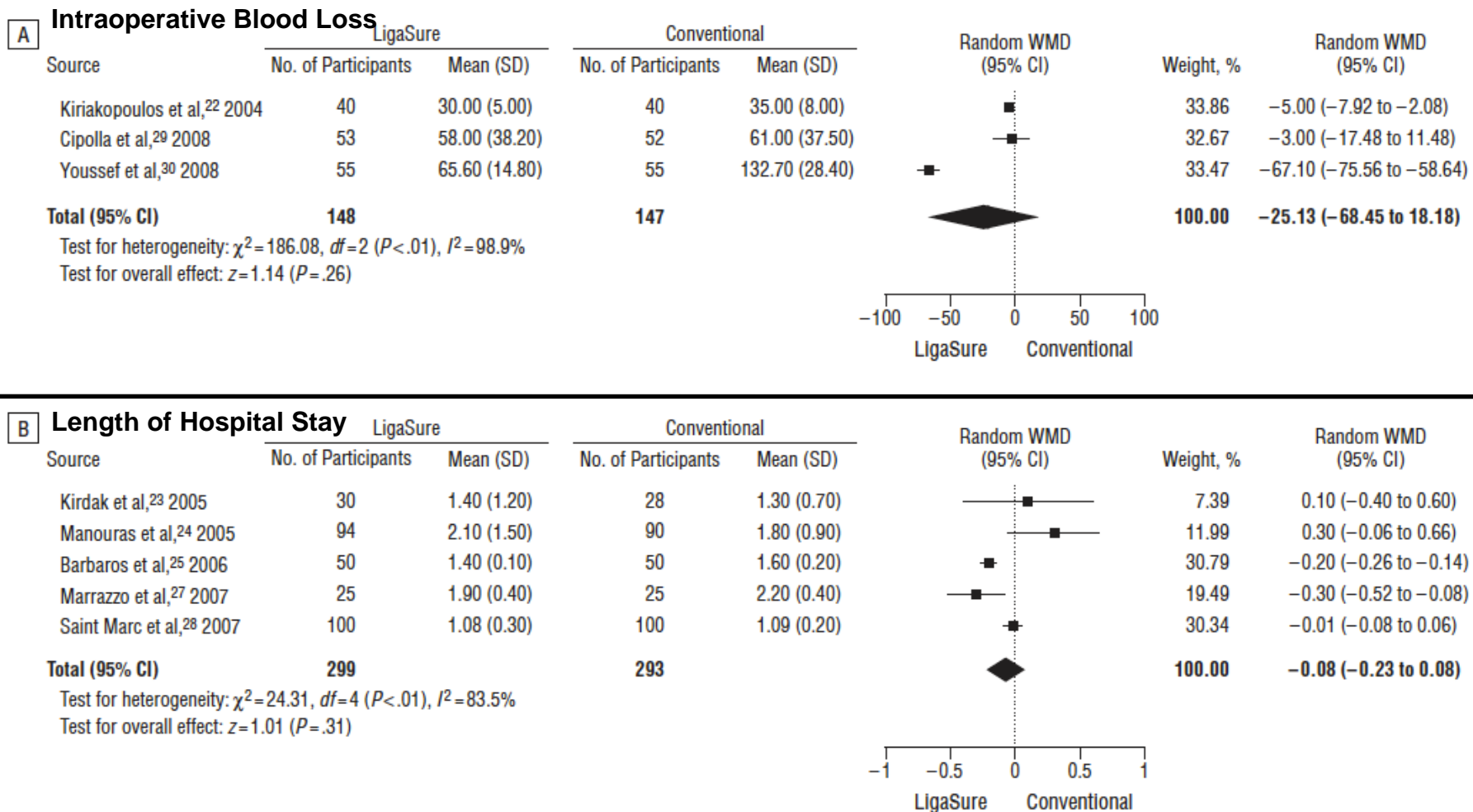


Figure 3. Forest plots for the amount of intraoperative blood loss (A) and length of hospital stay (B). Squares indicate the point estimates of the treatment effect (weighted mean difference [WMD]) with 95% confidence intervals (CIs) indicated by horizontal bars. Diamonds represent the summary estimate from the pooled studies with 95% CIs. Ligasure is a vessel-sealing device manufactured by Valleylab, Boulder, CO.

Ligasure Meta-Analysis Results

Ligasure reduced operative time by 22 minutes

Table 3. Quantitative Meta-analysis Results Based on the 9 Clinical Trials Comparing LT and CT^a

Outcome	No. of Trials (N=9)	No. of Participants Included in the Meta-analysis		I ² , %	Pooling Model	Effect Size (95% CI)	P Value
		LT	CT				
Operative duration							
Thyroidectomy	8	412	405	78.6	WMD (rand)	-11.97 (-16.42 to -7.53)	<.001
Total thyroidectomy	6	295	291	96.8	WMD (rand)	-20.32 (-33.86 to -6.79)	.003
Subtotal thyroidectomy	3	64	58	90.2	WMD (rand)	-21.74 (-38.32 to -5.16)	.01
Intraoperative blood loss	3	148	147	98.9	WMD (rand)	-25.13 (-68.45 to 18.18)	.26
Length of hospital stay	5	299	293	83.5	WMD (rand)	-0.08 (-0.23 to 0.08)	.31
Postoperative complications	9	63/467 ^a	67/460 ^a	0	OR (fixed)	0.91 (0.61 to 1.36)	.65
Transient complications	9	61/467 ^a	62/460 ^a	0	OR (fixed)	0.97 (0.65 to 1.45)	.87
Transient hypocalcemia	9	38/467 ^a	39/460 ^a	0	OR (fixed)	0.96 (0.59 to 1.55)	.87
Transient nerve lesions	8	18/467 ^a	17/460 ^a	0	OR (fixed)	1.05 (0.53 to 2.08)	.88
Permanent complications	9	2/467 ^a	5/460 ^a	0	OR (fixed)	0.49 (0.12 to 2.00)	.32

Abbreviations: CI, confidence interval; CT, conventional thyroidectomy; LT, LigaSure (a vessel-sealing device; Valleylab, Boulder, CO) thyroidectomy; OR (fixed), odds ratio (fixed effects model); WMD (rand), weighted mean difference (randomized effects model).

^aData are given as the number of patients with the complication/total sample size.

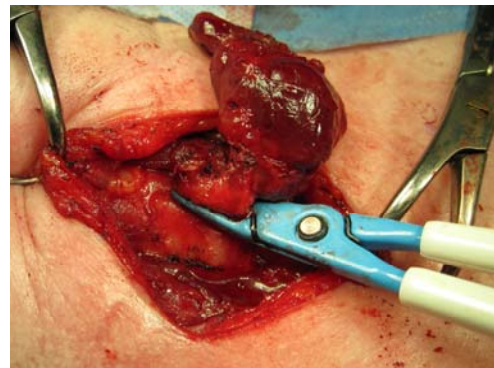
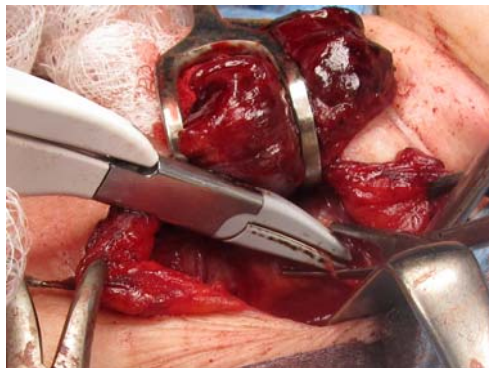
<p>Transient Postoperative Recurrent Laryngeal Nerve Dysfunction (25/927 (0.04%))</p>	<p>Transient Postoperative Hypocalcemia (77/927 (8.3%))</p>
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Impacted due to inclusion of lobectomy cases

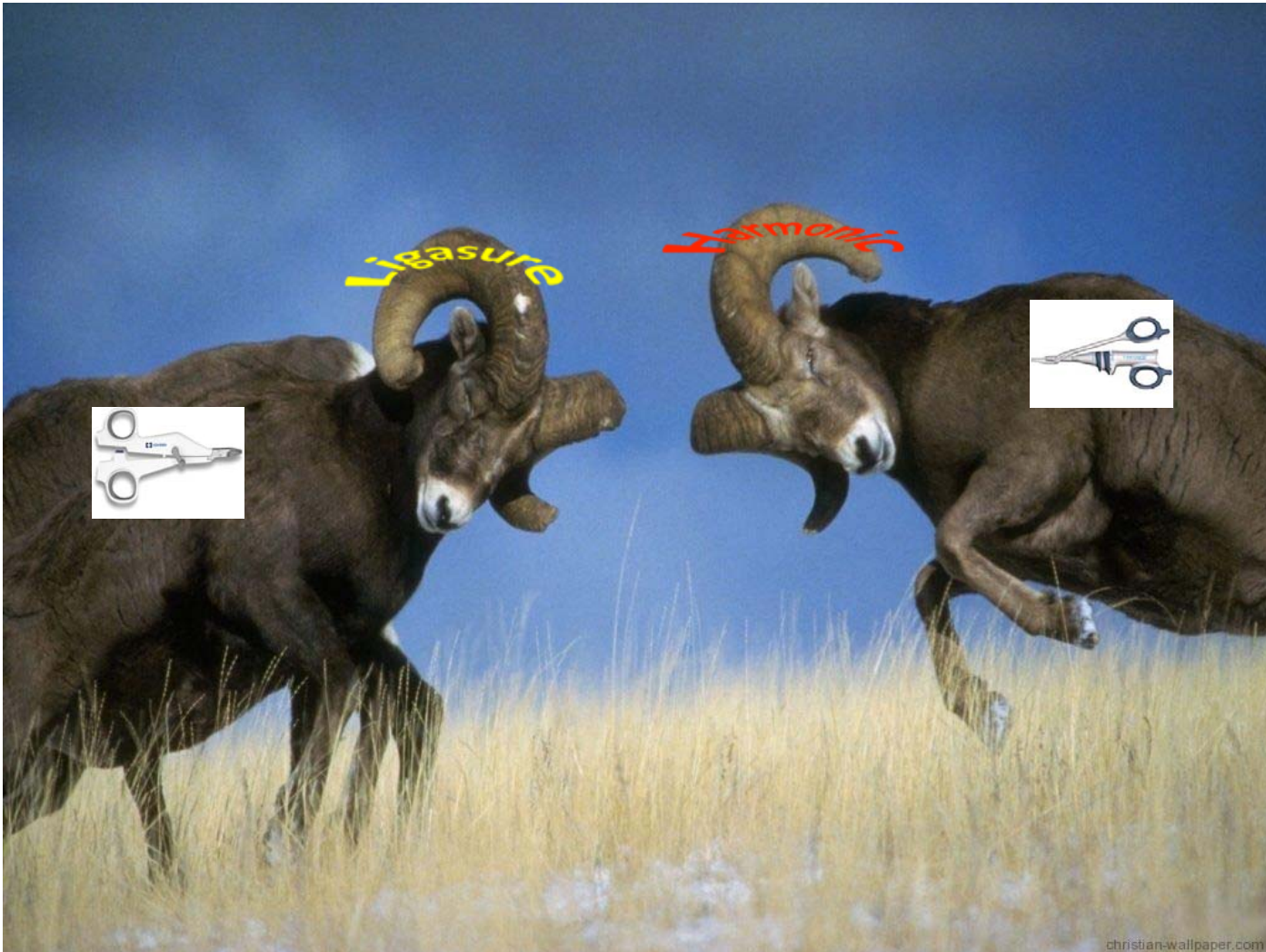


Ligasure Meta-Analysis Conclusions

Use of the Ligasure for thyroidectomy significantly reduces operative time but does not confer any advantage over conventional hemostasis techniques in terms of the amount of intraoperative blood loss, the length of hospital stay, and postoperative complication rates.



Any Head To Head Data?



Ligasure vs Harmonic vs Conventional Hemostasis

Table 4. Literature review: operative time. LigaSure™ versus Harmonic Scalpel versus conventional hemostasis.

Study (year)	Funding	Design	Procedure	Patients (n)	Conventional hemostasis (min)	LS™ (min)	Harmonic Scalpel (min)	Time saved by using LS compared with CH (%)	Conclusion
<i>Prospective studies</i>									
Dionigi <i>et al.</i> (2012)	Independent	Randomized	Total thyroidectomy	LS: 90; HS: 92	NA	73±9 (47–100)	76±10 (52–110)	NA	LS = HS
Rahbari <i>et al.</i> (2011)	Covidien (Dublin, Ireland)	Randomized	Total thyroidectomy, lobectomy	LS: 45; HS: 45	NA	187.6±52.6	184.2±66.2	NA	LS = HS
Di Rienzo <i>et al.</i> (2010)	NS	Randomized	Total thyroidectomy	CH: 31; LS: 31; HS: 31	72.7±13.6	68.9±7.4	62.7±14.1	5.20	HS < LS = CH
Singh <i>et al.</i> (2010)	Independent	Randomized	Total thyroidectomy, lobectomy	LS: 14; CH: 14	68.5±14.53	68.6±27.47	NA	0	LS = CH
Pors <i>et al.</i> (2009)	Independent	Randomized	Total thyroidectomy	CH: 20; LS: 20; HS: 20	151±15	122±10	114±9	21.90	HS < LS < CH
Goretzki <i>et al.</i> (2009)	Johnson & Johnson and Covidien for presentation of data	Randomized	Total thyroidectomy, lobectomy, subtotal thyroidectomy	CH: 41; LS: 41	118	87	NA	26.20	LS < CH
		Nonrandomized	NS	CH: 118; LS: 100; HS: 96	118±36	75±32	76±23	36.40	HS = LS < CH
Oussoultzoglou <i>et al.</i> (2008)	Independent	Case controlled	Total thyroidectomy	LS: 40; BC: 46	NA	170±57 (80–270)	NA	NA	BC 142±35 (75–265) < LS
Sartori <i>et al.</i> (2008)	NS	Randomized	Total thyroidectomy, lobectomy, Subtotal thyroidectomy	CH: 50; LS: 50; HS: 50	118±28	129±32	94±24	-9.30	HS < LS = CH
Youssef <i>et al.</i> (2008)	Nondisclosed	Case controlled	Total thyroidectomy	CH: 15; LS: 14	132.13±7.50	93.16±5.68	NA	29.50	LS < CH
			Lobectomy	CH: 13; LS: 13	67.25±4.49	37.65±4.68	NA	44.00	
			Subtotal thyroidectomy	CH: 27; LS: 28	101.20±7.51	68.80±4.56	NA	32.00	
Cipolla <i>et al.</i> (2008)	NS	Nonrandomized	Total thyroidectomy	CH: 52; LS: 53	110±15.6	104±12.7	NA	5.40	LS = CH
Kilic <i>et al.</i> (2007)	NS	Randomized	Total thyroidectomy	CH: 20; LP: 20	68.25±19.88	55.65±12.67	NA	18.50	LS < CH
Minner <i>et al.</i> (2007)	NS	Randomized	Total thyroidectomy, lobectomy	CH: 77; LS: 73	117.6±36.1	107.4±35.2	NA	8.70	CH = LS

<: Faster than; =: No difference; BC: BiClamp®; CH: Conventional hemostasis; HS: Harmonic Scalpel; Independent: Independent from industry; LS: LigaSure™; NA: Not applicable; NS: Not specified; VANS: Video-assisted neck surgery (Butskiy & Wiseman Exp Rev Med Dev 10 (2013))

Ligasure vs Harmonic vs Conventional Hemostasis

Table 4. Literature review: operative time. LigaSure™ versus Harmonic Scalpel versus conventional hemostasis (cont.).

Study	Funding	Design	Procedure	Patients (n)	Conventional hemostasis (min)	LS™ (min)	Harmonic Scalpel (min)	Time saved by using LS compared with CH (%)	Conclusion
<i>Prospective studies (cont.)</i>									
Saint Marc <i>et al.</i> (2007)	None reported	Randomized	Total thyroidectomy	CH: 100; LS: 100	48.9±6.8	41.5±11.2	NA	15.10	LS < CH (clinically irrelevant)
Marrazzo <i>et al.</i> (2007)	NS	Randomized	Total thyroidectomy	LS: 25; CH: 25	92.4±27.5	60±14.8	NA	35.10	LS < CH
Barbaros <i>et al.</i> (2006)	NS	Case controlled	Total thyroidectomy	LS: 50; CH: 50	75±23	58±21	NA	22.70	LS < CH
Manouras <i>et al.</i> (2005)	NS	Randomized	Total thyroidectomy	CH: 90; LS: 94	101.6±3.6	87.3±2.2	NA	14.10	LS < CH
Kirdak <i>et al.</i> (2005)	NS	Case controlled	Total thyroidectomy	CH: 9; LS: 8	128.89±19.73	102.50±16.69	NA	20.50	LS < CH
			Lobectomy	CH: 10; LS: 8	99.80±12.53	77.38±13.7	NA	22.50	LS < CH
			Subtotal thyroidectomy	CH: 9; LS: 14	119.33±11.77	103.36±23.48	NA	13.40	LS < CH
			Total	CH: 28; LS: 30	115.43±19.10	96.2±22.21	NA	16.70	LS < CH
Kiriakopoulos <i>et al.</i> (2004)	NS	Case controlled	Total thyroidectomy	CH: 40; LS: 40	89±7 (74–102)	84±6 (62–94)	NA	5.60	CH = LS
<i>Retrospective studies</i>									
Bove <i>et al.</i> (2012)	Independent	Case controlled	Total thyroidectomy	CH: 80; HS: 80; LP: 80	72.7±13.6	68.9±7.4	62.7±14.1	5.20	HS < LS = CH
Zarebczan <i>et al.</i> (2011)	American College of Surgeons	Case controlled	Total thyroidectomy	LS: 87; HS: 36	NA	74±17	59±11	NA	HS < LS
			Lobectomy	LS: 81; HS: 27	NA	42±15	35±11	NA	
Ignjatovic and Kostic (2011)	Independent	Prospective/retrospective case matched	Total thyroidectomy, Lobectomy	LS: 23; CH: 33	70±4	65±3	NA	7.10	LS < CH
Scilletta <i>et al.</i> (2010)	NS	Case controlled	Total thyroidectomy	CH: 112; LS: 144	170 (140–190)	140 (120–171.25)	NA	17.60	LS < CH
Prokopakis <i>et al.</i> (2010)	NS	Retrospective	Total thyroidectomy	CH: 559; LS: 174	78.5	52	NA	33.80	LS < CH
Cakabay <i>et al.</i> (2009)	Independent	Case controlled	Total thyroidectomy	CH: 217; LS: 41	98.2±6.2	74.1±4.5	NA	24.50	LS < CH
			Subtotal thyroidectomy	CH: 116; LS: 27	77.4±9.4	69.8±9.3	NA	9.80	

<: Faster than; =: No difference; BC: BiClamp®; CH: Conventional hemostasis; HS: Harmonic Scalpel; Independent: Independent from industry; LS: LigaSure™; NA: Not applicable; NS: Not specified; VANS: Video-assisted neck surgery.

Ligasure vs Harmonic vs Conventional Hemostasis

Table 4. Literature review: operative time. LigaSure™ versus Harmonic Scalpel versus conventional hemostasis (cont.).

Study	Funding	Design	Procedure	Patients (n)	Conventional hemostasis (min)	LS™ (min)	Harmonic Scalpel (min)	Time saved by using LS compared with CH (%)	Conclusion
<i>Retrospective studies (cont.)</i>									
McNally <i>et al.</i> (2009)	NS	Case controlled	Total thyroidectomy	LS: 59; HS: 15	NA	115.0 ± 38.3	88.0 ± 14.0	NA	HS < CH
Goretzki <i>et al.</i> (2009)	Johnson & Johnson and Covidien for data presentation	Retrospective	Total thyroidectomy	CH: 108; LS: 8	110 ± 17	88 ± 9	NA	20	LS < CH
Inabnet <i>et al.</i> (2008)	NS	Retrospective	Total thyroidectomy, lobectomy	LS: 224	NA	77 (20–420)	NA	NA	
Manouras <i>et al.</i> (2008)	NS	Case controlled	Total thyroidectomy	CH: 90; LS: 148; HS: 144	93.3 ± 12.5	74.3 ± 14.2	73.8 ± 13.8	20.40	HS = LS < CH
Musunuru <i>et al.</i> (2008)	NS	Retrospective	Lobectomy	CH: 99; LS: 51	92	52	NA	43.50	LS < CH
Lepner and Vaasna (2007)	NS	Case controlled	Total thyroidectomy	CH: 121; LS: 143	104.8 ± 28.5	78.3 ± 34.4	NA	25.30	LS < CH
			Lobectomy	CH: 52; LS: 50	75.3 ± 20.6	54.0 ± 27.2	NA	28.40	
			Subtotal thyroidectomy	CH: 26; LS: 11	106.0 ± 37.7	60.4 ± 19.2	NA	43.00	
Franko <i>et al.</i> (2006)	NS	Retrospective	Total thyroidectomy, lobectomy	CH: 50; LS: 50	162 ± 32 112 ± 25	127 ± 28 97 ± 30	NA NA	21.60 13.40	LS < CH
Fujita <i>et al.</i> (2006)	NS	Retrospective	Total thyroidectomy, lobectomy, subtotal thyroidectomy, VANS, VANS for cancer	CH: 30; LS: 22	100.6 (80–120)	135.3 (108–162)	NA	-34.50	LS = CH
Parmeggiani <i>et al.</i> (2005)	NS	Case controlled	Total thyroidectomy	CH: 120; LS: 70	91.35 ± 12.90	72.07 ± 12.49	NA	21.10	LS < CH
Shen (2005) <i>et al.</i>	NS	Case controlled	Total thyroidectomy	CH: 62; LS: 89	246 ± 6	192 ± 6	NA	22.00	LS < CH
			Lobectomy	CH: 37; LS: 46	162 ± 6	132 ± 6	NA	18.50	
Dilek <i>et al.</i> (2005)	NS	Case controlled	Total thyroidectomy, lobectomy, subtotal thyroidectomy	CH: 25; LS: 15	97	75 ± 11	NA	22.70	LS < CH
Lachanas <i>et al.</i> (2005)	NS	Prospective compared with retrospective	Total thyroidectomy	LS: 72	NA	58	NA	28.40	NA
Petrakis <i>et al.</i> (2004)	NS	Case controlled	Total thyroidectomy	CH: 247; LS: 270	86 ± 22	71 ± 14	NA	17.40	LS < CH

<: Faster than; =: No difference; BC: BiClamp®; CH: Conventional hemostasis; HS: Harmonic Scalpel; Independent: Independent from industry; LS: LigaSure™; N/A: Not applicable; NS: Not specified; VANS: Video-assisted endoscopic surgery.

Which Hemostatic Device in Thyroid Surgery? A Network Meta-Analysis of Surgical Technologies

George Garas,^{1,*} Koji Okabayashi,^{2,*} Hutan Ashrafian,³ Kunal Shetty,³ Fausto Palazzo,⁴
Neil Tolley,¹ Ara Darzi,³ Thanos Athanasiou,³ and Emmanouil Zacharakis³

➤ 35 Randomized trials: 2856 patients

• **HARMONIC > LIGASURE or CLAMP/TIE**

- Hypoparathyroidism
- Operative Time
- Blood Loss
- Drain Output
- Neck Collection
- Hospital Stay
- Cost

• **CLAMP/TIE > LIGASURE > HARMONIC**

- Recurrent Laryngeal Nerve Paralysis

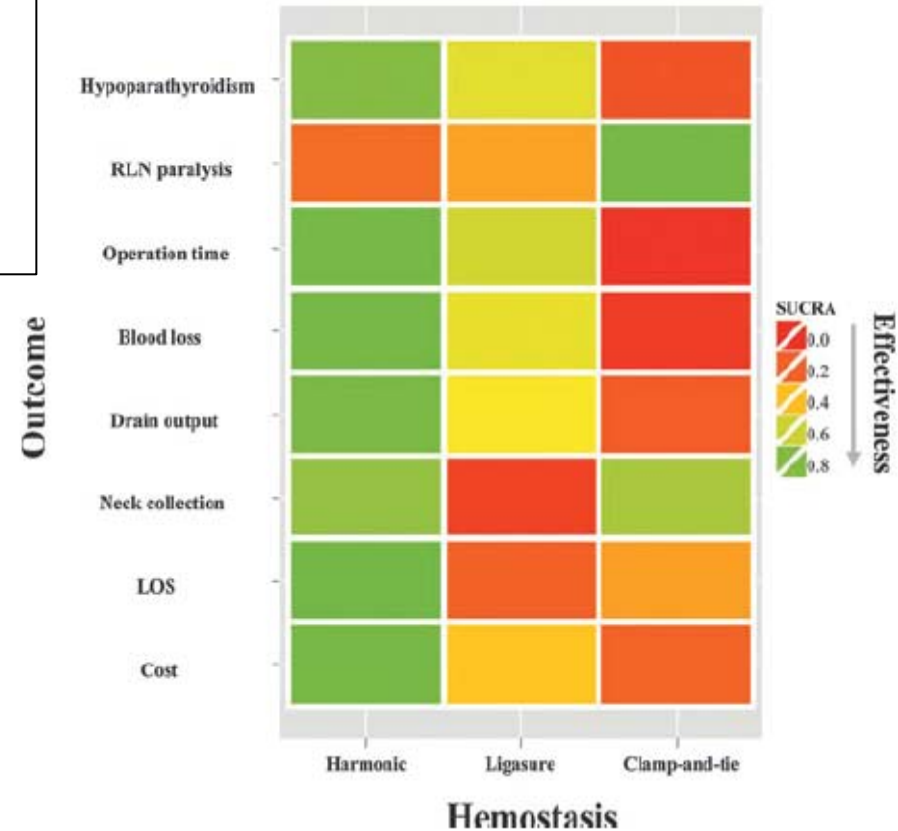


FIG. 3. Ranking of hemostatic devices on all outcomes of interest represented in the form of a heatmap as the surface under the cumulative ranking curve (SUCRA). The heatmap represents the efficacy of surgical devices on all outcomes of interest based on SUCRA scores. SUCRA=1 corresponds to an intervention that always ranks first and SUCRA=0 to an intervention that always ranks last. Similarly, green represents the best device and red represents the worst for each individual outcome in a qualitative approach. Color images available online at www.liebertpub.com/thy

A collage of various musical instruments including keyboards, drums, guitars, and brass instruments. The instruments are arranged in a dense, overlapping manner. The text "What About Currently Utilized Vessel Sealing Instruments?" is overlaid in the center in a white, bold, sans-serif font.

What About Currently Utilized Vessel Sealing Instruments?

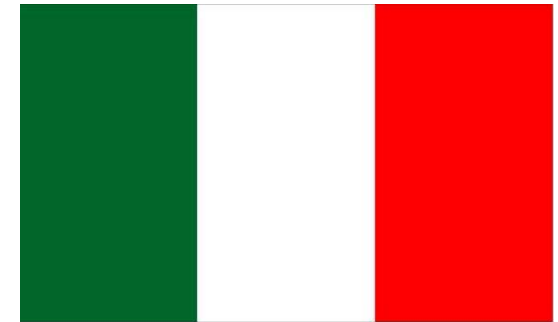




Ligasure (Small Jaw) vs Harmonic (Focus)



- Prospective Randomized Study (182 thyroidectomy patients)
 - No difference between 2 groups:
 - RLN dysfunction
 - Bleeding
 - Drainage
 - Operative Time
 - Postoperative Calcium Concentration
- However in the Harmonic group:
 - Mean length of incision greater
 - More likely to complain of pain with swallowing
 - PTH measurements were lower (normal range)
 - Oral calcium supplementation higher and longer





Ligasure (Small Jaw) vs Harmonic (Focus)



- Prospective Randomized Study (245 thyroidectomy patients)
 - No difference between 2 groups:
 - RLN dysfunction
 - Bleeding
 - Incision length
 - Length of hospital stay
 - Postoperative Calcium Concentration
 - However in the Harmonic group:
 - Mean duration of operation was significantly shorter than the Ligasure group
(Harmonic 16-70 min vs Ligasure 18-92 min)



Head To Head Study Conclusions

- Clear time benefit when comparing HS or LS to CH
- Little difference between HS and LS in terms of time savings or postoperative complications
- Both HS and LS are safe, useful and time saving alternatives to CH



Conclusions



- Vessel sealing technologies do represent an important technical advance for thyroid surgeons
- Both Harmonic Scalpel and Ligasure are **faster** (20 minutes for total thyroidectomy) than conventional hemostatic techniques
- These technologies are **safe** with complication rates similar to rates observed when utilizing conventional hemostatic techniques
- The choice of device is really based on the surgeon's preference

Future Directions



- **Evolving Vessel Sealing Technology**
 - Further development of novel energy platforms that allow for shorter tissue fusion cycles and less thermal spread for LS
 - Cooling systems and auto cut-offs that ensure safe temperatures for jaws of HS
 - Re-usable instruments
 - New vessel sealing instruments/systems

FUTURE



PlasmaKinetics
Sealer



BiClamp



ThermoStapler



EnSeal



Nightknife



marSeal



Thunderbeat

Future Directions



- Surgical guideline/policy development
- Large multicenter randomized prospective study using *current generation* instruments
- Rigorous economic analysis
 - Center/Surgeon Specific
- Study of oncologic implications of vessel sealing



THANK YOU