The Journal of Laryngology & Otology (2018), ***132***, *341–348*.

doi:10.1017/S0022215117002377

MAIN ARTICLE

New generation cut-and-seal devices in oral and oropharyngeal cancer resection: clinical and cost-effectiveness study

G TIRELLI[1], G C DEL PIERO[1], G VALENTINUZ[2], A MONTE[2], A GATTO[1], A REBELLI[3], E QUATELA[1]

[1]*ENT Department, Cattinara Hospital, University Clinical Department of Medical, Surgical and Health Sciences, University of Trieste,* [2]*Department of Economic, Business, Mathematical and Statistical Sciences 'Bruno de 'Finetti', University of Trieste, and* [3]*University Medical Center 'Ospedali Riuniti' of Trieste, Italy*

Abstract

Objectives: To evaluate the clinical efficacy and cost-effectiveness of ultrasonic shears and the electrothermal bipolar vessel sealing system, in comparison to the traditional cold knife and bipolar forceps, in oral and oropharyngeal cancer surgery.

Methods: Patients who underwent oral or oropharyngeal cancer resection and neck dissection with either ultrasonic shears ($n = 36$) or electrothermal bipolar vessel sealing ($n = 32$) were enrolled. Surgical time, intra-operative bleeding, blood drainage, post-operative pain, neck oedema, complications and hospitalisation duration were compared to those of an historical cohort of 36 patients treated using a cold knife and bipolar forceps. Additionally, a cost-effectiveness evaluation was performed.

Results: Ultrasonic shears and, in particular, electrothermal bipolar vessel sealing, were advantageous compared to the traditional techniques. The cost of ultrasonic shears and electrothermal bipolar vessel sealing was completely offset by declining time-driven costs for the surgical team and operating theatre.

Conclusion: Ultrasonic shears and, in particular, electrothermal bipolar vessel sealing, are more advantageous compared to the traditional techniques, from both a clinical and economic point of view.

Key words: Ultrasonics; Operative Time; Cost-Benefit Analysis; Surgical Instruments; Head And Neck Neoplasms

Introduction

Major head and neck surgery involves dissections close to crucial structures such as nerves and vessels. For this reason, it is very important to use safe instruments for dissection and haemostasis. In a wide variety of surgical procedures, advanced vessel sealing devices are replacing traditional techniques for vessel ligation.

The most common devices are ultrasonic shears and the electrothermal bipolar vessel sealing system. The first uses ultrasound technology that creates an axial vibration of the blade at a constant frequency of 55.5 kHz. By contrast, the electrothermal bipolar vessel sealing system uses radiofrequency currents, released in a precise and calibrated way through a new feedback sensor system that signals the completion of coagulation.[1,2] Both instruments allow simultaneous cutting through a process of tissue destruction, and haemostasis through protein denaturation and fusion of the vessel walls.[3]

These technologies offer potential clinical benefits: for example, decreased post-operative pain and seroma formation, with similar or lower complication rates, and significantly reduced operative times (20–30 per cent decrease).[4–7] However, the disadvantage of these devices is their cost.[8,9]

Quality, access, safety and cost reduction should be the main goals for any healthcare system, but none of them can serve as a unifying framework for healthcare delivery.[10] The economist Porter and his colleagues state that the main objective should be to increase the value delivered to patients; they define value on the basis of two parameters: patient outcomes and cost.[11,12] Maximising the value delivered to patients means achieving the best outcomes at the lowest cost,[12] or reducing costs while delivering the same or better outcomes.[10] Few studies have focused on the economic impact of the use of the new devices, and those that have report conflicting conclusions.

To our knowledge, no published study has investigated the clinical and economic outcomes associated with the use of ultrasonic shears and electrothermal bipolar vessel sealing in head and neck surgery. We

Accepted for publication 4 August 2017 First published online 18 December 2017

therefore assessed the clinical efficacy and cost-effectiveness of ultrasonic shears and electrothermal bipolar vessel sealing, compared to traditional surgery, in order to establish whether the higher cost of the new devices could be compensated by other advantages resulting from their use in the resection of oral and oropharyngeal cancer.

Materials and methods

Clinical study

This case series study was conducted at the ENT Department of Cattinara Hospital in Trieste with the collaboration of the Department of Economic, Business, Mathematical and Statistical Sciences, University of Trieste. We reviewed the charts of all consecutive patients affected by cancer of the oral or oropharyngeal cavity, who underwent surgical resection of the primary tumour and neck dissection at our centre between May 2006 and November 2013.

Exclusion criteria for the study was previous surgery or radiotherapy of the head and neck area, as this may alter the anatomy of the head and neck region, and thus affect surgical times. Also excluded were transoral procedures, because operative times are generally shorter than with the mandibulotomy approach and their inclusion could affect group homogeneity.

The surgical operations were classified as: hemiglossopelvectomy, with or without extension to the tonsillar region and/or soft palate; cheek resection, with or without extension to the retromolar trigone and/or soft palate; or pharyngo-tonsillectomy, with or without extension to the base of tongue and/or soft palate. All procedures were performed by the same senior surgeon.

Between May 2006 and March 2008, these operations were performed using conventional surgical techniques; that is, resection and dissection with a cold knife and/or dissecting scissors, and haemostasis using bipolar forceps or traditional vessel ligation. In April 2008, ultrasonic shears (Harmonic Focus; Ethicon Endo-Surgery, Cincinnati, Ohio, USA) were introduced to our clinic and these replaced the conventional techniques (cold knife) for dissection, resection and haemostasis (except for vessels exceeding 5 mm, which were sealed with a classic technique) until December 2010. In January 2011, the ultrasonic shears were replaced by a new tool, the electrothermal bipolar vessel sealing system (LigaSure Small Jaw; Valleylab, Boulder, Colorado, USA), which was used for the same skills (dissection, resection and haemostasis of vessels up to 7 mm) until November 2013. The instruments were used in different periods according to their availability in our clinic.

The results obtained in the patients operated on using ultrasonic shears or the electrothermal bipolar vessel sealing system were compared with data from a consecutive historical cohort who underwent the same surgical procedures performed with conventional surgical techniques (resection and dissection with a cold knife and/or dissecting scissors, and haemostasis using bipolar forceps or traditional vessel ligation) between May 2006 and March 2008.

The parameters taken into consideration in the three groups (ultrasonic shears, electrothermal bipolar vessel sealing system and cold knife groups) were: time required for tumour resection and neck dissection (measured separately in terms of minutes from the initial incision to removal of the surgical specimen); intra-operative bleeding (millilitres); post-operative blood drainage in the first 3 days after surgery (millilitres); post-operative pain from day 1 to day 5 after surgery (numerical rating scale from 0 to 10); and neck oedema, and possible device-related complications such as bleeding, haematoma, infection and dehiscence of wounds in the oral, oropharyngeal and cervical regions.

Comparison between procedures performed with ultrasonic shears or electrothermal bipolar vessel sealing and with a cold knife was possible because the new instruments replaced the traditional resection and haemostasis tools, whereas the technique and surgical steps remained unchanged.

The study was approved by the local ethical committee, and all patients signed a detailed informed consent form and privacy policy agreement.

Statistical analysis

A one-way analysis of variance (ANOVA) and Welch ANOVA were conducted to determine if tumour resection time, intra-operative bleeding and post-operative pain were different for the three groups operated on using different instruments (ultrasonic shears, electrothermal bipolar vessel sealing and cold knife). A one-way and a Welch ANOVA were also conducted for neck dissection time and blood drainage. In all of the groups, there were outliers and data were not normally distributed. Logarithmic transformation was used successfully in order to reduce the non-normality and outliers for tumour resection time and intra-operative bleeding. The Welch ANOVA was used because the homogeneity of variances was violated, as assessed by Levene's test of homogeneity. The Tukey post-hoc test was used in the ANOVA and the Games–Howell post-hoc test in the Welch ANOVA. Finally, the chi-square test was performed to determine if the occurrence of neck oedema was different in the three groups.

Cost evaluation

In order to determine whether the clinical benefits offset the higher cost of these new generation, single-use instruments, a cost-effectiveness study was conducted at the ENT Department of Cattinara Hospital in Trieste, with the collaboration of the Department of Economic, Business, Mathematical and Statistical Sciences, University of Trieste.

Cost analysis was based on a combination of absorption costing and time-driven activity-based costing.[13,14]

https://doi.org/10.1017/S0022215117002377 Published online by Cambridge University Press

In time-driven activity-based costing, only two estimates are required for each group of resources: the cost per time unit of supplying resource capacity and the unit times of consumption of resource capacity by unit of analysis.[14]

In addition to intra-operative and post-operative parameters, we collected data on the length of hospitalisation for each patient. Hospitalisation duration was measured in days. The cost for each day was calculated by adding the annual costs for personnel, cleaning services, laundering service, food given to patients, depreciation and maintenance costs of apparel, and other overhead costs incurred by the ENT department, divided by the product of the number of days and the practical departmental capacity. The resulting daily cost of hospitalisation amounted to 446.20 Euros.

The operating theatre costs and the surgical team costs were considered variable costs (related to capacity). We attributed these costs to the different groups, using a simple equation: cost = quantity × price. The duration of surgery was calculated by adding tumour resection time and neck dissection time, resulting in the total time of each surgical operation.

The clinical personnel costs were calculated on the basis of medical (surgeons and anaesthetist) and nursing costs, by dividing their mean wages, as stated in the national labour contract, by the product of: the mean number of working days and the minutes per day. In this way, we obtained a 1-minute production cost for the operating theatre team (medical and nursing) equal to 4.41 Euros.

From the hospital accounting system, we obtained the hourly operating theatre utilisation cost, which we divided by 60 to obtain a 1-minute production cost for its use; this amounted to 2.12 Euros. Every operation, independent from the instrument used to cut and seal, was then allocated an additional 422 Euros. This was calculated by using the full cost attribution process, which included costs for drugs, surgical supplies and other overheads related to the operating theatre.

Finally, the cost of each device, derived from the hospital's accounting system, was added. The purchasing cost was 548 Euros for the electrothermal bipolar vessel sealing system and 480 Euros for the ultrasonic shears. These costs refer to Cattinara Hospital in Trieste; the price of these instruments may vary by region and country, and is dependent on the number of units ordered. No depreciation costs for the generator were calculated as the unit purchasing costs of the two new instruments already included the cost for hiring the generator (service contract).

Regarding the cold knife group, we calculated that the traditional technique involves the use of an average of: one cold knife scalpel (5 Euros), seven ligation threads for each operation (a total of 9.45 Euros, 1.35 Euros per thread) and one multiple clip applier (32 Euros) for each operation. The total cost of the instruments in the cold knife group was 46.45 Euros.

All costs were derived from the hospital accounting system at the beginning of the study (August 2014).

Results

Clinical study

There were 36 patients in the ultrasonic shears group and 32 in the electrothermal bipolar vessel sealing group. These 2 groups were compared with a historical cohort of 36 patients treated with traditional instruments (cold knife). The characteristics of the patients are shown in Table I.

No differences were observed among the groups in terms of age, tumour stage, type of primary tumour surgery or lymph node surgery. A difference in sex was noted in the three groups, but this did not influence the results.

An ANOVA revealed statistically significant differences among the three groups (cold knife, electrothermal bipolar vessel sealing and ultrasonic shears) for all intra-operative and post-operative parameters ($p < 0.001$ for all five variables). Post-hoc analysis showed that use of the electrothermal bipolar vessel sealing

TABLE I
PATIENTS' CHARACTERISTICS

Characteristic	Cold knife	EBVS	Ultrasonic shears
Patients (*n*)	36	32	36
Females/males (%)	22/78	37/63	56/44
Mean age (years)	65.54	67.12	66.0
Tumour stage (*n* (%))			
– Stage II	9 (25)	8 (25)	9 (25)
– Stage III	14 (39)	10 (31)	11 (31)
– Stage IV	13 (36)	14 (44)	16 (44)
Primary tumour surgery (*n* (%))			
– Hemiglossopelvectomy ± extension to tonsillar region &/or soft palate	13 (36)	14 (44)	11 (31)
– Cheek resection ± extension to retromolar trigone &/or soft palate	13 (36)	9 (28)	15 (42)
– Pharyngo-tonsillectomy ± extension to tongue base &/or soft palate	10 (28)	9 (28)	10 (28)
Lymph node surgery (*n* (%))			
– Comprehensive neck dissection (hemi-neck)	18 (45)	20 (45)	19 (44)
– Selective neck dissection (hemi-neck)	22 (55)	24 (55)	24 (56)

EBVS = electrothermal bipolar vessel sealing system

https://doi.org/10.1017/S0022215117002377 Published online by Cambridge University Press

system or the ultrasonic shears was advantageous in each parameter compared to the traditional cold knife technique (Table II). Of the two new generation devices, electrothermal bipolar vessel sealing allowed statistically significant decreases in tumour resection time ($p = 0.004$), intra-operative bleeding ($p = 0.002$) and post-operative pain ($p = 0.004$) compared to the ultrasonic shears (Table III). Neck dissection time and post-operative drainage were significantly different between the cold knife and electrothermal bipolar vessel sealing and between the cold knife and ultrasonic shears; however, the Games–Howell post-hoc test revealed that the difference between the ultrasonic shears and electrothermal bipolar vessel sealing was not statistically significant for these parameters (neck dissection time, $p = 0.377$; drainage, $p = 0.514$). The results of the analyses are shown in Tables II and III.

Regarding complications, post-operative neck oedema was present in: 6 patients in the cold knife group, 5 in the electrothermal bipolar vessel sealing group and 12 in the ultrasonic shears group. However, according to the chi-square test, the occurrence of oedema was independent of the type of instrument used (chi-square = 4.033 and $p = 0.133$). Other procedure-related post-operative complications also occurred, affecting two patients in the cold knife group (one patient had dehiscence of the surgical wound and one had post-operative haematoma), one in the electrothermal bipolar vessel sealing group (dehiscence of the surgical wound) and one in the ultrasonic shears group (post-operative haematoma).

Cost evaluation

The analysis of surgical times and hospitalisation duration for each group are illustrated in Table IV. Compared to the cold knife, the two new generation cut-and-seal devices led to shorter mean surgical time (162.81 minutes for electrothermal bipolar vessel sealing and 175.81 minutes for ultrasonic shears, *vs* 217.28 minutes for cold knife) and mean hospitalisation duration (18.53 days for electrothermal bipolar vessel sealing and 21.61 days for ultrasonic shears, *vs* 23.26 days for cold knife). Electrothermal bipolar vessel sealing, in particular, proved to be the most advantageous with respect to these parameters.

By multiplying the cost per minute of the operating theatre and the surgical team by the mean surgical time, and the daily cost of hospitalisation by the mean number of hospitalisation days (Table IV), we obtained the mean overall cost per operation, for each of the three instruments (Table V).

The higher purchase cost of the two new devices was offset by declining time-driven costs for the surgical team and operating theatre (Table V). The electrothermal bipolar vessel sealing system produced greater savings as a result of the lower number of hospitalisation days.

Table VI shows the differences between the costs incurred with the cold knife, used as a benchmark, and the two new generation devices. Positive signs represent a cost saving and negative signs express a cost increase, in comparison to the benchmark.

Given the assumptions used to calculate the time-driven costs and allocate the overhead costs, the use of the electrothermal bipolar vessel sealing system resulted in greater cost savings (2009.05 Euros) compared to both the cold knife and ultrasonic shears, which produced savings of 617.92 Euros compared to the cold knife (Table VI).

The costs associated with the different instruments were explored for a range of values rather than for mean values only. In particular, the range we analysed was between the mean hospitalisation days ± 1 standard deviation (SD) and between the total surgical time ± 1 SD. Electrothermal bipolar vessel sealing proved to be more cost-efficient than the cold knife in eight scenarios out of nine. The exception was when both the total surgical time and the hospitalisation days were at their mean value minus 1 SD (i.e. 98.38 minutes and 7.71 days for electrothermal bipolar vessel sealing, and 131.06 minutes and 8.3 days for cold knife). In this case, electrothermal

TABLE II
PERI- AND POST-OPERATIVE PARAMETERS AND STATISTICAL ANALYSIS, FOR EACH DEVICE

Parameter	Cold knife (mean ± SD)	EBVS (mean ± SD)	Ultrasonic shears (mean ± SD)	Levene's test Statistic	ANOVA (or Welch ANOVA)		
					Significance	F value	Significance
Tumour resection time (min)*	103.06 ± 17.94	72.88 ± 42.12	90.19 ± 16.20	20.106	0.000	13.484†	0.000
Neck dissection time (min)	102.80 ± 15.96	65.41 ± 19.69	70.05 ± 11.71	11.673	0.000	66.871†	0.000
Intra-operative bleeding (ml)*	475.97 ± 110.91	67.97 ± 89.08	78.53 ± 16.23	66.690	0.000	601.854†	0.000
Pain (numerical rating scale 0–10)	2.51 ± 0.76	0.61 ± 0.67	1.24 ± 0.89	2.353	0.100	52.220	0.000
Drainage (ml)	55.26 ± 25.68	28.86 ± 15.02	25.30 ± 15.02	6.089	0.003	21.262†	0.000

Post-hoc test was Tukey or Games–Howell. *The mean value refers to the original variable. All other values (Levene, analysis of variance, post-hoc test) refer to logarithmic transformed variables. †Welch analysis of variance. SD = standard deviation; EBVS = electrothermal bipolar vessel sealing system; ANOVA = analysis of variance

https://doi.org/10.1017/S0022215117002377 Published online by Cambridge University Press

TABLE III
COMPARISON OF PERI- AND POST-OPERATIVE PARAMETERS AND STATISTICAL ANALYSIS, BETWEEN DEVICES

Group (I)	Group (J)	Tumour resection time*		Neck dissection time*		Intra-operative bleeding*		Pain		Drainage*	
		Mean difference (I–J)	Significance	Mean difference (I–J)	Significance	Mean difference (I–J)	Significance	Mean difference (I–J)	Significance	Mean difference (I–J)	Significance
Cold knife	EBVS	0.469	0.000	37.391	0.000	2.576	0.000	1.895	0.000	26.395	0.000
Cold knife	Ultrasonic shears	0.134	0.008	32.755	0.000	0.791	0.000	1.269	0.000	29.955	0.000
Ultrasonic shears	EBVS	0.335	0.004	4.636	0.377	1.785	0.002	0.626	0.004	3.561	0.514

*Games–Howell post-hoc test. EBVS = electrothermal bipolar vessel sealing system

TABLE IV
SURGICAL TIMES AND HOSPITALISATION DURATION FOR EACH DEVICE

Device	Surgical time (mins)		Hospitalisation duration (days)	
	Mean	SD	Mean	SD
Cold knife	217.28	86.22	23.36	15.06
EBVS	162.81	64.43	18.53	10.82
Ultrasonic shears	175.81	41.48	21.61	10.18

SD = standard deviation; EBVS = electrothermal bipolar vessel sealing system

bipolar vessel sealing had a slightly higher cost than the cold knife (5052.20 Euros *vs* 5027.16 Euros), though it remained less costly than ultrasonic shears. Conversely, ultrasonic shears were found to be more cost-efficient than the cold knife in six scenarios out of nine. The traditional scalpel was cheaper for any operating theatre time (between the mean and 1+ SD, i.e. from 131.06 to 303.50 minutes for cold knife and from 134.33 to 217.29 minutes for ultrasonic shears) when hospitalisation days were at their average value minus 1 SD (8.30 days for cold knife and 11.43 days for ultrasonic shears). The change in costs due to a decrease or increase by 1 SD in total surgical time was limited to ±2.32 per cent for ultrasonic shears, ±4.08 per cent for electrothermal bipolar vessel sealing and ±4.57 per cent for the cold knife. However, a similar change (1 SD from the average value) in hospitalisation days caused a greater difference: ±38.85 per cent for ultrasonic shears, ±46.87 per cent for electrothermal bipolar vessel sealing and ±54.59 per cent for the cold knife.

Discussion

The present study aimed to evaluate the impact of two new generation cut-and-seal devices – electrothermal bipolar vessel sealing and ultrasonic shears – on the clinical outcomes and hospital costs for patients undergoing oral and oropharyngeal cancer resection.

From a clinical point of view, both the electrothermal bipolar vessel sealing system and ultrasonic shears proved to be advantageous in every parameter considered, compared to the traditional cold knife technique. In particular, we observed the least intra-operative bleeding in the electrothermal bipolar vessel sealing group (67.97 ± 89.08 ml), followed by the ultrasonic shears (78.53 ± 16.23 ml) and cold knife groups (475.97 ± 110.91 ml).

While several studies in the literature have confirmed the superiority of ultrasonic shears or electrothermal bipolar vessel sealing to traditional techniques,[8,15–17] only two[6,18] have reported less bleeding with electrothermal bipolar vessel sealing compared to ultrasonic shears in thyroid surgery, whereas the majority found no difference between the two devices.[5,19,20] The superiority of electrothermal bipolar vessel sealing in

https://doi.org/10.1017/S0022215117002377 Published online by Cambridge University Press

TABLE V
AVERAGE COSTS PER OPERATION AND THEIR DETERMINANTS, FOR EACH DEVICE

Device	Device cost	Time-driven costs for surgical team	Time-driven costs for operating theatre	Other costs allocated to operating theatre	Hospitalisation costs	Total average costs per operation
Cold knife	46.45	957.99	459.91	422.00	10 423.23	12 309.58
EBVS	548.00	717.83	344.61	422.00	8268.09	10 300.53
Ultrasonic shears	480.00	775.15	372.13	422.00	9642.38	11 691.66

Data represent costs, in Euros. EBVS = electrothermal bipolar vessel sealing system

terms of haemostasis may be ascribed to the fact that this system provides an effective seal of arteries up to 5 mm in diameter and veins up to 7 mm, for pressure values up to three times the normal systolic pressure,[21,22] while haemostasis with ultrasonic shears is guaranteed for smaller vessels, up to 3 mm for arteries and 5 mm for veins.[8]

Post-operative blood drainage, on the other hand, showed no significant difference between the electrothermal bipolar vessel sealing system and ultrasonic shears, whereas the superiority of both devices to the cold knife was confirmed. While the superiority of ultrasonic shears to the cold knife in blood drainage has already been reported,[8,15,17] no studies have ever quantified post-operative drainage for electrothermal bipolar vessel sealing.

A study by Fakhry *et al*., published in 2012, evaluated the haemostatic efficacy of electrothermal bipolar vessel sealing in major head and neck cancer surgery, observing post-operative bleeding in 2 of 34 patients treated.[23] Nevertheless, the authors did not quantify the post-operative bleeding, nor did they compare electrothermal bipolar vessel sealing with other cut-and-seal instruments.

Another important advantage of the new generation devices over the traditional techniques is the significant reduction in operating time (electrothermal bipolar vessel sealing, 72.88 ± 42.12 minutes; ultrasonic shears, 90.19 ± 16.20 minutes; cold knife, 103.06 ± 17.94 minutes). This is probably accounted for by the fact that all steps were performed using the same surgical instrument, while in conventional cold knife surgery the instrument needs to be changed for haemostasis (bipolar forceps or traditional vessel ligation). Another possible reason could be that both ultrasonic shears and electrothermal bipolar vessel sealing create a bloodless surgical field with excellent visibility for the surgeon. This is an advantage commonly reported in the literature,[5,8,15–17,24] with the exception of Walen *et al*.[25] who found no difference between the ultrasonic shears and cold knife.

Comparison of the new devices revealed significantly shorter tumour resection time with electrothermal bipolar vessel sealing. This finding conflicts with previous studies,[19,20,26] which reported shorter thyroidectomy operating times with ultrasonic shears compared to electrothermal bipolar vessel sealing.

Another benefit of electrothermal bipolar vessel sealing observed in the present study was a significant decrease in post-operative pain compared to the use of ultrasonic shears and cold knife. In our opinion, the difference could be due to the lower temperatures and resulting reduction in tissue damage achieved by the electrothermal bipolar vessel sealing system compared to ultrasonic shears and bipolar forceps (cold knife).[27,28]

Post-operative complications were minimal, and there were no significant differences among the three groups. However, the ultrasonic shears group was more likely to develop neck oedema (ultrasonic shears, 12 out of 36 patients; electrothermal bipolar vessel sealing, 5 out of 32 patients; cold knife, 6 out of 36 patients), which resolved spontaneously within 7 days, with the aid of manual lymphatic massage. The oedema presented with the pitting characteristic of lymphatic stasis, and appeared in the neck tissues below and above the maxillary arch. This suggests it was caused by complete sealing of the lymphatic vessels by ultrasonic shears dissection, with lymph pooling in the anatomical regions upstream of the resection.

Our results suggest that both new generation devices could be advantageous and safe instruments compared

TABLE VI
COST SAVINGS OR INCREASES FOR EBVS AND ULTRASONIC SHEARS VERSUS TRADITIONAL COLD KNIFE

Device comparison	Device cost difference	Time-driven costs for surgical team	Time-driven costs for operating theatre	Other costs charged to operating theatre	Hospitalisation costs	Total average costs savings
EBVS *vs* cold knife	−501.55	+240.16	+115.30	0.00	+2155.14	+2009.05
Ultrasonic shears *vs* cold knife	−433.55	+182.84	+87.78	0.00	+780.85	+617.92

Data represent savings ('−') or increases ('+') in costs, in Euros. EBVS = electrothermal bipolar vessel sealing system

https://doi.org/10.1017/S0022215117002377 Published online by Cambridge University Press

to the traditional techniques (using bipolar forceps and cold knife) in major head and neck surgery. However, the main disadvantage of these cut-and-seal devices, according to several literature reports, is the increased cost of intervention.[8,9] We therefore conducted an economic analysis to compare the three instruments (electrothermal bipolar vessel sealing, ultrasonic shears and cold knife) from the perspective of Porter's notion of value in healthcare.[29]

Unlike some previous studies, we did not estimate an overall ratio of facility costs to facility charges (the 'top-down' approach[13]) because we believe that costs (rather than charges or tariffs) better approximate the value of consumed resources.[29] The results of our analysis show that, compared to the cold knife, ultrasonic shears and electrothermal bipolar vessel sealing reduce mean operating time and hospitalisation duration, providing savings that compensate for the higher cost of the new devices. These findings are based on mean values, but, when total surgery time and hospitalisation duration are at their average value minus 1 SD, use of the ultrasonic shears and electrothermal bipolar vessel sealing system increases the overall costs compared to the cold knife, as a result of the higher price of the handpiece. This finding indicates that the greatest impact on the overall cost of this kind of surgery is the overhead costs included in the hospitalisation costs and surgical time costs. It should be noted that the length of hospital stay also depends on other patient-related factors (age, co-morbidities), tumour stage and consequent surgical approach, and possible additional complications. In the present study, the three groups were homogeneous for every characteristic except for co-morbidities, which were not considered, a fact that could represent a possible bias of our study.

Although ours is the first study to investigate the clinical outcomes and cost-effectiveness of using the electrothermal bipolar vessel sealing system and ultrasonic shears in oral and oropharyngeal cancer surgery, the same aspects have been studied in the field of thyroid surgery, with conflicting results. Reported benefits include a more efficient utilisation (shorter time) of the operating theatre[2,3,30] and shorter operating time,[31] consistent with our results. Hallgrimsson *et al*. found no cost benefit for ultrasonic shears use in thyroid surgery.[32] However, Lombardi *et al*. reported cost savings with the ultrasonic shears compared to the traditional technique, as a result of the significant decrease in operative time (30 per cent), with lower costs for drugs, personnel and operating theatre charges.[4] Da Silva *et al*., by contrast, reported that ultrasonic shears and electrothermal bipolar vessel sealing increased the total cost of thyroidectomy procedures, despite the fact that mean operative times decreased by approximately 32 minutes with ultrasonic shears compared to the conventional technique.[3] This finding may be explained by the fact that there was no effect on the length of hospital stay, which we believe to be the most influential parameter in the final cost of any surgical procedure. The different results may also be related to the shorter duration of hospitalisation after thyroid surgery compared to oral and oropharyngeal cancer surgery.

There are several limitations to our study that need to be acknowledged. Our data and results refer to one hospital only, whereas costs may vary across different countries. In addition, the cost of these cut-and-seal devices may vary from region to region, and is also dependent on the number of units ordered. We did not consider the costs associated with training in the use of the new generation devices (learning curve); at our centre, these devices are used by an expert surgeon only. Moreover, our study considered patients with highly heterogeneous disease in terms of site and dimension; for this reason, we excluded stage 1 tumours. A multicentre study with cluster randomisation should be able to determine whether it is appropriate to introduce complex technologies in different organisational settings.

- **Ultrasonic shears and electrothermal bipolar vessel sealing system are new cut-and-seal devices, replacing traditional head and neck surgery techniques**
- **These devices allow simultaneous cutting via tissue destruction, and haemostasis via protein denaturation and vessel wall fusion**
- **Both new instruments have advantages compared to traditional techniques (cold knife and bipolar forceps)**
- **These include reduced surgical time, intra-operative bleeding, blood drainage, post-operative pain, neck oedema, complications and hospitalisation**
- **Their disadvantage is the high cost, but price was offset by declining time-driven costs for surgical team and operating theatre**
- **Electrothermal bipolar vessel sealing provided better clinical results with lower costs compared to ultrasonic shears**

The new ultrasonic shears and electrothermal bipolar vessel sealing devices provide a definite advantage over the traditional technique for all parameters examined in oral and oropharyngeal cancer resection and neck dissection. Of the two devices, electrothermal bipolar vessel sealing provided better results in terms of tumour resection time, intra-operative bleeding and post-operative pain. As for the economic aspects, our results suggest that the electrothermal bipolar vessel sealing is – under the assumptions used – the most efficient cut-and-seal device, reducing operating time and hospitalisation duration and thus the total costs per operation. This finding, combined with the (more important) clinical results, allows us to conclude that

https://doi.org/10.1017/S0022215117002377 Published online by Cambridge University Press

electrothermal bipolar vessel sealing fully embodies Porter's view of value in the hospital sector; that is, achieving better patient outcomes with lower costs.

These preliminary results need to be further investigated in prospective and randomised trials, in order to compare the two new generation instruments – ultrasonic shears and electrothermal bipolar vessel sealing – in terms of intra-operative and post-operative blood loss, surgical time, post-operative pain, and cost saving adopting the time-driven activity-based costing model.

Acknowledgement

This research was conducted as part of the 'Fondo per la Ricerca di Ateneo – FRA 2015' programme of the University of Trieste.

References

1 Jackson LL, Gourin CG, Thomas DS, Porubsky ES, Klippert FN, Terris DJ. Use of the harmonic scalpel in superficial and total parotidectomy for benign and malignant disease. *Laryngoscope* 2005;**115**:1070–3
2 Chang LY, O'Neill C, Suliburk J, Sidhu S, Delbridge L, Sywak M. Sutureless total thyroidectomy: a safe and cost-effective alternative. *ANZ J Surg* 2011;**81**:510–14
3 da Silva FB, Limoeiro AC, Del Bianco J, Teich V, Teich N, Teixeira JC *et al*. Impact of the use of vessel sealing or harmonic scalpel on intra-hospital outcomes and the cost of thyroidectomy procedures. *Einstein (Sao Paulo)* 2012;**10**:354–9
4 Lombardi CP, Raffaelli M, Cicchetti A, Marchetti M, De Crea C, Di Bidino R *et al*. The use of 'harmonic scalpel' versus 'knot tying' for conventional 'open' thyroidectomy: results of a prospective randomized study. *Langenbecks Arch Surg* 2008;**393**:627–31
5 Manouras A, Markogiannakis H, Koutras AS, Antonakis PT, Drimousis P, Lagoudianakis EE *et al*. Thyroid surgery: comparison between the electrothermal bipolar vessel sealing system, harmonic scalpel, and classic suture ligation. *Am J Surg* 2008;**195**:48–52
6 Youssef T, Mahdy T, Farid M, Latif AA. Thyroid surgery: use of the LigaSure Vessel Sealing System versus conventional knot tying. *Int J Surg* 2008;**6**:323–7
7 Koh YW, Park JH, Lee SW, Choi EC. The harmonic scalpel technique without supplementary ligation in total thyroidectomy with central neck dissection: a prospective randomized study. *Ann Surg* 2008;**247**:945–9
8 Salami A, Dellepiane M, Bavazzano M, Crippa B, Mora F, Mora R. New trends in head and neck surgery: a prospective evaluation of the Harmonic Scalpel. *Med Sci Monit* 2008;**14**:PI1–5
9 Kiriakopoulos A, Tsakayannis D, Linos D. Use of a diathermy system in thyroid surgery. *Arch Surg* 2004;**139**:997–1000
10 Kaplan RS, Witkowski ML. Better accounting transforms health care delivery. *Accounting Horizons* 2014;**28**:365–83
11 Porter ME, Teisberg E. *Redefining Healthcare: Creating Value-Based Competition on Results*. Boston: Harvard Business Press, 2006
12 Porter ME, Lee T. The strategy that will fix health care. *Harv Bus Rev* 2013;**10**:2–19
13 Macario A. What does one minute of operating room time cost? *J Clin Anesth* 2010;**22**:233–6
14 Kaplan R, Anderson S. Time-driven activity-based costing. *Harv Bus Rev* 2004;**82**:131–8
15 Salami A, Bavazzano M, Mora R, Dellepiane M. Harmonic Scalpel in pharyngolaryngectomy with radical neck dissection. *J Otolaryngol Head Neck Surg* 2008;**37**:633–7
16 Pons Y, Gauthier J, Clèment P, Conessa C. Ultrasonic partial glossectomy. *Head Neck Oncol* 2009;**1**:21
17 Tirelli G, Del Piero GC, Perrino F. Ultracision Harmonic Scalpel in oral and oropharyngeal cancer resection. *J Craniomaxillofac Surg* 2014;**42**:544–7
18 Dilek ON, Yilmaz S, Degirmenci B, Ali Sahin D, Akbulut G, Dilek FH. The use of a vessel sealing system in thyroid surgery. *Acta Chir Belg* 2005;**105**:369–72
19 Sartori PV, De Fina S, Colombo G, Pugliese F, Romano F, Cesana G. Ligasure versus Ultracision in thyroid surgery: a prospective randomized study. *Langenbecks Arch Surg* 2008;**393**:655–8
20 McNally MM, Agle SC, Williams RF, Pofahl WE. A comparison of two methods of hemostasis in thyroidectomy. *Am Surg* 2009;**75**:1073–6
21 Harold KL, Pollinger H, Matthews BD, Kercher KW, Sing RF, Heniford BT. Comparison of ultrasonic energy, bipolar thermal energy, and vascular clips for the hemostasis of small-, medium-, and large-sized arteries. *Surg Endosc* 2003;**17**:1228–30
22 Dubuc-Lissoir J. Use of a new energy-based vessel ligation device during laparoscopic gynecologic oncologic surgery. *Surg Endosc* 2003;**17**:466–8
23 Fakhry N, Michel J, Santini L, Lagier A, Turner F, Dessi P *et al*. Utility of the LigaSure vessel sealing system during major head and neck cancer surgery. *J Laryngol Otol* 2012;**126**:815–17
24 Prokopakis EP, Lachanas VA, Vardouniotis AS, Velegrakis GA. The use of the Ligasure vessel sealing system in head and neck surgery: a report on six years of experience and a review of the literature. *B-ENT* 2010;**6**:19–25
25 Walen SG, Rudmik LR, Dixon E, Matthews TW, Nakoneshny SC, Dort JC. The utility of the harmonic scalpel in selective neck dissection: a prospective, randomized trial. *Otolaryngol Head Neck Surg* 2011;**144**:894–9
26 Zarebczan B, Mohanty D, Chen H. A comparison of the LigaSure and harmonic scalpel in thyroid surgery: a single institution review. *Ann Surg Oncol* 2011;**18**:214–18
27 Sutton PA, Awad S, Perkins AC, Lobo DN. Comparison of lateral thermal spread using monopolar and bipolar diathermy, the Harmonic Scalpel and the Ligasure. *Br J Surg* 2010;**97**:428–33
28 Tirelli G, Camilot D, Bonini P, Del Piero GC, Biasotto M, Quatela E. Harmonic Scalpel and Electrothermal Bipolar Vessel Sealing System in head and neck surgery: a prospective study on tissue heating and histological damage on nerves. *Ann Otol Rhinol Laryngol* 2015;**124**:852–8
29 Sebag F, Fortainer C, Ippolito G, Lagier A, Auquier P, Henry JF. Harmonic scalpel in multinodular goiter surgery: impact on surgery and cost analysis. *J Laparoendosc Adv Surg Tech A* 2009;**19**:171–4
30 Dibidino R, Ruggeri M, Marchetti M, Lombardi N, Raffaelli M, Attinà G *et al*. The harmonic study: cost-effectiveness evaluation of the use of the ultrasonic scalpel in total thyroidectomy. *Int J Technol Assess Health Care* 2012;**28**:259–64
31 Petrakis IE, Kogerakis NE, Lasithiotakis KG, Vrachassotakis N, Chalkiadakis GE. LigaSure versus clamp-and-tie thyroidectomy for benign nodular disease. *Head Neck* 2004;**26**:903–9
32 Hallgrimsson A, Lovén L, Westerdahl J, Bergenfelz A. Use of the harmonic scalpel versus conventional haemostatic techniques in patients with Grave disease undergoing total thyroidectomy: a prospective randomised controlled trial. *Langenbecks Arch Surg* 2008;**393**:675–80

Address for correspondence:
Dr Eliana Quatela,
ENT Department,
Cattinara Hospital,
Strada di Fiume, 447,
34149 Trieste, Italy

Fax: 00 39 0403 994 180
E-mail: quatela.eliana@gmail.com

Dr E Quatela takes responsibility for the integrity of the content of the paper
Competing interests: None declared