



High-energy devices in different surgical settings: lessons learnt from a full health technology assessment report developed by SICE (Società Italiana di Chirurgia Endoscopica)

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Abstract

Background The present paper aims at evaluating the potential benefits of high-energy devices (HEDs) in the Italian surgical practice, defining the comparative efficacy and safety profiles, as well as the potential economic and organizational advantages for hospitals and patients, with respect to standard monopolar or bipolar devices.

Methods A Health Technology Assessment was conducted in 2021 assuming the hospital perspective, comparing HEDs and standard monopolar/bipolar devices, within eleven surgical settings: appendectomy, hepatic resections, colorectal resections, cholecystectomy, splenectomy, hemorrhoidectomy, thyroidectomy, esophago-gastrectomy, breast surgery, adrenalectomy, and pancreatectomy. The nine EUnetHTA Core Model dimensions were deployed considering a multi-methods approach. Both qualitative and quantitative methods were used: (1) a systematic literature review for the definition of the comparative efficacy and safety data; (2) administration of qualitative questionnaires, completed by 23 healthcare professionals (according to 7-item Likert scale, ranging from -3 to +3); and (3) health-economics tools, useful for the economic evaluation of the clinical pathway and budget impact analysis, and for the definition of the organizational and accessibility advantages, in terms of time or procedures' savings.

Results The literature declared a decrease in operating time and length of stay in using HEDs in most surgical settings. While HEDs would lead to a marginal investment for the conduction of 178,619 surgeries on annual basis, their routinely implementation would generate significant organizational savings. A decrease equal to -5.25/-9.02% of operating room time and to -5.03/-30.73% of length of stay emerged. An advantage in accessibility to surgery could be hypothesized in a 9% of increase, due to the gaining in operatory slots. Professionals' perceptions crystallized and confirmed literature evidence, declaring a better safety and effectiveness profile. An improvement in both patients and caregivers' quality-of-life emerged.

Conclusions The results have demonstrated the strategic relevance related to HEDs introduction, their economic sustainability, and feasibility, as well as the potentialities in process improvement.

Keywords High-energy device · Monopolar device · Bipolar device · HTA · Multidimensional evaluation · Economic analysis

A list of the HTA-HED Collaborative Group authors and their affiliations appears at the acknowledgements.

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Surgical practice has undergone major refinements with corresponding improvements in post-operative outcomes over the years. Standard monopolar and bipolar energy devices are currently widely used due to their inexpensive nature and reusability.

In the attempt to have better performance in the surgical practice, such as better vessel sealing, coagulation, and transection as well as an efficient tissue dissection, technological

solutions such as energy devices are some of the important innovations that have contributed to these improvements. Since the nineties, more and more operations have become feasible by means of the so-called “key-hole surgery.” The attempt of being less invasive has gone together with the difficulties of doing the same dissections and gestures typical of open surgery through an indirect approach to the viscera. This has typically regarded hemostasis, as putting clamps or sutures was more difficult in laparoscopic surgery. Thus, the introduction of vessel-sealing devices has given an important incentive to minimal invasiveness in surgery. Moreover they have contributed to an easier, teachable, and faster way of dissecting tissues, also in open surgery.

Based on this, in the last 30 years, surgeons have become progressively persuaded by the usefulness of the so-called “High-energy devices” (HEDs) in surgical practice, as alternative medical devices to standard monopolar or bipolar devices. This has become particularly evident together with the increasing rate of surgeries made by minimally invasive approaches [1].

Three different types of vessel-sealing devices have gained importance, starting with ultrasonic shears and electrothermal coagulation up to latest mixed ultrasound-radio-frequency instruments.

Scientific evidence, throughout the years, has ascertained the efficacy of HEDs in achieving a better dissection and hemostasis, faster operating times, safer procedures, and shorter hospitalizations if compared to traditional instruments like monopolar or bipolar scalpels, hooks, scissors, and forceps, including a Cochrane systematic review in 2011 concerning colectomies [2] and a rapid Health Technology Assessment (HTA) on ultrasonic devices conducted in Italy in 2014, endorsed by Ministry of Health [3].

However, HEDs are associated to a higher acquisition cost with respect to standard medical devices, thus, being responsible of a significant part of the entire cost of surgical procedure. Despite the above economic concern, the use of HEDs has become a standard, in most general surgical practices. A recent survey structured and promoted by the Italian Society of Endoscopic Surgery (SICE), demonstrated this widespread use [4]. However, today the choice to use HED or traditional monopolar or bipolar devices, is mainly based on the surgeon’s preferences [4].

Moving on from these premises, given the lack of a standardized use of such HEDs in the Italian clinical practice, the deep investigation of the impacts of their higher implementation in surgery, is strictly required by means of a Health Technology Assessment (HTA) approach comparing HEDs with traditional medical devices currently used.

As for any new technology, the deep analysis of efficacy and safety issues, economic, ethical, social, legal, and organizational dimensions could support physicians and health providers in the decision making, by combining

evidence-based results of multiple systematic reviews with a multimodal evaluation, also comprehending quantitative analysis to demonstrate both the economic and organizational sustainability in the standardized use of HEDs within different surgical settings [5, 6].

For the coverage of such knowledge gap, the SICE—Italian Society of Endoscopic Surgery—(affiliated with the EAES—European Association for Endoscopic Surgery) directory created a multi-disciplinary team (composed of surgeons selected by SICE, HTA experts, and healthcare sector researchers from Carlo Cattaneo—LIUC University, managerial engineers from Milan Politecnico and the AIIC—Italian Association of Clinical Engineers—methodology experts and statisticians from Mario Negri Institute of Research), with the aim to produce a scientific report, based on an HTA approach and trying to provide an answer to the following policy question: “Which are the main advantages, with reference to different domains typical of HTA evaluation, in adopting high-energy devices in comparison to the standard surgical equipment (bipolar and monopolar devices), for hospitals and patients?”

Methods

For the achievement of the above research activity objective, a Health Technology Assessment (HTA) analysis, grounded on the EUnetHTA Core Model was conducted, thus, being the reference framework useful to bring together evidence and other relevant and reliable information for hospital managers to guide good investment decisions [7]. IRB approval and written consent were not needed.

The HTA assumed the hospital point of view, with the aim to defining the different advantages regarding the use of HEDs (with respect to standard monopolar or bipolar devices) within the following eleven surgical settings: appendectomy, hepatic resections, colorectal resections, cholecystectomy, splenectomy, hemorrhoidectomy, thyroidectomy, esophago-gastrectomy, breast surgery, adrenalectomy, and pancreatectomy.

As suggested by the EUnetHTA Core Model and due to the multi-dimensional and multi-disciplinary nature of an HTA, several aspects were deeply analyzed: (1) health problems, in terms of definition of number of eligible patients undergoing a surgical procedure within the above-mentioned eleven settings, according to a 12-month time horizon; (2) description of the investigated technologies, by analyzing their technical characteristics; (3) safety aspects, in terms of potential development of any surgical complications or adverse events; (4) efficacy aspects, in terms of capability of the technology to reduce the operating time; (5) economic and financial dimension, for understanding the impact of the technologies on the hospital

internal processes, as well as their economic sustainability and affordability; (6) organizational impact, thus, defining both the organizational investments with regard to the innovative technologies introduction (in terms of meetings, learning curve, and training), as well as the healthcare professional intention to use HEDs; (7) social aspects, evaluating potential advantages for the patients' clinical pathway, thus, also quantifying their productivity loss related to the surgery; (8) equity impact, in terms of accessibility to the new technologies in specific hospitals' context and the definition of the potential capabilities of hospitals to take in charge a higher number of patients; and (9) legal aspects, thus, definition potential normative or laws that may obstacle HEDs adoption in the clinical practice.

For the deployment of the above HTA dimensions, a multi-method approach was used [8, 9]. In particular, the above dimensions were assessed, by means of a literature review for the collection of comparative advantages, health-economics tools that are useful for the economic assessment of the patients' clinical pathway undergoing surgery with HEDs or standard medical devices, and for conducting budget impact analyses, as well as for evaluating the organizational and accessibility advantages, in terms of time or procedures savings. Furthermore, a qualitative questionnaire was also developed and administered to surgeons to retrieve their perceptions, concerning HEDs' utilization.

According to the above methodological approach, efficacy and safety issues were evaluated with 11 different systematic reviews of the existing literature and outcomes following Cochrane methods for conducting reviews [10]. Meta-analyses were conducted whenever possible (by outcome and when at least 2 RCTs were eligible). The research questions were turned in search for major scientific databases with specific attention on population, intervention, control, and outcomes (PICO) [11] and run-on *PubMed*, *Embase*, *Cochrane Library*. For each surgical setting, details of search questions, PICOs, the whole screening process, and reasons for exclusion are reported in Appendix.

Titles and abstracts were screened by two independent surgeons with potential doubts solved by a consensus, and one methodologist when needed. Screening process was reported according to the PRISMA flow-chart model [12]. Quality of observational studies was assessed with Newcastle–Ottawa Scale (NOS) [13]. Risk of bias assessment for RCTs and forest plots were made with the Cochrane methodology and tools [10]. Primary outcomes were operating time (considered as an indirect driver of efficacy), bleeding, and intra-operative and post-operative complications (including surgical site infections—SSIs—and fistulas). Secondary

outcomes were length of stay (LOS), established as time to discharge from operation, quality of life (including patients' reported outcomes), costs (when available), pre-operative restraints (depending on the investigated setting), and exposition to surgical smoke (considered as a safety item for the operators, especially important in pandemic COVID times). Other outcomes were considered, stratified in reason of the surgical setting analyzed.

The economic dimension was deployed with an activity-based costing analysis [14] and a budget impact analysis [15], both assuming the hospital perspective, within a 12-month time horizon. At first, the patients' clinical pathway was economically valorized, considering the eleven settings, concerning the use of either HEDs or standard medical devices. The following hospital costs, representing the input data of the economic evaluation, were considered: (1) human resources involved; (2) laboratory and radiologic exams, performed before and after the surgical procedure, in accordance with the length of stay; (3) disposable devices for patients' and healthcare professionals working in the operating room; (4) instruments' kits; (5) medical devices used (HED or standard devices); and (6) drugs and any other medications administered to patients during surgery or hospitalization. Only direct costs were accordingly investigated, and the total cost for each patient was calculated by multiplying the quantity of resources consumed by their unit cost. In addition, general and fixed hospital costs were integrated, consisting of all those costs different from labor factors, consumables, and equipment usage, being necessary to taking in charge patients because they provide the logistic and infrastructure support, in the measure of 20% of direct costs [16].

In the definition of the two different clinical pathways, within the eleven surgical settings, the main drivers for differential costs have been stated in the reduction of both the operating room occupation and the overall hospital stay.

Once having defined the costs per patient, with the inclusion of the potential adverse events and complications management that may occur after surgery, a budget impact analysis was implemented to verify the financial sustainability of HEDs higher and standardized use within the investigated eleven surgical settings. In particular, the baseline scenario (AS IS Scenario) where surgeries were performed according to the current HEDs or standard devices implementations was compared to two different innovative scenarios (TO BE Scenario): (1) Innovative Scenario 1, where a higher use of HEDs were assumed, according to experts' opinions; (2) Innovative Scenario 2, where a complete replacement rate was assumed, in terms of HEDs use for all the eligible patients requiring surgery (i.e., Best-case Scenario). Table 1 depicts the specific market shares implemented concerning

Table 1 Market shares implemented for budget impact analysis

	AS IS scenario		Innovative Scenario 1		Innovative Scenario 2 (best-case scenario)	
	Monopolar/bipolar utilization rate (%)	HED utilization rate (%)	Monopolar/bipolar utilization rate (%)	HED utilization rate (%)	Monopolar/bipolar utilization rate (%)	HED utilization rate (%)
Appendectomy	100	0	95	5	0	100
Breast surgery	100	0	90	10	0	100
Thyroidectomy/parathyroidectomy	100	0	40	60	0	100
Adrenalectomy	100	0	16	84	0	100
Pancreasectomy	100	0	0	100	0	100
Liver resections	100	0	29	71	0	100
Cholecystectomy	100	0	97	3	0	100
Colorectal surgery	100	0	17	83	0	100
Esophago-gastric surgery	100	0	1	99	0	100
Haemorrhoidectomy	100	0	68	32	0	100
Splenectomy	100	0	85	15	0	100

the presence or absence of HED's utilization, within the eleven surgical settings.

Furthermore, a qualitative questionnaire was administered to 23 junior and senior surgeons to examine their perceptions on equity, social, legal, and organizational aspects, considering a comparative approach of HED and standard devices, in accordance with a 7-item Likert scale, ranging from -3 to +3 [17] and based on the specific items derived from EUnetHTA Core Model [6]. The above qualitative method was useful to collect a wide range of ideas and opinions that individuals carry out about issues and topics, as well as divulge viewpoint differences among stakeholders' groups [18, 19]. In fact, for under discovered research areas, qualitative methods attempt to fill in gaps that are left unexposed by survey-based research, as well as literature evidence [20]. Based on the collections of healthcare professionals' perceptions, all the dimensions were accordingly assessed, thus, giving important and comprehensive information, concerning multiple aspects of innovative medical technologies to be adopted in clinical practice.

In conclusion, the assessment of the above dimensions was integrated with a prioritization phase and a multi-criteria decision analysis [21], thus, simulating the technological appraisal phase and defining the technology presenting a higher added value for hospitals.

Focusing on statistical methods, economic and perceptions' data were first analyzed, considering descriptive statistics. Differences among technologies (standard monopolars/bipolars and HEDs) were evaluated, according to a significance level lower than 0.05 (p value), thus, using the Independent Sample T test, after having verified the normality nature of the different variables.

All the analyses were performed using the Statistical Package for Social Science of IBM SPSS (Version 22).

Results

Results from the HTA dimensions' assessment

Health problem relevance in the different settings

As previously mentioned, the analysis considered the possibility to optimize HEDs utilization in the following eleven surgical settings: appendectomy, hepatic resections, colorectal resections, cholecystectomy, splenectomy, hemorrhoidectomy, thyroidectomy, esophago-gastrectomy, breast surgery, adrenalectomy, and pancreatotomy. The definition of the target population requiring a surgery, and thus, potentially eligible to HEDs use, derived from the Italian "SDO Report" for the year 2019 [22], indicating the conduction of 178,619 surgeries within a 12-month time horizon considering the above-mentioned settings.

Table 2 detailed the rate of different operations inside each setting that was set concerning the case-mix of the questioned pool of surgeons (range from maximum to minimum coming from different realities of the Italian national health system) integrated and mixed with data coming from the Italian "SDO Report" (2019 DRG national reports).

The hypothesis under the HTA analysis proposed, considered that all the hospitals could conduct surgical procedures in all the above-mentioned eleven settings.

Table 2 Rate of surgeries within the eleven setting under assessment

	Minimum value related to the case-mix derived from clinical practice (%)	Maximum value related to the case-mix derived from clinical practice (%)	Case-mix derived from the Italian “SDO Report” (2019) (%)
Appendectomy	3	10	8
Breast surgery	3	7	9
Thyroidectomy/parathyroidectomy	17	8	18
Adrenalectomy	3	7	3
Pancreasectomy	3	5	13
Liver resections	3	7	6
Cholecystectomy	17	16	27
Colorectal surgery	34	23	5
Esophago-gastric surgery	7	11	5
Haemorrhoidectomy	3	7	5
Splenectomy	3	1	1

Technologies under assessment comparison

Several high-energy vessel-sealing systems have been introduced in the Italian market in the past years. All instruments need a dedicated external generator to provide electrical power and allow settings of functional parameters. Ultrasonic devices are based on mechanical ultrasonic vibrations produced by a high-frequency vibrating stem paired with an articulated inert plier; such devices allow coagulation and cutting of vessels usually up to 7 mm in diameter, with documented minimal lateral thermal damage. Radiofrequency units use high-frequency electrical current to generate the thermic effect responsible of tissue denaturation and consequent vessel sealing. Such systems need a subsequent mechanical action—usually via a manually activated blade—to cut in between the previously sealed tissue. Some forceps available in the market and used in radiofrequency sealing, provide cutting via an automated movement of the blade, although none uses radiofrequency to fulfill the cutting phase. There are also so-called combined systems which couple ultrasonic and radiofrequency energies in the same instrument.

Different dimensions and lengths of the forceps are used either for laparoscopic or open surgery, and most of the devices are for single patients' use. Some reusable radiofrequency HEDs are available on the market, and they can be reprocessed for a limited number of times. Among these, only few are equipped with the cutting mechanism. In most cases the generator is loaned for use, while single-use handpieces are subject to specific acquisition contracts. An evaluation of differences in performance, safety, general characteristics, and maintenance services are summarized in Table 3.

Evidence from the systematic literature review: efficacy and safety profiles

- Appendectomy:** The initial literature search revealed a total of 484 records, and one study fully matched the aim of this systematic review and was included in qualitative synthesis [23]. The retrospective cohort study was conducted on 1178 patients in a military hospital (460 treated with Endo Clip, 372 with Harmonic Scalpel—HS–, and 346 with the monopolar device). The three different groups did not report any differences in terms of age, gender, and body mass index (BMI). As for primary outcomes, Lee and colleagues analyzed operating time and complications [23]; whereas, for secondary outcomes analyzed time of discharge, conversion to open surgery, and costs, no results regarding exposition to smoke nor quality of life were reported. A reduction of the operating time (OT) emerged in patients treated with Harmonic Scalpel compared to monopolar device. No significant differences in other primary and secondary outcomes have been reported, apart from costs, which were higher for HS. According to the NOS scale, the quality of the study was low mainly because it was conducted in a military hospital, so that the main biases were the selection of patients, the assessment of the outcome (the study was not blinded), and the length of follow-up (discharge time, short follow-up).
- Colorectal surgery:** The initial literature search revealed a total of 209 records identified through database searching, but only 7 studies fully matched the aim of this systematic review and were included in the final sample and relative analysis. Out of the 7 included studies, 4 were RCTs, and it was possible to perform quantitative synthesis [24–27]; the other 3 records were observational, two retrospective, and one prospective study [28–30]. In

Table 3 Technical characteristics of HEDs

Company	Performance	Safety	General characteristics	Maintenance				
A	<i>Lap</i>	Acoustics “in function” and “end of synthesis cycle” Alarms Autodiagnosis Start test Integrated intelligence (each device comes with the latest upgrade)	Each generator with proper stack User-friendly visualization of error and solution, —intelligent device: measures tissue and applies adequate energy Tips can hold and dissect tissue Single active tip for optimal energy control Minimal thermal diffusion Synthesis time 0.3–2.7 s Burst pressure > 3 times systolic Sticking reduction	24 months guarantee Generator given in loan-for-use Substitution guaranteed for non-function				
	Pistol handhold							
	Curved or straight tips							
	Length: 37, 44, 23 cm							
	Diameter: 5 mm							
	Lifetime: 36 months							
	<i>Open</i>							
	Pistol handhold							
	Curved tips							
	Length: 20 cm							
	Rotation 180°							
	Scissors							
	Curved tips							
Length: 19.3 cm								
Lifetime: 26 months								
B	<i>Lap</i>	Acoustics or light “in function” and “end of synthesis cycle” Alarms Autodiagnosis Start test Integrated intelligence (each device comes with the latest upgrade) Thermal dispersion < 1 mm	Each generator with proper stack and pedal User-friendly visualization of error and solution 2 energies (210–300 W) Intelligent device: measures tissue and applies adequate energy Tips can hold and dissect tissue Single active tip for optimal energy control Minimal thermal diffusion Synthesis time 0.3–2.7 s Burst pressure > 3 times systolic Sticking reduction 80° articulation Progressive tip closure to guarantee against slipping of tissues Adjunct pedal activation	24 months guarantee Generator given in loan-for-use Annual check-up				
	Pistol handhold with fixed or articulated stem							
	Curved or straight tips							
	Length: 36, 44 cm							
	Diameter: 5 mm							
	Lifetime: 36 months							
	<i>Open</i>							
	Pistol handhold with fixed or articulated stem							
	Curved or straight tips							
	Length: 12, 5, 17 cm fixed, 24 cm fixed and articulated							
	Diameter 5, 12 mm							
	C				<i>Lap</i>	Acoustics or light “in function” and “end of synthesis cycle” Alarms Autodiagnosis Start test Integrated intelligence (each device comes with the latest upgrade) Thermal dispersion < 1 mm Touchscreen for setting, instructions and alarms	Each generator with proper stack and pedal also adaptable to previous instruments Use of both US and RF energies User-friendly visualization of error and solution 2 energies (210–300 W) Intelligent device: measures tissue and applies adequate energy Tips in inox-steel, ceramic zirconium, gold plated tungsten, inert tip covered with high density polyethilen to guarantee workout temperature of 100° Tips can hold and dissect tissue Progressive tip closure to guarantee against slipping of tissues	24 months guarantee Generator given in loan-for-use Annual check-up
					Pistol handhold with articulated stem			
Curved or straight tips (20/19 mm)								
Length: 35/45 cm								
Diameter: 5 mm								
Lifetime: 24/60 months								
<i>Open</i>								
Pistol handhold with fixed stem								
Curved or straight tips (20 mm)								
Length: 20/22/14/25 cm fixed, 24 cm fixed and articulated								
Diameter 13/12.5 mm								

Table 3 (continued)

Company	Performance	Safety	General characteristics	Maintenance
D	<p><i>Lap</i></p> <p>Pistol handhold</p> <p>Curved or straight tips, hook, L-shaped</p> <p>Length: 37/44 cm</p> <p>Diameter: 5 mm</p> <p><i>Open</i></p> <p>Pistol or forceps handhold with fixed stem</p> <p>Curved or straight tips</p> <p>Length: 12/18/19/23 cm fixed</p> <p>Diameter: 5/13.5 mm</p>	<p>Acoustics or light “in function” and “end of synthesis cycle”</p> <p>Alarms</p> <p>Autodiagnosis</p> <p>Start test</p> <p>Screen for setting, instructions and alarms</p>	<p>Each generator with proper stack and pedal</p> <p>RF, bipolar and monopolar energy</p> <p>User-friendly</p> <p>Intelligent device: measures tissue and applies adequate energy</p> <p>Tips covered with ceramic</p> <p>Tips can hold and dissect tissue through atraumatic milling of the surfaces</p> <p>Nano-polymers to reduce “sticking”</p> <p>Progressive tip closure to guarantee against slipping of tissues</p>	<p>24 months guarantee</p> <p>Generator given in loan-for-use</p> <p>Annual check-up</p>

general terms, HEDs do not add substantial advantages in comparison to traditional energy devices in terms of primary (operative time, intra- and post-operation complications, intra-operative blood loss) or secondary outcomes (time to discharge, conversion to open surgery). All RCTs and non-RCTs, except for Hubner et al. [24], analyzed the operation time and time of discharge. All the included studies, except for Scabini et al. [29], had intra-operative blood loss and post-operative complications as outcomes, while only Morino et al., Targarona et al., and Allaix et al. evaluated the intra-operative complications [25, 26, 28]. The RCTs of Hubner et al. and Targarona et al. were the only two that analyzed the costs of the different devices [24, 26]. Morino et al., Targarona et al., and Allaix et al. were the only three studies that evaluated the conversion from laparoscopic to open surgery [25, 26, 28]. According to the RCTs risk of bias (RoB), all the included RCTs were unclear for performance and detection biases, while 75% of them were at low risk for allocation concealment, attrition, and reporting biases; none of them had high risk of bias. These results, along with the absence of report analyzing the relevant clinical outcomes, such as quality of life and surgical smoke, do not allow to declare HED utilization as gold standard in colorectal surgery.

- Cholecystectomy:** The initial literature search revealed a total of 252 records identified through database searching. 19 papers corresponding to 18 studies fully matched the aim of this systematic review and were included in the final sample. Of the 18 included studies, 5 were observational, two retrospective and three prospective study [31–35], 11 were RCTs, and it was possible to perform quantitative synthesis [36–46]; only one was a systematic review [47]. Some of the included studies highlighted the substantial advantages of HEDs in comparison to traditional energy devices, in terms of operative time and blood loss, or the secondary outcome time to discharge. All the included studies (RCTs and non-RCTs) assessed the operative time outcome and reported significant differences in favor of the HED against monopolar or bipolar devices. Maybe the shorter HED operative time and the reduced exposition to pneumoperitoneo, lead to a shorter post-operative pain, VAS score, nausea, and vomiting. Only three RCTs [37, 41, 47] and two non-RCTs [31, 35] analyzed blood loss and all these studies agreed on the HEDs superiority compared to monopolar and bipolar devices. Nevertheless, none of the patients treated in these studies, except for Kandil et al. [35], required a blood transfusion. 7 RCTs [36–38, 41, 43, 45, 46] and 2 non-RCTs [32, 34] reported a reduction in terms of time to discharge when patients were treated with HEDs; however, this reduction was not statistically meaningful, except for Tempe et al. [45].

No relevant difference has been found in the analysis of intra- and post-operative complications, even then not always fully described. Considering economic outcome, only Tempé et al. [45] found a cost advantage in using HED due to a difference in hospital stay, not confirmed in other studies. No significant difference has been found on conversion to open surgery. Data on post-operative pain (regarding quality of life) were reported by single RCTs, proving a significant reduction in pain perceiving when using HEDs, an effect which ends after 48 h. No information was reported in regard of surgical smokes and pre-operative restrains. According to the RCTs RoB, only four RCTs were evaluate as at low risk of bias [36, 39, 41, 47]. High risk of bias has been encountered in the random sequence generation and blinding (both performance and detection).

- *Haemorrhoidectomy*: The initial literature search revealed a total of 66 records identified through database searching, 6 studies fully matched the aim of this systematic review and were included in the final sample and relative analysis. Of them 4 were RCTs [48–51] eligible for qualitative and quantitative analysis, and 2 were systematic reviews [52, 53]. Results of all the primary outcomes (post-operative pain, blood loss, operative time, and intra- and post-operative complication) analyzed by the 4 RCTs demonstrated superiority of the HEDs on monopolar or bipolar devices. Two RCTs were at a low risk of bias in two of the four RCTs [48, 51] and a high risk of bias in the other two RCTs [49, 50].
- *Liver resections*: The initial literature search revealed a total of 504 records identified through database searching, 7 studies fully matched the aim of this systematic review and were included in the final sample and relative analysis. Of them, 5 were observational studies (2 prospective and 3 retrospective) [54–58] and 2 RCTs [59, 60]. All the primary outcomes (blood loss, operative time, and intra- and post-operative complication) analyzed by the RCTs were in favor of the HEDs compared to crush clamping. All the included studies, both RCTs and non-RCTs, reported a significant risk reduction in terms of blood loss (during transection) and biliary fistulas. Both the RCTs, plus the observational study Sakomato et al., found that transection time and speed of transection were shorter when patients were treated with HEDs [54, 59, 60]. The observational studies from Galizia et al., Guo and Li, found that operative time was shorter when using the HEDs compared to crush clamping [55, 56, 58]. In regards of the secondary outcomes, no significant differences have been reported in terms of length of stay (LOS) and surgical site infections (SSIs). Data coming from the two RCTs confirmed a significant lowering of complications (biliary fistula). Also, no significant differences have been found concerning SSIs and post-operative blood loss. Both primary and secondary outcomes were analyzed for partial transections and major transections. Moreover, a potential bias of the two RCTs, is the heterogeneity in the treatment, with regards specifically the vessel diameter (Ichida et al. < 2 mm vs. Gotohda < 5 mm) [59, 60]. Nevertheless, HED technology seems to be superior also when applied on vessels with bigger diameter. According to The Newcastle–Ottawa Scale (NOS), all the observational studies had a high risk of bias in terms of exposure category, and a low risk of bias for the other categories.
- *Splenectomy*: The initial literature search revealed a total of 136 records identified through database searching, 3 RCTs [61–63] all comparing radiofrequency devices versus standard coagulation fully matched the aim of this systematic review and were included in the final sample and relative analysis. The primary outcome (referring to post-operative complications) was evaluated by all the three included RCTs, while operative time and intra-operative blood losses were evaluated by Shabaahang et al. and Amirkazem et al. [61, 62]. Data from the meta-analyses of the three studies show a significant reduction in OT and intra-operative bleeding, while no significance has been found regarding post-operative complications. Only one study [63] evaluates post-operative pain with a VAS scale, and LOS finding no differences for both secondary outcomes. A low risk of bias emerged for all the evaluated items, considering evidence reported by Amirkazem et al. and Yao et al. [62, 63]. On the contrary, Shabaahang et al. revealed a high risk of bias for “blinding outcome assessment” and an unclear risk for all the other categories [61].
- *Pancreatic resection*: The initial literature search revealed a total of 135 records identified through database searching, 1 RCT [64] and 2 observational studies [65, 66] fully matched the aim of this systematic review and were included in the final sample and relative analysis. All the three studies analyzed the primary outcomes bleeding, operative time, and post-operative complications, as well as for the time of discharge and intra-operative blood loss secondary outcomes. The RCT [64] and the observational study of Wu et al. [66] also evaluated the occurrence of post-operative pancreatic fistula and costs. The three studies reported that the use of HEDs do not significantly change pancreatic surgery pre-operative outcomes, which appears to be equivalent to the outcomes obtained with conventional techniques. The three studies had a low risk of bias.
- *Thyroidectomy*: The initial literature search revealed a total of 250 records identified through database searching, 20 RCTs [67–86] and 17 observational studies [87–101] fully matched the aim of this systematic review and were included in the final sample and relative analysis.

As for efficacy parameters, 20/20 RCTs and 15/17 observational (8 prospective and 7 retrospective) studies analyzed operative time, and all agreed upon a reduction in surgical time when using HEDs. Only the observational study of Cipolla et al., did not highlight any difference in reducing operative time while using HED [90]. A meta-analysis confirmed a significant reduction of operative time. 10/20 RCTs and 14/17 observational studies (7 prospective and 7 retrospective) evaluated intra-operative bleeding which was significantly reduced in patients treated with HEDs. The RCTs of Koh et al. [70], the observational studies Cipolla et al. [90] and Kuboki et al. [94] not highlighted any difference in reducing intra-operative bleedings while using HEDs. For secondary outcomes, length of hospital stays and costs, were the two parameters analyzed in the included studies. From the evaluation of the length of stay in 13/20 RCT and 13/17 observational studies (7 prospective and 6 retrospective), only in 3 RCTs was found a reduction of this outcome, the other studies did not highlight any clear impact while using HEDs. On the contrary, all the observational studies have experienced a significant reduction in the length of hospital stay. Costs were, differently from other settings, well studied in 25 studies, and, even if data were not comparable, all evidenced an increase in cost due to HEDs.

- **Breast surgery:** The initial literature search revealed a total of 184 records identified through database searching, 24 RCTs [102–125] fully matched the aim of this systematic review and were included in the final sample and relative analysis. All the included RCTs reported the primary outcomes of operative time, blood loss and intra- and post-operative complications. Three studies highlighted a statistically significant reduction in terms of operative time, using HEDs [105, 106, 119], while the other 15 studies, focused on the use of HEDs during mastectomy, highlighted a modest reduction in terms of operative time. 12/24 RCTs reported a statistically significant reduction of intra-operative bleeding using HEDs. All the included studies reported a moderate reduction of intra- and post-operative complications following the use of HEDs. All the 24 included RCTs reported information regarding the secondary outcomes of length of hospital stay, post-operative pain and their effects on the quality of life finding no statistically significant differences while using HEDs. None of the included studies reported information in terms of surgical smokes and costs. Kontos et al. was the only study reporting some information on HEDs costs, but cost analysis was done in 2008 when HEDs diffusion in the market was still low [114].
- **Adrenalectomy:** The initial literature search revealed a total of 100 records identified through database searching, only 2 observational retrospective studies [126, 127]

fully matched the aim of the review and were included in the final sample and relative analysis. Both studies regarded laparoscopic adrenalectomy. Overall, the two studies included 256 patients (165 in one study and 91 in the second one), of them 100 patients in the HED group and 156 in the monopolar/bipolar group. Significant differences were confirmed in both studies regarding a lower OT with HEDs. No statistical differences were noticed in conversions to laparotomy, complications or bleedings. One study evidenced that, in terms of costs, the use of HEDs was cost saving (70–105\$) as there was a reduced use of vascular clips [126]. All observational studies were at low risk of bias for all items assessed.

Economic and financial dimension

Table 4 reports the cost per patient related to the clinical pathway performed in the different eleven surgical settings, valorized based on the use of standard monopolar/bipolar devices, or HEDs, and considering the development of adverse events and complications. An economic advantage per patients is reported in most surgical settings, with the solely exception of cholecystectomy, colorectal and esophago-gastric surgeries, where a slight investment emerged. In the comparison between the weighted average costs, considering the different case-mix, the use of HEDs is related to an overall modification of cost per patients ranging from +0.81 to -3.14%.

In addition, a budget impact analysis (BIA) was implemented to define HEDs economic affordability and sustainability in the clinical practice. Given the economic evaluation previously mentioned, as well as the different scenarios under assessment, HEDs introduction would lead to a marginal investment ranging from +0.43% to +0.78%, with the possibility to report a higher economic saving if surgeries are performed in accordance with the distribution rate from the Italian “SDO Report” (2019) [22], for the conduction of 178,619 surgeries within a 12-month time horizon (Table 5).

Organizational dimension

From an organizational point of view, as for the economic dimension deployment, literature declared a decrease in both OT and LOS in using HED within specific surgical settings.

According to 178,619 surgeries, and assuming the same scenarios as the BIA, Table 6 reports that HEDs would generate significant organizational savings, ranging from a minimum of 5.25% and a maximum of 9.02% in terms of release of operating room time. Based on the above an advantage in accessibility to surgery can be hypothesized in a 9% of increase, due to the gaining in operatory slots derived from the implementation of new technologies.

The same trend emerged considering the improvement of the overall LOS: a standardized use of HEDs would lead to a decrease in LOS, ranging from a minimum of 5.03% to a maximum of 30.73%.

Results from the qualitative assessment

The analysis of the qualitative perceptions of the healthcare professionals involved (Table 7) (considering a 7-item Likert Scale, ranging from -3 to $+3$), reported no differences between traditional devices and HEDs, from an equity perspective (0.41 vs. 0.55, p value > 0.05). A negative impact emerged considering HED's accessibility (0.43 vs. 1.57, p value = 0.011), since their acquisition is not yet standardized, given the problem in the diffusion of HEDs, particularly between hub and spoke hospitals. However, these innovative devices could enhance the overall access to care given a potential clinical pathway optimization, due to an improvement in both the adverse events management (0.65 vs. -0.04 , p value = 0.007) and in the operating room occupancy time (0.91 vs. 0.09, p value = 0.012). In assuming the patients' point of view, the surgeons reported a preference for HEDs in comparison with traditional monopolar and bipolar devices (0.70 vs. 0.20, p value = 0.048). The introduction of the HEDs would improve patients' quality of life (1.17 vs. 0.35, p value = 0.005) and satisfaction (1.09 vs. 0.22, p value = 0.002), thus, being strictly related to a faster recovery time (1.13 vs. 0.30, p value = 0.005) and a better post-operative condition (1.22 vs. 0.26, p value = 0.001).

An analysis of the legal implications reported that the two technologies under assessment could be considered super-imposable in their measurement (p value > 0.05), even if additional legal efforts are required regarding the regulation of HEDs acquisition.

Focusing on the organizational dimension, no significant differences have been evidenced for the organizational point of view between the technologies being assessed (p value = 0.068), even if in a short-term time-horizon training courses are required when introducing HEDs, devoted to both surgeons and nurses. On the other hand, professionals' perceptions crystallized that HEDs could optimize the length of stay (p value < 0.05), timing of operations (p value < 0.05), and consequently occupation of the operating

Table 5 Budget impact analysis results

	Minimum value related to the case-mix derived from clinical practice (%)	Maximum value related to the case-mix derived from clinical practice (%)	Case-mix derived from the Italian "SDO Report" (2019) (%)
AS IS scenario versus innovative Scenario 1	+0.43	-0.42	-3.52
AS IS scenario versus innovative Scenario 2	+0.78	-0.04	-3.27

Table 4 Economic evaluation of the surgical pathways

Surgical settings	Monopolar/bipolar device	HEDs	Difference (€)	Difference (%)
Appendectomy	4822.94 €	4969.70 €	146.76 €	3.04
Breast surgery	4194.84 €	3941.20 €	-253.64 €	-6.05
Thyroidectomy/parathyroidectomy	3285.04 €	3296.27 €	11.23 €	0.34
Adrenalectomy	3792.12 €	3715.12 €	-77.00 €	-2.03
Pancreasectomy	9731.81 €	8385.03 €	-1346.78 €	-13.84
Liver resections	6370.83 €	6123.94 €	-246.89 €	-3.88
Cholecystectomy	3309.96 €	3392.71 €	82.76 €	2.50
Colorectal surgery	4516.50 €	4722.92 €	206.42 €	4.57
Esophago-gastric surgery	5712.27 €	5910.78 €	198.51 €	3.48
Haemorrhoidectomy	2766.81 €	2694.49 €	-72.32 €	-2.61
Splenectomy	4957.59 €	4595.36 €	-362.22 €	-7.31
Weighted total cost, considering the minimum value related to the case-mix derived from clinical practice	4331.07 €	4366.06 €	34.98 €	0.81
Weighted total cost, considering the maximum value related to the case-mix derived from clinical practice	4573.42 €	4572.04 €	-1.39 €	-0.03
Weighted total cost, considering the case-mix derived from the Italian "SDO report" (2019)	4676.11 €	4529.13 €	-146.98 €	-3.14

Table 6 Quantitative organizational impact

Organizational impact concerning the release in operating room time	Minimum value related to the case-mix derived from clinical practice (%)	Maximum value related to the case-mix derived from clinical practice (%)	Case-mix derived from the Italian “SDO Report” (2019) (%)
AS IS scenario versus innovative Scenario 1	-5.25	-4.98	-4.19
AS IS scenario versus innovative Scenario 2	-8.92	-8.75	-9.02
Organizational impact concerning the release in hospitalization days	Minimum Value related to the case-mix derived from clinical practice (%)	Maximum Value related to the case-mix derived from clinical practice (%)	Case-mix derived from the Italian “SDO Report” (2019) (%)
AS IS scenario versus innovative Scenario 1	-5.03	-5.64	-15.71
AS IS scenario versus innovative Scenario 2	-5.47	-6.02	-30.73

theaters. Reduction of morbidity could improve the overall organizational clinical pathway, in terms of hospital management of a patient requiring a specific surgery (p value = 0.006). The reduction of the operating times might have the consequence, in the opinion of surgeons, of freeing spaces and reducing the waiting lists.

Results from the appraisal phase

The final phase of the analysis required the implementation of a multi-criteria decision approach (MCDA), to define a final score, useful for an evidence-based policy-making appraisal [10].

In determining which aspect of the HTA dimensions was more important, all the surgeons tended to perceive safety and efficacy, followed by technical relevance and economic impacts as the most relevant. Junior surgeons are more prone to consider economical and legal issues important, while seniors agree on technical relevance and organizational impact to be more significant.

Results from the MCDA (Table 8) revealed that HEDs could represent the preferable medical devices to be used during surgery, having acquired a higher score than the comparator (0.51 vs. 0.43), when available in the clinical practice.

Discussion and conclusions

The results of the study generate an interesting scientific contribution, thus, covering an important knowledge gap, regarding the use of HEDs, within specific surgical settings, suggesting their consolidated use in the clinical practice.

In this full HTA report, both the assessment and the appraisal phases have confirmed that the introduction of HEDs in surgery is a valid alternative to standard monopolar and bipolar instruments in general surgical practice. Evidence-based information has proved a higher efficacy and safety of HEDs, even if this superiority is not to be extended to all the surgical procedures and settings. In this view, due to the lack of standardized suggestions and the related difficulties to have informed decision about merits of any energy devices. In fact, the efficiency of any energy source depends on seal time, lateral thermal spread, burst pressure, and smoke production.

However, from an economic perspective, the introduction of HEDs can lower the overall process costs, by freeing up economical and organizational resources for the hospital, thus, representing a sustainable choice of overall improvement and optimization of resources. This can potentially reduce the waiting lists which remain a critical item, especially during the current COVID-19 pandemic. This is strictly dependent from the organizational setting of each hospital, particularly its case-mix, and the organizational capability of the system, or its ability to take advantages of freed resources. Relevant advantages emerged in considering the patients' and the society point of view, in terms of reduction of productivity losses due to hospital stay, with important out-of-pocket expenditure savings ranging from a minimum of 4.74% to a maximum of 10.71%. On the other hand, surgeons' point of view suggests initially to re-invest these resources in training healthcare professionals to maximize the advantages of the new technology by using it properly.

The present paper presents two main limitations. On the one hand, this HTA has the defect of having analyzed the perception of this specific and highly technical item only through questionnaires targeted on surgeons and technology experts. It would be interesting to test the perception of such a diffuse technology also in other figures of the

Table 7 Results from healthcare professionals' perceptions

Organizational impact	Traditional monopolar/bipolar devices—"AS IS" scenario	HEDs—"TO BE" scenario	<i>p</i> -value
Need for additional staff, in terms of surgeons	0.00	-0.48	0.005
Need for additional staff, in terms of nurses or other healthcare professionals	0.00	-0.61	0.004
Training course, devoted to surgeons	-0.09	-1.13	0.003
Training course, devoted to nurses or other healthcare professionals	-0.30	-1.26	0.011
Hospital meetings	-0.22	-1.00	0.013
Learning curve	-0.09	-1.17	0.004
Equipment update	0.17	-1.00	0.004
Impact of the technology of the workflow standardization	0.26	0.26	0.767
Impact of the technology on the healthcare professional's productivity	0.35	0.78	0.146
Impact of the technology on the healthcare professional's resistance to change	0.09	0.17	0.782
Impact of the technology on the change management	0.26	0.78	0.106
Impact of the technology of the length of stay optimization	0.35	0.87	0.045
Impact of the technology on the OR timing	0.26	2.04	0.000
Impact of the technology on the OR occupancy rate	0.26	1.78	0.000
Impact of the technology on the length of stay	0.17	1.17	0.000
Impact of the technology on the management of intra-operative or post-operative complications	0.35	1.09	0.006
Impact of the technology on the number of post-operative hospital accesses	0.30	0.74	0.087
Impact of the technology on purchasing processes	0.26	-0.30	0.005
Impact of the technology on internal processes	0.13	0.70	0.005
Impact of the technology on hospital processes	0.04	0.22	0.246
Impact of the technology on the patient's clinical pathway	0.22	0.61	0.053
Average value for organizational impact	0.13	0.20	0.068
Equity impact	Traditional monopolar/bipolar devices—"AS IS" scenario	HEDs—"TO BE" scenario	<i>p</i> -value
Access to care on local level	1.57	0.43	0.011
Access to care for person with legally protected status	1.09	1	0.798
Impact on the hospital waiting list	0.17	0.96	0.007
Generation of health migrations phenomena	-0.09	0.78	0.005
Existence of factors limiting the use of the technology for a group of patients	0.22	-0.17	0.111
Level of iniquity of the technology	0.26	-0.17	0.181
Impact of the access to care, given a potential clinical pathway optimization, due to an improvement in the adverse events management	-0.04	0.65	0.007
Impatto sull'accessibilità correlata alla ottimizzazione del percorso chirurgico	0.09	0.91	0.012
Average value for equity impact	0.41	0.55	0.146
Ethical and social impact	Traditional monopolar/bipolar devices—"AS IS" scenario	HEDs—"TO BE" scenario	<i>p</i> -value
Ability of the technology to protect the patients' autonomy	0.17	0.52	0.18
Protection of human rights	0.13	0.13	0.257
Ability of the technology to protect the patients' integrity	0.09	0.57	0.087
Ability of the technology to protect the patients' dignity	0.09	0.43	0.157
Ability of the technology to protect the patients' religion	0.13	0.7	0.029
Ability of the technology to protect cultural and moral beliefs	0.13	0.13	0.486
Impact of the procedure on the social costs	0.22	1	0.011
Patients and citizens can have a good level of understanding of technology	0.22	0.26	0.811
Impact of the technology on the patient's satisfaction	0.22	1.09	0.002
Impact of the technology on the patient's perceived quality of life	0.35	1.17	0.005
Impact of the technology on the care giver's life and perception	0.22	0.65	0.125

Table 7 (continued)

Ethical and social impact	Traditional monopolar/bipolar devices—"AS IS" scenario	HEDs—"TO BE" scenario	<i>p</i> -value
Impact of the technology on the management of post-operative pain	0.09	1.04	0.001
Impact of the technology on the patients' sickness and nausea	0.22	0.39	0.423
Impact of the technology on the patient's recovery time	0.3	1.13	0.005
Impact of the technology on the post-operative period	0.26	1.22	0.001
Impact of technology on the timing of returning to usual work activities	0.35	0.96	0.055
Impact of the technology on the wound healing time	0.17	0.57	0.121
Average value for ethical and social impact	0.20	0.70	0.048
Legal impact	Traditional monopolar/bipolar devices—"AS IS" scenario	HEDs—"TO BE" scenario	<i>p</i> -value
Permission level of technology	1.39	1.17	0.618
Need for inclusion of the technology in registry	0.61	0.78	0.715
Fulfillment of the safety requirements	1.17	1.74	0.162
Production warranties	1.3	1.04	0.543
Price control	0.83	-0.09	0.066
Need to regulate the acquisition of technology	0.48	-0.22	0.19
The legislation covers the regulation of technology for all categories of patients	1.09	1.13	0.906
The user manual is complete and exhaustive	1.39	1.78	0.282
Infringement of intellectual property rights	0.26	0.22	0.868
Average value for legal impact	0.95	0.84	0.315

Table 8 Multi-criteria decision analysis

Dimensione	Normalized prioritization of the dimensions	Traditional monopolar/bipolar devices—"AS IS" scenario		HEDs—"TO BE" scenario	
		Standardized score	Final score	Standardized score	Final score
General relevance	0.09	0.75	0.07	0.75	0.07
Technical relevance	0.1	0.75	0.08	0.75	0.08
Safety	0.16	0.33	0.05	0.54	0.09
Efficacy	0.15	0.33	0.05	0.5	0.07
Economic and financial impact	0.1	0.67	0.07	0.64	0.06
Equity of access	0.07	0.63	0.04	0.67	0.05
Social and ethical impact	0.06	0.47	0.03	0.67	0.04
Legal impact	0.04	0.5	0.02	0.5	0.02
Organizational impact	0.05	0.5	0.03	0.71	0.04
Total			0.43		0.51

healthcare system, like associations of patients, healthcare providers, and managers, to strengthen the validity of the results. On the other hand, the analysis did not consider the use of HEDs within robotic surgery, thus, opening a further development of study. The reason why robotic surgery was not taken into account relies on the fact that, as described in other evidence, robotics is not fully recognized and utilized in all the surgical settings under assessment, at least in the Italian setting [128]. This is why the attention was focused on minimally invasive and open surgeries. Also, nowadays,

the introduction and development of different robotic platforms, not all of them, at present, with a standardized HED included, makes the analysis too difficult due to the high confounding biases.

In conclusion, the routine use of HEDs can be considered proper and sustainable, in a balance between costs and outcomes, suggesting a responsible use of such innovative devices, thus, improving surgical outcomes and guaranteeing, at the same time, cost savings and patients' satisfaction.

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