

The use of energy devices for thyroid surgical procedures.

Harmonic Focus versus Biclamp 150



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BACKGROUND: *Thyroidectomy is the most frequently performed endocrine surgery, and in recent years, the surgical instruments and techniques used in this surgery have greatly evolved. New devices are created to facilitate dissection, haemostasis increasing the intraoperative cost.*

MATERIAL AND METHOD: *We prospectively examined patients undergoing to traditional thyroidectomy using reusable vs disposable devices (BiClamp 150, ERBE® - group A vs. Harmonic Focus, ETHICON® - group B). The patients were treated for benign and malignant diseases from two experienced surgeons. The two groups were separated based on age, sex, skin-to-skin operative time, the number of parathyroid glands identified by the surgeon during the operation, pre- and post-operative serum calcium levels evaluated with PTH until 24 hours after surgery, the mean hospital stay, the evaluation of the content of the drainages at 6 hours and 24 hours, and the thyroid gland volume calculated via ultrasound preoperatively. The patients were asked to complete a form at 24 hours post-op to self-evaluate dysphagia to liquids and pain on a scale from 0 to 10.*

RESULTS: *The patients analysed were 80 pts. Analysis of the data showed no significant differences between the groups with respect to age, ($p = 0.48$), or gender, 9 males and 31 females in group A and 8 males and 32 females in group B. The thyroid volume (in ml), calculated on the basis of preoperative ultrasonography, was 43.89 ± 37.10 in group A vs. 54.54 ± 51.92 in group B ($p = 0.35$). The skin-to-skin operative time was equal to 50.16 ± 10.43 min. vs. 52.39 ± 11.54 min. ($p = 0.36$) in groups A and B, respectively. No statistically significant differences in pre e postoperative calcium levels. The amount of drainage at 6 hours after surgery was 16.63 ± 15.24 ml. in group A and 23.72 ± 21.93 ml. in group B ($p = 0.07$). At 24 hours after surgery, the amount was 57.84 ± 32.56 ml. in group A and 66.79 ± 39.94 ml. in group B ($p = 0.28$). For group A and group B, we analysed dysphagia for liquids on a scale from 0 to 10 (4.5 ± 2.35 vs. 4.18 ± 2.4 , $p = 0.48$, respectively), alterations in patients' tone of voice (1.97 ± 2.51 vs. 1.43 ± 0.48 , $p = 0.29$, respectively), and postoperative pain at 24 hours after surgery (2.76 ± 1.99 vs. 2.68 ± 2.12 , $p = 0.87$, respectively). The average cost for group A was equal to $\text{€ } 25 \times 40 = 1000$ vs. $\text{€ } 450 \times 40 = 18000$ for Group B. The hospital stay in days was equal to 1.70 ± 0.46 (Group A) vs. 1.66 ± 0.53 (Group B) ($p = 0.69$).*

CONCLUSIONS: *One limitation of the current study is its small sample size. Both devices are effective and safe for total thyroidectomy because they have similar effects on the operative time, postoperative bleeding and patient outcomes in endocrine experienced surgical team. On the other hand, in a time of the spending review and the standardisation of surgical techniques to ensure the highest quality of services offered, the BiClamp is a viable alternative tool with a high security standard and low cost that offers significant savings to the health care system.*

KEY WORDS: Energy devices, Health care, Thyroidectomy

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Thyroidectomy is the most frequently performed endocrine surgery, and in recent years, the surgical instruments and techniques used in this surgery have greatly evolved^{1,2}. Among some of these innovations were new devices to facilitate dissection and haemostasis, minimally invasive thyroidectomy and intraoperative monitoring of the recurrent laryngeal nerve. Post-operative bleeding, a severe complication of thyroidectomies, can lead to the development of a thyroid haematoma, which compresses the trachea causing dyspnoea and endangers the patient. The reported incidence of symptomatic haematomas varies from 0.1 to 2%, with a higher risk in elderly patients, male patients, and patients treated with anticoagulants or diagnosed with Graves' disease, which have a rich blood supply to the gland. Most cases of symptomatic haematomas occur within the first 6-12 hours post-surgery and are clinically manifested by swelling at the base of the neck, bleeding and drainage from the surgical wound, pain and dyspnoea; at which point, surgery is required to control the bleeding and decompress the airway. Careful haemostasis remains a primary objective of thyroid surgery not only because it prevents post-operative bleeding that potentially puts the patient at risk but also because it reduces the risk of injury to the recurrent laryngeal nerve and parathyroid glands. Haemostasis can be obtained with the traditional technique of ligation and division of the vessels using haemostatic clips in bipolar electrosurgery, which has more recently been based on ultrasound or radio frequency using high-energy devices. In addition, absorbable haemostatic agents should be applied to control bleeding from capillaries, veins or small arteries when other procedures are ineffective or impractical³. For many years, it has been argued that the best system for cauterising the thyroid vessels was bipolar electrosurgery, which reduces the transmission of heat to critical structures by focusing the energy and high temperatures to a confined area. The cauterisation was reserved for smaller vessels, whereas ligation and division was by far the most widely used technique to divide the vascular pedicles of the thyroid. In the last decade, other haemostatic systems that were already available in abdominal surgery have been introduced and shown to be useful in thyroid surgery. These new systems are better classified as "Energy devices" because they use different forms of energy such as ultrasound or radiofrequency. These energy devices cause the temperature of surrounding tissues to increase; however, this increase is not as pronounced as the increase seen with monopolar electrosurgery^{4,5}. The most modern tools to achieve haemostasis are divided into two categories:

- ultrasonic dissector;
- instruments based on radio frequency.

The ultrasonic dissector (**Harmonic Focus, ETHICON®**) is shaped like a pair of pliers, with a branch acting as the source of mechanical vibrations at ultrasonic frequencies. In this instrument, piezoelectric

crystals convert electrical energy into mechanical energy: one of the two blades vibrates axially with a frequency of 55500 Hz while the other blade is inactive. During each active vibration, the blade performs an oscillation that varies between 50 and 100 micrometres, in relation to the power level of the generator (Fig. 1).

The ultrasonic frequency of the mechanical vibrations has varying effects in tissues:

- Rapid vaporisation of the water molecules contained in cells (cavitation effect), obtained at a temperature lower than normal due to the pressure exerted on the fabric by the two blades;

- Coagulation of the proteins;

- Breaking of hydrogen bonds and protein denaturation. The coagulated proteins form a seal with the vessel wall, closing vessels with a diameter less than 3-5 mm. This effect can be obtained at temperatures between 50 and 100 °C; however, 60 °C is generally sufficient to obtain a satisfactory coagulation and dissection (the heat does not propagate beyond 3 mm from the instrument and does not cause tissue damage). In contrast, the electrosurgical technique can reach temperatures as high as 400 °C, which can result in tissue charring. The tip of the instrument, however, can reach very high temperatures, which may result in tracheal lesions. For this reason, it is necessary to keep the end of the scalpel under direct vision.

An advantage of this technology is the composition and behaviour of the two blades: the vibrating blade is composed of active metal, and the inactive blade is made of Teflon. Because the inactive blade does not reach high temperatures, the surgeon can avoid possible tissue damage by manoeuvring the tool to keep the metal blade at a distance from critical anatomical structures (i.e., the myelin sheath of the nerves which is known to be sensitive to heat) approaching the inactive blade.

The tissue to coagulate and section lies between the two branches of the clamp allowing for cutting, coagulation or dissection.

The amount of energy transferred to the tissue and the consequent effects depend on several factors, including the selected power level, the characteristics of the blade, the tissue tension, the pressure applied to the instrument and the surgical technique.

Cutting speed can be increased by increasing the power level, the tissue tension and the pressure applied to the instrument; the heat produced increases as the length travelled by the blade during each vibration increases and thus the mechanical effect is more evident, the consequent tissue dissection is faster, and the coagulation decreases.

Another advantage of the ultrasonic dissector is its safety of use. With this device, patients are not exposed to an electric current; thus, this device is safe to use on patients with a pacemaker.

Tools that use radiofrequency to coagulate blood vessels are also shaped like pliers; one branch of the calliper is

the source of the radio frequency energy used for coagulation, and the other branch supports the tissue. The BiClamp 150C, ERBE ® is a reusable tool with a guaranteed minimum of 50 sterilisation cycles that is used for the synthesis of the vessels and thermonuclear tissue structures (Fig. 2). This device reduces the procedure time and the amount of material suture needed. The BiClamp uses bipolar radio frequency and pressure created within the clamps of the handpiece to obtain the synthesis of vessels (in a compressed fabric that reaches a temperature of 70-90 °C). Both factors alter the structure of collagen and elastin vascular intima, creating a zone of thermal fusion, which is a sure sign of ligation. A feedback loop to the generator and measurement automatically adjusts the power required for the synthesis by identifying the impedance of the tissue located between the branches of the clamp. Additionally, an automatic shutdown feature (auto-stop) stops the clotting process once optimal haemostasis is reached. This reduces the lateral thermal spread, which affects the tissues adjacent to the branches of the forceps for 1-3 mm, and avoids charring, preventing injury to the nerves and other soft tissues adjacent to the point of application. A previous animal model showed that it can be safely used to coagulate vessels between 2 and 7 mm in diameter with a maximum pressure of rupture greater than 400 mmHg; that is, the synthesis of the arterial vessels resists pressure three times more than normal systolic pressure. Once the optimum level of synthesis is reached, one can proceed to mechanically cutting the tissue to the centre of the fusion zone. In some cases, it may be desirable to prepare two zones of thermofusion close to one another; the cut is then performed between the merger of the two. BiClamp's coagulation effectiveness makes further ligature or coagulation largely superfluous (6). The aim of this study was to evaluate the safety, ease of use, incidence of adverse effects and costs of these devices in thyroid surgery.

Materials and Methods

From 12/05/2013 to 05/29/2014, we prospectively examined patients undergoing total thyroidectomy or near total thyroidectomy with the conventional technique using reusable vs. disposable devices (BiClamp 150, ERBE ® - group A vs. Harmonic Focus, ETHICON® - group B). Patients were operated on in our unit for both benign and malignant disease according to the exclusion criteria listed in Table I.

We compared the two groups on the basis of the use of a disposable ultrasonic scalpel vs. a reusable radio frequency device. The two devices differ in the amount of energy required for the coagulation of tissue.

The surgical technique was similar in both cases; two experienced endocrine surgeons performed the interventions.

TABLE I - Exclusion criteria

Reoperative procedure
lobectomy
MIVAT
Anticoagulant therapy
age < 18 years
lymphadenectomy

The two groups were separated based on age, sex, skin-to-skin operative time, the number of parathyroid glands identified by the surgeon during the operation, serum calcium levels pre-and post-operative evaluated with PTH until 24 hours after surgery, the mean hospital stay, the evaluation of the content of the drainages at 6 hours and 24 hours, and the thyroid gland volume calculated via ultrasound preoperatively.

The patients were asked to complete a form at 24 hours post-op to self-evaluate dysphagia to liquids and pain on a scale from 0 to 10.

The cost of the devices averaged 1250 euros (50 performances) for the BiClamp 150 versus 450 Euro (for single supply) Harmonic Focus.

All data routinely collected in medical records were processed, and statistical analysis was performed using Student's t-test ($p < 0.05$).

Results

Analysis of the data showed no significant differences between the groups with respect to age, 57.10 ± 12.39 (group A) vs. 55.03 ± 13.79 (group B) ($p = 0.48$), or gender, 9 males and 31 females in group A and 8 males and 32 females in group B (Table III). The thyroid volume (in ml), calculated on preoperative ultrasonography, on which we base our inclusion criteria for a possible mini-invasive thyroidectomy was 43.89 ± 37.10 in group A vs. 54.54 ± 51.92 in group B ($p = 0.35$). The preoperative characteristics of the patients are reported in Tables II and III.

TABLE II - Preoperative characteristics of patients

	Group A	Group B	P
Age (years)	57.10 ± 12.39	55.03 ± 13.79	0.48
Sex (F : M)	31: 9	32:8	
Thyroid volume (ml)	43.89 ± 37.10	54.54 ± 51.92	0.35
Preoperative calcemia (mg/dl)	9.72 ± 0.37	9.21 ± 0.36	0.37

TABLE III - Preoperative cytology

	Group A	Group B
Goiter	19	18
Thyr 3*	4	6
Thyr 4*	7	8
Thyr 5*	4	2
Thyr 6*	3	2
Basedow	2	4
Plummer	1	0

*Bethesda System 2010

The number of parathyroid glands identified and reported by the surgeon in the operative report was equal to 2.77 ± 0.58 in group A vs. 2.57 ± 0.70 in group B ($p = 0.16$). The skin-to-skin operative time was equal to 50.16 ± 10.43 vs. 52.39 ± 11.54 ($p = 0.36$) in groups A and B, respectively.

The number of bindings performed in association with the use of the devices was 5.12 ± 1.23 vs. 4.80 ± 1.14 ($p = 0.25$) in groups A and B, respectively.

The values of the preoperative serum calcium levels in the two groups were 9.72 ± 0.37 vs. 9.21 ± 0.36 ($p = 0.37$); the postoperative calcium values were 8.21 ± 12.53 vs. 8.12 ± 0.55 ($p = 0.43$) in groups A and B, respectively. Evaluating the values of the pre- and postoperative serum calcium levels within the two groups, these levels declined, reaching significance in only group B ($p = 0.13$ and $p = 0.001$ in groups A and B, respectively). However, both groups maintained serum calcium concentration levels above 8 mg / dl, which is considered the threshold dose of serological hypocalcaemia.

The amount of drainage at 6 hours after surgery was 16.63 ± 15.24 in group A and 23.72 ± 21.93 in group B ($p = 0.07$). At 24 hours after surgery, the amount was 57.84 ± 32.56 in group A and 66.79 ± 39.94 in group B ($p = 0.28$).

For group A and group B, we analysed dysphagia for liquids on a scale from 0 to 10 (4.5 ± 2.35 vs. $4.18 \pm$

2.4 , $p = 0.48$, respectively), alterations in patients' tone of voice (1.97 ± 2.51 vs. 1.43 ± 0.48 , $p = 0.29$, respectively), and postoperative pain at 24 hours after surgery (2.76 ± 1.99 vs. 2.68 ± 2.12 , $p = 0.87$, respectively).

The data relating to post-operative morbidity are summarised in Table IV

Discussion

Thyroidectomy is one of the most frequently performed surgeries in our unit, and rapid and effective haemostasis is a fundamental component of the procedure due to the high vascularity of the gland. With the advancement of technology, the use of the new energy devices in thyroid surgery has become a common practice. Numerous studies have demonstrated the efficacy and safety of the ultrasonic scalpel and radio frequency instruments. Initially, ultrasonic instruments were developed for laparoscopic abdominal surgery but were later adopted in endocrine surgery, obstetrics, and thoracic surgery among others. Energy devices in thyroid surgery were first used in the late 90s, when an ultrasonic dissector (Harmonic Scalpel, Ethicon ®) was compared to the traditional technique of ligation and division of the vessels. The new instrument led to a reduction in operating time in addition to intraoperative and postoperative bleeding, decreasing the incidence of complications. Subsequently, numerous studies have been published that confirm the reduced operation times associated with using ultrasonic instruments (Ultracision Harmonic Scalpel and Harmonic Focus, Ethicon ®: the second is the latest ultrasonic scalpel with an ergonomic design that makes it easy to use, especially in the dissection procedure), largely due to their capacity to coagulate and dissect simultaneously and their the lower number of sutures needed⁷⁻¹⁶.

Similar operative time reduction benefits were also recorded when thyroidectomy was necessary for a laterocervical lymphadenectomy due to the presence of metastases resulting from thyroid carcinomas.

TABLE IV - Operative parameters and postoperative morbidity -

	Group A	Group B	P
Operative time (min)	50.16 ± 10.43	52.39 ± 11.54	0.36
Numbers of parathyroids	2.77 ± 0.58	2.57 ± 0.70	0.16
Numbers of ligatures	5.12 ± 1.23	4.8 ± 1.14	0.25
Calcemia at 24 hours (mg/dl)	8.21 ± 0.53	8.12 ± 0.55	0.43
PTH at 24 hours (pg/ml)	35.9 ± 25.44	34 ± 19.59	0.7
Drainage at 6 hours (ml)	16.63 ± 15.24	23.72 ± 21.93	0.07
Drainage at 24 hours (ml)	57.84 ± 32.56	66.79 ± 39.94	0.28
Disphagia at 24 hours (scale by 0 to 10)	4.5 ± 2.35	4.18 ± 2.4	0.48
Disphonia at 24 hours (scale by 0 to 10)	1.97 ± 2.51	1.43 ± 0.48	0.29
Pain at a 24 hours (scale by 0 to 10)	2.76 ± 1.99	2.68 ± 2.12	0.87
Hospital stay (days)	1.7 ± 0.46	1.66 ± 0.53	0.69

For meta-analyses, we have also highlighted other benefits of the use of an ultrasonic scalpel in thyroid surgery:

- Reduction in intra-operative bleeding;
- Reduction in the volume of drainage, due to lower intra-operative blood loss and more precise control of the vessels, with the ability to also reduce the risk of infection of the surgical wound;
- Reduction in hospital stay;
- Reduction in post-operative pain, due to less tissue damage, less traction and the manipulation of the thyroid gland and adjacent organs, and the non-neuromuscular stimulation (when using electrosurgery);
- Ability to carry out the intervention with a skin incision of reduced size and with a smaller number of ligatures¹⁷⁻²⁰.

However, despite these advantages, the adverse side effects from using the ultrasonic scalpel, in particular hypoparathyroidism and paralysis of the recurrent laryngeal nerve remain unclear and controversial²¹. Although some studies have reported a significant reduction in the hypoparathyroidism transitional amount due to the lower thermal damage to tissues and the resultant improved preservation of vascularisation of the parathyroid glands^{9,13,22}, others have found no differences in the incidence of complications. Due to the low frequency of recurrent nerve palsy and permanent hypoparathyroidism, further studies with larger study populations are needed to clearly define whether the use of ultrasonic instruments results in a reduction of these adverse events.

The major criticism of the Harmonic Focus® is its cost: it is a disposable device that exceeds an average cost of 450 Euros per device. However, it must be noted that the shorter duration of the intervention allows you to treat more patients during the same operative session, reducing the cost of personnel and drugs as well as the general expenses related to the use of the operating room. The reduced use of surgical materials and the shorter duration of hospital stay improve the cost to benefit ratio. Ultimately the use of the Harmonic Focus® is not necessarily associated with an increased cost but with a better use of health care resources and the possibility of reducing waiting lists²³.

The BiClamp 150C, HERB® is a multi-purpose tool designed specifically for thyroid surgery using radiofrequency coagulation of blood vessels. In 2006, Richter published the first study demonstrating the effectiveness of this tool in an animal model. Furthermore, Alesina et al. reported that the use of the BiClamp in a study of 186 patients reduced the surgery time as well as costs and the need to use drainages compared to the traditional technique. Additionally, they highlighted a rate of postoperative complications similar to those of traditional surgery. Therefore, they concluded that this tool could be routinely used in thyroid surgery²⁴. confirmed that the BiClamp reduces operative time, does not increase the incidence of hypoparathyroidism or recurrent nerve paralysis, and reduces postoperative bleeding compared to the tradition-

al technique of ligation and division of the vessels⁶. Oussoultzoglou et al., in a 2008 study, compared the BiClamp 150C, ERBE® with the LigaSure, Covidien®, Both were effective and neither resulted in bleeding complications. However, the BiClamp was more advantageous in reducing operating time, the incidence of post-operative hypocalcaemia and the need for an oral supplementation of calcium. The LigaSure, Covidien® is a tool with a mechanism similar to the BiClamp: it uses radio frequency combined with the pressure produced by the claws of the gripper for the thermal fusion of vessels. Unlike the BiClamp, the LigaSure is a disposable device, whose usefulness has been demonstrated in the intervention of thyroidectomy, reducing the operative time.

There are published studies and meta-analyses comparing the LigaSure with the ultrasonic scalpel²⁵⁻²⁶; however, there is a paucity of studies comparing the BiClamp with the Harmonic Focus. To that end, the objective of our study was to make a direct comparison between these two instruments, which are routinely used in our unit for total thyroidectomy.

We enrolled 80 patients consecutively treated for both malignant and benign disease who were divided into two groups: group A was treated with the BiClamp and group B was treated with the Harmonic Focus. Excluding the two devices, the operative technique was the same. The two groups were matched for age, sex, thyroid volume, benign / malignant disease ratio, and serum calcium and parathyroid hormone levels in pre-op.

We evaluated and compared the parameter operators and the incidence of post-operative complications. All the parameters were comparable (Table IV).

One limitation of the current study is its small sample size. To appropriately test the efficacy of these devices, a larger study is necessary. However, this case study could serve as preliminary data for a larger study.

In conclusion, both devices are effective and safe for total thyroidectomy because they have similar effects on the operative time, postoperative bleeding and patient outcomes in endocrine experienced surgical team. On the other hand, in a time of the spending review and the standardisation of surgical techniques to ensure the highest quality of services offered personalizing it to the patient, the BiClamp is a viable alternative tool with a high security standard and low cost.

One important thing to note is that the experience of the surgeon performing the thyroidectomies has a major impact on the incidence of adverse events in thyroid surgery regardless of the device used.

Riassunto

BACKGROUND: La Tiroidectomia è l'intervento maggiormente praticato in endocrinochirurgia. E negli ultimi anni la strumentazione chirurgica e le tecniche utilizzate in questa chirurgia si sono considerevolmente evolute.

Nuovi devices sono stati creati per facilitare la dissezione, l'emostasi aumentando i costi.

MATERIALI E METODI: Abbiamo esaminato in maniera prospettica una serie di paziente operati di tiroidectomia tradizionale con ausilio di un dispositivo monouso e di un dispositivo pluriuso (BiClamp 150, ERBE® - group A vs. Harmonic Focus, ETHICON® - group B). I due gruppi sono stati suddivisi in base all'età, al sesso, al tempo operatorio chirurgico, al numero di paratiroidi identificate dal chirurgo, ai valori di calcio sierico pre e postoperatori, PTH dopo 24 ore dall'intervento chirurgico, alla degenza media ospedaliera, al contenuto dei drenaggi a 6 e 24 ore dalla fine della procedura, dal volume tiroideo calcolato preoperatoriamente durante l'ecografia. I pazienti hanno risposto ad un test di autovalutazione con scala da 0 a 10, dopo 24 ore, riguardante la sensazione di disfagia ai liquidi ed il dolore postoperatorio.

RISULTATI: Abbiamo analizzato 80 casi. L'analisi dei dati non ha mostrato differenze statisticamente significative tra i gruppi rispetto all'età; al sesso, 9 maschi e 31 femmine nel gruppo A e 8 maschi e 32 femmine nel gruppo B. Il volume tiroideo (ml) era risultato essere 43.89 ± 37.10 nel gruppo A vs 54.54 ± 51.92 nel gruppo B ($p=ns$). Il tempo chirurgico operatorio era risultato uguale (50.16 ± 10.43 min vs 52.39 ± 11.54 min ($p=0.36$)). Nessun risultato statisticamente significativo per il calcio sierico pre e postoperatorio nei due gruppi.

La quantità di siero nei drenaggi a 6 ore, è risultata pari a 16.63 ± 15.24 ml. nel gruppo A ed a 23.72 ± 21.93 ml. nel gruppo B ($p = 0.07$). A 24 ore la quota di siero era pari a 57.84 ± 32.56 ml. nel gruppo A ed a 66.79 ± 39.94 ml. nel gruppo B ($p = 0.28$). Abbiamo analizzato la disfagia per i liquidi nei due gruppi con scala da 0 a 10 (4.5 ± 2.35 vs. 4.18 ± 2.4 , $p = 0.48$), alterazioni nel tono di voce (1.97 ± 2.51 vs. 1.43 ± 0.48 , $p = 0.29$), e dolore postoperatorio a 24 ore (2.76 ± 1.99 vs. 2.68 ± 2.12 , $p = 0.87$). I costi medi nel gruppo A sono risultati pari a $\text{€ } 25 \times 40 = 1000$ vs. $\text{€ } 450 \times 40 = 18000$ nel gruppo B.

La degenza media è risultata pari a 1.70 ± 0.46 nel gruppo A vs 1.66 ± 0.53 nel gruppo B ($p=0.69$).

CONCLUSIONI: Una limitazione dello studio è il numero limitato di casi. Entrambi i devices sono efficaci e sicuri in tiroidectomia perché hanno effetti simili sul tempo operatorio, sul sanguinamento postoperatorio e sull'outcome dei pazienti operati da chirurghi endocrini esperti. Inoltre in tempo di revisione dei costi e di standardizzazione delle procedure chirurgiche per garantire la migliore qualità il BiClamp è una alternativa che garantisce alti standard di sicurezza e costi contenuti con vantaggi per il servizio sanitario.

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