The utility of a reusable bipolar sealing instrument, BiClamp®, for pulmonary resection

Tohru Sakuragi a,*, Yukio Okazaki a, Masahiro Mitsuoka a, Fumio Yamasaki b, Masanori Masuda b, Daisuke Mori b, Toshimi Satoh b, Tsuyoshi Itoh a

a Department of Thoracic and Cardiovascular Surgery, Faculty of Medicine Saga University, Saga, Japan
b Department of Pathology, Faculty of Medicine Saga University, Saga, Japan

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Abstract

Objective: To assess the use of a combination of bipolar sealing and electrosurgical coagulation for pulmonary resection. Methods: The procedure was used in both dogs and humans. Initially, lung wedge resections were performed on six healthy, Beagle dogs using a voltage controlled electrosurgical system. The area of lung tissue to be resected was first coagulated to provide a distinct line of seal. The lung was then resected along the peripheral site of the sealing scar. Efficiency of sealing was assessed using a tracheally applied air pressure of 30 cmH2O. The electro-cauterized tissue was compared histologically to tissue sealed by a standard stapling technique. In the clinical phase, lung resections were performed after cauterization in 17 patients. Bullectomies were performed using video-assisted thoracic surgery in 4 patients, and thoracotomic procedures in 13 (1 bullectomy, 5 wedge resections, and 7 fissure separations). Results: Dogs: Tissue sealing was highly successful, without any air leakage, in all six dogs. Histologically, the clamped lesion showed tissue-fusion probably due to both the compression and thermal effects. The proximal zone adjacent to the clamped lesion revealed both collapsed alveolar spaces and fused alveolar walls. In comparison, the stapled lesions showed no tissue-fusion. Humans: There were no major complications. The median operation time was 189 min, and estimated median hemorrhage volume was 67 ml. Median chest drainage duration was 3 days (range: 1—7) and no patient suffered from prolonged air leakage (> 7 days). Conclusions: Lung parenchymal tissue resection following bipolar sealing and electrosurgical coagulation instead of staples was efficient and simple. Furthermore, the technique reduced the use of staples, reducing the cost of the surgery.

Keywords: Pulmonary resection; Reusable; Bipolar; Ecosurgery; Electrosurgical system; BiClamp®

1. Introduction

Automatic stapling devices have been routinely used for pulmonary resection [1—3] reducing the incidence of post-operative air leakage [4]. We have successfully used electrosurgical coagulation, utilizing Joule heat alone, for pulmonary resection. In this report, we describe our experiences with the technique and discuss its possible benefits.

The conventional electrosurgical systems generally use both Joule heat and electric sparking for coagulation. The output voltage increases as the target tissue is coagulated, leading to the generation of sparking to the tissue that induces a rapid temperature rise and tissue carbonization. On the contrary, both the SOFT COAG (monopolar) and BiClamp® (bipolar) outputs of the VIO300D electrosurgical system (ERBE Elektromedizin GmbH, Tuebingen, Germany) are microprocessor-controlled and the output voltage is maintained below 200 V to avoid sparking. In this way, the maximum tissue temperature remains below boiling point, and there is no tissue carbonization. These relatively new monopolar and bipolar coagulation outputs that do not generate sparking are based on tissue protein being sufficiently coagulated at temperatures between 70 and 80 °C [5]. In this report, the resection of the lung parenchyma using the bipolar output BiClamp® generated by the VIO300D is presented.

In the initial animal experiments the lung parenchyma was coagulated and sealed by applying this output via BiClamp® forceps and divided by scissors. High pressure was applied in the airway to confirm the absence of any leakage. The integrity of the sealing was also confirmed by histological examination. Our experiences in the use of this output in clinical cases are also presented. The potential cost and waste reduction benefits of the utilization of reusable accessories are also discussed.

* Corresponding author. 5-1-1 Nabeshima, Saga 849-8501, Japan. Tel.: +81 952 34 2345; fax: +81 952 34 2061. E-mail address: sakuragi@cc.saga-u.ac.jp (T. Sakuragi).

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2. Material and methods

2.1. Technology

We evaluated a reusable bipolar sealing instrument (BiClamp®) in combination with an electrosurgical system (VIO300D, both ERBE Elektromedizin GmbH, Tübingen, Germany) (Fig. 1) for the welding of the lung parenchyma prior to the mechanical resection with surgical scissors.

2.2. Animal study

All of the animals involved in this study received humane care in compliance with the Guide for the Care and Use of Laboratory Animals published by the National Institute of Health (NIH Publication No. 86-23, Revised 1985) and with the European Convention on Animal care. The Animal Research Committee of the Faculty of Medicine, Saga University approved all procedures. Six adult beagle dogs, weighing 14—17 kg, were anesthetized with an intravenous injection of pentobarbital sodium (15 mg/kg body weight) then endotracheally intubated. General anesthesia was maintained using inhalation of isoflurane under mechanical ventilation. The animal was placed in the left lateral position. The right chest was entered through the fifth intercostal space. Wedge resections of the lung were performed in the right upper lobe about 2.5 cm and 5 cm from the anterior apex of the lobe using the BiClamp® (Fig. 2, Video 1). The lung parenchyma to be separated was grasped with the BiClamp® instrument (Fig. 2a) that was connected to the multi function output socket on the VIO300D electrosurgical system. The dedicated output for the BiClamp® instrument was set at Effect 3 and Modulation 80. The system automatically detected the endpoint of sealing and the output ceased. The sealing time was determined by the automated feedback control of the energy producing system and was denoted by an acoustic signal from the generator. The process was repeated twice on the same site. After sealing, the lung was resected along the peripheral site of the sealing scar (Fig. 2b and c). Sealing failure was defined as air leakage from the treated site under an applied air pressure of 30 cmH₂O generated by the ventilator. An automatic stapling device was used in a single animal for the comparison of histological (Video 1).

For histological examination, all the specimens obtained were evaluated to elucidate the sealing mechanism and to define any thermal damage on the sealed lesion (the clamped lesion and the tissue adjacent to it). For light microscopy, formalin-fixed tissue samples were paraffin embedded. Sections (4 μm thick) were cut and stained with hematoxylin and eosin and elastica van Gieson (EVG) according to standard procedures. The slides were then examined by senior histopathologists. The area of the thermal damage was confirmed and compared to the macroscopic findings. We also compared the histological findings of the sealed lesion with that of the stapled-lung lesion.

2.3. Clinical study

Our institutional review board approved the study and the enrolled patients signed a full informed consent. From May 2007 to January 2008, we performed resections of the lung parenchyma, using the BiClamp®/VIO300D system, in 17 patients. All patients were placed in the lateral decubitus position and underwent general anesthesia with single-lung ventilation. We performed bullectomies using video-assisted thoracic surgery (VATS) in 4 patients, and thoracotomic procedures in 13 (1 bullectomy, 5 wedge resections, and 7 fissure separations). For the cases of thoracotomy we used the BiClamp® forceps (Fig. 1b) set at Effect 3 and Modulation 80 for open surgery, and for the VATS cases we used the forceps (Fig. 1c) set at Effect 2 or 3 and Modulation 80 during endoscopic surgery. The resection techniques of the lung parenchyma were the same as with our conventional procedures using mechanical staples buttressed with biodegradable polyglycol acid (PGA) sheet and fibrin glue, that was modified from the technique of Venuta et al. [4]. More specifically, the sealed lesion of the remnant lung was covered with PGA sheet and fibrin glue. Patient demographics, disease, operation procedure and various para-
meters (blood loss, operation time, concomitant staple use and drainage duration), were recorded.

3. Results

3.1. Animal study

Following surgery, the remaining upper lobe of the lung was tested for airway pressure tolerance. Sealing was highly successful along both cut edges (2.5 cm and 5 cm) and there was no air leakage, in any of the six dogs, under an applied airway pressure of 30 cmH\textsubscript{2}O.

Macroscopic evaluation of the formalin-fixed lung tissue revealed the clamped lesion and a characteristic zone formation adjacent to the clamped lesion: i.e. proximal soft, pale colored zone (Fig. 3a). A loupe view of the EVG-stained specimen demonstrated the clamped lesion (Fig. 3b, identified by the arrows) was well compressed and much thinner than that of the stapled one (Fig. 3c). Microscopically, the clamped lesion further showed a tissue-fusion probably due to both compression and thermal effects (Fig. 4a), while the stapled lesion did not (Fig. 3c). The proximal soft whitish zone, of which the mean width in the 22 specimens was 2.5 mm (ranged 0.9—4.2), revealed not only collapsed alveolar spaces but also collapsed and fused alveolar walls (Fig. 4b). The stapled lesion, on the other hand, lacked these alveolar wall-changes. These findings, of the alveolar wall fusion, were in contrast to the normal alveolar tissue (Fig. 4c) and might be an additional reason for the airway pressure tolerance following resection.

3.2. Clinical study

The clinical characteristics of the patients in the study are summarized in Table 1. The lung parenchyma was resected safely and no air leakage was recognized after the procedure in all cases. Thirteen out of the 17 patients were treated without concomitant staple use for the resection of the lung parenchyma. None of the lobectomy fissure-separation cases and only one of the five bullectomy cases (Video 2) required the use of staples. The reason for the concomitant staple use in four cases is that middle part of the lung parenchyma to be resected was in central site and too thick for the BiClamp\textsuperscript{W} usage, so both the peripheral sides of the lung were sealed by the BiClamp\textsuperscript{W} and the middle part was stapled by the autosuture device. Three cases underwent non-anatomical pulmonary wedge resection using the BiClamp\textsuperscript{W} during intraoperative diagnosis of a pathologically unconfirmed peripheral nodule. Radical lobectomy was performed in two of the three cases, which were diagnosed as being malignant. Histological examination of the lobes resected from these patients showed that the sealed lesion was similar to that revealed in our animal study. Although one patient suffered from pneumonia, unrelated to the sealed lesion, there were no noted complications including air leakage and post-operative bleeding in any of the patients. Finally, the use of staples was minimized in each case, thereby reducing the cost of each surgery.

4. Discussion

This is the first report of pulmonary resection using a reusable bipolar sealing system. This procedure, with BiClamp\textsuperscript{W} generated by the VIO300D, is very easy to use and safe for the resection of the lung parenchyma. In
procedure for sealing, future studies will include a randomized trial using the BiClamp\textsuperscript{*} alone for pulmonary resection, to clarify the situation.

Some surgical approaches and techniques for nonanatomical pulmonary surgery have been developed [9—12]. Shigemura et al. [11] and Santini et al. [12] reported a technique using the LigaSure system for nonanatomical pulmonary resection. A major difference is that the BiClamp\textsuperscript{*} is reusable, in contrast to the LigaSure which is disposable resulting in a high cost for a single-use instrument. Theoretically these systems achieve coagulation in a similar manner. Both diathermies use a high power current at a lower voltage than conventional, electric scalpels. Furthermore, the generators used in both systems are auto-regulated. Richter et al. [13,14] reported the equivalence of these systems in vessel ligation using a pig model. The BiClamp\textsuperscript{*} is as appropriate as the LigaSure instrument for successful ligation of small arteries and veins, demonstrating supraphysiological bursting strengths and adequate lumenal fusion healing [14].

While the instruments have equivalent tissue sealing abilities, the reusable BiClamp\textsuperscript{*} clamping system with the VIO300D is more economic than the LigaSure. The single use LigaSure system costs approximately 525 Euro in Japan. However, the BiClamp\textsuperscript{*} forceps (which can be used for up to 60 procedures) costs approximately 1750 Euro, reducing the cost of each procedure by greater than 90%. Furthermore, the use of reusable medical devices also contributes to the conservation of the global environment. The term ecosurgery has been coined to describe surgery respecting both the economy and ecology. Sitges-Serra [15] suggested that use of single-use devices should be avoided because used single-use devices require treatment as medical hazard waste in a similar manner to surgical staplers and cartridges. The incineration of these devices generates, and releases, carbon dioxide into our environment. Although there is no doubt about the usefulness of surgical staples and their significant contribution to the development of respiratory surgery, we should also consider their effect on the global environment. This aspect should no longer be neglected. We as surgeons should consider limiting their usage as much as possible. In this respect, use of the BiClamp\textsuperscript{*} with the VIO300D in lung parenchyma surgery may also be useful in supporting the goals of ecosurgery.

In conclusion we have reported the utility of the BiClamp\textsuperscript{*} generated by the VIO300D for pulmonary resection. While larger multi-center studies should be considered to further examine the use of this technology, we believe that this method is simple, efficient, cost effective and reduces the unnecessary use of single-use cartridges.

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**References**


Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.ejcts.2008.05.043.