

Lung biopsy using harmonic scalpel: a randomised single institute study

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Received 22 April 2005; received in revised form 16 June 2005; accepted 20 June 2005; Available online 25 August 2005

Abstract

Objective: Applicability of harmonic scalpel in lung biopsy was investigated in a randomised single institute study. **Methods:** Safety of the method, morbidity, drainage duration and in-hospital stays were compared in two randomised groups of patients in which either ultrasonic harmonic scalpel ($n:20$) or endostapler ($n:20$) were used for pulmonary biopsies during VATS. **Results:** An advantage of 16 min in average operation time was found in favour of the harmonic scalpel (30.75 vs 46.9 min) which was significant. There were no differences in average drainage duration (40.2 vs 30.6 h) and pleural fluid volume (258 vs 232 ml). Minor complication rates (3 vs 3) were identical and in-hospital stays (7.6 vs 7.2 days) were also similar. **Conclusions:** Overall, the vibration transmission method was shown not to be inferior to the standard endostapling technique. A safe new method offers an alternative technique for peripheral lung biopsy.

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Keywords: Harmonic scalpel; VATS; Diffuse parenchymal lung disease (DPLD); Lung biopsy; Postoperative complication; Air leak

1. Introduction

Guidelines [1] concerning the role of surgical lung biopsy in differential diagnosis of diffuse interstitial parenchyma disease, a group of more than 200 entities, have established the indications of this procedure [2]. The present surgical technique has been developed from lung biopsy via open thoracotomy. Chronologically, the original standard cut and oversew technique was replaced by the use of staplers [3]. Advent of endostaplers, especially the staple and cut tools, gave a further impetus to video-assisted thoracic surgery (VATS) to gain a present predominance in lung biopsy. Presently, this is the method of choice in all but the unfit for single lung ventilation patients. Parallel to the developments in the exposure of the lung, tissue handling was refined also. Buttressing the resection line [4] and surface adhesives minimised postoperative leaks responsible for the majority of surgery related complications. These two factors contributed to the increase in the numbers of eligible patients previously categorised as unfit for lung biopsy. Need for further minimisation of complication-rate and cost-benefit considerations are the main reasons of ongoing exploration of new techniques. Concern for metal pieces caused foreign body complications and potential for imaging

problems facilitate further researching alternatives to the staplers. Lasers and argon beam coagulators provide excellent local haemostasis [5,6]; however, long-term airtightness at the resection line remains unresolved. Saline-enhanced thermal sealing is a promising technique, but further studies are warranted [7]. Harmonic scalpel (HS) sufficiently fulfilled expectations of minimally invasive techniques in abdominal surgery, providing rationale for exploring potentials for intrathoracic applications. Harmonic scalpels, originally developed for hepatic surgery, are based on the principle of the transmitted vibration. Viscoelastic features of the tissues are utilised in the cutting and coagulating effects of the HS. Recent research investigating harmonic scalpels in animal lung models [8] have proven its safety [9]. Based on experimental data [8], accumulating reassuring personal clinical experience in open lung surgery and having been supported by reports of others [10,11], a randomised single institute study was conducted to evaluate the usefulness of harmonic scalpel in peripheral lung biopsy.

2. Material and method

Forty consecutive patients referred to the Thoracic Surgery Unit/Department of Surgery/University of Pecs for surgical lung parenchyma biopsy for suspicion of diffuse parenchymal lung disease (DPLD) [1] or for multinodular appearances of unknown pathology were enrolled. No solitary tumour biopsy case was selected in this study. Patient's informed consent and lack of free pleural fluid or

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Table 1
Characteristics of patients

Technique	Male	Female	Age (years)
Endostapler	12	8	46.57 SD 14.48
Harmonic Scalpel	11	9	45.25 SD 11.32

Table 2
Final pathological diagnosis

Underlying pathology	Endostapler	Harmonic Scalpel	Total
Multiple lung metastasis	8	12	20
Pulmonary fibrosis	3	3	6
Obliterative bronchiolitis	5	2	7
Lymphoma (lung manifestation)	0	1	1
Mesothelioma	0	1	1
Chronic pneumonia	2	1	3
Sarcoidosis	2	0	2

suspicion of concomitant pleural disease (confirmed by CT and/or ultrasound) were selection criteria. Expected free pleural space were confirmed in all cases, therefore no drop out was experienced. The treatment protocols were approved by the Local Bio-ethical Committee and informed consent was obtained from the patients. Patients were randomised using the dice method in one of the two pronges, i.e. standard endostapler (Group 1) vs harmonic scalpel (Group 2) groups. All procedures were performed by consultants either by TFM or IB. In both groups standard VATS lung biopsy technique was applied utilising a three-port approach. (Posterior and anterior axillary lines, 4th interspace, 7th interspace, posterior axillary line, 2 cm ports each) Single lung ventilations were maintained during the whole procedure. Endo-GIA Stapler 50 (Johnson and Johnson Ltd) tools were applied in Group 1. In Group 2 the harmonic scalpel (Ultracision harmonic Scalpel Johnson and Johnson Ltd) was functioning on 55,000 Hz vibration frequency with blade excursion of 70 μ m. Level 3 cutting force was applied with blunt jaw surface positions. Lung surfaces were tested at 30 wcm at completion of the procedure and one 28Ch tube was left behind in apical position. No prophylactic antibiotics were used. The patients received low molecule weight heparin thromboembolic prophylaxis for 72 h post-operatively. The standard suction volume was 10 wcm in every case. Chest drain was removed when two criteria were simultaneously met. The lung had to be fully expanded or at least a minimal (less than 10%) postoperative pneumothorax did not increase on the chest X-ray (CXR) and a swinging in the chest tube had to be stopped. Standard postoperative monitoring (Oxygen saturation, temperature, blood counts and chemistry) and care were provided. Satisfactory final

Table 3
Characteristics of procedures

	Length of procedure (min)	Duration of drainage (h)	Drainage volume (ml)	Hospitalisation (days)	Complication
Endostapler	46.9 SD 12.4	30.6 SD 15.2	232 SD 45.6	7.2 SD 1.3	Ptx:2 SE:1
Harmonic Scalpel	30.7 SD 9.8	40.2 SD 18.3	258 SD 54.5	7.6 SD 1.6	Ptx:2 SE:1
Correlation	0.771	0.0012	0.072	0.616	

Ptx, pneumothorax; SE, surgical emphysema.

CXR, normal temperature and a minimum of 24 h following the chest drain removal were the criteria of discharge. Patients demographics were comparable in both groups (Table 1). The underlying diseases represented two nearly identical groups (Table 2). The study aimed at the evaluation of the efficiency of the harmonic scalpel compared with the established standard method of mechanical stapling.

The endpoints were:

- Clinical course of the individual cases in the identical groups in terms of morbidity/pneumothorax/hydro or haemothorax/lung expansion.
- Length of surgery and hospital stay.

Statistical correlations were calculated by Student's test.

3. Results

All procedures were successful in terms of providing adequate amount and quality tissue for pathological diagnosis of diffuse or multifocal parenchymal lung lesion (Table 2). In the overall series 23 out of 40 cases, no DPLD were confirmed. Malignant lung secondaries prevailed in the HS group and dominated the stapled arm of the study. There was no mortality in either of the groups. Procedural characteristics are summarised in Table 3. There was no conversion to open procedure in any of the groups. In one case of the endostapler group, an additional ligaclip was required to control minor bleeding. No air leakage requiring additional clip or endo-stitch was experienced on-table in any of the groups. There was a 16.15-min advantage in the average procedural time in favour of the HS over the endostapler, which was statistically different. The difference was even more expressed in the last 10 cases of the cohorts. Volume of fluid and duration of intrapleural drainage did not differ significantly. Surgical emphysema was experienced in 5% of the cases following the removal of the chest tubes, but resolved naturally as usual in both groups. No patient developed fever ($t > 38.0$ °C) following the procedure and the inflammatory markers were identical in both groups in terms of pre- and postoperative values. Patient discomfort reflected in painkiller requirements (NSAID only following the first 24 h) did not show any difference in the two groups. All patients were discharged with their intercostals tubes removed (no flutter valves were applied). Two patients in each group had less than 10% pneumothorax at discharge which absorbed by the first outpatient clinic check up (2 weeks).

4. Conclusion

Our study confirms the safety and reliability of the application of the harmonic scalpel in peripheral lung biopsy. Following a short learning curve this method shortened the procedural time significantly without compromising the patients chances for a quick and complication free recovery. As an anecdotal observation, preference of the scrub-nurse's for the harmonic scalpel should be noted here. This subjective notion could be investigated further applying ergonometics and other workstation related research modalities, presently beyond of our competence. Specimen quality and quantity also were better in the HS group from a pathological processing point of view. If exactly the same size piece of lung was removed using endostapler or harmonic scalpel, this latter provided an extra length of tissue strip due to lack of mechanically crushed parenchyma. Further disadvantage and potential source of loss of information of the endostapler method is that the metal clips have to be removed prior to the specimen slicing. In this study, no economical and cost-benefit aspects were analysed because of the irrelevance resulting in the different socio-economic environments even within the European Community. Our unit is embedded in a multi-profile surgical theatre block, where HS is provided as shared tool like lasers. Resource efficacy considerations have been supporting the utility of the existing harmonic scalpel in this new field also. However, there are obvious limitations of the present study. Specific surgery related inflammatory markers and discomfort issues were impossible to address properly due to a limited cohort. Variety of the underlying pulmonary diseases and polymorbidities present statistical challenges which would lead to unacceptably strong biases.

Accepting the limitations of our experience it seems to be obvious that the HS provides a real alternative to the presently standard endostapling and cut procedure in lung biopsy. Obviously, HS does not give completely fulfilling answers to all the concerns explained in the Introduction. Also, it must state that anecdotal personal communications suggest that hurried resections with increased level of force can result in extended air leak, a phenomenon which we did not experience. It has to be emphasised that our experience was intentionally limited to tangential resections. As no deep

vertical resections [11] in the lung parenchyma were performed, our recommendations are limited to removal of lesions directly visible on or in close proximity of the surface. In spite of reassuring experience of others [10] we would refrain from performing HS resections during VATS procedure for removal of deeply seated lesions.

Acknowledgements

The project was supported by OTKA (No. TO37590), a Hungarian Ministry of Health fund.

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