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Institutional report - Thoracic oncologic Muscle sparing versus posterolateral thoracotomy for pulmonary lobectomy: randomised controlled trial

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Abstract

Muscle sparing thoracotomy (MST) has been proposed as an alternative to posterolateral thoracotomy (PLT) for pulmonary lobectomy. This issue has been addressed by few clinical reports. To explore that subject, a prospective, controlled randomised, double-blind trial comparing MST through the auscultatory triangle and PLT was planned. The study included patients scheduled for pulmonary lobectomy for stage I or II non-small-cell lung cancer and were followed for three years. The primary endpoints were pain, analgesic consumption and post-thoracotomy pain syndrome. The secondary endpoints included morbidity plus shoulder and pulmonary functions. The trial randomised 100 patients into two groups. Postoperative pain results were similar, although analgesic consumption was higher in the PLT group ($P=0.001$). The MST group had a shorter hospital stay ($P=0.003$). Three years post-thoracotomy syndrome was unaffected by the type of incision. The women suffered more than men during the early and late postoperative time. An inverse correlation between incision length and pain was found. Immediate shoulder strength was significantly better in the MST group ($P=0.004$) but postoperative pulmonary function and complications were comparable. The two incisions results were very similar in the patient outcome, however, few aspects indicated the MST as the more suitable incision for pulmonary lobectomy.

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Keywords: Posterolateral thoracotomy; Muscle-sparing thoracotomy; Thoracotomy; Postoperative pain; Post-thoracotomy syndrome

1. Introduction

Posterolateral thoracotomy (PLT) is the historic gold standard for thoracic incisions and one of the most painful surgical incisions [1]. Several authors have proposed muscle-sparing thoracotomy (MST) in order to minimize the detrimental effects of the muscular cut [2–5]. Advantages asserted for the MSTs include less acute and chronic pain, improved pulmonary and shoulder function, faster recovery, and superior cosmetic results. Some authors admitted that MSTs offered rather substandard access to the intra-thoracic organs when compared with PLTs [5, 6]. Moreover, MSTs seem to be charged by a higher incidence of seroma [6, 7]. Our purpose was to evaluate whether MST positively impacts the outcome compared to PLT during the hospitalisation and up to three years after the operation by a prospective, controlled, randomised and double-blind trial.

2. Materials and methods

From previous trials [6–9] the standard deviations and the differences between the means of the variables indicated that a total of 66 patients reached a power of 0.8. There-

fore, we planned a pool of 100 patients in order to increase the power or detect smaller differences.

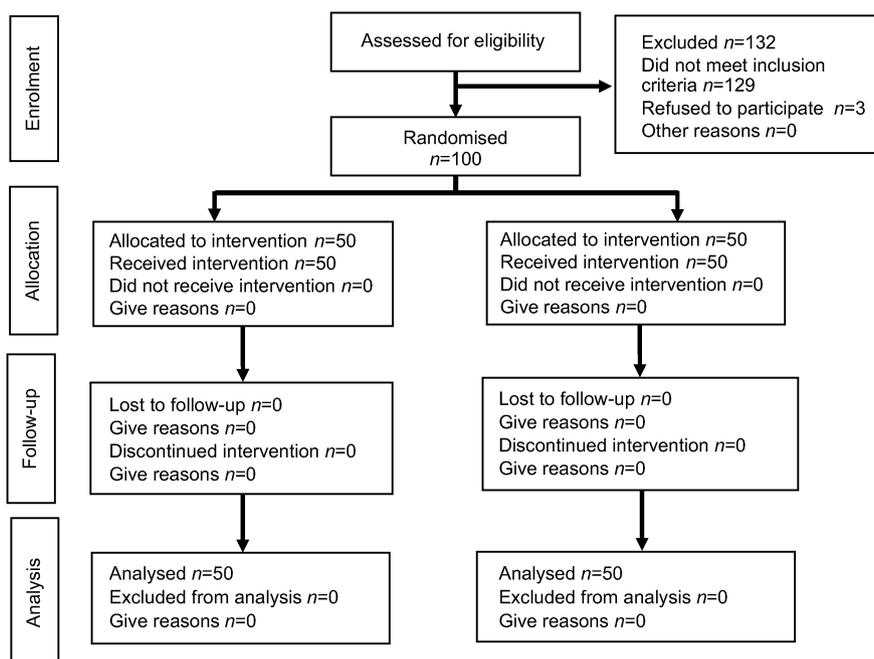
After an Institutional Ethical Committee approval for the study, all patients scheduled for thoracotomy and pulmonary lobectomy for stage I or II non-small-cell lung cancer were evaluated between July 2003 and 2006. The patients who denied their consent to epidural analgesia were enrolled for the study. After informed written consents were obtained, the eligible patients were allocated randomly into two groups according to the thoracotomy type: MST or PLT. Both the investigators and patients were blinded to the study treatment until the end of the follow-up. Table 1 shows the checklist.

The access for MST was through the auscultatory triangle starting with a 12–15 cm long skin incision in line with the fourth or fifth intercostal space. The *latissimus dorsi* and the trapezium were exposed and the triangle fascia was incised along the posterior border of the latissimus; the serratus fascia was incised in the same way. A small Finocchietto retractor was used to spread the ribs, while a second retractor was placed at a right angle to retract the latissimus anteriorly and the paraspinal muscles posteriorly. The thoracotomy was closed with three paracostal absorbable sutures and running sutures for the fascias; neither subcutaneous nor interfascial drains were placed. The PLT

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Table 1. Study checklist and patients demographics



Variables	MST group	PLT group	P-value
No.	50	50	n.a.
Age (years)	62.6 ± 12.4	61.8 ± 9.9	0.7
Male/female	27/23	29/21	0.6
Body mass index	24.9 ± 0.44	25.0 ± 0.44	0.8
FVC % predicted	96.2 ± 12.7	91.3 ± 15.0	0.07
FEV ₁ % predicted	96.2 ± 10.2	91.1 ± 18.9	0.09
Stage Ia	22	21	0.22
Stage Ib	14	8	
Stage IIa	4	2	
Stage IIb	4	10	
Stage IIIa	6	9	

MST, muscle-sparing thoracotomy; PLT, posterolateral thoracotomy; FVC, forced vital capacity; n.a., not applicable.

was performed in the standard manner with division of the *latissimus dorsi*.

Rib fractures were assessed by careful observation and palpation at the end of the operation; in addition specific requests were addressed to an independent radiologist. The same surgeon performed all the procedures. The patient discharge was decided by the surgeon who was blinded to randomisation; drainage removal, general medical condition and pain control were the parameters considered for discharge.

Patients were given access to a patient-controlled analgesia pump system containing morphine. After 72 h, the administration of morphine was discontinued and analgesia provided with ketorolac 30 mg i.v. every 8 h and acetaminophen/codeine 500/30 mg orally if required. After 48 h the administration of ketorolac was interrupted. Analgesic consumption during the hospital stay and the following two weeks was recorded.

The primary endpoints measured were pain, analgesic consumption and post-thoracotomy pain syndrome. The patients assessed pain severity four times a day in a relaxed position, and during coughing using a visual analogue pain scale. The eight scores were averaged to produce a daily composite score. Pain scores were measured preoperatively

and daily after surgery to postoperative day 7. After one, three, six, 12 months and three years following the operation the patients were asked about the occurrence of symptoms of post-thoracotomy pain syndrome (post-thoracotomy pain syndrome was defined as a sensation of burning, aching, numbness, hyperaesthesia, or pain localized in the scar or extending beyond the immediate area of the incision). Current analgesic consumption for pain at the site of the thoracotomy was recorded. An aggregate analgesic score (AAS) was computed adding one point for each mg of intravenous morphine used, five points for every dose of intravenous ketorolac (30 mg) and four points for each oral dose of acetaminophen-codeine (500/30 mg) administered¹. All of these surveys were administered and managed by the same blinded observer.

¹ The AAS intends to reduce the analgesic consumption to an equivalent dose of morphine: studying the morphine sparing effect of intravenous acetaminophen, demonstrated that 4 g of acetaminophen is equivalent to 9 mg of intravenous morphine; considering that the mean oral bioavailability of acetaminophen is 82.2%, we therefore assume that 520 mg of acetaminophen given orally is equivalent to 1 mg of intravenous morphine. It is known that codeine-morphine correspondence dose is 10:1, while the correspondence ketorolac-morphine was assumed on the basis of opioid-sparing studies as 6:1.

Table 2. Operative and postoperative parameters

Variables	MST group	PLT group	P-value
Operative time (min)	176±27	180±38	0.6
Intercostal incision length (cm)	15.1±2.7	16.1±2.6	0.08
Ribs spreading (cm)	7.3±1.4	7.4±1.2	0.7
Rib fracture	7	5	0.7
Tumor diameter (cm)	3.1±1.7	2.9±1.2	0.5
No. of lymphatic stations dissected	5.6±1	5.9±1.2	0.2
Postoperative stay	6.6±2.1	8.2±3.1	0.003
Postoperative complications (total)	7	11	0.4
Prolonged air-leak (>7 days)	5	8	0.4
Atelectasis	0	1	
Bleeding	1	0	
Dysrhythmia	1	2	
Wound seroma	0	0	
Death	0	0	
Aggregate analgesic score	159±18	173±15	0.0001

MST, muscle-sparing thoracotomy; PLT, posterolateral thoracotomy.

Secondary endpoints included shoulder mobility, pulmonary function, and major morbidity. A physiotherapist measured shoulder strength before surgery; the analyses were repeated at one, three, and seven postoperative days and after one and six months by the same blinded observer. Muscle strength was recorded during adduction, abduction, flexion and extension on the operated side; the results were graded on a scale from 0 to 5 (5=normal strength) according to the Daniels and Worthingham's muscle tests. Pulmonary function tests were obtained preoperatively and daily after surgery to postoperative day 7. The spirometry was repeated at one, three, six, 12 months and three years after the operation.

The data were analysed by means of statistical software (SAS Institute Inc, Cary, NC, USA): one-way analysis of variance was used for demographic data, multivariate analysis with Hoeffding's D-test for non-parametric variables and contingency for categorical data. Matched pairs analysis of grouped data investigated paired data (e.g. shoulder strength). A significance level of 0.05 was used.

3. Results

Of 378 patients scheduled for pulmonary lobectomy in the mentioned period of time, 107 consecutive patients were eligible for the study. Fifty patients were randomly assigned to the MST group and 50 to the PLT group, as planned; the follow-up was completed in January 2009. Of the seven patients excluded, three had surgery extension to pneumonectomy, two had unplanned chest-wall resections, one denied consent and one needed conversion from MST to PLT for massive pleural adhesions.

The two groups were similar in age, gender, body mass index, preoperative functional data, and stage (Table 1). The operative time, the incision length, the rib spreading, the rib fractures, the tumour diameter and the number of lymphatic stations dissected were comparable in both groups (Table 2). Postoperative stays were longer in the PLT group. The frequency and the nature of postoperative complications were similar between the incisions (Table 2). The results of pulmonary functional tests are shown in Figs. 1 and 2; all the differences between the two groups failed to approach any statistical significance.

The mean daily values of the visual analogue scale are reported in Fig. 3, the differences did not reach the

statistical significance between the groups. Considering the visual analogue scale in the total population, the mean values were less in the male patients from the first to the 30th postoperative day ($P=0.03$; Fig. 4). The incision length and the rib spreading width had an inverse correlation with the postoperative pain on the first postoperative day ($P=0.0072$ and $P=0.0355$, respectively). Also the operative time had an inverse correlation with the pain from the first to the 30th postoperative day. The incision length, and the rib spreading width had significant direct correlations ($P=0.0012$). The rib fractures did not affect the perception of early postoperative pain.

Analgesic consumption (AAS) during the hospital stay and the following two weeks was higher in patients with PLT

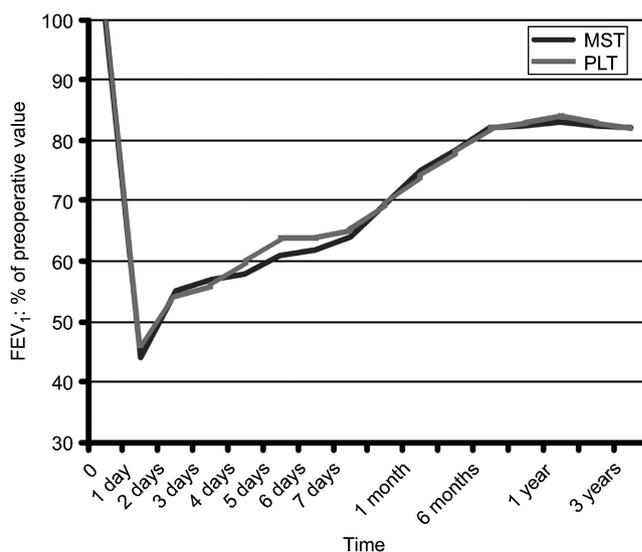


Fig. 1. Postoperative forced expiratory volume in one second (FEV₁). The data express the percentage of preoperative value; the differences between the two groups are not statistically significant. MST, muscle-sparing thoracotomy group; PLT, posterolateral thoracotomy group.

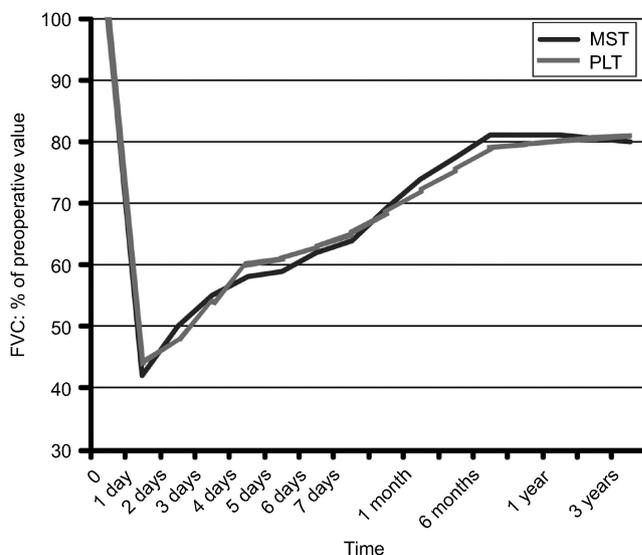


Fig. 2. Postoperative FVC. The data express the percentage of preoperative value; the differences between the two groups are not statistically significant. MST, muscle-sparing thoracotomy group; PLT, posterolateral thoracotomy group; FVC, forced vital capacity.

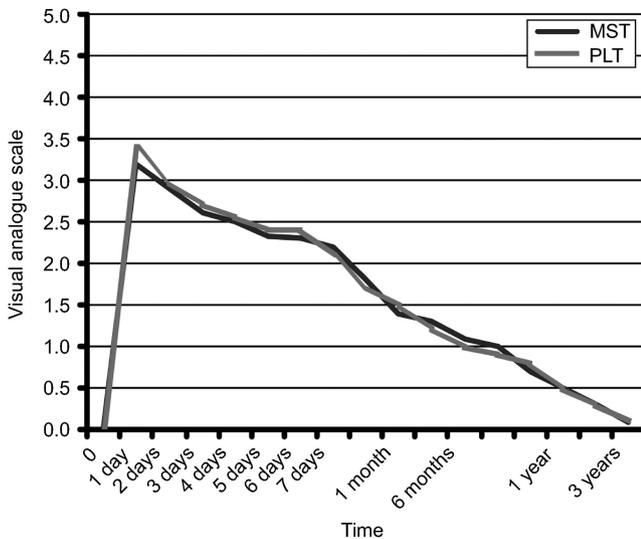


Fig. 3. Postoperative pain. Visual analogue scale values are expressed as daily mean; the differences between the two groups are not statistically significant. MST, muscle-sparing thoracotomy group; PLT, posterolateral thoracotomy group.

(Table 2); in the whole population, the incision length had an inverse correlation with AAS ($P=0.0058$). All the other parameters assessed, including rib fracture, did not affect the analgesic consumption.

At the three-year control, 87 patients were alive and answered the questionnaire: 20.6% of the patients had sporadic wound discomfort or pain; the incision type had no impact on post-thoracotomy syndrome ($P=0.71$). Analysing the whole population cohort, an inverse correlation between incision length and post-thoracotomy syndrome has been observed ($P=0.0019$). None of the other operative variables correlated with the post-thoracotomy syndrome

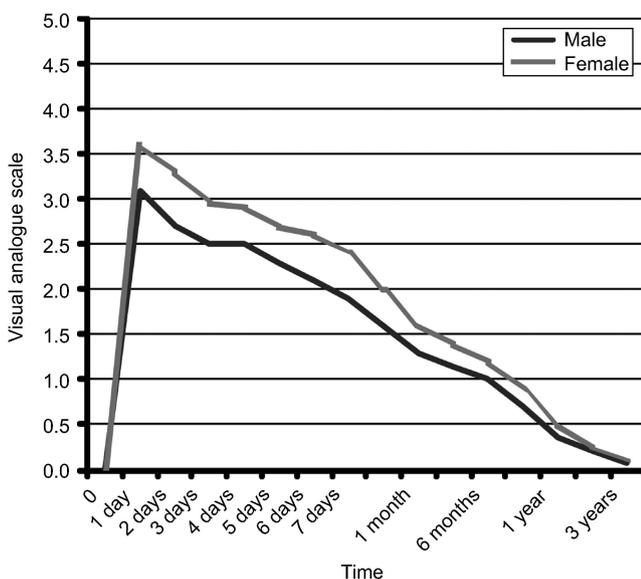


Fig. 4. Postoperative pain stratified by gender. Visual analogue scale values are expressed as daily mean; the differences between the two groups are statistically significant from the first to the 30th day ($P=0.03$).

except rib fracture that showed a tendency. Women suffered more than men ($P=0.019$), but stratifying the data, the incision length remained the strongest regressor of post-thoracotomy syndrome.

Shoulder strength was affected by operation during hospital stay ($P<0.0001$), while a complete recovery was achieved at one month controls in both groups. Matched-pairs analysis demonstrated a significant worst result of the adduction strength in the PLT group during the hospital stay ($P=0.0004$).

4. Discussion

Despite claims of better clinical outcome for MST, there has been a lack of evidence in the literature mainly due to study design [6–15]. It could be assumed from published data that pulmonary function is not affected by thoracotomy type [7, 9–11, 13]. On the contrary, MST results in better postoperative shoulder motion range [10, 11, 13] and strength [7, 11, 12, 15]. The influence of the thoracotomy type on postoperative pain and analgesic consumption is far from clear. Furthermore, a little evidence of higher postoperative complication in the MST could be noted [6, 7].

Designing our prospective, controlled, randomised and double-blind study we worked to avoid the biases of the previous published data. The study population was homogeneous: we chose only pulmonary lobectomies performed by the same surgeon. Of the wide range of the described MSTs, only the incision through the auscultatory triangle is actually free from a muscle cut, as reported by Horowitz et al. [4].

Even though the diameter of the pulmonary lesions and the number of lymph node stations dissected were similar between the study group and the control group, suggesting equal surgical exposure, the exclusion of a patient from the study group due to a conversion into PLT caused by the massive pleural adhesion, pointed out some degree of inferiority of the MST in the thoracic organs exposed.

We found a lack of difference in postoperative complications between the two groups. This result is common to the majority of the published trials [8, 10–15]. Seroma occurred in none of the MST patients even though no drainage was placed in the subcutaneous space; such a good outcome was most likely the consequence of the limited subcutaneous dissection needed for the auscultatory triangle thoracotomy. In spite of the similar complication rate between the two patients cohorts, the postoperative hospital stay was longer in the PLT group underlining the major invasiveness of the PLT.

Early and late postoperative pulmonary function tests did not disclose any significant disparity between the two groups. This result is shared by the majority of the published data, and could be explained by the negligible contribution of the *latissimus dorsi* and serratus anterior to the respiratory mechanics.

We failed to find any difference in the perception of postoperative pain. On the contrary, the analgesic consumption during the hospital stay and the following two weeks was higher in patients with PLT, revealing its greater

aggressiveness; nevertheless, this fact was free from increased postoperative complications or pulmonary functional impairments.

We found at least two 'regressors' on postoperative pain data affecting transversally the two patients cohorts: female gender and incision length. The shorter incision, the higher the pain on the first postoperative day and the analgesic consumption during the hospital stay. This finding, while apparently conflicting, could be explained by the fact that in short incisions a greater strength was applied to the rib retractors to obtain a satisfactory exposure.

The PLT group shoulder function has been shown to decrease more in the adduction test during the hospital stay. This result was expected, however, the transitory decreased strength seemed an insignificant factor on the patients' outcome.

In our patients' cohorts, we found a three-year post-thoracotomy syndrome rate of approximately 20%. The women were significantly more prevalent and the shortness of the incision was strongly related with the post-thoracotomy syndrome. On the contrary, the incision type did not affect the chronic pain.

In conclusion, the two incisions are very similar on the patients' outcome, but a few points should be underlined. The PLT is the most invasive incision causing more analgesic consumption, longer hospital stay and impairment in immediate shoulder strength. In addition to the standard use, the MST should be considered for its peculiar advantage to conserve the integrity of the great thoracic muscles, such a benefit could be important in paediatric surgery, in patients practicing muscular activity (athletes, etc.), and in patients requiring major lung resection when a high rate of bronco-pleural fistula is expected.

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