P-088

MULTICENTER RANDOMIZED CONTROLLED TRIAL COMPARING DIGITAL AND TRADITIONAL CHEST DRAIN IN A VIDEO-ASSISTED THORACOSCOPIC SURGERY (VATS) PULMONARY LOBECTOMY COHORT: INTERIM ANALYSIS

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Objectives:
The usefulness of digital chest drain is still discussed. We are carrying out a study to determine if the use of a digital system compared with a traditional system reduces the duration of chest drainage. To enable early recognition of inferiority if present, an a priori interim analysis was planned.

Methods:
This multicenter randomized controlled trial included adult patients who underwent VATS lobectomy (NCT03536130). The 1:1 randomization allocated patients to 2 arms: digital device (Drentech Palm Evo) or traditional drainage. Primary endpoint was chest tube duration; secondary endpoints were prolonged air leak, postoperative complications and predictors of chest tube duration. Data were described using mean and standard deviation or absolute frequencies and percentage. T-test for unpaired samples, Chi-square test and Poisson regression were used. P-value <0.05 was considered significant.

Results:
From April 2017 to November 2018, out of 317 patients were enrolled by 3 centers, 231 fulfilled inclusion criteria and were randomized. 22 of them dropped out after randomization. Finally, 209 patients were analyzed: among them 94 used the digital device and 115 the traditional one. The table reported the main clinical variables of the two groups. Mean chest tube duration was 3.4 and 3.8 days in digital and control group respectively (p=0.49). Prevalence of prolonged air leak was 1.1 and 2.7% in digital and control group respectively (p=0.41), whereas postoperative complications rate was 18.7% and 16.4% (p=0.86). Air leak at first postoperative day detected by digital and traditional device predicted increasing in tube duration of 1.6 day (CI 95% 0.8-2.5, p<0.001) and 2.0 days (CI 95% 1.0-3.1, p<0.001) respectively.

Table 1. Demoghraphic and clinical data.		
	Digital (n = 94)	**Traditional (n = 115)**
Age, years, mean (SD)	67 (9)	66(11)
Male, n (%)	57 (60.6)	61 (53.0)
Comorbidity, n (%)	68 (72.3)	89 (74.4)
COPD, n (%)	15 (16)	12 (10.4)
Asthma, n (%)	3 (3.2)	3 (2.6)
FEV1, %, mean (SD)	96.6 (20.2)	98.9 (20.4)
FVC, %, mean (SD)	101.6 (19.9)	103.9 (18.9)
Tiffeneau, %, mean (SD)	77.7 (9.7)	76.8 (12.0)
DLCO, %, mean (SD)	83.1 (18.4)	81.6 (19.0)
Induction CT, n (%)	49 (52.1)	52 (55.2)
Induction RT, n (%)	0 (0.0)	0 (0.0)
Surgical time, min, mean (SD)	164 (67)	169 (65)
Hemostatic devices, n (%)	49 (52.1)	52 (55.2)
Air leaks (POD1), n (%)	32 (34.0)	24 (20.9)
Post-operative complications, n (%)	17 (18.7)	18 (16.4)
PAL, n (%)	1 (1.1)	3 (2.7)
Chest tube duration, days, mean (SD)	3.4 (1.8)	3.8 (1.8)
Perioperative death, n (%)	0 (0.0)	0 (0.0)
Drop out, n (%)	13 (12.1)	9 (7.2)

Conclusions:

This interim analysis showed a trend towards short chest tube duration in the digital chest system group. Lack of strong evidence endorsed the completion of the randomized study to reach the planned sample size and to explore comprehensive clinical items currently recorded.

Disclosure: No significant relationships.
Keywords: chest drain, video-assisted thoracic surgery (VATS), pulmonary lobectomy