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“ Effectiveness, safety, patient and investigator satisfaction of the new mobile Thorax Drainage System (TDS-5L) ”

Medela Healthcare

Effectiveness, safety, patient and investigator satisfaction of the new mobile thorax drainage system (TDS-5L) in patients undergoing lobectomy, bilobectomy, wedge or segment resection

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Introduction

Air leak remains the most common pulmonary complication after elective pulmonary resection. Until today air leak is quantified by using the standard analogue classification system based on observing air bubbles. A new digital system is investigated for its efficacy in managing air leak after lung surgery. The new mobile drainage system (TDS-5L) uses a guaranteed continuous pressure difference maintained by a maximum flow of 5 liter per minute.

Aim

To compare in a randomized study the safety and effectiveness of the new device (TDS-5L) in treating patients requiring lung surgery (Lobectomy, bilobectomy or wedge resection). Patient's lung function and pain, patient's degree of mobility as well as patients and nurses satisfaction were recorded and analyzed.

Methods and Results

Two hundred patients were randomly allocated to either the (TDS-5L) device or to the standard control group (chest drain using wall suction). Patient undergoing lung surgery received the treatment according to group allocation. Data was collected every day until criteria for chest tube removal was fulfilled (200ml secretion and no air leak by bubble test assessment) and duration of treatment was calculated in days of treatment. Patient's mobility was compared using a pedometer (stepcounting). Lung function was monitored by measuring Vital Capacity (VC) and Forced Expiratory Volume (FEV1). Pain was assessed using a 0 to 100% scale. Patient and nurses' satisfaction were analysed with a questionnaire. Descriptive statistics were performed on all data for this interim analysis.

Figure 1: Number of days of treatment

Two criteria were defined and had to be fulfilled according to the study protocol in order for the drainage to be removed 1) volume of secretion less than 200ml/day and 2) no air leakage (no bubbles occurring at the third cough of the patient). The TDS-5L functioning with a max air flow of 5 liter per minute only is proven to be very efficient.

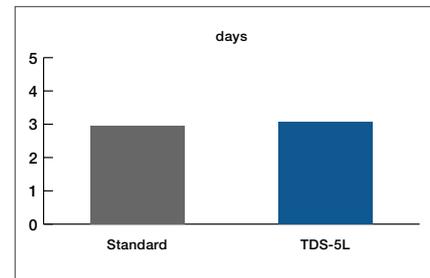
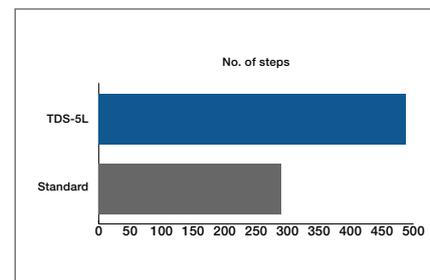


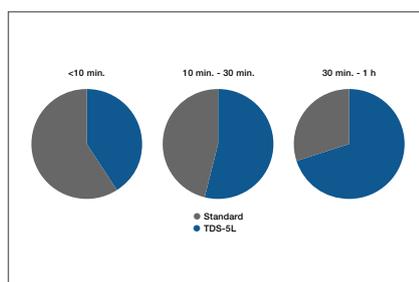
Figure 2 a, b, c: Patient's mobility

Mobility was measured using a pedometer system (Stepwatch) that recognizes patient's motion and saves the corresponding data electronically. The device was worn around the patient's ankle and the data was downloaded to a computer for analysis. The overall mobility (Number of steps), Fig 2a and the distance (bathroom, cafeteria, TV room etc...) were recorded Fig 2b. Patients with the TDS-5L system were significantly more mobile and walked further away for longer time periods than patient in the control group.

a) Average total number of steps



b) Period, in which patient was out of room.



c) Independent daily activities chosen by the patients (without assistance).

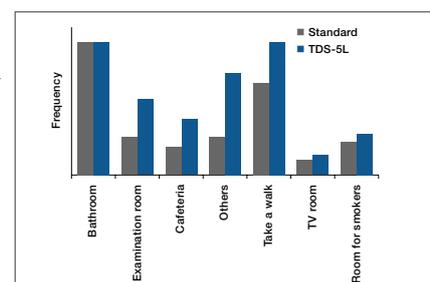


Figure 3: Pain assessment

Pain was assessed using a 0 to 100% scale in both groups. Pain during getting up and walking was at the same starting level in both groups and decreased progressively during the treatment period. At the end of the treatment time, there was less residual pain for patients treated with the new mobile system. Results from lung function indicate that patients from the TDS-5L group recovered faster (final data analysis ongoing, not yet available).

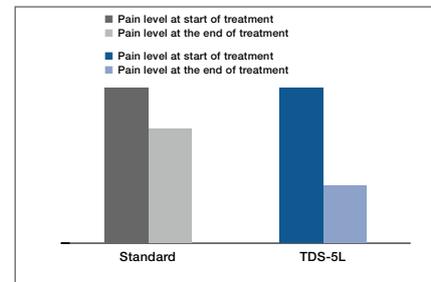


Figure 4: Patient' satisfaction

Patients were asked to fill out a questionnaire (5 questions) regarding activeness and ease of mobility. Responses were assessed using a visual analogue scale rating 1 to 4 (1=very satisfied, 4=very unsatisfied)

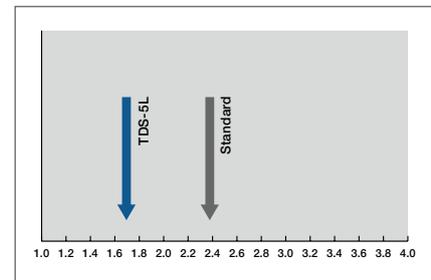


Figure 5: Nurses' satisfaction

Investigators and study nurses were asked to fill out a questionnaire (6 questions) regarding the ease of use and handling of the novel system compared to the standard they already knew. Responses were assessed using a visual analogue scale rating 1 to 4 (1=very satisfied, 4=very unsatisfied)

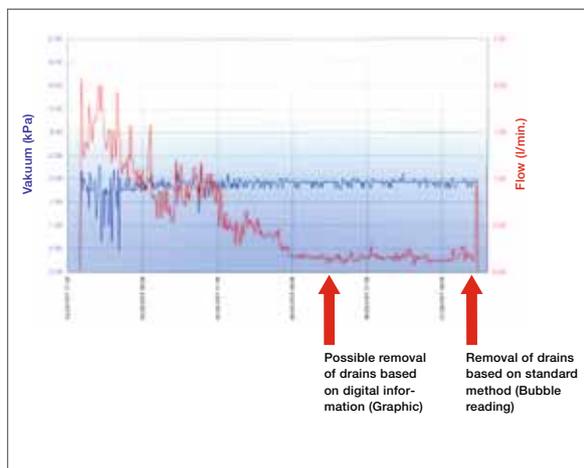
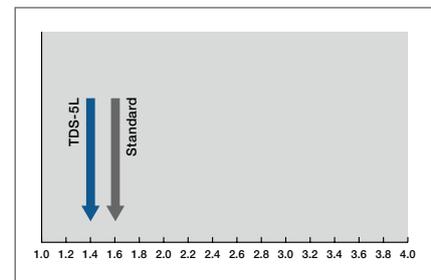


Figure 6: Digital curve

During this study, digital graphs have been additionally recorded by the TDS-5L system to analyze the more objective and more reproducible reading of the digital information replacing the current subjective bubble assessment. Continuous assessment of air leak is promising and further studies are needed to better understand the meaning of these graphs and use them for optimal chest tube management and conclusive statement about Length of stay (LOS).

Conclusions

The new mobile digital device (TDS-5L) which provides a lower flow than standard devices for treatment after lung surgery is clearly effective and noticeably enhances patient's mobility. Patients in the TDS-5L group suffered less pain, satisfaction was higher for both patients and staff. The risk of inaccuracy associated with the still standard air leak classification analogue system (observer variability and subjectivity) is noticeably reduced and is undoubtedly a step toward future assessment of air leak management and optimal chest tube management. In the practice, clinical results with the even smaller mobile digital drainage system Thopaz will be expected to be undoubtedly strengthened.



Overall success

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