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Safety and Tolerability of Vacuum vs Manual Drainage During Thoracentesis: A Randomized Trial

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Abstract

Background: Pleural effusions may be aspirated manually or via vacuum during thoracentesis. This study compares the safety, pain level, and time involved for these techniques.

Methods: We randomized 100 patients receiving ultrasound-guided unilateral thoracentesis in an academic medical center from December 2015 through September 2017 to either vacuum or manual drainage. Without using pleural manometry, the effusion was drained completely or until development of refractory symptoms. Measurements included self-reported pain before and during the procedure (from 0 – 10), time for completion of drainage, and volume removed. Primary outcomes were rates of all-cause complications and of early termination of procedure with secondary outcomes of change in pain score, drainage time, volume removed, and inverse rate of removal.

Results: Patient characteristics in the manual (n=49) and vacuum (n=51) groups were similar. Rate of all-cause complications was higher in the vacuum group (5 vs 0, p = 0.03): pneumothorax (n=3), surgically treated hemothorax with subsequent death (n=1) and re-expansion pulmonary edema causing respiratory failure (n=1), as was rate of early termination (8 vs 1, p = 0.018). The

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Katy LB Araujo contributed with data analysis, figures and writing of the manuscript.

Kelsey Cameron contributed with study design, data collection, and writing of the manuscript.

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vacuum group exhibited greater pain during drainage ($p < 0.05$), shorter drainage time ($p < 0.01$), no association with volume removed ($p > 0.05$), and lower inverse rate of removal ($p=<0.01$).

Conclusion: Despite requiring less time, vacuum aspiration during thoracentesis was associated with higher rates of complication and of early termination of procedure and greater pain. While larger studies are needed, this pilot study suggests that manual aspiration provides greater safety and patient comfort.

Introduction

Pleural effusions are diagnosed annually in more than 1.5 million people in the USA [1] resulting in 173,000 thoracenteses per year [2]. Most patients undergo thoracentesis to determine the etiology of the effusion and to relieve symptoms. Ultrasound guidance during thoracentesis is associated with lower complication rates [3, 4]. Specific complications and their risk factors have been extensively documented [2–7]. Pneumothorax is the most common complication requiring intervention, with hemothorax occurring rarely [2], and is most often due to introduction of atmospheric air, laceration of the lung or decrease in pleural pressure leading to rupture of visceral pleura [3, 8, 9]. The development of chest discomfort during thoracentesis is associated with a potentially unsafe drop in pleural pressure [10].

During thoracentesis, fluid can be aspirated from the thoracic cavity either manually via syringe or with continuous suction using a vacuum bottle or wall system. Beech et al. advocated the use of a 600 mL vacuum flask for drainage during thoracentesis [11] and a 1000 mL plasma collecting vacuum bottle was subsequently used [12]. Manual drainage via syringe with a one-way valve system became popular with the use of disposable thoracentesis kits made by a variety of manufacturers. Currently, both methods of drainage are used interchangeably without a clear standard of care in most institutions. The Canadian Agency for Drugs and Technologies has reported that between 1998 and 2009 there were no health technology assessments, systematic reviews, meta-analyses, clinical trials or observational studies evaluating the clinical benefits and harms of vacuum drainage during thoracentesis [13]. To our knowledge there has been no randomized trial to date comparing these aspiration types during thoracentesis.

In this single-center randomized study, we compared rate of complications, volume removed, time required for drainage completion, and self-reported pain during thoracentesis.

Methods

A prospective randomized study was conducted between December 2015 and September 2017 wherein all inpatients referred to the Interventional Pulmonary program for thoracentesis were eligible to participate. Yale-New Haven hospital is a tertiary care, urban, 1000-bed academic hospital. Approval for the study was obtained from the Yale University School of Medicine Institutional Review Board HIC# 1511016858 and all participants provided informed consent for both the procedure and for participation in this study. Given the lack of literature to guide any comparison of effect sizes between manual and vacuum aspiration, the number of participants (100) was chosen as a convenience sample.

Inclusion criteria for the study included age > 18 years, radiographic evidence of pleural effusion, and a clinically-justified need for thoracentesis. Patients were excluded if they refused enrollment or were unable to verbalize their pain during the procedure (non-English speaking, altered mental status), were known to have a trapped lung, underwent bilateral thoracentesis or had a history of pleurodesis or pleural procedure other than thoracentesis. All subjects were inpatient, on medical or surgical floors, or an intensive care unit. Demographics and medical history were obtained on the day of the index thoracentesis from the patient or surrogate along with information abstracted from the medical records.

Indications for thoracentesis included the need to define the effusion etiology or for symptomatic relief of dyspnea. After consent for procedures and enrollment, patients were randomized to one of two types of aspiration. In the manual group, the pleural effusion was aspirated from the chest cavity by the operator using a 60 mL syringe, a one-way valve system catheter and drainage into a bag (Safe-T-Centesis™ Carefusion kit). In the vacuum group, the catheter was connected to an evacuated container (Baxter). Otherwise, the procedural technique was similar between groups, including the amount of lidocaine used.

All thoracenteses were performed by advanced practice providers, pulmonary fellows or interventional pulmonary attending physicians. Ultrasound (SonoSite S-ICU, Bothell, WA) was used to locate and mark the pleural effusions at the time of thoracentesis. The intent of every thoracentesis was complete evacuation of the pleural space. The procedure was terminated early only if requested by the patient for reasons including chest pain and refractory cough. For both pain and cough, patients were encouraged to continue the procedure until it was determined to be intolerable, in which case the procedure was terminated as part of conscientious practice. Pleural manometry was not used and post-procedural radiographs were routinely obtained. Specimens were routinely sent for analysis to discern transudates from exudates and to better define the suspected etiology.

Data recorded during drainage included volume removed, time required for completion, and self-reported pain before and during the procedure. Volume removed was defined as total drainage minus that needed for samples. After procurement of the desired samples and a reconnection of all appropriate tubing, time was measured in seconds with a digital stopwatch and stopped once the operator determined that drainage was complete. Each patient was asked to record pain both before and during the procedure using the Numeric Pain Rating Scale (NPRS) from 0 – 10 and to exclude pain experienced during introduction of the needle or of the catheter in their chest cavity. Change in the pain score was calculated by subtracting pain reported before the procedure from that reported during the procedure. Complications were defined as post procedure pneumothorax, hemothorax, radiographic re-expansion pulmonary edema, and post-procedure respiratory failure. The primary outcomes were rates of all-cause complications and of early termination of procedure with secondary outcomes of change in pain score, drainage time, volume removed, and inverse rate of removal, where designations of primary and secondary were chosen apriori.

After each procedure, the etiology and pathophysiology of the pleural effusion were determined by two physicians using predefined criteria [14]. Effusions were considered secondary to malignancy only if cytology demonstrated malignant cells or if flow cytometry

was positive. If no etiology was identified and there was strong clinical suspicion of malignancy, the effusion was classified as para-malignant. In these cases, additional procedures were not performed unless the presence of pleural malignancy impacted patient care. Acknowledging that one thoracentesis often does not unequivocally identify a malignant effusion, cases were classified as paramalignant when it was judged that the effusion was directly related to the underlying malignancy.

Statistical Analysis

Demographic and patient characteristics were compared between participants randomized to the two aspiration methods. Continuous variables were compared using t-tests and categorical variables with chi-square or Fisher's exact statistics. Rates of all-cause complications and early termination of the procedure for each aspiration type were estimated using intercept only negative binomial regression and compared using Fisher's exact test. The four secondary outcomes were continuous and graphically verified as exhibiting symmetric, unimodal distributions: change in pain score, total drainage time in seconds, total volume removed in mL, and rate of removal (seconds per 100 mL). After adjustment for exudative effusion, loculation, malignancy, and recent cardiac procedure, multivariable linear regression evaluated associations between aspiration method and the four secondary outcomes. As a check of robustness, all associations significant in linear regression were checked using the non-parametric Wilcoxon test. All analyses were performed using SAS V9.4 with statistical significance defined as a p-value < 0.05.

Results:

Figure 1 depicts the randomization of the 100 patients into the manual (n=49) and vacuum (n=51) aspiration groups and their respective average values of change in pain score and drainage time. There were no significant differences in patient characteristics, medical history, and etiology of the effusions between the study arms, with most effusions deemed exudative (Table 1).

Complications were higher in the vacuum group, including the incidence of pneumothorax. Figure 2 illustrates the comparison of the primary outcomes; rate of all-cause complications was higher in the vacuum group (5 vs 0, p=0.03). Of the five vacuum patients with complications, only one had drainage greater than 1500mL (2000mL). These effusions were not loculated, suggesting that presence of loculations was not associated with pneumothorax and rupture of the visceral pleura. The three patients with pneumothorax did not require tube thoracostomy. In contrast, no complications were noted in the manual aspiration group.

Figure 2 also shows vacuum has a higher rate of early termination of procedure (8 vs 1, p=0.02). Of the vacuum patients with early termination, six were exudates, none were loculated and five had volumes removed greater than 1500 ml. In one patient the procedure was terminated early due to malfunction of the vacuum system. The one patient in the manual group who terminated early had a volume removed greater than 1500 mL. Several other patients experienced events that were not considered complications as they were deemed to have non-expandable lung. One patient experienced hemothorax that required

surgical exploration. That patient later had care withdrawn due to multiple comorbidities and ongoing critical illness. One patient required non-invasive positive pressure ventilation due to acute respiratory failure related to re-expansion pulmonary edema. Two additional vacuum patients had pneumothorax ex-vacuo related to malignancy.

In Table 2, multivariable regression showed that after adjustment for pathophysiology and etiology of the effusions, change in pain score was significantly higher in the vacuum arm, where on average, change in pain score was close to one point higher. Although the vacuum group drained faster, there was no significant difference in volume removed. Patients with recent cardiothoracic surgical procedures had less volume removed relative to other etiologies.

Discussion:

This single-center randomized study of 100 patients undergoing thoracentesis, 51 of whom had effusion drained by vacuum bottles, suggests that manual drainage provides greater safety, less frequent early termination and greater patient comfort. To our knowledge, this has not been rigorously evaluated in previous studies. In one paper evaluating the utility of post-thoracentesis radiographs [15], a minority (10%) of patients underwent drainage of pleural effusion using vacuum bottles. The authors noted that each unexpected pneumothorax was associated with the use of vacuum, and, given the need for chest tubes in that sample, suggested that the vacuum bottle may have increased severity of complications. They “strongly discouraged” the use of vacuum devices to aspirate pleural fluid.

We believe that greater safety and tolerability of the manual drainage is plausibly related, in part, to the lower negative pressure generated by manual use of a syringe and its allowance of more time to equilibrate the intrathoracic pressures during aspiration. Furthermore, the tactile sensation of catheter drainage may enable the operator to manually retract the catheter away from the diaphragm, thus lessening pain. Slowing drainage of the vacuum device may potentially reduce the magnitude of negative pressure using the vacuum device. More importantly, however, the operator’s tactile sensations of lung and pleura being drawn toward the drainage catheter are absent during vacuum drainage.

Pressures were not measured during thoracentesis in our study. Pressures generated by evacuated containers during paracentesis have been shown to reach −963 cm H_20 [16]. In a letter to the editor, clinicians performing thoracentesis noted fluctuations in pressure generated with manual suction. Using a digital manometer, pressures at their peak were larger than those measured in negative pressure bottles [17]. We tested this using a digital manometer (Compass, Centurion Medical) and noted operator-dependent differences in pressure during manual suction. With peak pressures ranging between approximately −150 to −300 cm H_20 across the four different operators, these values were consistently of lesser magnitude than the sustained vacuum pressures of approximately −450 cm H_20. We reached the high pressures seen with vacuum bottles only with vigorous suctioning techniques, suggesting operators should use caution during manual evacuation.

As described in the results, one patient had a hemothorax following thoracentesis using the vacuum system. We routinely perform the procedure above the rib but this was presumptively due to laceration of an intercostal artery, although the role of vascular damage due to intrapleural pressure changes can not be ruled out. It is also conceivable that the visceral pleura ruptured due to large changes in pressure, thereby causing bleeding. The significance of this event and its plausible relation to the use of vacuum suction was alarming but, given the patient's underlying medical problems that mandated hospitalization, cannot be strictly attributed to the procedure.

Because vacuum drainage was faster, our data suggests that operators could save an average of 3 minutes when draining 1500 mL of effusion. We believe the occurrence of fewer complications and lower average pain in the manual group strongly outweigh the small reduction in drainage time, which we do not consider to be clinically meaningful. Because it more frequently results in non-terminated drainage, manual aspiration may be preferable in those scenarios when complete drainage of effusions is essential. Due to its lower rate of complications, our group always uses manual aspiration for thoracentesis.

The strengths of the study include its randomization of participants, similarities between the groups and the lower rate of complications and pain in the manual group. The primary limitations of the study are its small sample size, its lack of pleural manometry, and the logistical restrictions that precluded blinding of operators and participants. In order to carefully monitor patients, all study participants were inpatients. We did not rigorously measure the volume of fluid remaining after each thoracentesis, but rather attempted to evaluate the groups so that drainage time and pain could be compared. Furthermore, as a single center study there was a small range of operator variability contributing to the recorded data. As a pilot study, however, its results may justify future multi-center studies that provide more generalizable results to practitioners.

For measurement of pain we used the NRPS because of its ease of use, its flexible verbal and graphical administration, and its brevity. A clinically meaningful change likely differs depending on the condition causing pain and has not been validated for thoracentesis. Although this instrument correlates with other self-reported pain scales [18] and a minimum clinically significant difference in pain of 1.3 has been reported in acute situations [19], our findings may represent only a statistical difference.

Acknowledging that we have not performed a cost analysis related to this study, there is potential for cost benefit with manual aspiration. While the price of the vacuum bottles varies by manufacturer, the kits for manual aspiration contain all necessary components. Vacuum bottles incur an additional expense, as do pneumothoraces [20].

Conclusion

This is the first systematic comparison of the two aspiration methods (vacuum and manual) commonly used for thoracentesis. Although a small study, the clear and consistent results warrant further investigation and suggest that manual aspiration is safer and more tolerable for patients.

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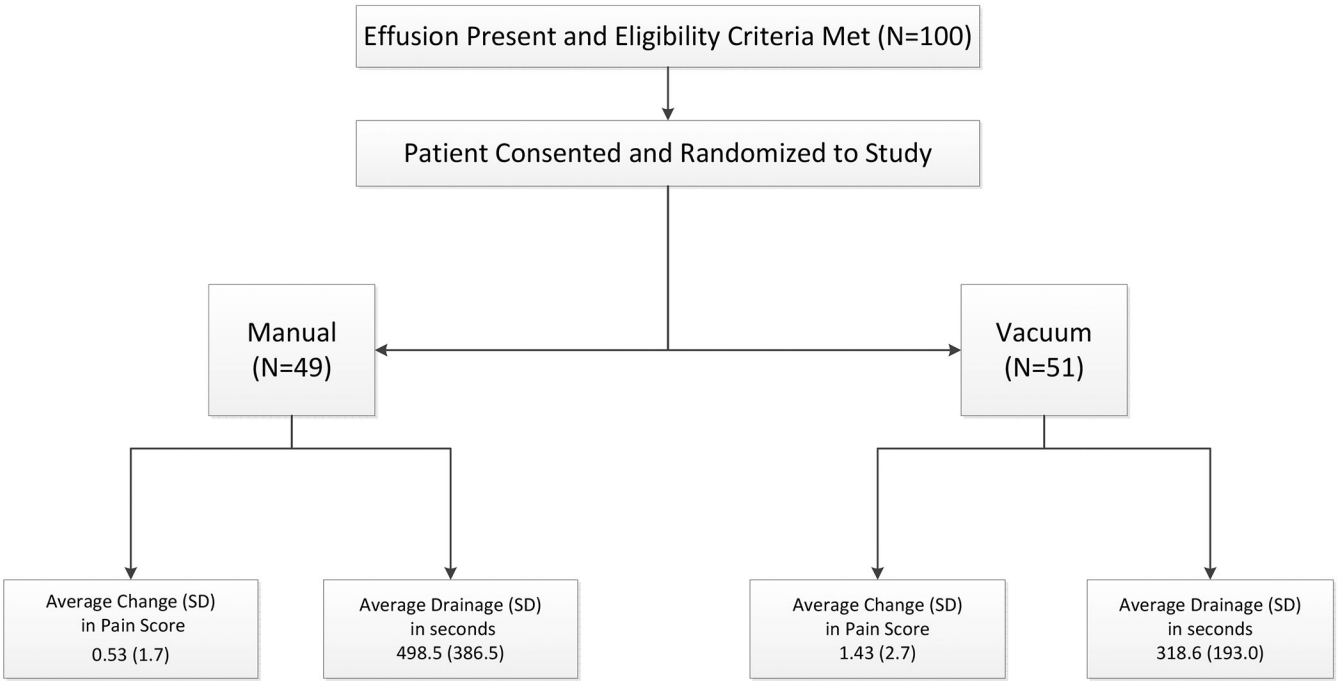

Figure 1: Consort Diagram

Randomization of the 100 patients into the manual (n=49) and vacuum (n=51) aspiration groups and their respective average values with standard deviation (SD) of change in pain score and drainage time in seconds.

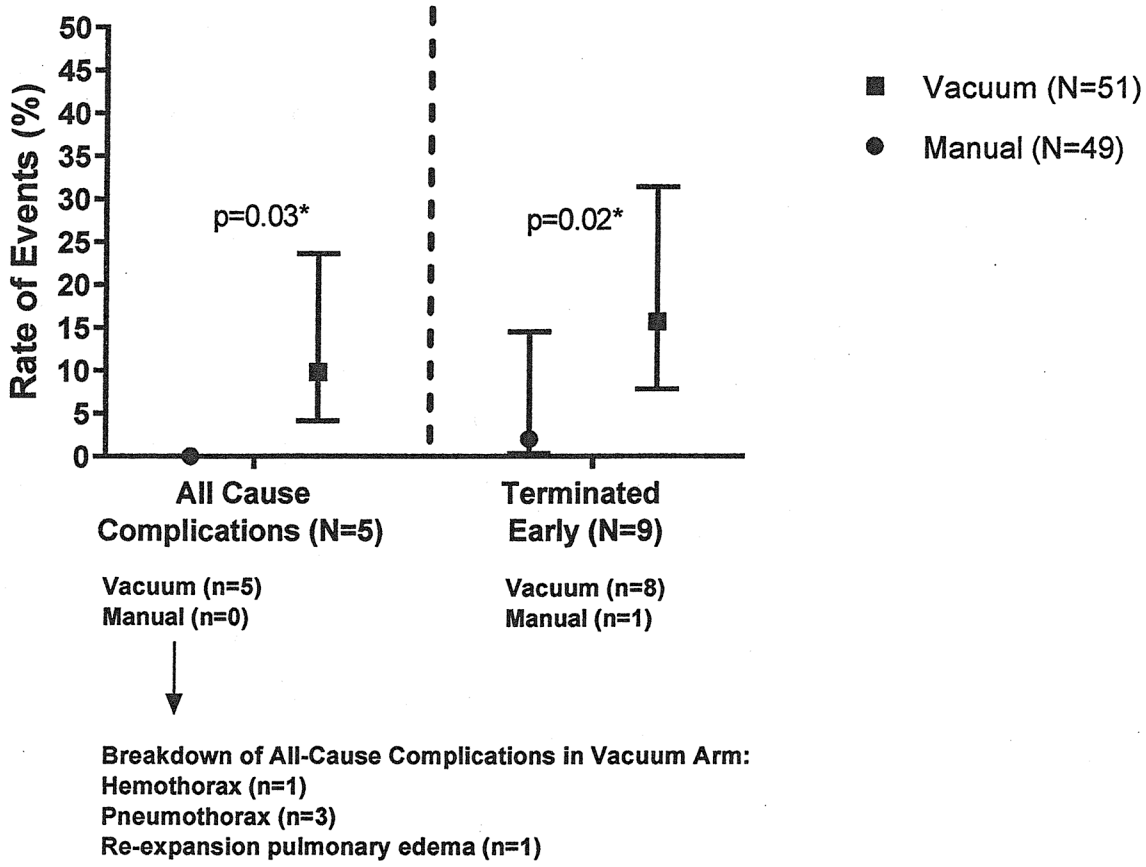

Figure 2: Rates of All-Cause Complications and Early Termination of Procedure by Aspiration Method

The comparison of the primary outcomes in the manual (n=49) and vacuum (n=51) aspiration groups with breakdown of all-cause complication in the vacuum group. The rate of all-cause complications was higher in the vacuum group (5 vs 0, p=0.03*) as was rate of early termination (8 vs 1, p = 0.018*). * Fisher's exact test was used to compare event types by aspiration method.

Table 1:

Patient and Effusion Characteristics by Aspiration Type

	Manual Aspiration (n=49)	**Vacuum Aspiration (n=51)**	**p-value***
	(*n* (%) or mean [SD])	(*n* (%) or mean [SD])	
Male	23 (46.9)	29 (56.9)	0.32
Age in years, mean [SD]	68.5 [16.2]	65.6 [15.5]	0.37
Right sided effusions	32 (65.3)	28 (54.9)	0.29
Medical History			
Active malignancy	21 (42.9)	17 (33.3)	0.33
Heart Failure	24 (49.0)	24 (47.1)	0.85
Recent cardiothoracic procedure	15 (30.6)	17 (33.3)	0.77
Liver failure	4 (8.2)	7 (13.7)	0.37
Arrhythmia	17 (34.7)	24 (47.1)	0.21
Renal Failure	7 (14.3)	7 (13.7)	0.94
Hypoalbuminemia	4 (8.2)	3 (5.9)	0.71
Fluid Resuscitation	4 (8.2)	5 (9.8)	1.0
Active pneumonia	6 (12.2)	8 (15.7)	0.62
Liver failure	4 (8.2)	7 (13.7)	0.37
Pathophysiology			
Exudative Effusion	37 (75.5)	35 (68.6)	0.44
Loculated Effusion	11 (22.5)	5 (9.8)	0.08
Etiology			
Malignant	13 (26.5)	8 (15.7)	0.18
Paramalignant	7 (14.3)	2 (3.9)	0.09
Heart failure	7 (14.3)	8 (15.7)	0.84
Hepatic hydrothorax	3 (6.1)	5 (9.8)	0.71
Post cardiothoracic procedure	13 (26.5)	17 (33.3)	0.46
Parapneumonic	3 (6.1)	2 (3.9)	0.67
Unknown	3 (6.1)	8 (15.7)	0.20

*Continuous variables were compared using t-tests and categorical variables with chi-square or Fisher's exact statistics as appropriate.

Table 2:

Vacuum and Manual Aspiration in Thoracentesis: Multivariable Associations of Explanatory Variables with Secondary Outcomes

Estimated Associations (95% Confidence Intervals)[a] in Multivariable Regression Models of Secondary Outcomes				
Explanatory Variables	**Secondary Outcomes**			
	Change Score in Pain[b] (Range: −4 to + 8)	**Total Drainage Time (seconds)**	**Total Volume Removed (mL)**	**Inverse Rate of Removal (seconds per 100 mL)**
Vacuum (relative to manual)	0.91 * (0.02, 1.79)	−175.85 ** (−291.4, −60.3)	72.73 (−202.0, 347.5)	−13.29 ** (−20.0, −6.6)
Exudate (relative to transudate)	0.31 (−0.76, 1.38)	−5.79 (−145.9, 134.3)	−73.09 (−4.6.2, 260.0)	−3.11 (−11.3, 5.1)
Loculated (relative to non-loculated)	−0.06 (−1.28, 1.17)	4.71 (−156.1, 165.5)	−126.78 (−509.1, 255.5)	1.89 (−7.5, 11.2)
Malignancy (relative to non-malignant)	0.04 (−1.01, 1.09)	−10.96 (−147.8, 125.9)	−204.73 (−530.1, 120.7)	6.30 (−1.7, 14.3)
Recent Cardiac Procedure (relative to other etiologies)	0.51 (−0.62, 1.65)	−178.81 * (−327.6, −30.0)	−564.38 ** (−918.1, −210.6)	3.75 (−5.0, 12.5)

[a] from multivariable linear regression of each outcome on explanatory variables listed

[b] self-reported pain during procedure minus self-reported pain at baseline, with each self-reported measure on 0 – 10 scale where values indicate magnitude of pain

* p-value < 0.05 in multivariable linear regression and in an unadjusted Wilcoxon test

** p-value < 0.01 in multivariable linear regression and in an unadjusted Wilcoxon test

Abbreviations: mL = milliliters;