STUDY

Contrast Booster™

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Influence of device-assisted suction against resistance (Mueller maneuver) on image quality in CTPA for suspected lung embolism

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Study Type:
Prospective single-center study.

Study Objectives:
To investigate the effect of a device-assisted suction against resistance Mueller maneuver (MM) on transient interruption of contrast (TIC) in the aorta and pulmonary trunk (PT) on computed tomography pulmonary angiogram (CTPA).

Clinically Relevant Outcome:
The device-assisted MM in CTPA improves contrast enhancement and prevents the TIC phenomenon if compared to the standard end-inspiratory breathing command (SBC).

Material and Methods:

Patient Collective and Study Design
In a prospective single-center study, 151 adult patients suspected of pulmonary embolism were divided by randomization into either device-assisted MM group or SBC group (one patient withdrew from the study just before the examination).
CTPA was performed using a 128-slice scanner system (SOMATOM Definition AS+, Siemens Healthcare GmbH) in the cranio-caudal direction and iodine-based contrast (60 ml). Bolus tracking was done in the pulmonary trunk, and images were reconstructed with a 1.5 mm slice thickness.

Device and Inspiration maneuver
Group 1: Mueller Maneuver
The Mueller maneuver was performed using the Contrast Booster™ System, a prototype developed by ulrich GmbH & Co. KG. This system facilitates biofeedback for the patient and allows radiological staff to monitor and interact with the patient's performance during the scan. The system includes:

- Patient Interface Unit (PIU): Equipped with a battery, a pressure sensor, and a visual display.
- Charger and Communication Units (CCU): Two units wirelessly connected to the PIU via Bluetooth.

The PIU's LED band displays a green light when the patient is sucking at the correct intensity level. An orange or red light indicates excessive or insufficient suction, respectively. The investigator, in the control room, can instruct the patient via microphone to start sucking to generate continuous negative pressure after the intravenous contrast injection.
The maneuver causes significant diaphragm contraction on the inferior vena cava, interrupting the flow of non-contrasted venous blood from the abdominal cavity to the right atrium. Simultaneously, there's increased flow in the superior vena cava, aiding the contrast medium bolus in reaching the right atrium and pulmonary artery in a highly concentrated form. Importantly, this concentration remains undiluted by non-contrasted blood from the abdominal cavity. To control the breathing command during suction against resistance, a flow volume curve is displayed to the investigator on a tablet.

Group 2: Standard Breathing Command
Participants in this group followed a standard breathing command – "breathe in and hold your breath"- just before starting the scan. After completing the scan, patients were told to "continue breathing".

Image Analysis

Image Analysis and ROI Placement: Image analysis was conducted using the Aycan workstation PRO (Version 3.14.006) PACS-viewer solution. Regions of interest (ROIs) were placed in both the pulmonary trunk and the descending aorta at the transverse level of the pulmonary trunk. The radiology resident, with 5 years of experience in CT imaging, performed these measurements.
Contrast Attenuation and Ratio Calculation: Contrast attenuation was measured in Hounsfield units (HU) in both the pulmonary trunk and the descending aorta. An ROI of 2 cm^2 was generated in these vessels. The ratio of the measured density value in the pulmonary trunk to that in the descending aorta was calculated. A ratio ≥ 1 was considered normal, while a value < 1 indicated the transient interruption (TIC) phenomenon if contrast inflow via the superior vena cava was detectable.
Evaluation of Contrast Presence and Artifacts: Adequate contrast presence was assessed at various levels (pulmonary trunk, lobar, segmental, and subsegmental) individually. Breathing artifacts and pulmonary embolism were evaluated. Respiratory artifacts were defined as having a detrimental effect on lung parenchyma evaluation.
Exclusion of Strong Respiratory Artifacts: To avoid the influence of strong respiratory artifacts on contrast evaluation, a separate evaluation was performed for patients with breathing artifacts.

Results:

- In total, 150 patients completed the study examination (MM group: 77; SBC: 73).
- There were no significant differences in age, sex, or pulmonary embolism rate between the study groups.
- In the MM group there was a higher rate of fully diagnostic image quality (defined as optimal diagnostic contrast) compared to SBC group (89.6% vs. 60.3%, p <0.001).
- Contrast at all investigated levels was higher in the MM group (all p <0.01).
- Slight breathing artifacts were more common in the MM group than in SBC, however breathing artifacts did not significantly affect pulmonary embolism evaluation.

In terms of specific parameters, the results were as follows:

- Pulmonary Embolism Incidence: MM group: 5 cases (6.5%) vs. SBC group: 7 cases (9.6%, p=0.691).
- Pulmonary trunk CT attenuation: MM group: Mean 338.24 HU vs. SBC group: Mean 313.71 HU (SD 109.12, p = 0.157).
- Minimum contrast in pulmonary trunk: MM group: 171.21 HU vs. SBC group: 73.88 HU.
- Descending aorta attenuation : MM group: Mean 134.42 HU (SD 72.77) vs. SBC group: Mean 177.83 HU (SD 80.64, p = 0.001).
- TP-aortic ratio: MM group: 3.86 HU (SD 3.56) vs. SBC group: 2.26 HU (SD 1.77, p = 0.001).
- TIC phenomenon: MM group: 0 cases vs. SBC group: 9 cases (12.3%) with p = 0.005.

Authors' Conclusion:

The authors stated that the results are in line with previous CTPA- pilot studies and show that performing the MM with the ulrich medical's prototype can increase contrast attenuation in CTPA and effectively prevent the TIC phenomenon, which previous studies have shown to occur in one in five patients when using SBC.
Moreover, implementation of a such device in PE diagnostics with CTPA may enhance diagnostic accuracy and lower the risk of missed PE. Possible reasons for better diagnostic quality in the MM group include reduced blood flow from the inferior vena cava (IVC) and increased blood flow into the pulmonary artery system due to negative pressure.

Limitations of the Publication:

The study's results should be interpreted with caution due to certain limitations. Blinding the readers to the presence or absence of the breathing device was challenging because of variations in arm positioning and visibility in the topogram. Device-associated artifacts were noted, and the applicability of the device may vary depending on the patient's condition. Despite these limitations, the device was used on a diverse group of patients in an emergency setting at a university medical center. Further research in different clinical settings or with specific patient sub-groups may provide additional insights.

Key Messages:

- Compared to the standard end-inspiratory breathing command (SBC), the device-assisted Mueller maneuver (MM) improves contrast enhancement:
  ➔ The attenuation ratio between pulmonary trunk and descending aorta was 3.86 HU in MM group vs. 2.26 HU in SBC group.
  ➔ MM prevents the transient interruption of contrast (TIC) phenomenon (0% cases in MM vs. 12.3% in SBC group) during computed tomography pulmonary angiography (CTPA).
  ➔ Contrast at all investigated levels was higher in the MM group.
- In the MM group there was a higher rate of fully diagnostic image quality compared to SBC group (89.6% vs 60.3%).
- This finding suggests that using the MM may optimize diagnostic workup and timely treatment for patients with pulmonary embolism.

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