Original Article

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TANAFFOS

Visualization and Analysis of the Role of an Inflated Tracheostomy Tube Cuff in the Human: A Preliminary Study

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Background: This study aimed to reconstruct ultra-high-resolution computed tomography (CT) and three-dimensional CT images of tracheostomy tubes, including the shaft, flange, inflation line, and cuff, with a particular focus on examining the degree and fold formation of the inflated tracheostomy tube cuffs within the human trachea.

Materials and Methods: All ten patients were inserted with a cuffed tracheostomy tube, and the cuff pressure was maintained at approximately 25 cmH_2O intra-cuff pressure using a pressure gauge. The levels of the inserted tracheostomy tube, the degree of inflation of the tracheostomy tube cuffs, the folds of the cuff, and the location of the distal tip of the tracheostomy tube.

Results: In this study, the pressure of the tracheostomy tube cuff was managed at an intracuff pressure; however, the degree of inflation of the tracheostomy tube cuffs and the form of the cuff folds inserted into the human trachea differed in each case. The distance between the skin and the tracheal anterior wall and the BMI value were associated with the inflation of the tracheostomy tube cuffs.

Conclusion: In cases with distances greater than 25 mm between the skin and the tracheal anterior wall, we think it may be better to use other methods, such as tracheal fenestration, rather than simple tracheostomy. Examination of the size of the tracheostomy tube inserted into the human trachea, the degree of inflation of the tracheostomy tube cuff, and the position of the distal tip of the tracheostomy tube may help in the selection of an appropriate tracheostomy tube clinically.

Keywords: Computed tomography; Cuffs; Larynx; Tracheostomy

INTRODUCTION

The tracheostomy tube is important for airway management, particularly the role of the tracheostomy cuff in assisting with effective ventilation and reducing the aspiration of subglottic secretions (1). If the pressure of the tracheostomy tube cuff is too low (underinflated), air leaks from the lungs, increasing the risk of saliva aspiration (2). If the tracheostomy tube cuff pressure is too high (overinflation), the risk of ischemic tracheal lesions, tracheal stenosis, and tracheoesophageal fistulas increases (3-6). It is recommended that the tracheostomy tube cuff pressure be maintained at 20-30 cmH_2O (1,2). The seal function differs because the cuff of a commercially available tracheostomy tube has various materials and styles, such as silicone, polyvinylchloride (PVC), and polyurethane. Experiments were conducted to determine whether leakage occurred using a rigid trachea model (a rigid circular syringe tube) (7-9). However, the human trachea is elliptical in shape because the tracheal wall consists of incomplete cartilage rings forming the anterior and lateral circumferences and the muscle trachealis at the posterior side (10-12). Hence, human tracheas are not similar to the tracheal models used in the experiments. It is possible to be better centered in the trachea by using an inflated tracheostomy tube cuff in vivo. However, if the tracheostomy tube cuff does not inflate evenly, the distal tip of the tube may face the tracheal wall. This may lead to damage to the tracheal wall and a reduction in the sealing of the aspirated saliva.

Recently, the multi-detector computed tomography (MDCT) was used, which allowed a wide range of various portions to be obtained easily in a short time. Ultra-high resolution computed tomography (UHRCT) has been developed, which is characterized by a smaller focal size of the detector elements and X-ray tube compared with the conventional high-resolution computed tomography, allowing clearer computed tomography (CT) images (13-15). Thus, this new imaging technology provides better image quality owing to its improved spatial resolution. The airways, including the pharynx, larynx, and trachea, which consist of air and soft tissues with wide differences in CT threshold values, have few artifacts. Hata et al. reported that a large matrix size maintained the spatial resolution and improved the image quality and assessment of lung diseases in UHRCT (13). In the field of larynx, Miyamoto et al. reported that UHRCT improved the visualization of the complicated configuration and kinetics of the larynx (16). However, it is impossible to visualize a cuff inserted into a living body.

This study aimed to reconstruct UHRCT and three-dimensional (3D) CT images of tracheostomy tubes, such as the shaft, flange, inflation line, and cuff, inserted in patients, and to examine the degree and the fold formation of the inflated tracheostomy tube cuffs in the human trachea.

MATERIALS AND METHODS

Subjects

Patients with a tracheostomy tube were enrolled in our institution during the 4-year study period. Data were retrospectively obtained from the medical records. All patients were inserted with a cuffed tracheostomy tube, and the size of the tracheostomy tube was determined by each surgeon. However, the cuff pressure, especially within one hour before UHRCT, was maintained at an intra-cuff pressure of approximately 25 cmH_2O using a pressure gauge.

Similar to conventional CT, patients lie down on a bed in the supine position with their neck extended using a pillow, and the head is immobilized. Suction over the tracheostomy tube cuff was performed before UHRCT.

This study was approved by the institutional review board of our institution. Informed consent was obtained from all the patients before they underwent UHRCT.

CT scan procedures

The UHRCT scanner used was a 160-row MDCT scanner (Aquilion Precision™; Canon Medical Systems Corporation, Tochigi, Japan). Laryngeal images were evaluated using the super-high-resolution mode. The detector matrix of the UHRCT is 1792 detector channels × 160 rows, and the size of each element is 0.25 × 0.25 mm in hybrid iterative reconstruction (Adaptive Iterative Dose Reduction 3D, Enhanced Strong). The beam collimation was 0.25 mm × 160 rows. The scanning parameters were set as follows: tube voltage, 120 kVp; noise index, 13 Hounsfield units (HU) for 0.25 × 0.25 mm through automatic exposure control; the CT HU was calibrated such that the standard deviation in the scanning range of 2 mm was 13; helical pitch, 0.569; rotation time, 0.5 second per rotation; and x-ray focus size, 0.6 × 1.3 mm. The UHRCT matrix size was 1024 × 1024, the slice thickness was 0.25 mm, and the slice interval was 0.2 mm. When the scanning was limited to the larynx and trachea, the scanning time was shortened to a few seconds. All data were transferred to a dedicated workstation (Ziostation, version 2.4; Ziosoft, Inc., Tokyo, Japan), and then reconstruction into 3D and virtual endoscopic images was done. The density value for extracting the trachea and tracheostomy tube, including the inflated cuff, was determined from thin-sliced images. A volume-rendering technique was used to reconstruct the virtual endoscope. The total time required to reconstruct 3D images of cartilage and virtual laryngoscopic images in one patient was approximately 20 min (16).

Evaluation

In this study, UHRCT was performed on patients with tracheostomy tubes. If a tracheostomy tube cuff is present, it is possible to consider the proper shape and pressure of the tube cuff to decrease the risk of saliva aspiration and damage to the tracheal wall mucosa. The levels of the inserted tracheostomy tube, degree of inflation of the tracheostomy tube cuffs, the folds of the cuff, the location of the distal tip of the tracheostomy tube, and the association between the size of the tracheostomy tube and the size on the inside of the inferior edge of the cricoid cartilage were evaluated. In addition, commercial tracheostomy tubes are made of PVC, including diethylhexyl phthalate (DEHP). PVC is softened at body temperature using plasticizers, of which DEHP is the most commonly used in tracheostomy tubes (1). A commercially available tracheostomy tube was adjusted to the tracheostomized stoma, and the tip of the tracheostomy tube was located in the trachea. The angles between the reconstructed and actual tracheostomy tubes were compared. The distance between the skin and the tracheal anterior wall and body mass index (BMI) were analyzed in association with the location of the tracheostomy tube.

RESULTS

Patient Characteristics

Patient characteristics are shown in Table 1. Ten patients with a tracheostomy tube (five men and five women; age range of 23-81 years and mean age of 57.7 years) were enrolled in this study. The inserted tracheostomy tubes were five commercially available tracheostomy tubes with an inner diameter (ID) ranging from 6.0 to 9.0 mm for nine patients and an outer diameter of 11.0mm for one patient.

Table 1. Characteristics of the patients with the tracheostomy tube cuffs

	Age Sex	BMI (kg.m²)	Underlying disease Cause of the tracheostomy	Type of the tracheostomy tube (commercial tracheostomy tube)	Size
Case 1	33 years, male	22.72	Cerebral hemorrhaging, quadriplegia, Persistent disturbance of consciousness	vocarade Smith-medical,	ID: 8.0mm
Case 2	57 years, female	18.30	Multiple system atrophy, Aspiration pneumonitis	NeoBreath Koken CO.,LtD,	OD: 11.0mm
Case 3	72 years, female	22.77	Disturbance of bilateral vocal fold movement after long intubation	Asper-Ace™ Medtronic	ID: 7.5mm
Case 4	67 years, female	24.95	Airway burns, Intubation management, Tracheal granuloma	Asper-Ace™ Medtronic	ID: 8.0mm
Case 5	72 years, female	24.62	Bilateral vocal fold paralysis	Mera Sofit Clear Senko Medical Instrument Mfg.Co.,Ltd	ID: 8.0mm
Case 6	80 years, male	24.69	Bilateral vocal fold paralysis	Mera Sofit Clear Senko Medical Instrument Mfg.Co.,Ltd	ID: 8.0mm
Case 7	81 years, female	19.25	Bilateral vocal fold paralysis	Mera Sofit Clear Senko Medical Instrument Mfg.Co.,Ltd	ID: 7.5mm
Case 8	30 years, Male	17.09	RP Subglottic stenosis	Asper-Ace™ Medtronic	ID: 9.0mm
Case 9	62 years, male	25.73	Multiple system atrophy, Bilateral vocal fold paralysis	Asper-Ace™ Medtronic	ID: 8.0mm
Case 10	23 years, male	16.36	Cerebral palsy Aspiration pneumonitis	Mera Sofit Senko Medical Instrument Mfg.Co.,Ltd	ID: 5.0m

3D reconstruction of the tracheostomy tube

Patients with tracheostomy tubes underwent UHRCT, and reconstruction was done using the UHRCT images (Figure 1). Reconstructed images were freely rotated in the software, and the assessments were performed using side-by-side and distal-to-proximal views of the reconstructed tracheostomy tube. The shaft, flange, inflation line, suction line, and inflated tracheostomy tube cuffs were visualized in the trachea (Figure 1a). In all 10 cases, the detailed structures of the tracheostomy tubes reappeared. The degree of inflation and folds of the tracheostomy tube cuffs, heat-moist exchanger, tape attachment, and one-way inflation valve were also confirmed. The formation of the inflated cuff was classified into three groups; the cuff was inflated evenly with or without small folds (Group I), the cuff was inflated on the posterior side of the tracheostomy tube (Group II), and the tracheostomy tube cuffs were inflated on the posterior side of the tracheostomy tube and with folds (Group III) (Figure 2).

A tracheostomy tube was inserted from the level of the subcricoid cartilage to the fourth tracheal ring. Considering the degree of inflation of the tracheostomy tube cuffs and the insertion levels of the tracheostomy tubes, the tracheostomy tubes in Groups II or III (cases 1,3,4, and 8) were inserted at the level of subcricoid cartilage to the second tracheal ring. In addition, two cases (cases 5 and 6) were inserted at the level of the second tracheal ring, and the superior anterior wall of the trachea was pushed into the trachea. In Group I, three cases (cases 2, 7, and 9), except for the patient with severe physical and mental disabilities (case 10), were inserted into the third or fourth tracheal ring.

The BMI value in Group I (except case 9) was <20kg/m^2, and that of five patients in Group II and III (except case 8) was >22kg/m^2. Especially, those of two patients (cases 5 and 6) were >24kg/m^2. The BMI value in Group I was smaller than that in Groups II and III.

The distance between the skin and the tracheal anterior wall in Group I (except case 9) was <11.0mm, and especially, those of two patients (case 5 and 6) were >25mm. In Group I, there were many shorter cases between the skin and the tracheal anterior wall.

In comparison with the inner size of the inferior edge of the cricoid cartilage, the tracheostomy tube sizes inserted in females were bigger than in males (Table 2).

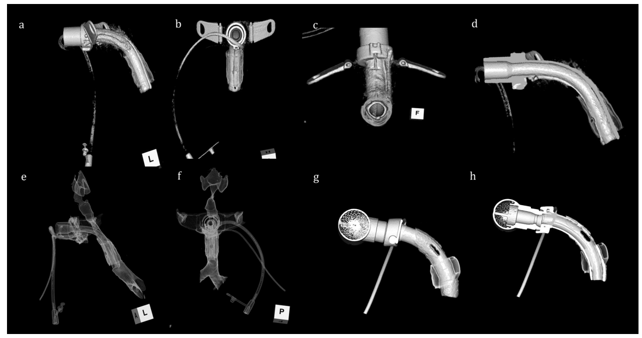

Figure 1. UHRCT images of the tracheostomy tube inserted into the trachea. The shaft, flange, suction line, and inflated tracheostomy tube cuff were reconstructed meticulously. (a) Side view, (b) frontal view, (c) tip side view, (d) the center slice from side view, (e) side view, (f) frontal view, (g) heat-moist exchanger (side view), and (h) heat-moist exchanger (the center slice from side view)
UHRCT, ultra-high-resolution computed tomography

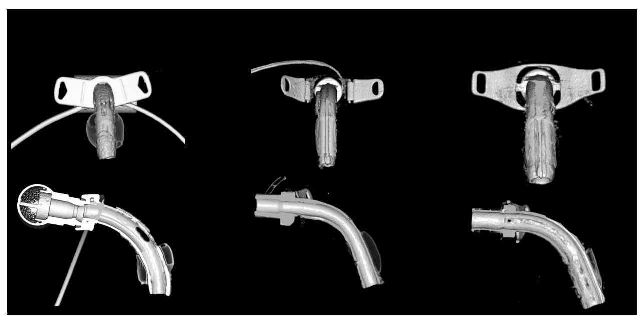

Figure 2. The classification of the degree of the inflated cuff. The formation of the inflated cuff was classified into three groups. Group I was the tracheostomy tube cuffs that inflated evenly with or without small folds. Group Ⅱ was the tracheostomy tube cuffs that inflated on the posterior side of the tracheostomy tube. Group Ⅲ was the tracheostomy tube cuffs that inflated on the posterior side of the tracheostomy tube with folds

The distal tip location of the tracheostomy tube

Six cases (cases 1, 4, and 7-10) were located at the center of the trachea, one (case 6) at the anterior position, one (case 5) on the left side, and two (cases 2 and 3) on the left posterior side. In one case (case 7), the distal tip of the tracheostomy tube was close to the tracheal bifurcation. However, the distal tip of the tracheostomy tube was not associated with the degree of cuff inflation. Compared with the measurement values of the reconstructed tracheostomy tube shaft and the commercially available tracheostomy tubes, the angles were different between -1° and 16°. Upon calculation of the angle, a negative angle was observed in only one case; on the other hand, nine cases had a wider angle than the commercially available tracheostomy tube. The tracheostomy tube shaft angle was not associated with the degree of cuff inflation.

Size of the tracheostomy tube and the inferior edge of the cricoid cartilage

Except for one case (case 8) of relapsing polychondritis, which had deformation of the cricoid cartilage, nine cases (four male and five female) were included in the evaluation of tracheostomy tube sizes. In the inferior edge of the cricoid cartilage, the mean diameter between anterior and posterior (AP diameter) was 17.6 mm (range, 12.76-23.19 mm) and the mean diameter between right and left (RL diameter) was 16.9 mm (range, 13.11-18.95 mm) in males. The mean AP diameter was 14.6 mm (range, 13.31-15.59 mm) and the mean RL diameter was 16.5 mm (range, 11.58-16.82 mm) in females. In the ratio of the tracheostomy tube size compared with the tracheal size, the mean AP diameter was 58.3% (range, 47.4-72.4%) and the mean RL diameter was 62.6% (range, 57.9-65.6%) in males. The mean AP diameter was 74.5% (range, 65.5-85.0%) and the mean RL diameter was 76.2% (range, 65.5-92.2%) in females. Compared with the tracheal size, the ratio of the outer diameter of the inserted tracheostomy tube in males was approximately two-thirds, and the ratio in females was approximately three-fourths. Tracheostomy tube size was larger in females than in males (Table 3).

Radiation Exposure

The median radiation dose to the larynx on UHRCT was 0.8 mGy. We calculated the radiation dose using the ICRP k-factor (17). The median radiation dose to the larynx and trachea on UHRCT was less than 2.0 mGy.

Table 2. Size and occupied ratio of the tracheostomy tube

	Between the skin and the tracheal anterior wall of the trachea (mm)	Group classification	The inserted levels of the tracheostomy tube	Position of the tracheostomy tube into the trachea
Case 1	12.03	III	under 2nd ring	The center of the trachea
Case 2	9.30	I	under 4th ring	The left-anterior side
Case 3	15.98	II	subcricoid level	The left-anterior side
Case 4	20.99	III	under 1st ring	The center of the trachea
Case 5	25.13	II	under 2nd ring (tracheal wall pushed into)	Close to the bifurcation
Case 6	26.16	II	under 2nd ring (tracheal wall pushed into)	The anterior position
Case 7	11.00	I	under 3rd ring	The center of the trachea
Case 8	19.38	III	under 1st ring	The center of the trachea
Case 9	17.89	I	under 4th ring	The center of the trachea
Case 10	5.37	I	subcricoid level	The center of the trachea

Table 3. Characteristics of the tracheostomy tube

	The inferior edge of the cricoid cartilage		tracheostomy tube size		The ratio of the tracheostomy tube size compared with the tracheal size (%)	
	AP diameter (mm)	RL diameter (mm)	ID (mm)	OD (mm)	AP ratio (%)	RL ratio (%)
Case 1	18.7	16.4	8.0	11.0	58.8	67.1
Case 2	15.4	16.8	8.5	11.0	65.5	71.4
Case 3	14.3	11.6	7.5	10.7	74.8	92.2
Case 4	13.3	15.6	8.0	11.3	85.0	72.4
Case 5	15.2	16.8	8.0	11.0	72.3	65.5
Case 6	23.2	19.0	8.0	11.0	47.4	57.9
Case 7	15.6	13.8	7.5	10.3	66.0	74.6
Case 8	-	-	9.0	12.8	-	-
Case 9	15.6	18.9	8.0	11.3	73.4	59.8
Case 10	12.8	13.1	5.0	8.6	67.2	65.6

DISCUSSION

The UHRCT matrix size used for this study was 512 × 512, 1024 × 1024, and 2048 × 2048 with a slice thickness of 0.25 mm, a slice interval of 0.2 mm, and a 160-row MDCT scanner. This new imaging technology provides better image quality because of its improved spatial resolution. The airways, including the pharynx, larynx, and trachea, which consist of air and soft tissues with wide differences in CT threshold values, have few artifacts. There have been a few reports using UHRCT scans (13-15) to visualize the complicated, detailed structures and kinetics of the arytenoid cartilage using UHRCT of the larynx (16). In this study, the tracheostomy tube was taken with a UHRCT scanner, and 3D CT images of the tracheostomy tube were reconstructed.

Reproducibility of the tracheostomy tube with 3D reconstructed images using UHRCT

The flange, shaft, cuff inflation line, and suction line of the tracheostomy tube can be visualized using conventional CT. The tracheostomy tube cuffs were made of PVC, similar to those of the tracheostomy tube; however, we believe that it was impossible to reconstruct them because of the thinness of the tracheostomy tube cuff. Compared to conventional CT, UHRCT images have improved spatial resolution. Hata et al. reported that UHRCT images provided clarity of image quality for small vessels, solid nodules, ground-glass opacities, and emphysema of the lungs (13). We hypothesized that the reconstructed UHRCT images would more clearly visualize the flange, shaft, cuff inflation line, and suction line of the tracheostomy tube, which allowed us to reconstruct and visualize the inflated tracheostomy tube cuffs.

The shape of the inflated cuffs and the association between tracheostomy level

In this study, the pressure of the tracheostomy tube cuff was managed at an intracuff pressure of approximately 25 cmH_2O using a pressure gauge. However, the degree of inflation of the tracheostomy tube cuffs and the form of the cuff folds inserted into the human trachea differed in each of the 10 cases. In the degree of inflation of the tracheostomy tube cuffs, four cases included in Group I had the cuffs inflated evenly with or without small folds. In Group II, the BMI of the patients was >22 kg/m^2, and the distance between the skin and the tracheal anterior wall was >25 mm, especially in cases where the superior anterior wall was pushed into the trachea. In cases with distances greater than 25 mm between the skin and the tracheal anterior wall, we believe it may be preferable to use alternative methods, such as tracheal fenestration, rather than simple tracheostomy. We hypothesized that the degree of cuff inflation was affected by the tracheostomy procedure (standard mid-tracheostomy or low-tracheostomy) and by factors such as tracheal deviation, lower displacement of the larynx, short neck, and obesity. The actual tracheostomy tube angles varied using the DEHP. However, the distal tips of the tracheostomy tubes were located at the center of the trachea in six cases and on the anterior, posterior, or left posterior sides in four cases. This suggests that the position of the distal tip of the tracheostomy tube was affected more by the distance from the skin to the anterior wall than by the shaft angle caused by the formation of tracheostomy tubes using DEHP. The trachea model was plastic and circular in shape. The experiment confirmed that the tracheostomy tube cuffs were evenly inflated, and the flow was not from over to under the cuff. Moreover, tracheal size is altered by respiration, swallowing, and phonation. If the tracheostomy tube cuffs are inflated in the human body, similar to the model trachea, the tracheostomy tube cuffs were inflated evenly and located at the center of the trachea, or were inflated unevenly and not located at the center of the trachea. The hardness and shape differed between the human and model tracheas. These differences affected the degree of cuff inflation.

The ID of the inserted tracheostomy tube is generally 8.0-8.5 mm in males, and 7.0-7.5 mm in females (1). The accurate dimensions of the second tracheal cartilage were not measured because these areas were damaged during tracheostomy. The trachea was connected to the cricoid cartilage, and the AP and transverse diameters of the subcricoid cartilage were measured instead of those of the second tracheal ring. These sizes were compared with the size of the tracheostomy tube. In males, the size of the tracheostomy tube compared with the cricoid cartilage was approximately 65%, and was approximately 75% in females. The rate of tracheostomy tube insertion was higher in females than in males. If a large tube is inserted into the trachea, then the tracheostomy tube cuff may not be properly inflated. Moreover, insufficiently inflated cuffs could affect the block between the upper and lower airways, as well as the secretion above the cuff to the trachea. The tracheostomy tube size affected the degree of inflation of the tracheostomy tube cuffs. Because the larger size of the tracheostomy tube was selected in females, the distal tip of the tracheostomy tube was not located in the center of the trachea and was instead closer to the bifurcation than in males.

Strengths and limitations

In this study, we examined 10 patients who underwent tracheostomy using a cuffed tracheostomy tube, and the reconstruction of the tracheostomy tube cuffs was analyzed with respect to certain conditions and levels of the tube inserted into the trachea. Tracheostomy tube cuffs protect against air leaks and prevent aspiration of the secretion above the cuff (1). It is recommended that the tracheostomy tube has a high-volume low-pressure cuff for decreased complication risks associated with the tracheostomy tube (e.g., over-swelling trachea, decreasing blood flow of the tracheal mucosa, tracheal necrosis, tracheal stenosis, and lethal tracheobrachiocephalic fistula) (3-5). Moreover, the pressure of the tracheal cuff was maintained between 20 mmH_2O and 30 mmH_2O (18-22 mmHg) (1,2). Tracheostomy tube cuffs showed different degrees of inflation between the model and the human trachea.

Our study had several limitations. First, our study included a small number of cases, and we did not assess all types of tracheostomy tubes. Second, although a cuff inflator/pressure gauge was used, the time lag difference between the cuff check time and CT scan time could induce a difference because the air from the inflated cuffs may leak naturally. Third, we did not investigate an association between cuff inflation degree and clinical outcomes like aspiration.

CONCLUSION

UHRCT is an emerging imaging technology that can be used for minimally invasive visualization and assessment of tracheal structures and tracheostomy tubes. In this study, a tracheostomy tube inserted into the human trachea was reconstructed using UHRCT imaging. The shape of the tracheostomy tube was faithfully reproduced, and even the cuff, which could not be reproduced using conventional CT, was reproduced. The tracheostomy tube cuffs were inflated evenly in a few cases and unevenly with folds in other cases, even though appropriate pressure was maintained using a pressure gauge before CT imaging. This suggests that the tracheostomy tube cuff may not have played a role in airway management of aspiration prevention. Examination of the size of the tracheostomy tube inserted into the human trachea, the degree of inflation of the tracheostomy tube cuff, and the position of the distal tip of the tracheostomy tube may help in the selection of an appropriate tracheostomy tube clinically in the future.

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