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Abstract

This study aimed to evaluate the performance of a therapeutic vibrating mesh-type nebulizer for the pulmonary delivery of radioaerosols for lung scintigraphy in healthy subjects. Six healthy subjects (mean age of 28.7 ± 6.2 y) inhaled 2 mL of Tc-99m diethylenetriaminepentaacetic acid (DTPA) and normal saline solution (20 mCi) via the therapeutic vibrating mesh nebulizer (DK010, DELBio, Taipei, Taiwan). The nebulizer's mass median aerodynamic diameter (MMAD) is between $2.3 \mu\text{m}$ and $5.0 \mu\text{m}$ ($3.47 \pm 0.37 \mu\text{m}$) and the nebulization rate is greater than 0.2 ml/min. Scintigraphy was performed to count radioaerosols in the regions of interest to determine the total and regional lung deposition and extrathoracic airway deposition of aerosols, penetration of aerosols, and radioactivity count balance. The total lung deposition of aerosols was $21.2 \pm 5.2\%$ (% ex-valve dose), $27.4 \pm 8.0\%$ (% ex-device dose) and $13.8 \pm 4.1\%$ (% initial dose) in nebulizer. The extrathoracic airway deposition was $4.8 \pm 1.1\%$. The radioactivity count balance was $5.4 \pm 3.0\%$. The ratio of outer vs inner lung deposition (O/I ratio, or penetration index) was 1.89 ± 0.55 . The delivery efficiency and the penetration of aerosols to the peripheral lung achieved by the DELBio DK010 vibrating mesh-type nebulizer are similar to the commercialized jet-type nebulizers dedicated

for radioaerosol lung scintigraphy nebulizer. The therapeutic vibrating mesh-type nebulizer (DELBio DK010) is feasible for radionuclide lung ventilation scintigraphy.

Keywords: therapeutic mesh-type nebulizer, aerosol, pulmonary scintigraphy, Tc-99m DTPA, radioaerosol deposition

Running title: Radioaerosols delivered by therapeutic mesh nebulizer

Introduction

Medical nebulizer has been used to deliver a therapeutic dose of the drug as an aerosol, such as bronchodilators, insulin and other hormones, painkillers and antibiotics.^[1-4] However, measurement of drug delivery through the nebulizer remains difficult.^[5] Nebulizer is probably the single most important factor influencing drug delivery efficiency and aerosol size properties.^[6] Scintigraphy techniques provide quantitative information on aerosol deposition using the radioactivity associated with an added radiopharmaceutical as an analog for drug dose. Deposition scintigraphy techniques have been applied with medical nebulizers, metered-dose inhalers, and powder inhalers and used in parallel with pharmacokinetic measurements.^[7] Aerosols have also been used to deliver radiopharmaceutical probes to the lungs for physiological imaging purposes. These aerosol-based imaging techniques allow measurements of ventilation, permeability, liquid absorption, and clearance in the lungs. In some cases, these measurements have proved to be a valuable outcome measure for therapeutic development.^[7] Gamma scintigraphy, with Tc-99m based radiopharmaceuticals, is considered one of the gold-standard methods to estimate deposition pattern of aerosols in human subjects, and probably to certify drug-delivery related performance parameters and quality control of nebulizers.^[8, 9] This technique can also be used with

advantage for quantifying nebulizer performance.

Jet nebulizers, ultrasonic nebulizers and the mesh nebulizers have been used for pulmonary nuclear medicine.^[6] With jet nebulizer, aerosolization results from the Bernoulli effect induced by a high velocity air jet. When equipped with baffles which remove larger particles, jet nebulizers can produce log-normal distributed aerosols. With ultrasonic nebulizers, aerosolization results from atomization of the solution under the effect of an oscillating piezoelectric crystal. The particle size is inversely proportional to the oscillating frequency of the quartz.^[10] Vibrating mesh nebulizers generate fine aerosols without requiring baffles by means of a vibrating mesh. The vibrating mesh nebulizer consists of a membrane (or mesh) with thousands of funnel-shaped apertures that dictate the particles sizes according to the exit diameter of the apertures.^[10] The vibrating mesh nebulizer has been associated with production of precise particle sizes without adding gas flow into the ventilator circuit and a low residual volume of drug remaining after nebulization is complete.^[11-14] This type of nebulizer has been shown to be promising in providing greater inhaled and pulmonary deposition compared with jet nebulizers during conventional mechanical ventilation using both in vitro and animal models.^[15, 16]

Pulmonary scintigraphy is an important tool to quantify aerosol drug deposition into the respiratory tract with a variety of aerosol-generating devices both on and off the ventilator.^[16-18] Jet-nebulizer is most commonly used in nuclear medicine for generation of radioaerosols for pulmonary inhalation scan. Compared to the jet-nebulizer, the vibrating membrane system is expected to deliver the same dose in a shorter time.^[11] Lung deposition of radioaerosols generated from vibrating-mesh nebulizer with a specific valved holding chamber using 2 mCi/4mL of Tc-99m DTPA has been evaluated by SPECT-CT.^[19] The pulmonary aerosol deposition was six times increased with the vibrating-mesh nebulizer.^[19] Another data of radioaerosol pulmonary deposition using mesh and jet nebulizers was measured during noninvasive ventilation.^[6] The mesh nebulizers delivered greater than 2-fold more radiolabeled drug into the respiratory tract compared with jet nebulizers.^[6] It is uncertain whether the conventional therapeutic vibrating mesh-type nebulizer is feasible for radioaerosol pulmonary scintigraphy.

The purpose of this study is to assess the delivery efficiency of water soluble drugs (Tc-99m DTPA) by DEL DK010 vibrating mesh-type nebulizer (DELBio, Taipei, Taiwan) as well as to evaluate the feasibility of

this clinical therapeutic nebulizer for radionuclide lung ventilation scan.

Methods

Six healthy non-smoking adult subjects (5M/1F) participated in this study. Inform consent was signed by all subjects and the study was approved by the institutional review board of the hospital (TPEVGH IRB No.: 2017-09-003C)

A mesh-type nebulizer (DELBio DK010) shielded by a sealed lead box which is attached with a high performance bacterial filter to trap the exhaled aerosols was used to generate a fine aerosol mist via a vibrating mesh (Fig. 1). The nebulizer's mass median aerodynamic diameter (MMAD) is between 2.3 μm and 5.0 μm ($3.47 \pm 0.37 \mu\text{m}$); $> 4.7 \mu\text{m}$ 15%, $< 1 \mu\text{m}$ 13%, $> 1 \mu\text{m} < 4.7 \mu\text{m}$ 71%; nebulization rate : greater than 0.2 ml/min. (DELBio DK010 Mesh Nebulizer specifications)

All subjects performed aerosol inhalation and then underwent scintigraphy. Two milliliters of 0.9% saline solution containing 20 mCi (740 MBq) of Tc-99m-labeled diethylene triamine penta-acetic acid (DTPA) was filled in the chamber (medication reservoir) and was nebulized over 10 min. ^[6] Each participant inhaled the aerosols for 10 min, or stopped inhalation

while the solution was completely nebulized before 10 min. The aerosol was inhaled via mouth-piece, with the subject seated upright, and was exhaled via the same mouth-piece through the fenestras into the sealed box equipped with bacteria filter. Immediately after aerosol administration scintigraphy was performed with a dual-head gamma camera (e·cam Signature, Siemens, Germany) during a period of 3 min with a matrix of $256 \times 256 \times 16$ in anterior and posterior positions, simultaneously. The radioactivity of the nebulizer and exhaled filter box was measured before and after inhalation by gamma camera.

Region of interests (ROIs) were drawn with the reference of chest X-ray image on the lungs, esophagus/trachea and stomach, on both anterior and posterior images, then the geometric mean of anterior and posterior counts from the ROIs were calculated (Fig. 2 A, B). The initial dose and retention dose in nebulizer and exhaled aerosols trapped in the filter and the box were also obtained by counting the radioactivity from each ROI (Fig. 2C). For analysis of regional lung deposition of aerosols, the lung was divided into inner (I) and outer (O) zones. A whole-lung rectangle is drawn around the lung ROIs. An I region with dimensions equal to half of the width of whole-lung rectangle and one-half of its height is positioned on the interior boundary of the lung, centered by height. The I and O

regions represent 25% and 75%, respectively, of the area of the whole-lung rectangle (Fig. 3).^[20] Parameters of regional lung distribution were obtained from the ratio of geometric means of outer lung deposition to geometric means of inner lung deposition (O/I).^[21] Calculation of doses from administration of Tc-99m DTPA is performed by the methods published previously^[22-24] to obtain the lung deposition (% ex-valve dose, % ex-device dose and % initial dose in nebulizer, respectively), extrathoracic airway deposition (% ex-valve dose), device retention (% ex-valve) and exhaled filter deposition (% ex-valve dose). (Table 1)

Quality assurance was done by a radioactivity count balance (RCB), which was defined as the difference between the initial counts in the nebulizer minus the sum of all counts post-nebulization in the lung and extra-pulmonary airway, in the nebulizer, on the expiratory filter and on the trapping container, all divided by the initial counts and expressed as a percentage. An acceptable discrepancy in the RCB was defined as 10% in keeping with the level of possible errors due to differences in geometry presented to the gamma camera.^[25, 26]

Results

All of the 5 healthy males and 1 healthy female completed the protocol. The mean values in the 6 subjects were: age 28.7 ± 6.2 years, body mass

index $23.1 \pm 3.9 \text{ kg/m}^2$, FEV_1 $100.8 \pm 5.7\%$ pred and FVC $99.0 \pm 5.9\%$ pred, FEV_1/FVC $86.3 \pm 4.6\%$. The deposition values were summarized in Table 2. The total lung deposition of aerosols was $21.2 \pm 5.2\%$ (% ex-valve dose), $27.4 \pm 8.0\%$ (% ex-device dose) and $13.8 \pm 4.1\%$ (% initial dose in nebulizer), respectively. The extrathoracic airway deposition (% ex-valve dose) was $4.8 \pm 1.1\%$. The residual in the nebulizer was $23.1 \pm 12.2\%$ and that on the exhaled filter and lead-shielded container was $51.0 \pm 9.5\%$. The radioactivity count balance was $5.4 \pm 3.0\%$. The analysis of the regional lung deposition was confined to the right lung to avoid problems of stomach and left lung overlap. The ratio of outer lung deposition over inner lung deposition (O/I ratio) was 1.89 ± 0.55 . The radiation of the subjects measured at one meter distance, immediately after completion of the examination was $35.7 \pm 10.5 \text{ } \mu\text{Sv/hr}$ (geometric mean of anterior and posterior measurements).

Discussion

The DELBio DK010 nebulizer delivered Tc-99m DTPA aerosols into the lungs with the efficiency comparable to the modern jet-type or mesh-type nebulizers (Table 3). The lung deposition of Tc-99m DTPA aerosols from DK010 nebulizer is $21.2 \pm 5.2\%$ (% ex-valve dose) and $27.4 \pm 8.0\%$ (% ex-device dose), respectively, which are higher than $13.3 \pm 6.5\%$ from

other electronic nebulizer (eFlow rapid nebulizer; PARI Respiratory Equipment Inc., Midlothian, VA, USA).^[11] The extrathoracic airway deposition of 4.8 ± 1.1 % was measured in the current study, whereas the deposition was 4.4 ± 3.5 % from eFlow rapid nebulizer; the device retention of DK010 nebulizer was 23.1 ± 12.2 %, and was 52.2 ± 10.1 % from eFlow rapid nebulizer; the exhaled filter deposition was 51.0 ± 9.5 % from DK010 nebulizer, and was 25.0 ± 11.3 % from eFlow rapid nebulizer.^[25] The results indicate that DK010 nebulizer has optimal efficiency to generate aerosols for inhalation. The lung deposition of % initial dose of Tc-99m DTPA in DK010 nebulizer is 13.8 ± 4.1 % comparable to that of 10.6 % from jet nebulizer but is less than that of 32.0 ± 3.4 % of eFlow[®] mesh-type nebulizer.^[11, 26, 27] The extrathoracic airway deposition in the current study is comparable with the eFlow[®] nebulizer (4.8 ± 1.1 % vs. 4.4 ± 3.5 %). DELBio DK010 nebulizer is not a close system, with ventilation windows (fenestras) at the base of mouthpiece to improve the airflow. During inhalation and exhalation, part of the aerosols leaks from the fenestras on the mouthpiece. This may account for the higher deposition on the exhaled filter and the sealed container (51.0 ± 9.5 % vs. 25.0 ± 13.3 %), and less lung deposition per initial dose in nebulizer than that from the similar mesh-type vibrating membrane device, eFlow[®] nebulizer (13.8 ± 4.1 % vs. 32.0 ± 3.4 %).^[11]

The penetration index (O/I deposition ratio), the ratio of peripheral (outer) to central (inner) lung deposition of aerosols (MMAD $3.47 \pm 0.37 \mu\text{m}$), in the current study was 1.89 ± 0.55 . The equivalent inner to outer lung deposition ratio (I/O) was 0.58 ± 0.18 , which is lower than the central to peripheral (nC/P) lung ratio of 1.61 ± 0.32 for the deposition of Tc-99m sulfur colloid aerosols (MMAD $5.4 \mu\text{m}$) generated by Devilbiss 646 jet nebulizer^[27], indicating better penetration of the aerosols delivered by DELBio DK010 mesh nebulizer. This advantage might be beneficial for drug delivery by inhalation. The value for the RCB of $5.4 \pm 3.0\%$ of DELBio DK010 nebulizer measured in the current study is encouraging with agreements of radioactivity pre- and post-nebulization within 10%.^[21] The radiation dosimetry of the participants measured at the end of the test is $35.7 \pm 10.5 \mu\text{Sv/hr}$ is comparable to that of $33.3 \mu\text{Sv/hr}$ from eFlow rapid nebulizer.^[11]

There are limitations of the current study. The case number was limited to 5 male and 1 female healthy young volunteers, because of the rigid local regulation of radionuclide clinical trial. The other limitation of this study is that considering the radiation burden and the medical ethics, we kept the radiation exposure of the volunteers as low as possible. Hence the

volunteers received the radionuclide inhalation test using the DELBio DK010 nebulizer only; we did not perform parallel tests with an equivalent mesh-type nebulizer, such as eFlow rapid, instead of comparison with the relevant data from the literatures.^[11, 27] The current study only assessed the distribution of aerosols of Tc-99m DTPA in normal saline generated from DEL DK010 mesh-type nebulizer. The main purpose is not only to evaluate the feasibility of DK010 mesh-type nebulizer for radionuclide lung ventilation scan, but also to provide reference data for lung distribution of water soluble drugs delivered by DEL DK010 nebulizer. Although there was some leakage of aerosols from the device during inhalation test, the RCB is $5.4 \pm 3.0 \%$, which is still lower than the upper limit of 10% of the quality assurance of nebulizer.

Conclusions

In summary, the delivery efficiency, expressed by per cent lung deposition of the initial fill dose, of DELBio DK010 mesh-type nebulizer and the penetration of aerosols to the peripheral lung achieved by the DELBio DK010 mesh-type nebulizer are similar to the commercialized jet-type and vibrating mesh-type nebulizer. The DELBio DK010 mesh-type, nebulizer which is dedicated for clinical therapeutic use, is also feasible for radionuclide lung ventilation scintigraphy.

Conflict of Interest

The authors have declared that no conflict of interest exists.

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Legends

Figure 1. (A) The DELBio DK010 consists of a nebulizer with a medication chamber on the top, connecting a mouthpiece with fenestras at the base. (B) The nebulizer (right) is mounted in the box with the fenestras of the mouthpiece keeping inside of the box. A high performance bacteria filter (left) is attached on the wall of the box for trapping of the exhaled aerosols. (C) After filling of Tc-99m DTPA normal saline solution, the box cover is sealed and then shielded by a lead container (not shown).

Figure 2. Planar scintigraphy of the lung at anterior projection (A) and posterior projection (B), and image of the nebulizer box (C). Regions of interest are determined from the anterior and posterior views. Both right and left lungs (Rt L and Lt L), trachea (T), esophagus (E), stomach (S), the nebulizer (D) and the box including the filter (F) are outlined. The geometric mean of the radioactivity counts from each ROI is calculated by multiplying the counts of ROIs from anterior and posterior projections together and then take a square root.

Figure 3. The inner (I) and outer (O) lung zones are defined from the anterior and posterior views. An inner region with dimensions equal to half of the width of a whole-lung rectangle and one-half of its height is positioned on the interior boundary of the lung, centered by height. The rest part of the lung other than the inner zone is defined as the outer zone. The geometric mean of the radioactivity counts from I and O zones of right lung from anterior and posterior projections is calculated.

Figures

Figure 1

(A) The DELBio DK010 consists of a nebulizer with a medication chamber on the top, connecting a mouthpiece with fenestras at the base. (B) The nebulizer (right) is mounted in the box with the fenestras of the mouthpiece keeping inside of the box. A high performance bacteria filter (left) is attached on the wall of the box for trapping of the exhaled aerosols. (C) After filling of Tc-99m DTPA normal saline solution, the box cover is sealed and then shielded by a lead container (not shown).

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