

Evaluating the Swirler™ nebulizer: A user's perspective

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Summary

The change from multi-use to single-use nebulizer systems could potentially result in greatly increased expense for aerosol ventilation imaging and a larger waste disposal problem. We have therefore investigated a new compact single-use nebulizer system, the Swirler™ (Amici), for ventilation lung imaging using ⁹⁹Tc^m-DTPA aerosol. Seventy-five patients requiring lung ventilation/perfusion imaging were studied. The ventilation imaging was assessed using three different fills: Group 1, 1000 MBq in 2 ml; Group 2, 1000 MBq in 4 ml; and Group 3, 2000 MBq in 4 ml. The nebulization times to give 1200 counts s⁻¹ on the posterior ventilation image were similar for Groups 1 and 3 (mean 4 min) but slower for Group 2 (mean 6 min). Room contamination was very low when performed in a room with an extractor device. The mean room air contamination was 117.0 Bq l⁻¹ min⁻¹ for Group 1 and 27.6 Bq l⁻¹ min⁻¹ for Group 2, comparable to previous nebulizers we have used. Dose rates measured at the surface of the lead shielded nebulizer were 6.8 μSv h⁻¹ for 1000 MBq in 2 ml and 10.9 μSv h⁻¹ for 2000 MBq in 4 ml. The mass median diameter (span) without the extension tubing was 1.39 μm (1.85) and with a small extension tube reduced to 1.11 μm (1.70). Qualitative and quantitative assessment of image quality showed good peripheral airways penetration of particles with no uninterpretable scans, comparable with other systems we have used. In practical terms, the device is much more compact than other systems and therefore generates a much smaller volume of waste. It is an easy device to use. However, when ventilating patients supine or erect, we found that it was necessary to use the small extension tube. (© 1998 Lippincott-Raven Publishers)

Introduction

Ventilation/perfusion lung imaging for the detection of pulmonary emboli is one of the most common investigations carried out in nuclear medicine departments. Over the years, different methods have been developed for the delivery of radiotracers intended to investigate the penetration of air into the lungs. Initially, work centred on the use of the gases xenon-133 (¹³³Xe) and krypton-81m (⁸¹Kr^m), but recent developments have led to the use of aerosol systems using ⁹⁹Tc^m-diethylenetriamine pentaacetate (⁹⁹Tc^m-DTPA) as the ventilation agent. White *et al.* [1] demonstrated that the majority of departments now use aerosols either as the primary ventilation agent or as a back-up agent for gases.

With the exception of ⁸¹Kr^m, most delivery systems have a common ventilation reservoir and/or inspiratory tubing, resulting in an area where microbiological contamination could be transferred from one patient to another. Although there is little evidence that such contamination occurs or is detrimental to a further patient using the system, it is difficult to prove that such cross-contamination does not occur. Therefore, suppliers of commercially available nebulizer systems have adopted a policy of marketing their devices as single-use. Guidelines on the re-use of many medical devices have been laid down by the EEC, and the UK Medical Devices Agency bulletin of January 1995 [2] stated clearly: 'If a medical device, labelled by the manufacturer "Single use" or in similar terms, is reused, any manufacturer's warranties for the product are likely to be voided and

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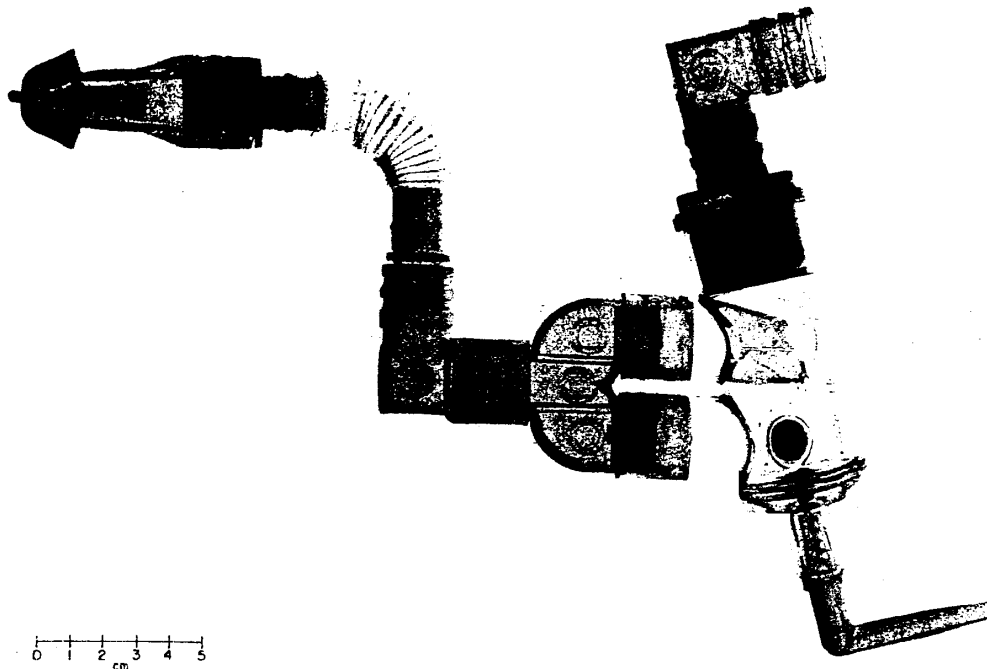


Fig. 1. The Swirler™ nebulizer.

the manufacturer's legal obligations and potential liabilities are likely to cease, or to be limited. If such a device during reuse causes damage or injury, the reprocessor and the re-user are likely to become personally liable'.

This strong wording has important implications for users and manufacturers alike, since most nebulizers are now sold on a single-use basis only [3]. The sale of devices previously used as multi-use and now labelled as single-use has cost implications. We therefore assessed the ability of a new single-use nebulizer, the Swirler™ (Amici), to provide diagnostic ventilation images, its ease of use and disposal, and cost-effectiveness.

Methods

The nebulizer

The Swirler™ nebulizer (Fig. 1) is a very compact device compared to conventional jet systems. The name derives from the design of the air intake to the $^{99}\text{Tc}^{\text{m}}$ -DTPA reservoir. A plastic 'corkscrew' creates a swirling vortex of air which impacts shearing forces onto the liquid to generate the particles. The device is designed to facilitate ventilation in both the supine and erect positions,

although, as with other devices, the orientation of the nebulizer (upright) is crucial to aerosol delivery. The Swirler™ is housed in a specially designed lead shield when filled and, although not recommended by Amici, an extension tube (9.5 cm expandable to 14 cm) can be fitted to the inspiratory tubing. The suggested fill activity is 750–1110 MBq, with a fill volume of 4 ml. Compressed air delivery to the Swirler™ should be at 8 litres per minute at 345 pascals (50 psi). The device can also be used for patients with assisted ventilation.

Study protocol

Consecutive patients referred to the Departments of Nuclear Medicine at Kent and Canterbury and Guy's and St Thomas' Hospitals for possible pulmonary embolism were ventilated in the supine position using the nebulizer. All patients were ventilated to a count rate of 1200 counts per second. The data were acquired using IGE Starport gamma cameras fitted with low-energy, general-purpose collimators (LEGP) in each centre. The camera was situated posteriorly under a scanning couch during the dynamic acquisition. The time taken to reach the required count rate was assessed either by a simple stopwatch method or more usually by a dynamic acquisition (15 s per frame) and assessing the time at which

1200 counts per second were achieved. The patients were then scanned in four positions: anterior, posterior, right posterior oblique and left posterior oblique.

The patients were separated randomly into three groups, each group covering a different activity and fill volume ($n = 75$): Group 1 = 25 patients using 1000 MBq in a fill volume of 2 ml; Group 2 = 25 patients using 1000 MBq in a fill volume of 4 ml; and Group 3 = 25 patients using 2000 MBq in a fill volume of 4 ml. No selection of patients was carried out and each of the three groups encompassed a wide range of patient conditions, compliance and ability.

Performance assessment of the nebulizer was carried out in five categories:

1. Qualitative and quantitative evaluation of image quality, including central to peripheral deposition ratios. The time taken to achieve the desired count rate was recorded as stated above.
2. Measurement of particle sizes generated.
3. Quantification of any room air contamination.
4. Measurement of radiation dose rates from the shielded, filled nebulizer.
5. Housekeeping evaluation of ease of use and disposal.

1. *Image quality.* Qualitative evaluation of image quality was performed by qualified staff. Quantitative data on central to peripheral deposition ratios (C/P ratios) were obtained by analysing posterior ventilation images using computer software to separate the lungs into different regions of interest. Quantitative assessment of images was performed using in-house software on a Park Medical Systems MICAS X computer at St Thomas' Hospital using data from both centres. A region of interest was drawn around the complete lung on the posterior image using either the perfusion or the ventilation image as a template (whichever was the more anatomically interpretable). The medial half of the middle third of this region of interest was defined as the central area with the remainder considered as peripheral. The counts within these regions (with the central area corrected for any peripheral contribution) were expressed in terms of a percentage central to peripheral (C/P) ratio. The categorization criteria were as described previously [4].

- *Category A:* good, even peripheral tracer distribution with no evidence of central airways deposition.
- *Category B:* good peripheral tracer deposition but evidence of central airways deposition.
- *Category C:* poor peripheral deposition with gross central airways deposition.

2. *Particle sizing.* Particle size measurements were carried out using a Malvern Mastersizer X laser particle

sizer. The particle sizing was performed at room temperature (21°C). The particle size distribution was expressed as a mass median diameter and a span. The sizes were measured at the beginning and near the end of nebulization for each different fill volume and different concentration and repeated on three occasions each.

3. *Room air contamination.* During the ventilation procedure, any airborne room contamination was collected using an air sampling device operating at a velocity of 100 l min⁻¹ onto a glass microfibre filter. Ventilations were carried out with the use of a high-velocity extractor device (Nederman), which is standard procedure. The extractor was positioned close to the patient to remove escaping DTPA. The filter samples were counted in a gamma counter (Wallac) calibrated for ^{99m}Tc, centred on the 140 keV photopeak with a 20% window. Contamination levels were expressed in Bq l⁻¹ min⁻¹.

4. *Radiation dose rate measurements.* Measurements were made of the radiation dose rate from the shielded, filled nebulizer covering the three groups under investigation. Measurements were made using a Mini Instruments Series 1000D mini-monitor (calibrated in μSv h⁻¹). The dose rates were assessed on the shield face (0 cm) and at distances of 20 cm and 50 cm.

5. *Qualitative evaluation of ease of use and disposal.* Use and disposal of the Swirler™ was assessed qualitatively. The ease of filling the nebulizer, removal from the lead shielding and potential storage problems were assessed.

Results

Seventy-five patients were studied. The air contamination measurements were performed on 20 patients who were ventilated in the same room and conditions as a previous study [4]. The dose rates were measured on 25 patient devices. The image quality was assessed on all 75 patients for each activity and fill volume. The time to achieve 1200 counts per second was assessed for all nebulizers.

Image quality

All images were of diagnostic quality. As the results for the C/P ratios given below show, the device is capable of delivering aerosol efficiently to the peripheral lung with little central airways deposition. The image quality was assessed as:

- Group 1: 16 Category A, 8 Category B and 1 Category C

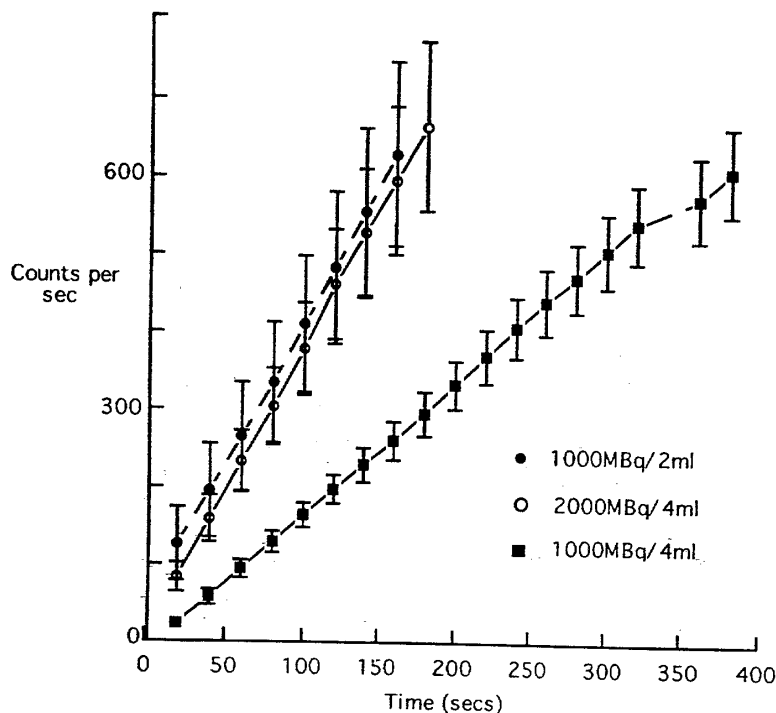


Fig. 2. The dynamic deposition curves for the three nebulizer fills over the right lung for patients who had normal ventilation scans as assessed visually.

- Group 2: 17 Category A, 7 Category B and 1 Category C
- Group 3: 16 Category A, 8 Category B and 1 Category C

The mean (\pm s.e.m.) measurements for the C/P ratios were 9.9 ± 1.5 , 8.1 ± 0.8 and $9.0 \pm 1.3\%$ for Groups 1, 2 and 3 respectively. There was no statistical difference between these results using a Student's *t*-test.

Particle sizing

Particle sizing was measured using three systems each for the 2 ml and 4 ml of inactive $^{99}\text{Tc}^{\text{m}}$ -DTPA, 1 min from the start of nebulization and before discontinuous nebulization commenced. The mass median diameter (span) without the extension tubing was $1.39 \mu\text{m}$ (1.85) at the start and $1.30 \mu\text{m}$ (1.94) after 7 min. There was no difference between the two volumes (concentrations) of the DTPA, and the addition of the short extension tubing slightly reduced the particle sizes to $1.11 \mu\text{m}$ (1.70) at 1 min and to $1.15 \mu\text{m}$ (2.20) at 7 min.

Delivery performance. The time to nebulize for the different fill activities is shown below (minutes:seconds):

- Group 1: mean = 4:26 (range 1:03–7:08)
- Group 2: mean = 6:09 (range 3:48–13:30)
- Group 3: mean = 4:04 (range 1:11–8:47)

The deposition characteristics for the three groups are shown in Fig. 2. The mean deposition rates for Groups 1 and 3 were comparable, but for Group 2 the mean deposition rate was almost half that for Groups 1 and 3.

Room air contamination

We were able to collect contamination samples for 17 of the patients imaged. The contamination results for two of the different fill activities and volumes used were:

- Group 1 ($n = 12$): contamination mean = $117.0 \text{ Bq l}^{-1} \text{ min}^{-1}$ (range 10.2–510.7)
- Group 2 ($n = 10$): contamination mean = $27.6 \text{ Bq l}^{-1} \text{ min}^{-1}$ (range 13.4–46.9)

The results for Group 1 were skewed by two non-compliant patients.

Dose rate measurements

Dose rates were measured for the three groups. Table 1 shows low dose rates, increasing with activity of fill.

Table 1. Radiation dose rates ($\mu\text{Sv h}^{-1}$) from the shielded, filled nebulizer at varying distances (mean \pm S.E.M. and range in parentheses).

Group	Distance from shield face		
	0 cm	20 cm	50 cm
1	6.8 \pm 1.2 (4.6–11.5)	1.6 \pm 0.2 (1.2–2.0)	0.8 \pm 0.04 (0.7–0.8)
2	5.5 \pm 0.3 (4.1–6.6)	1.7 \pm 0.3 (0.8–2.5)	0.7 \pm 0.1 (0.3–1.2)
3	10.9 \pm 0.8 (8.2–13.1)	2.3 \pm 0.2 (1.6–3.0)	1.2 \pm 0.1 (0.8–1.6)

Qualitative evaluation of the ease of use and disposal

The fundamental difference between the Swirler™ and other systems is its compact size. There is easy access for filling the nebulizer while in the shield. The whole device needs to be placed close to the patient's face and therefore we found the extension tubing to be necessary to allow different shaped patients to be ventilated. A heavily weighted base to the supporting stand was also needed to support the shielded nebulizer. Each nebulizer was supplied with its own disposal bag. The design of the shielding allowed removal of the system from the shield without a great deal of handling. One major issue in the adoption of a single-use system is the potential for large volumes of rubbish to be generated from the used radioactive nebulizers and the packaging. This was not found to be a problem, since the small size of the nebulizers allowed a large number to be easily stored in a mobile lead disposal bin.

Discussion

The Swirler™ nebulizer is a single-use device with suitable characteristics for routine ventilation imaging. It is a jet nebulizer and works on the same basic principle as all jet nebulizers, but each differs in its design and therefore has differing outputs and particle sizes. A number of factors affect the particle size of any nebulizer, including the rate of airflow [5], the volume of nebulizer fluid [6], the viscosity of the fluid [7, 8] and the intrinsic design of the nebulizer [8]. Therefore, the Swirler™ was tested by measuring the aerosol particle size at the mouthpiece with and without the extension tubing present. The particle size measured in terms of the MMD and the span showed that the size with and without the extension using the recommended airflow was approximately 1.11 μm with a span of approximately 2.0, indicating a heterodisperse particle production. These sizes are in the so-called 'respirable' range and are very similar to the particle sizes that we have previously measured for the Microcirrus and the Medicaid nebulizers [4] and slightly

larger than our previous measurements for the Ventic II [9]. The dilution of the $^{99}\text{Tc}^{\text{m}}$ -DTPA had little effect on the particle size. The particle size distribution is, however, probably slightly too large for lung 'permeability' studies.

The delivery of the aerosol to patients with normal ventilation (defined by the deposition pattern on the posterior image) showed that, the higher the activity concentration in the nebulizer, the more rapid the deposition. Of interest is that similar deposition was found with the low fill volume of 2 ml and the 4 ml volume and that deposition in the lungs was linear over the time to reach 1200 counts per second in patients with 'normal' ventilation. The low volume of fill was satisfactory in all patients it was tried on. This suggests that there is a sufficiently small dead volume in the nebulizer to operate with a 2 ml volume in compliant patients. The time to achieve deposition was variable and was undoubtedly influenced by the patients. The other potential problem during jet nebulization is that significant cooling occurs [6, 10, 11]. Temperature, however, was not measured during nebulization, but no coughing was produced in patients. The time to reach 1200 counts per second was quite variable depending on the compliance of the patients, reaching nearly 10 min. If the nebulizer starts to run dry, then there is an opportunity to top up with additional $^{99}\text{Tc}^{\text{m}}$ -DTPA.

The deposition pattern was similar to that which we have previously reported with other nebulizers. Most of the images produced sufficient peripheral deposition to allow interpretation, but there were images with significant central deposition. The C/P ratios were similar to other nebulizers previously reported [4]: Microcirrus 8.1% (range 0.1–62.6%) and Medicaid 8.5% (0.1–22.4%) compared with the current device 9.0% (0.1–41.9%). Airborne contamination, which was only measured at one site (since we had previous measurements to compare with in the same room geometry and the same technician performing the measurements), was broadly comparable.

The use of a single-use nebulizer has a possible disadvantage in that the technician's finger dose may be increased during the changing of the device. This was not measured during this study. However, the device is easy to remove from the lead shielding and is disposed of into a lead shielded waste container. The activities added to the new device are comparable to 'top ups' required in a device that is re-used. Also, the changing of the Y-piece and mouthpiece in multiple-use devices is likely to produce a similar if not greater finger dose and contamination hazard than disposing of the single-use device, since there is heavy radioactive contamination of the mouthpiece and Y-piece. The other area of concern is the storage space for the number of single-use devices.

This is comparatively easy, since the system is compact with little extraneous tubing and therefore the storage volume is small.

The major potential advantage is that the device can only be used once, since the patient's respiration is in direct contact with the nebulizer fluid, which leads to contamination. The other advantage at present is one of cost. Alternative nebulizers cost £30 per circuit and, if they are re-used, the minimum that must be performed to allow re-use, if one flouts the MDA guidance, would be to change the Y-piece, mouthpiece and the inspiratory and expiratory valves at a cost of approximately £5. Therefore, if five patients per day were being treated in a unit with this arrangement, each scan would cost £10. There is, however, a potential risk, since the circuit that is re-used could cause cross-infection between patients. If the single-use circuit costs approximately £10, then there is no extra cost for ensuring there is no risk of transmitting infection. There is another potential saving if the British Thoracic Society recommendation [12] to scan patients within 24 h of their presenting symptoms of pulmonary embolism is followed, because if on any day fewer than five scans are performed, the test will be cheaper per patient.

The introduction of single-use terminology over the last 6–12 months by manufacturers has placed the onus on the user to provide evidence that there is no risk to the re-use of nebulizers. The presence on the market of a single-dose device at a lower unit price provides the opportunity to perform ventilation scans at a similar cost to the previous (responsible) user who used a single circuit per day and changed the Y-piece and mouthpiece assembly. Until positive proof can be obtained that no cross-infection occurs in doing this, the use of a single-dose device would appear to be the way providers will need to deliver their service. Our evaluation of the Swirler™ shows that it is no better or worse for the routine ventilation of patients than other devices on the market, but has the advantage of being cheaper to use for five or less lung scan requests per day.

Acknowledgement

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