Health worker exposure risk during inhalation sedation with sevoflurane using the (AnaConDa®) anaesthetic conserving device

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Abstract
Introduction and objective: Occupational exposure to sevoflurane should not exceed 2 ppm. During inhalation sedation with sevoflurane using the anaesthetic conserving device (AnaConDa®) in the post-anaesthesia care unit, waste gases can be reduced by gas extraction systems or scavenging devices such as CONTRAfluran®. However, the efficacy of these methods has not been clearly established. To determine the safest scenario for healthcare workers during inhalation sedation with sevoflurane in the post-surgical intensive care unit.

Materials and methods: An experimental study on occupational exposure was conducted in a post-cardiothoracic care unit during March–August 2009. The measurements were performed in four post-cardiac surgery sedated adults in post-surgical intensive care unit and four nurses at the bedside, and at four points: scenario A, inhalation sedation without gas extraction system or contrafluran as a reference scenario; scenario B, applying a gas extraction system to the ventilator; scenario C, using contrafluran; and scenario 0, performing intravenous isolation sedation. Sevoflurane concentrations were measured in the nurses’ breathing area during patient care, and at 1.5 and 8 m from the ventilator using diffusive passive monitor badges.

Results: All badges corresponding to the nurses’ breathing area were below 2 ppm. Levels of sevoflurane detected using prevention systems were lower than that in the control situation. Only one determination over 2 ppm was found, corresponding to the monitor placed nearest the gas outlet of the ventilator in scenario A. Trace concentrations of sevoflurane were found in scenario 0 during intravenous sedation.

Conclusions: Administration of sevoflurane through the AnaConDa® system during inhalation sedation in post-surgical intensive care units is safe for healthcare workers, but gas extraction
Introduction

Sedation of postoperative patients who require mechanical ventilation is routinely performed using intravenous drugs.\(^1\,^2\) Inhalational anaesthetic agents (IAA) are an effective and promising alternative to intravenous sedation. IAA such as sevoflurane, desflurane or isoflurane can be administered through the AnaConDa\(^\circledR\) device (Anaesthetic Conserving Device; Sedana Medical AB, Sweden) during mechanical ventilation. AnaConDa\(^\circledR\) is a bacterial filter and gas humidifier that allows direct administration of IAA to the respiratory system through a continuous infusion syringe pump without the need for vapoourisers. The IAA most commonly used in our setting is sevoflurane. This drug has myocardial protection effects and it produces fewer hemodynamic alterations than other IAA. Furthermore, systemic accumulation is low because only 10% of sevoflurane is metabolised. The remaining 90%, however, is eliminated to the atmosphere, posing a potential environmental risk to healthcare workers.\(^3\,^9\)

In 1967, Vaisman suggested that environmental contamination by old IAA in operating rooms was associated with headache, fatigue and irritability. He also reported that anaesthetists using IAA had more spontaneous abortions and their offspring had a higher rate of congenital abnormalities than the general population. These data have since been corroborated in other studies and in a meta-analysis. Sevoflurane, desflurane or isoflurane were not analysed by this meta-analysis.\(^10\,^11\)

Acute exposure to sevoflurane above 1000 ppm can lead to confusion, vertigo, nausea, somnolence, and dryness and reddening of the mucosae. In rare instances, cases of hepatic...
necrosis have been described. Chronic exposure to lower concentrations of sevoflurane can lead to perception disorders, cognitive and motor ability changes, and liver function changes.\textsuperscript{12}

Occupational exposure (OE) risk to the inhalation of a gas is evaluated by comparing the concentration of this gas with the environmental level value (ELV). ELV is the time-weighted average representing the permissible average ambient air concentration underlying an 8-h exposure.\textsuperscript{13}

For many years, there has been considerable controversy to regulations concerning the ELV to IAA. In 1977 the National Institute for Occupational Safety and Health (NIOSH) established a recommended ELV of exposure of 2 ppm for 60 min for IAA such as chloroform, trichloroethylene, nitrous oxide, halothane, methoxyflurane, fluoroxyne and enflurane. Isoflurane, desflurane and sevoflurane were later included in this recommendation. These values proposed by NIOSH are based on the lowest concentration able to be detected using the procedures described for sample collection and analysis and not based on studies on OE. Once again, in 1996, the Health Services Advisory Committee (HSAC) published the ELV for nitrous oxide (100 ppm), isoflurane (50 ppm), enflurane (50 ppm) and halothane (10 ppm). However, sevoflurane was not included. It was decided that the limit of 20 ppm recommended by the sevoflurane manufacturer on the technical data sheet would be imposed. This strategy of using the ELV of other IAA for sevoflurane is due to the NIOSH recognition that adverse effects can occur in exposed workers, but the data available on exposure in humans and animals are insufficient to establish a safe and specific ELV for sevoflurane.\textsuperscript{12-13}

We took 2 ppm as the ELV for sevoflurane because to date, neither NIOSH, the Occupational Safety and Health Administration (OSHA), the American Conference of Industrial Hygienists (ACGIH), nor the Spanish or European Community agencies that are responsible for workplace safety have specific ELV for sevoflurane. This way, 2 ppm is the strictest limit to guarantee worker safety for exposure to this drug.

Safety data concerning reduction of sevoflurane traces during inhalation sedation have not been clearly established. During inhalation sedation, waste gas can be scavenged actively or passively. Gas from the ventilator and the gas analyser can be actively led into a central evacuation system, a gas extraction system (SEGA), or through a specially designed, commercially available, active carbon canister. This type of canister, such as CONTRAfluran\textsuperscript{TM} (Zeosys, Berlin, Germany), is a passive scavenger system that passively absorbs waste sevoflurane.\textsuperscript{16}

There is considerable controversy about the use of scavenging systems during inhalation sedation. The manufacturer of the AnaConDa\textsuperscript{®} device and several recent studies recommend that SEGA systems or scavenging systems should be applied to ventilators to reduce the amount of gas in working areas. Other investigators, however, consider this unnecessary.\textsuperscript{16-23}

Sevoflurane contamination has been studied during inhalation sedation but no specific studies have yet compared levels of waste sevoflurane in the different possible scenarios of AnaConDa\textsuperscript{®} use.

The aim of the present study was to evaluate OE and environmental pollution (EP) levels of sevoflurane during

\begin{figure}
\centering
\includegraphics[width=0.5\textwidth]{fig1}
\caption{Picture and schematic diagram of the diffusive passive monitor badges SKC-575-002 used during EP and OE evaluation.}
\end{figure}

inhalation sedation using AnaConDa\textsuperscript{®} in different scenarios of during postoperative mechanical ventilation.

\section*{Materials and methods}

This study was carried out in a cardio-thoracic post-surgical critical care unit (PACU) at a Spanish tertiary care university hospital. The study was approved by the institutional review board and written informed consent to participate in the study was obtained from all patients (Trial registration: No. 08-1230BS. Ref.HSCSP). All patients had undergone cardio-thoracic surgery under general anaesthesia with inhaled sevoflurane.

We measured trace concentrations of sevoflurane using diffusive passive monitor badges (DPMB) (Halogenated Anaesthetics Vapour Monitor Cat No. H-10) that have been validated in both laboratory and field experiments\textsuperscript{14-25} (Fig. 1).

We used DPMB instead of a portable ambient air analyser, which uses a single infrared spectrophotometer, because they allowed us to obtain four samples simultaneously.

The DPMB is worn near the breathing zone to measure personal exposure to the vapour, or placed in a room to measure the area contamination.

We followed UNE-EN 689 recommendations concerning the minimum number of samples needed to study exposure to gases over a period of at least 2 h.

The minimum level that can be measured with the analytical procedure is about 6 μm per sample. Based on the collection rates this corresponds to 0.07 ppm for an 8-h exposure time.

US OSHA 29 methods were used to detect traces of sevoflurane in each DPMB, and a time-weighted average was calculated for each sample over an 8-h period.\textsuperscript{16-27}
Scenario design

The study was carried out during the post-operative sedation period in the PACU. We studied the OE in conjunction with the EP of sevoflurane in four different scenarios of mechanical ventilation after major surgery. We called them scenarios A, B, C and 0.

As we assumed that the nurse was the team member with the highest risk of exposure, a DPMB was attached to the uniform of the nurse in charge of patient care.

Three other DPMBs were distributed in the same location in all four scenarios to measure sevoflurane levels in two different working areas (Fig. 2). Two passive diffusion monitors were placed 1.5 m apart at both left and right sides of the ventilator, and the third monitor was placed 8 m away from the ventilator. The distance of 1.5 m was chosen because it is at this point where most care tasks are carried out. The distance of 8 m was chosen because we considered it represents the common working area required for all staff in the post-operative care unit.

In scenario A we used sevoflurane as a sedation drug via the AnaConDa® system without scavenging waste gas. In scenario B we used sevoflurane via the AnaConDa® system and we connected a gas extraction system (SEGA) to the ventilator gas outlet (the flow used on the SEGA's is 25 l min⁻¹). In scenario C we used sevoflurane via the AnaConDa® system, and a scavenging canister of contrafluran was connected to the ventilator gases outlet.

Scenario 0 was the control situation in which we used intravenous sedation and measured basal sevoflurane waste gas levels in the atmosphere.

We recorded how long each passive diffusion monitor was exposed to the atmosphere.

Sedation management

Sevoflurane syringes were prepared following the AnaConDa® manufacturer's instructions prior to sedation. This was performed outside the PACU.

The sevoflurane infusion regimen was calculated based on minute volume and the patients' weight to obtain an $ET_{sevo}$ of 0.5%, measured using a gas analyser (Sam Module, General Electrics, Wisconsin, USA).

A remifentanil infusion-based sedation (0.05–0.15 μg/ kg/min) was administered in scenario 0.

Sevoflurane and remifentanil were administered to achieve a RASS score (Anexo see additional material online) of −1 or −2 for a minimum of 2 h, until stop sedation criteria for extubation were met.

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.redar.2013.11.011.

Depth of sedation, processing EEG waves, was monitored using the IoC-View (Morphues Medical, Barcelona, Spain) anaesthesia monitor.

When the stop sedation criteria were fulfilled, the sevoflurane and remifentanil infusions were interrupted and all four passive diffusion monitors were closed down.

The stop sedation criteria were: $PAFI (PaO_2/FIO_2) \geq 200$ with a positive end-expiratory pressure ≤5 and arterial carbon dioxide tension <7 kPa; body temperature between 36.5 and 37.5 °C; decreased infusion rates of cathecolamines (upper limit norepinephrine) <0.25 μg/kg/min, dobutamine <10 μg/kg/min or epinephrine <0.25 μg/kg/min; bleeding in drains <100 ml/h for 2 consecutive hours; RASS score <−1; a revision surgery deemed not necessary; and confirmation of the above by the attending physician.

Any type of disconnection from the ventilation system was noted.

The thermo-hygrometric conditions and the quality of the air inside the unit were recorded before the treatment, as well as the number of air exchanges.

Results

The four sedation scenarios were analysed on different days. Table 1 shows data describing the physical conditions in the PACU immediately prior to sedation. Number of air changes (in changes per hour) and the unit volume (in cubic meters) were the same in all four scenarios.

Table 2 shows data concerning the sedation characteristics for the different scenarios.

A total of sixteen sevoflurane samples were taken, four samples in each scenario: three measured the environmental pollution levels of sevoflurane and one measured the occupational exposure.

Table 3 shows the time-weighted average of sevoflurane values for EP and OE over an 8-h period for each scenario.

All DPMBs corresponding to the nurses' breathing zone was below 2 ppm.

Levels of sevoflurane detected using prevention systems were lower than results obtained in the control situation.

We found little variance of environmental sevoflurane traces in scenarios B and C. Only the sampler placed further away in scenario C detected a higher amount of sevoflurane than the other samplers.
Table 1  Physical conditions in the postoperative unit at the beginning of the sedation periods. Values in brackets indicate values according to the UNE-100713:2005.

<table>
<thead>
<tr>
<th></th>
<th>Scenario 0</th>
<th>Scenario A</th>
<th>Scenario B</th>
<th>Scenario C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit volume (m³)</td>
<td>270</td>
<td>270</td>
<td>270</td>
<td>270</td>
</tr>
<tr>
<td>Air changes (cph) [-6cph]</td>
<td>10-12</td>
<td>10-12</td>
<td>10-12</td>
<td>10-12</td>
</tr>
<tr>
<td>Temperature (°C) [24–26 °C]</td>
<td>22</td>
<td>24</td>
<td>23</td>
<td>21</td>
</tr>
<tr>
<td>Humidity (%) [45–55%]</td>
<td>46</td>
<td>45</td>
<td>47</td>
<td>45</td>
</tr>
<tr>
<td>CO₂ (ppm)</td>
<td>764</td>
<td>871</td>
<td>756</td>
<td>789</td>
</tr>
</tbody>
</table>

Table 2  Characteristics corresponding to the sedations carried out.

<table>
<thead>
<tr>
<th></th>
<th>Scenario 0</th>
<th>Scenario A</th>
<th>Scenario B</th>
<th>Scenario C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical diagnosis</td>
<td>Coronary bypass</td>
<td>Coronary bypass</td>
<td>Coronary bypass</td>
<td>Aortic valve replacement</td>
</tr>
<tr>
<td>Duration of anaesthesia (min)</td>
<td>280</td>
<td>285</td>
<td>300</td>
<td>270</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>72</td>
<td>55</td>
<td>89</td>
<td>80</td>
</tr>
<tr>
<td>Ventilator minute volume (l/min)</td>
<td>7.5</td>
<td>6.2</td>
<td>9.2</td>
<td>7.4</td>
</tr>
<tr>
<td>Time sedation began</td>
<td>18:47</td>
<td>14:20</td>
<td>19:52</td>
<td>18:52</td>
</tr>
<tr>
<td>Time sedation ended</td>
<td>22:34</td>
<td>16:20</td>
<td>22:24</td>
<td>20:50</td>
</tr>
<tr>
<td>Sedation time (min)</td>
<td>227</td>
<td>120</td>
<td>152</td>
<td>118</td>
</tr>
<tr>
<td>Mean sevoflurane velocity (ml/h)</td>
<td>0</td>
<td>5.2</td>
<td>4.76</td>
<td>5</td>
</tr>
<tr>
<td>Total sevoflurane consumption (ml)</td>
<td>0</td>
<td>10.5</td>
<td>10.71</td>
<td>9.5</td>
</tr>
<tr>
<td>Number of circuit disconnection</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Number of healthcare staff</td>
<td>8</td>
<td>8</td>
<td>8</td>
<td>8</td>
</tr>
<tr>
<td>Patients in the unit (total number)</td>
<td>12</td>
<td>12</td>
<td>12</td>
<td>12</td>
</tr>
</tbody>
</table>

Only one determination over 2 ppm was found during the study. This corresponded to the DPMB placed nearest to the gas outlet of the ventilator in scenario A.

Trace concentrations of sevoflurane were found in scenario 0 during the intravenous sedation.

Discussion

The main finding in our study was that the 2 ppm limit of OE to sevoflurane was not exceeded in any of the three scenarios during inhalation sedation using the AnaConDa® device. This study illustrates the safety of inhalation sedation in PACU through the AnaConDa® and shows that the preventive measures, SEGA and CONTRAfluran™, effectively reduce sevoflurane OE.

The 2 ppm ELV for sevoflurane recommended by NIOSH was surpassed only in one sample, this being one of the 3 samples collected to measure the EP in scenario A, the scenario with no preventive measures. It was obtained from the DBPM located 1.5 m from the gas outlet of the ventilator. These results indicate that there is a sevoflurane exposure risk in this area but not 8 m apart due to the rate of air changes.

Furthermore, our results obtained following application of prevention systems (scenarios B and C) show that exposure reduction methods such as SEGA and contrafluran reduce the levels of OE and EP sevoflurane.

It is of interest to point out that traces of sevoflurane were found during intravenous sedation. These traces were very small and most likely were remains from the inhalation general anaesthesia during surgery. This suggests that contamination in the other scenarios could also be partly due to basal waste sevoflurane.

Table 3  Time-weighted average of sevoflurane concentrations over an 8-h period in the four different scenarios (in parts per million). Samples 1, 2 and 3 correspond to the environmental sevoflurane levels. Sample 4 corresponds to the personnel diffusive passive monitor badge.

<table>
<thead>
<tr>
<th></th>
<th>Scenario 0</th>
<th>Scenario A</th>
<th>Scenario B</th>
<th>Scenario C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental contamination</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample 1–1.5 m to the right of the ventilator</td>
<td>0.17</td>
<td>4.4</td>
<td>0.25</td>
<td>0.3</td>
</tr>
<tr>
<td>Sample 2–1.5 m to the left of the ventilator</td>
<td>0.1</td>
<td>1.2</td>
<td>0.25</td>
<td>0.3</td>
</tr>
<tr>
<td>Sample 3–8 m from the ventilator</td>
<td>0.09</td>
<td>1.1</td>
<td>0.25</td>
<td>0.45</td>
</tr>
<tr>
<td>Occupational exposure</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sample 4–personnel monitor</td>
<td>0.09</td>
<td>1.4</td>
<td>0.25</td>
<td>0.3</td>
</tr>
</tbody>
</table>
Our EP results obtained with the SEGAs and contraflu-
ratan are similar to those found in previous studies.22–36 The homogeneity in the results obtained from scenario B, C and 0 suggests that SEGa and contrafluran scavenging systems have a similar efficacy but specific studies are necessary to confirm this.

This study is limited by its sample size but it is the first report to compare sevoflurane exposure in all possible combinations of inhalation sedation, with and without preventive measures. Although the low OE observed to sevoflurane through the AnaConDa system without scavenging waste gas during inhalation sedation in PACU, preventive measures such as SEGa or the scavenger contrafluran should be routinely attached to the mechanical ventilators to reduce occupational exposure risk as much as possible.

The regulations of the control of substances hazardous to health and the occupational exposure standards have been enforced since January 1996 in an attempt to control the healthcare workers working environment. It appears that using the AnaConDa system during inhalation sedation with sevoflurane administered by the technique we have described complies with environmental standards and it is not necessarily associated with greater sevoflurane gas exposure over 2 ppm, especially when scavenging systems are available.

Role of the funding source

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Conflict of interest

The authors declare no conflicts of interest.

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