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Original Article

Evaluation of a novel waste anaesthetic gas scavenger device for use during recovery from anaesthesia

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Summary

Volatile anaesthetic agents are a potential occupational health hazard to theatre and recovery staff. Operating theatres and anaesthetic rooms are required to be equipped with scavenging systems, but recovery units often are not. We compared exhaled, spectrophotometric sevoflurane and desflurane concentrations 15 cm from the mouth ('patient breathing zone') and 91 cm laterally to the patient ('nurse work zone') in 120 patients after tracheal extubation who were consecutively allocated to either ISO-Gard mask oxygen/scavenging or standard oxygen mask, 0 min, 10 min and 20 min after arrival in the theatre recovery unit. Median (IQR [range]) duration of anaesthesia was similar between groups (control 76 (44–119 [15–484]) min vs. study group 90 (64–130 [15–390]) min, p = 0.136). Using the ISO-Gard mask, the 20-min mean patient breathing zone and nurse work zone exhaled anaesthetic levels were ~ 90% and 78% lower than those recorded in the control group, respectively, and were within the recommended 2 ppm maximum environmental exposure limit in the patient breathing zone of 53 out of 60 (88%) and the nurse work zone of all 60 (100%) patients on first measurement in the recovery room (vs. 10 out of 60 (17%) and 40 out of 60 (67%) in the control group). Our study indicates that the ISO-Gard oxygen/scavenging mask reduces the level of exhaled sevoflurane and desflurane below recommended maximum exposure limits near > 85% of extubated patients within ~ 20 s of application in the recovery unit after surgery. We encourage the use of this mask to minimise the occupational exposure of recovery staff to exhaled volatile agents.

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Introduction

Volatile anaesthetic agents are potentially hazardous to theatre and recovery staff [1]. Short-term effects include drowsiness and headaches, and genetic abnormalities have been associated with some agents [2].

Control of Substances Hazardous to Health (COSHH) regulations dictate that exposure to occupational pollutants should be minimised [3]. The National Institute for Occupational Safety and Health (NIOSH) in the USA recommends that exposure to halogenated agents should not exceed two parts per million (ppm) [4].

To date, observational studies have measured occupational waste anaesthetic agents exposure only in operating theatres [5–10], where scavenging is available. Traditionally, scavenging devices have not been used in the theatre recovery unit, exposing staff and

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patients to relatively high inspired levels of waste anaesthetic agents [11].

A device for scavenging waste anaesthetic agents in the recovery unit has been available since 2013. The ISO-Gard® Mask (Teleflex, Morrisville, NC, USA) delivers oxygen via nasal prongs at up to 10 $l.min^{-1}$, whilst scavenging waste anaesthetic agents from the lower mask by applying suction of up to 50 mmHg (Fig. 1). One-way valves allow entrainment of supplemental room air, but prevent the escape of exhaled gases into the atmosphere. The manufacturer claims this device scavenges waste anaesthetic agents effectively, based on data from a small pilot study undertaken by investigators with a financial conflict of interest [12].

We tested the manufacturer's claims quantitatively, by comparing waste sevoflurane and desflurane levels using an infrared spectrophotometer near patients wearing either an ISO-Gard scavenger mask (study group) or a standard oxygen mask (control group).

Figure 1 ISO-Gard® scavenging mask. (a) oxygen inlet scavenger, (b) tubing, (c) one-way inhalation valves, (d) CO_2 monitoring port.

Methods

Formal ethical approval was not sought for this licensed product evaluation. The project was registered on the Integrated Research Application System.

Patients emerging from inhalational anaesthesia who arrived in the recovery unit without airway devices in situ were non-randomly and consecutively allocated to either the control group or the study group. All patients were transferred from theatre receiving 6 $l.min^{-1}$ cylinder oxygen via a standard oxygen mask (adult medium concentration mask, product no. 1104000, Intersurgical Ltd., Wokingham, UK).

Two control groups were evaluated, both before and after the study group evaluation, to account for any temporal change in staff practices during the study group evaluation period.

In control groups 1 and 2, the oxygen tubing was transferred from the trolley oxygen cylinder to wall-mounted oxygen on arrival in the recovery unit. Patients in control groups 1 and 2 continued to receive 6 $l.min^{-1}$ wall-mounted oxygen via the standard oxygen mask.

In the study group, the standard oxygen mask was replaced with the ISO-Gard mask on arrival in the recovery unit, and patients received 6 $l.min^{-1}$ wall-mounted oxygen via this mask, with wall-mounted scavenging connected and limited to 40 mmHg displacement pressure.

There was no blinding of patients, staff or the primary investigator as to which mask was being studied. Patients were not studied if they could not tolerate either mask or required therapeutic suction.

Sevoflurane and desflurane levels were recorded on arrival and 10 min and 20 min after arrival, from the 'patient breathing zone' (PBZ) and the 'nurse work zone' (NWZ). A portable MIRAN SapphIRe XL Ambient Air Analyser (Thermo Fisher, Foxborough, MA, USA) was used to measure exhaled waste anaesthetic agent levels by infrared spectrophotometry, from the PBZ (15 cm from the mouth) and the NWZ (91 cm laterally to patient) on arrival in the recovery unit. We

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defined 'time zero' as the first sample measurement time after the oxygen tubing was switched from the trolley cylinder to a wall-mounted source for both control groups, and the ISO-Gard mask was applied for the study group; further PBZ and NWZ measures were taken in the recovery unit 10 min and 20 min after time zero. The analyser samples air at a rate of 14 $l.min^{-1}$ and takes 20 s to analyse the sample. For atmospheric sevoflurane and desflurane levels, the published accuracy is ± 10%, and the detection range is 0.03–100 ppm, and 0.04–100 ppm, respectively [13].

Data were recorded for atmospheric anaesthetic agent levels (ppm), and time from start of anaesthetic to arrival in the recovery unit (minutes). We analysed data using SPSS v.22 for Windows (IBM, Chicago, IL, USA). Time from anaesthetic start to arrival in the recovery unit was compared between groups using a Mann–Whitney U-test. Atmospheric volatile agent levels were compared using Student's t-test. Variance in anaesthetic agent levels at each time horizon was compared between groups using a two-way MANOVA test. A convenience sample of patients was determined by the availability of the primary investigator (RT).

Results

Atmospheric volatile agent levels were measured from 144 patients; 24 (12 control, 12 study) patients did not complete the study period (removed mask, required suction), and were not included in further analysis. Data were analysed for 120 patients (60 control, 60 study).

Median (IQR [range]) time from anaesthetic start to arrival in the recovery unit was not significantly different between groups (control 76 (44–119 [15–484]) min vs. study group 90 (64–130 [15–390]) min, p = 0.136. Seventy-one (59%) patients receiving desflurane had significantly longer median (IQR [range]) operations than those receiving sevoflurane (113 (70–177 [19–484]) min vs. 61 (31–89 [15–249]) min, respectively, p < 0.001).

Twenty-minute mean (SD) levels (ppm) of sevoflurane and desflurane in the PBZ and NWZ are shown in Table 1.

Median (IQR [range]) time from anaesthetic start to arrival in the recovery unit was not significantly different between control groups 1 and 2 patients receiving either sevoflurane (50 (25–90 [15–128]) min vs. 59 (27–76 [20–249]) min, respectively, p = 0.736) or desflurane (106 (74–166 [38–428]) min vs. 85 (42–169[19–484]) min, respectively, p = 0.288).

Table 1 Twenty-minute levels (ppm) of sevoflurane and desflurane, in the patient breathing zone (PBZ) and nurse work zone (NWZ), in control and study groups. Values are mean (SD).

Zone	Anaesthetic agent	Control group	Study group	p
PBZ	Sevoflurane	3.52 (2.26)	0.41 (0.22)	< 0.001
	Desflurane	9.06 (5.97)	0.74 (0.41)	< 0.001
NWZ	Sevoflurane	1.12 (1.11)	0.26 (0.13)	< 0.001
	Desflurane	1.96 (1.24)	0.39 (0.17)	< 0.001

Twenty-minute mean (SD) levels (ppm) of sevoflurane and desflurane in the PBZ and NWZ in control groups 1 and 2 are shown in Table 2. There was a significant difference in recorded sevoflurane and desflurane concentrations between control groups at the NWZ.

Median (IQR [range]) volatile agent concentrations in the PBZ and NWZ on arrival, and at 10 min and 20 min after arrival, in the recovery room are shown in Figs. 2 and 3, respectively.

Using ISO-Gard after sevoflurane anaesthesia, the 20-min mean PBZ and NWZ levels were 88% and 77% lower than recorded in the control group, respectively. Using ISO-Gard after desflurane anaesthesia, the 20-min mean PBZ and NWZ levels were 92% and 80% lower than recorded in the control group, respectively.

Mean waste anaesthetic gas levels in the PBZ exceeded the NIOSH-recommended 2 ppm exposure limit in 50 out of 60 (83%) control group patients and 7

Table 2 Twenty-minute levels (ppm) of sevoflurane and desflurane, in the patient breathing zone (PBZ) and nurse work zone (NWZ), in control groups 1 and 2. Values are mean (SD).

Zone	Anaesthetic agent	Control group 1	Control group 2	p
PBZ	Sevoflurane	3.03 (1.53)	3.87 (2.67)	0.356
	Desflurane	8.31 (5.88)	10.43 (6.14)	0.339
NWZ	Sevoflurane	0.61 (0.23)	0.49 (1.35)	0.043
	Desflurane	1.59 (0.92)	2.62 (1.50)	0.045

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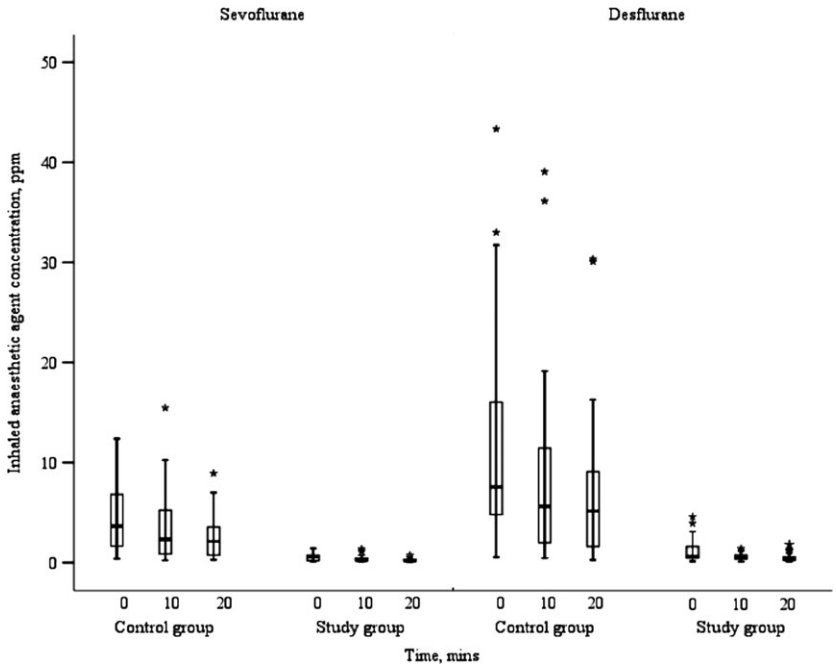

Figure 2 Median (IQR [range]) volatile concentrations in the patient breathing zone on arrival, and at 10 min and 20 min after arrival, in the recovery room. Asterisks denote outliers.

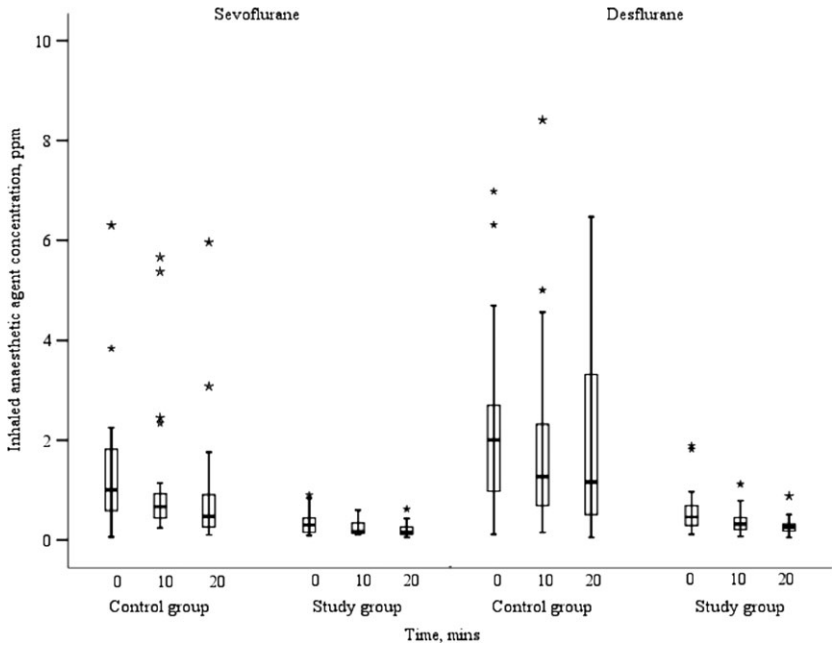

Figure 3 Median (IQR [range]) volatile concentrations in the nurse work zone on arrival, and at 10 min and 20 min after arrival, in the recovery room. Asterisks denote outliers.

out of 60 (12%) study group patients on first measurement in the recovery room, and in 38 out of 60 (63%) and 0 out of 60 (0%) patients after 20 min, respectively.

Mean waste anaesthetic gas levels in the NWZ exceeded the NIOSH-recommended 2 ppm exposure limit in 20 out 60 (33%) control group patients and 0

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out of 60 (0%) study group patients on first measurement in the recovery room, and in 14 out of 60 (23%) and 0 out of 60 (0%) patients after 20 min, respectively.

Discussion

Our results indicate that the ISO-Gard mask is effective at reducing environmental exposure among healthcare workers to exhaled sevoflurane and desflurane in the recovery unit, compared with standard use of a non-scavenging oxygen mask. The ISO-Gard mask reduces the level of these agents below the recommended maximum exposure limit in > 85% of patients within ~ 20 s of application, as shown by the minimal concentrations of volatile measured at time zero for the study group.

Our findings are broadly similar to those of McGlothlin et al.'s. [12], but demonstrate an increased scavenging effect with the ISO-Gard mask, possibly due to either our use of higher oxygen flow rates (6 $l.min^{-1}$ vs. 4 $l.min^{-1}$) and suction pressures (40 mmHg vs. 30 mmHg), and/or our practice of extubating patients' trachea in theatre rather than in the recovery unit. Transition of the extubated patient may have diluted the exhaled anaesthetic agents we recorded en route. McGlothlin et al. did not specify median operation duration, which is an independent predictor of volatile anaesthetic washout, complicating any further comparison.

Desflurane levels were higher than sevoflurane. Pharmacokinetically, desflurane undergoes more rapid washout owing to its lower blood/gas partition coefficient (0.42 for desflurane, 0.65 for sevoflurane). However, because of its higher minimum alveolar concentration (MAC) (5.8% for desflurane, 2.0% for sevoflurane), there are more desflurane particles than sevoflurane particles required for a given level of anaesthesia. Ambient air analysers measure numbers of particles, so higher desflurane levels may not correlate with an increased potential for harm. If exposure limits are deemed necessary, it should be determined which agents at what levels cause which effects, and limits for specific agents should be set.

We noted that the ISO-Gard mask was as well tolerated as standard oxygen masks, with similar number of exclusions in both groups for reasons of mask removal or application of suction.

We did not randomly allocate patients to either the study or control groups, which is a potential limitation of our study. Sequential cohort allocation (control group 1, study group, control group 2) was chosen as the most practical methodology because staff required specific training for the ISO-Gard mask, and we expected compliance and compliance to remain highest early after training. Our use of a second control group (reporting similar results to the first control group) appears to confirm that the ISO-Gard mask achieved results similar to those that we have reported, rather than any change in practice as a result of the additional training. Furthermore, the relatively long duration of each study phase reduced the likelihood of bias due to casemix, personnel and/or practice changes.

In conclusion, our study indicates that the ISO-Gard mask reduces the level of exhaled sevoflurane and desflurane below recommended maximum exposure limits near > 85% of patients after tracheal extubation within ~ 20 s of application in the recovery unit after surgery. Based on these findings, we would encourage the use of an ISO-Gard mask to minimise the occupational exposure of recovery staff to exhaled volatile agents.

Acknowledgements

The spectrophotometer rental was paid for by Teleflex, the manufacturer of the ISO-Gard mask. The ISO-Gard masks used in the study were provided free of charge. To ensure there was no potential conflict of interest beyond the MIRAN hire, a medical student employed by neither Teleflex nor Salford Royal NHS Foundation Trust performed the measurements. The study protocol was devised independently from Teleflex, after careful appraisal of the previous pilot study [12]. No other external funding or competing interests declared.

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