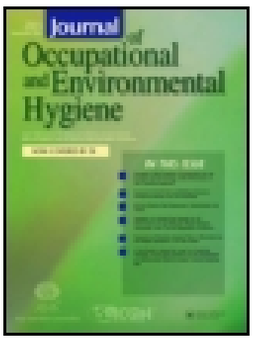

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Assessment of occupational exposure to airborne chlorine dioxide of healthcare workers using impregnated wipes during high-level disinfection of non-lumened flexible nasoendoscopes

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ABSTRACT

Routine flexible nasoendoscopy in otolaryngology clinics is well established, the rate-limiting step of which being the speed of the nasoendoscopes reprocessing method used. Non-lumened flexible nasoendoscopes are expensive, heat-sensitive, delicate instruments that cannot be sterilized in an autoclave but must be disinfected by means of high level disinfection (HLD). In one of the public hospitals in Singapore, the method of disinfection was recently changed to the use of commercial impregnated wipes which generates less than 1% chlorine dioxide upon activation. An exposure assessment was performed to assess the potential exposure of healthcare workers (HCWs) to airborne chlorine dioxide during nasoendoscope disinfection. A total of fourteen long-term personal samples, four short-term personal samples and sixteen long-term area samples were collected over eight days in midget impingers containing 0.02% potassium iodide in sodium carbonate/sodium bicarbonate buffer during the nasoendoscope disinfection. The samples were then analyzed by ion-chromatograph. The chlorine dioxide concentrations and upper confidence limit at 95% confidence level ($UCL_{95\%}$) for personal and area samples collected were all below the occupational exposure limits (OEL) for chlorine dioxide (Singapore workplace Safety and Health PELs, ACGIH TLVs, U.S. OSHA PELs). The study presented evidence that the exposure of HCWs to chlorine dioxide during high-level disinfection of flexible nasoendoscopes were deemed insignificant.

INTRODUCTION

Flexible nasoendoscopy as a routine, quick and simple procedure in outpatient clinics of Otolaryngology Departments is well established. Reprocessing of the nasoendoscope is required between patients to minimize cross-contamination and iatrogenic infection. The rate-limiting step in the use of these instruments is the speed of the reprocessing method used. With its costly, heat-sensitive and delicate attributes, non-lumened flexible nasoendoscope cannot be sterilized in an autoclave but must be disinfected by means of high level disinfection (HLD).

In the Otolaryngology Outpatient Clinics of a public hospital in Singapore, a three-step process involving Cidex OPA (ortho-phthalaldehyde), a high level disinfectant had been used for reprocessing heat sensitive reusable semi-critical medical devices. However, due to the health hazard concerns from open handling of the aqueous solution and longer turnaround time (average 20 min) for the reprocessing of the non-lumened flexible nasoendoscopes, Cidex OPA was replaced in 2017 by commercial citric acid-impregnated non-wovened wipes.

To perform HLD of nasoendoscopes, two measures of activator foam comprising 100% sodium chlorite[(1)] would be pumped onto the citric-acid impregnated non-wovened wipe, which would be scrunched together in 15 sec for activation. As a result, less than 1% chlorine dioxide[(2)] was generated. The activated wipe would be used to wipe the entire surface areas of the pre-cleaned nasoendoscope until it has been fully covered with the <1% chlorine dioxide. After a 30-sec contact time, a rinse wipe is used to wipe and rinse off the residue on the nasoendoscope.

Chlorine dioxide is a greenish yellow to orange gas at room temperature with a characteristic pungent chlorine-like odor.[(3)] Despite the absence of reliable quantitative human

data, the main health effect in relation to occupational exposure to chlorine dioxide is irritation of the respiratory tract, skin and eyes.[3]

An independent study had been conducted by the manufacturer to assess the safety of use of the commercial wipes. In the study, three simulated cleaning cycles at hourly intervals were carried out with each cycle consuming five activated wipes.[4] There was no forced ventilation within the room during the cleaning cycle, but the room was ventilated for approximately 5–10 minutes between each cycle by natural ventilation.[4] A personal sample and an area sample had been taken during the trial and both samples were each tested with a chlorine dioxide concentration of 0.01 mg/m^3 (0.004 ppm) at an 8-hr time-weighted average.[4]

Though the study conducted by manufacturer indicated personal exposure and ambient chlorine dioxide level when using activated wipes were at 4% of the OEL, it was conducted in a setting that differed from its use in Otolaryngology Outpatient Clinics in several aspects: exposure patterns, ventilation conditions, and room setting, as these clinics are sited at basement level with general ventilation instead of natural ventilation. Hence, an air monitoring was conducted to assess the potential exposure of HCWs to chlorine dioxide during HLD of non-lumened flexible nasoendoscopes in a hospital setting.

In this paper, the term “nasoendoscope” refers to non-lumened heat-sensitive flexible nasoendoscope and “nasoendoscope disinfection” refers to disinfection of non-lumened heat-sensitive flexible nasoendoscope with HLD.

METHODS

Observation of the nasoendoscope disinfection was performed to identify procedures where HCWs were potentially exposed to chlorine dioxide. HCWs were then interviewed to obtain information on their exposure profiles for chlorine dioxide and those performing similar tasks were allocated to the same group that was known as similar exposure group (SEG). The information gathered was used to develop the sampling strategy for air monitoring of chlorine dioxide. Prior to the commencement of air sampling, the air change rates of all affected consultation rooms where nasoendoscope disinfection was performed were rebalanced from 4 to 30 air change per hr (ACH) to 12–19 ACH.

In developing the sampling strategies, workers were assigned to different SEGs identified for the occupational exposure to chlorine dioxide during the nasoendoscope disinfection. Two SEGs with the highest estimated exposure risk for chlorine dioxide were prioritized for the personal monitoring.

a. Type I nursing staff who performed nasoendoscope disinfection in consultation rooms
b. Type II nursing staff who assisted physicians in the affected consultation room while nasoendoscope disinfection was performed by type I nursing staff

Based on the developed sampling strategy, the following samples were collected (Figure 1):

a. 11 long-term personal samples on type I nursing staff (30% population);
b. 3 long-term personal samples on type II nursing staff (10% population);
c. 4 short-term personal samples on type I nursing staff (10% population);
d. 8 long-term area samples next to the source of chlorine dioxide (42% affected consultation rooms); and

e. 8 long-term area samples on consultation table located approximately 1.5 m away from the source of chlorine dioxide (42% of affected consultation rooms)

Long-term samples were collected for a duration of at least 80% of the HCW's average daily work duration (10 hr) where 8–17 cycles of nasoendoscope disinfection was performed, while short-term samples were collected for 15 min where only one cycle of nasoendoscope disinfection was performed. One activated wipe was used for each cycle of disinfection. There was no window in the affected consultation rooms. However, there was general ventilation in the affected rooms, and most of the long-term personal and area samples were collected with the affected room doors opened.

Samples were collected and analyzed according to Occupational Safety and Health Administration (OSHA) Method ID-202, in which both the personal and area samples were collected in midget impingers containing 0.02% potassium iodide in sodium carbonate/sodium bicarbonate buffers at an average flow rate of 0.2 L/min via battery-operated portable air pumps (Gilian GilAir-5, Sensidyne, LP, St. Petersburg, Florida).[5] For personal samples, the inlets of the tubing attaching to the midget impinger samplers were placed on the shoulders in the HCWs' breathing zones. Area samples were collected at approximately 1.5 m from the ground next to the wash basin where nasoendoscope disinfection was performed; and at approximately 0.8 m from the ground on the consultation table where physician was providing consultation to patient. Before and after the sampling, the air flow rates of all the air sampling pumps were measured with a Defender 510 Medium BIOS International calibrator (Mesa Labs, Inc., Butler, New Jersey) and the difference of the air flow rates were all within the range of ± 5%.

The samples were collected and analyzed by a laboratory accredited by the Singapore Accreditation Council (SAC) under Singapore Accreditation Council-Singapore Laboratory

Accreditation Scheme (SAC-SINGLAS). SAC's Mutual Recognition Arrangement (MRA) partners included but not limited to Asia Pacific Laboratory Accreditation Cooperation (APLAC) and International Laboratory Accreditation Cooperation (ILAC).[6] Both APLAC and ILAC were also MRA partners of American Industrial Hygiene Association (AIHA) Laboratory Accreditation Programs, LLC.[7,8] Ion Chromatography analysis was performed on all the collected samples according to OSHA Method ID-202. A 10-hr or 15-min time weighted average concentration in parts per million (ppm) was then calculated as the sample result.

For quality assurance (QA) and quality control (QC) purposes, daily field blanks amounting to 10% of total number of sample collected daily were collected using unused midget impinger samplers without the aid of sampling pump. Reagent blanks, calibration checks, method quantitation limit (MQL) checks, and matrix spike checks were also included. All field blanks, reagent blanks and quality control checks were then analysed using the same analysis method.

There were two approaches used to characterize the exposure level of HCW to chlorine dioxide during the nasoendoscope disinfection.

First Approach

The first approach was the direct comparison of the sample results (X_i) with the 0.1 ppm time-weighted average occupational exposure level (OEL) for chlorine dioxide as stipulated in the following:

a. Singapore Workplace Safety and Health (General Provisions) Regulation, First Schedule: Permissible Exposure Levels of Toxic Substances;

b. American Conference Governmental Industrial Hygienists (ACGIH) Threshold Limit Value (TLV); and
c. Occupational Safety and Health Administration (OSHA) Permissible Exposure Limit.

The short-term (15-min) exposure limit for all three exposure limit guides for chlorine dioxide was 0. 3 ppm.

As the HCWs monitored worked for an average of 10 hours daily, the $OEL_{8\ hours}$ was adjusted to $OEL_{10\ hours}$ using the Brief and Scala model[9] as shown below:

$$Daily\ Reduction\ Factor = \frac{8}{h} \times \frac{(24-h)}{16}, where\ h = Total\ work\ duration\ in\ hour \quad \textbf{(1)}$$

$$Adjusted\ OEL_{10\ hours} = OEL_{8\ hours} \times DailyReduction\ Factor \quad \textbf{(2)}$$

If the fractional proportion of sample results (X_i) to $OEL_{10\ hours}$ was more than 1, the exposures of HCWs to chlorine dioxide were classified as non-compliance.

Second Approach

In this paper, the term "non-detects" was used to represent sample results (X_i) of less than Method Quantitation Limit (MQL). A bounding method was used to account for non-detects where they were replaced by randomly selected values from a uniform distribution between zero and the detection limit.[10, 11] Summary statistics (sample mean and sample standard deviation) were computed and recorded. A total of 10,000 bounding iterations were performed for each data set.

$$Sample\ mean, \bar{X} = \frac{1}{n}\sum_{i=1}^{n} X_i\ , where\ n = sample\ size \quad \textbf{(3)}$$

$$Sample\ standard\ deviation, s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(X_i - \bar{X})^2} \quad \textbf{(4)}$$

The summary statistics were used to compute 95% upper confidence level (UCL_{95}%) based on the Chebyshev Inequality with no distributional assumption.[10, 11]

$$UCL_{1-\alpha} = \bar{X} + \sqrt{\frac{1}{\alpha} - 1\left(s/\sqrt{n}\right)} \quad \textbf{(5)}$$

If the fractional proportion of the largest $UCL_{95\%}$ to $OEL_{10\ hours}$ was more than 1, the exposures of HCWs to chlorine dioxide were classified as non-compliance.

RESULTS

The results of the personal and area samples collected were summarized in Table 1. All long-term personal and area samples collected were less than the 0.001 ppm MQL; except for one personal sample monitored on type I nursing staff (0.003 ppm); and one personal sample monitored on type II nursing staff (0.002 ppm). Short-term personal samples were all less than the 0.03ppm short-term MQL. All results were below 10% of OEL for chlorine dioxide (Adjusted $OEL_{10\ hours}$ = 0.07 ppm; $OEL_{Short\text{-}term}$ = 0.3ppm) as stipulated in the Singapore PEL, ACGIH TLV and US OSHA PEL.[12,13]

The $UCL_{95\%}$ ranged from 0.0013ppm to 0.0036ppm for all long-term personal and area samples and was 0.052ppm for all short-term personal samples. The fractional proportions of $UCL_{95\%}$ to $OEL_{10\ hours}$ computed were all less than 1.

For QA and QC analysis, all field blanks and reagent blanks were tested to be less than the MQL. The recoveries for calibration checks, MQL checks and matrix checks ranged from 80.0% to 99.6%.

DISCUSSION

As the results and $UCL_{95\%}$ of the personal samples monitored on type I and type II nursing staff with the highest estimated exposure risk level were all below the OELs, it suggested that the potential exposure levels for the other SEGs – physician and housekeeper groups, presumably, were also below the short-term and long-term OELs. The prediction of physician's exposure to chlorine dioxide below the OELs was substantiated by the results of the area samples collected on the consultation table where physician was sitting at while nasoendoscope disinfection was performed by type I nursing staff in the same room.

Despite the fact that all results were below the OELs, one of the personal samples on type II nursing staff was found to have relatively higher result (0.002 ppm). That could be attributed to her close proximity to the nasoendoscope disinfection activity during monitoring. Individual variability in performing nasoendoscope disinfection could be a factor that contributed to the relatively higher result (0.003 ppm) of another personal sample on type I nursing staff. The personal exposure was expected to be relatively higher if the task was performed in close proximity to the breathing zone.

Apart from the insignificant exposure of HCWs to chlorine dioxide in the short-term and full-shift samples, the area sample results below the MQL also suggested that the ambient concentration of chlorine dioxide in the affected consultation rooms was insignificant.

Chlorine dioxide is unstable and degrades rapidly in air to chlorine gas and oxygen.[14] In view that chlorine gas is also very reactive and will not remain in the environmental media for long periods of time,[15] only chlorine dioxide was monitored in the study. With the consideration of the short half-life for chlorine dioxide, air samples were taken near the point of generation,[14]

which is near the nasoendoscope disinfection activity, for the achievement of a more conclusive result.

Due to the facts that the proportion of non-detects was high (67–100%), the sample size was small (n = 3–11), and the distributions of the data sets might have been altered when the non-detects were replaced by randomly selected values, the bounding method and non-parametric Chebyshev Inequality method were adopted in the computation of $UCL_{95\%}$.[10, 11]

In accordance with ANSI/ASHRAE/ASHE Standard 170, the minimum total ACH for function of endoscope cleaning was 10 ACH.[16] Hence, the well ventilated affected consultation rooms with air change rates (12-19 ACH) higher than the standard during air sampling could be an essential factor contributing to the insignificant chlorine dioxide exposure levels.

The air monitoring conducted did not completely characterize the exposures of all HCWs, especially over time, as it only provided a snapshot of the exposures of HCWs to chlorine dioxide in the Otolaryngology clinics. For other workplaces with similar activity performed, the facility would have to consider the current air monitoring results with any future results. In addition, the operating conditions including room layout, ventilation rates, and product usage may be unique to the sampling period.

The study characterizing the exposure of HCWs to chlorine dioxide could also be applied to other commercial disinfectants of different formulation that might generate similar by-products. Some examples of these commercial disinfectants are citric acid or hydrochloric acid solution that generate less than 1% chlorine dioxide upon activation by 100% sodium chlorite solution.[17-20]

CONCLUSIONS

HCWs were exposed to airborne chlorine dioxide at concentrations of less than the recommended exposure limits, both short-term and full-shift, during high-level disinfection of non-lumened flexible nasoendoscopes. Hence, it was concluded that the exposures of HCWs to chlorine dioxide during nasoendoscope disinfection in the short and long run were deemed insignificant. The study also presented evidence that the ambient air in the affected consultation room was not significantly contaminated by the chlorine dioxide generated during the nasoendoscope disinfection.

RECOMMENDATIONS

Despite the insignificant exposure of HCW to chlorine dioxide during nasoendoscope disinfection, refresher training was recommended to reinforce HCWs with the proper skills to perform nasoendoscope disinfection, which included performing the task away from breathing zone. For any future refurbishment of any room where nasoendoscope disinfection was performed, the air change rate of the room was recommended to be 10 ACH or higher, preferably, to provide allowance for the reduced ACH over time as a result of wear and tear of air-conditioning and mechanical ventilation (ACMV) system.

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FIGURE

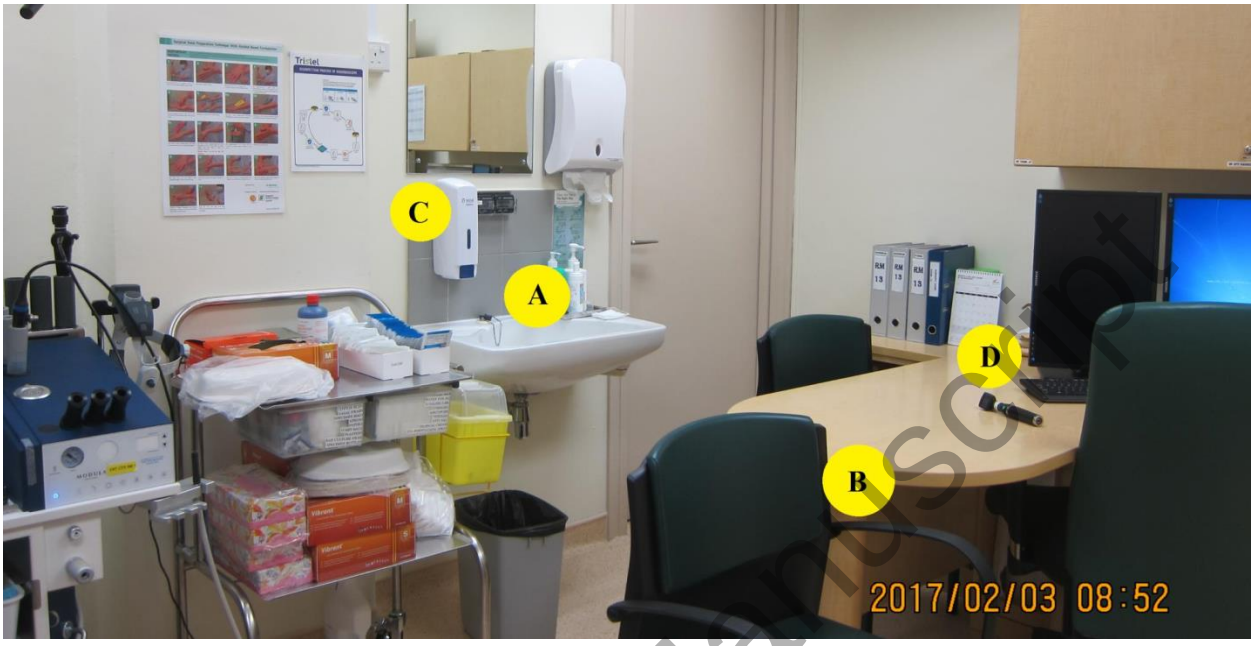

Figure 1. One of the sampled consultation rooms.

A – Personal monitoring point for type I nursing staff
B – Personal monitoring point for type II nursing staff
C – Area monitoring point next to nasoendoscope disinfection activity
D – Area monitoring point on consultation table (approximately 1.5m away from the nasoendoscope disinfection activity

TABLE

Table 1. Characteristics of air samples for chlorine dioxide from consultation rooms of a public hospital in Singapore.

Type of Sample	Job Task Involving Chlorine Dioxide	Sampling Location	Number of Samples	Maximum Concentration[A], ppm	$\frac{Maximum\ Concentration_B}{OEL}$	$UCL_{95\%}$, ppm	$\frac{UCL_{95\%}C}{OEL}$
Personal (Long-term)	HLD	-	10	<0.001	<0.015	0.0019	0.027
		-	1	0.003	0.043		
Personal (Long-term)	HLD with assistant physician in room	-	2	<0.001	<0.015	0.0036	0.051
		-	1	0.002	0.029		
Personal (Short-term)	HLD	-	4	<0.03	<0.010	0.052	0.173
Area (Long-term)	-	Next to dinsinfection	8	<0.001	<0.015	0.0013	0.019
Area (Long-term)	-	Physician's consultation table	8	<0.001	<0.015	0.0013	0.019

[A]Maximum time-weighted average concentration of airborne chlorine dioxide over a 10-hour work shift or 15-minute short-term sample

[B]Fractional proportion of maximum concentration to occupational exposure level (OEL), where $OEL_{Long\text{-}term\ (10\ hours)}$ = 0.07ppm; $OEL_{Short\text{-}term}$ = 0.3 ppm

[C]Fractional proportion of 95% upper confidence level of airborne chlorine dioxide concentration to either the $OEL_{Long\text{-}term\ (10\ hours)}$ = 0.07 ppm or $OEL_{Short\text{-}term}$ = 0.3 ppm