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SCIENCE

CHLORINE DIOXIDE HIGH-LEVEL DISINFECTANT WIPES: A PUBLISHED DATA REVIEW*

THIS RESEARCH DOCUMENTS IN-USE EFFICACY AS REPORTED IN PUBLISHED SCIENTIFIC LITERATURE. OTHER TOPICS EXPLORED INCLUDE MATERIAL AND DEVICE COMPATIBILITY, SPEED OF BACTERICIDAL AND SPORICIDAL ACTIVITY, TOXICOLOGY AND HEALTH ECONOMICS FOR THE END USER. THIS SUMMARY IDENTIFIES THE USE OF THE TRISTEL SPORICIDAL WIPE AS A HIGH-LEVEL DISINFECTANT.

*Argent, F. (2018) 'Disinfection of non-lumened endoscopes: review of published data on a chlorine dioxide high-level disinfectant wipe', *Polish Association Of Nurses In Epidemiology*, no. 1, vol. 72, pp. 35-38.

STUDY IN SUMMARY

BACKGROUND: ENDOSCOPES ARE WIDELY USED FOR THE DIAGNOSIS AND TREATMENT OF CLINICAL DISORDERS. AS ENDOSCOPES COME INTO CONTACT WITH MUCOUS MEMBRANES, HIGH-LEVEL DISINFECTION IS REQUIRED AFTER PATIENT USE. METHODS FOR DISINFECTION INCLUDE AUTOMATED AND MANUAL PROCESSES.

AIM: TO ASSESS THE EVIDENCE OF A CHLORINE DIOXIDE HIGH-LEVEL DISINFECTANT WIPE'S SUITABILITY TO DISINFECT NON-LUMENED ENDOSCOPES.

METHODS: A REVIEW WITH A THREE-STEP SEARCH STRATEGY WAS USED TO IDENTIFY PUBLISHED ARTICLES. INTERNET SEARCH ENGINES WERE USED TO SOURCE MATERIAL COMPATIBILITY AND TOXICOLOGY DATA.

Non-lumened endoscopes are designed to speed up the diagnosis of medical disorders and are also used to provide treatment. Currently, more than 20 million endoscopic procedures are performed annually in the United States alone[1]. Upon entry to the body endoscopes are contaminated with the natural human flora, and other potentially more sinister microorganisms, that can possess antibiotic resistance. Inappropriate methods of disinfection have been responsible for life threatening infections[2] and even death[3]. Reprocessing using steam sterilisation is not possible due to most non-lumened endoscopes being heat-sensitive, therefore high-level disinfection (HLD) with chemicals is required. One of the available methods is a chlorine dioxide disinfectant wipe. This paper presents a review of evidence to determine if HLD with a chlorine dioxide wipe is a suitable method for non-lumened endoscopes.

METHODS

The aim of the review was to assess literature with the specific objective of identifying evidence that a chlorine dioxide wipe can provide broad antimicrobial efficacy; rapid activity; material compatibility; lack of toxicity to humans and the environment; and cost savings.

Search strategy: A three-step search strategy was used to identify published studies.

First Step: An initial search of ScienceDirect and Google Scholar was undertaken to identify keywords in titles, abstracts and index terms used to describe articles.

Second Step: A second search, using the keywords and index terms was repeated in these databases. The following search words were used:

- High-level disinfection, decontamination, disinfectant(s), cleaning, reprocessing
- Disinfection guidelines
- High-level disinfectant wipe(s), chemical wipes
- Chlorine dioxide sporicidal wipe, sporicidal wipe, chlorine dioxide, chlorine
- Infection control
- Nasendoscope disinfection, nasendoscope, nasopharyngoscope, nasoendoscopy, flexible nasal endoscope, otolaryngology, endoscope, laryngoscope, flexible laryngoscope, transoesophageal echocardiography probe, gastrointestinal endoscopy
- Heat-sensitive ENT endoscopes
- Ear nose and throat, ENT
- Sporicidal activity, mycobactericidal activity
- Guideline

Third Step: The reference lists of all identified reports and articles were searched for additional studies. To determine the validity and plausibility of the articles, the PROMPT criterion was used (Table 1.)

The material compatibility of the chlorine dioxide wipe with non-lumened endoscopes was evaluated by searching the websites of the following brands of manufacturers:

- BK Ultrasound
- Karl Storz
- Pentax
- Philips
- Siemens
- Sonosite Fujifilm
- Toshiba
- Verathon

RESULTS AND DISCUSSION

The search identified 19 relevant studies, 16 of which were subsequently retrieved and reviewed for further assessment.

Of the studies found, one evaluated the disinfection capability of the chlorine dioxide wipe versus an automated procedure[4], two studies[5,6] compared the chlorine dioxide wipe with a manual soaking procedure and one[7] study compared the chlorine dioxide wipe with both automated and manual procedures.

Evidence demonstrated the chlorine dioxide wipe provided equivalent efficacy to both manual soaking and automation in disinfection capability. For those studies where microbiological swabs were taken post disinfection in clinic, any positive cultures were deemed to stem from improper handling of endoscopes or contamination in the sampling procedure[6,7]. One study in which only the chlorine dioxide wipe was evaluated provided similar results.

TABLE 1: SELECTION AND EVALUATION PROCESS FOR INCLUDED PAPERS.

PRESENTATION	Is the information clearly communicated? Evaluate the language, writing style, structure and layout.
RELEVANCE	Does the information match the required needs? Look at the introduction or overview – what is it mainly about?
OBJECTIVITY	Is the author's position of interest made clear? Do the writers state their position on the issue? Is the language emotive? Are there hidden/vested interests?
METHOD	Is it clear how the data was collected? Were the methods appropriate? How much data is there? Is the sample representative? Are there sources of bias?
PROVENANCE	Is it clear where the information has come from? Can you identify authors or organisations? Are they well known? How was it published?
TIMELINESS	Is it clear when the information was produced? Does the date of information meet your requirements? Is the information obsolete?

All microbiological swabs from the tip of the endoscope (n=31) and handle (n=31) after disinfection were negative for growth. Only after storage and transportation three swabs returned positive for staphylococcal growth on the handle, concluded by the authors to be representative of contamination from the user[8].

One study was found assessing the mycobactericidal activity of the wipe. The method used was a modified version of the European Standard prEN 14563 carrier test with test organism Mycobacterium avium. This organism was chosen as environmental and patient isolates have shown to be particularly resistant to chlorine dioxide. Activity, determined as a reduction by a factor of 10^4, was shown after 30 seconds and 60 seconds with and without mechanical action, respectively[9]. Another study assessed the sporicidal and bactericidal activity of the wipe. A nasendoscope was artificially contaminated with these organisms and 3 g/L organic soiling. A reduction by a factor of 10^5 for bacteria and a reduction of 10^3 for spores was shown after 30 seconds contact time[5].

There was some evidence of user acceptability in respect to odour strength during disinfection. In a study comparing the chlorine dioxide wipe to soaking with peracetic acid and disinfection within an endoscope reprocessor using an ortho-phthalaldehyde solution, the wipe had the highest percentage of undetectable smell (55.6% versus 14.8% for automation, none for peracetic acid) as reported by nurses[7].

Cost considerations have been reported by four studies comparing the chlorine dioxide wipe to automated and soaking procedures. One study concluded that over a ten year period, the use of an automated reprocessor was only cheaper than the chlorine dioxide wipe when four endoscopes are decontaminated in each cycle. Costs pertaining to repair, electricity, water bills and extra staff for transportation were not taken into account[4]. Hitchcock et al. (2016) reported that the chlorine dioxide wipe is the only disinfectant with no capital outlay cost (versus automation and soaking) and overall per disinfection procedure is the most cost effective[7]. A 2006 study by Street et al. found a cost saving of £3145 per month when using the chlorine dioxide wipe versus a disposable sheath[10]. Sowerby and Rudmik (2017) conclude that using a chlorine dioxide wipe was most cost effective when up to 22 disinfection procedures a week are performed versus automation with peracetic acid, ortho-phthalaldehyde or soaking with hydrogen peroxide[11].

Disinfection of endoscopes with chlorine dioxide or the chlorine dioxide wipe was found in six guidelines and one journal[12,13,14,15,16,17,18]. The literature originated from the UK, Europe and America.

Human and environmental toxicity data on chlorine dioxide was found on the ECHA website under the 'Table of harmonised entry in Annex VI to CLP' section. Chlorine dioxide is classified as an Acute Toxicity Category 3, Skin Corrosive Category 1B and Aquatic Acute Category 1[19]. Regulation (EC) No 1272/2008 of the European Parliament and of the council of 16 December 2008 on CLP of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 states the concentration limit for Acute Toxicity Category 3 and Aquatic Acute Category 1 is $\geq 0.1\%$. For Skin Corrosion the limit is $\geq 1\%$[20]. No data in the published studies found in this review stipulated the concentration of chlorine dioxide in the wipe, however Isomoto et al. (2006) comment that activity against Mycobacterium and Bacillus spores is achieved with a chlorine dioxide concentration of 0.003%[21]. It is not expected that levels of chlorine dioxide higher than $\geq 1\%$ are in the wipe, as mycobacteria and bacterial spores are regarded as some of the most resistant microorganisms to disinfectants[22].

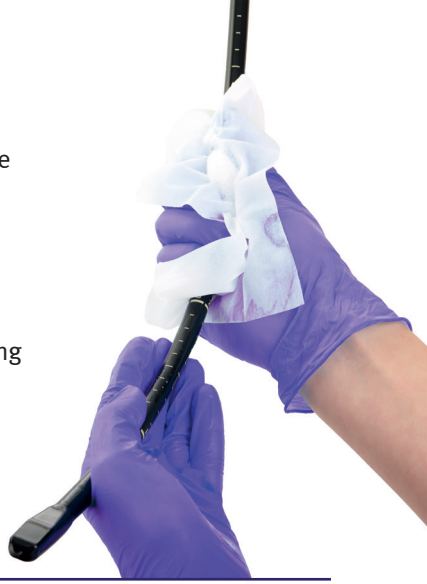
Material compatibility data was difficult to navigate and source from manufacturers websites. From those searched, compatibility was identified from BK Ultrasound, Karl Storz, Philips, Siemens, Toshiba and Verathon. As endoscopes share similar properties in terms of materials of construction and design it is expected that the compatibility data found in this review is largely underestimated. Only a small selection of endoscope manufacturers were searched for in this review.

FINDINGS: 16 RELEVANT STUDIES WERE INCLUDED FROM INTERNATIONAL GUIDELINES AND PEER REVIEWED SCIENTIFIC LITERATURE. THERE WAS EVIDENCE OF THE WIPE'S ABILITY TO PROVIDE EFFICACY, COMPATIBILITY, RAPID ACTION AND COST SAVINGS.

CONCLUSIONS: HIGH-LEVEL DISINFECTION WITH A CHLORINE DIOXIDE WIPE PROVIDES A SUITABLE ALTERNATIVE TO HIGH-LEVEL DISINFECTION WITH AUTOMATED AND SOAKING PROCEDURES.

CONCLUSION

In conclusion, this review has provided a narrative synthesis of the literature available on the chlorine dioxide wipe. Published articles have provided evidence demonstrating the wipe is as efficacious as automated and manual soaking systems[4,5,6,7], can provide cost savings in comparison to the use of sheaths, automated or soaking systems where relevant[4,7,10,11], and provides broad and rapid activity, killing organisms in 30 seconds[4-10]. The limited review of toxicological data confirms that concentrations of chlorine dioxide ‹ 0.1% are not acutely toxic, aquatically toxic or skin corrosive[20]. Compatibility with the wipe was found in six leading endoscope manufacturers although this data is expected to be largely underestimated. The data found within this review indicates that a chlorine dioxide wipe is a suitable method for the high-level disinfection of non-lumened endoscopes.



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