International Journal of Otorhinolaryngology and Head and Neck Surgery
Gan YJ et al. Int J Otorhinolaryngol Head Neck Surg. 2018 Jan;4(1):18-23
http://www.ijorl.com
pISSN 2454-5929 | eISSN 2454-5937

Original Research Article

DOI: http://dx.doi.org/10.18203/issn.2454-5929.ijohns20175607

Flexible nasoendoscopy decontamination: a comparison between Rapicide and Tristel wipes, a prospective cohort study

Yijin Jereme Gan, Alex Mathews, Phua Chuqin, Ivan Khoo, David Loke*

Department of Otolaryngology, Khoo Teck Puat Hospital, Singapore

Received: 09 May 2017
Revised: 01 October 2017
Accepted: 03 October 2017

***Correspondence:**
Dr. David Loke,
E-mail: loke.david.kt@alexandrahealth.com.sg

ABSTRACT

Background: The current disinfection of nasoendoscopes in our clinic setting is a 3-step process involving Rapicide, a peracetic acid based disinfectant. Our study aimed to validate the efficacy of Tristel wipes, a chlorine dioxide based disinfectant, as a comparable alternative.
Methods: We recruited a hundred volunteers undergoing routine flexible nasoendoscopic examinations in a general ENT. We used two separate endoscopes for each examination, following which a microbiological swab was sent from the tip of each nasoendoscope. The two nasoendoscopes were then subjected to a similar 3-step decontamination process except for the second step, where they were disinfected either tristel wipes or rapicide disinfectant. After decontamination, we took a second swab from the tip of each nasoendoscope.
Results: Out of 200 swabs from the tip of the nasoendoscopes prior to decontamination, there were 82 positive cultures for the Rapicide cohort and 76 positive cultures for the Tristel wipes cohort. Regarding the post decontamination results, there were four positive swab cultures for those disinfected with Tristel wipes and one positive swab culture for the Rapicide cohort. These were analyzed by the Z score and there was no statistical difference between either the pre-decontamination swabs or the post decontaminations swabs with the p-values at p=0.298 and p=0.174 respectively. The efficacy of decontamination for the Rapicide solution was 98.8% compared to 94.7% for the Tristel wipes with p=0.147.
Conclusions: This study validates the efficacy of Tristel wipes as a comparable alternative to peracetic acid based disinfectants for disinfection of flexible nasoendoscopes.

Keywords: Nasoendoscope, Decontamination, Tristel wipes, Peracetic acid, Rapicide

INTRODUCTION

The regular use of flexible nasoendoscopes in Otolaryngology departments is well established. They are routinely used in both the inpatient and outpatient setting to examine the upper aero digestive tract. Flexible nasoendoscopes are expensive, heat sensitive and delicate instruments. They are significantly different from other endoscopes as they are shorter, thinner and do not have an internal channel. Reprocessing is required to prepare the scope for reuse in the next patient. Inadequate decontamination may lead to cross-contamination and iatrogenic infection in subsequent patients.[1] Many disinfectant guidelines have been written to address the respiratory and digestive tracts but far fewer have been written for the disinfection of flexible nasoendoscopes.

The Spaulding classification classifies medical equipment based on the risk of infection depending on their usage.[2] They can be divided into critical, semi-critical or non-critical devices. Given that flexible nasoendoscopes have contact with intact mucosal membrane surfaces, they are

classified under semi-critical devices. Depending on how medical equipments are classified, they are then subjected to various levels of disinfection. Sterilization requires the destruction of all microbial life, including bacteria and their endospores, mycobacteria, viruses, fungal spores, and parasites. High-level disinfection refers to the destruction of all vegetative microorganisms, mycobacteria, viruses, fungal spores, and some but not all bacterial endospores. Whereas low-level disinfection refers to the destruction of most bacteria, some viruses, and fungi but not all endospores or mycobacterium. Given that flexible nasoendoscopes fall into the category of semicritical devices, they should be subjected to high-level disinfection at a minimum, after each use.

Three common methods in which high-level disinfection can be achieved are immersion in liquid high-level disinfectants, automated endoscope re-processors and disposable endosheaths.[3]

The current disinfection practice for nasoendoscopes in our clinical setting is a 3-step process involving Rapicide PA, a peracetic acid base as the disinfectant solution. This is in concordance to the ENT UK published guidelines in 2005 to outline the practical steps in which one should adhere to when decontaminating nasoendoscopes.[4] They describe a four-step procedure with the last step being a step for transportation which we have excluded in this setting as we reuse the scopes for the next patient within the same clinic. In 2006, the NHS Health and Safety classified disinfecting agents into different hazard classes, of which peracetic acid was a Class C (medium hazard) disinfecting agent. Comments were made of it damaging of copper alloys in automatic preprocessors and a strong odour of acetic acid, which may be unpleasant.[5]

A recent study in the UK validated the 'in use' efficacy of tristel wipes system in 2012, a chlorine dioxide based disinfectant, in the cleaning of flexible nasoendoscopes in preventing bacterial transmission in a clinic setting.[6] The tristel wipes system is a 3-part system that kills all organisms on a pre-cleaned surface in 30 seconds.[7] It is known to be easy to use and more economic than endoscope sheaths.[6] The health and safety executive of the NHS illustrated that Tristel wipes is the safer disinfectant, Class A (low hazard), when compared to Rapicide PA.[5] Additionally as a portable system, it is useful in an inpatient setting without access to disinfecting facilities.

The current study aimed to evaluate the efficacy of tristel wipes as a comparable alternative to peracetic acid based disinfectants.

METHODS

This study was conducted from January 2014 to December 2014 at Khoo Teck Puat Hospital at the ENT Clinic. We recruited 100 patients who were scheduled to be examined with the nasoendoscope for various ENT conditions in our clinic. Inclusion criteria were any patient that was planned for a nasoendoscopy. Pregnant women and patients under the age of 21 were excluded from our study. Volunteers were subjected to a standardized flexible nasoendoscopic examination. Two separate endoscopes were used for each examination, one through each nasal cavity. A swab was sent from the tip of each nasoendoscope once the procedure was completed to be used as the control. The two nasoendoscopes were then subjected to a similar 3-step decontamination process. The first step was done with a multizyme solution. For the second step, one scope was placed in Rapicide PA for 20 minutes and the other was cleaned with the Tristel wipes per the manufacturer's guidance. Lastly, both were then washed with distilled water. A second swab was taken from the tip of each nasoendoscope after decontamination and sent for cultures (Figure 1).

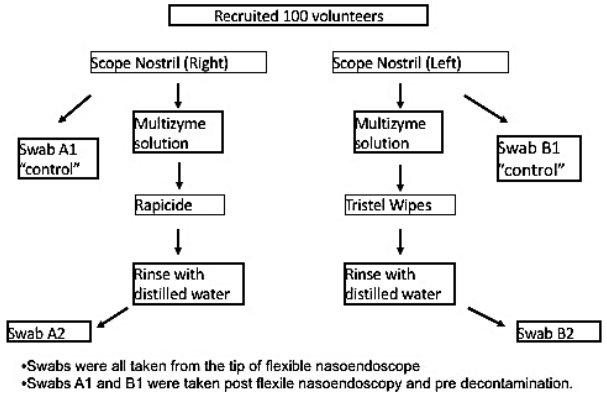

Figure 1: Methodology.

The flexible nasoendoscopy and all the cleaning episodes were performed by either one of two clinicians fully trained in the practice of nasoendoscope decontamination as per the manufacturer's instructions. The swabs were sent to our microbiology lab and their origins were blinded from the microbiologist. These swabs were broken off into a tube of 0.85% saline (1.5 ml) and vortexed for 30s. They were then inoculated on TSA sheep blood agar plate with a 10ul loop and incubated at 35 degrees Celsius in normal air incubators for 7 days and read each day.

We used a Z score as recommended by our institution's independent statistician to test our hypothesis.

Ethical considerations

This study was approved by the National Health Group Domain Specific Review Board, application number 2014/00264. Firstly, informed consent from all volunteers was taken in a private room by the principal or co-investigators before proceeding with the study. Secondly, the subject's participation was completely voluntary. Thirdly, this is a relatively safe study as aside from the standard co-phenylcaine spray pre-nasoendoscopy, no

other medications were administered to the patient. The flexible nasoendoscopy is a very commonly practiced procedure in otolaryngology with minimal side effects. In addition, we enrolled patients only if there was an indication to do a nasoendoscope. Lastly, regarding security of information, all subjects were assigned a number which can only be identified in the hardcopy excel sheet. The hardcopy was kept in the ENT office, under lock and key. All collected data were de-identified and stored in an excel file. These data were password protected and were only available to the study investigators.

RESULTS

The volunteers recruited had a mean age of 40.9 years (SD±15.8). There were 62 males and 38 females. The patients recruited had flexible nasoendoscopy performed for a variety of clinical diagnosis including allergic rhinitis, obstructive sleep apnoea to inflammatory causes like sinusitis (Table 1).

Table 1: Demographics (N=100).

Characteristics	Number
Age	
Mean (years)	40.99
SD	15.8
Sex	
Male	62
Female	38
Diagonisis	
Allergic rhinitis	19
Laryngopharyneal relux/ Larygeal pathology	19
Inflammatory	14
OSA	12
Head and neck related	11

A total of 400 swabs were performed. Out of the 200 control swabs taken from the tips of the nasoendoscopes prior to decontamination, we grew 82 positive cultures prior to cleaning with Rapicide solution and 76 positive cultures prior to cleaning with tristel wipes. These outcomes were analyzed using the Z score (Z=1.042) and the difference between either was not considered to be statistically significant, p=0.298 with p<0.05 to be statistically significant. With regards to the 200 post-decontamination swab culture results, there were 4 positive culture swabs for those disinfected with tristel wipes and 1 positive culture swab for the Rapicide cohort. These outcomes were analyzed using the Z score (Z=1.359) and the difference between either was not considered to be statistically significant p=0.174 (Table 2).

Table 2: Number of positive cultures swabs.

	Categories	Positive cultures	Percentage (%)
1	A1- pre-decontamination cultures (Rapicide)	82/100	82
2	A2- post-decontamination cultures (Rapicide)	1/100	1
3	B1- pre-decontamination cultures (Tristel)	76/100	76
4	B2- post-decontamination cultures (Tristel)	4/100	4

Table 3: Bacteriology (pre-decontamination swabs).

Organisms grown	No. (Right)	No. (Left)
***Staph* species**	67	63
Diptheroid bacilli	26	27
Strep species	7	3
Klebseilla pneumonia	8	2
***Cornybacterium* species**	7	9
Moraxella	1	1
Escherichia coli	1	-
Citrobacter	3	2
Enterobacter	3	5
Rothia	1	1
Proteus	1	-
Haemophillus	-	1

In terms of bacteriology of the control swabs from the pre-decontamination nasoendoscopes, the three most common organisms were *Staphylococcus* species, *Diptheroid bacilli* and *Streptococcus* species (Table 3). These are common commensals identified in the nasal cavity and pharynx of healthy subjects.[8]

Table 4: Positive cultures of post-decontamination swabs and their respective growths pre-decontamination.

Diagnosis	Pre-decontamination cultures (Rapicide)	Post-decontamination cultures (Rapicide)
Hemoptysis	*Staph. aureus*	*Staph aureus; Staph epidermidis*
Diagnosis	**Pre-decontamination cultures (Tristel)**	**Post-decontamination cultures (Tristel)**
Hemoptysis	No bacterial growth	*Staph. epidermidis; Strep. viridans*
Obstructive sleep apnoea	*Diptheria bacilli*	*Diptheria bacilli; Staph hemolyticus*
Septal ulcer	*Staph. aureus*	*Diptheria bacilli; Staph. hemolyticus*
Nasopharyngeal cancer post treatment follow up	No bacterial growth	*Staph. epidermidis; Strep. viridans*

Table 5: Efficacy.

	No growth post-decontamination swab/total positive pre-decontamination swab	Efficacy (%)
Rapicide solution	81/82	98.8
Tristel wipes	72/76	94.7

Concerning the post-decontamination swabs, the only positive culture swab growth from the Rapicide cohort grew *S. aureus* and *S. epidermidis* from a pre-decontamination swab with growth of *S. aureus*. With regards to post-decontamination swabs of Tristel wipes cohort out of four positive cultures, two of which had previously no bacteria growth for the pre-decontamination swab (Table 4). The positive cultures were for nasopharyngeal commensals.

Following which, we analyzed the efficacy of Tristel wipes and Rapicide solution, which we termed as the number of positive growth cultures eradicated (the cultures that had no growth) over the total positive pre-decontamination growth swabs. The efficacy of Rapicide solution was 98.8% compared to 94.7% for the Tristel wipes cohort. These were analyzed using the Z score (Z=1.451) and the p=0.147 suggesting no significant difference between the 2 decontamination solutions (Table 5).

DISCUSSION

Improper disinfection of nasoendoscopes can lead to increased risk of disease transmission and spread of nosocomial infection. Although only a few published reports have documented disease transmission associated with flexible nasoendoscopy, the increasing prevalence of methicillin resistant *S. aureus* (MRSA) in the community as well as the threat of MERS-CoV virus only serve to emphasize the need to reprocess these semicritical instruments with care.[1,9] Flexible endoscopes are heat sensitive and therefore cannot be sterilized in an autoclave but must be disinfected. Cavaliere and Iemma in 2012, published guidelines for reprocessing of ENT endoscopes and classified Tristel wipes as an emerging system of high-level disinfection.[10] The benefits of Tristel wipes are its rapid turnaround time and being safe from a health standpoint as it is nontoxic and nonirritating. Immersion methods do carry certain disadvantages notably the possible damage to endoscopes, the risk of errors or forgetfulness on the part of operators and the duration of the disinfectant times.

Concerning cost comparison, the Rapicide PA solution is more economical when compared to Tristel as each set of solution can be used for 14 days, providing the minimum recommended concentration is kept constant. This minimum concentration is tested via daily test strips. Two sets of solution including the daily test strips will cost about S$260 for a 14-day duration.[11] Whereas each use of Tristel wipes set, cost about S$7.50. Considering we may scope up to 40 patients per morning clinic session, this may cost about S$300 in one morning. Interestingly, our study did show that it may be possible to replace the first and third wipe of the Tristel wipes system with multizyme solution and sterile water respectively without compromising the result. Hence, this may allow Tristel wipes to be more cost competitive as we may only need to use the sporicidal (chlorine dioxide based) wipe out of the set of three which cost S$3.60.

However, Tristel wipes does have a few important advantages. Firstly, being a portable system, it can be brought to the emergency department or to the wards. This is important as even though most of ENT patients are outpatients, those that are inpatients often may be carriers of MRSA, vancomycin-resistant *Enterococci* (VRE) or even tuberculosis. Secondly, it takes about 2 to 3 minutes for decontamination with Tristel compared to the 15-minute turnaround time that Rapicide requires.[7] This difference is significant given the fast turnaround time we have in the ENT setting and the number of naeoendoscopes we have in our inventory given its costs is usually a limiting factor.

In 2004, Bhattacharyya and Kepnes illustrated that soaking flexible nasoendoscopes in High Level disinfectant- Cidex solution (2.5% glutaraldehyde) for 20 minutes was successful in eradicating bacteria contamination and hence cross contamination between patients.[12] Phua et al via a sequential in vivo study compared the efficacy of Chlorine dioxide wipes and automated washer and found that there was no statistical difference between them.[13] Tzanidakis et al illustrated that tristel wipes is a viable alternative in a clinical setting for flexible nasoendoscopy decontamination.[6] Most recently Hitchcock et al showed that Tristel wipes are equal to Perasafe and Cidex OPA in terms of microbiological efficacy.[14] From our study, given the efficacy of Rapicide solution was 98.8% compared to 94.7% for the Tristel wipes cohort with a p value of 0.147 suggesting no significant difference between the 2 decontamination solutions, we do believe that Tristel wipes is a viable alternative to high level disinfectants. We do note that there were four positive cultures post decontamination on the Tristel wipes cohort and one positive culture post decontamination from the Rapicide cohort. We believe the positive cultures post decontamination are likely due to improper handling of the nasoendoscopes post decontamination rather than a result of inadequate disinfection. We postulate that the nasoenedoscopes may have inadvertently touched the sink or surrounding objects post decontamination, which

would have resulted in these positive cultures. Although proper hand hygiene was observed, the use of new non-sterile gloves during the reprocessing of scopes may have also been a contributing factor. This can only emphasize the need to be meticulous in decontamination of nasoendoscopes.

We do note that there are a few limitations with our study. Firstly, given our sample size of 100 patients with a total of 400 pre-and post-decontamination swabs, it is still lacks sufficient power to detect a significant difference between the two disinfecting methods. Although the study numbers were small, the results are encouraging, as it showed no significance difference between the two respective cohorts in terms of post decontamination positive cultures or efficacy. Hence, providing further evidence that Tristel wipes may be a viable alternative to high-level disinfectants.

Secondly, we were unable to test the scopes for mycobacterium, viral or parasitic contamination due to the limitations of our grant funding. An ideal study would require each virus to be tested specifically. We do indeed acknowledge that virus transmission does pose a cross-infection risk and this is a potential area to be addressed in the future. Also, given the incidence rate of tuberculosis of 40.5 per 100,000 in Singapore in 2012 we should consider this aspect of potential mycobacteria cross-infection as well.[13] In the prior study by Tzanidakis et al, the investigators did test for mycobacteria from the tip of scopes post decontamination from Tristel wipes but they did note that swabs for mycobacteria are suboptimal for detection.[6] In the future, we will also be looking to test the scopes in a clinical setting on how well both Tristel wipes and high-level disinfectants eradicate multi-resistant bacteria strains like methicillin-resistant *S. aureus* and *vancomycin-resistant enterococcus*.

Lastly, we did not take a pre-decontamination and post decontamination swabs from the handles of the nasoendoscopes for a variety of reasons. Firstly, the handle of the scope is not directly involved in or in direct contact with the patient hence, we did not think this was necessary. Secondly, this was previously analyzed by Tzanidakis et al which illustrated that post Tristel wipes decontamination there were no organisms cultured from the handles of the scopes.[6] They do note however, that staphylococcus species was cultured from the handles of three scopes between cleaning and application on the patient suggesting this was likely due to a nosocomial source. Thirdly, we were limited by our grant funding. Lastly, but more importantly, according to the manufacturer's guidelines, we do need to clean the scope starting from the handle to the tip. Hence, the handle should be the cleanest of portion of the scope.

CONCLUSION

This study validates the efficacy of Tristel wipes as a comparable alternative to peracetic acid based disinfectants for disinfection of flexible nasoendoscopes. Tristel wipes being a more portable and faster system compared to high-level disinfectants, does provide us with a more convenient and ergonomic alternative. Furthermore, this study suggests that to bring down the cost of the Tristel trio wipe system, it is possible to use only the sporicidal (chlorine dioxide based) wipe coupled with a multizyme solution and sterile water. We would also like to highlight there is a need to be meticulous in each step of disinfection of the nasoendoscopes regardless of the type of disinfection used.

ACKNOWLEDGMENTS

We will like to thank Alexandra Health for providing the enabling grant which covered the costs of the study. The authors have no financial interest to disclose.

We will like to thank Mr. Duncan Stuart and his team from the microbiology department in Khoo Teck Puat Hospital for being ever so supportive of this study.

Funding: This study was funded by the Alexandra Health Enabling grant
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Gan YJ, Mathews A, Chuqin P, Khoo I, Loke D. Flexible nasoendoscopy decontamination: a comparison between Rapicide and Tristel wipes, a prospective cohort study. Int J Otorhinolaryngol Head Neck Surg 2018;4:18-23.