A randomised single-blind comparison of the effectiveness of the high-level disinfectants Tristel Wipes (chlorine dioxide), Cidex OPA (ortho-phthalaldehyde) and Perasafe (peracetic acid/peracetyl ions) for use with flexible nasoendoscopes

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Interests to Declare

- This study was funded by Tristel through Tauranga Clinical School
- We have received grants to present at this conference
Flexible nasoendoscopes in otolaryngology require a high level disinfection that is:

- Safe
- Affords rapid turnover
- Not destructive to nasoendoscopes
- Cognisant there is no working port in nasoendoscopes
Introduction

- Currently there is no uniform decontamination system
- Worldwide tendency to eliminate risk of cross infection
- Tendency to opt for central decontamination – the most expensive option
Hypothesis

The study hypothesis is that Tristel Wipes and Perasafe are at least as effective and safe as Cidex OPA in clinical use.
High Level Disinfectants - 1

- Cidex OPA (ortho-phthalaldehyde)
High Level Disinfectants - 2

- Tristel 3 part system (Chlorine Dioxide)
High Level Disinfectants - 3

- Perasafe (peracetic acid/peractyl ions)
Study Design

- This was a randomised, single-blind study comparing the high level disinfectants Tristel Wipes, PeraSafe and Cidex OPA.

- Clinics were randomly allocated to 1 of the 3 disinfectants

- Participants were blinded to the disinfectant used

- Evaluation of efficacy was determined by assessing microbiology samples, patient perception, cost-effectiveness, ease of use and safety.
Inclusion/Exclusion

INCLUSION:
- Required diagnostic flexible nasoendoscopy
- Provided written informed consent
- Were 18 years old on the day of consent

EXCLUSION:
- Known to be allergic to topical cophenylcaine spray or any of the disinfectants to be used in the study
- Current or recent treatment with antibiotics
- Nasal surgery in the last 6 months
Patient Population

- 377 participants screened
- 203 participants randomised
- 100 males and 103 females with a mean age of 57.1 years
- 8 participants incomplete
Microbiology Protocol

All Scopes:

- Immediately after disinfection prior to use of the nasoendoscope on a study participant the tip and the shoulder of the nasoendoscope was swabbed and sent for culture.
Microbiology Protocol

Cidex Equipment Process:
- Pre and post clinic swabs of the Cidex OPA Medivator were taken from the exit port and from the inner rim of the lid.

Perasafe Equipment Process:
- Post clinic swabs were taken from the bottom of the cylinder when the solution was emptied at the end of the clinic.
Results
## Microbiology Efficacy Endpoints

In total 541 samples \([203 \times 2 + 4 \times 27 + 27]\) swabs and samples were taken for microbiology.

<table>
<thead>
<tr>
<th>Chemistry Used</th>
<th>Sample Description</th>
<th>Organism Grown</th>
<th>Relevance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tristel</td>
<td>Tip &amp; Shoulder of Nasoendoscope</td>
<td>No Growth</td>
<td></td>
</tr>
<tr>
<td>Cidex</td>
<td>Inner rim of Mediator Lid</td>
<td>Pseudomonas species isolated</td>
<td>Likely environmental organism of low pathogenic potential.</td>
</tr>
<tr>
<td>Cidex</td>
<td>Tip of Nasoendoscope</td>
<td>Light growth of Coagulase negative staphylococcus</td>
<td>Skin commensal of low pathogenic potential</td>
</tr>
<tr>
<td>Cidex</td>
<td>Inner rim of Mediator Lid</td>
<td>Light growth of Coagulase negative staphylococcus</td>
<td>Skin commensal of low pathogenic potential. Possibly due to inadequate exposure to disinfectant at this site of the mediator.</td>
</tr>
<tr>
<td>Perasafe</td>
<td>Shoulder of Nasoendoscope</td>
<td>Light growth of Stenotrophomonas maltophilia</td>
<td>Environmental organism of low pathogenic potential, except in immunocompromised patients. Inherently quite a resistant organism to Antibiotics.</td>
</tr>
<tr>
<td>Participant</td>
<td>Agent</td>
<td>Event</td>
<td>Outcome</td>
</tr>
<tr>
<td>-------------</td>
<td>-------</td>
<td>----------------------</td>
<td>------------</td>
</tr>
<tr>
<td>124</td>
<td>Perasafe</td>
<td>Rhinorrhea</td>
<td>Resolved</td>
</tr>
<tr>
<td></td>
<td>Perasafe</td>
<td>Epiphora</td>
<td>Resolved</td>
</tr>
<tr>
<td></td>
<td>Perasafe</td>
<td>Head pressure</td>
<td>Resolved</td>
</tr>
<tr>
<td></td>
<td>Perasafe</td>
<td>Epistaxis</td>
<td>Resolved</td>
</tr>
<tr>
<td>146</td>
<td>Perasafe</td>
<td>Metastatic Carcinoma</td>
<td>Death*</td>
</tr>
<tr>
<td>158</td>
<td>Perasafe</td>
<td>Nasal discharge</td>
<td>Resolved</td>
</tr>
<tr>
<td>186</td>
<td>Perasafe</td>
<td>Dysphagia</td>
<td>Lost F/U</td>
</tr>
<tr>
<td>012</td>
<td>Tristel</td>
<td>Rhinorrhea</td>
<td>Resolved</td>
</tr>
<tr>
<td>013</td>
<td>Tristel</td>
<td>Rhinorrhea</td>
<td>Resolved</td>
</tr>
<tr>
<td>104</td>
<td>Tristel</td>
<td>Post nasal discharge</td>
<td>Resolved</td>
</tr>
<tr>
<td>177</td>
<td>Tristel</td>
<td>Nasal discomfort</td>
<td>Resolved</td>
</tr>
</tbody>
</table>
Patient Comfort

- Patient Perception of the comfort of the procedure, using a 10cm visual analogue scale (VAS)
  - Immediately following nasoendoscopy
  - 3-7 days post nasoendoscopy

![Graph showing comfort levels post scope for Cidex_OPA, PeraSafe, and Tristel immediately after and 3-7 days after.](image)
Ease of disinfection

- A 5-point Likert rating scale was used by the nurses to rate the ease of use of the disinfection system on each study day.
The strength of any odour detected during the disinfection.
Capital Cost

This is the one off purchase cost this does not include any equipment maintenance.

<table>
<thead>
<tr>
<th>Agent</th>
<th>Equipment</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cidex</td>
<td>Medivator</td>
<td>$76,106.25</td>
</tr>
<tr>
<td>Perasafe</td>
<td>Cyclinder &amp; Jug</td>
<td>$227.00</td>
</tr>
<tr>
<td>Tristel</td>
<td>Nil</td>
<td>$0.00</td>
</tr>
</tbody>
</table>
Cost for Disinfectant Cycles

- The cost for Cidex and Perasafe are set regardless of how many scopes are reprocessed due to the expiry of the product as noted in frequency.
- The Tristel cost is only as required as this product has a long shelf life.

<table>
<thead>
<tr>
<th>Disinfectant</th>
<th>Frequency</th>
<th>Cost $NZ</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cidex</td>
<td>Every 14 days</td>
<td>$578.62</td>
</tr>
<tr>
<td>Perasafe</td>
<td>Every 24 hours</td>
<td>$3.79</td>
</tr>
<tr>
<td>Tristel</td>
<td>Each Disinfection</td>
<td>$9.50</td>
</tr>
</tbody>
</table>
Average Time for Disinfection Cycle

The mean cycle time includes preparation time.

Average Cycle Time - minutes

- Tristel: 2.7 minutes
- Persasafe: 14.6 minutes
- Cidex: 27.4 minutes
Conclusion

- No agent proved harmful to patients

- Cidex in an automated endoscopic reprocessor
  - Significantly most expensive agent
  - Slowest to recycle nasoendoscopes

- Tristel Wipes
  - Fastest to recycle nasoendoscopes
  - Low running costs

- Perasafe - soak
  - Intermediate recycling of nasoendoscopes
  - Low running costs
Final conclusion

A rationalisation of the method of flexible nasoendoscopy disinfection is warranted
Danke