

A randomised single-blind comparison of the effectiveness of the high-level disinfectants Tristel Fuse (chlorine dioxide) and Cidex OPA (ortho-phthalaldehyde) for use with flexible cystoscopes

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Summary

The effectiveness of Tristel Fuse was compared with Cidex OPA for high-level disinfection of flexible cystoscopes. The clinical and microbiological efficacy, safety, cost-effectiveness and ease-of-use were compared.

To do this a randomized single-blind study comparing the high level disinfectants Tristel Fuse (Chlorine Dioxide) as a soak and Cidex (ortho-Phthalaldehyde; 1,2 – benzenedicarboxaldehyde) using an automated reprocessor was performed. Participants were blinded to the disinfectant used on the flexible cystoscope prior to use. All patients had a negative mid-stream urine (MSU) at baseline, no symptoms of UTI on the day of investigation, no recent antibiotic use or current indwelling urinary catheter. Patients who underwent a cystoscopic biopsy during the procedure were excluded. MSU analysis before and 3-5 days after, cystoscopy and equipment cultures were performed. The Urogenital Distress Inventory (UDI 6+2), AUA and QoL scores were performed before and after cystoscopy, ease-of-use assessments and a full cost analysis were also done.

A total of 180 participants were randomized 1:1. The mean age overall was 72.1 years, 17% were females and 57% of procedures were performed for bladder tumor surveillance. The MSU was positive in 5.4% of patients in each group and 29% (Tristel) vs. 20% (Cidex) of patients had urinary leucocyturia (p=ns) post-procedure. The turnover (minutes per cycle) was 7.5 (Tristel) vs 26.7 (Cidex). The cost per disinfection was USD11.2 (Tristel) vs. USD75.8 with fixed costs of USD4,553 (Tristel) vs USD57,543 (Cidex).

Tristel Fuse appears to be more cost-effective than Cidex OPA for high-level disinfection of flexible cystoscopes.

Introduction

There are several methods and agents which can be used to provide high-level non-corrosive disinfection of flexible cystoscopes. The first step in cleaning flexible cystoscopes is the removal of all biological material, this is necessary so that the disinfectant or sterilising agent can contact all cystoscopy surfaces. High-level disinfection, rather than sterilisation, is appropriate for cystoscopes as this process kills all organisms, except some bacterial spores which do not pose a risk for patients undergoing cystoscopy².

Tristel Fuse (Tristel Solutions Limited UK) is a high level chlorine dioxide-based disinfecting and sporicidal solution often used for disinfection of flexible cystoscopes. Tristel Fuse is supplied as two solutions (2.1% sodium chlorite and 5% citric acid) in a plastic envelope, separated by a plastic membrane. In preparation for use the membrane is broken and the two solutions mix.

Cidex OPA (ortho-Phthalaldehyde; 1,2 – benzenedicarboxaldehyde) is the standard high-level disinfectant used in many institutions for high level disinfection of flexible cystoscopes. Its risks are known and it has good efficacy. It is an FDA-Cleared High Level Disinfectant with general claims for processing reusable medical and dental devices.

This 'in-use' study evaluated whether Tristel Fuse is as effective as Cidex OPA as a high level disinfectant, following a standardised protocol for cleaning flexible cystoscopes.

Sample size

It was intended to enrol 180 participants in this study. This allowed for approximately 10% of participants not completing the study (not returning for the 3-7 day visit) and so provided a minimum of 80 participants completing the study in each group. This sample was estimated on the basis of showing non-inferiority (not more than 10% worse) of the Tristel Fuse (using the Stella Disinfection System) compared with Cidex OPA with regards to the incidence of MSU detected UTIs. This was based on data that suggested that the rate of UTIs post cystoscopy was between 2-10%⁴. We assumed a post-cystoscopy UTI rate of 2.5% for Cidex OPA, if the rate for Tristel Fuse is 5% or less then there would be an 80% chance that the upper limit on the 95% one-tailed confidence interval of the difference would be less than 10%.

Results

The demographic and other baseline characteristics of the 181 participants are provided by randomised group in the Table.

The primary endpoint was the rate of urinary tract infections as determined by a mid-stream urine test (MSU) 3-7 days post intervention. The difference in the UTI rate between Tristel Fuse and Cidex OPA was -1.4% [95% CI -5.6% to 3.5%], indicating that Tristel Fuse is well within the non-inferiority range of +10% in terms of UTIs.

The microbiology results from the equipment washings are shown in the Table below as the number of positive cultures and the total number of samples taken. Only one positive culture was identified and this was identified as C. Albicans and came from the inner tray rim used for Tristel Fuse.

Methods

The objectives of this study were to compare the effectiveness of Tristel Fuse with Cidex OPA in terms of clinical efficacy, safety, cost-effectiveness and ease-of-use. Outcomes.

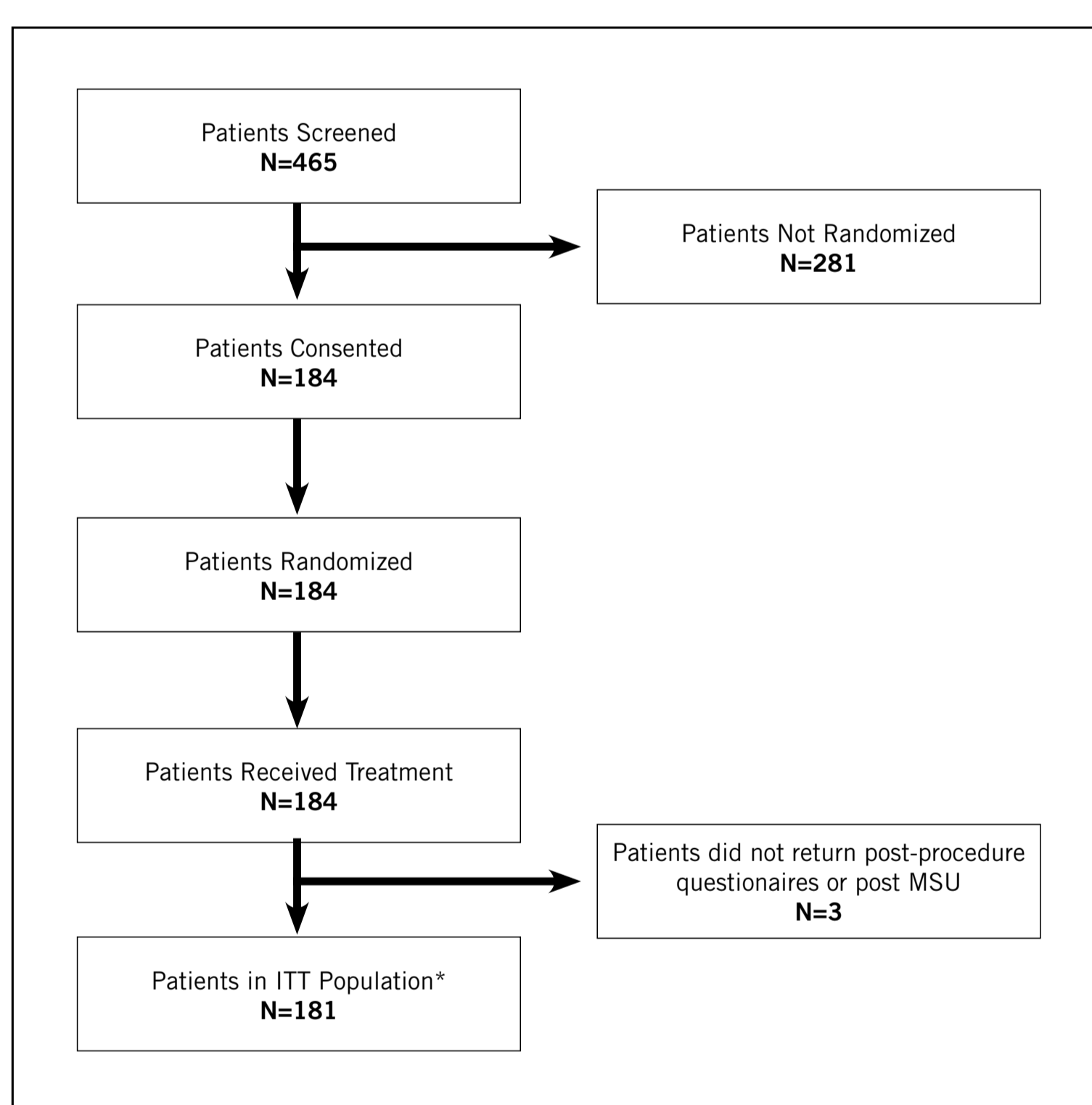
The primary endpoint was the rate of urinary tract infections as determined by a mid-stream urine test (MSU) 3-7 days post intervention in participants who have had flexible cystoscopy with a cystoscope that has been disinfected with either Tristel Fuse (using the Stella Disinfection System) or Cidex OPA.

The secondary endpoints for the comparison include clinical, microbiological, cost-effectiveness, ease-of-use and safety endpoints.

Clinical endpoints were; the Short Form Urogenital Distress Inventory (UDI-6) + 2 questions from the long form addressing the symptoms of Nocturia and Urgency, the American Urological Association Symptom Index (AUA-7) and a single Question Quality of Life Score (QoL). These were assessed on the day of the procedure and 3-7 days afterwards.

Microbiological cultures were grown from equipment samples collected after the first and last disinfection on each Study clinic (as per SNZ HB 8149:2001 Microbiological Surveillance of Flexible Hollow Endoscopes). These samples included sterile washings (10 ml Normal Saline) and sterile brushings of the working channel of the flexible cystoscopes, which were inoculated onto Blood Agar and MacConkey Agar and incubated aerobically. Further samples were taken from the Medivator AER (lid, rinsing solution and entry and exit ports), Stella inner tray and exit port.

Diagram of Patient Disposition



Clinical efficacy outcomes

Clinical efficacy measures	Tristel Fuse		Cidex OPA		p-value
	Pre	Post	Pre	Post	
AUA-7 (Max 35)	11.0 (7.7)	10.8 (8.7)	11.2 (8.3)	11.2 (8.4)	0.684
QoL (Max 6)	2.6 (1.7)	2.3 (1.7)	2.8 (1.7)	2.9 (1.9)	0.087
UDI 6 (Max 18)	5.0 (4.1)	4.9 (4.3)	5.3 (4.4)	5.5 (4.3)	0.582
UDI 2 (Max 6)	2.8 (1.7)	2.7 (1.8)	3.2 (1.8)	3.1 (1.9)	0.749

Microbiology efficacy outcomes

Sample Description	# positive cultures	If positive, specify organism cultured
Washing of cystoscope	0/88	
Brushing of cystoscope	0/88	
Glass lid (Cidex OPA)	0/42	
Rinsing solution (Cidex OPA)	1/21	
Drainage outlet (Cidex OPA)	0/21	
Inner tray rim (Tristel Fuse)	1/46	C. Albicans
Exit port (Tristel Fuse)	0/46	

Table 6 – Timings

Tristel Fuse Timings (n=38)

Item	Mean	Range
Mix components (Sec)	30.9	18 - 40
Add with water and pour(Sec)	60.6	34 - 101
Disinfection cycle(Sec)	290.4	61 - 315
Drain(Sec)	65.7	40 - 298
TOTAL (Mins)	7.5	6.9 – 8.3

Cidex OPA Timings (n=18)

Item	Mean	Range
Test strip (Sec)	31.4	15 - 67
Disinfection cycle (Min)	26.0	25 - 28
TOTAL (Mins)	26.8	25.5 – 27.6

Table 7 – Combined Costs

Disinfection	Fixed Costs	Cost per Disinfection
Tristel Fuse	\$5875	\$14.43
Cidex OPA	\$74250	\$26.77

Table 8 – Nurse and Surgeon ratings

Ease of Use Measure	Tristel Fuse (n=23)	Cidex OPA (n=21)
Nurse		
Ease of Use	4.3 (3 - 5)	3.7 (2 - 5)
Odour	3 (3 - 3)	3 (3 - 3)
Strength of Odour	1.4 (1 - 3)	1.5 (1 - 3)
Surgeon		
Odour	3 (3 - 3)	3 (3 - 3)
Strength of Odour	1 (1 - 1)	1 (1 - 1)

Demographic and Baseline Characteristics

Participant Characteristic	Tristel(n=94)	Cidex(n=97)	Total(n=181)
Gender(M:F)	74:20	74:13	148:33
Age (Mean, range)	72.6 (36-90)	72.3 (43-89)	72.5 (36-90)
Indication* for cystoscopy (S:D)1	55:39	48:39	103:78
Baseline scores: Mean (SD)			
Urinary symptoms AUA-7	11.0 (7.7)	11.2 (8.3)	11.1 (8.0)
QoL	2.6 (1.7)	2.8 (1.7)	2.7 (1.7)
UDI 6	5.0 (4.1)	5.3(4.4)	5.1 (4.2)
UDI 2	2.8 (1.7)	3.2 (1.8)	3.0 (1.7)

Urinary Tract Infections

UTI	Tristel Fuse	Cidex OPA	Total
Positive MSU at Day 3-7 N(%)	3 (3.2%)	4 (4.6%)	7 (3.9%)

Fixed costs

Tristel Fuse

Item	Frequency	Cost SNZ
Cost of Tristel Fuse	Each disinfection	10.00
Stella disinfection tray	Once	5850.00
5L plastic bottle	Once	25.00
Sterile Gloves	Each disinfection	1.03
20ml syringe	Each disinfection	0.27
Tap water	Each disinfection	0.00

Cidex OPA Timings (n=18)

Item	Frequency	Cost SNZ
Cidex test strip*	Daily	2.94
Medivator AER machine	Once	74250.00
Cidex OPA Solution	Every 14 days+	1152.00
Sterile Gloves	Each disinfection	1.03
Ethanol rinse	Each disinfection	0.39

*Tests if current Cidex OPA Solution still valid
 +Or earlier if the Cidex OPA Solution fails testing with test strips



Figure 1: Flexible Cystoscope



Figure 2: Stella Disinfection Tray

Conclusions:

This study confirms that the two high-level disinfectants studied provide microbiological sterilization of flexible cystoscopes when employed following the manufacturers recommendations.

The costs both fixed and per-procedure favoured Tristel Fuse suggesting that this product may be more cost-effective in this setting. Surgeon and nurse data on safety, acceptability and ease-of-use were comparable.