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The use of triclosan eluting stents effectively reduces ureteral stent symptoms: a prospective randomized trial

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Accepted for publication 30 September 2011

Study Type – Therapy (RCT)
Level of Evidence 1b

What's known on the subject? and What does the study add?
Infection, encrustation and ureteral-stent-related symptoms (USRS) including pain, urgency and frequency are all major problems associated with stent use. No current ureteral stent or exogenously applied therapy adequately deals with these problems and antibiotic use is ineffective once a bacterial biofilm forms on the device. Triclosan is a broad spectrum antibacterial agent widely used in numerous healthcare products and has been previously shown to reduce inflammation on the skin and in the oral cavity. This study tested a triclosan-impregnated ureteral stent for its ability to reduce infection, encrustation and USRS.

This study shows that while a triclosan-impregnated ureteral stent cannot reduce infection rates alone compared with antibiotic use, the stent can reduce several USRS including pain during indwelling. This study suggests that the triclosan eluting stent may have a role in treating patients, perhaps in combination with standard antibiotic therapy.

OBJECTIVE

- To evaluate the capacity of triclosan-loaded ureteral stents to reduce stent-associated bacterial attachment, biofilm formation and encrustation, thereby potentially reducing infection development and other device-related sequelae.

PATIENTS AND METHODS

- Twenty subjects requiring short-term stenting (7–15 days) were randomized to receive either a Percuflex Plus® non-eluting stent (control) or a Triumph® triclosan eluting stent.
- Control-stented subjects received 3 days of levofloxacin prophylaxis (500 mg once daily) while Triumph®-stented subjects did not.
- All subjects were assessed for positive urine and stent cultures, stent biofilm development and encrustation.
- Following device removal, each subject completed an analogue-scale symptom assessment questionnaire.

RESULTS

- Ureteral stenting was performed after nine ureteroscopic and one extracorporeal shock wave lithotripsy procedure in the control group and eight ureteroscopic and two shock wave lithotripsy procedures in the triclosan group.
- No significant differences were observed for culture, biofilm and encrustation between the two groups.
- Subjects in the triclosan group reported significant reductions in lower flank pain scores during activity (58.1% reduction, $P = 0.017$) and urination (42.6%, $P = 0.041$), abdominal pain during activity (42.1%, $P = 0.042$) and urethral pain during urination (31.7%, $P = 0.049$).

CONCLUSIONS

- In this study, the use of the Triumph® triclosan eluting stent had no marked impact on biofilm formation, encrustation or infection development in short-term stented patients.
- The Triumph® device led to significant reductions in several common ureteral-stent-related symptoms, supporting its use in this patient population.

KEYWORDS

drug eluting stent, triclosan, stent symptoms, ureteral stent, anti-inflammatory agent

INTRODUCTION

Ureteral stents are a routinely used tool in modern urology, being commonly inserted after ureteroscopy or extracorporeal shock wave lithotripsy to achieve or maintain urinary tract drainage. However, ureteral stent use is a double edged sword, since up to 80% of stented patients complain of bothersome lower urinary tract symptoms and pain [1]. The impact of these ureteral-stent-related symptoms (USRS) in the

patients' quality of life can be considerable, with many reporting lost days at work, sexual dysfunction and a decrease in urinary autonomy. Furthermore, these devices can become encrusted and/or colonized with microorganisms, resulting in blockages, biofilm formation and device-related UTI [2,3]. Once formed, microbial biofilms do not respond to antimicrobials and devices must be removed or replaced for complete infection eradication.

The aetiology of USRS is as yet still poorly understood, with current theories including vesico-ureteric reflux of urine during voiding (occurs in up to 80% of patients) [4], a rise in renal pelvic pressure, or outflow obstruction [5]. However, the incidence of loin pain is not universal in stented patients (19–70%) [6,7] and does not explain several lower urinary tract symptoms such as dysuria, frequency and urgency. Urothelial inflammation in response to a foreign body [8] and mechanical injury of the urothelium via stent movement [9] have been theorized to account for these symptoms, suggesting that USRS on the whole are probably caused by a combination of factors.

Triclosan, a widely utilized antimicrobial compound found in numerous healthcare products, was previously incorporated into a ureteral stent (Triumph®, Boston Scientific, Natick, MA, USA) in an attempt to decrease stent-related UTI and infection-related encrustation. While initial *in vitro* [10] and *in vivo* work using a rabbit model [11] by our group with this stent demonstrated significant antimicrobial activity against numerous uropathogens, a subsequent human trial involving chronically stented subjects (>3 months) showed no improvement in overall positive urine and stent cultures compared with controls [12]. However, an interesting finding of that trial was the fact that patients in the triclosan group had significantly fewer symptomatic episodes and were prescribed significantly fewer antibiotics, despite actually having a greater number of positive urine cultures. Triclosan had previously been shown in multiple *in vitro* studies to exhibit potent anti-inflammatory properties, including work by our group demonstrating its ability to downregulate the expression of several pro-inflammatory cytokines in bladder and kidney cell lines following bacterial and physical challenge [9,13–15]. Ultimately, triclosan's impact as an anti-inflammatory in the human urinary tract and its effects on stent symptoms remain unreported. In this study, we describe the results of a randomized trial involving short-term stented subjects (7–15 days) comparing the triclosan eluting stent to a non-eluting control stent with regard to urine and stent cultures, biofilm and encrustation development, lower urinary tract symptoms and pain.

TABLE 1 Subject baseline characteristics

	Percuflex Plus®	Triumph®
Sex	4 female, 6 male	3 female, 7 male
Age, years (mean)	44	56
Preoperative antibiotics	Cephazolin 1 g (six)	Cephazolin 1 g (one)
	Gentamicin 80 mg (one)	Gentamicin 80 mg (five)
	Levofloxacin 500 mg (one)	Unknown (three)
	Unknown (one)	None (one)
	None (one)	
Stented side	Five left, five right	Eight left, two right
Size of stent, cm (mean)	27.4	27.0
Procedure	Ureteroscopy (nine)	Ureteroscopy (eight)
	ESWL (one)	ESWL (two)
Postoperative antibiotics	Levofloxacin 500 mg – once daily × 3 days	No antibiotics

PATIENTS AND METHODS

STUDY DESIGN

This study was approved by the Research Ethics Board at the University of Western Ontario. Twenty subjects (21 with one exclusion) requiring short-term stenting were enrolled prospectively to compare two ureteral stents for an indwelling period of 1–2 weeks. Subjects were randomized to receive either the triclosan eluting stent (Triumph®: test group) or a non-antimicrobial eluting stent (control stent: Percuflex Plus®, Boston Scientific) (10 per group). Control patients were prescribed prophylactic antibiotic therapy following the insertion of stents while nothing was prescribed for test subjects. Following the removal of every stent, both subject and physician completed a qualitative summary questionnaire regarding symptoms and device-related characteristics, respectively.

STENT PLACEMENT

Immediately prior to stent placement the majority of subjects in both groups received preoperative antibiotics (Table 1). Following insertion, control subjects were prescribed 500 mg once daily oral levofloxacin for the first 3 days of indwelling (postoperative antibiotics), while subjects stented with the triclosan eluting device received nothing as the device is already antimicrobial impregnated.

URINE AND STENT PROCESSING

Midstream urine samples were collected from each subject just prior to both stent placement and removal. Urine samples were sent for culture analysis (Gamma Dynacare Laboratory, London, ON, Canada) and isolated organisms were enumerated, typed and profiled for antibiotic susceptibility. Upon removal, stents were cut into three equal length sections (termed bladder end, ureteral segment and kidney end), placed in sterile saline and processed within 30 min. To assess biofilm formation and encrustation, three representative segments (0.5 cm each) from each section were selected by a blinded technician and air dried. Segments were cut open transversely and total surface material were removed and weighed. To isolate and enumerate stent-adherent organisms, 5 cm segments from each section were placed in 5 mL of saline, sonicated for 10 min to remove attached organisms, vortexed for 1 min at full speed and dilution plated on brain heart infusion agar supplemented with 0.5% yeast extract (VWR, Mississauga, Canada). Stent isolates were sent for identification and standard antibiotic susceptibility testing (Gamma Dynacare).

TABLE 2 Physician stent scores

Stent insertion and removal characteristics		Percuflex Plus® mean (range)	Triumph® mean (range)
Stent insertion	Ease of insertion	4.9 (4–5)	4.9 (4–5)
	Passage over guidewire	4.7 (3–5)	4.9 (4–5)
	Stent deployment	5 (5–5)	4.9 (4–5)
Stent removal	Ease of removal	5 (5–5)	5 (5–5)
	Visible stent colour change	Yes 1, no 9	Yes 3, no 7
	Visible encrustation	Yes 1, no 9	Yes 0, no 10
	Grade of bladder oedema	Mild 9, moderate 1	Mild 8, moderate 2

Numerical scoring range: 1, very difficult; 5, easy.

TABLE 3 Urine and stent culture results CoN, coagulase negative

	Percuflex Plus®	Triumph®
Infected urine at stent removal ($\geq 10^5$ CFU/mL)	3/10 (2/10)*	4/10 (3/10)*
Organisms isolated (urine)	1 CoN *Staphylococcus* sp. 1 *Enterococcus* sp. 1 unknown	1 *Staphylococcus auricularis* 2 *Enterococcus* sp. 1 *Streptococcus viridans* 1 *Lactobacillus* sp. 1 unknown
Infected stents at removal	1/10	1/10
Organisms isolated (stent)	1 *Enterococcus* sp.	1 *Staphylococcus auricularis*

**Not statistically significant using Fisher's exact test (P = 0.50).*

QUESTIONNAIRES

Following the removal of each stent, subjects completed a qualitative summary questionnaire developed at our centre, assessing symptoms typically related to stent indwelling [16]. The questionnaire uses a visual analogue scale to assess flank and lower abdominal pain during rest, activity and urination, urethral pain during urination and urinary urgency and frequency. The attending physician also completed a stent scoring sheet regarding the ease of stent insertion and removal, the presence of visible encrustation, any observed stent colour change and the degree of bladder oedema at removal.

STATISTICAL ANALYSES

Results were analysed via Student's *t* test (questionnaire data, indwelling time) and Fisher's exact test (culturing data, non-parametric) using GraphPad Prism 4 software (GraphPad Software Inc., San Diego, CA, USA). Significance was assessed at $P < 0.05$.

RESULTS

To achieve the desired 20 subjects (10 in each arm) for the study, 21 patients needed to be recruited. The excluded subject was from the control group and was removed due to a failure to provide a post-stenting urine sample. Baseline characteristics for the experimental and control groups are summarized in Table 1. The majority of subjects in both groups were stented following ureteroscopy, and each group had a comparable female to male ratio of subjects. Nine out of 10 subjects in each group received preoperative antibiotics, although the two groups differed in which agent was used most frequently (control, cefazolin, 6/10; triclosan eluting, gentamicin, 5/10).

Physician stent scores are summarized in Table 2. Overall, no significant differences were observed between the groups for stent insertion and removal parameters, as scoring means identified both devices as extremely easy to insert and remove. In the control group, one stent had minimal visible encrustation at time of removal while another demonstrated a slight visible colour change. In the triclosan group, no devices showed any visible encrustation and three demonstrated visible colour changes during indwelling.

All 20 urine samples were negative for microorganisms at the time of stent insertion. Urine samples collected at the time of stent removal were assessed for both the presence of any viable microorganisms and whether that level was considered clinically relevant ($\geq 10^5$/mL) (Table 3). In the control group, three of 10 subjects had positive urine cultures with two of those having detectable bacterial levels above the 10^5 threshold. Four of 10 subjects in the triclosan group had positive cultures with three of them containing levels considered clinically relevant. This difference was found not to be statistically significant ($P = 0.50$). Both groups had one positive stent culture each, with both devices harbouring organisms matching that isolated from the respective subject's urine (Table 3). The predominant organisms isolated from the urine and stent samples of both groups were species of coagulase-negative staphylococci and enterococci. Device encrustation was found to be negligible in both groups, with only one control device harbouring any visible crystalline material. This material was identified as a thin layer localized to several small sections of the bladder curl and did not block any access holes or impact device removal.

USRS are summarized in Table 4. Symptoms were compared between the triclosan and control groups for all 20 study subjects as well as only those subjects with negative urine cultures throughout the study. Overall, the results were fairly consistent with eight of the nine numerical parameters in both analyses showing reduced symptom scores in the triclosan group compared with controls. In the analysis involving all study subjects, four of the six pain categories were significantly reduced in the triclosan eluting stent group, specifically flank pain during

TABLE 4 Patient symptom scores

		All subjects (20)				Subjects with negative urine cultures throughout study (13)			
Patient symptoms		Percuflex Plus® (PP)	Triumph® (TCN)	Per cent reduction (TCN vs PP)	*P* value	Percuflex Plus® (PP)	Triumph® (TCN)	Per cent reduction (TCN vs PP)	*P* value
Flank pain	At rest	3.4 ± 0.8	1.8 ± 0.7	47.1	0.075	3.8 ± 1.0	1.6 ± 0.9	57.9	0.067
	During activity	4.3 ± 0.9	1.8 ± 0.6	58.1	0.017*	4.3 ± 0.9	1.7 ± 0.7	60.5	0.020*
	During urination	5.4 ± 0.9	3.1 ± 0.9	42.6	0.041*	4.9 ± 1.2	3.6 ± 1.2	26.5	0.222
Abdominal pain	At rest	2.7 ± 0.7	2.6 ± 0.7	3.7	0.47	3.2 ± 0.9	2.7 ± 1.0	15.6	0.36
	During activity	3.8 ± 0.6	2.2 ± 0.6	42.1	0.042*	4.0 ± 0.5	2.1 ± 0.9	47.5	0.042*
	During urination	5.2 ± 0.7	5.3 ± 0.8	−1.9	0.44	5.1 ± 1.0	6.2 ± 1.1	−17.7	0.20
Urination	Urethral pain	6.0 ± 0.7	4.1 ± 0.8	31.7	0.049*	6.1 ± 0.9	5.4 ± 1.0	11.5	0.33
	Urgency	5.3 ± 0.8	4.5 ± 1.0	15.1	0.27	5.6 ± 1.0	4.6 ± 1.5	17.9	0.30
	Frequency	6.0 ± 0.6	4.8 ± 0.7	20.0	0.12	6.4 ± 0.8	5.0 ± 0.9	21.9	0.13
	Gross haematuria	10/10	10/10	0	1.0	7/7	6/6	0	1.0

**Statistically significant using Student's* t *test (*P *< 0.05).*

activity (58.1%, $P = 0.017$) and urination (42.6%, $P = 0.041$), abdominal pain during activity (42.1%, $P = 0.042$) and urethral pain during urination (31.7%, $P = 0.049$). In addition, flank pain at rest was reduced by 47.1% in the triclosan group but this was not significant ($P = 0.075$). Comparisons involving only the 13 subjects (six triclosan, seven control) with negative urine cultures throughout the study showed an overall similar trend of reduced levels in the triclosan group, although the reductions in flank pain at rest and urethral pain during urination were no longer statistically significant. Aside from those two, six of the remaining seven scaled symptoms actually demonstrated even greater reductions in the triclosan group over controls than when all subjects were compared. The only patient symptom found to be higher in the triclosan group at any point during the study was abdominal pain during urination (1.9% and 17.7% higher in the two analyses conducted), although this was also not significant (Table 4). Overall, the data demonstrated that no USRS category was found to be significantly lower in the control group throughout the entire study. Furthermore, during stent indwelling, three subjects in the control group were treated for symptomatic renal colic while no subjects in the triclosan group had similar problems. Finally, all 20 subjects in the study acknowledged visible haematuria at some point during stent indwelling.

DISCUSSION

The most frequent adverse effects reported by patients undergoing ureteral stenting are pain and urinary tract difficulties [1]. These issues are not only bothersome to the patient but can significantly impact their quality of life with lost days at work, urinary leakage and sexual difficulties. While the source of these symptoms is still under debate, possible causes are thought to be related to distension of the renal cavities due to urinary reflux, stent-related dysfunctional urinary drainage and urothelial inflammation [1,2,5,6]. In addition to these common problems, device-related infection and encrustation can occur, with an increasing probability roughly proportional to the length of indwelling time. While novel polymers, coatings and exogenously applied compounds are constantly being developed and tested in attempts to significantly reduce these problems, no ureteral stent currently on the market or externally applied compound has demonstrated any clinically relevant success.

Our group previously developed an *in vitro* model mimicking the impact of an indwelling ureteral stent on the urothelium with regard to physical trauma in both human bladder (T24) and kidney (A498) epithelial cell lines [9]. The data from that study demonstrated that stent movement evokes both local inflammatory and tissue repair mechanisms, mediated by significantly increased levels of interleukin-6 (IL-6), IL-8, tumour necrosis factor α, basic fibroblast growth factor and platelet derived growth factor BB. Interestingly, the addition of triclosan either via elution from a Triumph® stent or added directly in solution resulted in significant reductions in the secreted levels of most of the inflammatory factors listed. This is in agreement with several previous studies outside urology demonstrating triclosan's ability to reduce inflammation on the skin and in the oral cavity [14,15,17,18]. In fact, the anti-inflammatory characteristics of this antimicrobial are one of the main reasons why it is found in a plethora of toothpastes, mouthwashes, soaps and hand sanitizers. Based upon these studies, it is possible that triclosan may provide both antimicrobial and anti-inflammatory benefits to the urinary tract during stenting.

As mentioned in the introduction, a previous clinical trial conducted by our group compared the triclosan eluting stent to a non-eluting control stent in patients requiring chronic stenting [12]. As these patients are widely prone to device infection and encrustation, our primary foci were urine and stent culturing, device-associated biofilm formation and encrustation development. While the triclosan eluting stent was no better than controls in

reducing any of these factors, it was found that subjects in the triclosan group had fewer symptomatic episodes and as a result were prescribed significantly reduced incidences of antibiotics. Based upon this finding, we hypothesized that triclosan may reduce urinary symptoms through its anti-inflammatory properties and increased our focus on this during the current short-term study. Importantly, subjects with the Triumph® device reported significantly lower amounts of multiple USRS and did not present with renal colic at any time during indwelling. When all 20 study subjects were compared, four major symptoms were significantly reduced in the triclosan group while none was in the controls. Furthermore, since the triclosan group did not receive postoperative antibiotics, it is possible that the positive urine cultures in several of this group's subjects may have negatively impacted triclosan's ability to relieve USRS. Therefore, a second analysis was performed using only the data from patients with negative urine cultures throughout the study to see if triclosan's effects were maintained outside of microbial involvement. In this comparison, two of the four symptoms originally identified as significantly reduced in the triclosan group maintained this significance despite the fact that the analysis only involved 13 subjects (six triclosan vs seven controls). Furthermore, four other symptoms had greater reductions in the triclosan group over controls than the analysis involving all subjects, although none was statistically significant. Additional studies involving more patients may further clarify these findings. Finally, urine culture, stent culture and encrustation levels were not significantly different between the two groups, and both devices were equivalent with regard to ease of insertion and removal. It is therefore reasonable to argue that the Triumph® device may offer increased comfort to patients while not compromising other device-related factors associated with stenting.

Several studies have investigated the application of anti-inflammatory, anticholinergic, anaesthetic and analgesic agents for the prevention of USRS [16,19–21]. While several of these agents have led to measurable decreases in the use of pain medication during stenting, the effects have often been limited or only affected a small cohort of patients. A study by Beiko *et al.* [16] found that intravesical instillation of the non-steroidal, anti-inflammatory ketorolac decreased flank pain at rest at 1 h after stent insertion. This was followed by a controlled trial using a ketorolac eluting stent that appeared only to impact the use of pain medication in a small subset of the studied cohort (male patients younger than 45 years) [19]. Norris *et al.* [20] investigated the application of oxybutynin and phenazopyridine for reducing USRS but found no significant differences for either agent vs controls. Finally, Sur *et al.* [21] examined the submucosal application of the long-acting local anaesthetic ropivacaine in the bladder but, aside from decreased narcotic use at 2 h after stent placement, found no clear differences in pain, frequency or urgency.

Our study is novel in that it is the first to evaluate the impact of triclosan on stent-related bothersome urinary tract symptoms. However, we must acknowledge the limitations of the current trial, namely its small size and inconsistencies in preoperative antibiotic selection and documentation. Furthermore, we did not measure the inflammatory response of subjects through either bladder histology or serum assessment of humoral inflammatory mediators. Thus, we can only hypothesize that the pain reduction observed in the triclosan eluting stent group was due to its anti-inflammatory properties. If further corroborated by larger and multicentric trials, our findings could represent an effective form of USRS control in patients requiring ureteral stenting, such as those undergoing surgical or endourological procedures.

STUDY LIMITATIONS

A significant limitation of the present study is the lack of an additional patient group containing subjects receiving both the triclosan eluting stent and postoperative antibiotics. Such a group would have enabled the separation of triclosan's potential antimicrobial and anti-inflammatory effects during short-term stenting and potentially provided insight into whether triclosan could reduce stent-related infections and/or clinical symptoms when used in conjunction with oral antimicrobials.

ACKNOWLEDGEMENTS

Geoffrey Wignall and Mrinal Dhar recruited multiple subjects.

CONFLICT OF INTEREST

Ben H. Chew and John D. Denstedt are Consultants for Boston Scientific Corporation Inc. (BSCI). This work was supported by a research grant from BSCI, which had no direct input into the recruitment, data collection and analysis, or preparation of the paper.

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Abbreviation: **USRS**, ureteral-stent-related symptoms.