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The Effectiveness of UroShield in Reducing Urinary Tract Infections and Patients' Pain Complaints: Retrospective Data Analysis from Clinical Practice

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ABSTRACT

Objective: Antibiotic resistance is a common complication in long-term urinary tract infections (UTIs). Alternative treatments, such as UroShield acoustic wave technology prevents bacteria from attaching to the surface of catheters and has reduced the number of treated UTIs. The objective of the study was to compare quantitative and qualitative outcomes in patients with long-term UTIs at the start of UroShield treatment and after a 12-week trial.

Methods: 23 patients with reoccurring UTIs were offered to use UroShield for a period of 12 weeks. Objective and subjective measures of improvement were recorded every week, including the number of UTIs, antibiotic treatment, catheter blockage and changes, bladder washout, hospitalisations or nurse visits due to UTIs, level of pain, sleep, and mobility. The patients' qualitative reports about the device were recorded. The ongoing study started in 2018.

Results: Wilcoxon signed ranks non-parametric test and thematic analysis were used to detect changes in UTIs and self-reported measures of pain and ease of wear. Patients reported a significant decrease in the number of UTIs and antibiotic treatment after a 12-week use of the Uroshield device ($p < .001$ and $p = .009$, respectively). Similarly, they had fewer catheter blockages and catheter changes ($p = .006$ and $p < .001$, respectively). Bladder washouts did not decrease over time. The pain was mild to moderate at the start of the trial which reduced significantly by the end of the trial ($p = .017$). Qualitative analysis confirmed the impact of the device on patients' well-being, but an expanded study is needed to confirm these results. Further improvements to the device hardware have been identified by the patients.

Conclusions: UroShield reduced the number of UTIs, catheter blockages and changes, and consequently the need for antibiotics. Patients reported the device is easy to use, were related to little to no pain, and overall improved patients' well-being and mobility. We suggest the device should be considered as an appropriate treatment in long-term persistent UTIs.

Keywords: Antibiotics; Antimicrobial resistance blockages; Catheter changes; Effectiveness; Pain; Preventative healthcare; Thematic analysis; Urinary tract infections; Uroshield

INTRODUCTION

A total of 150 million people worldwide are affected by urinary tract infections (UTIs) making it one of the most common bacterial infections [1]. UTIs are more common in women than in men: almost 50% of women will experience at least one UTI in their life while 33% of women will receive antibiotic treatment for a UTI before the age of 24 [2,3]. A prior UTI, sexual activity, vaginal infection, diabetes, obesity and genetic susceptibility have also been identified as significant risk factors [4,5].

UTIs can be categorized as uncomplicated or complicated [6]. Uncomplicated UTIs typically affect healthy individuals that are not afflicted by structural or neurological urinary tract issues [7,8]. Complicated UTIs occur when the urinary tract or host defence are compromised, and are commonly associated with urinary obstruction, urinary retention caused by neurological disease, immunosuppression, renal failure, renal transplantation, pregnancy and the presence of foreign bodies such as calculi, indwelling catheters or other drainage devices [9,10].

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Historically, antibiotics such as trimethoprim sulfamethoxazole, ciprofloxacin and ampicillin have been common treatment options for uncomplicated and complicated UTIs [4]. However, prophylactic antibiotic use is no longer the best course of action as it has been shown to contribute to the development of antibiotic resistant mechanisms [11-13].

Different home remedies have been used to treat and prevent catheter associated UTI (CAUTI), such as the consumption of cranberry products [7,14], methenamine salts [7,15], and a sublingual bacterial vaccine [16,17]. However, most studies on the effectiveness of home remedies are inconclusive or insufficient at best [7,18].

UroShield (NanoVibronix) is a disposable ultrasound device designed to reduce the risk of CAUTI through the reduction of bacterial colonization and biofilm formation on indwelling urinary catheters. It uses surface acoustic wave technology to prevent bacteria attaching to the surface of catheters, which reduces antibiotic resistance and the patient's dose or shortening their treatment course [19]. UroShield was shown to be effective in significantly reducing the number of colony-forming units (CFUs) in patients with indwelling catheters as well as reducing the number of treated UTIs [20-23]. There was also a decrease in catheter-related pain scores in the UroShield group while they increased in the control group [24].

Further replications are needed to establish the effectiveness of UroShield, not just about reducing UTIs, but also its impact on associated issues, such as catheter changes and blockages. The ease of use and patients' feedback has not been recorded to the authors' knowledge and we therefore strived to accompany quantitative measures with qualitative data from the patients' experience.

MATERIALS AND METHODS

Patients

Ideal Medical Solutions (IMS) approached a range of NHS trusts across the UK to offer them FOC (free of charge) evaluations of the UroShield Device. This was based across both primary and secondary care and any of the trusts willing to engage with the evaluation were provided with the devices and monthly consumables for their 'worst affected patients'. In the end we had engagement from the following trusts: Frimley Park Hospital, Broomfield Hospital, Northampton Community Team; Worcester Community Team, St. James's Hospital and Pinderfields Hospital Spinal Injury Unit.

Data collection took place between 2018 and 2020, and 23 of the patients are still utilising and benefitting from the UroShield device.

The clinical teams at each site identified adult patients with repeated UTI with a frequency of 2 or more UTIs in the last 6 months or 3 more UTIs in the last 12 months (European Association of Urology, 2017) and where they had exhausted all other avenues. At the beginning of each evaluation, consent was sought from all participants and NHS trusts included within this study.

29 patients were originally recruited for the study, yielding a power of 84%. This was reduced to 73% by the end of the study with a total complete data set from 23 participants. During the evaluation, 2 patients passed away from other healthcare complications and four others withdrew for various medical reasons. Most patients

were on a trial for a period of 12 weeks, with a range between 5-17 weeks.

UroShield

The UroShield device is designed to prevent bacterial biofilm formation on both urethral and suprapubic catheters through the delivery of low frequency/low intensity ultrasound Surface Acoustic Waves (SAW). The ultrasound waves cannot be heard by the user; however, it prevents bacteria from being able to stick to the surface, and thus prevents the formation of biofilm. The device itself comprises of a driver element and a small disposable actuator clip which is replaced every 30 days. The driver element produces the ultrasound waves, and the actuator delivers them as it attaches to either the urethral or suprapubic catheter. It is designed to be worn consistently to prevent the build-up of bacteria and is considered a preventative tool.

Design and self-reported measures

The baseline and end of trial surveys took information about the frequency of wear, and reasons when the device was turned off. It asked the patients about the number of urine infections in the past 30 days, use of antibiotics, catheter changes, blockages and bladder washouts. It enquired about the need to see a GP, nurse or stay in a hospital due to UTIs related problems. Finally, the patients reported on their catheter related pain, quality of sleep, the ease of Uroshield wear and general mental health. The patients were encouraged to voice any comments related to the device.

Statistical analysis

The primary outcomes were UTIs and issues related to them. Secondary outcomes were qualitative data from the patients' experience. Presence of symptoms was recorded on a continuous scale; the level of pain was measured on a 10-point Likert scale. Associations between baseline and end of study responses were examined using Wilcoxon signed ranks non-parametric test (SPSS v.14.0; IBM Corp., Armonk, NY, USA). Thematic analysis was used to uncover themes related to the device wear [24], in order to understand patients' experience better and provide better care in the future. All statistical tests were two-tailed, and significance defined as $p < .05$.

RESULTS

Patients

Most patient wore Uroshield 93% of the time (SD = 8.60), with no patient wearing it less than 67% of the time. Most disconnections happened accidentally at night, commonly due to flat battery. 80% of patients were taking antibiotics while testing the device (some were on long-term Nitrofurantoin 100mg).

Changes over time

Data was not normally distributed, and Wilcoxon signed ranks non-parametric test was used to detect significant changes between the baseline and the average mean results of the last month of the trial (Table 1).

Patients reported significant decrease in the number of UTIs and antibiotic treatment. Similarly, the patients had fewer catheter blockages and catheter changes. Bladder washouts did not decrease over time. Pain was mild to moderate at the start of the trial which

Table 1: Descriptive statistics and Wilcoxon test for UroShield parameters over time.

Variables	N	Mean	SD	Z	p-value
UTI, baseline	21	3.24	3.42	-3.179	.001*
UTI, end	22	.50	.91		
Antibiotics, baseline	22	2.05	2.33	-2.614	.009*
Antibiotics, end	22	.77	1.11		
Blockage, baseline	22	2.59	3.75	-2.755	.006*
Blockage, end	22	.36	.90		
Change, baseline	22	2.91	3.57	-3.310	.001*
Change, end	22	.32	.48		
Bladder, baseline	17	2.71	6.01	-1.625	.104
Bladder, end	17	.65	1.69		
Pain, baseline	21	3.30	2.23	-2.395	.017*
Pain, end	20	2.60	1.86		

*p < 0.05

reduced significantly by the end of the trial.

While most patients (N=16) did not report any improvement in their sleep patterns, 50% reported they felt happier about their urinary catheter (no one reported feeling worse). Similarly, 9 patients (41%) reported they were able to do more things in their life due to using UroShield (four did not report changes; the rest of the data was missing). All patients who responded said UroShield was simple and easy to use, they felt comfortable using UroShield and they thought the device has benefitted them. This data is further corroborated by the qualitative responses from the patients.

Thematic analysis

Thematic analysis revealed two themes, one relating to the positive outcomes and the other to the issues related to the device. Positive outcomes had two further sub-themes: change to wellbeing and design of the device. The device issue had two subthemes: issues caused by the patients' other conditions and minor inconveniences.

Positive outcomes: Patients shared many positive comments about UroShield. They mainly related to changes in their life and overall wellbeing but also the design of the device. This theme has been represented by the largest volume of comments from the patients.

Change to wellbeing: UroShield was designed to reduce the risk of catheter-associated urinary tract infections by producing low frequency low intensity ultrasonic SAW throughout the catheter, which interferes with the attachment of bacteria. The analysis of the patients' comments during the 12-week trial shows that the device fulfils its task competently. It prevents further UTIs, catheter blockages and sediment build up.

'This is now longest period I have had without getting an infection (for over 4 years).'

'Huge success! In nearly 7 years, this is the first time able to go a month before needing catheter changes.'

'Not be continuously catheterised (often in the middle of the night), is a big plus.'

'The overall effect whilst not being black and white immediately is the feeling of general improvement and the life of this particular catheter has been extended by at least one week on this occasion resulting in longer periods between changes.'

The changes to patients' conditions resulted in a better overall

wellbeing and quality of their life. For many patients it means becoming more social, less worried about their conditions, and becoming more independent:

'So happy I have got the UroShield again. Since the first trial finished and I no longer had the device my catheter was constantly blocking. Having the UroShield has changed my life!'

'I haven't felt this good in years. It is lifechanging. Whoever thought of it deserves a medal.'

'It gives me more confidence and freedom feeling I am unlikely to need a nurse due to catheter issues.'

Design of the device: The patients had mostly positive comments regarding the design of UroShield. Its instructions were written clearly and were easy to follow by patients. It was reported the device was easy to get used to because of its conveniently small size and unrecognisable work:

'It was well explained to me [...] and the handbook was very straight forward.'

'Like anything new, once I got used to using it there was nothing to get uncomfortable about.'

'The driver unit fits into a pocket.'

Device issues: Some patients reported issues during the UroShield trial. Most of these have been caused by comorbid conditions. The build-ups in the catheters occurred during the trial but UroShield was successfully preventing blockages, which was a positive outcome.

Caused by patients' other conditions- Some patients had comorbid conditions, which negatively impacted the overall outcome of the treatment. Because of those some patients had a UTI during the trial or the device had to be taken off. Some patients were suffering from UTIs just before or during the first weeks of using the device. In that case UroShield did not help, and it is stated that UroShield is not supposed to be used to treat an active UTI.

'I have been unable to drink due to having dental problems which resulted in a UTI.'

'In the beginning of the week my fluids were cut down because of a sickness bug.'

Minor inconveniences- The other group of discomfort during the UroShield trial were sediment build-ups, appearing in the catheter.

In those cases, the device was still successfully preventing blockages and catheter changes:

'Slight sediment build-up in the catheter but no blockage.'

'The blockages were general build-up of rubbish that could be cleared by manipulation.'

'Have had a lot of discomfort as a result of catheter. Also blood and blood clots noticed on 3 consecutive days when emptying leg bag.'

'UroShield had to be removed for a couple of days as it caused irritation.'

Patients reported issues with the hardware malfunctions, most of which were battery related. The patients did not know the level of battery left:

'I wish there was more warning when battery was low on charge.'

'I wish there was a second battery and that the unit shows when it is charging.'

'I quickly realised that a powerpack would be beneficial. For under £20, the powerpack gives so much more freedom. I carry it always therefore never run out of power as the duration of the one supplied is restricting.'

'It would be very useful if there was some way of knowing how much charge was left in the driver.'

'The battery wasn't working properly, [...], needed new device.'

'Battery pack stopped working.'

Patients also reported some issues with the design of the device, especially the lead from the driver to the activator. It caused problems with sleep and was uncomfortable during the day. Two patients mentioned that the clip device stopped working during the trial (although resetting it always helped) and that device should have its own holder which would be more comfortable in everyday use:

'The only negative point about the UroShield is that the charging lead is attached to the extension socket [...]. If the Uroshield had its own holder that could be attached to the same holder that could be attached to the leg that would be great as it currently is put in the same holder as the catheter bag.'

'Using the two leads when in bed is a nuisance. I now tape it to my leg.'

'The extra lead from the driver to the catheter night bag is uncomfortable.'

'Leads from the activator could have been longer.'

DISCUSSION

The results showed that a 12-week UroShield wear in patients with repeated UTIs significantly reduced the amount of UTIs. This is in line with previous studies where the device significantly reduced the number of CFUs in patients with indwelling catheters as well as reducing the number of treated UTIs 20–23. Similarly, the need for antibiotics decreased in the patient sample, and the number of catheter blockages and changes significantly reduced during the trial.

The study additionally addressed the level of pain related to catheter pain, and while the level of reported pain was mild to moderate at baseline it reduced further by the end of the trial period, which is consistent with one previous study 19.

All patients responded UroShield was simple and easy to use, they felt comfortable using it and they thought the device has benefitted them. This data is further corroborated by the thematic analysis of

the qualitative responses from the patients, which revealed that the most common theme was the recognised positive outcomes about the changes to their lives as well as the convenience of the device. The patients reported a relief to be free from UTIs and pain, and experienced increased freedom and independence in their day-to-day life.

While the device itself was mainly positively perceived by the patients, particularly about its small size and ease of use, some recognised the need to get used to the device, particularly about clearing the build-up and routinely charging the battery. These have been incorporated in the future instructions to the patients.

CONCLUSION

The first qualitative analysis of the UroShield patients has established a clearer picture about the usefulness of the device, which has been invaluable in understanding the patients' lived experience. However, in the follow up study, the researchers have incorporated a standardized measure of quality of life to allow for a quantitative measure of the changes the device brings to patients' quality of life. It will focus on the effectiveness of UroShield on suprapubic catheters as research in this area is limited. UroShield device should be considered as an effective treatment option for patients with repeated UTIs, as it not only reduces the number of UTIs, but also the need for antibiotics, the number of catheter changes and blockages, and catheter related pain. It is easy to use and discrete in its size, which results in improvement to patients' wellbeing.

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