Original Article

Is plasma sterilization the modality of choice of sterilization today for endourological procedures such as ureterorenoscopy and retrograde intrarenal surgery? A single-center retrospective evaluation of 198 patients

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Abstract

Introduction: The prevalence of infective complications among patients undergoing Retrograde Intrarenal Surgery (RIRS) for renal stone is 1.7%-18%, including fever, Systemic Inflammatory Response Syndrome (SIRS) and sepsis. The infectious complications of RIRS can be minimised by strict aseptic precautions and plasma sterilization. The Sterrad Next Generation (Sterrad NX) System, a low-temperature sterilizer represents the next generation of low-temperature hydrogen peroxide gas plasma sterilizers. This study was conducted to evaluate the efficacy of plasma sterilization among patients undergoing ureterorenoscopy (URS) and RIRS. The primary endpoint of this study was incidence of septicemia or related complications. Till date, there is no study on the incidence of infection rate in RIRS in relation to a specific mode of sterilization.

Material and Methods: This is a retrospective study comprising of 198 patients undergoing URS and/or RIRS. The parameters studied were incidence of post-operative fever, Systemic Inflammatory Response Syndrome (SIRS), pyelonephritis or septicemic shock.

Results: Out of 198 patients, incidence of post-operative fever was 3.5%, SIRS was 1.7%, pyelonephritis was 0.7% and septicemic shock was 0%. This is statistically significantly low septicemia rate among patients undergoing URS and /or RIRS as compared to the available literature. No health hazards of plasma sterilization were noted. No damage to the endoscopes or instruments was noted.

Conclusion: Sterrad NX based on hydrogen peroxide gas plasma (HPGP) technology is highly efficacious, safe and the modality for sterilization of instruments, including heat labile instruments such as semi rigid, flexible and chip on the tip endoscopes and other EndoUrology armamentarium.

Keywords: Plasma, retrograde intrarenal surgery, sterilization, STERRAD, ureterorenoscopy, urology

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INTRODUCTION

Sterilization is a vital yet ignored topic even in the 21st century endourology where the urologist has percutaneous nephrolithotomy (PCNL) and its miniaturized versions, ureterorenoscopy (URS), and

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retrograde intrarenal surgery (RIRS) as the treatment modalities for upper tract calculi. Any invasive surgical procedure involves contact of the patient's sterile tissues with a foreign substance like a medical device or surgical instrument. A major risk of all such procedures is the introduction of pathogenic microbes leading to infection which can pose further medical and surgical complications to the patients.[1] RIRS is considered a safe procedure for the management of upper tract calculi in terms of complications like bleeding, renal injury, pleural injury, colon injury, etc.[2] However, septicemia is a common complication due to intraoperative rise in intrapelvic pressures and improper sterilization.[3-5]

Sterilization is the process of eliminating, killing, or deactivating all forms of life and other biological agents (such as fungi, bacteria, viruses, spore forms, prions, and unicellular organisms such as plasmodium) present in a specified region, such as a surface, a volume of fluid, medication, or in a compound such as biological culture media.[1,6,7] Ethylene oxide (ETO) and plasma sterilization are the recommended modes of sterilization for semi rigid and flexible endoscopes, chip on tip digital scopes, camera, baskets, cautery cables, electrical cords, dilators ureteric access sheaths (UASs), laser fiber, and sheaths.[8] This is the first study till date to note the incidence of septicemia in RIRS in relation to a specific mode of sterilization.

MATERIALS AND METHODS

Aim

To evaluate the rate of septicemia or infection related events in patients undergoing URS and/or RIRS with the use of plasma sterilization.

Ethics

The study was approved by the Institutional Ethics Committee and consent from the patients was waived off to analyze the data for current study.

Study design

This was an observational, retrospective, single-center study performed in patients undergoing URS and/or RIRS in our hospital from January 2015 to March 2018. The ureteroscope and other surgical instruments were sterilized using STERRAD NX. Furthermore, the linen, disposables, and surgical pads were sterilized using STERRAD NX with a fast load sterilization process at the end of the procedure.

Inclusion criteria

Patients with

- Upper tract calculi of age >12 years to geriatric age
- Single/multiple renal and/or upper ureteric stones
- Stones in the upper, middle, and lower calyces; multiple calyces; pelvis; and upper ureteric stones.
- Stone burden ranging from <1 to >2 cm
- Previous history of ureteroscopy (URS), PCNL, or extracorporeal shock-wave lithotripsy
- Comorbidities such as diabetes, hypertension, and ischemic heart disease and patients on anticoagulants
- Anatomically abnormal kidneys such as solitary kidney, horseshoe kidney, and ectopic kidney.

Exclusion criteria

- Pediatric age group <12 years
- Complete staghorn calculi
- Stone burden more than 3.5 cm.

In our study, we used prophylactic 1st-generation cephalosporins preoperatively for the patients with a negative urine culture and 5 days of culture-specific antibiotics were given to those with positive urine cultures. Postoperative intravenous cephalosporin was given on the day of surgery. Patients were discharged on 2nd day with oral fluoroquinolone for 5 days. We routinely don't pre stent the patients. Pre stenting is done only in cases with,

1. Pre-operative febrile urinary tract infection (UTI).
2. Difficult ureteric anatomy (such as tight ureter) when RIRS needs to be staged.

Cystourethroscopy followed by URS with a semirigid 4.5 flexible URS was done initially followed by placement of UAS. Ureteric balloon dilatation was required in selected cases. Next flexible ureteroscope was back-loaded over guide wire. Initially, all the calyces are inspected followed by basketing of lower calyx stones >1 cm into upper calyx or desirable calyx followed by laser dusting of the stones. Double J stent was placed in all patients. We do not use any pathfinder or pressurized system or pump for irrigation. We attach a 100-cm extension tube to the flexible ureteroscope and irrigate manually just enough to have a clear vision. This helps avoid putting extra fluid and thereby increasing the intrapelvic pressure.

Postoperatively, the bpatient was monitored for hematuria, flank pain, and signs of septicemia such as fever, chills, hypotension, tachycardia, tachypnea, and flank pain. Follow-up was with noncontrast computed tomography (kidneys, ureters and bladder) after 4 weeks to evaluate for residual stones. Re-RIRS was performed for residual stone >3 mm.

Statistics

Preoperative variables include age, gender, total stone burden, preoperative urine culture, preoperative serum creatinine,

history of stone surgery, and comorbidity (diabetes mellitus and ischemic heart disease). Postoperative event of fever or hypothermia, tachycardia, tachypnea, hypotension, flank pain, or shock was noted. The statistical test applied was Chi-square test and Fischer's exact test under expert guidance. $P<0.01$ was considered to be significant. Statistical analysis was performed under statistician's expert guidance.

RESULTS

Of 198 patients, operated between January 2015 and March 2018, 26 patients (13%) underwent URS and 172 (87%) patients underwent URS + RIRS. 123 patients (62%) were males and 75 patients (38%) were females. 54 patients (27%) had history of stone disease out of which 46 patients (23%) had history of some form of urological surgery. 28 patients (14%) had comorbidity in the form of diabetes mellitus or ischemic heart disease. 26 patients (13%) presented with raised serum creatinine and 25 patients (12.6%) had preoperative positive urine culture.

Infectious complications were considered when patients developed fever of >38°C that persisted for 48 h, acute pyelonephritis, positive results in blood culture, and sepsis. The occurrence of fever postoperatively was defined as an increase in the body temperature to >38°C, which persisted for 48 h. Sepsis was defined as the presence of systemic inflammatory response syndrome (SIRS) that was caused by a suspected infection. As per American College of Chest Physicians and the Society of Critical Care Medicine, the patients should meet 2 or more of the following diagnostic criteria for SIRS:

- Body temperature >38°C or <36°C
- Heart rate >90 beats/min
- Respiratory rate >20 breaths/min or $PaCO_2$ <32 mmHg
- White blood cell count >12,000 cells/μL or <4000 cells/μL.[9-11]

Postoperatively, infection related events were noted in total 11 patients of 198 patients (5.5%) [Table 1].

DISCUSSION

Over 45 years ago, Spaulding devised a rational approach to disinfection and sterilization of patient care items or equipment.[6] This classification has been retained, refined, and successfully used by infection control professionals and others when planning methods for disinfection or sterilization.[3] Spaulding divided instruments and items for patient care into three categories based on the degree of risk of infection involved in the use of the items.

- Critical items are those that enter sterile tissue or the vascular system (surgical instruments, cardiac and urinary catheters, implants, and ultrasound probes used in sterile body cavities), which must be sterile
- Semi-critical items are those that come in contact with mucous membranes or nonintact skin (respiratory-therapy and anesthesia equipment, some endoscopes, laryngoscope blades, esophageal manometry probes, anorectal manometry catheters, and diaphragm-fitting rings), which should be free of all microorganisms (i.e., mycobacteria, fungi, viruses, and bacteria), although small numbers of bacterial spores may be present
- Noncritical items are those that come in contact with intact skin but not mucous membranes (bedpans, blood-pressure cuffs, crutches, bed rails, linens, bedside tables, patient furniture, and floors).

Sterilization of endoscopic instruments is not only important but also challenging because of the material they are made of and the narrow lumen sizes. Autoclaving is an excellent and economic sterilization process for heat insensitive instruments. Flexible ureteroscopes and chip on tip digital endoscopes are liable to get damaged by autoclaving. ETO is inflammable, toxic, carcinogenic, time-consuming but economic mode of sterilization.[8] Sterilization using Hydrogen peroxide gas plasma (HPGP) technology is considered an environmentally safer and more time-efficient alternative to ETO with shorter cycle times. One of the first sterilizer systems using HPGP approved by the US Food and Drug Administration was the STERRAD™ System.[1,12,13]

The STERRAD NX System, a low-temperature sterilizer, represents the next generation of low-temperature HPGP sterilizers. It involves the combined use of hydrogen peroxide and low-temperature gas plasma. Hydrogen peroxide is an oxidizing agent that affects sterilization by oxidation of key cellular components. Plasma is a state of matter distinguishable from a solid, liquid, or gas. Gas plasmas are highly ionized gases, composed of ions, electrons, and neutral particles that produce a visible glow.[14] The STERRAD NX System produces a biocidal environment that is capable of inactivating microorganisms

Table 1: Postoperative infection events

Postopeartive infection-related events	Number of patients of 198, *n* (%)
Fever	7 (3.5)
SIRS	3 (1.5)
Pyelonephritis	1 (0.5)
Septicemic shock	0

SIRS: Systemic inflammatory response syndrome

Figure 1: STERRAD NX

Figure 2: STERRAD 100 NX

by chemical interactions at multiple biologically important reaction sites. In addition, it utilizes a secondary plasma that minimizes surface modification since the item in the sterilizer is not exposed to the direct or primary plasma discharge. On completion, no toxic residues remain on the sterilized items. The technology is particularly suited to the sterilization of heat and moisture sensitive instruments since process temperatures do not exceeded about 50°C (140°F) and sterilization occurs in a low moisture environment.[15]

STERRAD is available in two size configurations, STERRAD NX (smaller unit with standard and advanced cycles of 28 min and 38 min respectively) and STERRAD 100 NX (larger unit with standard, flex, express and duo cycles of 47, 42, 27, and 60 min, respectively) [Figures 1 and 2]. It requires special unit for housing the machine with dedicated staff for its use, packing and maintaining the machine. Adequate drying of the instrument before loading in the machine is essential to prevent failure.[8,16,17]

Rutala *et al*. in 1999 demonstrated that STERRAD 50 (older version) was highly effective in killing the *Bacillus stearothermophilus* spores. Although in another study, Rutala *et al*. demonstrated that as the lumen diameter decreased with the lumen test unit, the STERRAD 100 demonstrated reduced ability to kill *B. stearothermophilus* spores present on the carrier. At the smallest diameter tested (1 mm), the STERRAD 100 System failed 74% of the time.[15] However, the new generation STERRAD 100NX sterilizer, can adequately process single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a maximum length of 500 mm using standard cycle sterilizing conditions.[18] STERRAD 50 and 100 were older versions of the machine which were replaced by improved versions like STERRAD NX and 100NX which are now further replaced by STERRAD NX ALLClear and STERRAD 100NX ALLClear.[18]

Prions cause various transmissible spongiform encephalopathies and are highly resistant to the chemical and physical decontamination and sterilization procedures. Rogez *et al*. evaluated efficacy of sterilization with STERRAD NX sterilizer on prions.[19] The STERRAD NX sterilizer was found to be 100% efficient (0% transmission and no protease-resistant form of the prion protein signal detected on the surface of the material). Van Meeteren *et al*. found the efficacy of STERRAD sterilizer to be 100% in their study in sterilization of bone pencil, where all culture plates showed no growth during the incubation process.[20]

Till date most of the studies conducted for evaluation of efficacy of sterilization of STERRAD sterilizer are *in vitro* studies. Although laboratory values and culture results are ultimate guide to the assessment of efficacy of sterilization but *in vivo* studies have their own importance. In their attempt to evaluate the efficacy of plasma sterilization of endoscopic material contaminated by *Cryptosporidium parvum* in an immunosuppressed rat cryptosporidiosis model, Vassal *et al*. observed that no rat was found infected after gas plasma exposure of oocysts and the efficacy of low-temperature HPGP for sterilization was 100%.[21]

Our study is different from earlier studies as we conducted our study among patients undergoing endoscopic urology procedures and the endpoint for evaluation of efficacy of sterilization was incidence of any bacteremia and/or septicemia. This gave us advantage of assessment of the efficacy of STERRAD sterilizer in real life setting which is

Table 2: Statistical comparison between infection rates postretrograde intra renal surgery

	Tian Li *et al*. (*n*=484), (%)	Beradinelli F *et al*. (*n*=403), (%)	Parikh-Jain (*n*=198), (%)	*P*
Fever	59 (17.5)	18 (4.4)	7 (3.5)	<0.01 (Significant)
SIRS	22 (6.5)	7 (1.7)	3 (1.5)	<0.01 (Significant)
Pyelonephritis	3 (0.9)	3 (0.7)	1 (0.5)	0.94 (NS)
Septicemic shock	2 (0.6)	3 (0.7)	0	0.44 (NS)
Total	85 (17)	31 (7.7)	11 (5.5)	<0.01 (Significant)

NS: Not significant, SIRS: Systemic inflammatory response syndrome

influenced by patient factors also. Factors contributing to infection rates in RIRS have been studied and comprise of gender, age, comorbidity (diabetes, mellitus, hypertension, hydronephrosis, and renal insufficiency), routine urinalysis results, urine culture results, stone size, operative duration, residual stones, and stone composition.[9]

RIRS today is the first line modality for managing stones <2 cm and second line modality after PCNL for lower calyx stones and stone burden >2 cm. The relatively lower morbidity of RIRS as compared to PCNL raised the popularity of this surgery.[2,3] RIRS is an excellent modality for patients with comorbidities including obesity, renoureteral malformations, infundibular stenosis, musculoskeletal deformities, and bleeding disorders.[22] However, septicemia is a known and dreaded complication following RIRS.[3-5] The incidence rate of postoperative infectious complications ranges from 1.7% to 18.8% in the studies in the literature.[23-30]

Table 2 shows the comparison of infective complications between studies by Berardinelli, Tian Li, and Parikh-Jain. In our study, statistically significant low rates of fever and SIRS were noted as compared to Berardinelli and Tian Li. Incidence of pyelonephritis was not statistically significant. However, no event of septicemic shock was noted in our study as compared to 2 cases (Tian Li) and 3 cases (Berardinelli) although it was not statistically significant. The mode of sterilization has not been mentioned by Li *et al*. and Berardinelli *et al*.[4,5] However, no mention of plasma sterilization has been mentioned in either of the study. No health hazards were noted in the personnel involved in the sterilization process. No wear and tear effects on the endoscopes or other instruments were noted in our study.

The factors we believe to have contributed to low septicemia rate in our study are aseptic precautions, preoperative negative urine culture, use of UAS which helps lower intra pelvic pressures,[31,32] controlled irrigation system (100 cm extension tube) thus lowering intra pelvic pressures,[33] and plasma sterilization of all flexible, digital, and semirigid endoscopes, camera and light cables, and other surgical instruments.

Limitations

The limitations of this study include nonrandomized, small sample size, single-center study and lack of comparison with ETO and other modes of sterilization in patients undergoing RIRS and URS.

CONCLUSION

STERRAD NX based on HPGP technology is a highly efficacious method of sterilization of instruments including heat labile instruments such as endoscopes. Today in an era of modern EndoUrology, when UTI and septicemia postendourological procedures is unacceptable, plasma sterilization with STERRAD NX seems to be the ultimate answer to the mode of sterilization. With time, plasma sterilization can be cost-effective and widely acceptable across different hospital settings.

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Conflicts of interest

There are no conflicts of interest.

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