Thai Journal of Obstetrics and Gynaecology
September 2024, Vol. 32, No. 5, pp. 358-364.

GYNAECOLOGY

Efficacy of the Si-Washer in Cleansing Gynaecological Laparoscopic Instruments: A randomized controlled trial

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ABSTRACT

Objectives: This study aimed to evaluate the efficacy of the 'Si-Washer' in cleansing gynaecological laparoscopic instruments.

Materials and Methods: The instruments were randomized into either a control group or an experimental group using a block randomization method, with sequences securely concealed in sealed envelopes. The control group underwent traditional manual cleansing, whereas the experimental group utilized the Si-Washer.

Results: A total of 302 instruments were randomized, with 151 allocated to each group. The median operative duration was 135.0 minutes (interquartile range [IQR] 115.0–175.0), and the median blood loss was 50.0 mL (IQR 20.0–100.0). No significant differences were observed between the groups regarding diagnostic parameters, operator expertise, operation types, operative time, instrument types, surgical complications, irrigation volume or blood loss. The Si-Washer achieved 100% cleanliness at an adenosine triphosphate cut-off of <150 relative light units, markedly surpassing the manual method, which achieved 58.9% cleanliness at the same threshold.

Conclusion: The Si-Washer effectively decontaminated gynaecological laparoscopic instruments and alleviating the workload of operating theatre nursing staff.

Keywords: cleaning, washer, instrument, laparoscopy, Innovation.

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Received: 4 April 2024, **Revised:** 24 June 2024, **Accepted:** 27 June 2024

ประสิทธิภาพของการใช้เครื่องล้าง "the Si-Washer" สำหรับเครื่องมือผ่าตัดผ่านกล้องทางนรีเวช: การทดลองแบบสุ่มที่มีกลุ่มควบคุม

ศิริพร สมจิต, น้ำผึ้ง อินทโพธิ์, สุธาสินี เหลืองรัตนเจริญ, สาริศา ทะปะละ, กชกร ถึงกลาง, จิตรา เกิดเพ็ชร, ไอรีน เรืองขจร

บทคัดย่อ

วัตถุประสงค์*: การศึกษานี้มีวัตถุประสงค์เพื่อประเมินประสิทธิภาพของ Si-Washer ในการทำความสะอาดเครื่องมือผ่าตัดส่องกล้องทางนรีเวช*

วัสดุและวิธีการ*: เครื่องมือผ่าตัดถูกสุ่มแบ่งเป็นกลุ่มควบคุมหรือกลุ่มทดลองโดยใช้วิธีการสุ่มแบบบล็อก โดยลำดับการสุ่มถูกเก็บรักษาอย่างปลอดภัยในซองจดหมายที่ปิดสนิท กลุ่มควบคุมได้รับการทำความสะอาดด้วยวิธีการทำความสะอาดด้วยมือแบบดั้งเดิม ในขณะที่กลุ่มทดลองใช้ Si-Washer ในการทำความสะอาด*

ผลการศึกษา*: เครื่องมือทั้งหมด 302 ชิ้น ถูกแบ่งออกเป็นกลุ่มละ 151 ชิ้น ค่ากลางของเวลาในการทำผ่าตัดเท่ากับ 135.0 นาที (ช่วงระหว่างควอไทล์ [IQR] 115.0–175.0 นาที) ค่ากลางของการเสียเลือด 50.0 มิลลิลิตร (IQR 20.0–100.0 มิลลิลิตร) ไม่มีความแตกต่างกันระหว่างกลุ่ม ในด้านของโรคที่ได้รับการวินิจฉัย ความเชี่ยวชาญของแพทย์ ประเภทของการผ่าตัด ระยะเวลาการผ่าตัด ประเภทของเครื่องมือ ภาวะแทรกซ้อนจากการผ่าตัด ปริมาณสารน้ำที่ใช้ล้างขณะผ่าตัด หรือการสูญเสียเลือด เครื่องล้าง "Si-Washerสามารถทำความสะอาดได้ร้อยละ 100 ที่ค่าอเดโนซีนไตรฟอสเฟต (adenosine triphosphate) ต่ำกว่า 150 หน่วยแสงสัมพัทธ์ ซึ่งสูงกว่าวิธีการทำความสะอาดด้วยมือที่ทำได้ร้อยละ 58.9 ที่ค่าเกณฑ์เดียวกันอย่างชัดเจน*

สรุป*: เครื่องล้าง Si-Washer มีประสิทธิภาพในการกำจัดสิ่งปนเปื้อนบนเครื่องมือผ่าตัดส่องกล้องทางนรีเวชและลดภาระงานของพยาบาลในห้องผ่าตัด*

คำสำคัญ*: การทำความสะอาด, เครื่องล้าง, เครื่องมือ, การส่องกล้อง, นวัตกรรม*

Introduction

Laparoscopic surgery is increasingly recognized globally. The effective and prompt reprocessing of surgical instruments is vital for infection control, yet the complexity of laparoscopic tools presents significant challenges in achieving cleanliness. Post-cleaning, several rapid methods, including visual inspection, microscopy and adenosine triphosphate (ATP) bioluminescence assays, are utilized to ascertain cleanliness[1,2]. The ATP bioluminescence assay, particularly suited for instruments with narrow lumens, deems ATP levels ≤ 150 relative light units (RLUs) to be sufficiently clean[3-6].

While manual cleaning is effective, it has certain constraints. Ling et al's study on the cleanliness of various surgical instruments, including hollow suction tubes and long forceps, revealed that 92% of instruments with no visible contaminants achieved an ATP cleanliness threshold of ≤ 150 RLUs[6]. Other research has demonstrated comparable effectiveness between manual and automated methods for sterilizing endoscopic and laparoscopic instruments[7, 8].

Despite their benefits, automated washers face barriers to their widespread adoption, primarily due to their high costs[9,10]. In response, the authors developed an economical, machine-assisted cleaning system named the 'Si-Washer' (Fig. 1). This system features a 60-watt electric pump with a flow rate of 2,800 litres per hour, and it uses polyvinyl chloride pipes with a diameter of 1.26 cm. The cost of the Si-Washer is approximately USD 55.

This study aimed to compare the effectiveness of the Si-Washer and manual flushing in cleaning laparoscopic instruments with narrow lumens.

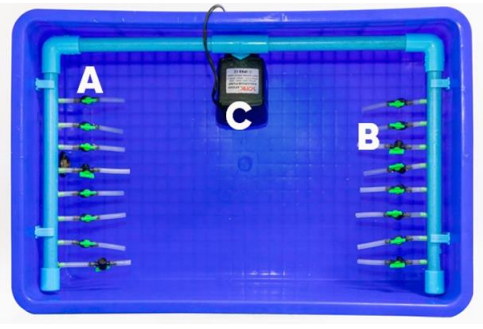

Fig. 1. The Si-washer machine

A: Water valve, B: Plastic tubing for connecting with instruments, C: Electrically powered pump

Materials and Methods

Instrument selection and allocation

The sample size was calculated based on a 92% effective cleaning rate for manual methods and an anticipated 99% effectiveness for the Si-Washer. Allowing for a 10% potential attrition rate and setting a power (1-β) of 0.80, an α level of 0.05 and a 1:1 randomization ratio, we determined that 151 instruments per group were needed.

In the Gynaecologic Surgical unit, instruments meeting the inclusion criteria were enrolled between July and September 2023. After surgery, laparoscopic instruments such as graspers, Allis forceps and suction irrigation tubes that had been used for more than an hour were selected and randomized. These instruments underwent an initial rinse to remove surface debris. Randomization was facilitated by sequentially opening numbered envelopes. For both the manual and Si-Washer cleaning arms, a cleaning solution consisting of clean water and 3E-enzyme detergent at a 10:1 ratio was prepared. All study instruments were cleaned by N.I. and S.L. In the manual cleaning arm, the instruments were immersed for 15 minutes, followed by internal flushing with a 20

mL syringe until visibly clear. The duration of this flushing process was recorded with a stopwatch. In the Si-Washer arm, the instruments were connected to the machine tubing (Fig. 1.) and rinsed for 15 minutes. All 302 instruments were then dried. Cleanliness assessment was conducted using the 3M Clean-Trace™ water Test and the 3M Clean-Trace™ Luminometer LX 25, providing quantitative results in terms of RLUs.

Data collection

After submitting the protocol to the Siriraj Institutional Review Board (SiIRB) for ethical approval, the authors received a recommendation to exempt the requirement for informed consent. This exemption was due to the classification of the research as non-human in nature. Data on operative procedures and instrument contamination, operative duration, estimated blood loss, manual flushing duration and cleanliness levels, were meticulously gathered.

Statistical analysis

PASW Statistics, version 18 (SPSS Inc., Chicago, IL, USA), was utilized for all the statistical analyses. The data were presented as numbers and percentages or as medians and interquartile ranges (IQRs). Categorical variables were compared using the chi-squared test or Fisher's exact test. A p value < 0.05 was considered to indicate statistical significance.

Results

The Si-Washer is shown in Fig. 1, and The experimental setup flowchart is depicted in Fig. 2. Details of the operations, diseases, surgeon experience, operative times, complications and the types of the 302 instruments were enrolled. The median operative time was 135.0 minutes (IQR115.0-175.0). Fellows conducted surgery on one patient in the manual cleaning arm and three patients in the Si-Washer arm. All operations were completed without complications, with the sole exception of one instance of ureteric injury in the Si-Washer arm. The instrument components included in this study were suction irrigation tools and the outer sheaths of graspers, forceps and dissectors. The median time for manual flushing was 50.0 seconds (IQR 45.0–60.0).

Table 1 compares variables between the study arms. The Si-Washer arm exhibited significantly better cleaning outcomes than the manual cleaning arm, achieving 100% cleanliness. This outcome was evidenced by all of the instruments in the Si-Washer arm reaching the target cleanliness standard of an ATP level ≤ 150 RLUs.

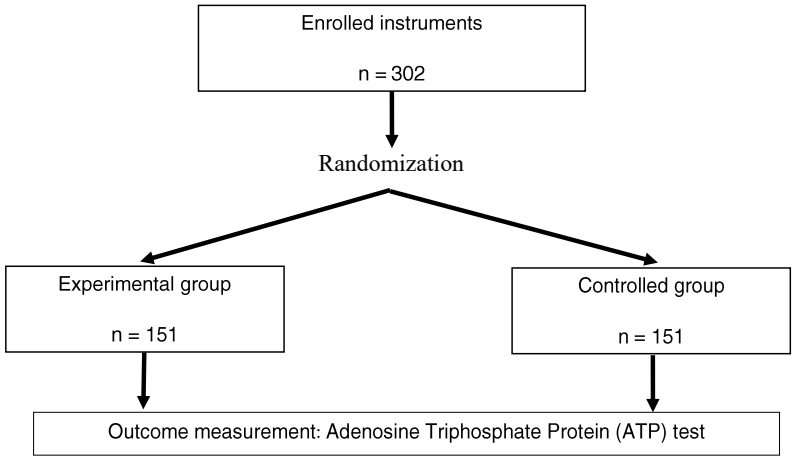

Fig. 2. Flowchart of the study.

Table 1. Compared variables between two study arms.

Variables	Manual clean (n = 151)	Si-washer (n = 151)	p value
Operated by staffs, n = 298	150	148	0.314
Operations			0.158
Total laparoscopic hysterectomy, n = 192	96	96	
Myomectomy, n = 62	26	36	
Adnexal surgery, n = 48	29	19	
Instruments			0.741
Outer sheath of graspers, n = 155	76	79	
Outer sheath of forceps, n = 89	44	45	
Outer sheath of dissectors, n = 36	21	15	
Suction irrigation, n = 22	10	12	
Complication occurred, ureteric injury	0	1	0.317
Operative time (mins)	145.40 ± 49.499	152.42 ± 58.637	0.267
Intra-operative Irrigation volume (mL)	882.78 ± 443.924	884.11 ± 441.640	0.979
Estimated blood loss (mL)	82.91 ± 117.104	83.97 ± 121.532	0.939
ATP (RLU)	130.0 [72.0-180.0]	15.0 [8.25-30.0]	< 0.001
ATP < 150	89 (58.9%)	151 (100%)	
ATP ≥ 150	62 (41.1%)	0	

TLH: total laparoscopic hysterectomy, ATP: adenosine triphosphate protein; RLU: relative light units

Discussion

Since its inception in 1957, the Spaulding classification system has categorized laparoscopic instruments used in gynaecological surgery as 'critical use items', highlighting the importance of comprehensive reprocessing to avert hospital-acquired infections[11]. Several steps are needed for effective reprocessing: cleaning, high-level disinfection, validation, drying, sterilization and storage[2,12]. The initial step, cleaning, employs chemical detergents and mechanical action, which can be manual or automated.

Research has consistently demonstrated the efficacy of manual cleaning[7,8,13]. For instance, a study examining the cleaning phase for flexible endoscopes (bronchoscopes, duodenoscopes and colonoscopes) revealed a reduction of more than 99.9% in haemoglobin and protein contamination, with residual organic material below 6.4 μg/cm^2. Additionally, there was no significant difference in viable organism counts between manual cleaning (ranging from 2.06 to 6.21 μg/cm^2) and automated cleaning (ranging from 2.10 to 5.93 μg/cm^2)[7]. Another investigation compared manual and automated cleaning methods for laparoscopic trocars and dissecting forceps, examining four distinct cleaning protocols: (1) manual cleaning followed by a tap water rinse, (2) manual cleaning, a tap water rinse and then ultrasonic cleaning, (3) manual cleaning, a tap water rinse, ultrasonic cleaning, and another tap water rinse, and (4) manual cleaning, a tap water rinse, ultrasonic cleaning, another tap water rinse, and a final rinse with sterile distilled water. The four approaches achieved protein contamination reductions of 95.1%, 100.0%, 98.3%

and 100.0%, respectively. The corresponding post-cleaning mean residual protein levels were 0.42, 0.16, 0.00 and 0.79 µg/cm^2 for trocars and 0.57, 0.24, 0.65 and 0.04 µg/cm^2 for laparoscopic instruments[8]. The current study demonstrated that the manual method achieved only 58.9% cleanliness. This discrepancy may be attributed to differences in cleanliness assessment methods and cut-off values compared to previous studies[7,8]. Additionally, the manual cleaning method in our study did not incorporate additional methods such as the use of an ultrasonic machine, as seen in the study by de Camargo et al.

A systematic review compared traditional manual cleaning to automated devices employing hydrogen peroxide or ultraviolet mycobactericidal light. The review concluded that there is limited value in conducting studies that directly compare the cost benefits of these methods. The review recommended that manual cleaning should continue to be used while cautioning against overreliance on novel technologies[13]. The various investigations collectively suggest that endoscopes and laparoscopic instruments can be effectively cleaned using either manual or automated methods, with both approaches demonstrating similar efficacy.

Automated washers outperform traditional manual cleaning of laparoscopic instruments due to their complex design and human factors that impair the effectiveness of manual methods[9,10]. A specific study on Crile forceps revealed the greater efficacy of ultrasonic automated cleaners compared to manual methods in removing Staphylococcus epidermidis, a biofilm-forming bacterium commonly isolated from surgical instruments during cleaning[10]. Another investigation evaluated manual versus automated cleaning of tubular laparoscopic instruments, such as scissors and forceps. Soil tests and bacterial cultures revealed that automated cleaners were markedly more efficient than manual cleaning for both ported and non-ported devices, achieving more than 99% reduction in soil tests. Additionally, only automated cleaning of ported devices accomplished a 103- to 104-fold reduction in bacterial counts[14]. Prominent medical organizations have established guidelines for cleaning gastrointestinal endoscopy instruments. The Asia Pacific Society of Infection Control approves of both effective manual and mechanical cleaning processes[15]. In contrast, the American Society of Gastrointestinal Endoscopy, the United States Food and Drug Administration and the United States Centers for Disease Control and Prevention strongly advocate for automated endoscope reprocessors to enhance consistency, reliability and efficiency. Nevertheless, the American Society of Gastrointestinal Endoscopy insists on supplementary manual cleaning, regardless of manufacturers' claims of its redundancy[9,16,17].

This study demonstrated the high cleanliness efficacy of the Si-Washer. A noted limitation is the reliance on ATP bioluminescence for cleanliness validation, which may not directly indicate the presence of organisms. Future investigations should compare the cleaning efficacy of the Si-Washer against that of commercial ultrasonic washers, with microbiological cultures used as the primary evaluation criterion.

To further improve the effectiveness of the Si-Washer for cleaning, enhancements could involve increasing the motor's flushing power, maintaining a high-water quality, and using hotter water during the washing cycle. Safety improvements, such as fabricating the washing chamber from stainless steel, are also recommended. Consistent cleaning effectiveness requires establishing standardized international training for medical personnel in disinfection and sterilization, including competency assessments. Moreover, implementing systematic cleaning and validation protocols, such as daily or weekly monitoring, is essential.

Conclusion

The study established that the Si-Washer was more efficient than manual cleaning, consistently achieving 100% cleanliness.

Acknowledgments

This study was funded by the Routine to Research Unit of Siriraj Hospital (grant no. R016635051). The authors would like to thank Miss Sarocha Boonkate for administrative coordination.

Potential conflicts of interest

The authors declare no conflicts of interest.

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