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Original Article

Effectiveness and economic outcomes in patients undergoing laparoscopic radical prostatectomy with a new surgical shear with an integrated energy system: A retrospective study based on a tertiary hospital database in China

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Cost-effectiveness

Abstract *Objective:* This study aimed to demonstrate a new surgical shear with an integrated energy system (Harmonic ACE®+7) value by determining its effectiveness and economic outcomes compared with conventional ultrasonic shears (CUSs) in a real-world setting.
Methods: This was a retrospective study of adults with prostate cancer undergoing laparoscopic radical prostatectomy with the ACE®+7 shear or CUSs between August 2019 and April 2021 at Shanghai Ruijin Hospital (the headquarters and Luwan Center in China). Demographic and diagnosis information, intraoperative and postoperative clinical outcomes, and total and categorical costs were collected. Propensity score matching was performed to form the study population for each clinical group. Data were compared between the two groups using *t*-test and Chi-squared test.
Results: The ACE®+7 was associated with a lower mean number of hemostatic clips used per surgery compared with CUSs (12.8 *vs.* 19.8, $p<0.001$), a moderate but not significant difference in mean postoperative drainage duration (6.6 [standard deviation, SD 2.2] days *vs.* 7.9 [SD 4.1] days, $p=0.082$), a reduction on mean total drainage volume (275.5 [SD 374.3 mL *vs.* 492.9 [SD 1495.0] mL, $p=0.321$), and a lower mean rate of postoperative hemostatic drug usage (16.0% *vs.* 52.0%, $p<0.001$). There was no significant difference in total costs between the ACE®+7 and CUS groups.

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Conclusion: This study provides real-world data demonstrating that the ACE®+7 shear with an integrated energy system improves clinical outcomes compared with CUSs and can offer cost savings for hospitals and health systems. Using the ACE®+7 during laparoscopic radical prostatectomy allows physicians to help their patients achieve better outcomes and not spend additional money.

1. Introduction

Each year over 1.4 million men are diagnosed with prostate cancer (PCa) [1]. PCa is the second most common cancer in men and has a higher burden in men over 65 years of age. Therefore, its incidence is expected to rise as life expectancy increases [2]. Although improved therapy and diagnostic tools have decreased PCa-related mortality, access to innovative and lifesaving PCa care is not available worldwide [2,3]. In turn, incidence and mortality rates of PCa are rising in some countries such as China [4]. As the burden of PCa grows in the coming years, it is essential to ensure that people have access to clinically effective and cost-effective treatments regardless of where they live. Through effective care, people worldwide can live long and productive lives.

Treatments for PCa include surgery, radiation therapy, high-intensity focused ultrasound, cryotherapy, chemotherapy, and immunotherapy [2]. Physicians choose a treatment to use based on the patient's disease progress [2]. For example, in China, radical prostatectomy is recommended for the management of resectable prostate tumors [5]. Radical prostatectomy offers patients with early-stage PCa a high likelihood of remission and has low reoperation rates. Most Chinese surgeons perform this surgery laparoscopically as laparoscopic radical prostatectomy (LRP) is less invasive than open prostatectomy, decreases operation time and blood loss, and has a lower risk of causing postoperative urinary leakages and sexual dysfunction [6]. However, parts of the procedure, including the resection of collateral ligaments, take significant pressure and energy [7]. To mitigate challenges associated with the surgery, researchers are constantly developing new surgical techniques and tools to make LRP safer.

One example of these tools is a new surgical shear with an integrated energy system (HARMONIC ACE®+7, Ethicon Endo-Surgery, Chihuahua, Mexico). It is an integrated ultrasonic and electrosurgical energy system that leverages adaptive tissue technology with a predictive analytic system to modulate energy delivery during the sealing cycle [6]. With greater burst pressure than those from older bipolar technologies, the HARMONIC ACE®+7 shear with an advanced hemostasis mode can seal vessels up to 7 mm in diameters [7]. Several clinical trials demonstrate the ACE®+7's hemostasis efficacy, ability to seal large vessels, and its lower thermal energy output [6–9]. Furthermore, the innovative device can improve operative efficiency by eliminating the need for instrument exchanges during surgery, making it best suited for surgery that require dissection, mobilization, and large vessel sealing [10]. Thus, it could be a useful tool for LRP.

Although current evidence establishes the ACE®+7's clinical benefits, few studies have used real-world data to assess the economic value of the ACE®+7. For more surgeons to use the ACE®+7, it is essential to offset the premium price by showing the ACE®+7 is a high-value, cost-effective surgical tool. This study aimed to demonstrate the ACE®+7's value by determining its effectiveness and economic outcomes compared with conventional ultrasonic shears (CUSs) in LRP in a real-world setting.

2. Methods

2.1. Study population and data source

This is a retrospective observational study of adults (≥18 years old) with PCa undergoing an LRP procedure with the ACE®+7 shear or CUS between August 2019 and April 2021 at Ruijin Hospital (the headquarters and Luwan Center in China), Shanghai Jiao Tong University School of Medicine, Shanghai, China. Patients were excluded from the study if they had robotic-assisted surgery or an intra-fascial prostate resection.

The demographic, diagnosis, and surgical information, intraoperative and postoperative clinical outcomes, and hospitalization costs were collected retrospectively using existing data from the Electronical Hospital Intervention System in Shanghai Ruijin Hospital. The researchers were given permission to use the data for this project. Data extraction was performed by trained physicians and validated by a research assistant to ensure the data accuracy. The study was reviewed and approved by the Ruijin Hospital Ethics Committee, Shanghai Jiao Tong University School of Medicine (reference number: 2020-304) in September 2021 and all methods were performed in accordance with the relevant guidelines and regulations. Waiver of informed consent elements was approved by Ruijin Hospital Ethics Committee in Shanghai Jiao Tong University School of Medicine as the research was a retrospective, observational study based on data from the existing Electronical Hospital Information System and no human intervention was involved, and the research involved no more than the minimal risk to participants and would not adversely affect the rights and welfare of the participants.

Surgeon preference dictated which type of the ultrasonic shear was used during surgery. Propensity score matching (PSM) was performed to form the study population for each clinical group (ACE®+7 or CUSs). PSM is a standard, widely applied technique that simulates an experimental study to estimate a causal effect in an observational data set [11]. It attempts to control confounding biases by making the groups receiving treatment and no treatment comparable to the control variables. The propensity scoring was performed according to age, study

site, body mass index, comorbidities, abnormal rate of coagulation, Gleason score, lymph node dissection, and pelvic adhesiolysis using 1:1 matching.

2.2. Clinical effectiveness

Researchers assessed several endpoints to evaluate the clinical effectiveness of the ACE®+7 shear with an integrated energy system compared with CUSs. These included intraoperative hemostatic clip usage, intraoperative blood loss, transfusion rate, operation time, postoperative rate of using hemostatic drugs (*i.e.*, banting, tamsulosin, tranexamic acid, and aminomethylbenzoic acid), postoperative length of drainage, postoperative drainage volume, length of stay, postoperative length of stay, reoperation rate during the LRP procedure hospitalization, and postoperative readmission within 30 days.

2.3. Hospitalization costs

To determine the cost-effectiveness of the ACE®+7 compared with CUSs, direct medical costs during index hospitalization on each patient were collected through an electronic hospital information system. Direct hospitalization costs included the total cost and cost breakdown comprised of the device cost, treatment cost, pharmaceutical cost, nursing cost, board and room cost, lab test cost, examination cost, transfusion cost, oxygen therapy cost, traditional Chinese medicine cost, diagnosis cost, and other costs.

2.4. Statistical analysis

The descriptive analysis of baseline characteristics was performed before and after PSM. Means and standard deviations (SDs) were tabulated for continuous variables. Frequencies and percentages were tabulated for categorical variables. Statistical differences of continuous variables between the ACE®+7 and CUS groups were analyzed by the *t*-test. Categorical outcome variables were compared using the Chi-square test when the expected frequency is greater than or equal to 5 for all cells or the Fisher exact test when the expected frequency is less than 5 in at least one of the cells. Hospitalization costs were compared between the two groups using the *t*-test.

All statistical analyses were performed using R software version 3.5.3 (R Foundation for Statistical Computing, Vienna, Austria), with *p*-values of <0.05 considered as statistically significant.

3. Results

A total of 222 patients met the inclusion criteria and an additional 29 patients were excluded from the analysis for having missing data. Of the 193 patients included for the descriptive analysis at baseline, 70 were in the ACE®+7 group and 123 were in the CUS group (Fig. 1).

Baseline characteristics were compared in the initial 193 patients. It was found that the distributions of patients at study sites were statistically different between the two groups ($p=0.005$). The percentage of preoperative abnormal coagulation function ($p=0.028$) and the percentage of lymph node dissection during surgery ($p<0.001$) were statistically higher in the ACE®+7 group compared with the CUS group (Table 1).

After 1:1 PSM, there were 50 patients in each treatment group with no statistical difference in baseline characteristics between the groups (Table 2). The mean age of patients was 68.2 (SD 6.2) years in the ACE®+7 group, and 68.4 (SD 7.1) years in the CUS group. The distributions of underlying conditions were similar between groups. In the ACE®+7 group, 26 (52.0%) patients had hypertension, and 9 (18.0%) were diabetic. In comparison, 25 (50.0%) patients in the CUS group had hypertension, and 21 (42.0%) were diabetic. Patients in each group had similar disease progression with mean Gleason scores of 7.6 and 7.7 in the ACE®+7 and CUS groups, respectively.

3.1. Clinical effectiveness

The number of hemostatic clips used per surgery was significantly different between the ACE®+7 and CUS groups. Surgeons used a mean of 12.8 hemostatic clips for patients in the ACE®+7 group compared with a mean of 19.8 clips for patients in the CUS group ($p<0.001$). There was a moderate but not significant difference in mean postoperative drainage duration: 6.6 (SD 2.2) days in the ACE®+7 group versus 7.9 (SD 4.1) days in the CUS group ($p=0.082$). Additionally, there was nearly a 50% reduction in mean total drainage volume in the ACE®+7 group compared with the CUS group: 275.5 (SD 374.3) mL in the ACE®+7 group versus 492.9 (SD 1495.0) mL in the CUS group ($p=0.321$). The ACE®+7 group had a significantly lower mean postoperative hemostatic drug usage rate: 16.0% *vs.* 52.0% ($p<0.001$). No significant differences were found in the amount of intraoperative blood loss, transfusion rate, operation time, total hospital length of stay, or postoperative length of stay (Table 3).

3.2. Hospitalization costs

Although the price of the ACE®+7 shear is higher than that of CUSs, there was no significant difference in total cost between the ACE®+7 group and CUS group: 42 675.0 RMB *vs.* 41 426.3 RMB ($p=0.349$) (Table 4). This was explained by cost savings in several line items, including lab test costs, oxygen therapy costs, and device costs (Table 4). The total cost

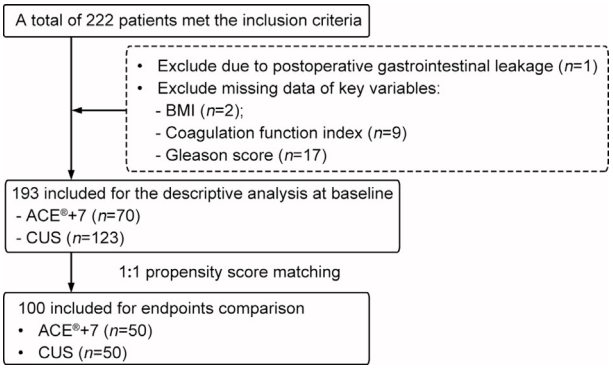

Figure 1 Patient population selection. BMI, body mass index; CUS, conventional ultrasonic shear.

Table 1 Comparisons of baseline characteristics between the ACE®+7 group and CUS group.

Baseline characteristic	ACE®+7 group[a] ($n=70$)	CUS group[a] ($n=123$)	p-Value
Age, year	68.6±6.6	68.9±6.5	0.736
Study site			0.005
Headquarters	35 (50.0)	88 (71.5)	
Ruijin Luwan center	35 (50.0)	35 (28.5)	
BMI, kg/m^2	24.5±2.4	23.9±2.7	0.156
Comorbidity of hypertension	34 (48.6)	61 (49.6)	1.000
Comorbidity of diabetes	13 (18.6)	18 (14.6)	0.608
Preoperative abnormal coagulation function	36 (51.4)	42 (34.1)	0.028
Gleason score	7.5±1.0	7.3±0.9	0.115
Lymph node dissection during surgery	57 (81.4)	63 (51.2)	<0.001
Pelvic adhesiolysis during surgery	35 (50.0)	58 (47.2)	0.818

CUS, conventional ultrasonic shear; BMI, body mass index.
[a] Values are presented as mean±standard deviation, or n (%).

excluding intervention cost was 38 357.8 RMB in the ACE®+7 group compared with 39 983.1 RMB in the CUS group. This difference was not statistically significant ($p=0.223$)

4. Discussion

While other studies have shown the device's clinical effectiveness [7–9], this study showed real-world evidence to demonstrate that the ACE®+7 shear could improve intraoperative and postoperative outcomes without increasing the total hospitalization cost. This study's results are comparable to previous studies and showed that the ACE®+7 shear with an integrated energy system provided better hemostasis effectiveness than the CUS [7,8]. Previous studies have focused explicitly on the technical processes and modes of improvement associated with the ACE®+7, such as decreased thermal energy and increased burst energy, but have not investigated clinical outcomes related to the new ACE®+7 technology compared with CUS [6,7]. This study provides evidence that there are clinical benefits associated with using the ACE®+7 in LRP procedures.

In particular, the new surgical shear was associated with decreased use of hemostatic clips and hemostatic drugs. A recent systematic review found that excessive bleeding was one of the most common LRP complications, affecting 12% of patients [12]. This is considerably higher than 3% of the patients who experience excessive bleeding in surgery [13]. Excessive bleeding can cause hemodilution, hypothermia, consumption of clotting factors, and acidosis [14]. The greater bleeding control could lower surgical complications.

Similarly, in older populations, hemostasis medications are associated with a high risk of gastrointestinal bleeding [15]. Therefore, decreasing hemostatic drug usage is particularly important as older men are more likely to develop PCa. Adopting medical innovations to reduce complications in the populations most affected by PCa is essential to provide high-quality care and achieve better outcomes.

The ACE®+7 did not reduce total hospital costs for LRP patients but lowered several categorical costs. Most notably, patients in the ACE®+7 group experienced cost savings through needing fewer hemostatic clips. While hemostatic clips are not extremely expensive, it is essential to cut costs wherever possible during surgery to compensate for the tool's higher price. The premium price of the ACE®+7 shear is offset by cost reductions in the treatment cost, pharmaceutical cost, nursing cost, and room and board cost. These cost savings are relevant results of the

Table 2 Comparisons of baseline characteristics between the ACE®+7 group and CUS group after 1:1 propensity score matching.

Baseline characteristic	ACE®+7 group[a] ($n=50$)	CUS group[a] ($n=50$)	p-Value
Age, year	68.2±6.2	68.4±7.1	0.858
Study site			0.682
Headquarters	32 (64.0)	29 (58.0)	
Ruijin Luwan center	18 (36.0)	21 (42.0)	
BMI, kg/m^2	24.3±2.6	23.6±3.2	0.224
Comorbidity of hypertension	26 (52.0)	25 (50.0)	1.000
Comorbidity of diabetes	9 (18.0)	7 (14.0)	0.785
Preoperative abnormal coagulation function	20 (40.0)	21 (42.0)	1.000
Gleason score	7.6±1.0	7.7±1.0	0.477
Lymph node dissection during surgery	39 (78.0)	37 (74.0)	0.815
Pelvic adhesiolysis during surgery	32 (64.0)	25 (50.0)	0.226

CUS, conventional ultrasonic shear; BMI, body mass index.
[a] Values are presented as mean±standard deviation, or n (%).

Table 3 Comparisons of clinical outcomes between the ACE®+7 group and CUS group after 1:1 propensity score matching.

Clinical outcome	ACE®+7 group[a] ($n=50$)	CUS group[a] ($n=50$)	p-Value
Intraoperative hemostatic clip usage, n	12.8±5.8	19.8±6.6	<0.001
Intraoperative blood loss, mL	191.1±152.8	204.2±181.6	0.782
Transfusion	1 (2.0)	3 (6.0)	0.610
Operation time, min	162.6±44.8	158.0±37.4	0.586
Postoperative hemostatic drug usage	8 (16.0)	26 (52.0)	<0.001
Postoperative length of drainage, day	6.6±2.2	7.9±4.1	0.082
Postoperative drainage volume within 24 h, mL	72.0±59.1	133.4±282.0	0.135
Postoperative drainage volume within 48 h, mL	143.4±135.5	239.6±495.9	0.189
Postoperative total drainage volume, mL	275.5±374.3	492.9±1495.0	0.321
Length of stay, day[b]	10.7±3.4	11.3±4.8	0.413
Postoperative length of stay, day[c]	7.9±3.0	8.6±4.2	0.337
Re-operation during the LRP procedure hospitalization	0	0	NA
Postoperative readmission within 30 days	0	0	NA

NA, not available; CUS, conventional ultrasonic shear; LRP, laparoscopic radical prostatectomy.
[a] Values are presented as mean±standard deviation, or n (%).
[b] The time elapsed between the hospital admission and discharge.
[c] The time elapsed between the operation and discharge.

better clinical outcomes associated with the ACE®+7 shears. For example, if patients in the ACE®+7 group needed fewer hemostatic drugs, they would have lower pharmaceutical costs.

Medical innovations such as the ACE®+7 shear with an integrated energy system are essential to giving patients value-based care (VBC) or care that offers people the best outcomes for the lowest costs. When evaluating the cost of a new technology, it is essential to take the total relevant costs into consideration, rather than narrowly focusing on the device price. For example, if a device improves a surgical process, perioperative hospitalization costs could be affected by the introduction of the new technology and should be analyzed comprehensively. In the context of VBC, the ACE®+7 technology results in better outcomes but does not increase overall costs. Although the tool itself costs the health system more money, there are areas for further cost savings that offset the device cost.

VBC is essential if China wants to reach universal health coverage. In 2009, China launched an extensive health reform plan to provide all citizens equal access to quality health and financial risk protection [16]. In response to current gaps in this plan, the WHO released recommendations to help China achieve the goal, such as improving

Table 4 Direct hospitalization cost comparisons between the ACE®+7 group and CUS group after 1:1 propensity score matching.

Cost, RMB	ACE®+7 group[a] ($n=50$)	CUS group[a] ($n=50$)	Difference[b]	p-Value
Total cost	42 675.0±5134.5	41 426.3±7623.7	1248.7	0.349
Device cost	23 308.4±5702.0	19 467.5±5946.7	3840.9	0.002
Treatment cost	3287.0±3902.9	4412.4±4097.2	−1125.4	0.176
Pharmaceutical cost	6800.3±4169.0	7436.4±4481.4	−636.1	0.478
Nursing cost	555.6±275.8	649.9±352.1	−94.3	0.149
Board and room cost	723.0±636.0	858.7±694.4	−135.7	0.325
Lab test cost	2636.8±805.9	3132.3±1280.2	−495.5	0.025
Examination cost	3591.3±763.4	3792.1±1178.1	−200.8	0.324
Transfusion cost	20.0±141.4	49.2±192.0	−29.2	0.400
Oxygen therapy cost	44.3±8.4	62.9±50.8	−18.6	0.012
TCM cost	996.5±1034.8	765.4±999.0	231.1	0.275
Diagnosis cost	376.0±88.7	384.4±106.0	−8.4	0.677
Other cost	335.8±355.5	415.1±426.8	−79.3	0.328
Total cost excluding intervention cost[c]	38 357.8±5127.1	39 983.1±7618.3	−1625.3	0.223

CUS, conventional ultrasonic shear; TCM, traditional Chinese medicine.
[a] Values are presented as mean±standard deviation.
[b] The difference is calculated as the mean cost of ACE®+7 group minus that of CUS group.
[c] Intervention cost for ACE®+7 group is the service fee of an integrated ultrasonic and electrosurgical energy system (800 RMB) and the cost of Harmonic ACE®+7 shear (3500 RMB) which has a separate billing code; intervention cost for CUS group is the service fee of ultrasonic shear system (1400 RMB) which contains the cost of ultrasonic shear and relevant service.

quality of care through patient-centered care and VBC to overcome these shortfalls in the hopes of patients having better health, higher quality care, and care at affordable costs [17]. Overall, increasing the ACE®+7 shear uptake for LRP can lead to high-quality, cost-effective care for patients with PCa.

There are several limitations in this study. Firstly, in the initial study population, patients had more complex conditions in the ACE®+7 group than the CUS group. For example, the percentages of abnormal coagulation function and conducting lymph node dissection during surgery are both much higher in the ACE®+7 group. Although we conducted PSM to control the difference, the inconsistence could not be entirely eliminated since some confounders could not be recorded in our study, such as the tumor size, tumor-nodes-metastasis stage, and prostate tissue condition. There was also a loss of sample size due to the inconsistence of baseline characteristics. Secondly, we did not capture indirect costs, such as the patient care cost after discharge, nor did we collect data on continence, erectile dysfunction, or re-admissions, and further work is needed to incorporate these outcomes into the evaluation. Lastly, according to Hospital Management Institute's 2020 China Hospital rankings, Ruijin hospital is one of the top Tier III hospital in China. In turn, the surgeons' surgical skills in Ruijin Hospital are relatively advanced compared with those in Tier II hospital. As a result, the study results might not be the same in Tier II hospitals. However, we assume the new technology with a stable clinical effectiveness could help to standardize the surgical procedures and reduce reliance on surgical skills, thus improving junior surgeons' performance. Similarly, we did not measure vesico-urethral anastomosis quality which influences the postoperative drainage volume. While this could cause bias, this risk is minimized because both patient groups had similar proportions and extent of lymph node dissection, and as the occurrence of postoperative urinary leakage did not differ significantly between the groups, we can infer that there was no significant difference in the quality of the anastomosis. Additionally, this is a retrospective study and is prone to biases such as selection bias, the inability to control which treatment a patient received, and the lack of measurements for several confounders. The PSM method was used to mitigate the biases.

5. Conclusion

This real-world study demonstrated that the ACE®+7 shear with an integrated energy system improved clinical outcomes compared to CUSs for patients receiving LRP. While the device costs more compared with CUSs, the ACE®+7 can offer other cost savings for hospitals and health systems.

Author contributions

Study concept and design: Yi Gao, Danfeng Xu.
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Data analysis: Yi Gao, Yu Zhu, Fukang Sun.
Drafting of manuscript: Debra Winberg.
Critical revision of the manuscript: Yi Gao, Danfeng Xu.

Conflicts of interest

The authors declare no conflict of interest.

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