

Multicenter, Prospective, Randomized Controlled Clinical Study Protocol: Pelvic Drain Placement versus No Pelvic Drain Placement after Robot-Assisted Radical Prostatectomy

Clinical Study Protocol

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Protocol Synopsis

Item	Design Recommendation
Study type	Multicenter, prospective, randomized, controlled, non-inferiority study
Allocation	1:1 allocation to the no-drain group versus the drain-placement group
Blinding	Open-label
Randomization time point	Written informed consent and pre-registration before surgery; final randomization recommended after completion of the

	intraoperative vesicourethral anastomosis, a negative water-tightness test, and satisfactory hemostasis
Stratification factors	Center, D'Amico or EAU risk stratification, surgeon or annual surgical volume may serve as stratification or adjustment factors
Primary analysis sets	Intention-to-treat set (ITT), per-protocol set (PP), and safety set (SS) will all be reported
Follow-up period	Postoperative day (POD) 90 as the primary endpoint observation window; continence, sexual function, and PSA/biochemical recurrence-free survival may be extended to 6–12 months, and to 24 months where conditions permit

1. Background

Robot-assisted radical prostatectomy (RARP) has become an important curative treatment for localized and selected locally advanced prostate cancer. Pelvic drains have traditionally been used to monitor for or drain urine leakage from the vesicourethral anastomosis, postoperative bleeding, pelvic fluid collections, and lymphatic fluid after pelvic lymph node dissection (PLND). However, with continuous improvements in surgical visualization, hemostasis, anastomotic technique, and perioperative management in RARP, the necessity of routine prophylactic pelvic drain placement has been re-evaluated.

The EAU Guidelines on Prostate Cancer, in the section "Postoperative care — pelvic drainage," state that pelvic drains have traditionally been used to manage urine, bleeding, or lymphatic fluid after radical prostatectomy that may originate from the vesicourethral anastomosis or from PLND; in the robot-assisted laparoscopic setting, two randomized controlled trials, both of which excluded patients with urine leakage detected by intraoperative anastomotic water-tightness testing, demonstrated that omitting drains was non-inferior with respect to complication rates. The guidelines further note that when a water-tight anastomosis is confirmed intraoperatively, avoiding pelvic drain placement is reasonable; for the setting of PLND, there is currently no evidence to guide drain placement. [1]

Previous prospective randomized non-inferiority studies provide a direct basis for the design of this study. In the single-center randomized non-inferiority trial by Chenam et al., RARP patients were randomly allocated to a no-drain group or a pelvic drain group; the vesicourethral anastomosis was tested with 120 mL of saline intraoperatively, and patients with urine leakage, inadequate hemostasis, or intraoperative injury underwent drain placement and were excluded. The primary endpoint was overall Clavien–Dindo grade I–V complications within 90 days postoperatively; the complication rate in the historical drain group was estimated at 13%, and the non-inferiority margin was set at 10%. A total of 189 patients were enrolled. The results showed a 90-day overall complication rate of 17.4% in the no-drain group versus 26.8% in the drain group; major complication rates were 5.4% and 5.2%, respectively; and symptomatic lymphocele rates

were 2.2% and 4.1%, respectively. Omitting drains was non-inferior to drain placement for both overall and major complications. [2]

The single-center randomized clinical trial by de Luyk/Porcaro et al. enrolled patients undergoing RARP with or without extended PLND, comparing drain placement for 24 hours postoperatively versus no drain placement. The primary endpoint was the Clavien–Dindo complication rate; secondary endpoints included length of hospital stay and readmission rate. The final analysis showed comparable complication rates, hospital stay, and readmission rates between the two groups. The authors concluded that in a contemporary RARP cohort, a no-drain strategy is comparable to drain placement, although short-term drainage may be considered when the anastomosis is difficult or its watertightness is uncertain. [3]

Recent systematic reviews and meta-analyses further support the value of prospective verification of this question. A 2023 systematic review in BJU International included 8 studies related to pelvic drainage after RARP and found no significant differences between no-drain and drain strategies in any complication, severe complications, all lymphoceles, or symptomatic lymphoceles, with no-drain associated with a lower risk of postoperative ileus. [4] A 2023 meta-analysis in BJS Open included 6 studies with 1,480 patients and similarly showed no differences between no-drain and drain strategies in estimated blood loss, overall complications, low-grade and high-grade complications, or length of hospital stay, concluding that pelvic drainage can be omitted after RARP in appropriately selected patients. [5]

On the other hand, drains are not entirely harmless. Drains may increase local discomfort, limit mobility, and complicate the discharge process, and may cause drainage-site infection, drain fracture, or rare mechanical complications. Case reports have described drain-related intestinal obstruction or mechanical bowel obstruction after RARP combined with PLND, indicating that the drain itself may cause infrequent but clinically meaningful harm. [6] Therefore, in patients with a watertight vesicourethral anastomosis, satisfactory intraoperative hemostasis, and no organ injury, validating the safety, feasibility, and potential recovery benefits of a "no-drain" strategy through a rigorously designed clinical study is of clear clinical significance.

Source of Evidence	Study Design	Direct Implications for This Study
EAU Guidelines on Prostate Cancer	International guideline	With an intraoperatively confirmed water-tight anastomosis, pelvic drainage can reasonably be avoided; evidence remains insufficient in the PLND setting. [1]
Chenam et al.	Prospective randomized non-inferiority trial	90-day overall complications as the primary endpoint, 10% non-inferiority margin; supports the safety and feasibility of omitting drains. [2]
de Luyk/Porcaro et al.	Randomized clinical trial	No-drain comparable to 24-hour drainage in

		complications, length of stay, and readmission rate. [3]
Yanagisawa et al.	Systematic review and meta-analysis	No-drain did not increase overall/severe complications or lymphoceles and may reduce the risk of ileus. [4]
Ma et al.	Systematic review and meta-analysis	In selected patients, omitting drainage after RARP does not increase perioperative adverse outcomes. [5]

2. Study Title

Safety and Efficacy of No Pelvic Drain Placement versus Routine Pelvic Drain Placement after Robot-Assisted Radical Prostatectomy: A Prospective, Randomized, Controlled, Non-Inferiority Clinical Study.

3. Objective

3.1 Research Hypothesis

Null hypothesis: The complication rate in the no-drain group is 10 percentage points or more higher than that in the drain group; omitting drainage is inferior to drain placement. (H0)

Alternative hypothesis: The absolute increase in complication rate in the no-drain group relative to the drain group is less than 10 percentage points; omitting drainage is non-inferior to drain placement. (H1)

3.2 Study Objective

To evaluate, in RARP patients, whether omitting pelvic drain placement does not result in an increase in the overall incidence of complications within 90 days postoperative that exceeds a clinically acceptable margin, while potentially reducing drain-related discomfort, promoting mobility, and shortening the hospitalization process.

4. Intervention(s)

- No-drain patients: the no-drain strategy is executed after completion of the intraoperative vesicourethral anastomosis, a negative water-tightness test, and satisfactory hemostasis.
- Drain group patients: at the end of surgery, a silicone tube is inserted through the abdominal wall under laparoscopic guidance and placed adjacent to the surgical field in the pelvis.

5. Trial Design

This trial is designed as a multicenter, prospective, randomized, controlled, non-inferiority study with two parallel groups. The primary endpoint is a binary outcome, namely the occurrence of any Clavien–Dindo grade I–V complication within 90 days postoperatively.

5.1 Groups

Randomization will be performed with a 1:1 allocation ratio.

- No pelvic drain: no pelvic drain is placed after RARP.
- Pelvic drain placement (control group): a pelvic drain is placed.

6. Eligibility Criteria

Patients (or their representatives) must provide written informed consent before any study procedure begins.

6.1 Inclusion Criteria

All patients must meet the surgical criteria of the Chinese Guidelines for the Diagnosis and Treatment of Prostate Cancer. In addition, patients eligible for the trial must meet ALL of the following conditions at randomization:

- Histologically confirmed prostate cancer, life expectancy > 10 years, and planned RARP as curative treatment;
- Clinically localized or locally advanced disease with no definite distant metastasis;
- No simultaneous PLND/ePLND planned per guideline recommendations and surgeon judgment;
- ECOG performance status score 0–2;
- Able to understand the study and sign written informed consent;
- Able to complete at least 90 days of postoperative follow-up.

6.2 Exclusion Criteria

- Salvage prostatectomy;
- Previous pelvic radiotherapy;
- Previous complex pelvic surgery resulting in severe anatomical alteration;
- Requirement for concurrent other major pelvic or abdominal surgery;
- Uncorrectable coagulopathy;
- Active infection or severe systemic disease unsuitable for study follow-up;

- Any other condition considered by the investigator to make enrollment inappropriate.

7. Sample Size Estimation

The primary endpoint is a binary outcome, namely the occurrence of any Clavien–Dindo grade I–V complication within 90 days postoperatively. Therefore, the sample size can be calculated based on a non-inferiority test for the difference between two independent proportions. Let the no-drain group be the experimental group and the drain group the control group; the primary comparative measure is the risk difference:

$$RD = pT - pC$$

where pT is the overall 90-day complication rate in the no-drain group and pC is the overall 90-day complication rate in the drain group. The non-inferiority hypotheses can be written as:

$$H_0: pT - pC \geq \Delta$$

$$H_1: pT - pC < \Delta$$

where Δ is the prespecified non-inferiority margin. This protocol recommends $\Delta = 10\%$, i.e., the study team considers that if omitting drainage results in an absolute increase in the 90-day overall complication rate of less than 10%, while reducing drain-related discomfort, nursing burden, and potential drain-related complications, then its safety is clinically acceptable. This margin is consistent with a previous randomized non-inferiority trial of pelvic drainage after RARP. [2]

Under the assumption of 1:1 equal allocation and equal true complication rates in the two groups, the sample size per group can be estimated by the following formula:

$$n = (Z_{1-\alpha} + Z_{1-\beta})^2 \times [pT(1-pT) + pC(1-pC)] / \Delta^2$$

where α is the one-sided type I error rate, $(1-\beta)$ is the power, and Z denotes standard normal quantiles. As non-inferiority studies typically use one-sided testing, this protocol recommends a confirmatory setting of one-sided $\alpha = 0.025$ and 80% power.

The control-group event rate is assumed to be 13% as the base assumption. This value comes from the 90-day overall complication rate estimated from the previous standard-of-care drain cohort at the same institution in the study by Chenam et al. and was used in their non-inferiority sample size design. [2]

Under the base assumptions ($pC = 13\%$, $pT = 13\%$, $\Delta = 10\%$, one-sided $\alpha = 0.025$, 80% power, 10% dropout rate), the uncorrected sample size per group is 177.54, rounded up to 178; after accounting for a 10% dropout, 197.27 patients per group are required, rounded up to 198 per group, for a total sample size of 396. To facilitate execution and allocation across centers, a total enrollment of 400 patients is planned, i.e., approximately 200 per group.

Scenario	Expected control complication	Non-inferiority margin	One-sided α	Power	Dropout rate	Enrollment per group	Total sample size
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	rate						
Recommended confirmatory plan	13%	10%	0.025	80%	10%	198	396
Lenient plan consistent with the Chenam et al. trial	13%	10%	0.05	80%	10%	156	312

8. Standard Operating Procedures (SOP)

8.1 All patients must meet the surgical criteria of the Chinese Guidelines for the Diagnosis and Treatment of Prostate Cancer.

8.2 Perioperative management must comply with relevant guidelines and local health authority requirements; attention must be paid to pain management.

8.3 After reporting relevant information to the Quality Control Committee (QCC), eligible patients who are confirmed intraoperatively to undergo RARP are randomly allocated in a 1:1 ratio to the two groups (no-drain group and drain group).

8.4 Simple randomization is performed using a computer-generated random number sequence produced by the Quality Control Committee.

8.5 Quality requirements: all operations must be performed by experienced surgeons who have completed at least 300 RARP procedures before the study. All perioperative treatment must comply with relevant guidelines.

8.6 Criteria for completion of the no-drain strategy: after standard RARP, if the intraoperative water-tightness test of the vesicourethral anastomosis is negative, hemostasis is satisfactory, and there is no organ injury, no pelvic drain is placed.

8.7 For drain-group patients, at the end of surgery, a silicone tube is inserted through the abdominal wall under laparoscopic guidance and placed adjacent to the surgical field in the pelvis.

8.8 The drain is secured to the skin with sutures and connected to a drainage bag.

8.9 At the surgeon's discretion, when the drainage volume is low and the character of the fluid is unremarkable, the drain may be removed on postoperative days 1–2; if the drainage volume is high (e.g., > 100 mL over 8 hours or exceeding the center-specific threshold over 24 hours), drain fluid creatinine should be measured and compared with serum creatinine to determine whether urine leakage is present. If urine leakage, bleeding, or lymphatic leakage is suspected, drainage should be prolonged, the urethral catheter retained longer, or imaging evaluation performed according to the prespecified procedures.

8.10 If a patient develops intolerable pain, early drain removal is permitted.

8.11 Both groups must follow an identical perioperative management pathway, including antimicrobial prophylaxis, thromboprophylaxis, analgesia, early postoperative mobilization, dietary resumption, urethral catheter management, and discharge criteria. Urethral catheter removal is recommended uniformly on postoperative day 14.

8.12 The overall incidence of complications within 90 days postoperatively is set as the primary follow-up endpoint, defined as any Clavien–Dindo grade I–V complication occurring from the end of surgery to postoperative day 90.

9. Follow-up Plan

9.1 Follow-up period: within 90 days after surgery.

9.2 A designated investigator will maintain contact with discharged patients and instruct them to return to the hospital for follow-up if they feel unwell.

9.3 The follow-up plan must cover the perioperative period, the urethral catheter removal period, the early high-incidence period of complications, and the 90-day primary endpoint window. Functional and oncological follow-up is recommended to be extended to at least 12 months, focusing on continence, sexual function, and PSA/biochemical recurrence-free status.

10. Outcome Measures

10.1 Primary Outcome Measure

The overall incidence of complications within 90 days postoperatively is the primary endpoint, defined as any Clavien–Dindo grade I–V complication occurring from the end of surgery to postoperative day 90.

10.2 Secondary Outcome Measures

N o.	Secondary outcome	Recommended definition or measurement	In-hospital	At catheter removal	At discharge	30 d	90 d	1 mo	3 mo	6 mo	12 mo	24 mo
1	Major complication rate	Clavien–Dindo grade $\geq$ III complications within 90 days postoperatively, including events requiring interventiona				✓	✓					

		l, endoscopic, reoperative, or ICU treatment, or life-threatening events										
2	Urine leakage or anastomosis-related event rate	Imaging-confirmed urine leakage; drain fluid creatinine significantly higher than serum creatinol; or prolongation of urethral catheterization, re-catheterization, percutaneous drainage, or other interventions due to suspected/definite anastomotic problems	✓	✓		✓	✓					
3	Symptomatic pelvic fluid collection/lymphoceles rate	Pelvic fluid collection or lymphocele with pain, fever, infection, lower-limb edema, compressive symptoms, or requiring antibiotics, puncture, catheterization, readmission, or re-				✓	✓					

		intervention										
4	Postoperative recovery and healthcare resource utilization	Length of postoperative hospital stay as the core quantitative indicator, with 90-day readmission and re-intervention rates recorded concurrently to explain differences in resource utilization			✓	✓	✓					
5	Urinary continence recovery rate	Primary definition: 0 pad or security pad only; patient-reported outcomes recommended to be quantified with ICIQ-SF and the EPIC-26 urinary incontinence domain				✓				✓		

10.3 Demographic and Baseline Characteristics

(1) Demographics: age, height, weight, and body mass index (BMI) will be collected for each subject.

(2) Medical history: medical history will be determined at the screening visit, recording diseases, health disorders, and concomitant medications within the preceding three years:

- Diseases or trauma requiring hospitalization within three years and related sequelae;
- Chronic diseases requiring long-term medication or other treatment;

- Confirmed or under observation but not yet actively treated diseases that may require intervention due to rapid progression and deterioration;
- Allergic reactions.

(3) Prostate cancer diagnosis:

- Clinical staging: the American Joint Committee on Cancer (AJCC) TNM staging system will be used for clinical staging of primary prostate cancer;
- Clinical grading: the Gleason scoring system will be used for clinical grading of prostate cancer;
- Tumor size — imaging: MRI scans used to measure tumor diameter (mm); pathology: core length (mm) of prostate needle biopsy.

(4) Performance status: subjects will be classified using the WHO performance status scale.

(5) Serum PSA level.

11. Data Collection Methods

Data to be collected include, but are not limited to, the following: preoperative information including sex, age, and contact details; basic inpatient information; relevant examination results including CT, MRI, PET, etc.; surgical information including surgical approach, operative time, blood loss, etc.; postoperative information including laboratory results such as blood counts and albumin, patient symptoms, signs, pelvic drainage and fluid characteristics, and related measurements. See the Case Report Form (CRF) for details.

11.1 Case Report Form (CRF)

In this trial, all required observations or examinations must be recorded in the CRF. The content of the CRF must be fully consistent with source data. For results calculated from source data, the calculation basis must be documented.

11.2 Source Data Documentation

All information must be recorded in the CRF in a timely, truthful, and detailed manner. The data manager will check the completeness and accuracy of the CRFs and make necessary corrections or additions.

11.3 Quality Control

Corresponding examinations and assessments must be performed as required and recorded in the CRF. All forms must be completed, signed, and dated by the investigator. The principal investigator will check CRF completion every 6 months, supervise completion of the CRFs, and review and sign them. All items must have corresponding objective evidence, be kept available for inspection, and must not be fabricated. The data manager will carefully verify each CRF and sign after confirming its completeness and accuracy. Medical records must be truthful and reliable, properly kept, and available for spot checks at any time. Corrections must be signed and dated, with the original entry remaining legible.

12. Statistical Analysis Plan

12.1 A biostatistician and the principal investigator will develop the statistical analysis plan based on the study protocol; the data manager will perform the statistical analyses according to the statistical plan.

12.2 Non-inferiority studies use one-sided tests; this protocol adopts a confirmatory setting of one-sided $\alpha = 0.025$ and 80% power.

12.3 Analyses of primary and secondary endpoints are based on the intention-to-treat (ITT) principle. Under ITT, all randomized participants are included in the primary analysis according to the group to which they were originally allocated, and are not excluded or reallocated because of non-compliance, crossover, or treatment discontinuation.

12.4 The per-protocol (PP) analysis includes only participants who strictly followed the study protocol and completed the entire course of treatment per protocol. The PP analysis is limited to participants meeting the inclusion criteria and the requirements of the intervention and outcome assessment protocols.

12.5 In non-inferiority studies, the ITT analysis may be biased toward no difference between groups because of protocol deviations; the PP analysis serves as an important verification. It is therefore recommended that non-inferiority be declared robust only when both analyses support it. The primary effect measure is the risk difference with its two-sided 95% confidence interval; if the upper bound of the risk difference is below 10%, omission of drainage will be declared non-inferior.

12.6 The safety set (SS) will be used for the analysis of safety endpoints, including all subjects who received at least one study intervention, to assess the actual safety exposure of the no-drain strategy.

12.7 For secondary endpoints that are binary or time-to-event variables — such as major complications, urine leakage or anastomosis-related events, symptomatic pelvic fluid collection/lymphocele, continence recovery, sexual function recovery, and biochemical recurrence-free probability — the risk difference, relative risk, odds ratio, Kaplan–Meier estimates, or Cox model results with 95% confidence intervals may be reported.

12.8 Continuous variables such as length of hospital stay may be reported as mean $\pm$ standard deviation or median with interquartile range depending on distribution, and analyzed using the t-test, Wilcoxon rank-sum test, or generalized linear models.

12.9 Prespecified subgroup analyses should include D'Amico or EAU risk stratification, BMI ≥ 25 or ≥ 30 kg/m², previous TURP or bladder neck reconstruction, nerve sparing, prostate volume, and center/surgeon volume.

12.10 Missing data: for the primary endpoint, telephone follow-up, outpatient visits, the inpatient system, and records from other hospitals should be used to complete missing information as far as possible. If the proportion of missing primary endpoint data is low, a complete-case analysis may

be performed with worst/best-case sensitivity analyses; if the proportion is high, multiple imputation should be used and the variables in the imputation model reported.

13. Research Ethics Approval

13.1 Ethics Committee Approval

This protocol and the informed consent form template will be reviewed and approved by the sponsor and the applicable ethics committees with respect to scientific content and compliance with applicable research and human-subject regulations. The protocol, center-specific informed consent forms, patient education and recruitment materials, and other required documents — as well as any subsequent amendments — will also be reviewed and approved by the ethics review bodies.

13.2 Informed Consent

Trained resident physicians will introduce the trial to patients. Patients will also receive an information sheet. The study resident will discuss the trial with the patient based on the information provided in the information sheet. The patient may then have an informed discussion with a consulting physician participating in the study. The study resident will obtain written consent from patients willing to participate.

13.3 Participant Confidentiality

All study-related information will be kept securely at the research center. All participant information will be stored in locked filing cabinets in restricted-access areas. All laboratory specimens, reports, data collection, processing, and management forms will be identified only by coded ID (identification number) to maintain participant confidentiality. All records containing names or other personal identifiers (such as enrollment logs and informed consent forms) will be stored separately from study records identified by code numbers. All local databases will be secured with password-protected access systems. Forms, lists, logs, appointment books, and any other lists linking participant ID numbers to other identity information will be stored in a separate locked file in a restricted-access area. Without the participant's written permission, participant study information will not be released outside the study.

13.4 Protocol Amendments

After this protocol is approved by the ethics committee, if any substantial changes occur during implementation, the contact investigator will draft an amendment explanation, sign it, and report it to the ethics committee for approval before implementation. The Quality Control Committee will discuss with methodological investigators and co-sign. Administrative changes to the protocol are minor corrections and/or clarifications that do not affect the conduct of the study. Such administrative changes will be agreed upon by the Quality Control Committee and recorded in a memorandum.

14. Committees

Before the trial begins, project team members will study this clinical study protocol to fully understand and master the requirements and content of the study.

14.1 Lead Investigator

At each participating center, a lead investigator will be designated, responsible for identification, recruitment, data collection, completion of the CRF, follow-up of study patients, and compliance with the study protocol and investigator manual. The lead investigator will be a member of the Quality Control Committee.

The lead investigator will conduct a check every 6 months, supervise the completion of CRF forms, and review and sign them. All items must have corresponding objective evidence for review and use and must not be falsified. Source data related to this trial include: (1) medical records: case registration forms, case registration confirmation forms, informed consent forms, patient background surveys, symptoms and signs, treatment and treatment content; (2) examination reports (pathology, imaging findings); (3) laboratory data (blood biochemistry, etc.). Investigators must retain all clinical trial-related data for five years after completion of the trial.

14.2 Data Manager

Responsible for data collection and verification. He/she will check the completeness and accuracy of the CRFs and make necessary corrections or additions.

14.3 Quality Control Committee (QCC)

Composed of the lead investigator and the data manager. Its responsibilities include: agreeing on the final protocol; reviewing study progress and, when necessary, agreeing on amendments to the protocol and/or investigator manual to facilitate smooth conduct of the study; study planning; and responsibility for the trial master file and randomization.

15. Adverse Events

Investigators will be trained to report adverse events proactively at any time when they occur. In addition, investigators should check for adverse events through inquiry and interview at regular study visits. The condition of patients experiencing adverse events should be discussed and reported to the Quality Control Committee for cause analysis. After discussion, if a problem directly related to the study design actually exists, the protocol should be amended.

15.1 Adverse Event Classification

For the assessment of adverse events in this study, please refer to CTCAE v5.0 (Chinese version) and the [Accordion Severity Grading System]. Grading refers to the severity of the adverse event. CTCAE provides specific clinical descriptions of the severity (grades 1–5) of each adverse event according to the following general guidelines:

Grade 1: Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; no intervention indicated.

Grade 2: Moderate; minimal, local, or noninvasive intervention indicated; limiting age-appropriate instrumental activities of daily living (e.g., cooking, shopping for clothes, using the telephone, managing finances).

Grade 3: Severe or medically significant but not immediately life-threatening; hospitalization indicated or prolongation of hospitalization indicated; disabling; limiting self-care activities of daily living (e.g., bathing, dressing/undressing, eating, washing, taking medication; not bedridden).

Grade 4: Life-threatening; urgent intervention indicated.

Grade 5: Death.

15.2 Adverse Event Recording

All adverse events must be recorded on the Adverse Event Report Form attached to the CRF. For each adverse event, the lead investigator must assess and record its severity, duration, relationship to the surgery or TDT, management measures, and outcome of the event.

15.3 Adverse Event Reporting

If any "serious adverse event" or "unexpected adverse event" occurs, the investigator must report it to the Quality Control Committee within 24 hours of becoming aware of the event. The Quality Control Committee is responsible for handling serious adverse events, regardless of whether the event is related to treatment. The outcomes of all reported serious adverse events (including death) will be followed up and documented. Reporting to the relevant regulatory authorities in accordance with national regulations will be completed by the responsible entity; in all cases, all participants must comply with local laws, regulations, and requirements.

Appendix 1. ECOG Performance Status

ECOG Score	Criteria
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light housework or office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any self-care; totally confined to bed or chair
5	Dead

Appendix 2. Clavien–Dindo Classification of Surgical Complications (Grades I–V)

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological, surgical, endoscopic, or radiological intervention; acceptable therapeutic regimens include drugs such as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy; this grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than those allowed for grade I; including blood transfusions and total parenteral nutrition
Grade III	Requiring surgical, endoscopic, or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including central nervous system complications) requiring intermediate care or intensive care management
Grade IVa	Single-organ dysfunction (including dialysis)
Grade IVb	Multi-organ dysfunction
Grade V	Death

Appendix 4. ICIQ-SF

[Original ICIQ-SF questionnaire figures — see the Chinese protocol for the images.]

Appendix 5. Gleason Scoring System

The Gleason score is a grading system (grades 1–5) used to determine the aggressiveness of prostate cancer:

Grade	Characteristics
Grade 1	Uncommon grade. Well-differentiated, small, uniform glands with a normal appearance.
Grade 2	Irregular glands with mild atypia; glands loosely aggregated within small nodules.
Grade 3	The most common grade. Tumor glands are usually smaller than grade 1 or 2; tumor infiltrates between non-neoplastic prostatic acini.
Grade 4	Larger irregular cribriform or fused, poorly

	circumscribed glands with poor luminal formation.
Grade 5	Cribriform or solid tumor nests with central comedo-like necrosis; tumor cells individually or in cords and trabeculae infiltrating the stroma.

Note: Value of the Gleason score. Gleason score 2–4 (well differentiated); Gleason score 5–6 (moderately differentiated); Gleason score 7 (moderately–poorly differentiated); Gleason score 8–10 (poorly differentiated).

Appendix 6. TNM Staging of Primary Prostate Cancer

Tx: Primary tumor cannot be assessed;

T0: No evidence of primary tumor;

T1: Clinically inapparent tumor not palpable or visible by imaging;

T1a: Tumor incidental histologic finding in $\leq 5\%$ of tissue resected;

T1b: Tumor incidental histologic finding in $> 5\%$ of tissue resected;

T1c: Tumor identified by needle biopsy (e.g., because of elevated PSA).

T2: Tumor confined within the prostate*

T2a: Tumor involves one half of one lobe or less;

T2b: Tumor involves more than half of one lobe but not both lobes;

T2c: Tumor involves both lobes.

T3: Tumor extends through the prostatic capsule**

T3a: Extracapsular extension (unilateral or bilateral);

T3b: Tumor invades seminal vesicle(s).

T4: Tumor is fixed or invades adjacent structures other than seminal vesicles, e.g., bladder, external sphincter, rectum, levator muscles, and/or pelvic wall.

Notes: Tumors found by needle biopsy in one or both lobes but not palpable or visible by imaging are classified as T1c; tumors that invade the prostatic apex or the prostatic capsule but not beyond it are classified as T2 rather than T3.

References

- [1] EAU Guidelines on Prostate Cancer, Treatment chapter, 2026.
<https://uroweb.org/guidelines/prostate-cancer/chapter/treatment>
- [2] Chenam A, et al. Pelvic drain placement vs no pelvic drain placement after robot-assisted radical prostatectomy. *BJU International*. 2018;121:358–365. <https://doi.org/10.1111/bju.14010>
- [3] Porcaro AB / de Luyk N, et al. Is a drain needed after robotic radical prostatectomy with or without pelvic lymph node dissection? *Journal of Endourology*.
<https://doi.org/10.1089/end.2018.0176>
- [4] Yanagisawa T, et al. Role of pelvic drain and timing of urethral catheter removal following RARP: a systematic review and meta-analysis. *BJU International*. 2023.
<https://doi.org/10.1111/bju.16022>
- [5] Ma J, et al. Pelvic drain placement after robot-assisted radical prostatectomy: meta-analysis. *BJS Open*. 2023;7(6):zrad143. <https://doi.org/10.1093/bjsopen/zrad143>
- [6] Case report evidence on surgical drain-related intestinal obstruction after robot-assisted laparoscopic radical prostatectomy. <https://doi.org/10.1089/cren.2020.0007>