

An innovative approach for robotic-assisted laparoscopic radical prostatectomy: a single-hospital study

Submission date 11/08/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/08/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/08/2023	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Robot-assisted laparoscopic radical prostatectomy (RARP) is a surgical treatment for prostate cancer patients without metastasis (when the cancer hasn't spread). Injury of the nerve near the prostate during the operation could lead to incontinence or erectile disability. The pubovesical complex-sparing RARP technique can preserve essential nerves for urine and sexual function better. This study aimed to describe the steps of the pubovesical complex-sparing laparoscopic RARP technique and report the functional and oncological outcomes.

Who can participate?

Clinically localized prostate cancer patients aged between 18 and 70 years

What does the study involve?

All patients received pubovesical complex-sparing laparoscopic RARP. Personal data including urine and sexual function is recorded before the operation. The surgical outcome was recorded after the operation. The treatment course was the same as other prostate cancer patients. The only difference was the surgical method.

What are the possible benefits and risks of participating?

A benefit is that the outcome of pubovesical complex-sparing laparoscopic RARP is expected to achieve an international level. There are no major complications.

Where is the study run from?

Tungs' Taichung MetroHarbor Hospital (Taiwan)

When is the study starting and how long is it expected to run for?

January 2019 to December 2022

Who is funding the study?

Tungs' Taichung MetroHarbor Hospital (Taiwan)

Who is the main contact?
Chin-Heng, Lu, chinhenglu@gmail.com (Taiwan)

Contact information

Type(s)

Public

Contact name

Dr Chin-Heng Lu

ORCID ID

<http://orcid.org/0000-0003-3707-6423>

Contact details

Tung's Taichung Metroharbor Hospital
No.699, Sec. 8, Taiwan Blvd.
Taichung City
Taiwan
435
+886 (0)980985308
chinhenglu@gmail.com

Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Pubovesical Complex-sparing Technique during Robotic-assisted Laparoscopic Radical Prostatectomy functional and oncologic outcomes report: a single-institution case series

Acronym

Modified PCS RARP

Study objectives

This study aimed to describe the steps of the PVC-sparing technique and report functional and oncological outcomes.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 15/04/2020, Institutional Review Board of Tungs' Taichung Metroharbor Hospital (No. 699, Section 8, Taiwan Boulevard, Wufeng District, Taichung City, 43503, Taiwan; +886-4-26581919#4635; d3905@ms3.sltung.com.tw), ref: 109007

Study design

Single-institution case series observational report for 2 years

Primary study design

Observational

Secondary study design

Case series

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Surgical skill introduction and surgical outcome report for clinically localized prostate cancer patients with specific surgical treatment

Interventions

Surgical skill introduction and surgical outcome report for patients who received pubovesical complex-sparing robotic-assisted laparoscopic radical prostatectomy.

Intervention Type

Procedure/Surgery

Primary outcome measure

Erectile function measured using the International Index of Erectile Function (IIEF)-5 score preoperatively and at follow-up for at least 2 years

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/01/2019

Completion date

31/12/2022

Eligibility

Key inclusion criteria

1. Male patients aged over 18 years and <70 years
2. Clinically organ-confined disease (cT1–cT2) staged by CT scan
3. Gleason score ≤ 7
4. Total PSA ≤ 10 ng/mL. PSA or biochemical failure was defined as two serial serum PSA results >0.2 ng/mL
5. Prostate volume <60 mL
6. Normal preoperative continence and sexual function. Patients had to be completely continent (pad-free) and have an IIEF score ≥ 17 at baseline. Continence was defined as not using pads. Potency was defined as achieving full erection during sexual intercourse with or without using phosphodiesterase 5 inhibitors (PDE5-Is).

Participant type(s)

Patient

Age group

Mixed

Lower age limit

18 Years

Upper age limit

70 Years

Sex

Male

Target number of participants

35

Total final enrolment

33

Key exclusion criteria

1. Neoadjuvant hormonal therapy
2. Previous prostate, urethra, or bladder neck surgery
3. Bilateral NVBs were not preserved
4. Salvage RALP
5. Anteriorly located tumours

Date of first enrolment

01/01/2019

Date of final enrolment

30/09/2020

Locations

Countries of recruitment

Taiwan

Study participating centre

Tungs' Taichung MetroHarbor Hospital

No.699, Sec. 8, Taiwan Blvd

Taichung City

Taiwan

43503

Sponsor information

Organisation

Tungs' Taichung MetroHarbor Hospital

Sponsor details

No.699, Sec. 8, Taiwan Blvd

Taichung City

Taiwan

435

+886 (0)4-26581919#4960

ycou228@gmail.com

Sponsor type

Hospital/treatment centre

Website

<https://en.sltung.com.tw/>

ROR

<https://ror.org/0452q7b74>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Tungs' Taichung MetroHarbor Hospital

Alternative Name(s)

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

Taiwan

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to ethical and legal restrictions.

IPD sharing plan summary

Not expected to be made available