ISRCTN10803536 https://doi.org/10.1186/ISRCTN10803536

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

Submission date
11/08/2023

Recruitment status
No longer recruiting

Registration date
30/08/2023

Overall study status
Completed

Last Edited
23/08/2023

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
https://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

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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, Wuqi 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

Study type(s)
Treatment

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

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
Male

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

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

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