

# Effect of a modified technique of urinary reconstruction during radical prostatectomy on early continence: a randomized controlled trial

<b>Submission date</b> 03/07/2024	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 03/07/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 02/08/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

The aim of the study was to evaluate whether a modification to the current technique of reconstruction during radical prostatectomy could improve early recovery of urinary continence after surgery.

### Who can participate?

All patients undergoing this surgery could participate unless they had conditions that could also impact urinary continence.

### What does the study involve?

The study involves adding a suspensory suture to provide additional support to the urethra or using the standard technique without this additional suture.

### What are the possible benefits and risks of participating?

The possible benefits were an earlier recovery of socially acceptable continence after surgery while the risks were minimal and could in theory include urinary retention and pain after the surgery.

### Where is the study run from?

Centre Hospitalier Universitaire de Québec (Canada)

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

August 2018 to March 2020

### Who is funding the study?

Fondation CHU de Québec (Canada)

### Who is the main contact?

kaleem.atchia.1@ulaval.ca

# Contact information

## Type(s)

Public, Scientific, Principal investigator

## Contact name

Mr Kaleem Atchia

## Contact details

11, côte du Palais

Québec

Canada

G1R 2J6

+1 4185254444

kaleem.atchia.1@ulaval.ca

# Additional identifiers

## Clinical Trials Information System (CTIS)

Nil known

## Protocol serial number

CER-CHUQ 2019-4193

# Study information

## Scientific Title

Effect of a modified technique of posterior reconstruction by iliopectineal ligament suspension during robot-assisted laparoscopic radical prostatectomy on early continence: a randomized controlled trial

## Study objectives

A modified posterior urethral support would aim to recreate a suspensory mechanism to enhance early continence by reducing urethral mobility and restoring a normal urethra-vesical angle during increases in abdominal pressure.

## Ethics approval required

Ethics approval required

## Ethics approval(s)

approved 26/06/2018, Comité d'éthique de la recherche du CHU de Québec-Université Laval (11, côte du Palais, Québec, G1R 2J6, Canada; +1 4185254444; ethiquedelarecherche@chudequebec.ca), ref: CER-CHUQ 2019-4193

## Study design

Single center single surgeon single-blinded randomized trial

## Primary study design

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Prostate cancer

**Interventions**

Posterior reconstruction was done using a standard technique in the control group and was modified for the experimental group by incorporating not only the "Rocco" stitch between Denonvilliers' fascia and the rhabdosphincter but also the iliopectineal ligaments bilaterally to further improve posterior support with this suspensory 'hammock'. Both groups of patients were followed for a year with periodic questionnaires and 24-hour pad tests.

**Randomization:**

Sealed envelope before surgery, randomised preoperatively by randomisation software.

**Intervention Type**

Procedure/Surgery

**Primary outcome(s)**

Recovery of continence after prostatectomy measured using Expanded Prostate cancer Index Composite (EPIC-26) questionnaire sent at 1, 3, 6 and 12 months post-operatively

**Key secondary outcome(s)**

Measured at 1, 3, 6 and 12 months post-operatively:

1. Long term continence measured using Expanded Prostate cancer Index Composite (EPIC-26) questionnaire
2. Erectile function measured using Erectile Function (IIEF-5)
3. Severity of SUI measured using 24-hour pad test at 3, 6 and 12 months

**Completion date**

31/03/2020

**Eligibility****Key inclusion criteria**

Localised prostate cancer staged with conventional imaging who chose to be treated with radical prostatectomy

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

40 years

**Upper age limit**

85 years

**Sex**

Male

**Total final enrolment**

171

**Key exclusion criteria**

1. Patients with clinical stage T4
2. Neoadjuvant hormone therapy
3. Previous history of radiation therapy
4. Endoscopic or open surgeries of the prostate
5. Urethral stricture
6. Urinary incontinence
7. Neurologic disease

**Date of first enrolment**

01/08/2018

**Date of final enrolment**

31/03/2020

**Locations****Countries of recruitment**

Canada

**Study participating centre**

Hôtel-Dieu de Québec Hospital

11, côte du Palais

Québec

Canada

G1R 2J6

**Sponsor information****Organisation**

Centre Hospitalier Universitaire de Québec

**ROR**

<https://ror.org/006a7pj43>

# Funder(s)

## Funder type

Charity

## Funder Name

Fondation CHU de Québec

## Alternative Name(s)

CHUQ Foundation, Fondation CHUQ

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## Location

Canada

# 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 limitations from the consent obtained from participants

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		21/07/2024	02/08/2024	Yes	No
<a href="#">Participant information sheet</a>	version 2	19/06/2018	03/07/2024	No	Yes
<a href="#">Protocol file</a>			03/07/2024	No	No