

Impact of surgeon's experience on operative outcomes of surgical prostate tissue removal.

Submission date 16/12/2018	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 06/03/2019	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/09/2021	Condition category Urological and Genital Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

The number of cases needed to become proficient in Green Light endoscopic enucleation of the prostate (GreenLEP) is the subject of continuous debate. The aim of this study is to investigate the effect of surgical experience (EXP) on perioperative outcomes of GreenLEP.

Who can participate?

Men aged over 18 years who have lower urinary tract symptoms due to Benign prostatic obstruction.

What does the study involve?

This is a retrospective review of patients diagnosed with lower urinary tract symptoms due to Benign prostatic obstruction and management with Green Light endoscopic enucleation between 2013 and 2018. The researchers gathered data about the surgery, the demographic characteristic of patients and their follow up. This is done to assess the surgical outcomes to this procedure.

What are the possible benefits and risks of participating?

There are no benefits or risks with participating.

Where is the study run from?

Rennes University Hospital.

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

January 2013 to July 2018.

Who is funding the study?

The University of Rennes.

Who is the main contact?

Dr Zine-Eddine Khene
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Study website

N/A

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Rennes

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35000

Additional identifiers

EudraCT/CTIS number

N/A

IRAS number

ClinicalTrials.gov number

N/A

Secondary identifying numbers

2210559

Study information

Scientific Title

The surgical learning curve for green light endoscopic enucleation of the prostate: an international multicenter study

Acronym

N/A

Study objectives

The aim of this study was to define the surgical learning curve for GreenLEP using a large, multi-institutional dataset of patients treated by surgeons with extensive experience in transurethral resection of the prostate and open simple prostatectomy but none of them had any previous experience with the enucleation procedure. Our hypothesis proposed an initial learning phase, where clinical outcomes are heavily affected by surgical experience followed by a later plateau phase, where the impact of experience is negligible.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 17/10/2018, CNIL, ref: 2210559.

Study design

Retrospective, observational cohort study

Primary study design

Observational

Secondary study design

Cohort study

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Benign prostatic obstruction

Interventions

Medical records of patients diagnosed with lower urinary tract symptoms due to Benign prostatic obstruction and management with GreenLEP procedure (technical surgery of BPO) with a standardized technique between 2013 and 2018 was assessed. The perioperative results of Surgeons were evaluated and modelling to assess their learning curve.

A prospectively maintained database of patients diagnosed with lower urinary tract symptoms due to BPO and management with GreenLEP procedure with a standardized technique between 2013 and 2018 at five tertiary care referral European Centres was assessed. Multivariable linear and logistic regression models were fitted to evaluate the effect of EXP on total operative time (OT), the probability of at least one intraoperative complication (IOC), and the probability of Pentafecta achievement.

Intervention Type

Procedure/Surgery

Primary outcome measure

To be taken from the surgical reports:

1. The total operative time is measured using the data from the cases.
2. The probability of at least one complication during the surgery. Complications include:
 - 1.1. Capsule perforation.

- 1.2. Bladder wall injury.
- 1.3. Intraoperative bleeding requiring conversion to TURP or open simple prostatectomy or leading to a failed morcellation.

Secondary outcome measures

1. Achievement of optimum outcomes in prostate enucleation will be measured using Pentafecta achievement (defined as a combination of complete enucleation and morcellation within <90 min without any conversion to standard TURP, no postoperative complications and no stress urinary incontinence) at 3 months
2. Three-month postoperative symptom score reduction will be measured using the IPSS questionnaire.

Overall study start date

01/05/2018

Completion date

15/11/2018

Eligibility

Key inclusion criteria

1. Diagnosed with lower urinary tract symptoms due to benign prostatic obstruction (BPO)
2. Being treated with GreenLEP procedure

Participant type(s)

Patient

Age group

Adult

Sex

Male

Target number of participants

900

Total final enrolment

922

Key exclusion criteria

N/A

Date of first enrolment

10/05/2018

Date of final enrolment

28/07/2018

Locations

Countries of recruitment

France

Italy

Spain

Study participating centre**Department of Urology**

Rennes

France

35000

Study participating centre**Department of Urology- Clinique Pasteur**

Toulouse

France

31000

Study participating centre**Department of Urology,**

Hospital Quiron Barcelona

Barcelona

Spain

08000

Study participating centre**Department of Urology,**

Hesperia Hospital

Modena

Italy

41121

Study participating centre**Department of Urology,**

ICUA-Clinica CEMTRO

Madrid

Spain

28000

Sponsor information

Organisation

Rennes University Hospital, department of Urologie

Sponsor details

Rennes

Rennes

France

35000

Sponsor type

Hospital/treatment centre

ROR

<https://ror.org/015m7wh34>

Funder(s)

Funder type

University/education

Funder Name

Université de Rennes 1

Alternative Name(s)

University of Rennes 1

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

France

Results and Publications

Publication and dissemination plan

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

Intention to publish date

31/12/2019

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		17/09/2019	20/09/2021	Yes	No