

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

<b>Submission date</b> 16/12/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 06/03/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 20/09/2021	<b>Condition category</b> 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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# Contact information

## Type(s)

Scientific

## Contact name

Dr Zine-Eddine Khene

## ORCID ID

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## Contact details

Department of Urology

Rennes

France

35000

# Additional identifiers

## Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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.

## **Key secondary outcome(s)**

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.

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

Male

**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

**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

## 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?
<a href="#">Results article</a>		17/09/2019	20/09/2021	Yes	No