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

Submission date
16/12/2018

Recruitment status
No longer recruiting

Registration date
06/03/2019

Overall study status
Completed

Last Edited
20/09/2021

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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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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