Economic evaluation of Prostatic Urethral Lift (Urolift) (ECOLIFT)

First published: 20/02/2020

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Study Ongoing

Administrative details

EU PAS number

EUPAS33766

Study ID

43662

DARWIN EU® study

No

Study countries

France

Study description

Transurethral surgery such as transurethral resection of the prostate (TURP), laser enucleation or laser vaporisation, is the first line surgical treatment for bladder outlet obstruction secondary to benign prostatic hyperplasia.

Even if bipolar and laser surgery have improved surgical outcomes in terms of length of hospital stay and post-operative complications, these procedures remain associated with a significant amount of infectious and bleeding complications, as well as with some persistent side effects such as sexual dysfunction and urinary incontinence. Prostatic urethral lift (Urolift) has been developed as a minimally invasive alternative to TURP with no need of general anaesthesia, less need of urinary catheter and less exposure to post-operative complication.

Its efficacy and safety have been assessed by 2 clinical randomized trials with evidence of urinary symptom improvement remaining inferior to TURP but durable for 5 years. Urolift preserved overall quality of life better than TURP. Urolift has been recommended by the EAU guidelines and recognized by French authorities but cannot be financed by the hospital itself. Reimbursement of the implants by healthcare system is therefore needed for the distribution of Urolift in France.

The additional cost of the implants could be compensated by a reduced length of hospital stay and a lower rate of post-operative complications inducing healthcare expenditures.

This study aims to assess if Urolift could be a cost-effective therapeutic strategy compared to transurethral surgery with 2 phases design: a field study comparing patients treated with Urolift to those treated with TURP/laser during 1 year follow-up, and an additional study comparing healthcare consumptions during 3 years follow-up between each group using data of the French National Claims Database (SNDS database).

Study status

Ongoing

Research institutions and networks

Institutions

Bordeaux University Hospital (CHU de Bordeaux)

France

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Institution | Hospital/Clinic/Other health care facility

Bordeaux PharmacoEpi, University of Bordeaux

France

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

University Hospital of Bordeaux Bordeaux, France, University Hospital of Lyon Lyon, France, University Hospital of Montpellier Montpellier, France, University Hospital of Lille Lille, France, Hôpital Cochin - APHP Paris, France, University

Hospital of Tours Tours, France

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Grégoire ROBERT

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/02/2020

Actual: 04/02/2020

Study start date

Planned: 01/06/2020

Actual: 21/04/2021

Data analysis start date

Planned: 01/03/2022

Actual: 23/10/2024

Date of interim report, if expected
Planned: 30/09/2026

Date of final study report
Planned: 30/09/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

NEOTRACT, INC

Study protocol

2019-A03269-48_PROTOCOLE_V6.0 20230131_ECOLIFT_clean.pdf (1.74 MB)

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

If ‘other’, further details on the scope of the study

Economic evaluation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The main objective is to assess the incremental cost-effectiveness ratio of prostatic urethral lift (Urolift) compared to transurethral surgery (TURP/laser) 4 months after initial hospitalization.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Benign prostatic hyperplasia

Population studied

Age groups

- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

1360

Study design details

Outcomes

Incremental cost per avoided complication (based on Clavien Dindo classification) of Urolift compared with classic transurethral surgery (TURP/laser) 4 months after the surgical procedure.
Incremental cost/QALY of Urolift compared to transurethral surgery (1year).
Real cost of hospitalization for each surgery. Healthcare consumptions(4, 12, 36 months).
Benign prostatic hyperplasia retreatment(12, 36 months). Urinary symptoms, sexual side effects, quality of life (4, 12 months).
Time to recovery/return to professional activity (1, 2, 3, 4 months).
Complications associated with surgery (4 months).

Data analysis plan

SNDS patients will be matched to Urolift patients using a high dimensional disease risk score (hDRS) based on the 1-year SNDS information before surgery.
Analyses will be done for each cohort according to matched treatment group:
Description of populations
- Comparison of baseline characteristics between Urolift and TURP/Laser cohorts

and between Urolift and SNDS cohorts (before/after hDRS matching)
- Estimation of cost-effectiveness ratios between Urolift and TURP/Laser cohorts (4 months,1 year)
- Estimation of hospitalization cost for each surgery during hospital stay
- Description of healthcare consumptions, disease retreatments, urinary symptoms, quality of life, time to recovery/return to professional activity, sexual side effects, associated complications
- Comparison between Urolift and TURP/Laser cohorts and between Urolift and SNDS cohorts at 1, 3 years (intention-to-treat analysis using linear regression model and logistic regression model adjusted on potential confounding).

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No