Economic evaluation of robot-assisted laparoscopic radical prostatectomy vs conventional laparoscopic radical prostatectomy and open retropubic radical prostatectomy in prostate cancer: a real-life study based on the French National Healthcare Data System (SNDS). (ECOREPAR)

First published: 29/01/2020

Last updated: 17/12/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/43648

EU PAS number

EUPAS33290

Study ID

43648

DARWIN EU® study

No

Study countries

☐ France

Study description

Over the last 15 years, robot-assisted laparoscopic radical prostatectomy surgery has seen a considerable rise in France. To date, it represents the most common surgical technique for radical prostatectomies, compared with standard procedure such as open retropubic radical prostatectomy or laparoscopic radical prostatectomy (8000 procedures/year, 40% of surgeries). In 2016, the French Health Authority (HAS) published a report on the robot-assisted laparoscopic radical prostatectomy practice that highlighted the small amount of available convincing data to provide evidence for a significant clinical benefit. There were no published data on overall or progression-free survival compared with other surgical procedures, with an important organizational and financial impact for healthcare institutions and patients. The question of the clinical benefit and the cost-effectiveness ratio of this surgical procedure is still relevant taking into account that randomized studies are difficult to carry out and that results of prospective registers will be available in many years. In this context, the use of the French National Claims Database (SNDS) appears to be the best short-term and reduced-cost solution to identify patients who benefited from the three surgical procedures since the rise of robotics. It would provide real-life data to national institutions in order to conclude on the opportunity to set a specific hospital tariff for the robot-assisted laparoscopic radical prostatectomy. This study aims to assess the cost-effectiveness ratio and the

clinical benefit (survival, disease recurrence, functionnal results) of the robot-assisted laparoscopic radical prostatectomy compared with other procedures using real-life data from SNDS. The population of patients who benefited from robot-assisted surgery will be identified in the SNDS through a practices survey, allowing the identification of centres fully converted to robotics.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux University Hospital (CHU de Bordeaux)

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Hospital/Clinic/Other health care facility

Bordeaux PharmacoEpi, University of Bordeaux

France

First published: 07/02/2023

Last updated: 08/02/2023

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

University Hospital of Bordeaux, Clinical Research and innovation direction - Department of innovation and economic evaluation France, University Hospital of Bordeaux, Department of Urology and Kidney Transplantation France

Contact details

Study institution contact

Gregoire ROBERT

Study contact

gregoire.robert@chu-bordeaux.fr

Primary lead investigator

Laurent PIAZZA

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 11/09/2019

Study start date
Planned: 01/01/2020

Actual: 05/10/2020

Data analysis start date
Planned: 01/09/2020

Actual: 10/12/2020

Date of interim report, if expected
Planned: 01/04/2021

Actual: 24/11/2021

Date of final study report
Planned: 01/01/2023

Actual: 28/03/2023

Sources of funding

- Other

More details on funding

Ministère des Solidarités et de la Santé - Direction Générale de l'Offre de Soins – PRME 2018

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 type:

Non-interventional study

Scope of the study:

Other

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

Economic evaluation/ cost-effectiveness evaluation

Main study objective:

The main objective is to assess thereal-life incremental cost-effectiveness ratio at 5 years, of the robot-assisted laparoscopic radical prostatectomy compared with laparoscopic radical prostatectomy and open retropubic radical prostatectomy in the the French National Claims Database (SNDS).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Prostate cancer

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

10400

Study design details

Outcomes

Incremental cost / progression-free (without additional treatment) life-year saved 5 years after initial surgery, 1)Incremental cost / life-year saved at 8 years. 2)Cost of robotic surgery.3)Outcomes measured at 5 and 8 years: Overall survival, Disease progression requiring a new treatment for prostate cancer,Continence disorders requiring treatment,Erectile dysfunction requiring

treatment,Total healthcare consumptions.4)Urological hospitalizations within 90 days following the initial surgery.

Data analysis plan

Following analyses will be done:1) Conditional probability of benefiting from the three surgical procedures using the high-dimensional propensity score (hdPS). Subjects from each group will be 1:1 matched on the score value.2) Progression-free survival at 5 and 8 years using Kaplan-Meier method. 3) Comparison of events rates between groups using proportional Cox models in total population with/without adjustment on hdPS, and in hdPS-matched populations. 4) None-adjusted estimation of cost-effectiveness ratios (95% CI estimated by boostrap).5) Net Monetary Benefit estimation of each surgical procedure (NMB = E x λ – C) with λ = differential cost-effectiveness threshold.6) hdPS-adjusted analysis using simple linear regression model, with BNM as dependent variable and type of surgery and hdPS as independent variables: one model to compare robot-assisted procedure with open procedure, and another to compare robot-assisted procedure with laparoscopic procedure.

Data management

Data sources

Data source(s), other

SNDS NATIONAL CLAIMS DATABASE France

Data sources (types)

Administrative healthcare records (e.g., claims)

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