DA VINCI TRANSORAL ROBOTIC-ASSISTED SURGERY OF PITUITARY GLAND

ACRONYM: ROBOPHYSE

BIOMEDICAL RESEARCH RELATING TO A MEDICAL DEVICE

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Introduction

In recent years, pituitary surgery has been enriched with endoscopic techniques. However, the latter still have some problems: endonasal complications, tightness of the focus, limited instrument handling, 2D vision. Many surgical specialties have adopted the da Vinci system (urology, oto rhino laryngology, gynecology, etc.) to improve their interventions with the following advantages: 3D vision, instrument maneuverability, abolition of physiological tremor.

Hypotheses

Following our published cadaveric work (Chauvet *et al.*, Neurosurgical Review 2014), we propose a new minimally invasive technique of pituitary surgery, transoral, assisted by the da Vinci robot.

Primary Objective

To confirm the feasibility of a new minimally invasive technique of pituitary surgery, transoral, assisted by the da Vinci robot

Secondary Objectives

- To improve post-operative outcomes and comorbidities related to this surgery
- To improve average lengths of stay

Main Evaluation Criterion

Feasibility of tumor (pituitary adenomas) resection

Secondary Evaluation Criteria

1) Accessibility of the sella turcica
2) Occurrence of adverse events attributable to surgery
3) Duration of postoperative hospital stay

Methodology

This is a biomedical research on a group of patients with pituitary adenoma.

This work seeks to test a new robot surgical technique - already used in other surgical specialties - in neurosurgery for pituitary tumors.

The operative indications will be set according to the usual criteria and confirmed during collegial meetings in the Department of Neurosurgery of the Ophthalmological Foundation A. de Rothschild (Paris, France).

The surgical procedure will be performed in the operating room of the Otorhinolaryngology and Head and Neck Surgery Department of the European Hospital Georges Pompidou (Public Assistance of Paris Hospitals, France), which already uses the da Vinci robot. An intraoperative radiography system will be used during the guiding procedure. At any time during surgery, a conversion for a conventional endoscopic pathway will be feasible to overcome any technical problems related to the robot (never reported during cadaveric work).

The postoperative follow-up will be done in the Neurosurgery Department of the Ophthalmological Foundation A. de Rothschild (Paris) according to the standard protocols.

Inclusion Criteria

1) Pituitary adenoma with an indication for surgery: visual compression and chiasmatic syndrome, HTIC, hormonal syndrome (hypopituitarism and hypersecretion), failure of drug treatments for prolactinoma
2) Absence of pituitary apoplexy requiring emergency surgery;
3) Spontaneous mouth opening greater than 35 mm
4) Patient affiliated to a social security scheme (or benefiting from the "Couverture Médicale Universelle");
5) Patient having signed a prior, free and informed consent.

Non-inclusion Criteria

1) Insufficient mouth opening
2) Intercurrent pathology (such as infection) of the oropharyngeal sphere and cavum
3) Complicated forms of pituitary adenoma with invasive pituitary adenoma type
4) Haemostatic disorders (thrombocytopenia <75,000 platelets / mm3, TP <60%, INR> 1.5, ongoing antiplatelet or anticoagulant therapy)
5) Phlebitis or active pulmonary embolism
6) Patient under judicial protection
7) Pregnant or lactating woman

Statistical Analysis Plan

The statistical analyzes will be exclusively descriptive.

Continuous variables will be described using the usual position and dispersion statistics, namely mean, median, variance, minimum, maximum and quartiles. The modalities of the qualitative variables will be described using numbers and proportions.

Number of subjects needed: 8
Total duration of study: 31 months
Inclusion period: 24 months
Duration of participation for a patient: approximately 7 months
Number of participating centers: 1
Average number of inclusions per month per center: 1