***Title*** Assessment of Clinical and Organisational Aspects of Robot-Assisted Surgery for Radical Prostatectomy

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**Aim**

The aim of this report is to evaluate the clinical and organisational aspects of robot-assisted radical prostatectomy (RARP) compared with open radical prostatectomy (ORP) and conventional laparoscopic radical prostatectomy (LRP), in order to decide whether it should be reimbursed for hospital use.

**Conclusions and results**

Among various surgical techniques for treating localised prostate cancer, robot-assisted laparoscopic surgery has seen a considerable rise. In France, the number of healthcare organisations equipped with a surgical robot has increased from 39 in 2011 to 84 in 2015. Almost 40% of radical prostatectomies were robot-assisted in 2015. In France, like the other countries concerned, this expansion has occurred with no studies to validate this new technology and no organising regulations on quality and access to care.

For this reason, the French General Directorate for Healthcare Provision (DGOS) has asked HAS to assess the technology with a view to reimbursement for hospital use and in order to provide clear and objective information for patients. HAS conducted a critical analysis of all data available, with the following objectives:

- scientifically assess the efficacy and safety of this technology;
- determine organisational procedures and training requirements;
- where applicable, specify any short-term or long-term missing data that need to be collected.

The analysis had the following findings:

- in terms of efficacy, there are no data on overall survival from robot-assisted radical prostatectomy. Surgical excision of the prostate, whether performed via open surgery, conventional laparoscopy or robot-assisted laparoscopy, often causes urinary incontinence and erectile dysfunction that may be persistent;
- in terms of intermediate cancer endpoints, there are no data on progression-free survival. No conclusions can be drawn regarding improvement or reduction in positive surgical margin rates or biochemical recurrence rates with robot-assisted prostatectomy versus other techniques, due to the heterogeneous results available;
- in terms of safety, an analysis of the small number of rigorous comparative studies available did not identify any evidence of an increased risk of serious adverse effects during robot-assisted radical prostatectomy. Surgical excision of the prostate, however it is performed, is a procedure that causes haemorrhage. The available data consistently show significantly less blood loss during robot-assisted radical prostatectomy than during open surgery.

As such, despite 15 years of experience, the small amount of convincing data available does not provide any evidence for the superiority or non-inferiority of robot-assisted radical prostatectomy compared with existing surgical techniques such as conventional laparoscopy.

The analysis also shows that the introduction of robot-assisted radical prostatectomy involves significant organisational constraints for healthcare organisations, particularly in terms of:

- managing and controlling risks, taking into account the complex environment;
- managing and processing surgical instruments (requires a dedicated logistics circuit and low-temperature sterilisation on site);
- operating room architecture (requires sufficient surface area and ergonomics allowing the team and anaesthetist to move around easily. If the theatre is not exclusively for robotic surgery, additional space is required to store the robot);
- initial and ongoing training for the whole surgical team (the learning curve for robot-assisted prostatectomy seems to be easier than for conventional laparoscopic prostatectomy, but this cannot be quantified).

Taking these elements into account, HAS considers that robot-assisted surgery is a possible technique for radical prostatectomy in the treatment of localised prostate cancer, if it is performed under the conditions and following the recommendations below:

- HAS considers that well-conducted prospective comparative studies and long-term patient follow-up are still needed. HAS also emphasises the need to monitor the practice of robot-assisted surgery by setting up a dedicated registry. In all cases, endpoints

(especially functional and cancer endpoints) should be standardised;

- HAS recommends implementing a quality assurance system for procedures dedicated to robot-assisted surgery within healthcare organisations, so that organisational procedures can be standardised including management of serious adverse effects, processing and management of surgical instruments, the sterilisation circuit, theatre planning and the protocol for managing cardiorespiratory emergencies;
- HAS also recommends standardising the content of initial and ongoing training for surgical teams. In addition, HAS has questions about the composition of surgical teams which, based on the data collected, seems to vary by healthcare organisation; HAS considers that healthcare professionals need to reflect on the subject, particularly as concerns the qualifications of theatre assistants;
- HAS recommends that the choice between different methods of radical prostatectomy should be based on a clinical decision made jointly by healthcare professionals and the patient. Patients should receive clear and accurate information on all techniques available and on the uncertain added value of a robot-assisted radical prostatectomy procedure, as well as on the follow-up of patients treated – especially long-term follow-up – when making this decision.

Finally, for other indications, HAS wishes to point out that claims of added value from robot-assisted surgery can only be considered if there are comparative clinical studies with good-quality methodology.

**Recommendations**

The Haute Autorité de Santé considers that the robot-assisted laparoscopic radical prostatectomy is one of the therapeutic options for treatment of localised prostate cancer.

**Methods**

The method of assessment used in this report involves critical analysis of data identified in the scientific literature; substantiated opinions sought from healthcare professionals and a patient association as stakeholders; and a survey sent to Regional Health Authorities (ARS) and hospital federations to obtain data on the practice of robot-assisted surgery in France.
A literature search was performed for the period 2001 to 2015 and the literature was then monitored until September 2016. Stakeholders were consulted in July 2015. The surveys for 26 Regional Health Authorities (including 22 in metropolitan France and four in overseas departments and territories under the old region system) and three hospital federations were sent out in July 2015 (and re-sent until May 2016). The manufacturer was also asked questions in 2015.

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