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CLINICAL INVESTIGATION **Prostate**

BRACHYTHERAPY VERSUS PROSTATECTOMY IN LOCALIZED PROSTATE CANCER: RESULTS OF A FRENCH MULTICENTER PROSPECTIVE MEDICO-ECONOMIC STUDY

CATHERINE BURON, PH.D.,* BEATRICE LE VU, M.D.,* JEAN-MARC COSSET, M.D.,† PASCAL POMMIER, M.D., PH.D.,‡ DIDIER PEIFFERT, M.D.,§ MARTINE DELANNES, M.D.,‖ THIERRY FLAM, M.D.,¶ STEPHANE GUERIF, M.D., PH.D.,# NAJI SALEM, M.D.,** LAURENT CHAUVEINC, M.D., PH.D.,†† AND ALAIN LIVARTOWSKI, M.D.*

Department of *Medical Information and †Oncology/Radiotherapy, Institut Curie, Paris, France; ‡Department of Radiotherapy, Centre Leon Berard, Lyon, France; §Department of Radiotherapy, Centre Alexis Vautrin, Nancy, France; ‖Department of Radiotherapy, Centre Claudius Regaud, Toulouse, France; ¶Department of Urology, Hôpital Cochin, Paris, France; #Department of Radiotherapy, Centre Hospitalier Universitaire, Poitiers, France; **Department of Radiotherapy, Institut Paoli-Calmettes, Marseille, France; ††Department of Radiotherapy, Clinique Hartmann, Neuilly sur Seine, France

Purpose: To prospectively compare health-related quality of life (HRQOL), patient-reported treatment-related symptoms, and costs of iodine-125 permanent implant interstitial brachytherapy (IB) with those of radical prostatectomy (RP) during the first 2 years after these treatments for localized prostate cancer.

Methods and Materials: A total of 435 men with localized low-risk prostate cancer, from 11 French hospitals, treated with IB (308) or RP (127), were offered to complete the European Organization for Research and Treatment of Cancer core Quality of Life Questionnaire QLQ-C30 version 3 (EORTC QLQ-C30) and the prostate cancer specific EORTC QLQ-PR25 module before and at the end of treatment, 2, 6, 12, 18, and 24 months after treatment. Repeated measures analysis of variance and analysis of covariance were conducted on HRQOL changes. Comparative cost analysis covered initial treatment, hospital follow-up, outpatient and production loss costs.

Results: Just after treatment, the decrease of global HRQOL was less pronounced in the IB than in the RP group, with a 13.5 points difference ($p < 0.0001$). A difference slightly in favor of RP was observed 6 months after treatment (−7.5 points, $p = 0.0164$) and was maintained at 24 months (−8.2 points, $p = 0.0379$). Impotence and urinary incontinence were more pronounced after RP, whereas urinary frequency, urgency, and urination pain were more frequent after IB. Mean societal costs did not differ between IB (€8,019 at T24) and RP (€8,715 at T24, $p = 0.0843$) regardless of the period.

Conclusions: This study suggests a similar cost profile in France for IB and RP but with different HRQOL and side effect profiles. Those findings may be used to tailor localized prostate cancer treatments to suit individual patients' needs. © 2007 Elsevier Inc.

Localized prostate cancer, Prostatectomy, Brachytherapy, Health-related quality of life, Societal costs.

INTRODUCTION

Prostate cancer is the commonest male cancer in many industrialized countries and the second leading cause of cancer death in men. In France, more than 40,000 new cases of prostate cancer were diagnosed in 2000 (1) and the increase in the annual number of new cases can be explained by aging of the population and by changes in the

Reprint requests to: Alain Livartowski, M.D., Department of Medical Information, Institut Curie, 25 rue d'Ulm, 75005 Paris, France. Tel: (+33) 1-4432-4683; Fax: (+33) 1-5310-4039; E-mail: alain.livartowski@curie.net

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mode of detection with the recent widespread use of prostate-specific antigen (PSA) screening, which has resulted in a dramatic increase in the number of men diagnosed at both a younger age and at an earlier stage of the disease.

Currently the most common curative options for men with clinically localized (T1–T2) prostate cancer are radical prostatectomy (RP), external beam radiation therapy (EBRT), and interstitial brachytherapy (IB), which consists of inserting permanent radioactive sources into prostatic tissue. Management of localized prostate cancer by high-intensity focused ultrasound and active monitoring is also being explored, but no long-term follow-up data are available so far.

At present, there are no published trials that directly compare long-term survivals after the various treatments of clinically localized disease, leaving the question of survival benefit unanswered. However, studies have reported biochemical relapse-free survival rates that are similar up to 10 years after RP, EBRT, or IB for localized "low-risk" patients (T1–T2a, PSA $\leq$10 ng/mL, and Gleason score $<$7) (2–5). In the absence of any evidence of overall differences in survival between IB and conventional treatments, health-related quality of life (HRQOL), treatment-related symptoms, and economic cost impact may become key factors.

The objective of this article is to compare IB with RP in terms of HRQOL, patient-reported treatment-related symptoms, and cost impact during the first 2 years after these treatments for localized prostate cancer. In this study, IB is compared with RP, as RP is considered to be the reference treatment in routine French medical practice for men with localized prostate cancer and a life expectancy of more than 10 years (6). Although EBRT can also be used as a treatment option, most of the time it is proposed for patients with a larger extension or for patients who are unsuitable for RP (*e.g.*, age, comorbidities). In addition, at present, neither active monitoring nor high-intensity focused ultrasound are considered to be a treatment option in France for these patients with a life expectancy of more than 10 years (6).

The present article is part of a larger "French prostate cancer medico-economic study" whose purpose was threefold: (*1*) to compare HRQOL and economic data of IB with RP; (*2*) to document an EBRT patient cohort with the same HRQOL and economic criteria; and (*3*) to compare the physician's and patient's points of view concerning treatment-related symptoms. A total of 546 patients (T1/T2N0M0 localized prostate cancer, PSA $\leq$20 ng/mL, biopsy Gleason score $<$8) were included in the whole study. The present paper deals with the first part and main objective; the two other points will be subsequently reported.

METHODS AND MATERIALS

Patients and treatments

Between March 2001 and June 2002, 435 patients diagnosed with localized prostate carcinoma, from 11 French hospitals, were treated without randomization of treatment with permanent implant IB (n = 308) or with RP (n = 127). Interstitial brachytherapy was performed in five cancer centers and one teaching hospital, while RP was performed in six teaching hospitals. For each type of treatment, patients were followed prospectively for at least 2 years.

In the IB group, all patients were implanted with radioactive iodine ^{125}I seeds. The majority (n = 243) were treated using a real-time ultrasound (US)-based planning technique (real-time computer-assisted dosimetry with dynamic seed localization performed in the operating room suite). The other 65 patients were treated by a US-based preplanning technique in a single center. Based on US-based dosimetry, the mean dose to 90% of the outlined prostate volume (D90) was 185.9 Gy and the mean percentage of prostate volume receiving at least 100% of the prescribed dose, 145 Gy (V100) was 99.4%. According to the reference posttreatment computed tomography (CT)-based dosimetry, the mean D90 was 172.6 Gy, the mean V100 was 96.0%, and the mean rectal volume receiving 145 Gy was 1.4 cc.

Among RP patients, the surgical approach was retropubic for 86% and laparoscopic for 14%. Iliac node sampling was performed for 75% of cases, and the absence of nodal involvement was confirmed in all patients. A blood transfusion was necessary for 28% of the RP patients, and a second surgical procedure was necessary for 6% of these patients. Nine patients in the RP group (7%) received adjuvant EBRT. Neoadjuvant hormonal therapy was given to 6% of RP patients vs. to 43% of IB patients (Table 1).

Procedures

The study received national approval from French authorities. At the pretreatment visit with the urologist or radiation oncologist, the treatment options were presented to the patients and treatment choice was most of the time tailored conjointly by the patient and the physician in charge. Patients were invited to participate in the medico-economic study and were informed about the follow-up

Table 1. Patient baseline demographics and clinical conditions

	RP n = 127	IB n = 308	$p_{IB\text{-}RP}$
Mean age (σ)	62.7 (6.0)	65.2 (6.3)	0.0003
Level of education (%)			
Low	39.3	32.0	
Middle	27.9	32.0	0.3590
High	32.8	36.0	
Working status (working %)	30.0	18.2	0.0083
Neoadjuvant hormonal therapy (%)	6.3	43.5	$<$0.0001
Mean prostate volume (σ)	38.8 (16.9)	37.3 (13.0)	0.3909
Clinical T stage (%)			
T1	52.8	64.8	
T2	47.2	35.2	0.0228
Mean PSA level (σ)	8.9 (4.0)	7.5 (2.7)	0.0003
Mean Gleason score (σ)	5.9 (1.1)	5.5 (1.1)	0.0003
Comorbidities (%)			
Hypertension	29.7	33.3	0.5564
Mean IPSS score	7.8	5.9	0.0071

Abbreviations: RP = radical prostatectomy; IB = interstitial brachytherapy; PSA = prostate-specific antigen; IPSS = International Prostate Symptom Score.

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