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ORIGINAL ARTICLE

Radical retropubic prostatectomy versus brachytherapy for low-risk prostatic cancer: a prospective study

C. Giberti · L. Chiono · Fabrizio Gallo · M. Schenone · E. Gastaldi

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Abstract
Objectives To compare the oncological and functional outcomes reported after radical retropubic prostatectomy (RRP) versus brachytherapy (BT) in the treatment of low-risk prostatic cancer (CaP).
Methods Between May 1999 and October 2002, 200 patients (mean age 65.3 ± 8.7) were enrolled and randomized into two groups of 100 patients each to undergo RRP (group 1) or BT (group 2).

Prior to and following treatment, all patients were evaluated by physical examination, PSA assay and compilation of IPSS, IIEF-5 and EORTC-QLQ-C30/PR25 questionnaires. Oncological results were reported at 5 years, while functional outcomes were reported at 6 months, and 1 and 5 years mean follow-up.
Results Of the 200 patients studied, 174 completed the 5-year follow-up assessment. With regards to oncological outcomes, similar 5-year biochemical disease-free survival rates were reported for RRP (91.0%) or BT (91.7%). At 6 months and 1 year, both techniques produced a significant decrease in quality of life aspects, while group 2 patients reported a significantly higher and longer lasting rate of urinary irritative disorders and better erective function than group 1. No differences in functional outcomes were encountered after 5 years in either group.
Conclusions RRP and BT are two different options for the treatment of low-risk CaP, which produce different short-term sequelae in terms of urinary disorders and erective functions, but similar biochemical disease-free survival. Further studies with a higher number of patients and a longer follow-up are needed to evaluate their comparative effectiveness on overall disease-specific survival and metastatic disease.

Keywords Retropubic prostatectomy · Brachytherapy · Prostatic cancer · Urination disorders · Erectile dysfunction

Introduction

Despite advances in the primary treatments of localized prostatic cancer (CaP), up to now, no randomized controlled trial has proven the superiority of any one technique in terms of cancer control and many different options can be equally offered to patients [1, 2]. Radical retropubic prostatectomy (RRP) and external beam radiation therapy (EBRT) or brachytherapy (BT) are the most commonly used techniques for the treatment of low risk CaP [3, 4]. In spite of their similar oncological results, attention must be directed toward the different functional outcomes of these treatments, especially regarding postoperative urinary and erectile functions [5–7].

At our institution, patients with low-risk CaP [8] are usually treated with RRP or BT, while we reserve the other options for patients with contraindications to surgery or a life expectancy <10 years. The aim of this manuscript was to compare the oncological and functional outcomes reported after RRP versus BT in the treatment of low-risk CaP.

Methods

Patients

In the period between May 1999 and October 2002, 200 caucasian patients from 51 to 74-year-old (mean age

C. Giberti · L. Chiono · F. Gallo (✉) · M. Schenone · E. Gastaldi
Division of Urology, Department of Surgery,
San Paolo Hospital, Via Genova, 38, 17100 Savona, Italy
e-mail: fabrizio.gallo@fastwebmail.it

65.3 ± 8.7) with low-risk CaP (clinical stage T1c or T2a, PSA value ≤10 ng/ml and Gleason sum ≤6) [8] were enrolled and randomized, using a computerized blocked random number list, into two groups of 100 patients: group 1 patients were scheduled to undergo RRP, while group 2 patients were scheduled to undergo BT. Randomization was perfomed by a urologist, not participating in the operations, while the outcome assessment was performed by another urologist blinded to patient treatment.

In accordance with the American Brachytherapy Society (ABS) [9], exclusion criteria included previous pelvic irradiation, large median lobes, uroflow-Q max lower than 10 ml/s, history of multiple pelvic surgeries, previous transurethral resection of prostate, prostate volume greater than 60 ml and positive seminal vesicles biopsy.

Before the enrollement, all the patients provided a written, informed consent. The trial was approved by the local ethical committee.

Preoperative evaluation

Patient evaluation included history, physical examination, routine laboratory tests and transrectal ultrasound-guided needle biopsy. Before treatment all patients were invited to fill in four different questionnaires concerning urinary function (IPSS [10]), erectile function (IIEF-5 [11]) and quality of life (QoL) (EORTC-QLQ-C30/PR25 [12, 13]).

Surgical techniques

Bilateral nerve sparing RRP, in accordance with Walsh's principles, and standard lymph node dissection were performed on all the patients by a single surgeon (C. G.) [14].

Brachytherapy was performed, by a team, which included a urologist, a radiation therapist and a primary care physician, through a transperineal template-guided peripheral loading real-time technique and seeds of I 125 [15]. A D90 > 140 Gy was considered the cut-off value in order to predict a good quality implant [16].

Postoperative evaluation

Both groups of patients were monitored by physical examination and PSA assays 1 month after treatment. Further controls with PSA measurements and digital rectal examination were scheduled every 3 months for the first year, every 6 months in the second year and then annually. The mean follow-up of the study was 68.2 months (range 60–102 months).

In group 1 patients, biochemical failure was defined as two consecutive PSA values ≥0.2 ng/ml [17]. For group 2 patients, it was defined as a PSA increase ≥2 ng/ml higher than the PSA nadir value independent of the serum concentration of the nadir [18]. At every visit, patients filled in IPSS, IIEF and EORTC-QLQ-C30/PR25 questionnaires.

Oncological results were reported, based on biochemical disease-free survival rate, at a mean follow-up of 5 years. Functional outcomes were evaluated by comparing preoperative and postoperative mean scores for the four questionnaires at 6 months, and 1 and 5 years mean follow-up. A comparison between the two groups concerning the rates of erectile function recovery and postoperative urinary disorders was also performed.

Statistical evaluation

Baseline characteristics and clinical condition before treatment were compared between the two groups of patients using the Mann–Whitney test. The percentages concerning oncological and functional outcomes between the two groups were compared using chi-squared analysis or Fisher's exact test. The Friedman test was employed to compare preoperative and postoperative IPSS, IIEF and EORTC-QLQ-C30/PR-25 scores within each group. P values <0.05 were considered to be significant [19].

Results

There were no statistically significant differences in baseline characteristics between the two groups of patients (Table 1). Of the 200 patients enrolled in this study, 174 completed the 5-year follow-up assessment (89 group 1 vs. 85 group 2 patients), while 26 patients were lost to follow-up (11 group 1 vs. 15 group 2 patients).

For oncological outcomes, pathological evaluation among group 1 patients confirmed a pT2 stage in 84 (84.0%) patients, while pT3a and pT3b stages were reported in 14 (14.0%) and 2 (2.0%) patients, respectively. Positive surgical margins were reported in two (2.0%) and ten (10.0%) pT2 and pT3 patients, respectively. A nodal CaP involvement was assessed in two (2.0%) pT3b patients. Upgrading was found in 24%, while downgrading was seen in 5% of the group 1 patients. Thus, the overall pathology error rate based on needle biopsy alone was 29%, with a net upgrading of 19%.

Overall, the 5-year biochemical disease-free survival rate was 91.0% (81/89 pts) for group 1 patients and 91.7% (78/85 pts) for group 2 patients (Fig. 1).

The eight (9.0%) group 1 patients with biochemical failure (six pT3 patients with positive surgical margins and two patients with nodal CaP involvement) were treated, after the first follow-up visit, with EBRT or androgen therapy deprivation. Among the seven (8.3%) group 2 patients with biochemical failure, prostatic biopsy samples showed a persistent CaP in five patients and two cases were treated with

Table 1 Baseline demographic and clinical conditions in the two groups of patients

	Group 1	Group 2	*P* value
No. of patients	100	100	–
Mean age (years)	65.2 (57–74)	65.6 (56-74)	n.s.
Clinical stage			
T1c (no of pts)	64	59	n.s.
T2a (no of pts)	36	41	n.s.
Mean Gleason score	5.9	5.7	n.s.
Mean PSA value (ng/ml)	7.8 (3.5–10)	7.5 (2.9–9.3)	n.s.
Prostate volume (ml)	43.9 (19–56)	41.7 (21–60)	n.s.
Mean IPSS	4.6 (1–7)	4.9 (1–7)	n.s.
Mean flow rate (ml/s)	17.9 (12.3–28.0)	18.4 (13.1–25.9)	n.s.

Data are reported as mean values with range in parenthesis

n.s Not significant

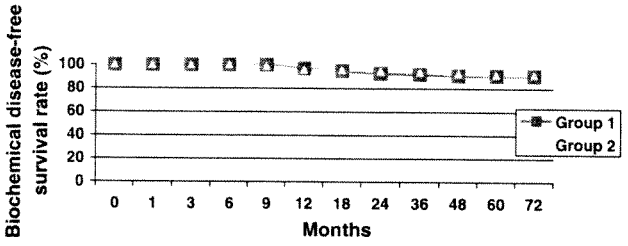

Fig. 1 Biochemical disease-free survival rate in group 1 and 2 during the 5 years follow-up

EBRT, while three cases, reporting a pathological evaluation of CaP with Gleason sum >8, were treated with RRP. The remaining two patients with negative biopsies were treated with androgen therapy deprivation.

With regard to functionality and quality of life outcomes, Table 2 reports extensive data derived from compilation of the four questionnaires.

The EORTC-QLQ-C30 questionnaire, compiled at 6 months follow-up showed, for both groups of patients, a significant worsening of physical, role, emotional, social functions and global health with a significant increase in fatigue and pain. In group 1, a slight but significant decrease in cognitive functions and a significant increase in insomnia were also reported. After 1 year of follow-up, a significant worsening of physical and emotional functions was still reported by both groups, while, after 5 years, no significant variation in these parameters was reported.

Regarding urinary function, data from the EORTC-QLQ-PR25 questionnaire showed an increase in urinary symptom scores in both groups of patients at 6 months, although this was only confirmed in group 2 patients at the 1-year-follow-up. A significant increase in IPSS score was only detected in group 2 patients at 6 months and at 1 year after BT.

Table 2 Mean values derived from the compilation of the questionnaires at four time points: before treatment (T0), at 6 months (T 6 months), 1 year (T 1 year) and 5 years (T 5 years) mean follow-up

	T0	T 6 months	*P* value	T 1 year	*P* value	T 5 years	*P* value
EORTC-QLQ-C30							
Physical function							
Group 1	91	86	0.02	86	0.02	90	n.s.
Group 2	94	90	0.03	90	0.03	94	n.s.
Role function							
Group 1	93	87	0.01	90	n.s.	90	n.s.
Group 2	95	90	0.02	93	n.s.	94	n.s.
Emotional function							
Group 1	82	87	0.02	86	0.03	84	n.s.
Group 2	80	86	0.01	84	0.03	82	n.s.
Cognitive function							
Group 1	91	88	0.04	90	n.s.	90	n.s.
Group 2	87	88	n.s.	88	n.s.	88	n.s.
Social function							
Group 1	89	84	0.02	89	n.s.	89	n.s.
Group 2	92	87	0.02	93	n.s.	94	n.s.
Global health/QoL							
Group 1	79	74	0.02	78	n.s.	78	n.s.
Group 2	83	79	0.03	81	n.s.	82	n.s.
Fatigue							
Group 1	16	20	0.03	18	n.s.	18	n.s.
Group 2	17	22	0.02	19	n.s.	18	n.s.
Nausea/vomiting							
Group 1	0	1	n.s.	1	n.s.	1	n.s.
Group 2	0	2	n.s.	2	n.s.	1	n.s.
Pain							
Group 1	8	12	0.02	9	n.s.	9	n.s.
Group 2	5	15	<0.01	8	n.s.	8	n.s
Dyspnea							
Group 1	8	8	n.s.	8	n.s.	8	n.s.
Group 2	9	11	n.s.	10	n.s.	11	n.s.
Insomnia							
Group 1	21	24	0.04	23	n.s.	22	n.s.
Group 2	20	21	n.s.	20	n.s.	20	n.s.
Appetite loss							
Group 1	3	4	n.s.	4	n.s.	3	n.s.
Group 2	5	4	n.s.	4	n.s.	4	n.s.
Constipation							
Group 1	3	4	n.s.	4	n.s.	3	n.s.
Group 2	1	2	n.s.	1	n.s.	0	n.s.
Diarrhea							
Group 1	4	4	n.s.	6	n.s.	5	n.s.
Group 2	5	6	n.s.	8	n.s.	6	n.s.
Financial problems							
Group 1	2	3	n.s.	3	n.s.	3	n.s.
Group 2	3	2	n.s.	2	n.s.	2	n.s.

Table 2 continued

	T0	T 6 months	*P* value	T 1 year	*P* value	T 5 years	*P* value
IPSS							
Group 1	4.6	4.9	n.s.	4.7	n.s.	4.7	n.s.
Group 2	4.9	15.2	<0.01	10.1	0.01	5.1	n.s.
EORTC-QLQ-PR25							
Urinary symptoms							
Group 1	9	17	<0.01	10	n.s.	10	n.s.
Group 2	8	36	<0.01	15	<0.01	17	n.s.
Bowel symptoms							
Group 1	2	3	n.s.	2	n.s.	2	n.s.
Group 2	2	6	0.03	4	n.s.	5	n.s.
Treatment-related symptoms							
Group 1	5	11	0.01	9	0.03	8	n.s.
Group 2	6	10	0.03	9	0.04	8	n.s.
Sexual function							
Group 1	5	9	0.03	7	n.s.	7	n.s.
Group 2	6	10	0.03	7	n.s.	8	n.s.
Sexual activity							
Group 1	6	10	0.03	8	n.s.	8	n.s.
Group 2	6	11	0.02	8	n.s.	8	n.s.
IIEF							
Group 1	23.2	16.3	0.02	22.2	n.s.	22.0	n.s.
Group 2	22.9	18.5	0.03	21.9	n.s.	21.2	n.s.

EORTC-QLQ-C30 and PR25 questionnaires are reported considering all the items requested, while IPSS and IIEF values are reported as total score. When the parameter at the time point after treatment was significantly different for the pretreatment value (T0), the *P* value was reported. In all other cases, the difference was not significant (n.s.)

Among group 1 patients in particular, the main urinary disorder was urinary incontinence, which was reported by 18.4% of patients (severe in 5.4% and mild in 13.0%) at 6 months. Mild incontinence spontaneously disappeared during follow-up, while severe incontinence was treated 6 months after surgery with bone anchored sub-urethral sling or artificial urinary sphincter positioning. Other urinary disorders were anastomotic urethral stricture, reported by 6.5% of patients, and irritative symptoms, reported by 5% of patients, which were successfully treated with transurethral laser incision and parasympathicolytic agents, respectively.

In group 2 patients, the main urinary disorder was irritative symptomatology, which was reported by 80 and 20% of patients after 6 months and 1-year follow-up, respectively. Other urinary disorders were urinary retention, reported by 10% of patients, and urethral stricture, reported by 2% of patients, which were treated successfully with intermittent catheterization or transurethral procedures. Seeds expulsion during micturition or ejaculation occurred in 6% of patients. None of the group 2 patients reported urinary incontinence throughout the follow-up. No significant urinary disorders were reported at a follow-up of 5 years in both groups of patients.

With regard to bowel disorders, proctitis was reported only in group 2 patients after 6 months of follow-up and was successfully treated with anti-inflammatory drugs.

Regarding sexual activity, a preoperative good erective function (mean IIEF score >22) was reported by 55/89 (62%) of group 1 patients and by 51/85 (60%) of group 2 patients. At 6 months follow-up, both groups of patients reported a significant worsening of QLQ-PR25 and IIEF scores, which improved throughout the follow-up. In particular, among group 1 patients, a recovery of erective function was reported by 40% of patients 6 months after surgery, and by 68 and 65% of patients at a follow-up of 1 and 5 years, respectively. Among those group 2 patients, a good erective function was reported by 58% of patients at a follow-up of 6 months, and 78 and 68% of patients at 1 and 5 years, respectively.

Discussion

The aim of this study was to report the 5-year outcomes of a prospective comparison between RRP and BT for the treatment of low-risk prostatic cancer, with particular attention to functional aspects. Although oncological and functional outcomes of RRP and BT have been widely reported in literature, very few authors performed a prospective randomized study comparing the results and complications of these two techniques at different time points [5, 6, 20, 21].

With regard to oncological outcomes, our data reported similar 5-year biochemical disease-free survival rates in both groups of patients (91.0 vs. 91.7%). These good results, which seem comparable to those reported by other authors who showed biochemical relapse-free survivals rates higher than 90% up to 10 years after RRP and BT [2–4, 22–24] surely need to be confirmed in the future by a higher number of patients and a longer follow-up.

We think that the main value of the current report is the 5-year evaluation of QoL and functional aspects. In terms of quality of life outcomes, all patients reported similar significant decreases in some functional and symptom EORTC-QLQC-30 scales after 6 months and 1-year regardless of the treatment. However, in spite of some functional limitations, which could justify this reported discomfort, both groups of patients reported a normal global health after 1 and 5 years probably due to a progressive improvement of the overall quality of life. Based on these aspects, as already reported in literature, also in our experience the QoL following RRP or BT does not generally differ significantly throughout the follow-up period [5, 6].

Concerning urinary symptoms, all the patients reported a significant worsening of the EORTC-QLQ-PR25 score after 6 months of follow-up; after 1 year this score remained unchanged in group 2, while it returned to baseline in group 1 patients. Furthermore, a significant increase in IPSS score was reported in group 2 patients after 6 months and 1 year of follow-up, while no change in this score was observed in group 1. These data could be due to the different frequency and duration of urinary problems in the two patient groups. In fact, while irritative disorders were reported by 80and 20% of group 2 patients at 6 months and 1 year after BT, respectively, group 1 patients reported mainly urinary incontinence at 6 months, which was eventually cured 1 year after RRP. Therefore, our data specify how postoperative urinary symptoms were significantly greater and more persistent in the BT group rather than in the RRP group of patients.

Interestingly, no significant urinary disorders were reported at a follow-up of 5 years in both groups of patients, while a chronic late urinary morbidity was often shown by other authors in BT patients [6, 20]. However, the follow-up reported in these series was never longer than 3 years, and the further decrease in urinary morbidity showed in our 5 years' experience would suggest a very late complete recovery of urinary function after BT.

Regarding erectile function, as expected, both groups of patients described a significant worsening of the EORTC-QLQ-PR25 and IIEF questionnaires scores at 6 months of follow-up due to the surgical sequelae, QoL impairment and urinary disorders [5, 25]. However, in spite of this comparable worsening, a significantly better erectile function was reported by group 2 (58%) with respect to group 1 (40%) patients after 6 months, and a further significant improvement was also reported in the BT group rather than in the RRP group at 1-year follow-up (78 vs. 68%). No significant differences in sexual activity were reported in either group 5 years after the respective treatments.

These data seem to be in favor of BT. In spite of the fact that patients treated with BT reported a decrease in erectile function, probably due to an impairment in physical, cognitive and social functions, the quality of the erections in these patients was significantly less impaired at the 6 months and 1-year follow-up when compared to patients who had undergone RRP. This indicated that there had been no immediate damage to the neurovascular bundles, which can occur following RRP [24, 26]. After BT, the proportion of patients who remained potent decreased more gradually over time reaching a potency rate similar to that reported after RRP only 5 years after the respective treatments.

This study has some limitations. As already reported, the small number of patients evaluated and the shorter follow-up decreased the power of the oncological results, especially concerning the assessment of overall and disease-specific mortality or metastatic disease.

Conclusion

RRP and BT are two different options for the treatment of low-risk CaP, which produce different short-term sequelae in terms of urinary disorders and erective functions, but similar long-term functional outcomes. Concerning the oncological outcomes, our data reported similar 5-year biochemical disease-free survival rates in both groups of patients. Further studies with a higher number of patients and a longer follow-up are needed to confirm these good results.

Conflict of interest statement There is no conflict of interest.

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