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RESEARCH ARTICLE

Reduced recurrence of prostate cancer with novel autologous cancer vaccine (FK- PC101) post-prostatectomy: long-term results from a single-center phase 1/2 study

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ABSTRACT

Background: Prostate cancer is a major contributor to cancer-related mortality in men. High-risk patients, particularly those with biochemical recurrence (BCR) following radical prostatectomy (RP), face poor long-term outcomes. Adjuvant options such as radiotherapy, chemotherapy, and androgen deprivation therapy (ADT) have shown limited benefit in this setting.

Methods: This retrospective analysis evaluated the safety, feasibility, and efficacy of FK-PC101, an autologous immunomodulated tumor cell vaccine, in high-risk post-RP patients. Data were drawn from the FK002-2001 trial, a phase 1/2, non-randomized, open-label study conducted in Brazil. A total of 62 patients were included: 23 in the vaccine group and 39 controls. Primary endpoints were safety and feasibility; secondary endpoints included biochemical recurrence-free survival (BRFS) and overall survival (OS).

Results: The vaccine was well tolerated, with most adverse events being grade 1–2 local reactions. PSA recurrence at 4 years was significantly lower in the vaccine group (11.8%) when compared to controls (36.8%; $P=0.0453$). OS did not differ significantly between groups. A higher rate of erectile dysfunction was observed in the vaccine group ($P=0.047$).

Conclusion: FK-PC101 demonstrated safety and potential clinical benefit in reducing prostate specific antigen (PSA) recurrence after RP in high-risk prostate cancer patients. These findings support further evaluation in a randomized phase 2 trial.

ARTICLE HIGHLIGHTS

- K-PC101 is a novel autologous tumor cell vaccine for high-risk prostate cancer post-prostatectomy.
- The vaccine was safe and well tolerated, with mostly mild local reactions.
- PSA recurrence at 4 years was lower in vaccinated patients (11.8% vs. 36.8%).
- Immunologic responses may contribute to long-term disease control.
- Study limitations: retrospective design and baseline imbalances.
- Findings support further evaluation in a randomized phase 2 trial.

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Prostate cancer; biochemical recurrence; immunotherapy; vaccine; radical prostatectomy

Introduction

Prostate cancer ranks as the second most common malignancy and the fifth leading cause of cancer-related deaths in men worldwide [1]. Prostate cancer with high-risk features, despite representing only 22.3% of diagnoses, accounts for 66.2% of prostate cancer-related deaths within ten years, highlighting the critical importance of focusing on this subgroup for therapeutic advancements [2]. Approximately 40%–50% of these patients who undergo surgery experience biochemical recurrence (BCR), typically within 2–3 years postoperatively [3]. Despite various efforts, the use of adjuvant therapies following surgery, such as radiotherapy, chemotherapy, or androgen deprivation therapy, remains a subject of ongoing debate.

Recent studies suggest that early salvage radiotherapy (SRT) may be more favorable than adjuvant radiotherapy (ART) for high-risk prostate cancer patients following radical prostatectomy [4,5]. Two trials, RADICALS-RT and RAVES, have demonstrated that early SRT provides similar biochemical control to ART, with lower rates of treatment-related toxicities, such as increased urinary symptoms and erectile dysfunction [5,6].

While ADT combined with radiotherapy has shown survival benefits, its role in the absence of radiotherapy remains less well-defined [7]. Moreover, the use of chemotherapy—specifically docetaxel—in the

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adjuvant setting post-prostatectomy has not consistently demonstrated a survival benefit [8,9]. Trials such as SPCG-12 and VACSP553 did not show significant improvements in relapse-free survival with adjuvant docetaxel [8,9].

In addition, novel hormonal agents, including androgen receptor signaling inhibitors, are being investigated in early-phase trials for their potential role in the adjuvant setting. These agents have shown promising activity in metastatic disease; however, conclusive evidence supporting their use post-prostatectomy is still lacking [10,11].

Vaccines for oncologic purposes have been a topic of ongoing debate. For instance, Euhus et al., who analyzed a whole melanoma cell vaccine, demonstrated some degree of anti-tumor activity following injection. In that case series, nearly 50% of patients showed an increase in antibody levels [12].

Adjuvant vaccines for high-risk prostate cancer following radical prostatectomy are an area of active investigation, with the goal of reducing BCR and improving long-term outcomes. One promising strategy involves dendritic cell (DC) vaccines. A study demonstrated that a personalized DC vaccine, administered post-prostatectomy, showed potential to prolong the time to BCR in patients with high-risk disease [13]. In that study, 20 patients received DC vaccinations, and 11 remained BCR-free over a median follow-up of 96 months. The vaccine was well tolerated, with no significant adverse events reported [13].

Sipuleucel-T, an FDA-approved vaccine for metastatic castration-resistant prostate cancer, has demonstrated a survival benefit in this setting, although its role in the adjuvant context post-prostatectomy remains unclear [14,15]. Other vaccine platforms, such as those based on viral vectors encoding prostate-specific antigens, have been investigated; however, their clinical efficacy as monotherapies has been limited. These vaccines may demonstrate enhanced activity when combined with other immune-modulating agents [16].

Overall, while the use of vaccines in the adjuvant setting for high-risk prostate cancer is promising, additional studies are needed to establish their efficacy and optimal integration into clinical practice in larger patient populations.

FK-PC101 is a novel autologous immunomodulated tumor cell vaccine with unique immunologic properties that may elicit specific immune responses, including those targeting patient-specific neoantigens present on the tumor. FK-PC101 is designed for intradermal administration as adjuvant therapy following radical prostatectomy. It is a personalized treatment with a short treatment duration (seven intradermal doses over 6 months), administered in an outpatient setting, and may offer pharmacoeconomic advantages over currently available therapies.

Material and methods

Study sample

We retrospectively analyzed data from subjects enrolled in study FK002-2001, an open-label, matched-control, non-randomized, phase 1/2 clinical trial conducted at the Hospital de Clínicas de Porto Alegre (HCPA), Brazil. In this study, subjects aged 18–80 years, with preoperative serum PSA ≥10 ng/mL and localized or locally advanced prostate cancer who underwent radical prostatectomy between 2002 and 2006 were included. Only patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0–2, Gleason grade 7–10, and tumor stage ≥ pT2b were eligible. Bone scans and CT scans were used for staging. Patients in the vaccine group were also required to have viable tumor tissue available for autologous vaccine production.

We conducted a retrospective analysis using medical records from patients enrolled in the FK002-2001 study at Hospital de Clínicas de Porto Alegre. Data were collected from electronic health records, pathology reports, and follow-up clinical evaluations. All clinical and pathological variables were reviewed and verified independently by two investigators.

Control patients were matched to the vaccine group based on age (±5 years), Gleason score category, and tumor stage. All control patients had undergone radical prostatectomy during the same period (2002–2006) at the same institution, with available follow-up data and no administration of FK-PC101 or other experimental therapies.

Adjuvant or salvage treatments—including radiotherapy, androgen deprivation therapy (medical or surgical), or chemotherapy—were allowed in both groups if completed at least four weeks prior to inclusion in the study.

A total of 62 patients were analyzed and divided into two groups. In the vaccine group, 23 patients (37.1%) were included, while 39 patients (62.9%) comprised the control group. Radiotherapy, chemotherapy, or ADT—either via medication or orchiectomy—were permitted only if completed at least four weeks prior to enrollment.

Statistical analysis

The primary aim was to evaluate the safety and feasibility of the autologous tumor cell vaccine FK-PC101 in patients with high-risk prostate cancer features. Adverse events were recorded and classified into two severity categories: grade 1–2 and grade ≥3. The secondary objective was to assess BRFS and OS during follow-up. PSA values were considered undetectable when ≤0.04 ng/mL. BRFS was defined as PSA levels >0.04 ng/mL, confirmed by two consecutive measurements within a 4-week interval. Time to PSA recurrence was calculated from the date of radical prostatectomy to the first confirmed detectable PSA value following an initially undetectable post-surgical PSA.

Two different cohorts were analyzed for BRFS. Cohort 1 included patients whose PSA became undetectable at any point after surgery. If PSA levels never became undetectable, the patient was censored. Cohort 2 included patients whose PSA became undetectable within one year post-prostatectomy. If PSA remained detectable, censoring occurred at the date of prostatectomy.

Time-to-event endpoints, including PSA recurrence and overall survival, were analyzed using Kaplan–Meier methodology. Cox proportional hazards models were applied to estimate hazard ratios (HRs) between treatment groups. All statistical analyses were two-tailed and conducted using Stata version 12.0 (StataCorp, College Station, TX). A p-value ≤0.05 was considered statistically significant (NCT06636682).

Results

Among the 106 patients screened, 62 were included after applying the inclusion criteria. Twenty-three participants (37%) were assigned to the vaccine group (inoculated with FK-PC101), and 39 (63%) to the control group. The mean baseline age was 65 years in both groups. In the vaccine group, 21 patients (91.3%) were White, while in the control group, 33 patients (84.6%) were White. All 62 patients had a postoperative ECOG performance status of 0.

Gleason score 9 was the most prevalent in the vaccine group (30.4%), whereas Gleason score 6 was most common in the control group (43.6%). There was a statistically significant difference between the groups regarding pathological tumor stage (P = 0.003). In the vaccine group, pT3b was observed in 13 patients (56.5%) versus 3 patients (7.7%) in the control group. Six patients (26.1%) in the vaccine group had positive pathological lymph nodes, compared to 4 (10.3%) in the control group ($P = 0.101$). No patients had metastatic disease prior to surgery.

Seven patients (30.4%) in the vaccine group and 19 (48.7%) in the control group received adjuvant or salvage therapy (P = 0.191) (Table 1). Aggressive cancer features at baseline, such as Gleason score ≥8, pathological T stage ≥ pT3a, and N stage pN1, were more prevalent in the vaccine group (Table 2). The vaccine group exhibited a more aggressive pathological stage (≥pT3a) and a higher median PSA level compared to the control group ($P = 0.02$ and $P = 0.02$, respectively).

All 23 patients in the vaccine group received all 7 doses of the vaccine within the protocol-specified 6-month treatment period. No patients discontinued treatment due to toxicity or any other reason. The median time from radical prostatectomy (RP) to the first dose of FK-PC101 was 5.1 months (range, 1.7–14.1). The median follow-up duration was 11.1 years (range, 2.8–15.4) for the vaccine group and 9.6 years (range, 1.0–16.5) for the control group (Table 3).

Adverse events (AEs) are summarized in Table 4. Local reactions, including induration, erythema, pruritus, and nodules at the injection site, were significantly more frequent in the vaccine group, with most events graded 1 or 2 in severity ($P < 0.0001$). Notably, erectile dysfunction occurred more frequently in the vaccine group ($P = 0.047$). No patient discontinued treatment due to AEs.

In Cohort 1, the median time to PSA recurrence was 104.6 months in the vaccine group and 77.4 months in the control group (HR = 0.56; 95% CI, 0.27–1.18; $P = 0.1229$) (Figure 1). In Cohort 2, median time to PSA recurrence was 116.5 months in the vaccine group and 54.8 months in the control group (HR = 0.67; 95% CI,

Table 1. Baseline characteristics.

	Vaccine ($N=23$)	Control ($N=39$)	Statistical analysis
Median age (years), (min, max)	65 (47, 73)	65 (43, 77)	$p=0.764$
Race, *n* (%)			
White	21 (91.3)	33 (84.6)	$p=0.447$
Black or African American	2 (8.7)	5 (12.8)	
Other	0 (0)	1 (2.6)	
Gleason Score[a], *n* (%)			
Primary			
2	0 (0)	0 (0)	$p=0.111$
3	9 (39.1)	25 (64.1)	
4	9 (39.1)	11 (28.2)	
5	5 (21.7)	3 (7.7)	
Secondary			
2	0 (0)	0 (0)	$p=0.144$
3	8 (34.8)	23 (59.0)	
4	13 (56.5)	15 (38.5)	
5	2 (8.7)	1 (2.6)	
Total Gleason Score			
≤5	0 (0)	0 (0)	$p=0.089$
6	3 (13.0)	17 (43.6)	
7 (3+4)	6 (26.1)	8 (20.5)	
7 (4+3)	5 (21.7)	6 (15.4)	
8	2 (8.7)	4 (10.3)	
9	7 (30.4)	4 (10.3)	
10	0 (0)	0 (0)	
Pathologic Tumor Stage[b], *n* (%)			
pT2a	0 (0)	4 (10.3)	**$p=0.003$**
pT2b	0 (0)	2 (5.1)	
pT2c	3 (13.0)	10 (25.6)	
pT3a	4 (17.4)	12 (30.8)	
pT3b	13 (56.5)	3 (7.7)	
pT4	3 (13.0)	8 (20.5)	
Pathologic Nodal Stage, *n* (%)			
N0	17 (73.9)	35 (89.7)	$p=0,101$
N1	6 (26.1)	4 (10.3)	
Distant Metastasis[c], *n* (%)			
M0	23 (100%)	39 (100%)	
Patients without adjuvant or salvage therapy	7 (30.4)	19 (48.7)	$p=0,191$

[a]https://ecog-acrin.org/resources/ecog-performance-status.
[b]Epstein JI, et al. Am J Surg Pathol. 2016 Feb;40(2):244–52.
https://www.hopkinsmedicine.org/health/conditions-and-diseases/prostate-cancer/prostate-cancer-stages.
P < 0.05

Table 2. Summary of high-risk factors for prostate cancer recurrence.

	Vaccine ($N=23$)	Control ($N=39$)	Statistical analysis
Total Gleason Score of 8–10[a], *n* (%)	9 (39.1%)	8 (20.5%)	$p=0.112$
Pathologic T stage ≥ pT3a[b], *n* (%)	20 (87.0%)	24 (61.5%)	**$p=0.020$**
Pathologic N1 stage[b], *n* (%)	6 (26.1%)	4 (10.3%)	$p=0.101$
Median baseline PSA (ng/mL)	13.6	11.5	**$p=0.023$**

Abbreviation: PSA = prostate-specific antigen.
[a]Epstein et al. Am J Surg Pathol. 2016 Feb;40(2):244–52.
[b]https://www.hopkinsmedicine.org/health/conditions-and-diseases/prostate-cancer/prostate-cancer-stages.
P < 0.05

Table 3. Summary of time to PSA recurrence (Kaplan-Meier).

	Vaccine ($N=23$)	Control ($N=39$)
Method 1[a]		
Median time to PSA Recurrence (months), (95% CI)	104.6 (59.5, 146.8)	77.4 (50.2, 89.6)
PSA Recurrence[b], *n* (%)	12 (52.2)	21 (53.8)
Censored[c], *n* (%)	11 (47.8)	18 (46.2)
Method 2[d]		
Median time to PSA Recurrence (months), (95% CI)	116.5 (59.5, 146.8)	54.8 (14.3, NE)
PSA Recurrence[b], *n* (%)	9 (39.1)	13 (33.3)
Censored[c], *n* (%)	14 (60.9)	26 (66.7)

Abbreviations: CI = confidence interval; NE = not estimable; PSA = prostate-specific antigen.
[a]Includes the PSA tests if the PSA becomes undetectable at any point post-prostatectomy.
[b]Confirmed detectable PSA ('detectable' is defined as PSA >0.04 and 'confirmed' is defined as two detectable PSA values >4 weeks apart without an intervening undetectable PSA).
[c]Censored at the prostatectomy date if PSA remains detectable.
[d]Includes the PSA tests only if the PSA becomes undetectable within one year post-prostatectomy.

Table 4. Treatment-emergent adverse events by severity occurring in ≥2 patients.[a]

Preferred termb	Vaccine ($N=23$)	Control ($N=39$)	Statistical analysis
Any AE	23 (100.0)	18 (46.2)	$p < 0.0001$[e]
Local Induration	23 (100.0)	0 (0)	
Grade 1–2	23 (100.0)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Pruritus	22 (95.7)	0 (0)	$p < 0.0001$
Grade 1–2	22 (95.7)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Erythema	18 (78.3)	0 (0)	$p < 0.0001$
Grade 1–2	18 (78.3)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Erectile Dysfunction	9 (39.1)	10 (25.6)	**$p=0.047$**
Grade 1–2	4 (17.4)	9 (23.1)	
Grade ≥3	5 (21.7)	1 (2.6)	
Vaccination Site Nodule	9 (39.1)	0 (0)	$p < 0.0001$
Grade 1–2	9 (39.1)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Urinary Incontinence	6 (26.1)	7 (17.9)	$p=0.525$
Grade 1–2	6 (26.1)	7 (17.9)	
Grade ≥3	0 (0)	0 (0)	
Rash Pustular	5 (21.7)	0 (0)	$p=0.0052$
Grade 1–2	5 (21.7)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Pain	4 (17.4)	1 (2.6)	$p=0.0586$
Grade 1–2	4 (17.4)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Depression	0 (0)	3 (7.7)	$p=0.2885$
Grade 1–2	0 (0)	3 (7.7)	
Grade ≥3	0 (0)	0 (0)	
Hypersensitivity	2 (8.7)	0 (0)	$p=0.1338$
Grade 1–2	2 (8.7)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Laryngeal Squamous Cell Carcinoma	2 (8.7)	0 (0)	$p=0.1338$
Grade 1–2	0 (0)	0 (0)	
Grade ≥3	2 (8.7)	0 (0)	
Nocturia	2 (8.7)	0 (0)	$p=0.1338$
Grade 1–2	2 (8.7)	0 (0)	
Grade ≥3	0 (0)	0 (0)	
Anemia	0 (0)	2 (5.1)	$p=0.5256$
Grade 1–2	0 (0)	1 (2.6)	
Grade ≥3	0 (0)	1 (2.6)	
Cystitis Radiation	0 (0)	2 (5.1)	$p=0.5256$
Grade 1–2	0 (0)	2 (5.1)	
Grade ≥3	0 (0)	0 (0)	

Abbreviation: AE = adverse events.
P < 0.05.

0.27–1.62; $P=0.3678$) (Figure 2). Patients in Cohort 2 had a PSA recurrence rate at 4 years post-RP of 11.8% in the vaccine group and 36.8% in the control group ($P=0.0453$).

A total of 5 patients (12.8%) in the control group died from advanced prostate cancer, compared to 1 patient (4.3%) in the vaccine group ($P=0.398$). For overall survival (OS), 6 deaths (15.4%) occurred in the control group and 2 (8.7%) in the vaccine group. Median OS was not reached in either group

Discussion

Several studies have shown that patients with high-risk features experience biochemical recurrence (BCR) in approximately 40% of cases following local treatment. In this scenario, higher Gleason scores and locally advanced tumors (≥pT3a or N1 disease) are major predictors of disease recurrence [3]. Moreover, BCR is directly associated with metastatic progression and increased mortality [17].

Recently, some authors have suggested that adjuvant treatments such as radiotherapy should be deferred until PSA elevation, in order to reduce toxicity and avoid overtreatment [5,6]. Additionally, androgen deprivation therapy (ADT) and chemotherapy have been studied in this setting but have not demonstrated significant benefit [7]. Conversely, adjuvant vaccines have shown promising results. To date, however, only sipuleucel-T has demonstrated a survival benefit in patients with metastatic castration-resistant prostate cancer [14].

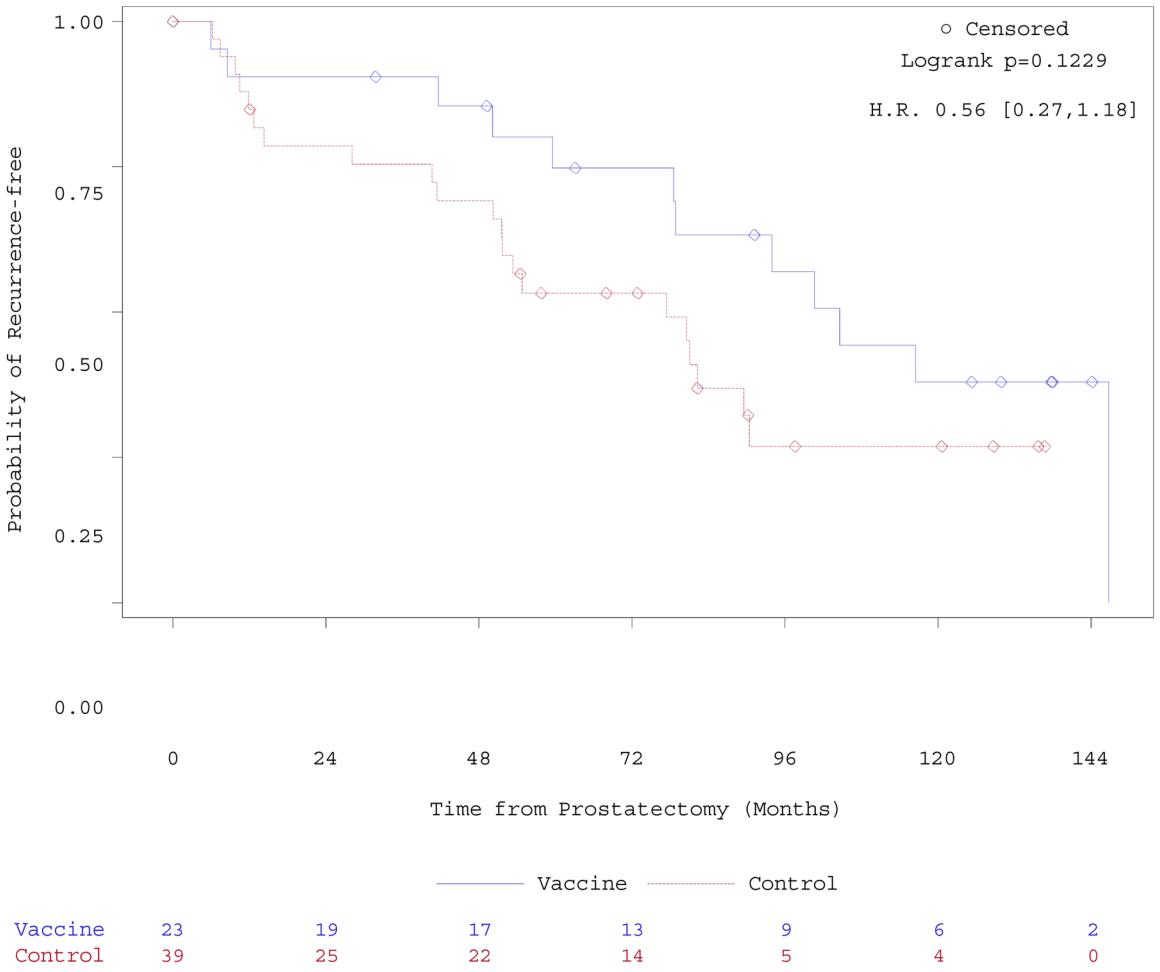

Figure 1. Recurrence of detectable PSA (Method 1) – Includes the PSA tests if the PSA becomes undetectable at any point post-prostatectomy.

In this initial clinical trial (FK002/2001) conducted in Brazil, treatment with the FK-PC101 vaccine was found to be safe and feasible. We also observed that patients in the vaccine group had a lower frequency of PSA recurrence than those in the control group.

In our study, the use of FK-PC101 highlights the potential of antitumor vaccines to modify disease trajectory in high-risk prostate cancer patients. By eliciting immune responses against tumor-associated antigens, such vaccines may reduce the likelihood of biochemical recurrence and contribute to long-term disease control. These findings align with previous observations that personalized immunotherapy can engage both innate and adaptive immune mechanisms, potentially improving patient outcomes beyond what is achieved with conventional adjuvant therapies [18–20]. Importantly, our results suggest that integrating autologous tumor cell vaccines into post-prostatectomy management could provide a complementary strategy for patients at highest risk of recurrence.

A recent study on prostate tumor growth dynamics suggested that vaccine-based therapies could slow tumor progression and result in improved long-term survival outcomes [20]. This contrasts with conventional treatments, such as chemotherapy, which may only temporarily halt tumor growth during active therapy and have limited long-term impact [21]. These findings are consistent with our results, as the vaccine group demonstrated improved BRFS compared to the control group.

Recent investigations have also explored the role of vaccines in prostate cancer (PC) across different risk profiles. For example, the ProVent trial evaluated patients newly diagnosed with ISUP grades 1 and 2, administering sipuleucel-T to prevent progression to more aggressive grades over a 36-month period of active surveillance [22]. Another study, a randomized trial of ProstVac-VF, included patients with low- or intermediate-risk PC also under active surveillance (23). The primary endpoint of that trial was the immune response, measured via tissue and serum biomarkers after 5 months of vaccine or placebo administration.

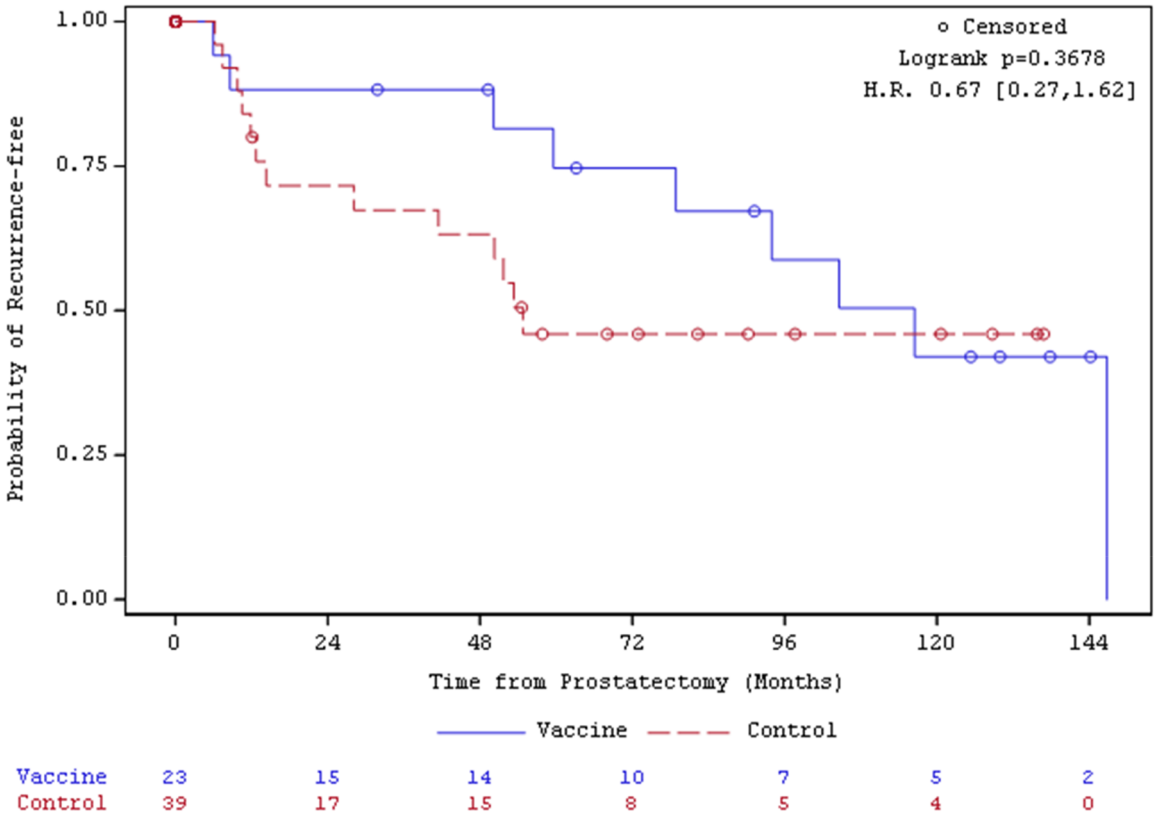

Figure 2. Recurrence of detectable PSA (Method 2) – Includes the PSA tests if the PSA becomes undetectable within one year post-prostatectomy.

However, the design and population of these trials are not directly comparable to our study. While both focused on lower-risk patients during active surveillance, our study assessed adjuvant vaccination in high-risk PC patients following radical prostatectomy. Additionally, those trials focused on short-term immunologic responses, while our study emphasizes long-term clinical outcomes, including PSA recurrence and overall survival, in a cohort with more aggressive disease. Notably, the control group in our study had a higher prevalence of lower Gleason scores, further underscoring the clinical relevance of our findings.

Thus, while both approaches aim to enhance immune responses to prevent disease progression, this study highlights the unique potential of adjuvant vaccination in high-risk patients after surgery.

Limitations of this study include the inherent biases of retrospective data collection, the non-randomized design, a relatively small sample size, and a disproportionately higher number of high-risk patients in the vaccine group. However, the results of this phase 1/2 study support further investigation of this personalized immunotherapy. Notably, there was a trend toward reduced PSA recurrence in the vaccine group at 4 years post-RP (~12% vs. ~37%), along with a corresponding trend in prostate cancer-specific mortality. The potential advantages of this treatment approach include continued disease management within urology outpatient settings, favorable pharmacoeconomic factors such as efficient manufacturing, intradermal administration, and a short duration of treatment. This study has limitations inherent to its retrospective design. The division of patients into cohorts based on biochemical recurrence at 1 year, while clinically relevant, may introduce selection bias. Furthermore, the control group was not fully matched for baseline characteristics, which could affect comparability between groups. To address this, adjusted analyses for potential confounding variables were performed, and the results remained consistent.

Therefore, a phase 2 randomized, open-label trial of the FK-PC101 vaccine in patients with high-risk localized prostate cancer is currently planned, with 1- and 2-year PSA progression-free survival (PFS) as key endpoints.

Conclusion

Among men with high-risk prostate cancer who underwent radical prostatectomy, adjuvant treatment with FK-PC101—a novel autologous immunomodulated tumor cell vaccine—was shown to be safe and feasible. Patients in the vaccine group also demonstrated improved biochemical recurrence-free survival (BRFS) compared to the control group. A larger randomized trial is currently underway to further validate these findings (NCT06636682).

Author contributions

All authors contributed equally to this manuscript.

Disclosure statement

Dr Daniel Melecchi de Oliveira Freitas and Dr Milton Berger have no disclosures. Drs Alberto Costa Stein and Fernando Kreutz work at FK Biotech, the company responsible for the development of the FK-PC101 vaccine evaluated in this study.

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