

## Pathological Results and the Absence of Biochemical Recurrence-Free Survival Following Radical Prostatectomy in High Risk Prostate Cancer Patients (HRCaP) with in the Indian Demographic

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### Abstract:

**Background:** This study investigates outcomes in HRCaP post-surgery, emphasizing long-term biochemical recurrence-free survival (BRFS) and exploring subgroups based on aggressive tumor criteria in the Indian context.

**Method:** The study involved 200 prostate cancer patients who underwent radical prostatectomy (RP), with 98 categorized as high-risk per D'Amico criteria. We analyzed pre/postoperative and pathological data, assessing BRFS for different risk factors. Independent predictors of BCR included Gleason Score, pT, pN, and PSA. Surgical technique didn't significantly affect outcomes.

**Results:** Single high-risk factor patients had better outcomes. BRFS rates were 45% (2-year) and 35% (5-year). More risk factors correlated with increased margin positivity. Many patients received adjuvant or salvage therapy (33.94%). Complication rates were low, and continence remained favorable.

**Recommendation:** Primary RP is suitable for select high-risk cancer patients (HRCaP) alone or combined with other treatments, guided by specific criteria to identify aggressive cases.

**Conclusion:** RP shows positive oncological outcomes for Indian HRCaP patients, with BRFS influenced by preoperative risk factors. Regardless of surgical technique, continence rates are generally good, with low complications. Study limitations include sample size, retrospective design, and evolving treatments. Further research is needed for better understanding in the Indian context.

**Keywords:** Prostate Cancer, Radical Prostatectomy, High-Risk, Biochemical Recurrence and Indian Population

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### Introduction

This study analyzes the results of HRCaP patients who had surgery at our center, focusing on their long-term risk of biochemical recurrence-free survival (BRFS). We also aim to categorize patients into subgroups based on different combinations of aggressive tumor criteria to see if having more risk factors leads to a higher chance of biochemical recurrence. Prostate cancer is becoming increasingly common in urban India and is predicted to double by 2024. Despite improved testing and biopsies, many patients still have advanced cancer or tumors when they first visit. The specific characteristics of prostate cancer in the population of India and the surgery patients' subsequent outcomes are not well understood, as opposed to Western countries where screening has led to earlier detection. [1,2]

High-risk patients, as defined by the D'Amico classification, preoperative Gleason score or

clinical stage, face a significant risk of progression even after radical treatment. Various treatment options are available, such as radiation therapy (RT) and androgen deprivation therapy (ADT), alone or in combination, but recurrence rates remain high regardless of the chosen treatment. [3] (RP) with or without adjuvant treatments like RT or ADT has been used to treat HRCaP individuals as ongoing investigations have shown positive oncologic outcomes. This study delves into the pathology findings and the long-term chances of biochemical recurrence in HRCaP who underwent RP at our center. We also explore different combinations of aggressive tumor criteria to assess their impact on biochemical recurrence-free survival. [4]

The aim of this study is to ascertain if biochemical recurrence (BCR) in HRCaP patients undergoing RP in the Indian population is related to the

quantity and kind of risk variables (cT2c-T3b, prostate-specific antigen >20 ng/ml, Gleason score >7). [5]

### Methodology

#### Study Design:

This study was a retrospective in nature.

#### Study Setting:

This study was conducted by reviewing inpatient and outpatient case records of patients who had gone through [ORP], [LRP], and [RRP]) of AIIMS, Patna in 2021-2022.

#### Participants:

Participants with (HRCaP) who had undergone radical prostatectomy (RP) were reviewed.

#### Inclusion and Exclusion Criteria:

This study focused on HRCaP in urban areas of India, diagnosed before 2023, who underwent PSA testing and received treatments like RP, RT, ADT, or combinations, with available long-term follow-up data. We excluded rural patients, those from different regions, post-2023 diagnoses, individuals without PSA testing, early-stage or low-risk cases, those not meeting D'Amico's high-risk criteria, untreated or unknown history patients, and those lacking accessible long-term follow-up data.

#### Study Size:

200 patients were reviewed, 98 whom had D'Amico HR disease, undergone [ORP], [LRP], and [RRP]) at our centre after meeting the inclusion criteria. The D'Amico classification was used to analyze data on pathological, surgical, and preoperative outcomes for patients suffering from HR ailment.

#### Data Collection and Analysis:

The study examined preoperative patient characteristics: age, serum PSA, clinical T stage (cT), and TRUS-guided biopsy (GS). Staging included TRUS, abdominal MRI, skeletal scan, and prostate-specific membrane antigen PET scan.

After institutional approval, surgeries (ORP, LRP, or RRP) were performed. Initial cases of LRP and ORP skipped lymph node (LN) dissection. Extended LN dissection included internal iliac chain for the patients. Patients were categorized by D'Amico criteria, focusing on the high-risk group (HR): PSA >20 ng/ml, clinical T2c+, and biopsy Gleason 8–10.

#### Bias:

To minimize bias, the goal of the research was not disclosed to the participants or healthcare providers during data collection. Additionally, data analysts were blinded to the identity of the participants.

#### Variables:

The mean value  $\pm$  standard deviation was employed to express continuous, whereas frequency and proportions were used to express categorical variables. To identify the relevant variable versus BCR, univariate analysis was performed. Binary logistic regression was utilized in multivariate analysis to identify variables that were significant for BCR.

#### Statistical Analysis:

The study utilized Microsoft Excel for data compilation and SPSS 20.0 for statistical determination. Chi-square tests determines the relationships among categorical variables, while independent student's t-test compared continuous variables. Survival analysis using the Kaplan-Meier method estimated BCRFS at two and five years. To assess differences in BCRFS between groups, the Kaplan-Meier technique with logrank test was employed. Statistically significant findings were defined as p-values < 0.05.

#### Ethical Considerations:

The study was carried out in accordance with ethical guidelines, which included getting each participant's informed consent. The ethics committee examined and approved the study protocol.

#### Results

**Table 1: "Patient Characteristics Stratified by Risk Factors in a Study of 200 RP Patients"**

Parameter	Description
Number of Patients	200
High-Risk (D'Amico HR)	98
<b>Preoperative Parameters:</b>	
Age	Mean: 64.38 $\pm$ 6.6
Serum PSA	Mean: 19.66 $\pm$ 15.1
Clinical T Stage (cT)	T2: 48.6%, T3: 46.8%
Biopsy Gleason Sum	$\leq$ 7: 70.6%, >7: 29.4%
<b>Pathological Outcomes:</b>	
Pathological T Stage (pT)	pT2: 45%, pT3: 53%, T4: 2%
Positive Surgical Margin (PSM)	Overall: 50.5%
Increased within HR groups	1HR: 33.9%, 2HR: 68.2%, 3HR: 83.3%

This study analyzes the results of HRCaP who had surgery at our center, focusing on their long-term risk of (BRFS). We also aim to categorize patients into subgroups based on different combinations of aggressive tumor criteria to see if having more risk factors leads to a higher chance of biochemical recurrence.

Prostate cancer is becoming increasingly common in urban India and is predicted to double by 2024. Despite improved testing and biopsies, there are still a lot of patients who show up with metastases or advanced disease. The specific characteristics of prostate cancer in the Indian population and the long-term outcomes of surgical patients are not well understood, as opposed to Western countries where screening has led to earlier detection.

High-risk patients, as defined by the D'Amico classification, preoperative Gleason score, face a significant risk of progression even after radical treatment. Various treatment options are available, such as (RT) and (ADT), alone or in combination, but recurrence rates remain elevated regardless of the therapy strategy selected. (RP) with or without adjuvant treatments like RT or ADT has been used to treat high-risk prostate cancer patients, and long-term studies have shown positive oncologic outcomes. This study delves into the pathology findings and the long-term chances of biochemical recurrence in HRCaP who underwent RP at our center. We also explore different combinations of aggressive tumor criteria to assess their impact on biochemical recurrence-free survival.

### Discussion

This study involved 200 prostate cancer patients who underwent (RP), including (RRP), (LRP), and open (ORP) procedures. Among them, 98 were classified as greater risk based on D'Amico classification. The analysis covered preoperative, postoperative, and pathological outcomes. Key findings included identifying independent predictors of biochemical recurrence such as Gleason Score, (pT), (pN), and serum PSA. The study found no significant differences in outcomes among the surgical techniques (ORP, LRP, RRP) and reported 2-year and 5-year BCR-free survival rates of 45% and 35%.

This study focused on RP results in the population of India with (HRCaP). Around 109%, or 56.7%, of all individuals experiencing RP had HRCaP, which differs from Western databases showing lower HRCaP prevalence [6]. Among these patients, 45.5% had multiple high-risk characteristics. The most prevalent risk factor that led to high-risk classification is cT, while PSA alone was less common [7, 8]. Patients with a single high-risk factor benefited the most from surgery, and more risk factors correlated with lower (BCRFS). In general, the two-year and five-year BCRFS rates

were 45% and 35%, respectively, with higher risk factors associated with increased margin positivity [9]. A significant portion (33.94%) received adjuvant or salvage therapy, with 8.2% requiring adjuvant therapy and 25.68% undergoing salvage treatment. About 10% of patients experienced complications, with 5.5% having severe issues (Clavien-Dindo grades 3 and 4) [10].

At the 12-month follow-up, 80% of patients remained continent, and surgical technique did not significantly impact continence rates. In conclusion, RP showed positive oncological outcomes for HRCaP in the Indian population, with BCRFS affected by preoperative risk factors. Many patients required adjuvant or salvage therapy, and margin positivity increased with risk factors. Regardless of the surgical technique, continence rates were generally favorable, and complication rates were relatively low [11].

### Conclusion

The group of patients with localized (HRCaP) has diverse oncological outcomes. When selected carefully, primary (RP) can provide long-term cancer management along with good functional results and accurate pathological staging. Substratification based on three specific criteria can help identify the most aggressive cancers and determine when additional treatments are needed. RP can be a suitable initial treatment for certain men with HRCaP, either alone (for those with a single high-risk factor) or in combination with other therapies.

**Limitations:** The current study has some limitations, including a small sample size, a brief follow-up time, and a retrospective design. The study examined data collected over a long period, and during that time, therapy types and techniques changed significantly. This could have complicated our analysis. Nonetheless, this study offers some insight into HRCaP in this part of the world because there is a dearth of data on CaP in the Indian community.

**Recommendation:** Primary RP is suitable for select high-risk cancer patients (HRCaP) alone or combined with other treatments, guided by specific criteria to identify aggressive cases.

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### List of abbreviations:

1. RP: Radical Prostatectomy
2. HRCaP: High-Risk Prostate Cancer Patients
3. BRFS: Biochemical Recurrence-Free Survival
4. RRP: Robotic Radical Prostatectomy

5. LRP: Laparoscopic Radical Prostatectomy
6. ORP: Open Radical Prostatectomy
7. PSA: Prostate-Specific Antigen
8. BCR: Biochemical Recurrence
9. cT: Clinical T Stage
10. pT: Pathological T Stage
11. pN: Pathological N Stage
12. GS: Gleason Score
13. RT: Radiation Therapy
14. ADT: Androgen Deprivation Therapy
15. LN: Lymph Node
16. BCRFS: Biochemical Recurrence-Free Survival
17. MRI: Magnetic Resonance Imaging

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