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Original Research Article

Avoiding prostate bed radiation for the PSMA-PET detected nodal recurrence patient post prostatectomy

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ABSTRACT

Background: Nodal only recurrence post radical prostatectomy (RP) is increasingly recognised in the PSMA scan era. Management is controversial with a curative approach usually incorporating prostate bed and nodal irradiation (PB + NRT) in combination with long-term hormonal therapy. It is unknown whether omitting prostate-bed irradiation (PBRT) is safe in a subgroup of these patients.

Purpose: To document the outcomes for pelvic nodal only salvage radiation therapy (NRT) plus concurrent androgen deprivation therapy (ADT) for patients with PSMA PET documented nodal relapses.

Methods and materials: Eligible patients included PSMA PET documented nodal only relapses post RP who received NRT with or without PBRT at Royal North Shore Hospital (NSCC), Gosford Hospital (CCCC) or Genesis Care (GC) between January 2015 and December 2021. Baseline demographics, surgical pathology, radiation details, ADT use and outcomes were documented.

Results: Forty-six patients were identified, 22 in the PB + NRT cohort and 24 in the NRT cohort. Compared to the PBRT + NRT group, the NRT cohort had lower stage disease (pT2 = 7 (29 %), pT3a = 15 (63 %), pT3b = 1 (4 %) vs pT2 = 0, pT3a = 10 (45 %), pT3b = 12 (55 %)) (p=<0.001) and lower rates of R1 resection (0 % vs 63.6 % (n = 14)) ($p < 0.001$) respectively. The median follow-up from radiotherapy was 3.9 years.

Four-year biochemical failure- free survival (BFFS) was 64 % in the NRT group vs 67 % in the PB + NRT group. Of the ten (41.6 %) failures in the NRT group, 1 (4 %) was a biochemical failure only, 2 (8 %) recurred in the PB and received further salvage treatment, 4 (17 %) had nodal failure outside the pelvis and 3 (13 %) had distant metastases.

One patient (4 %) in the NRT group recorded late grade ≥2 GU toxicity compared with 7 (32 %) in the PB + NRT. No patients in the NRT group recorded late grade ≥2 GI toxicity compared with 2 (9 %) in the PB + NRT cohort.

Conclusion: This study provides early evidence for the feasibility of PBRT sparing to avoid local toxicity. Most patients in this cohort failed distantly. This data suggests that for selected men PB-avoidance may be considered given informed consent.

Introduction

Radical prostatectomy (RP) is the most common treatment for patients with localised prostate cancer (PCa). However, post operative biochemical failure (BF) occurs in approximately 30 %. At BF, PSMA-PET detected nodal only recurrence is now increasingly recognised as its own entity [1–3]. Its course is variable [4] and management is controversial, ranging from SBRT to involved nodes, salvage

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radiotherapy to the prostate bed (PB) and pelvic nodal irradiation (NRT) with androgen deprivation therapy (ADT) [5,6] to systemic therapy alone.

Salvage radiotherapy to the PB and pelvic nodes with ADT is regarded as the treatment approach with the highest likelihood of long-term cure [7]. However, the PBRT component in particular has the potential to cause significant late genitourinary (GU) and gastrointestinal (GI) toxicity. In the SPPORT [2] trial amongst the group whose PB alone was treated late grade ≥2 GU and GI occurred in 37 % and 10 % respectively.

It is well recognised that patients with nodal disease have a high risk of developing further systemic disease [8]. There is likely a subgroup of these patients who are at a lower risk of local recurrence including those with organ confined disease and clear surgical margins. In this subgroup it is attractive to explore the possibility of avoiding PBRT, which has not been previously published. Furthermore, if a local recurrence occurs, there is the potential for salvage local treatment.

We hypothesised that in selected node positive patients post RP deemed at lower risk of local recurrence, there will be a decrease in late toxicity with no compromise in clinical outcomes by omitting PBRT with nodal treatment.

The aims of this study were: 1) to report the patterns of failure for NRT plus concurrent ADT for a PSMA PET documented nodal relapse; 2) to record the toxicity data in these men.

Methods

Patients who received NRT with or without PBRT post RP at Royal North Shore Hospital (NSCC), Gosford Hospital (CCCC) or Genesis Care (GC) between January 2015 and December 2021 were included from a prospective database (NSLHD reference: RESP/15/255). Baseline demographics, PSA dynamics, tumour and treatment details, toxicity, and subsequent patterns of failure were documented. Biochemical failure was defined as a PSA > 0.2 ng/mL with a subsequent confirmatory PSA reading of ≥0·2 ng/mL. Clinician recorded GU and GI toxicity were documented as per Radiation Therapy Oncology Group (RTOG) criteria [7].

All patients needed to have a PSMA PET scan demonstrating pelvic nodal only uptake. ADT was recommended for all patients. Patients were treated by one of the three radiation oncologists, who are authors, and their case was discussed prior at a multidisciplinary team meeting with nuclear medicine physician review (EH). The decision to avoid PBRT was at the discretion of the treating radiation oncologist taking into account: clear surgical margins, lack of seminal vesicle (SV) invasion, lower grade disease (Gleason ≤ 7), and longer disease-free interval (DFI) (>1 year) as well as patient preference.

These patients were then retrospectively identified. Analysis was performed using R Version 4.3. Group comparison was generated using: Wilcoxon rank sum test, Wilcoxon rank sum exact test, Fisher's exact test, and Pearson's Chi-squared test. This study was approved by the Human Research Ethics Committee of the Northern Sydney Local Health District (2023/ETH02803).

Results

Baseline characteristics

Baseline characteristics are summarised in Table 1. In brief, 46 men had pelvic node only disease identified on PSMA PET post RP and received either NRT (n = 24) or PB + NRT (n = 22). The median age at treatment was 66 years old (interquartile range of 62–73 years old). PSA prior to radiotherapy was 0.48 (ng/mL) with an IQR of 0.28 to 0.81.

Compared to the PB + NRT group, the NRT cohort had less ISUP 4/5 disease (33 % vs 64 % (p = 0.054)) and pT3b or greater disease (4.2 % vs 54.5 % (p < 0.001)). There was also a lower rate of R1 resection (0 % vs 63.6 % (n = 14) (p < 0.001)) respectively. Time from RP to RT was 3 years (IQR 1.5–6.4) in the NRT group versus 0.9 years (IQR 0.4 – 2.5) in the PB + NRT (p = 0.009). The median follow-up from RT commencement was 4.1 years in the NRT group and 3.9 years in the PB + NRT group.

Table 1
Baseline demographic and clinical characteristics.

Characteristic	NRT = 24	PB + NRT = 22	p-value
Age at RT (IQR)	66 (60–73)	65 (64–71)	>0.9
Median Follow Up in Years (IQR)	4.1 (3.8–5.3)	3.9 (3.6–5.8)	0.16
PSA Prior to RT	0.44 (0.21–0.85)	0.55 (0.40–0.66)	0.2
Time from RP to RT in Years (IQR)	3.0 (1.5–6.4)	0.9 (0.4–2.5)	0.009
Staging (T,N)			<0.001
pT2	7 (29 %)	0 (0 %)	
pT3a	15 (63 %)	10 (45 %)	
pT3b	1 (4 %)	12 (55 %)	
pN0	15 (63 %)	9 (41 %)	
pN1	8 (33 %)	8 (36 %)	
Nx	0	5 (23 %)	
Not Available	1 (4 %)	0	
Gleason Score			0.054
3 + 4	1 (4 %)	2 (9 %)	
4 + 3	14 (58 %)	6 (27 %)	
≥8	8 (33 %)	14 (64 %)	
Not Available	1 (4 %)	0	
R0 Resection	24 (100 %)	8 (36 %)	<0.01
R1 Resection	0	14 (64 %)	
Number of PET Positive Nodes			
1	13 (54 %)	12 (55 %)	
2	6 (25 %)	4 (18 %)	
≥3	3 (13 %)	4 (18 %)	
Not Available	2 (8 %)	2 (9 %)	
ADT			>0.9
Short	19 (79 %)	17 (77 %)	
Long	3 (13 %)	4 (18 %)	
Not used	2 (8 %)	1 (5 %)	

Interquartile Range (IQR), Prostate-Specific Antigen (PSA), Radiotherapy (RT), Androgen Deprivation Therapy (ADT).

Node positive patients at surgery were included in this study. Eight (33 %) patients in the NRT group were node positive on initial staging versus 8 (37 %) who were node positive in the PB + NRT group. One patient in the NRT group could not have his initial staging confirmed.

In the NRT group, 13 patients (54 %) had a solitary positive lymph node, 6 (25 %) had 2–3 and 3 (12.5 %) had 3 or more. The PB + NRT group had 12 patients (55 %) with a solitary positive lymph node, 4 (18 %) with 2–3 and 4 (18 %) with 3 or more.

Radiotherapy treatment

All patients were treated with intensity modulated radiotherapy (IMRT). Nodal volumes in the NRT arm received 44–45 Gy in 20 fractions (daily) with a simultaneous integrated boost (SIB) to the PSMA-delineated nodal disease (55–58 Gy). All patients in the PB + NRT arm were managed with a dose fractionation schedule of 64–68 Gy in 32–34 fractions to the prostate bed, and an elective nodal dose of 54–56 Gy in 32–34 fractions with a SIB to the PSMA-PET delineated gross nodal disease. Nodal volumes were contoured as per RTOG guidelines [9]. The PB was contoured as per FROGG guidelines [10]. Patients were supine throughout their treatment with a comfortably full bladder throughout their treatment. All patients had daily CBCT verification.

Androgen deprivation

ADT was recommended for all patients. Short term ADT (≤6 months) was used in 19 (79 %) patients with 3 (13 %) having long course in the NRT group (defined as >6 months). Of these patients on long term ADT, 1 (4 %) was on ADT for more than 24 months, 1 (4 %) for 15 months, 1 (4 %) for 12 months. Seventeen (77 %) had short term ADT in the PB + NRT cohort and 4 (18 %) had long course. Of the 4 (18 %) on long term ADT, 2 (9 %) were on ADT for 18 months, 1 (5 %) was on ADT for 12 months, and 1 (5 %) for 8 months. Two (8 %) and 1 (5 %) patient declined ADT respectively in each cohort.

Outcomes

Median follow up was 4.1 years for the NRT group and 3.9 years for the PB + NRT group. Of the 46 patients, 10 (42 %) in the NRT group (not significant) had a biochemical failure compared to 6 (27 %) in the PB + NRT. Median BFFS was 4.8 years (IQR 3.9 – not reached) in the NRT group and not reached in the PB + NRT group (IQR 3.4-not reached) (see Fig. 1). Four-year BFFS was 64 % and 67 % respectively.

Of the 24 NRT patients, 9 of 10 had subsequent PSMA PET documented failure (see Fig. 2). The other 1 failed biochemically with no avidity seen on PSMA PET with a PSA > 0.2 (ng/mL). Four (17 %) failed distantly in the nodes alone above the pelvic brim and of these 2 (8 %) had further radiotherapy and 2 (8 %) were referred to medical oncology for palliative management. Three (13 %) failed distantly with visceral metastases +/- distant nodal disease and were referred for palliative management. Two patients (8 %) recurred in the PB and had salvage treatment to the PB (matched to previous pelvic field). Both patients had R0 resections with Gleason 3 + 4 and 4 + 4 disease respectively. Of these, 1 (4 %) subsequently failed in the pelvic nodes (in field). It is unclear whether he reseeded from the PB recurrence. All patients were alive at time of data analysis.

Toxicity data

Clinician recorded GU and GI toxicity were documented as per RTOG criteria [8]. Late toxicity was defined as onset after 90 days post treatment. One patient (4 %) in the NRT group recorded new grade ≥2 GU toxicity (pad dependent urinary incontinence) commencing 3 months after completion of radiotherapy and resolving within 2 years. Two further patients (8 %) were pad dependent prior to RT and remained pad dependent following. This was not altered by the radiotherapy treatment.

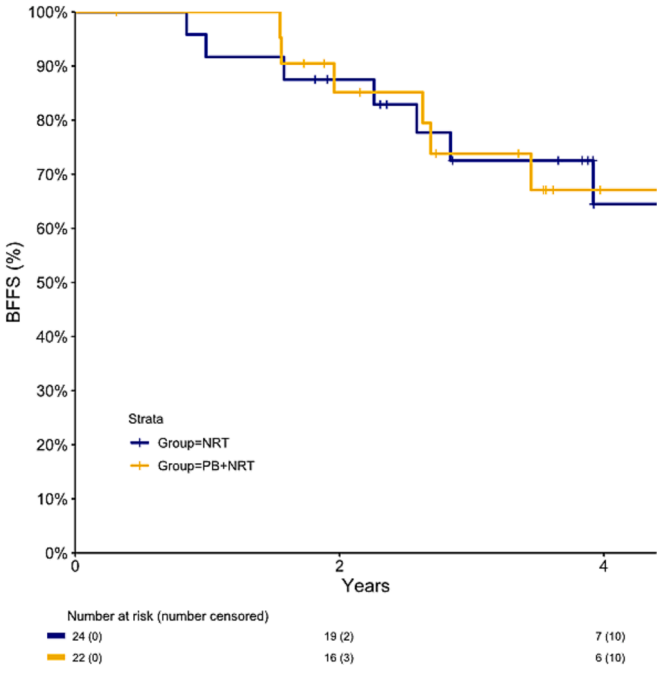

Fig. 1. Kaplan-Meier Biochemical Failure Free Survival estimates.

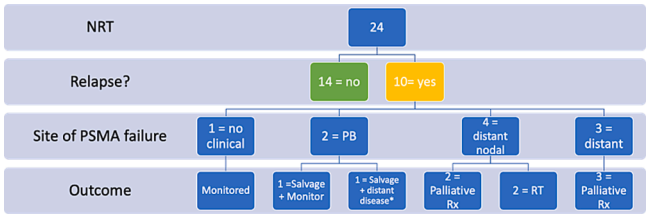

Fig. 2. Flow-chart demonstrating clinical outcomes in the NRT cohort and documented sites of failure.

Seven (32 %) in the PB + NRT group recorded late grade ≥2 GU toxicity. One (5 %) had increased urinary frequency of 40 times daily and another had urinary retention needing urological intervention. One (5 %) had haematuria needing urology intervention and hyperbaric oxygen treatment. Four (18 %) had new incontinence requiring pad use.

No patients in the NRT cohort recorded grade ≥2 GI toxicity. Two patients (9 %) reported new rectal bleeding in the PB + NRT cohort.

Discussion

To our knowledge, this represents the first study to demonstrate the feasibility and potential benefit of PB sparing RT in the salvage setting for PSMA-detected nodal only recurrence in selected patients. Our results demonstrate a statistically significant difference in time between RT and RP as a longer disease-free interval was thought to confer a better prognosis and lower likelihood of local failure by the treating clinician. Of the 24 men who received NRT, only 2 (8 %) failed in the PB with a likely reduction in late GU and GI toxicity. The two local failures received salvage PBRT, with one remaining off any further palliative treatments and the other progressing to metastatic disease. For the 7 (29 %) patients that had documented PSMA-PET distant failure without PB recurrence it is unlikely that including the PB in the treatment field would have altered their disease trajectory.

Management of PET-detected nodal only recurrence post RP remains controversial. Management options include, but are not limited to: stereotactic radiotherapy (SBRT) or nodal dissection, systemic therapy alone, or PB + NRT with systemic therapy [7,11–15]. The international phase 2 PEACE-V trial [16,17], has had its toxicity data and 3-year biochemical failure free survival published at ESTRO, highlighted this conundrum, comparing metastasis-directed therapy (MDT) versus elective nodal pelvic radiotherapy (ENRT) with 6 months of ADT in both groups Their 3-year BFFS and regional relapse-free survival was superior in the ENRT group compared to MDT with equivalent toxicity. Of note, 17 % of their patients were staged using Choline PET with 83 % being PSMA-PET staged. Our 4-year BFFS of 64 % compares favourably to their 3-year BFFS of 69 % at 3 years. Furthermore, we suspect that the isotoxicity seen amongst the two groups in the PEACE trial could be from prostate bed avoidance. The Oligopelvis trial [14], which used Choline-PET direct IMRT and ADT in oligorecurrent (five or fewer) pelvic lymph nodes, demonstrated a BFFS of 58 % and 46 % at 2 and 3 years respectively. Thus, for the clinician, there are no published randomised trials to guide practice. Panje et al. explore the difficulties in this landscape, creating decision trees from 14 different Swiss units [18]. We hypothesise that now pelvic nodal RT may be a further option that can be offered to highly selected patients with a promising 4-year BFFS of 64 %, which is very similar to our PBRT + NRT group of 67 %. In the absence of other evidence our data suggest that for select individuals concerned about toxicity, outcomes between PB inclusion and avoidance are likely to be similar.

We feel that if attempting a cure, treating all pelvic nodes with fractionated radiotherapy in combination with ADT is important. This opinion has been supported by the Radiation Therapy Oncology Group (RTOG; 2009) [19], the PIVOTAL trialists (2015) [20], and the NRG Oncology Group (2021) [21] who have suggested validated elective nodal radiotherapy templates. In recent years, SBRT nodal only treatment has fallen out of favour with a high failure rate, particularly if not coupled with ADT. A PSMA-PET directed nodal only SBRT oligometastatic trial conducted at our institution without ADT use conferred a 15 % 5-year BFFS (nadir + 0.2 ng/mL definition) for allcomers. On subgroup analysis, 46 of 57 pelvic nodes biochemically failed (81 %) with a median follow up of 5 years [22]. In addition, Schmidt-Hegemann et al. [23] compared surgical dissection to nodal radiotherapy in patients with PSMA-PET detected recurrences post RP. They treated 67 patients with RT to the nodes and fossa. Fifty-one (76 %) patients had pelvic nodal only recurrence prior to treatment. With a 2-year median follow up, their BFFS for all PET positive patients was 78 %, a similar result to our 2-year rates (88 %) and highlighting the advantage of combining ADT, pelvic nodal fields and PSMA-PET directed management rather than targeting selective nodes.

The study confirms that PB avoidance is associated with less clinician recorded GI and GU toxicity. The PB + NRT group had a 32 % $\geq$ grade 2 GU toxicity, consistent with the literature reported range of up to 40 % as seen in the SPPORT trial in their equivalent PB and nodal arm (group 3). In our series, 2 men in the PB + NRT needed urological intervention or hyperbaric oxygen therapy. There was only one recorded grade $\geq$2 GU or GI toxicities in the NRT cohort (4 %). This resolved after 2 years. As hypothesised, sparing of the PB did correlate to a reduction in clinician recorded grade 2 and above toxicity. For men with already severe toxicity secondary to RP and poor GU baseline function, this data may help advise patient-informed and clinician decision making.

The challenge of offering PB avoidance is in selecting those patients who are at low risk of local recurrence. In our study, the allocation was based on clinician and patient preference rather than a rigid selection protocol. They were generally chosen for nodal only radiotherapy due to their favourable resection status, lower T stage and favourable Gleason Score.

There are certain limitations in this study. Firstly, numbers are small with only 46 patients in total being eligible for inclusion. Patients with nodal only relapse post RP represent a small but growing subset of those that fail [24]. This makes any attempt to study this cohort difficult. These results should serve for hypothesis generation rather than to define recommendations in this group of patients. A larger retrospective cohort or prospective study is clearly required to address questions raised in these data. Secondly, although median follow up is close to 4 years, prostate cancer is generally slow growing with delayed patterns of failure. This holds especially true for patients who remain on ADT. An argument could be made that the BFFS, although statistically indistinguishable, between the two groups should have been better in the men treated to the bed alone given they were the more favourable subgroup. Again, more time will be needed to separate these cohorts for full analysis. Finally, toxicity data was clinician recorded with variable temporality and by multiple different physicians.

Conclusion

This study suggests that selected patients with PSMA documented pelvic nodal recurrence post RP can do well with pelvic nodal alone radiation whilst avoiding the morbidity of PB treatment. Most patients with nodal recurrence who subsequently fail will do so beyond the pelvis.

CRediT authorship contribution statement

Benjamin Challis: Conceptualization, Methodology, Writing – original draft, Writing – review & editing. **Andrew Kneebone:** Conceptualization, Methodology, Resources. **Thomas Eade:** Conceptualization, Methodology, Resources, Supervision. **Lesley Guo:** Data curation. **John Atyeo:** Writing – review & editing. **Chris Brown:** Formal analysis, Visualization. **George Hruby:** Conceptualization, Methodology, Resources, Supervision.

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None

Data Availability

Research data are stored in an institutional repository and will be shared upon request to the corresponding author.

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