Journal of Nuclear Medicine, published on January 20, 2022 as doi:10.2967/jnumed.121.263521

The change in management by ^{18}F-DCFPyL PSMA PET scanning in patients undergoing post-prostatectomy radiotherapy, with early biochemical response outcomes.

Author	Affiliations	Contribution
Michael Ng[1]	MBBS (Hons) FRANZCR	Principle Investigator
Mario Guerrieri[2]	MBBS FRANZCR	1,2
Lih Ming Wong[3,4]	MBBS, MS, DMedSci, DipSurg Anat, LMusA	2,3
Kim Taubman[5]	MBBS FRACP AANMS	2
Tom Sutherland[6,7]	MBBS MMed GDip Clin Ed FRANZCR	2
Angela Benson[8]	BHIM, GDipEpidBiostats	1,2
Graeme Byrne[9]	PhD, MLitt, BAppSci	2 & statistics
Sam Koschel[8]	MBBS	1,2,3
Kelvin Yap[6]	MBBS RACP FRANZCR	2
Michelle Starmans[8]	BSc MMR	2
Grace Ong[10]	MB BAO BCh FRANCZR	1,3
Craig Macleod[11]	MBBS FRANZCR	2
Marcus Foo[12]	MBBS BMedSci FRANZCR	2
Michael Chao[13]	MBBS FRANZCR AFRACMA DMedSc	1,2,3

(1) Contributing to conception and design, or acquiring data, or analyzing and interpreting data;

(2). Drafting the manuscript, or critically contributing to or revising the manuscript, or enhancing its intellectual content;

(3) Approving the final content of the manuscript.

Affiliations

1. GenesisCare St Vincent's Hospital, Melbourne, Australia
2. GenesisCare, Footscray, Australia
3. Department of Surgery, University of Melbourne
4. Department of Surgery, St Vincent's Hospital, Melbourne, Australia.
5. Department of Nuclear Medicine, St Vincent's Hospital Melbourne, Melbourne, Australia
6. Department of Medical Imaging, St Vincent's Hospital Melbourne, Melbourne, Australia
7. Faculty of Medicine, University of Melbourne, Melbourne, Australia
8. GenesisCare CancerCare Research, Melbourne, Australia

9. La Trobe University Statistics Consultancy Platform, Melbourne, Australia
10. GenesisCare, Shepparton, Australia
11. GenesisCare, Albury, Australia
12. GenesisCare, Berwick, Australia
13. GenesisCare, Ringwood, Australia

Corresponding Author/First Author

Dr Michael Ng

GenesisCare Radiation Oncology Centre

St Vincents Hospital

41 Victoria Parade

Fitzroy, Victoria, AUSTRALIA

P: +613 9427 6500

F: +613 9427 6510

E: michael.ng@genesiscare.com

KEYWORDS: ^{18}F-DCFPyL; management change; prostate cancer; prostatectomy; pet; psma; radiotherapy; salvage

WORD COUNT: 4993

SHORT TITLE: PSMA PET & post-prostatectomy radiation

ABSTRACT

Rationale: Prostate specific membrane antigen (PSMA) tracers have increased sensitivity in detection of prostate cancer compared to conventional imaging. We assessed the management impact of ^{18}F-DCFPyL PET/CT in patients with PSA recurrence post radical prostatectomy (RP) and report early biochemical response in patients who underwent radiation treatment.

Methods: One-hundred patients were enrolled into a prospective study, with a prior RP for prostate cancer, PSA 0.2-2.0ng/mL and no prior treatment. All patients underwent a diagnostic CT and ^{18}F-DCFPyL PSMA PET/CT, and management intent was completed at 3 times points (original, post-CT and post-PSMA) and compared. Patients who underwent radiotherapy with 6-month PSA response data are presented.

Results: Ninety-eight patients are reported with a median PSA 0.32 ng/mL (95% CI 0.28-0.36), with 71.4% pT3a/b disease and International Society of Urological Pathology (ISUP) grade group ≥3 in 59.2%. ^{18}F-DCFPyL PET/CT detected disease in 46.9% of patients compared to 15.5% using diagnostic CT (PSMA PET 29.2% local recurrence and 29.6% pelvic nodal disease). Major change in management intent was higher post-PSMA vs post-CT (12.5% vs 3.2%, p=0.010) and similarly, moderate change in intent (31.3% vs 13.7%, p=0.001). The most common change was an increase recommendation of elective pelvic radiation (15.6% to 33.3%), nodal boost (0% to 22.9%) and concurrent androgen deprivation therapy (ADT) use (22.9% to 41.7%) from original to post-PSMA intent due to detection of nodal disease. 86 patients underwent ^{18}F-DCFPyl guided radiotherapy. 55/86 patients did not receive ADT or ADT recovered with 18 month PSA response from 0.32 ng/mL to 0.02 ng/mL, 94.5% of patients with PSA ≤0.20ng/mL and 74.5% with PSA ≤0.03 ng/mL.

Conclusion: ^{18}F-DCFPyL PET/CT has significant impact to management intent in patients being considered for salvage radiotherapy post-RP with PSA recurrence. Increased detection of disease, particularly in the pelvic lymph nodes resulted in increased pelvic irradiation and

concurrent ADT use. Early results in patients who are staged with ^{18}F-DCFPyL PET/CT-staged show favourable PSA response.

INTRODUCTION

Prostate specific antigen (PSA) recurrence following radical prostatectomy (RP) for prostate cancer occurs in up to 20-50% (*1,2*) and is defined by PSA levels >0.2ng/mL. Salvage radiotherapy, most commonly to the prostate bed, results in 5-year biochemical control of 56% (*3*). Failure following salvage radiotherapy is most likely due to disease outside the prostate bed which can include the pelvic lymph nodes, para-aortic lymph nodes and distant metastases.

Positron-emission tomography (PET) using prostate specific membrane antigen (PSMA) tracers have increased detection of disease compared to more conventional imaging with computed tomography (CT) and bone scintigraphy. PSMA is a type II cell-surface glycoprotein overexpressed in more than 90% of prostate cancer epithelial cells (*4*). Various PSMA tracers are available including ^{68}Ga-PSMA-11 which has the most evidence for superior sensitivity of detecting disease. Newer tracers include ^{18}F labelled agents such as ^{18}F-DCFPyL and have advantages of increased manufacturing capacity, improved spatial resolution and higher tumour to background ratio (*5*). PSMA PET/CT is now recommended in international guidelines as staging for biochemical failure when PSA is >0.2ng/ml (*6*).

We aim to evaluate the role of ^{18}F-DCFPyL PET/CT in patients being considered for salvage radiotherapy, primarily assessing the change in management, and also reporting early 6-month biochemical response rate in patients who then undergo radiation therapy.

MATERIAL AND METHODS

We performed a prospective non-randomised trial at nine GenesisCare sites within Victoria, Australia. Between August 2018 and July 2020, we recruited 100 patients who had evidence of rising PSA between 0.2-2.0ng/ml post RP and were referred to a radiation oncologist for consideration of salvage radiotherapy. Exclusion criteria included previous pelvic radiotherapy and previous androgen deprivation therapy (ADT). The protocol was approved by the St Vincent's Hospital Melbourne Human Research Ethics Committee, was registered Australian New Zealand Clinical Trials Registry (ACTRN12618001530213) and all patients gave written informed consent.

All patients underwent a diagnostic CT of the chest, abdomen and pelvis (CTCAP) and ^{18}F-DCFPyL PET/CT on the same day at the Department of Nuclear Medicine St Vincent's Hospital. Scans were performed on a GE Discovery 710 PET/CT (General Electric Medical Systems, Milwaukee, WI) combining a 64 slice multidetector CT scanner with a dedicated, full ring PET scanner. For the diagnostic CTCAP, 100ml of intravenous contrast was administered, and patients scanned from apex of the lungs to lesser trochanters 70 seconds post contrast. An additional 10-minute delayed pelvis CT was also obtained to assist in distinction between ureters and lymph nodes. For the ^{18}F-DCFPyL PET/CT, 250MBq of GMP quality ^{18}F-DCFPyL manufactured by Cyclotek Australia and was administered with an uptake time of 120 minutes post injection.

Imaging acquisition and interpretation

CTCAP images were interpreted by an experienced genitourinary radiologist, and ^{18}F-DCFPyL PET/CT images were reported by two experienced nuclear medicine physicians. Reporting physicians did not have access to the images or reports of the

other modality, except for the delayed pelvis CT to allow the nuclear medicine physician localisation of the ureters and anastomosis on PET.

Both scans were reported using a standardised template that encompassed local, nodal and distant disease, with each section being designated as positive, equivocal or negative. Positive or equivocal disease was defined as focal uptake of ^{18}F-DCFPyL on PET/CT that was not physiological and higher than surrounding background. Local recurrence was sub-classified into prostate bed (which includes the anastomosis) or seminal vesicle bed (the bilateral rectovesical lateral areas on CT where soft tissue densities are seen and where the seminal vesicles are usually located +/- surgical clips). Lymph node involvement on CTCAP was defined based on size and morphology and designated as positive, equivocal or negative.

Change in management

Following patient registration and prior to imaging, the radiation oncologist was required to outline their treatment plan on a questionnaire (Supplemental Table 1), specifying whether radiotherapy would be offered or the proposed alternative management. If radiotherapy was to be offered, target sites dose and fractions needed to be specified, as well as use of pelvic nodal boost, stereotactic radiotherapy and addition of ADT. This was referred to as the ‘original intent’, and following completion of this, patients underwent diagnostic CTCAP and ^{18}F-DCFPyL PET/CT. The diagnostic CT results were released first, and the clinician was required to complete a second questionnaire (‘post-CT intent’). Then, the results of the ^{18}F-DCFPyL PET/CT were released and the clinician completed a final questionnaire (‘post-PSMA intent’). Change in management was graded based on impact to management, and defined as major, minor or no change as

demonstrated in Table 1. This grading system was based on a publication by van Leuuwen et al and further modified (*7*).

Radiotherapy treatment and disease outcome

For this analysis, we assessed early biochemical response at 6 months following the last day of radiotherapy, and also performed a subgroup analysis for the patients who did not receive concurrent ADT. The radiotherapy treatment protocol did not mandate what target volumes and dose prescription. However clinical target volumes guidelines for prostate bed (*8*) and elective pelvic nodal irradiation (*9*) were provided, and recommended dose prescription for prostate bed was 70.2Gy, elective nodal irradiation 56Gy, and nodal boost 68Gy in 39 fractions. Stereotactic radiotherapy to nodes or bone was recommended in 3-5 fractions with dose range of 30-40Gy. Concurrent ADT, if prescribed, was recommended using a luteinising hormone releasing hormone agonist for 6 months.

Statistical methods

McNemar's exact test was used to compare change in management between original intent to post-CT intent vs original intent to post-PSMA intent. Kendall's Tau-b correlation was used to assess association of change in intent with positive versus negative scan (both CT and PSMA PET/CT), International Society of Urological Pathology (ISUP) grade and pre-treatment PSA. Statistical summaries were performed for patients undergoing radiotherapy with 6-month PSA response data available. Particularly, for patients who did not receive ADT, T-tests, ANOVA with multiple comparisons and regression were used to compare difference and percent change between PSA at 6

months follow up and pre-scan PSA across levels of a number of factors (PET scan positivity, pTN staging, ISUP grade, margin status, biochemical recurrence vs persistence).

RESULTS

Between August 2018 to July 2020, 100 participants were enrolled across nine sites by 6 radiation oncologists. Two patients were excluded on review as their pre-scan PSA level was outside the eligibility criteria (PSA≥2.0), leaving 98 patients suitable for final analysis (Supplemental Figure 1). A further two patients were excluded due to incomplete management intent forms, leaving 96 patients eligible for this analysis. Baseline characteristics (Supplemental Table 2) included a median age of 68.0 years, a median pre-scan PSA of 0.32ng/ml (95% CI 0.28-0.36 and 58.9%, had ISUP grade group of ≥3 at RP. 60.2% of patients had biochemical recurrence versus 39.8% with biochemical persistence. Pelvic nodal sampling/dissection was performed in only 32.7% of patients with median nodal count 5.0 (95% CI 4.1-7.9) and 5.1% overall having pN1 disease. Histopathological characteristics from RP revealed extra-prostatic extension in 68.4%, seminal vesicle invasion in 24.5% and positive surgical margin in 37%.

Patterns of disease detection on ^{18}F-DCFPyL PET/CT and diagnostic CTCAP

Overall, 46.9% (n=46) of our cohort had positive ^{18}F-DCFPyL PET/CT scans and a further 5.1% (n=5) were equivocal. Location of PSMA avid disease is available in Supplemental Table 3. Local disease recurrence was identified in 28 patients (29.2%), nodal disease in 29 patients (29.6%), and distant bony metastases in 7 patients (7.1%). One patient was unable to have the CTCAP, resulting in 97 available for analysis. Local

recurrence was diagnosed in 9 patients (5 positive, 4 equivocal), nodal disease 11 patients (9 positive, 2 equivocal) and an equivocal distant bone metastasis 1 patient.

Change in management

Change in treatment original intent to post scan (post-CT and post-PSMA) are shown in Table 2. Overall, 43.8% (42/96) of patients demonstrated a change in management (major or moderate) following ^{18}F-DCFPyL PET/CT vs 16.7% (16/95) change following diagnostic CTCAP. There was 12.5% vs 3.2% major change for post-PSMA vs post-CT, the difference being significant (p=0.010). There were more patients post-PSMA vs post-CT with moderate changes, 31.3% vs 13.7% (p=0.001). Either a positive or equivocal finding on CT or PSMA was strongly associated with a major or moderate treatment intent change (p<0.001). Particularly for a positive or equivocal ^{18}F-DCFPyL PET/CT scan there were major or moderate change in 42/50 patients (84%) compared to no changes in 46 patients with a negative scan. Both higher PSA (p=0.009) and higher ISUP grade (p<0.001) were associated with a higher likelihood of major or moderate change in management post ^{18}F-DCFPyL PET/CT (Supplemental Figure 2). Positive nodal disease findings on ^{18}F-DCFPyL PET/CT (nodal only or in combination) always resulted in a change in management (moderate or major) (Supplemental Table 4).

Change in management – original vs post-CT vs post-PSMA

Change in management count following post-CT and post-PSMA intent is shown in Figure 1 and Supplemental Table 5. Original treatment intent was curative for most patients (n=94/96) with minimal change following post-CT (n=92/95) and post-PSMA (n=92/95). A similar number of patients were recommended radiotherapy original

(n=88), post-CT(n=87) and post-PSMA(n=88). Of these, almost all recommended prostate bed radiotherapy (original n=88, post-CT n=87, post-PSMA n=88). Both CT and PSMA PET largest effect was increased recommendation for elective pelvic radiotherapy, nodal boost or concurrent ADT. Elective nodal irradiation increased to 20% (19/95) post-CT and 33.3% (32/96) post-PSMA compared to 15/96 (15.6%) originally. Nodal boost was offered in more patients post-PSMA at 22.9% (22/96) vs 7.4% (7/95) post-CT. Concurrent ADT use increased from 22.9% (22/96) originally to 24.2% (23/95) post-CT and 41.7% (40/96) post-PSMA. No stereotactic radiotherapy was recommended at original intent, with small number of patients recommended stereotactic nodal irradiation (post-CT n=1, post-PSMA n=1), and stereotactic irradiation to bony metastases (post-CT n=1, post PSMA n=4). There was only 1 patient with change in dose (not fractions) with dose-escalation of prostate bed PSMA-avid local recurrence (70.2Gy to 75.6Gy).

Individual change in management from original intent to post ^{18}F-DCFPyL PET/CT

Figure 2 depicts the change in management flow for each individual patient between original intent to post-PSMA scan. The majority of patients (n=61/96) were originally recommended prostate bed radiotherapy alone and after ^{18}F-DCFpyL PET/CT, 41 remained on same recommendation (no change), 19 patients were recommended a change in radiotherapy treatment volume (moderate change), and 1 patient no longer recommended any radiotherapy and 1 had the additional stereotactic radiotherapy (both major change). The remaining 27/96 patients for radiotherapy were recommended prostate bed radiotherapy, with ADT in 22 patients and elective pelvis radiotherapy in 15 patients at original intent. Following PSMA-PET there were some changes in these 27 patients, with no consistent dominant change.

There were 12 patients who had major change in management following ^{18}F-DCFPyL PET/CT. Four of eight changed from active surveillance originally to recommendation of radiotherapy post-PSMA scan. Four of 88 (4.5%) changed from radiotherapy to no radiotherapy post-PSMA scan (ADT alone n=1, ADT+chemotherapy (n=2), and surveillance (n=1). Four of 88 patients were recommended to have addition of stereotactic radiotherapy to nodal or bone metastases.

Biochemical response in patients undergoing salvage radiotherapy

86 patients have received radiotherapy, and the majority of patients received prostate bed radiotherapy only (50/86) and ADT was prescribed in 33/86 patients (6 months duration) (Table 3). The median pre-treatment PSA was 0.32 ng/mL (range 0.20-1.84) and 59 patients had 18-month post-treatment PSA response data with median PSA of 0.02 ng/mL (range 0.01-0.29).

55 of 59 patients with 18-month follow-up data had either not received concurrent ADT or had ADT recovery (defined by testosterone >5nmol/L). At 18-months follow-up, 52/54 (92.5%) had a PSA ≤0.20 ng/mL and 41/54 (74.5%) had an undetectable (≤0.03) with no difference between a positive vs negative PSMA scan.

DISCUSSION

Our prospective study shows that just under 50% of patients planning to have salvage radiotherapy for PSA recurrence post-RP have a change in management when undergoing ^{18}F-DCFPyL PET/CT. The change in management was more than double the change in management with diagnostic CT. There have been various studies demonstrating significant change in management using ^{68}Ga-PSMA-11 (*10-12*) and ^{18}F-DCFPyL (*13-15*) tracers in PET imaging for prostate cancer. Many of these studies limitations contain heterogenous group of patients such as 1) use of PET as staging or for PSA failure, 2) prior treatment included surgery, radiotherapy and ADT and 3) high pre-scan PSA. We postulate the slightly lower management changes in our study are due to lower detection rates and a homogenous post-RP cohort without prior treatment, lower pre-treatment PSA (mean 0.32 ng/mL) and lower proportion of higher grade disease (ISUP 4≥ was less than 20%).

We previously reported patterns of disease detection and safety of ^{18}F-DCFPyL PET/CT in our cohort (*16*), and provided a nomogram to predict for positive scan. The improved detection of pelvic nodal disease was responsible for the moderate management change (31.3%) in our study doubling the recommendation of pelvic nodal irradiation, nodal boost and concurrent ADT with prostate bed radiotherapy. Many studies have shown PSMA-PET scans have improved detection of disease post-RP outside the prostate bed (*10,11,17-19*) with disease not encompassed by standard salvage prostate bed radiotherapy volumes.

Major changes were small and occurred in only 12.5% (12/96) of patients post ^{18}F-DCFPyL PET/CT. These were patients who were not recommended radiotherapy due to detection of metastatic disease, surveillance patients changing to treatment and the addition of stereotactic radiotherapy (node or bone). Improved detection of distant

metastasis in the PSA recurrence setting can avoid radiotherapy toxicity/costs by omitting futile prostate bed radiotherapy and the use of targeted radiotherapy to oligometastatic disease can improve progression free survival (*20*) or delay the use of ADT (*21*). It important to recognise there was no change in management in 56.3% patients using ^{18}F-DCFPyL PET/CT, which was driven by a negative scan. The positive vs negative scan rate in our study is similar to other studies in the post-RP PSA recurrence setting using ^{68}Ga-PSMA-11 (*22-24*) and ^{18}F-DCFPyL (*15,25-29*). The high negative scan rate raises the additional role of elective nodal radiotherapy to prostate bed radiation with trials supporting improved biochemical control (*30,31*).

With the impact management change by ^{18}F-DCFPyL staging, we have shown early favourable PSA response in patients who then underwent radiotherapy. Of patients who had 18 months response data available, who did not receive ADT or had ADT recovery, 92.5% had a PSA <0.20 ng/mL and 74.5% had an undetectable PSA with no difference in patients with a positive or negative scan. Previous studies have shown using ^{68}Ga-PSMA-11 guided salvage radiotherapy has favourable disease outcomes with similar follow-up (*32,33*). These studies including ours have shown a negative PSMA scan is not associated with inferior response or outcomes, and we recommend salvage radiotherapy in patients with a negative PSMA PET/CT. A recent randomised trial by Jani et al., showed ^{18}F-fluciclovine PET/CT staged patients undergoing salvage radiotherapy have improved 3-year event survival compared to patients who were conventionally staged (*34*), and we await the results of a similar trial using ^{18}F-DCFPyL (*35*).

Strengths of our study include the prospective conduct, with controlled high compliance stepwise assessment of management intent change. Our eligibility criteria reflect a very common scenario facing patients and clinicians with a rising PSA post-RP, having had

no prior therapy with a PSA entry criteria of 0.2-2.0ng/mL. Our study is relevant given recent guidelines and trials support early referral for radiotherapy when PSA >0.1-0.2ng/mL (*36*-*38*). The limitations of our study include the lack of histopathological or radiological confirmation of disease, management change could vary at different institutions and the limited follow-up. We will follow-up patients to 3 years post-radiotherapy to validate ^{18}F-DCFPyL-staged radiotherapy. Another limitation is our analysis of ^{18}F-DCFPyL PET/CT scans did not utilize newer guidelines (PROMISE, PSMA-RADS, E-PSMA) which were not available at time of protocol development, which we will incorporate in future trials.

CONCLUSION

^{18}F-DCFPyL PET/CT has a significant impact in patients being considered for salvage radiotherapy. With improved detection of local recurrence and nodal disease, ^{18}F-DCFPyL PET/CT improves confidence when irradiating the prostate bed and results in increased use of pelvic nodal irradiation. We recommend all patients being considered for salvage radiotherapy post-RP with a PSA >0.2ng/mL be considered for a PSMA PET/CT, with early results of ^{18}F-DCFPyL staged patients receiving radiotherapy showing favourable PSA response rate, but longer term follow-up will be necessary.

ACKNOWLEDGEMENT

We acknowledge the financial support of the sponsor GenesisCare along with Cyclotek (Aust) Pty Ltd for their financial support and access to their GMP Approved product, ^{18}F-DCFPyL-PSMA radiopharmaceutical, and through Cyclotek the support of the Department of Industry, Science, Energy and Resources, Cooperative Research Centre Program – Project Grant.

DISCLOSURE

No potential conflicts of interest relevant to this article exist.

KEY POINTS

QUESTION

How does improved detection of disease by ^{18}F-DCFPyL PSMA PET change management in patients with prostate cancer being considered for salvage radiotherapy for PSA recurrence post-prostatectomy?

PERTINENT FINDINGS

This study was a prospective non-randomised study in 100 patients with prostate cancer with a detectable PSA (0.2-2.0 ng/mL) post-prostatectomy being considered for salvage radiotherapy. ^{18}F-DCFPyL PSMA PET detected disease in 46.9%, resulting in major change in management in 12.5% of patients and moderate change in 31.3% of patients; the greatest change was the increase in pelvic nodal irradiation.

IMPLICATIONS FOR PATIENT CARE

Increased detection of disease by PSMA-PET allows better selection of patients for salvage radiotherapy, and appropriate radiation fields with favourable treatment response in patients who received PSMA guided radiotherapy.

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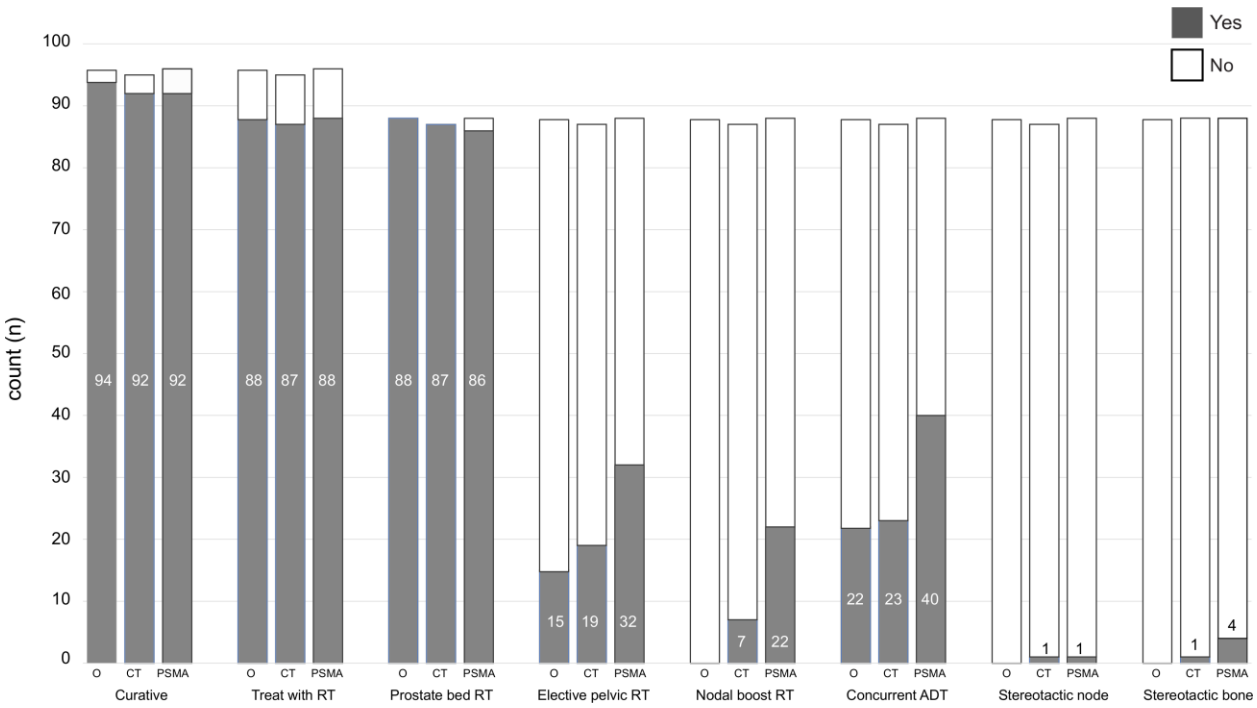


Figure 1: Overall management intent at original (O) vs post-CT (CT) vs post-PSMA (PSMA). CT, computed tomography; PSMA prostate-specific membrane antigen; RT, radiotherapy; ADT, androgen deprivation therapy.

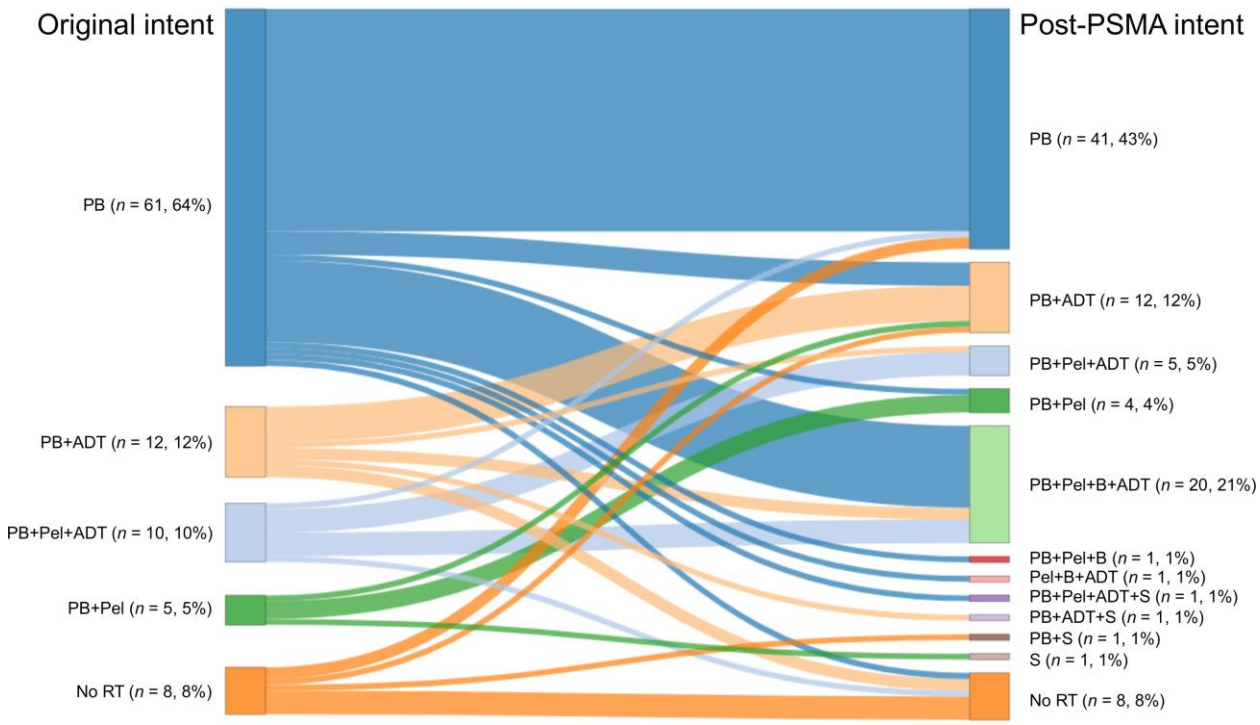
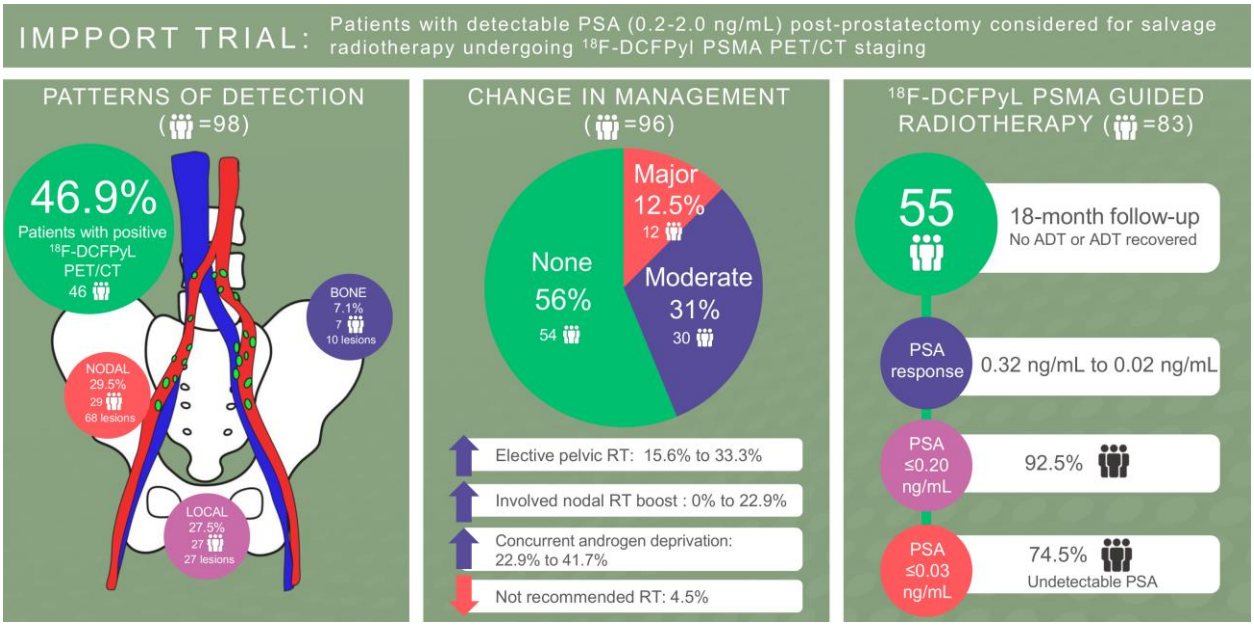


Figure 2: Sankey diagram demonstrating the specific change in management per patient from original intent to post-PSMA scan, particularly for radiation target volumes.

PB, prostate bed; Pel, elective pelvic radiation; ADT, androgen deprivation therapy; B, boost to node, RT, radiotherapy; S, stereotactic radiotherapy.



Graphical Abstract

Table 1

Grade of Management Impact	Definition
None	No change to management intent or plan
Moderate	Changes to specific treatment delivery of RT but no change in the intent This includes but is not limited to: - Change to volume of RT - Change to dose of RT - A combination of change in volume and dose e.g. addition of elective pelvic nodal RT and dose escalation to involved PSMA positive pelvic node/s (nodal boost) - The addition of ADT to salvage RT
Major	Significant change to treatment intent This includes but is not limited to: - Detection of significant metastatic disease resulting in change to palliative intent, recommendation no salvage RT or change to palliative intent RT - Detection of oligometastatic disease resulting in change of intent to treat oligometastases such as with stereotactic RT

Table 1: Definition of changes in management intent, graded as none, moderate and major impact. RT, radiotherapy; ADT, androgen deprivation therapy.

TABLE 2

Change in management	Major change	Moderate change	No change	Total
Original to post-CT intent	3 (3.2%)	13 (13.7%)	79 (83.2%)	95 (100.0%)
Original to post-PSMA intent	12 (12.5%)	30 (31.3%)	54 (56.3%)	96 (100.0%)

Table 2: Change in management intent from original to post-CT vs post-PSMA: major, moderate and no change. CT, computed tomography; PSMA prostate-specific membrane antigen.

TABLE 3

	All patients (n=86)	No ADT (n=53)
PB alone	50	41
PB + elective pelvic RT	13	4
PB + elective pelvic RT + nodal boost	18	5
Stereotactic RT +/- pelvis RT	5	3
PB		
Median Dose Gy (range)	70.2 (68.0-75.6)	
Median fx (range)	39 (34-42)	
Elective Pelvic		
Median Dose Gy (range)	56.0 (54.0-56.0)	
Median fx (range)	39 (34-39)	
Nodal Boost		
Median Dose Gy (range)	68.0 (64.0-70.2)	
Median fx (range)	39 (39-39)	
Stereotactic nodal		
Median Dose Gy (range)	30.0 (30.0-30.0)	
Median fx (range)	3 (3-5)	
Stereotactic bone		
Median Dose Gy (range)	27.0 (25.0-30.0)	
Median fx (range)	5 (3-5)	

Table 3: Radiotherapy treatment volumes and dose and fractionations delivered. PB, prostate bed; RT, radiotherapy; Gy, Gray; fx, fraction.

SUPPLEMENTAL MATERIAL

1. Management intent:	☐ Curative ☐ Palliative	
2. Treat with RT?	☐ Yes ☐ No	
3. *If NO RT,* what is your plan?	☐ Surveillance ☐ Chemotherapy ☐ ADT only ☐ Palliative care ☐ Surgery ☐ Other ……	
***4.* Prostate bed RT**	☐ Yes ☐ No	☐☐.☐ Gy ☐☐ fractions
5. Elective pelvic nodal RT	☐ No ☐ Whole pelvis ☐ Left pelvis ☐ Right pelvis	☐☐.☐ Gy ☐☐ fractions
6. Boost pelvic nodes (with elective pelvic RT)	☐ No ☐ Yes	☐☐.☐ Gy ☐☐ fractions
7. Concurrent ADT to RT?	☐ No ☐ Yes	☐☐ months of ADT planned
***8.* Other RT**	Site 1 …… Site 2 …… Site 3 ……	Site 1 ☐☐.☐ Gy ☐☐ fractions Site 2 ☐☐.☐ Gy ☐☐ fractions Site 3 ☐☐.☐ Gy ☐☐ fractions

Table 1: Clinician questionairre (same questionairre for original intent, post-CT and post-PSMA). RT, radiotherapy; ADT, Androgen deprivation.

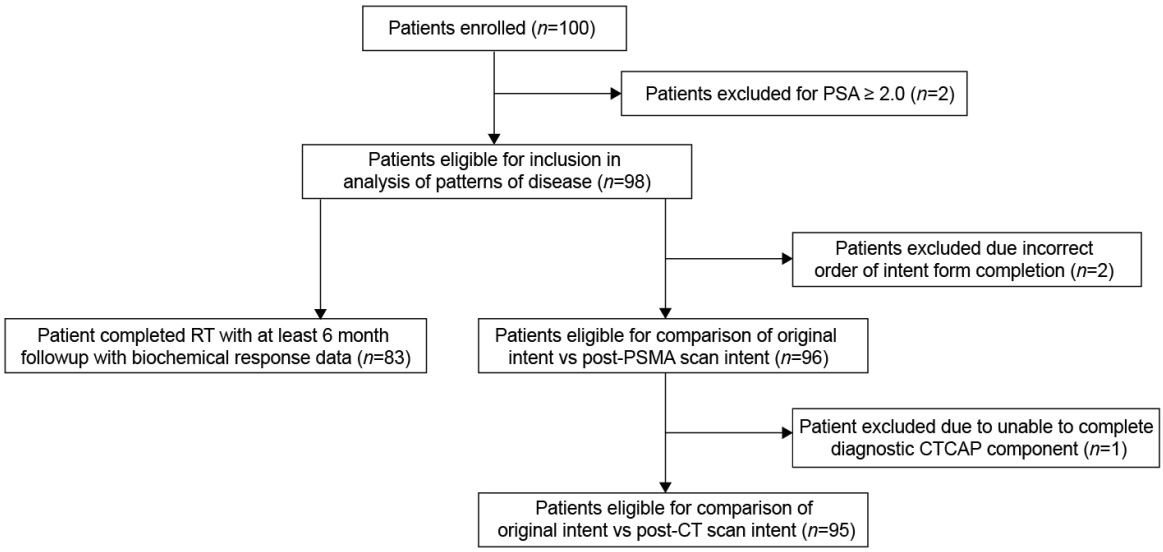


Figure 1: STARD flow diagram of patients in this study

	All patients (n=98)
Age, years	
Median (95% CI)	68.0 (66.0-71.0)
PSA, ng/ml	
Median (95% CI)	0.32 (0.28-0.36)
Time between RP and imaging, days	
Median (95% CI)	951.5 (755-1117)
Prior PSMA PET Scan	
Yes	12 (12.2%)
Biochemical recurrence vs persistence	
Biochemical recurrence	59 (60.2%)
Biochemical persistence	39 (39.8%)
Pathological T stage	
T2	28 (28.6%)
T3a	46 (46.9%)
T3b	24 (24.5%)
ISUP grade group	
1	4 (4.1%)
2	36 (36.7%)
3	39 (39.8%)
4	3 (3.1%)
5	16 (16.3%)
Pathological N stage	
Nx	66 (67.3%)
N0	27 (27.6%)
N1	5 (5.1%)
Extraprostatic extension	
No	31 (31.6%)
Yes	67 (68.4%)
Seminal vesicle invasion	
No	74 (75.5%)
Unilateral	13 (13.3%)
Bilateral	11 (11.2%)
Positive surgical margin	
No	60 (61.0%)
Equivocal	2 (2.0%)
Yes	36 (37.0%)

Table 2: Baseline patient and histopathological characteristics.

PSA, prostate-specific antigen; RP, radical prostatectomy; ISUP, International Society of Urological Pathologists.

	Positive lesions	Equivocal lesions	Total lesions
Local (n=28 patients)	n=27	n=1	n=28
Prostate bed	15 (55.6%)	1 (100%)	16 (57.1%)
Seminal vesicle bed	12 (44.4%)	-	12 (42.9%)
Nodal (n=29 patients)	n=68	n=3	n=71
Internal iliac	20 (29.4%)	1 (33.3%)	21 (29.6%)
External iliac	18 (26.4%)	-	18 (25.4%)
Common iliac	8 (11.8%)	-	8 (11.3%)
Obturator	1 (1.5%)	-	1 (1.4%)
Presacral	14 (20.6%)	-	14 (19.7%)
Mesorectal	6 (8.8%)	2 (66.4%)	8(11.3%)
Perivesical	1 (1.5%)	-	1 (1.4%)
Distant (n=7 patients)	n=10	n=1	n=11
Pelvis	3 (30.0%)	-	3 (27.3%)
Femur	4 (40.0%)	-	4 (36.4%)
Rib	1 (10.0%)	1 (100.0%)	2 (18.2%)
Scapula	1 (10.0%)	-	1 (9.1%)
Thoracic spine	1 (10.0%)	-	1 (9.1%)

Table 3: Breakdown of 18F-DCFPyL avid disease in 51 patients with descriptive positive, equivocal and total lesion count.

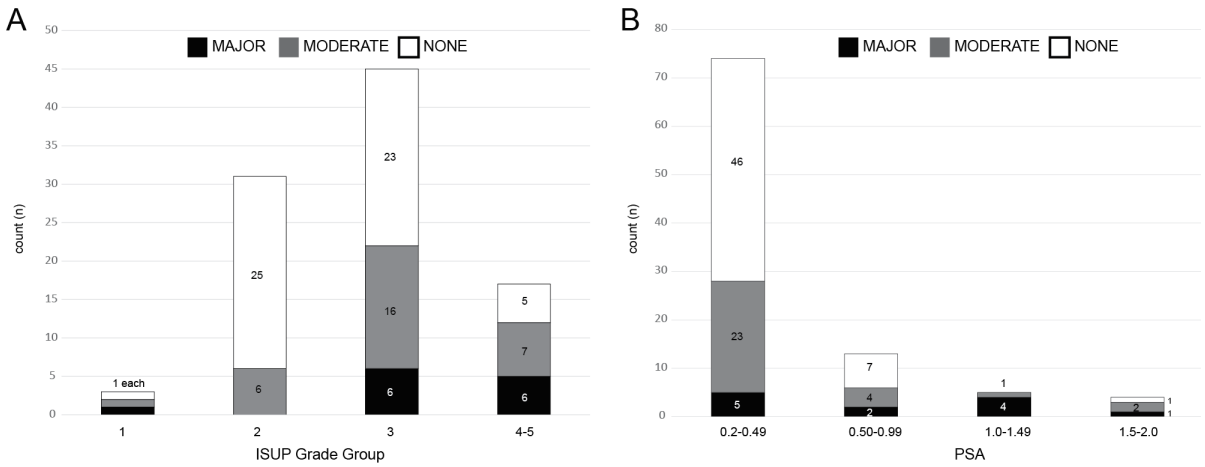


Figure 2: Change in management grades based on A) ISUP grade group and B) PSA (pre-treatment). PSA, prostate-specific antigen; ISUP, International Society of Urological Pathologists.

	All	No change	Moderate change	Major change
Positive PSMA	*n*	*n*	*n*	*n*
Local only	16	5	8	3
Nodal only	17	0	15	2
Distant only	2	0	0	2
Local & Nodal	7	0	6	1
Local & Distant	2	0	0	2
Nodal & Distant	0	0	0	0
Local & Nodal & Distant	2	0	0	2
Positive CT CAP	*n*	*n*	*n*	*n*
Local only	6	5	1	0
Nodal only	8	2	5	1
Distant only	0	0	0	0
Local & Nodal	0	0	0	0
Local & Distant	0	0	0	0
Nodal & Distant	1	0	1	0
Local & Nodal & Distant	0	0	0	0

Table 4: Change in management (no, moderate and major) vs positive PSMA local, nodal and distant disease locations and for CT CAP local, nodal and distant disease locations.

	Original n=96		Post-CT n=95		Post-PSMA n=96	
	n	%	n	%	n	%
Curative intent	94	97.9	92	96.8	92	95.8
Palliative intent	2	2.1	3	3.2	4	4.2
Treat with RT - Yes	88	91.7	87	91.6	88	91.7
Treat with RT - No	8	8.3	8	8.4	8	8.3
Prostate Bed RT – Yes	88	91.7	87	91.6	86	89.6
Prostate Bed RT - No	0	0.0	0	0.0	2	2.1
Elective Pelvic RT – Yes	15	15.6	19	20.0	32	33.3
Elective Pelvic RT - No	73	76.0	68	71.6	56	58.3
Boost Nodes – Yes	0	0.0	7	7.4	22	22.9
Boost Nodes - No	88	91.7	80	84.2	66	68.8
Concurrent ADT – Yes	22	22.9	23	24.2	40	41.7
Concurrent ADT - No	66	68.8	64	67.4	48	50.0
Stereotactic Nodes – Yes	0	0.0	1	1.1	1	1.0
Stereotactic Nodes - No	88	91.7	86	90.5	87	90.6
Stereotactic Bone RT – Yes	0	0.0	1	1.1	4	4.2
Stereotactic Bone RT - No	88	91.7	87	91.6	84	87.5

Table 5: Overall change in management at original vs post-CT vs post-PSMA. RT, radiotherapy; ADT – androgen deprivation therapy