

Objectives

To determine the safety, quality of life and short-term oncological outcomes of IRE for primary and salvage treatment of prostate cancer (PCa). To identify potential risk factors for oncological failure.

Materials and Methods

Patients that met both the consensus guidelines on patient criteria and selection methods for primary and salvage focal therapy were analysed. 91 men with organ-confined clinically significant PCa (i.e. high-volume Gleason sum score 6 or Gleason 7 for primary, any Gleason for salvage) were treated with focal IRE. Oncologic, adverse event and quality of life outcome data were analysed. Wilcoxon's Signed Rank Test and Wilcoxon's Rank Sum Test were used to assess statistically significant differences in paired continuous variables and unpaired continuous variables respectively. All analyses were performed for primary IRE and salvage IRE separately.

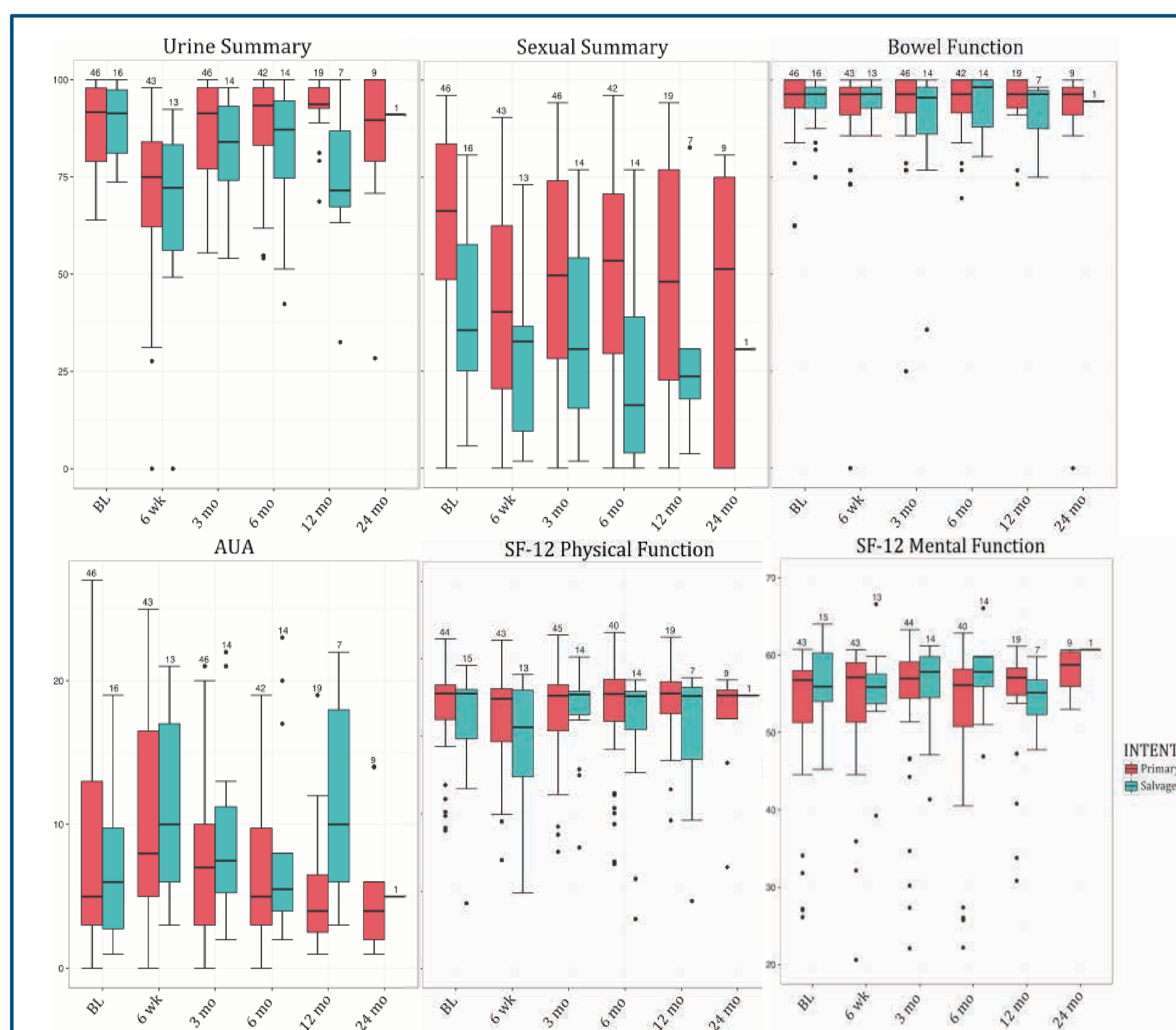


Figure 1 Quality of life after primary and salvage IRE, measured with EPIC questionnaire including the urinary (A), sexual (B) and bowel (C) domains. Urinary function after IRE measured with the AUA symptom score (D). Health status measured with SF-12 physical (E) and mental (F) summary score. Box and whiskers plots indicating the median scores with the IQR (boxes) and range (whiskers).

Results

- A total of 91 patients were included, 63 patients underwent primary IRE treatment, 28 patients salvage treatment.
- No high-grade adverse events occurred. Quality of life analysis demonstrated no significant change in overall, physical, mental, bowel and urinary QoL; there was a mild decrease in sexual QoL scores in both the primary IRE cohort and in the salvage cohort.
- Compared to baseline PSA a decline of 70% (1.8, IQR 0.96-4.8) and 83% (0.65, IQR 0.21-3.5) was seen between 6-12 months for primary and salvage patients respectively.
- In-field and whole-gland oncological control on follow up biopsies was 84% (38/45) and 76% (34/45) for primary and 83% (10/12) and 75% (9/12) for salvage.
- This increased to 97% (38/39) and 87% (34/39) for primary and 100% (10/10) and 90% (9/10) for salvage when patient were excluded treated with a narrow safety margin and/or system errors.

Conclusion

Our data supports the safety and feasibility of IRE in both the primary and salvage setting as a potential and effective treatment of localized primary and recurrent PCa in carefully selected men.

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Patient Characteristics

	Primary pts	Salvage pts
Number of pts	63	28
Age (median; range)	67 (61-71)	71 (67-76)
Serum PSA (median; IQR)	6 (3.2-8.4)	3.9 (2.5-6.2)
Prostate volume on MRI (mL) (median; IQR)	43 (30-60)	25 (17-34)
MRI results		
PIRADS < 3	2	2 neg.
PIRADS 3	12	26 pos.
PIRADS 4	26	
PIRADS 5	23	
Disease distribution on biopsy		
Significant unilateral disease	43	21
Significant bilateral disease		1
Significant single midline lesion (anterior/posterior)	8	4
Significant unilateral disease + contralateral insignificant	12	2
Gleason score		
Gleason 3 + 3 (ISUP Grade 1)	9	1
Gleason 3 + 4 (ISUP Grade 2)	38	11
Gleason 4 + 3 (ISUP Grade 3)	16	10
Gleason 4 + 4 (ISUP Grade 4)		1
Gleason 4 + 5 (ISUP Grade 5)		4
Gleason 5 + 4 (ISUP Grade 5)		0
Ungraded (high)		1

Patient Criteria and Selection Methods

Primary IRE	Salvage IRE
Patient Criteria	
<ul style="list-style-type: none"> Low- to Intermediate-Risk PCa (D'Amico) Gleason score ≤ 7 (ISUP Grade ≤ 3) Unilateral or single midline anterior/posterior index tumour, allowing single targeted ablative therapy Life expectancy ≥ 10 years No previous treatment for their PCa (e.g. radiotherapy of focal therapy) No previous androgen suppression/hormone treatment for their PCa 	<ul style="list-style-type: none"> Patients with recurrent PCa after primary treatment for localised PCa (e.g. LDR/PDR/HDR brachytherapy, External beam radiation therapy, focal therapy) Any Gleason Score Any number of positive cores/core involvement No evidence of metastatic or nodal disease outside the prostate If applicable, should stop previous androgen suppression/hormone treatment for their PCa
Selection Methods	
Pretreatment mpMRI performed with targeted biopsies, in conjunction with (previous) transrectal or transperineal template mapping biopsies	Baseline cross-sectional imaging to rule out lymph node or bone metastasis (e.g. bone scan, (choline/PSMA PET-) CT scan, whole-body MRI)
	Pretreatment mpMRI performed with mpMRI-TRUS fusion targeted biopsies, in conjunction with (previous) 12 to 24 systematic biopsies

Oncological Follow-Up Results

	Primary IRE	Salvage IRE
6-12 mo. PSA (median, IQR)	1.8 (0.96-4.8)	0.65 (0.21-3.5)
MRI results		
Clear	47 (85.5%)	17 (85.7%)
In-field lesions	4 (7.3%)	1 (4.8%)
Out of field lesions	2 (3.6%)	2 (9.5%)
In- and out of field lesions	2 (3.6%)	0
Adjacent and out of field lesions	0	0
Biopsy results		
Number of cores taken (median, IQR)	25 (22-30)	20 (15-32)
Number of positive cores (median, IQR)	2 (0-4)	0 (0-4)
Significant in-field disease all patients	7 (15.6%)	2 (16.7%)
Significant in-field disease 5mm safety margin	4 (4/10; 40%)	2 (16.7%)
Significant in-field disease 10mm safety margin	3 (3/35; 8.6%)	0
Significant out-field disease	4 (9.8%)	1 (10%)
Gleason score 3 + 3 (ISUP Grade 1), >5mm/50% core involvement	0	0
Gleason score 3 + 4 (ISUP Grade 2)	7	0
Gleason score 4 + 3 (ISUP Grade 3)	2	0
Gleason 4 + 4 (ISUP Grade 4)	1	0
Gleason 4 + 5 (ISUP Grade 5)	0	3
High-grade	1	0

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