How many cores are needed to detect clinically significant prostate cancer on targeted MRI-US fusion biopsy?

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Introduction

While mpMRI-guided biopsies offer a high degree of accuracy in the detection of clinically significant cancer, there is no universally accepted standard for the number of targeted cores to take from a particular region of interest (ROI). Given the risk of infection, pain, high procedural and pathologic costs, and other complications associated with prostate biopsy, there is a clear need to define the optimal sampling technique at the time of mpMRI-guided biopsy.

Objective

To better understand the optimal approach to lesion targeting, we aimed to examine the cancer detection rate based on sequential number of cores obtained.

Table 1: Demographic and lesion characteristics

No. of patients	379	**No. of mp-MRI targets**	581
Age	66 (IQR 60-72)	**Target Volume (cm3)**	0.33 (IQR 0.12-0.9)
PSA	7.1 (IQR 4.8-11.5)	**No. of cores per target**	5 (IQR 3-5)
Prostate Volume (cm3)	41 (IQR 30-56)	**1**	2% (11/581)
Biopsy Status		**2**	6% (33/581)
Biopsy Naïve	43.5% (165/379)	**3**	11% (64/581)
Prior Negative	25.9% (98/379)	**4**	11% (63/581)
Active Surveillance	30.3% (115/379)	**5**	44% (256/581)
Post-radiation Therapy	0.2% (1/379)	**6**	15% (88/581)
		7+	11% (66/581)
		Core length (cm)	1.3 (IQR 1-1.6)
		PI-RADS	
		1, 2, 3	13% (73/581)
		4	28% (161/581)
		5	22% (126/581
		Likert or N/A	38% (221/581)

Table 2: 5-core sensitivity analysis of lesions with exactly 5 cores

No of Cores	≥3+4	CDR ≥3+4 (n=140)	>3+4	CDR >3+4 (n=63)
1 core	81	57.9% $_a$	33	52.4% a
2 cores	102	72.9% $_b$	42	66.7% a,b
3 cores	120	85.7% $_c$	49	77.8% b
4 cores	130	92.9% $_c$	58	92.1% c
5 cores	140	100% $_d$	63	100.0% d

Methods

We identified 628 men with targets on multi-parametric MRI (mpMRI) who underwent targeted and systematic fusion biopsy using the Artemis platform for clinical suspicion (n=465) or known history of PCa (n=163). mpMRI studies were reviewed by genitourinary radiologists using a 3-tiered Likert scale and PI-RADS classification schema.

Biopsy was performed by two urologists performing a high volume of fusion biopsies. Cores were taken sequentially from each ROI with an even distribution. The primary outcome was the proportion of high-grade (Gleason ≥3+4) cancers missed on a 2-core lesion biopsy.

Table 3: Cancer Detection Rate (CDR) per lesion for all patients

No of Cores	≥3+3	CDR ≥3+3 (n=581)	≥3+4	CDR ≥3+4 (n=361)	>3+4 Cancer	CDR >3+4 (n=189)
1 core	400	69% $_a$	223	62% $_a$	102	54% $_a$
2 cores	490	84% $_b$	279	77% $_b$	137	72% $_b$
3 cores	531	91% $_c$	319	88% $_c$	156	83% $_c$
4 cores	557	96% $_d$	341	94% $_d$	173	92% $_d$
5 cores	574	99% $_e$	355	98% $_e$	181	96% $_d$
>5 cores	581	100% $_f$	361	100% $_f$	189	100% $_e$

Each subscript letter denotes a subset of core numbers that do not differ significantly within each column (P>.05).

Table 4: PI-RADS 4 and 5 and Cancer Detection Rate (CDR)

No of Cores	PI-RADS 4	CDR ≥3+4 (n=84)	PI-RADS 5	CDR ≥3+4 (n=104)
1 core	53	63.1% $_a$	70	67.3% $_a$
2 cores	61	72.6% $_a$	85	81.7% $_b$
3 cores	72	85.7% $_b$	93	89.4% $_b$
4 cores	75	89.3% $_b$	101	97.1% $_c$
5 cores	77	91.7% $_b$	103	99.0% $_c$
>5 cores	84	100.0% $_c$	104	100.0% $_c$

Each subscript letter denotes a subset of core numbers that do not differ significantly within each column (P>.05).

Results

- We identified 744 patients with 581 lesions with PCa (Table 1)
- Sensitivity analysis: Among patients receiving only 5 cores, two-core biopsy detected 72.9% of G≥3+4 and 66.7% of G>3+4 (Table 2)
- 77% (279/361) of G≥3+4 tumors, and 72% (137/189) of G>3+4 tumors were detected on two-core sampling (Table 3). Sampling significantly increased CDR of G≥3+4 with each additional core.
- For patients with PI-RADS 4 lesions, additional sampling beyond 5 cores significantly improved G≥3+4 detection (P<0.05), while for PI-RADS 5 lesions, sampling beyond 4 cores did not improve G≥3+4 detection (Table 4)
- Clinically significant CDR using a two-core approach was 84% (147/176) in biopsy-naïve patients, 73% (69/94) in prior negative, and 68% (60/88) of men on active surveillance (Figure 1).

Conclusions

On a per-lesion basis, sampling two cores of mpMRI-evident lesions at the time of fusion biopsy misses nearly one-quarter of clinically significant PCa that would be detected on additional sampling.

Figure 1: Clinically significant cancer detection by biopsy status