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Platinum Priority – Review – Prostate Cancer

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Image-Guided Prostate Biopsy Using Magnetic Resonance Imaging–Derived Targets: A Systematic Review

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Abstract

Context: Technical improvements in prostate magnetic resonance imaging (MRI) have resulted in the use of MRI to target prostate biopsies.
Objective: To systematically review the literature to compare the accuracy of MRI-targeted biopsy with standard transrectal biopsy in the detection of clinically significant prostate cancer.
Evidence acquisition: The PubMed, Embase, and Cochrane databases were searched from inception until December 3, 2011, using the search criteria '*prostate OR prostate cancer*' *AND* '*magnetic resonance imaging OR MRI*' *AND* '*biopsy OR target*'. Four reviewers independently assessed 4222 records; 222 records required full review. Fifty unique records (corresponding to 16 discrete patient populations) directly compared an MRI-targeted with a standard transrectal approach.
Evidence synthesis: Evidence synthesis was used to address specific questions. Where MRI was applied to all biopsy-naive men, 62% (374 of 599) had MRI abnormalities. When subjected to a targeted biopsy, 66% (248 of 374) had prostate cancer detected. Both targeted and standard biopsy detected clinically significant cancer in 43% (236 or 237 of 555, respectively). Missed clinically significant cancers occurred in 13 men using targeted biopsy and 12 using a standard approach. Targeted biopsy was more efficient. A third fewer men were biopsied overall. Those who had biopsy required a mean of 3.8 targeted cores compared with 12 standard cores. A targeted approach avoided the diagnosis of clinically insignificant cancer in 53 of 555 (10%) of the presenting population.
Conclusions: MRI-guided biopsy detects clinically significant prostate cancer in an equivalent number of men versus standard biopsy. This is achieved using fewer biopsies in fewer men, with a reduction in the diagnosis of clinically insignificant cancer. Variability in study methodology limits the strength of recommendation that can be made. There is a need for a robust multicentre trial of targeted biopsies.

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1. Introduction

In a lecture delivered in 2008, Dr. Patrick Walsh made the following statement: "The discovery that would have the greatest impact on our field would be the development of accurate imaging of tumour within the prostate" [1].

The original six-core transrectal prostate biopsy, termed *random systematic* by Stamey in 1989 [2], has incorporated

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more cores over time, with 10–12 cores being an accepted practice standard. This has increased the negative predictive value of the transrectal biopsy but has led to an increase in the detection of low-volume, low-risk disease. Worldwide postmortem studies using 3-mm step section histology have demonstrated that such disease is present in >40% of men >50 yr of age [3].

In addition, the standard transrectal approach is poor at sampling cancers in the anterior, midline, and apex, leading to the underdiagnosis of clinically significant disease. Up to one in three biopsy diagnoses of low-volume, low-risk cancers are upgraded or upstaged at whole mount step section pathology [4].

The prostate is the only solid organ in which a standardised approach to sampling is taken. All other diagnostic pathways for solid or hollow organ cancers incorporate either direct (eg, cystoscopic) or radiologic imaging (ultrasound, computed tomography [CT], magnetic resonance imaging [MRI]) to identify areas of greater likelihood of cancer for subsequent assessment.

MRI has been shown to have a high degree of accuracy in the detection of clinically significant prostate cancer when compared with radical prostatectomy histology [5]. When functional parameters such as dynamic contrast enhancement (DCE), diffusion-weighted imaging (DWI), and spectroscopy are used, in addition to standard T1- and T2-weighted sequences, MRI may afford an opportunity for a similar image-guided approach to the prostate [6].

This systematic review addresses the following question: In men with a clinical suspicion of prostate cancer, based on a raised prostate-specific antigen (PSA) or an abnormal digital rectal examination (DRE), does an MRI-guided biopsy strategy result in a higher detection rate of clinically significant cancer and a lower detection rate of clinically insignificant cancer compared with standard transrectal ultrasound (TRUS)-guided biopsy?

2. Evidence acquisition

An initial search was carried out to identify articles for further review, using PubMed and Embase databases, Cochrane reviews, the Cochrane database of clinical trials, and the database of abstracts of reviews of effects. The search terms used were '*prostate OR prostate cancer*' *AND* '*magnetic resonance imaging OR MRI*' *AND* '*biopsy OR target*'. Abstracts were reviewed for relevance to the defined review question. If it was not clear from the abstract whether the paper might contain relevant data, the full paper was assessed. The references cited in all full-text articles were also assessed for additional relevant articles. The initial search was carried out independently for each database by two of four primary reviewers (N.A., C.M., T.M., and N.R.). Any disagreements between the two primary reviewers

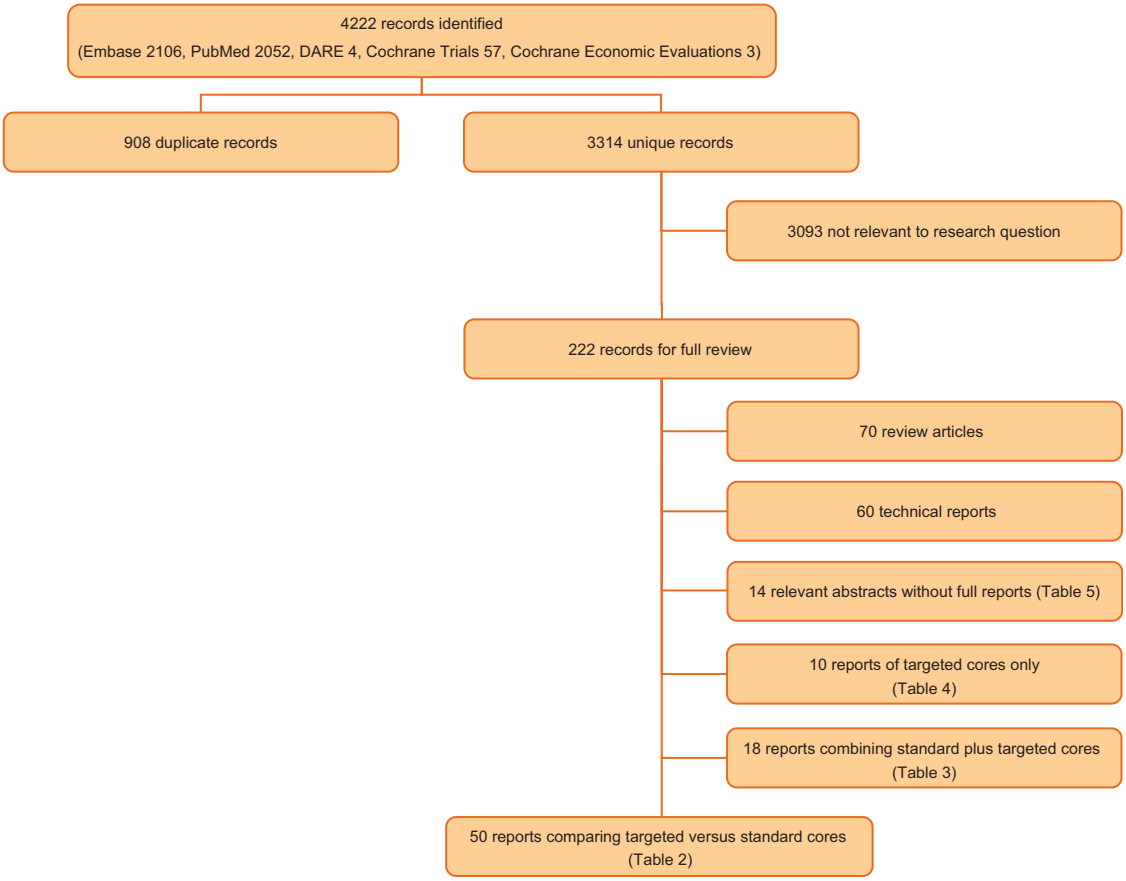

Fig. 1 – Preferred Reporting Items for Systematic Reviews and Meta-Analysis flow diagram showing the outcome of the initial and additional searches resulting in the full studies included in the review. DARE = database of abstracts of reviews of effects.

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were refereed by a third reviewer (CM or NR). The Preferred Reporting Items for Systematic Reviews and Meta-Analyses process for reporting included and excluded studies was followed, with the recommended flowchart showing the numbers of papers identified and included or excluded at each stage (Fig. 1 [7]). Each paper reviewed in full was assessed for the quality of reporting according to the QUADAS checklist [8]. The risk of bias was assessed in a qualitative manner and is discussed.

2.1. Population studied

The populations reported in the literature exhibited considerable heterogeneity. The ideal population to answer our research question is one where all men referred with a clinical suspicion of prostate cancer (due to a raised PSA or abnormal DRE) undergo MRI, with targeted biopsy in those in whom a lesion is seen, and standard biopsy in all, conducted independently of the knowledge of the MR findings. The only study to fully conform to such a population was that published by Haffner and colleagues [9]. A number of variations on this study design were reported. Park and colleagues conducted a randomised study in which biopsy-naive men with a clinical suspicion of prostate cancer were randomised to MR or no MRI, with targeted biopsy incorporated into the biopsy scheme for men with an MRI suspicious of cancer and a standardised biopsy scheme for men randomised to biopsy alone [10]. Another group described a pathway where all men underwent MRI before a decision regarding biopsy, but full clinical details were not given [11]. Other reported study populations include a single case of a man unable to undergo TRUS examination due to proctocolectomy [12] as well as populations of men who all had a previous negative biopsy [13–15], mixed populations including men on active surveillance and men with a negative biopsy [16], and one study that included one man with a postprostatectomy recurrence [17]. The populations for each reported study are indicated in Tables 2–4. Complete data are reported in Supplementary Tables 1–5 in the online version of this paper.

2.2. Conduct of magnetic resonance imaging and magnetic resonance imaging–targeted biopsy

All studies used anatomic imaging (T1- or T2-weighted imaging) to assess the prostate (Table 1) [9,10,12,14–23,27,28,30–43,45,47–53,56–60]. Most of the more recent studies have also incorporated functional imaging, using at least one of the following: dynamic contrast enhancement (DCE), diffusion weighted imaging (DWI) and MR spectroscopy (MRS).

The manner in which an MRI-derived lesion was targeted at biopsy also varied. We identified three broad categories: (1) targeting within the magnet (in-bore targeting); (2) use of registration or fusion software to allow a lesion defined on MRI to be identified on ultrasound during a TRUS-guided biopsy procedure, either with or without a tracking device; or (3) *cognitive targeting*, where the physician performing an ultrasound-guided biopsy reviewed the lesion seen on MRI and used this knowledge to select the appropriate area for a targeted biopsy using ultrasound visualisation of the prostate.

2.3. Comparators to magnetic resonance imaging–targeted biopsies

To answer the research question, it was necessary to compare the detection rate for clinically significant prostate cancer between MRI-targeted biopsies and standard TRUS-guided cores (Table 2). Three of these studies report a comparison between two different groups of men, rather than applying both tests to each man. The first of these was carried out in a biopsy-naive population in which men were randomised to standard TRUS or MRI followed by biopsy incorporating cores targeted to suspicious areas [10]. The other two studies that compared distinct groups of men included men with a previous negative biopsy. One of these, a retrospective study, compared men who had standard TRUS biopsy with a subsequent cohort that had MRI followed by standard cores and MRI-targeted cores [18]. The other study was a prospective randomised study, where biopsy-negative men with a persistent PSA of 4–10 ng/ml were either allocated to standard TRUS-guided cores alone or MRI with the subsequent biopsy directed to MR abnormalities, in addition to standard cores [19].

Our a priori research question was constructed to incorporate a clinically meaningful target condition: clinically significant prostate cancer. However, only a minority of the studies we identified chose to report clinically significant prostate cancer as their target condition. Haffner and colleagues reported this with clear definitions based only on histologic parameters [9]. One of the papers from the National Institutes of Health group [14] reported clinical significance according to D'Amico risk stratification.

In a number of studies, both targeted biopsies and standard biopsies were taken, but overall cancer detection rates were reported for the two approaches combined rather than for each biopsy strategy. This type of reporting made it impossible for us to address our research question, although it remains of interest when looking at the overall cancer detection rates when targeted cores are added to standard cores. These studies are listed in Table 3 [16,34–50].

Studies using in-bore targeting, CT-guided MRI targeting, and one of the studies using cognitive MRI targeting took only targeted cores without a standard series, and so, again, a comparison of an image-guided and standard approach was not possible. These studies are shown in Table 4 [51–60]. In addition, these studies only recruited men with a lesion seen on MRI. No attempt was made in any of these reports to cite the denominator from which these men were derived, that is, those men with the same clinical parameters of suspicion (PSA, DRE) but a negative MRI.

3. Evidence synthesis

Use of evidence synthesis has allowed us to address some clinically important questions in relation to the use of MRI to inform the conduct of the biopsy.

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Table 1 – Technical details of magnetic resonance and biopsy techniques (all studies with full reports)

Identifier	Patient population	MRI				Biopsy				
Reference	No.	MRI	No. of lesions, mean (range; max allowed)	Sequence used to define target	ER coil	Navigational system for biopsy	Analgaesia	Standard cores taken blind to location of lesions	Targeted cores per lesion (mean per patient)	Total cores taken
Studies where targeted cores are reported separately to standard cores										
[9]	555	1.5T Philips Gyroscan Intera	1.9 (NR; NR)	T2/DCE	No	US (cognitive)	LA	No	2 (3.8)	NR
[10]	85[CG1]	3T Philips Achieva	NR	T2/DCE/DWI	No	US (cognitive)	NR	No	0–3 per patient	10–12 standard + up to 3 targeted
[14]	101	3T Philips Achieva	2.6 (1–7; any)	Any 3 positive	Yes	US (EM tracking device)	GA	Yes	Mean 2.2 (range 1–8) (5.8)	17.8 (mean)
[15]	85	1.5T Philips Interna Pulsa	1.15 (1-2; NR)	T2	No	US (software)	Spinal anaesthesia	No	1–2 (2.3)	Total 12 cores
[18]	71	3T TrioTim	Median 1 (1–3; 3)	T2,DWI, DCE	ER coil Or pelvic coil	MRI	NR	No	2 (median 4, range 2–7)	Targeted only
[19]	180[CG2]	1.5T Siemens Avanto	NR	DCE or MRS	Yes	US (cognitive)	LA	No	NR (2.17)	Mean 12.7 in group B (range 10–16), 10 in group A
[20]	42	1.5T Signa GE	NR	MRS	Yes	US (software)	LA	No	2–3 (NR)	NR
[21]	87	3.0T Philips Intera Achieva	NR	T2/DWI	No	US (MRI images also displayed on US screen)	GA	No	NR (median 9, up to 14)	Up to 26
[22]	260[CG3]	1.0T Siemens Harmony	3	All	Yes	US (cognitive)	LA	NR	3 (NR)	Group A 21; group B 18
[23]	13	3T Philips Intera	NR (NR; max 2 sextants)	T2/DCE	Yes	MRI	Sedation	No	2 per abnormal sextant (4)	Max 10 cores: 2 for tissue bank, 8 cores for analysis
[17]	106	3T Magnetom Trio	UK	T2	No	US (BiopSee software)	GA	No	2-6 (2–6)	Mean 23.2
[27]	47	3T Siemens TrioTrim/Somatom	1.4 (NR; NR)	NR	No	US (Artemis software with tracking device)	LA	Yes	NR	NR
[28]	43	3T Philiips Intera Achieva	1 (1; 1)	DWI	No	US (cognitive)	NR	No	At least 2 (at least 2)	NR
[30,12]	1	1.5T diagnostic	2 ($n = 1$)	T2	No	0.5T side access T2	GA	No	1 (2)	8
[32]	1	1.5T Siemens Magnetom Sonata & Avanto	1 ($n = 1$)	T2	For diagnostic scan	MRI	NR	No	3 (3)	4
[33]	1	1.5T GE Sigma Horizon	1 ($n = 1$)	T2/MRS	Yes	US (cognitive)	LA	No	3	5

Reference	No.	MRI	No. of lesions, mean (range; max allowed)	Sequence used to define target	ER coil	Navigational system for biopsy	Analgaesia	Standard cores taken blind to location of lesions	Targeted cores per lesion (range)	Total cores taken
Studies where targeted and standard cores are reported together										
[34]	42	1.5T Signa GE	NR	T2, MRSI	Yes	US (cognitive)	NR	NR	1–4	10 core standard + 1–4 targeted
[16]	12	1.5T Siemens Magneton	NR	T2, or prebiopsy MRI if not directly visualised	Yes	Closed in-bore MRI	NR	NR	Up to 2	8 maximum
[35]	21	1.5T GE	NR	T2	No	US (cognitive)	GA	NR	4 per patient	12 standard + 4 targeted
[36]	154[CG4]	3T Siemens Magnetom Vario	NR	NR	Yes	US (cognitive)	NR	NR	NR	10–12 standard + targeted
[37]	54	1.5T Signa GE	NR	NR	Yes	US (cognitive)	NR	NR	1–3	10 standard + up to 6 targeted
[38]	155	1.5T NR	NR	T2	Yes	US (cognitive)	NR	NR	NR	6 standard + targeted
[39]	123	1.5T Siemens	NR	T2	Yes	US (cognitive)	NR	NR	NR	6 standard + targeted
[40]	83	1.5T	NR	T2	Yes	US (cognitive)	NR	NR	2–3	6 standard + targeted
[41]	26	3T Philips or 1.5T GE	NR	T2, DCE	Yes	US (cognitive)	Controlled anaesthesia	NR	NR	12 standard + targeted
[42]	33	NR	NR	T1	Yes	US (cognitive)	NR	NR	NR	6 standard + targeted
[43]	68	1.5T Philips	NR	T2	Yes	US (cognitive)	NR	NR	≥2 (2–14)	10–20 standard + targeted
[45]	114	1.5T Siemens Avanto	NR	T2, DCE, DWI	No	US (cognitive)	NR	NR	NR	10–12 standard + targeted
[47]	40	NR	NR	T2	No	US (cognitive)	NR	NR	NR	6 standard + targeted
[48]	54	1.5T Signa GE	NR	MR-MRSI	Yes	US (cognitive)	NR	N	1–3	12 standard + up to 3 targeted
[49]	81[CG5]	1.5T Signa GE	NR	T2	Yes	US (cognitive)	NR	NR	NR	6 standard + targeted
[50]	24	1.5T GE	NR	T2	Yes	US (cognitive)	NR	NR	Up to 4 cores	10 standard + max 4 targeted
Studies where only targeted cores are taken										
[51]	37	1.5T Siemens Magnetom Symphony	NR	T2w	Yes	Closed unit 1.5T MRI (T1,T2)	None	NA	NR (6)	4–9
[52]	26	1.5T Siemens Magnetom Symphony	2	T2w	Yes	US (cognitive)	LA	NA	3	NR
[53]	100	1.5T Medrad GmbH	1.16	T2w	Yes	1.5T Magnetom Avanto Siemens MRI (T1,T2)	NR	NA	NR (4)	2–8
[56]	55	1.5T Siemens Avanto;	3 (1–8)	T2w	Yes	Closed unit 1.5T MRI (T2)	NR	NA	NR (4)	4 (1–9)
[57]	20	1.5T Siemens Magnetom Sonata	NR	T2w	Yes	Closed unit 1.5T MRI; Innomotion robotic system (T1, T2)	LA	NA	NR	NR
[58]	25	1.5T Siemens Magnetom Symphony	NR	T2w	Yes	0.2T Concerto Siemens MRI; (T1)	LA	NA	NR (3.8)	4
[59]	21	3T	2 (1–3)	T2w	Yes	3T Trio Tim Siemens MRI (T2)	None	NA	1–3 (4)	4 (1–7)
[60]	1	0.3T Fonar	1	T1w	No	CT	NR	NA	NR	NR

CT = computed tomography; DCE = dynamic contrast enhancement; DRE = digital rectal examination; DWI = diffusion weighted imaging; EM = electromagnetic; ER = endorectal; GA = general anaesthesia; LA = local anaesthesia; MRI = magnetic resonance imaging; MRS = magnetic resonance spectroscopy; MRSI = magnetic resonance spectroscopic imaging; NA = not applicable; NR = not reported; PSA = prostate-specific antigen; US = ultrasound.

[CG1] Randomised groups: MRI, 44; no MRI, 41.

[CG2] Randomised groups: Group A, repeat standard biopsy (90); Group B, MRI plus standard plus targeted biopsy (90).

[CG3] Non randomised groups: Group A, suspicious MRI (170); Group B, nonsuspicious MRI (90).

[CG4] Non randomised groups: Group 1, prebiopsy MRI (51); Group 2, MRI postbiopsy (103).

[CG5] Non randomised groups: Group A, PSA 4–10 (52); Group B, PSA 10–20, negative DRE (29).

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Table 2 – Histologic outcomes of studies in which targeted biopsies are compared with standard biopsies

Identifier		Patient population			Histologic outcomes						
Reference	Duplicate papers (abstracts)	No.	Proportion positive MRI/ targeted biopsy	Comparator	Overall cancer detection (TB and SB)	Cancer detection per lesion	Cancer detection per core (TB)	Cancer detection per core (SB)	Cancers detected by targeted cores alone	Targeted cores demonstrate superiority to standard cores?	Missed cancers with each technique
Biopsy-naïve men											
[9]	[61] ([62,63])	555	351/555 (63%)	10–12 core TRUS	302/555 (54%)	NR	NR	NR	236/555 (43%) significant cancers	Yes; greater detection accuracy, representation of disease burden and Gleason grade	Standard missed 12 cancers (12 significant); targeted missed 66 cancers, (13 significant)
[10]	None	85[CG1]	T2, 23/44; DWI, 17/44; DCE-MRI, 15/44	10–12 core TRUS (plus targeted cores from hypoechoic areas on US in non-MRI group)	MRI group, 13/44 (30%); no MRI, 4/41 (10%)	NR	14/37 (38%) from MR targets; 0/6 from US targets	38/490 (8%) in MRI group; 11/450 (2%) in non-MRI group	NR	Yes; increased cancer detection from 10% to 30%	NR but if a target lay within a systematically sampled region, the core was counted as systematic
Negative previous biopsy											
[19]	[64,65] ([66,67])	180[CG2]	Any sequence 45/90 (50%); MRSI 6/90 (6%); DCE 3/90 (3%); DCE plus MRSI 36/90 (40%)	10-core TRUS	A: 22/90 (24%); B: 44/90 (49%)	NR	NR	NR	NR	Yes; greater detection accuracy, high detection rate of clinically significant disease from group B to A	NA (comparison between cohorts rather than within patients)
[22]	([68–70])	260[CG3]	N	18-core TRUS	Group A: 126/170 (74%); Group B: 17/90 (19%)	57%	NR	18%	56%	Yes; in group A, 18% had cancer detected on standard cores alone; 56% on targeted alone.	NA (comparison between cohorts rather than within patients)
[20]	None	42	31/42 (74%)	12-core TRUS	17/42 (40%)	42/96 (44%) sextants	NR	10/252 (4%) sextants	NR	Yes; 4% abnormal sextants positive in TRUS biopsy group, vs 44% in TB group	NR
[21]	([71,72])	87	82/87 (94%)	12-core TRUS	46/87 (53%)	19/32 (59%) for anterior lesion; 19/30 (63%) for apical lesions.	149/518 (29%)	32/903 (4%)	39/46 (85%)	No, all cancers found on targeting were also found on systematic biopsy	2 cancers found in men with no lesion on MR
[18]	[29] ([73–76])	71	70/71, 98.6% positive MRI; (68/71, 9% targeted biopsy)	Historical matched repeat TRUS group	40/68 (59%) vs 22% control group	46/114 (40%)	NR	NR	All (no standard cores)	Yes; greater detection accuracy (biopsy session 2 55/248 (22%), session 3 10/65 (15%) in historical repeat TRUS cohort)	NA (historical cohort comparison)

[23]	None	13	37 targets n T2 and 16 targets in DCE	Max 10 cores per patient; 2 for tissue bank, hence 8 cores for analysis	2/13 (15%)	1/37 T2 targets; 1/16 DCE targets	NR	NR	1/2 (50%) of all cancer; 1/13 (8%) of whole group	Yes; targeted biopsy detected Gleason 8, standard biopsy detected Gleason 6	1/2 missed with standard; 1/2 missed with targeted
[15]	([77])	85	85/85 (100%)	Combined TRUS/ transperineal biopsy; total combined targeted plus standard 12 cores	52/85 (61%)	NR	m	75/833 (9%)	18/52 (35%) or 18/85 ((21%)	Yes	Standard missed 18/52; targeted missed 7/52
Mixed patient population											
[17]	[78] ([79,80])	106	24/106 highly suspicious; 42/106 moderately suspicious	12–36 core transperineal biopsy	63/106 (59%)	63/142 (44%)	101/410 cores (25%)	179/2951 (9%)	NR	Yes: MR-GB detected 25% vs 9% systematic cores	NR
[14]	[13,81] ([82–89])	101	101/101 (100%)	12-core TRUS biopsy	55/101 (55%)	24/34 (71%) strong suspicion; 29/72 (40%) moderate suspicion; 23/158 (15%) low suspicion.	20.6% overall (54%, 21%, and 5% for strong, moderate and low suspicion on MRI)	11% overall (30%, 12% and 4% for strong, moderate and low suspicion on MRI)	10/55 (18%); 10/101 (10%)	Yes; mean 2.6 cores vs 12 cores required for equal performance	Standard missed 10/55; targeted missed 10/55.
[27]	([90])	47	47/47 (100%)	12-core TRUS	30/47 (64%)	23/65 (35%)	19/57 (33%) for highly suspicious lesions	9/124 (7%)	5/30 (17%)	Yes	Modified technique: standard missed 4/12, targeted missed 3/12.
[28]	None	43	NR	6- to 10-core TRUS (volume dependent)	17/43 (40%)	NR	30/38 (79%)	35/140 (25%)	17/17 (100%)	Yes	5/17 missed with standard; none missed with targeted.
Case reports											
[30]	[12,30]	1	1/1	Sextant transperineal	1/1	1/1	1/1	0/6	1/1	Yes	NA
[32]	None	1	1/1	Previous 2× negative TRUS: single core from contralateral peripheral zone	1/1	1/1	3/3	1/1	1/1	Yes	NA
[33]	None	1	1/1	1 core from TZ, 1 core from left lobe	1/1	1/1	3/3	1/2	NA	No; TZ core showed highest grade (Gleason 8) predicted as no cancer	NA

DCE = dynamic contrast enhancement; DWI = diffusion weighted imaging; MR-GB = magnetic resonance–guided biopsy; MRI = magnetic resonance imaging; MRSI = magnetic resonance spectroscopic imaging; NA = not applicable; NR = not reported; SB = standard biopsy; TB = targeted biopsy; TRUS = transrectal ultrasound; TZ = transition zone; US = ultrasound.

[CG1] Randomised groups: MRI, 44; no MRI, 41.

[CG2] Randomised groups: Group A, repeat standard biopsy (90); Group B, MRI plus standard plus targeted biopsy (90).

[CG3] Nonrandomised groups: Group A, suspicious MRI (170); Group B, nonsuspicious MRI (90).

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Table 3 – Histologic outcomes of studies in which targeted and standard cores are reported together

Reference *(related abstract)*	Patient population				Histologic results				
	No.	% biopsy naive	Positive previous biopsy (%)	Negative previous biopsy (%)	All cancer detected (SB + TB)	Cancer detection per positive MRI	Definition of clinically significant disease	% significant disease	% insignificant disease
[34]	42	0/42	0/42	42/42	15/42 (36%)	15/23 (66%)	NR	NR	NR
[16]	12	1/12	1/12	10/12	5/12 (42%)	NR	NR	NR	NR
[35]	21	0/21	0/21	21/21	2/21 (10%)	2/5 (40%)	* Gleason ≥7	0/2 (0%)	2/2 (100%)
[36]	154[CG4]	NR	NR	Group 1: 36/51	Group 1: 31/51 (61%)	Group 1: 31/37 (84%)	NR	NR	NR
[37]	54	0/54	0/54	54/54	17/54 (31%)	17/30 (57%)	* Gleason ≥7	5/17 (29%)	12/17 (71%)
[38]	155	NR	NR	NR	NR	NR	NR	NR	NR
[39]	123	NR	NR	NR	Group 2: 13/61 (21%)	10/10 (100%)	* Gleason ≥7	Group 2: 5/13 (39%)	Group 2: 8/13 (62%)
[40]	83	NR	NR	NR	11/83 (13%)	11/44 (25%)	* Gleason ≥7	2/11 (18%)	9/11 (82%)
[41]	26	0/26	0/26	26/26	14/26 (54%)	14/24 (58%)	* Gleason ≥7	7/7 (50%)	5/5 (50%)
[42]	33	0/33	0/33	33/33	7/33 (21%)	6/15 (40%)	NR	NR	NR
[43 (44)]	68	0/68	0/68	68/68	28/68 (41%)	NR	NR	NR	NR
[45 (46)]	114	NR	NR	NR	58/114 (60%)	NR	Gleason ≥7 with any CCL; ≥3 mm (definition 1); ≥5 mm (definition 2)	Gleason ≥7 = 47/68 (69%); ≥3mm = 42/68 (62%); ≥5mm = 36/68 (53%)	Gleason <7 = 21/68 (31%); <3mm = 26/68 (38%); <5mm = 32/68 (47%)
[47]	40	NR	NR	NR	27/40 (68%)	NR	* Gleason ≥7	4/12 (33%)	8/12 (66.6%)
[48]	54	0/54	0/54	54/54	22/54 (41%)	NR	* Gleason ≥7	6/22 (73%)	16/22 (72.7%)
[49]	81[CG5]	NR	NR	NR	23/81 (28%); Group A:11/52 (21%); Group B:12/29 (41%)	Group A: 6/14 (63%); Group B: 10/16 (63%)	NR	NR	NR
[50]	24	0/23	0/23	23/23	7/24 (29%)	7/15 (47%)	* Gleason ≥7	3/7 (43%)	4/6 (57%)

CCL = cancer core length; DRE = digital rectal examination; MRI = magnetic resonance imaging; NR = not reported; PSA = prostate-specific antigen; SB = standard biopsy; TB = targeted biopsy.
[CG4] Nonrandomised groups: Group 1, prebiopsy MRI (51); Group 2, MRI postbiopsy (103).
[CG5] Nonrandomised groups: Group A, PSA 4–10 (52); Group B, PSA 10–20, negative DRE (29).

Table 4 – Histologic outcomes of studies in which targeted biopsies were taken without standard cores

Reference (duplicate papers) (*abstracts*)	Population						Histologic outcomes				
	No.	% biopsy naive	Negative previous biopsy (%)	Positive previous biopsy (%)	Mean no. previous negative TRUS (range)	Proportion positive MRI/targeted biopsy	All cancer detected	Definition of clinically significant disease	% significant disease	% insignificant disease
[51]	37	0/37 (0%)	37/37 (100%)	0/37 (0%)	1.4 (1–4)	37/37 (100%)	14/37 (37.8%)	* Gleason ≥7	3/14 (21.4%)	11/14 (78.6%)
[52]	26	18/26 (69.2%)	8/26 (30.8%)	0/26 (0%)	NR	26/26 (100%)	12/26 (46.1%)	* Gleason ≥7	2/12 (16.7%)	10/12 (83.3%)
[53,54 (55)]	100	0/100 (0%)	100/100 (100%)	0/100 (0%)	2 (1–9)	100/100 (100%	52/100 (52%)	If undergoing RRP: (a) Gleason ≥4, (b) final T stage ≥pT3a and/or pN1, (c) tumour volume >0.5 cm^3. If undergoing radiotherapy/ surveillance: (a) Gleason ≥4, (b) PSA >10, (c) PSAD >0.15	42/52 (80.8%)	10/52 (19.2%)
[56]	55	0/55 (0%)	55/55 (100%)	0/55 (0%)	2 (1–6)	54/55 (98.2%)	21/54 (39%)	* Gleason ≥7	10/21 (47.6%)	11/21 (52.4%)
[57]	20	0/20 (0%)	20/20 (100%)	0/20 (0%)	NR	19/20 (95%)	3/20 (15%)	NR	NR	NR
[58]	25	8/25 (32%)	17/25 (68%)	0/25 (0%)	NR	25/25 (100%)	10/25 (40%)	* Gleason ≥7	3/10 (30%)	7/10 (70%)
[59]	21	NA	21/21 (100%)	NA	NR	21/21 (100%)	8/21 (38%)	* Gleason ≥7	3/8 (37.5%)	5/8 (62.5%)
[60]	1	NR	NR	NR	NR	1/1 (100%)	1/1 (100%)	NR	NR	NR

MRI = magnetic resonance imaging; NA = not applicable; NR = not reported; PSA = prostate-specific antigen; PSAD = prostate-specific antigen density; TRUS = transrectal ultrasound.

3.1. *What is the prevalence of a magnetic resonance lesion suggestive of cancer in men with a clinical suspicion of prostate cancer?*

This crucial point addresses whether an opportunity exists to defer biopsy in a group of men who have a normal MRI, much in the same way that women with a normal mammogram are not routinely offered a biopsy.

The studies best suited to addressing this question have adopted the policy of MRI prior to biopsy in all men referred with a clinical suspicion of prostate cancer. Two groups report such an approach, with a total of 374 of 599 men (63%) having suspicious findings on MRI [9,10]. This MRI lesion prevalence figure is sensitive to the underlying prevalence of prostate cancer in the population being studied. The MRI lesion prevalence rate also depends on the quality and conduct of the MRI and the lower threshold adopted by the radiologists that is used to declare a lesion as present or absent. Inclusion of a *grey zone*, or indeterminate zone, as opposed to binary reporting will also confer a bias, although this may be bidirectional.

In a pooled analysis of men with an initial negative biopsy [18–22], 328 of 479 (69%) had a suspicious MRI. Lee reports the highest prevalence (82 of 87 [95%]), with inclusion criterion of a persistently rising PSA with a velocity >0.75 ng/ml per year, as well as a lower limit of 4 ng/ml in men with a previously negative 12-core biopsy [21]. Labanaris et al. report a lower prevalence of 170 of 260 (65%) of men with a single negative biopsy having a suspicious MRI [22].

3.2. *What is the likelihood of a magnetic resonance lesion being positive for clinically significant prostate cancer if it is targeted at biopsy?*

This question is confounded by the precision of targeting. For example, a targeted biopsy that misses a true focus of prostate cancer that was correctly declared by the MRI will appear as an MRI false positive because the histology will likely be benign. This unavoidable source of error comprises both specificity and positive predictive value (PPV). The question can be best addressed by looking at those studies in which the targeted cores are reported independently of the nontargeted cores (Table 2) and from studies of targeted cores only (Table 4).

In biopsy-naive cohorts, where targeted and systematic cores were reported independently, just under two-thirds of men (374 of 599 [62%]) from the pooled analysis had suspicious findings on MRI. Two-thirds (248 of 374 [66%]) of these men had prostate cancer on biopsy [9,10]. In comparison, a standard biopsy approach in the same group of men gave a detection rate of 50%. Only one study assessed this in terms of clinically significant disease, defined as any cancer core length >5 mm or any Gleason pattern >3. In this study the targeted approach detected cancer in 236 of 555 men (43%) with the standard approach detecting cancer in 248 of 555 men (45%). Thirteen clinically significant cancers were missed with a targeted approach alone, and 12 significant cancers were missed with a standard approach.

Insignificant cancer was detected in 53 of 55 men (10%) in the standard approach and in no men using the targeted approach.

In men with at least one negative prior biopsy, just over two-thirds (328 of 479 [69%]) had an MRI abnormality with a similar positive biopsy rate of 70% (229 of 328) [18–21].

The positive biopsy rate reflects the sampling density for a given lesion, which varied between studies. For example, in one study where the "targeting" was directed only at a sextant and a maximum of eight cores in total were analysed (with up to two abnormal sextants having two cores and "normal" sextants having one core taken), the detection rate per "target" was very low: Only 1 of 37 T2 targets and 1 of 16 DCE targets were positive [23].

Studies using targeted biopsy alone (Table 4) showed that less than half of men with a lesion on MRI had cancer on biopsy (120 of 283 [42%]). In the few studies where clinically significant disease was defined, just over half of the cancers were deemed significant (63 of 117 [54%]).

3.3. What is the chance of missing cancer if men with a nonsuspicious magnetic resonance imaging do not undergo biopsy?

This question is addressed in Table 2. These studies report the histologic outputs stratified by MRI status. Pooled analysis from the two studies of biopsy-naive men showed that 38% of men (225 of 599) had an MR that was not suspicious for disease. Around a quarter of these (51 of 225 [23%]) had cancer on standard biopsy [9,10]. Crucially, only 13 of 599 (2.3%) of the cohort had clinically significant cancer (broadly defined as >5-mm cancer core length and/or any Gleason pattern >3), which would have been missed by an approach targeted to MR lesions alone [10].

A slightly lower rate of detection for any cancer (22 of 151 [15%]) was reported in men who had had at least one prior biopsy that was negative and had a normal MRI [18–21]. Unfortunately, none of these studies reported the pathology in such as way as to make it possible to calculate the proportion of men with clinically significant prostate cancer.

3.4. Can the magnetic resonance imaging phenotype be used to attribute risk?

MR reporting that incorporates a probabilistic clinometric scale (defining thresholds for the likelihood of clinically relevant disease) has been proposed [5,24] and recommended by a number of groups [25,26]. Few reports that we identified incorporated such a measure. Those that did observed an ordinal progression of risk. For example, the study by Hadaschik and colleagues reported prostate cancer detection rates for any cancer in nearly all cases (23 of 24 [96%]) that were deemed "highly suspicious" [17]. In the same study, when detection rates for any cancer were calculated for "any suspicious" MRI, the detection rates fell to 71% (47 of 66). In men with "nonsuspicious" MRIs, a third of men had prostate cancer diagnosed (13 of 37 [35%]). Once again, it was not possible to extract data from this report to calculate the proportion of men with clinically significant prostate cancer. The work of Pinto and colleagues supports the notion of increased prostate cancer detection rates with stronger MRI signal both at lesion level and at the prostate level of analysis [13]. Using the analysis at the prostate level, the PPV of an MRI was 90% (17 of 19), 67% (26 of 39), and 30% (12 of 43) for MRIs with attributions of strong, moderate, and low suspicion, respectively. This cohort included only those men who had an MR lesion. A further analysis of this cohort by Rastinehad et al. reported a correlation between D'Amico risk category and strength of suspicion of disease based on MRI [14].

A PPV of 75% (12 of 16) was associated with MRS scores of 5 of 5 by Prando et al. [20]. "Strongly suspicious" MRIs were associated with a PPV of 91% by Sciarra et al. [19] and 96% by Hadaschik et al. [17].

3.5. Comparison of standard and targeted cores for the detection of all cancer

Standard and targeted approaches can be compared on either a per patient or a per-core basis. The latter allows some assessment of the potential efficiency of a targeted approach. When data from studies that report on a per core basis are pooled, cancer was detected in 30% of targeted cores (375 of 1252) versus 7% of systematic cores (368 of 5441) [10,15,17,21,27,28]. On a per patient basis, where standard and targeted approaches were compared either in the same man or in randomised groups, cancer detection was 526 of 1442 (36%) for standard biopsy and 650 of 1345 (48%) for targeted biopsy [9,10,14,15,17–23,27,28].

3.6. Comparison of standard and targeted cores for detection of clinically significant cancer

There was no consistent definition of clinically significant disease in those studies that reported it. Haffner et al. reported both cancer core length and Gleason grade in the discussion of clinical significance [9]. They found that targeted biopsies demonstrated greater maximum cancer core length than systematic biopsies, with values of 5.56 mm and 4.70 mm, respectively. They also noted that the targeted biopsies showed a 16% greater detection of Gleason grade 4/5 than the systematic biopsies. Sciarra and colleagues reported the Gleason grade of targeted versus systematic biopsies in a randomised study, with 13 of 22 (59%) of all cancers detected by standard biopsies having Gleason 4 + 3, whereas only 17 of 44 (39%) of cancers detected by MR-targeted biopsies were in this category [19]. There were 90 men in each group, however, giving a clinically significant cancer detection rate of 13 of 90 (14%) and 17 of 90 (19%) for repeat 18-core standard biopsy versus standard plus targeted cores. It is interesting that there was, therefore, a greater proportion of less significant prostate cancer reported in the MR-targeted group (27 of 90 [30%]) versus 9 of 90 (10%) for repeat biopsy alone. The threshold for clinical significance was set very high in this study, and many would argue that 7 mm of Gleason 3 + 4, deemed insignificant in this analysis, should be considered clinically significant.

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Table 5 – Studies reported as abstracts or conference presentations only

Reference	Population			MRI		Conduct of biopsy		Histologic outcomes			
	No.	% biopsy naïve	Comparator	MRI	Mean no. of lesions (range; max allowed)	Navigational system for biopsy	No. of standard cores	All cancer detected (TB and SB)	Definition of clinically significant disease	% significant disease	% Insignificant disease
[91]	92/93 (98.9%)	92/92 (100%)	TRUS or template biopsy	NR	NR	NR	NR	NR	Any Gleason 4 or >3 mm Gleason 3 + 3	NR	NR
[92]	34	0/34 (0%)	Previous TRUS biopsy (6 core)	MRSI	NR	Group 1: MR-US fusion; group 2 cognitive targeting	NR	NR	NR	NR	NR
[93]	43	NA	Prior TRUS biopsy	1.5T; T2,DCE, DWI, ADC, and MRS	Median 3	TRUS with cognitive registration	NR	21/43 (48.8%)	* Gleason ≥7	10/21 (47%)	11/21 (52%)
[94]	70[CG6]	NA	TRUS biopsy (12 core) in study 20; comparator 50 patients with no MRI/targeting	Including DWI	NR	TRUS with cognitive registration	12	18/50 in no MRI group; MRI group not reported in abstract	NR	NR	NR
[95,96]	362	NR	TRUS biopsy (8 cores) and RP histopathology	T2 and DCE	NR	NR	8	152/362 (42%) across MR pos and neg groups;	NR	NR	NR
[97]	28	NA	TRUS biopsy (12 core)	MRI, MRSI	NR	NR	12	10/28 (35%)	NR	NR	NR
[98]	42	NA	TRUS biopsy	3T ER MRI	NR	NR	NR	15/42 (36%)	Gleason >6	10/12 detected by MRI (83%)	2/12 detected by MRI (17%)
[99]	34	NR	TRUS biopsy (10 core)	1.5T T2 MRI and real-time electrosonography	NR	NR	10	16/34 (47%)	NR	NR	NR
[100]	32[CG7]	NA	NR	MRI, MRSI	NR	TRUS and Pro-Mag 2.2L Biopsy System Urotech	NR	NR	NR	NR	NR
[101]	70	NA	16-core TRUS biopsy	MRI, MRSI	NR	NR	12 + 4 TZ cores	NR	NR	NR	NR
[102]	335	NR	Template biopsy and RP histopathology	1.5T MRI T2, DCE, DWI	NR	TRUS	NR	NR	NR	NR	NR
[103]	11	NA	24-core TRUS biopsy	T1, DCE, DWI	NR	TRUS	24	5/29 (17%) of suspicious lesions	NR	NR	NR
[104]	256	NR	6–10 TZ plus 8 PZ plus 2 anterior apex	1.5T T2 plus DWI/ADC	NR	NR	14-20	108/256 (42%)	NR	NR	NR

ADC = apparent diffusion coefficient; DCE = dynamic contrast enhancement; DWI = diffusion weighted imaging; ER = endorectal; MR = magnetic resonance; MRI = magnetic resonance imaging; MRS = magnetic resonance spectroscopy; MRSI = magnetic resonance spectroscopic imaging; NA = not applicable; NR = not reported; PZ = peripheral zone; RP = radical prostatectomy; SB = standard biopsy; TB = targeted biopsy; TRUS = transrectal ultrasound; TZ = transition zone; US = ultrasound.

[CG6] Nonrandomized groups: study group had prebiopsy MRI (20); retrospective control group, no MRI/targeting (50).

[CG7] Group 1: MRI-US fusion; Group 2: MRI-guided biopsy.

Hambrock et al. chose an unusual definition of clinical significance [29], contingent on the mode of therapy conferred on the patient. For those who underwent radical prostatectomy, a definition of Gleason grade >4, stage >T3a/N1, and tumour volume >0.5 ml was applied. For men who chose radiotherapy or active surveillance, the definition incorporating Gleason >4, or PSA >10, or PSA density >0.15 was adopted. When this broad definition was applied, 93% (37 of 40) of cancers diagnosed using image-guided targeting were deemed clinically significant.

3.7. What is the effect of different magnet strengths and sequences on cancer detection?

Ten groups used a 3-T magnet, and 22 used a 1.5-T magnet (Table 1). Labanaris et al. reported a comparable lesion prevalence with other groups (65%) using anatomic (T2) sequences on a 1.0-T magnet only [22]. The per patient cancer detection rate of targeted biopsies was 183 of 403 (45%) for the groups comparing standard and targeted cores using a 3-T magnet, and 467 of 942 (50%) for the groups using a 1.5-T magnet, demonstrating no clear advantage for the higher magnet strength [9,10,14,15,17–23,27,28]. Around two-thirds of these groups used an endorectal coil, with a higher per patient cancer detection rate in those using a coil (56%) compared with those not using one (44%). Sciarra's group reported lesion detection for each of the different functional sequences (DCE, DWI, and MRS) [19]. When all sequences are taken together, 45 of 90 men had an MRI suspicious for prostate cancer. Breaking this down, 3 of 90 (3%) had a lesion on DCE alone, 6 of 90 (6%) on MRS alone, and 36 of 90 (40%) on DCE plus MRS. It is likely that a combination of factors, including the use of different functional sequences and reader experience, as well as targeting methods, are important contributors to cancer detection.

3.8. Assessment of study quality

An assessment of the quality of the reporting of each study was made for all studies cited in Table 1. The QUADAS checklist was used because it was specifically developed for the assessment of studies addressing diagnostic accuracy [8]. The maximum score within QUADAS is 15. Only two studies scored ≥12. Only the Haffner et al. [9] and Park et al. [10] papers scored positively for the selection of an appropriate population for the purposes of this review, although we accept that the use of MRI in a biopsy-negative population is also of considerable interest. Studies also tended to score poorly on describing withdrawals from the study and the reporting of the outcome of intermediate test results separately from the whole population.

3.9. Methodological limitations of studies and reporting

We identified a number of methodological issues. The first is double reporting [13,61,90], matched to original reports in the online supplementary table version of Table 2. This occurred in a number of series and was often not declared in the secondary or tertiary reports. One case report of a man who underwent MRI-guided biopsy in a transperineal manner due to proctocolectomy was reported three times [12,30,31]. This is unlikely to distort the literature. In contrast, the re-reporting of larger, more widely cited cohorts is more difficult to distinguish. Papers and abstracts that appear to report the same patient population are indicated in Tables 2–4. Where this was unclear, the first or senior author for the most recent paper was contacted to confirm this was the case. Authors tend to present work at conferences initially; Table 5 [91–104] shows studies where this was the only publication of the work to date. Authors appropriately update their results as cohorts mature; this must be made explicit.

The second methodological issue relates to sampling methods. Cancer detection rates are contingent on the sampling density applied to a target. Because the volume of the target is never declared, the precise density of sampling is not possible to calculate for any given study. What is the relative yield of additional targeted samples versus additional standard samples? In most reports, this question cannot be answered. Only one group recognised this uncertainty. Singh and colleagues added additional biopsy cores (in the contralateral lobe) to mirror those dedicated to the target. Unfortunately, the effect of the added samples is not discussed, and the positive biopsy rate for the cohort as a whole was very low (1 of 13 targeted biopsy sets; 1 of 13 standard biopsy sets) [20].

Incorporation bias occurs when targeted and systematic cores are taken in the same patient. If targeted sampling is undertaken first, the resulting needle tracks may make it more likely that a standard biopsy samples the same volume of tissue as the targeted biopsy. This bias can result in overperformance of standard sampling. Alternatively, if the operator deliberately avoids these visible needle tracks (to sample more areas of the prostate), the standard cores may underperform. Some groups have attempted to overcome this problem by having different operators take the targeted and standard cores.

4. Conclusions

In men with a clinical suspicion of prostate cancer, a biopsy of the prostate that used MRI to inform the sampling was associated with a detection rate of clinically significant prostate cancer of 42%. This approach might permit a reduction in the number of men—possibly up to a third—who need to undergo biopsy if they are deemed to have a normal MRI. The efficiency (number of clinically significant prostate cancers/number of men biopsied) of the targeted sampling appeared superior to the standard approach (70% vs 40%). The standard approach was associated with a diagnosis of insignificant prostate cancer in 10% of men biopsied. This cancer diagnosis might have been avoided if men had undergone targeted biopsy alone.

Several benefits appear to be associated with an image-guided approach to prostate biopsy. In summary, fewer men are biopsied overall, a greater proportion of men with clinically significant prostate cancer are biopsied, and fewer men are attributed a diagnosis of clinically insignificant

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prostate cancer. More comprehensive and rigorous clinical research will be required before these qualified recommendations are ready for widespread adoption. Our estimates are based on relatively few studies that used different thresholds for declaring a target, a variety of methods for targeting, and a host of definitions of disease. There exists an urgent need for a large multi-institutional study with clearly defined MRI reporting, standardised sampling, and a priori definitions of clinical significance. The potential benefit is large.

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Study concept and design: Moore, Emberton.
Acquisition of data: Moore, Robertson, Middleton, Arsanious.
Analysis and interpretation of data: Moore, Robertson, Emberton.
Drafting of the manuscript: Moore.
Critical revision of the manuscript for important intellectual content: Emberton, Taneja, Klotz, Villers.
Statistical analysis: Moore.
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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.eururo.2012.06.004.

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