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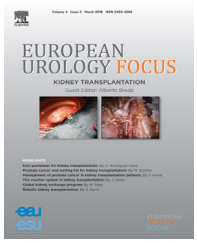

Review – Prostate Cancer

Elastic Versus Rigid Image Registration in Magnetic Resonance Imaging–transrectal Ultrasound Fusion Prostate Biopsy: A Systematic Review and Meta-analysis

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Abstract

Context: The main difference between the available magnetic resonance imaging-transrectal ultrasound (MRI-TRUS) fusion platforms for prostate biopsy is the method of image registration being either rigid or elastic. As elastic registration compensates for possible deformation caused by the introduction of an ultrasound probe for example, it is expected that it would perform better than rigid registration.
Objective: The aim of this meta-analysis is to compare rigid with elastic registration by calculating the detection odds ratio (OR) for both subgroups. The detection OR is defined as the ratio of the odds of detecting clinically significant prostate cancer (csPCa) by MRI-TRUS fusion biopsy compared with systematic TRUS biopsy. Secondary objectives were the OR for any PCa and the OR after pooling both registration techniques.
Evidence acquisition: The electronic databases PubMed, Embase, and Cochrane were systematically searched for relevant studies according to the Preferred Reporting Items for Systematic Review and Meta-analysis Statement. Studies comparing MRI-TRUS fusion and systematic TRUS-guided biopsies in the same patient were included. The quality assessment of included studies was performed using the Quality Assessment of Diagnostic Accuracy Studies version 2.
Evidence synthesis: Eleven papers describing elastic and 10 describing rigid registration were included. Meta-analysis showed an OR of csPCa for elastic and rigid registration of 1.45 (95% confidence interval [CI]: 1.21–1.73, $p < 0.0001$) and 1.40 (95% CI: 1.13–1.75, $p = 0.002$), respectively. No significant difference was seen between the subgroups ($p = 0.83$). Pooling subgroups resulted in an OR of 1.43 (95% CI: 1.25–1.63, $p < 0.00001$).
Conclusions: No significant difference was identified between rigid and elastic registration for MRI-TRUS fusion-guided biopsy in the detection of csPCa; however, both techniques detected more csPCa than TRUS-guided biopsy alone.
Patient summary: We did not identify any significant differences in prostate cancer detection between two distinct magnetic resonance imaging-transrectal ultrasound fusion systems which vary in their method of compensating for prostate deformation.

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1. Introduction

Prostate cancer (PCa) is the most common malignancy among Western men and it is the second leading cause of cancer-related mortality [1]. Measurement of serum prostate specific antigen and a digital rectal exam are the first steps in PCa diagnoses. The pathologic evaluation of 10–12 core systematic transrectal ultrasound (TRUS) guided biopsies of the prostate is the standard to confirm the diagnosis [2]. Unfortunately, TRUS-guided biopsy is prone to random and systematic error and it is associated with several problems, for example, the overdiagnosis of insignificant cancer and the underdiagnosis of significant cancer [3].

Recently, multiparametric (mp) magnetic resonance imaging (MRI) has been introduced for the detection and localization of PCa. mpMRI allows for the accurate assessment of the prostate and it can improve the diagnostic pathway of PCa. Despite the accurate assessment of mpMRI, pathologic confirmation of obtained biopsies remains the gold standard to finally objectify PCa and assess the aggressiveness. However, mpMRI can be used for direct in-bore or MRI-TRUS fusion-guided biopsy. MRI-TRUS fusion-guided biopsy can be divided into cognitive and software-assisted fusion. In the latter procedure the prostate is visualized in real-time using TRUS and the location of the tumor, annotated in the prebiopsy mpMRI, is registered to these ultrasound images with the use of software. Both direct in-bore targeted biopsy studies and software-assisted MRI-TRUS fusion biopsy studies have shown promising results in the detection of PCa [4–7].

Software-assisted MRI-TRUS fusion-guided biopsy is less expensive and more readily available compared with direct in-bore biopsy and therefore it is most used to target suspected lesions seen on mpMRI. Software-assisted MRI-TRUS fusion is offered by various commercially available platforms, each with its own specific features. The main difference between the platforms is the type of image registration being either rigid or nonrigid (elastic). Rigid image registration overlays the mpMRI images onto the TRUS images during the biopsy procedure without adjustment for possible deformation of the prostate due to patient movement or the introduction of the TRUS probe [8,9]. Elastic registration, however, tries to compensate for this deformation and it is therefore expected that it would be more accurate than rigid image registration [10–12]. The aim of this systematic review and meta-analysis is to compare the detection rates of clinically significant (cs)PCa between rigid MRI-TRUS fusion and elastic MRI-TRUS fusion.

2. Evidence acquisition

2.1. Search strategy

The electronic databases PubMed, Embase, and Cochrane were systematically searched for relevant studies. No limitations on language or date were used. The following search terms were used: (“magnetic resonance imaging” or “MRI” or “MR” or “NMR” or “mpMRI” or “ultrasonography” or “US” or “MR-TRUS” or “MR-US”or “MR/US”) AND (“fusion” or “registration” or “targeted” or “target” or “software”) AND (“prostate” or “prostate cancer” or “prostatic neoplasm” or “PCA” or “cancer”) AND (“detection” or “rate” or “utility” or “yield” or “efficiency” or “results”). Reference lists and two recent review articles were searched for missed eligible articles [4,13]. The last search was performed on July 7, 2015. All studies were imported into Endnote (version X7.2; Thomson Reuters, PA, USA). This study was performed according to the Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines [14].

2.2. Study selection and data extraction

One reviewer (W.V.) performed the study selection and data extraction. A first eligibility assessment was performed based on the title and abstract screening. The remaining articles were selected after a full text assessment. Conference abstracts were not included. Only studies comparing software-assisted MRI-TRUS fusion and systematic TRUS-guided biopsies in the same patient were included.

The main outcome measure was the detection rate of csPCa. The definition of clinical significance elected in the original report was used in this review. Therefore, different definitions of clinical significance were used. The secondary outcome measure was the detection rate of any PCa.

A data extraction form was used to extract the following data: study, population, MRI, and biopsy characteristics. The detection rates were calculated from the published data.

2.3. Quality assessment

The quality assessment of the included studies was performed by two reviewers (W.V. and M. de R.) using the Quality Assessment of Diagnostic Accuracy Studies version 2 [15]. Disagreements were resolved by consensus. The two reviewers were not blinded during this quality assessment. The signaling questions of domain 2 (Index Test) and domain 4 (Flow and timing) were adjusted so that the quality assessment fit our research question. Domain 2 includes the signaling questions: (1) is the systematic biopsy operator blinded for the location of the lesion found on mpMRI, and (2) was it clear at which threshold patients underwent targeted biopsy. Domain 4 includes the signaling questions: (1) was an appropriate time interval used between mpMRI and biopsy, (2) was targeted biopsy performed prior to systematic biopsy, (3) all patients underwent the same biopsy procedure, and (4) were all patients included in the analysis.

2.4. Data synthesis and analysis

We calculated the detection rates for each study of both csPCa and any PCa. To compare the elastic and rigid registration methods two subgroups were made. The detection rate was defined as the proportion of men in

which csPCa was detected divided by the number of men in the entire cohort.

Detection odds ratios (OR) were calculated and compared using Review Manager (version 5.3; The Cochrane Collaboration, London, England) [16]. The OR is the ratio of the odds that csPCa will be detected to the odds that it will not be detected with targeted biopsy compared with systematic biopsy. As we expect heterogeneity between the included studies a random-effects model was used. Significance of the overall OR and the OR of each subgroup was determined using a Z-test. To determine significant differences between the OR of the two subgroups a chi-square test was used. To illustrate any heterogeneity of the results, the ORs of the different studies are displayed using forest plots. The I^2 statistic was used to quantify heterogeneity. An I^2 below 40% indicates no substantial heterogeneity.

3. Evidence synthesis

3.1. Literature search and study selection

Figure 1 shows an overview of the literature search and the study selection. The search yielded 8653 records with 6616 records left after removing duplicates. Based on the screening title and abstract 45 articles remained. After removing articles using the same dataset and removing articles not fulfilling the inclusion criteria 19 relevant articles remained. One article was added after cross-reference searching which resulted in 20 included relevant articles.

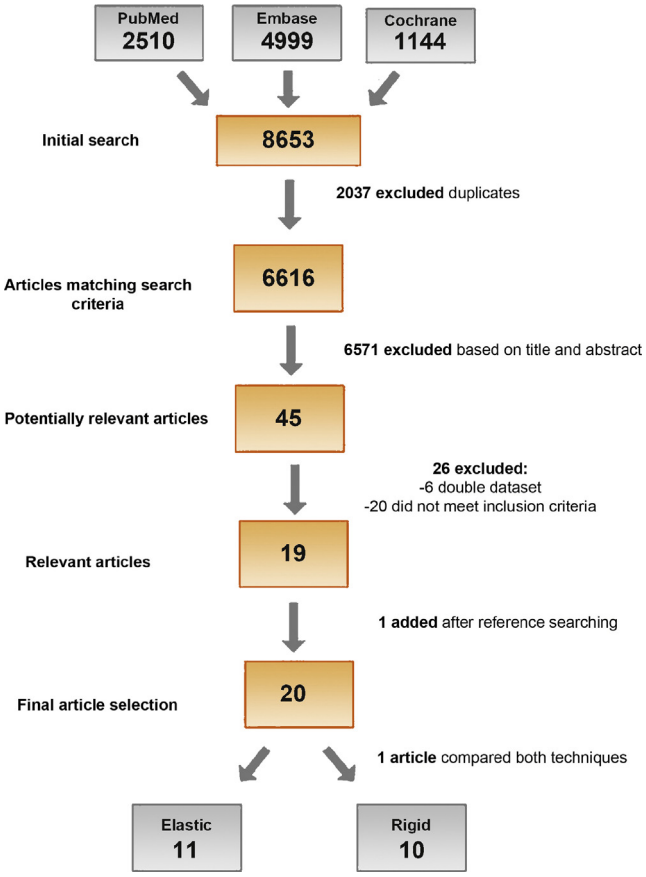

Fig. 1 – Chart showing the results of the literature search.

3.2. Study and patient characteristics

Supplementary Table 1 summarizes the study, population, MRI, and biopsy characteristics of the included studies. Eleven papers using elastic image registration [9,17–26] and 10 papers using rigid image registration [9,27–35]. As one paper compared both techniques, it was included in both subgroups. The subgroup using elastic registration comprised 1598 men and the rigid registration subgroup comprised 2318 men. In four studies the detection rate of csPCa could not be measured [24,29–31] and in one study the detection rate of any PCa could not be measured [18].

3.3. Quality assessment

The results of the quality assessment are depicted in Figure 2 and Supplementary Figure 1. The risk of bias regarding patient selection was unclear in nine studies [18,20,28,29,31–35]. The unclear risk was mainly caused by a lack of data on patient enrollment or patient exclusion. The risk of bias concerning the index test was low in three studies as these studies explicitly reported the operator of systematic biopsies was blinded for the target lesion [19,29,35]. The concerns about applicability regarding the reference test scored high in all studies except for one as all studies used systematic TRUS-guided biopsy as an inadequate reference test. Only one study used transperineal template saturation biopsy [32]. The risk of bias regarding flow and timing was low in four studies [18,25,28,34]. Five studies mentioned an appropriate time interval between MRI and the biopsy procedure [18,20,25,28,34]. Some studies performed a systematic biopsy prior to targeted biopsy [9,19,20,23,26,32].

3.4. csPCA

The detection rates for the individual studies are displayed in Table 1. The OR for csPCa was 1.45 (95% confidence interval [CI]: 1.21–1.73, $p < 0.0001$) and 1.40 (95% CI: 1.13–1.75; $p = 0.002$) for the elastic and the rigid registration subgroup, respectively both in favor of targeted biopsy. No significant difference was seen between the subgroups ($p = 0.83$). Figure 3 shows a forest plot to illustrate heterogeneity. I^2 was 9% for the elastic and 39% for the rigid subgroup.

The median detection rate of csPCa in the elastic registration subgroup was 34.59 (interquartile range [IQR]: 20.30–43.97) and 25.34 (IQR: 14.29–36.05) for targeted and systematic biopsy, respectively. The median detection rate of csPCa in the rigid registration subgroup was 25.19 (IQR: 22.58–35.74) and 23.13 (IQR: 12.16–28.52) for targeted and systematic biopsy, respectively.

Pooling both subgroups resulted in an OR of 1.43 (95% CI: 1.25–1.63; $p < 0.00001$) in favor of targeted biopsy with an I^2 of 19%. The median for targeted biopsy was 25.96 (IQR:

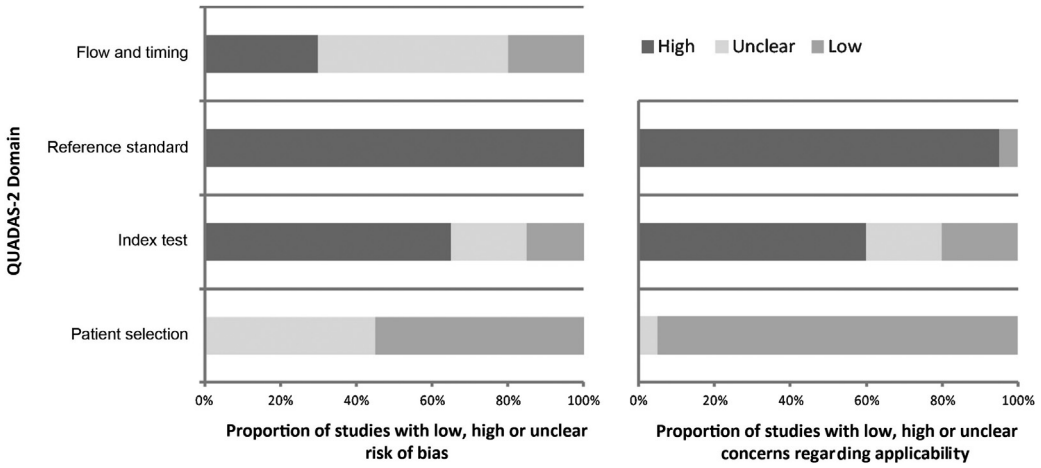

Fig. 2 – Methodologic quality overview of risk of bias and concerns regarding applicability of the 20 studies included in this systematic review using Quality Assessment of Diagnostic Accuracy Studies (QUADAS-2) [15].

21.44–43.25) and for systematic biopsy 25.00 (IQR: 14.06–29.90). The funnel plot depicted in Supplementary Figure 2 is symmetric so there appears to be no presence of publication bias.

3.5. *Any PCa*

The OR of any PCa was 1.28 (95% CI: 0.97–1.71, $p = 0.09$) and 1.01 (95% CI: 0.80–1.27, $p = 0.94$) in the elastic and the rigid registration subgroup, respectively, both in favor of targeted biopsy. There is no significant difference between the subgroups ($p = 0.19$). Figure 4 shows a forest plot to illustrate heterogeneity. I^2 was 69% and 64% in the elastic and the rigid subgroup respectively.

The median detection rate of PCa in the elastic registration subgroup was 43.46 (IQR: 33.65–51.82) and 37.78 (IQR: 23.81–45.45) for targeted and systematic biopsy respectively. The median detection rate of any PCa

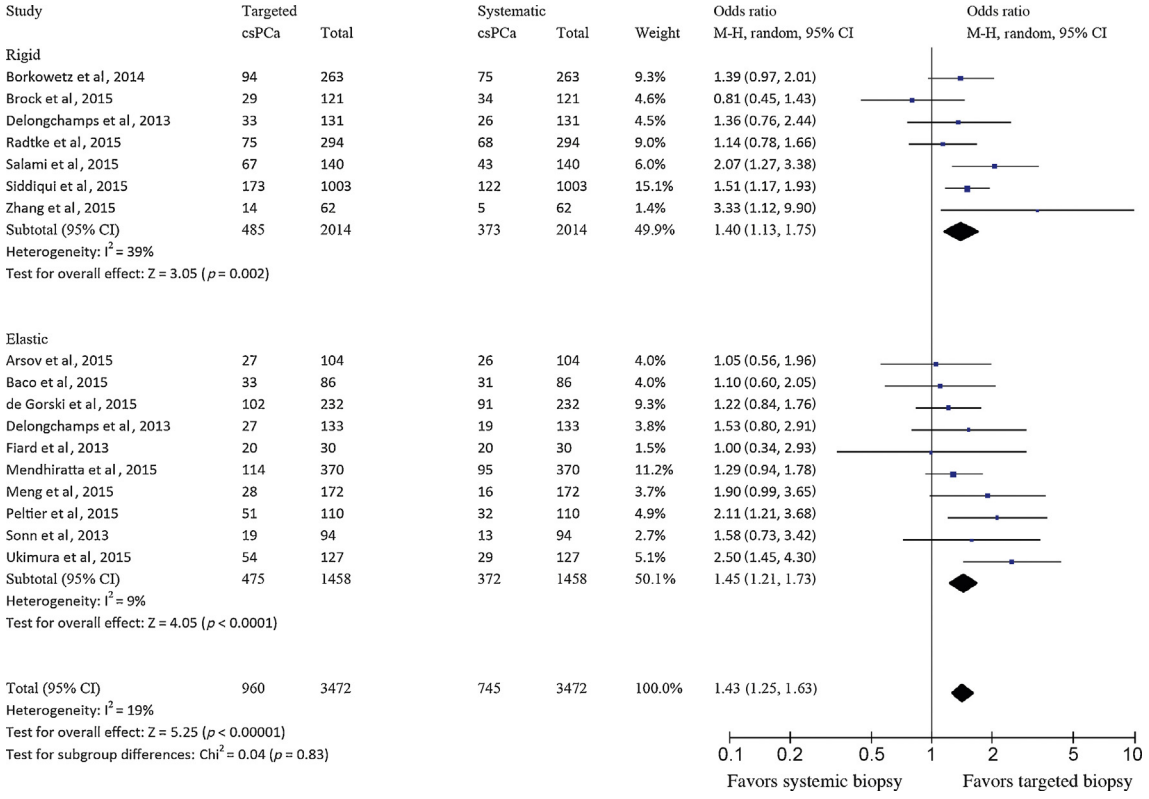

Fig. 3 – Forrest plots showing results of the meta-analysis of included studies reporting the detection rate of clinically significant prostate cancer (csPCa) detected by magnetic resonance imaging-transrectal ultrasound fusion-guided biopsy versus systematic transrectal ultrasound-guided biopsy. The squares indicate the mean, the whiskers indicate the 95% confidence interval (CI), and the diamonds indicate the pooled estimate. M-H_2 = Mantel-Haenszel method for random-effects.

Table 1 – Detection rates of targeted and systematic biopsy of the included studies

Study	Definition csPCa	Included patients		Detection rate							
				Targeted biopsy				Systematic biopsy			
				csPCa		Any PCa		csPCa		Any PCa	
		Entire cohort	No. of patients with a target lesion	Entire cohort (%)	Part of cohort with target lesion (%)	Entire cohort (%)	Part of cohort with target lesion (%)	Entire cohort (%)	Part of cohort with a target lesion (%)	Entire cohort (%)	Part of cohort with target lesion (%)
Arsov et al [17]	Gleason ≥3+4	104	104	–	26.0	–	33.7	–	25.0	–	34.6
Baco et al [18]	Gleason ≥3+4 or cancer core length ≥5 mm	86	63	38.4	52.4	NA	NA	36.0	44.4	NA	NA
de Gorski et al [19]	Gleason ≥3+4 or cancer core length ≥4 mm	232	232	–	44.0	–	54.3	–	39.2	–	55.6
Delongchamps et al [9]	Gleason ≥3+4	133	82	20.3	32.9	46.6	75.6	14.3	NA	33.1	NA
Fiard et al [20]	Gleason ≥ 3+4 or cancer core length ≥10 mm	30	20	33.3	50.0	36.7	55.0	33.3	45.0	43.3	50.0
Mendhiratta et al [21]	Gleason ≥3+4	370	370	–	30.8	–	43.5	–	25.7	–	47.3
Meng et al [22]	Gleason ≥3+4	172	172	–	16.3	–	23.8	–	9.3	–	18.0
Peltier et al [23]	Gleason ≥ 3+4 or cancer core length ≥6 mm[a]	110	100	46.4	51.0	51.8	57.0	29.1	NA	45.5	NA
Portalez et al [24]	Gleason ≥3+4	129	129	–	NA	–	43.4	–	NA	–	20.9
Sonn et al [25]	Gleason ≥ 3+4 or cancer core length ≥4 mm	94	94	–	20.2	–	22.3	–	13.8	–	26.6
Ukimura et al [26]	Gleason ≥3+4 or cancer core length ≥5 mm	127	127	–	42.5	–	61.4	–	22.8	–	40.9
Borkowetz et al [27]	Epstein [46]	263	263	–	35.7	–	44.1	–	28.5	–	34.6
Brock et al [28]	Epstein [46]	121	114	24.0	25.4	26.4	28.1	28.1	28.9	38.0	38.6
Delongchamps et al [9]	Gleason ≥3+4	131	78	25.2	42.3	48.9	82.1	19.8	NA	45.8	NA
Junker et al [29]	NA	50	50	NA	NA	–	46.0	NA	NA	36.0	–
Maxeiner et al [30]	NA	169	169	NA	NA	–	26	NA	NA	–	39.6
Miyagawa et al [31]	NA	85	85	NA	NA	–	52.9	NA	NA	–	40.0
Radtke et al [32]	Gleason ≥3+4	294	196	25.5	38.3	38.1	57.1	23.1	34.7	45.9	68.9
Salami et al [33]	Epstein [46]	140	140	–	47.9	–	52.1	–	30.7	–	48.6
Siddiqui et al [34]	Gleason ≥4+3	1003	1003	–	17.2	–	46.0	–	12.2	–	46.8
Zhang et al [35]	Gleason ≥3+4 high volume[a]	62	62	–	22.6	–	43.5	–	8.1	–	33.9

csPCa = clinically significant prostate cancer; NA = not applicable; PCA = prostate cancer.
[a] The definition for clinically significant prostate cancer in systematic biopsy is the same as for targeted biopsy but in systematic biopsy Gleason 6 in ≥3 cores is also considered clinically significant prostate cancer.

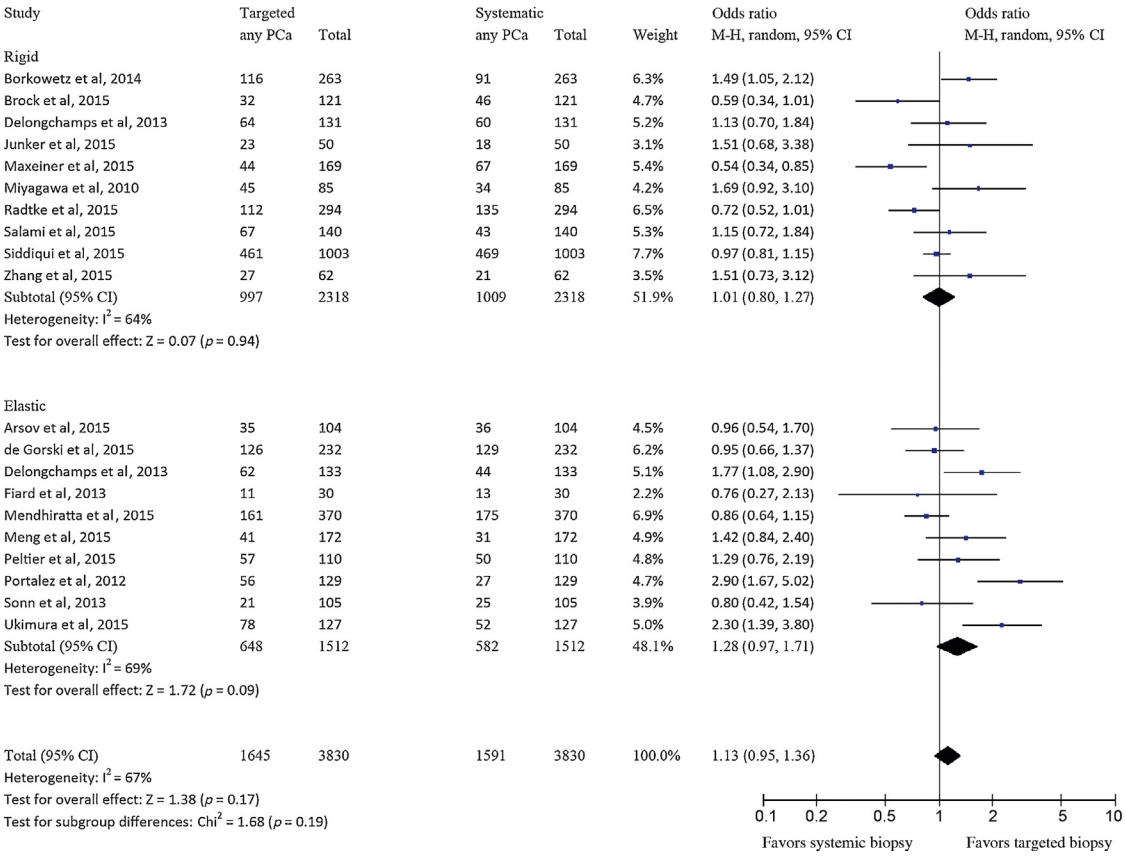

Fig. 4 – Forrest plots showing results of the meta-analysis of included studies reporting the detection rate of any prostate cancer (PCa) detected by magnetic resonance imaging-transrectal ultrasound fusion-guided biopsy versus systematic transrectal ultrasound-guided biopsy. The squares indicate the mean, the whiskers indicate the 95% confidence interval (CI), and the diamonds indicate the pooled estimate.
M-H_2 = Mantel-Haenszel method for random-effects.

in the rigid registration subgroup was 45.04 (IQR: 38.10–48.85) and 39.82 (IQR: 36.00–45.92) for targeted and systematic biopsy respectively.

Pooling both subgroups resulted in an OR of 1.13 (95% CI: 0.95–1.36, $p = 0.17$) in favor of targeted biopsy with an I^2 of 67%. The median for targeted biopsy was 43.83 (IQR: 35.16–50.34) and for systematic biopsy 39.82 (IQR: 34.24–45.86). The funnel plot depicted in Supplementary Figure 3 is symmetric so there appears to be no presence of publication bias.

4. Conclusions

This systematic review did not identify significant differences in the detection rates of both any and csPCa between elastic image registration and rigid image registration for MRI-TRUS fusion-guided biopsy, while MRI-TRUS fusion-guided biopsy as a whole detects more csPCa compared with TRUS-guided biopsy. The results for any PCa did not differ between MRI-TRUS fusion and TRUS guided biopsy.

These findings can be explained by the fact that rigid registration requires a cognitive optimization of the registration; after rigid software-assisted fusion the operator compensates cognitively for any prostate deformation.

The role of mpMRI in detecting and assessing the aggressiveness of a tumor is increasingly being recognized and implemented in daily practice [36–38]. As a consequence MRI-targeted biopsies are more and more being performed, both direct in-bore as MRI-TRUS fusion-guided biopsy. Many studies reported higher or similar rates of csPCa detection, whilst lower rates of clinically insignificant PCa were detected with MRI-targeted biopsy compared with TRUS-guided biopsy [7,39,40]. Results of cognitive fusion studies are contrasting, as some studies show superior and others show inferior detection rates compared with TRUS-guided biopsy, although software-assisted fusion seems to be not superior to cognitive fusion [41–43].

The results of our review are in line with other studies showing that software-assisted MRI-TRUS fusion-guided biopsy detects more csPCa without increasing the detection of insignificant PCa [4,34]. The best biopsy strategy for PCa would only detect csPCa and not clinically insignificant PCa. The crux, however, is the definition of csPCa as no uniform definition exists [44,45]. The included studies in this review used seven different definitions of csPCa, with Gleason score $\geq$3+4 being most used. Furthermore, almost all included studies applied the same definition for csPCa for both targeted and systematic biopsy. The definitions of clinically significance, however, are based on systematic TRUS-guided biopsy instead of targeted biopsy. As targeted biopsy obtains a few cores from an identified lesion on mpMRI which is likely to be PCa, it is much easier for

targeted biopsy to fulfill the criteria for clinical significance compared with systematic TRUS biopsy. Ideally whole-mount sections of prostatectomy would be used as a reference to draw the conclusion that targeted biopsy would detect more csPCa than systematic TRUS-guided biopsy.

A difference in accuracy between direct in-bore biopsy and MRI-TRUS fusion has not yet been demonstrated. Arsov et al [17] concluded after a prospective randomized controlled trial that MRI-TRUS fusion combined with systematic TRUS-guided biopsy did not improve the PCa detection rate compared with direct in-bore guided biopsy in patients with at least one previously negative TRUS-guided biopsy. To our knowledge, a study comparing direct in-bore guided biopsy with MRI-TRUS fusion alone has not yet been performed. The cost-effectiveness of both direct in-bore and fusion-guided biopsy has not yet been proven definitely as presented evidence regarding the cost-effectiveness is contradictory [47,48]. Although the procedure of MRI-TRUS fusion-guided biopsy is less expensive, less time-consuming, and more readily available than direct in-bore guided biopsy and therefore there might be an important role for MRI-TRUS fusion-guided biopsy in the diagnostics of csPCa.

MRI-TRUS fusion-guided biopsy is offered by several commercially available fusion platforms. No clear advantage of one platform over another has been demonstrated [13]. One study was included in our review comparing the two software-assisted image registration techniques [9]. They found a difference in favor of elastic registration, though the difference was not significant. This systematic review did not identify such a difference As a result of this review, costs and usability should be directive in the choice as to whether to use elastic or rigid registration or not.

The most important strength of this study is that it is the first to investigate the difference between elastic and rigid image registration used for MRI-TRUS fusion-guided biopsy. A second important strength of this study is the calculation of OR between the detection of PCa by targeted biopsy compared with systematic biopsy. We tried to exclude bias introduced by a higher prevalence of PCa in one group over. This can be seen by the higher median detection rate for targeted biopsy in the elastic image registration subgroup compared with the rigid registration subgroup. As the detection rate for TRUS-guided biopsy is also higher for that subgroup the OR between both subgroups does not significantly differ. Not all bias, however, can be excluded. Also, a strength of this review is its focus on only studies assessing detection rates of targeted biopsy and systematic biopsy both in the same patient. In this way we attempted to reduce heterogeneity between studies. However, many included studies failed to mention the awareness of the operator of TRUS-guided biopsy of the identified lesion on mpMRI. This resulted in a poor outcome of the quality assessment of included studies. As a result the detection rate for TRUS-guided biopsy might be overestimated.

A major limitation of this study is the heterogeneity between the included studies. Different definitions of csPCa, biopsy thresholds, mpMRI protocols, and scoring systems were used. Furthermore, significant heterogeneity can be introduced as there is a variation in nonrigid registration. The platforms use different in-house developed software. Also, some heterogeneity is introduced as some patients had a TRUS biopsy before while others were biopsy naïve. More homogeneity can be achieved using the Standards of reporting for MRI-targeted biopsy studies recommendations published by Moore et al [49]. Another limitation is the exclusion in some studies of patients without a lesion seen on mpMRI. This results in a selection bias probably in favor of targeted biopsy. A recurrent limitation in prostate biopsy studies is the impossibility of estimating the rate of true negative results of prostate biopsy. Studies are using TRUS-guided biopsy as a reference test. This test, however, lacks accuracy. Studies using prostatectomy as gold standard are also biased as the study population consists of patients with PCa who need surgery. As both analyzed subgroups suffer this limitation it will not affect the comparison between these subgroups. A last limitation might be the fact that the elastic image registration subgroup only exists of two different platforms, while the rigid subgroup exists of eight different platforms.

To conclude, we did not identify a significant difference between rigid and elastic image registration for MRI-TRUS fusion-guided biopsy in the detection of csPCa; however, both MRI-TRUS fusion-guided biopsy techniques detect more csPCa than TRUS-guided biopsy. To address the aim of this review more appropriately, a study that compares elastic and rigid image registration more directly will be needed. Hereby, heterogeneity between both groups can be excluded.

Author contributions: Wulphert Venderink had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Venderink, Fütterer.
Acquisition of data: Venderink.
Analysis and interpretation of data: Venderink, de Rooij.
Drafting of the manuscript: Venderink.
Critical revision of the manuscript for important intellectual content: de Rooij, Sedelaar, Huisman, Fütterer.
Statistical analysis: Venderink.
Obtaining funding: None.
Administrative, technical, or material support: None.
Supervision: Fütterer.
Other: None.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.euf.2016.07.003.

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