Cognitive-Targeted versus Magnetic Resonance Imaging-Guided Prostate Biopsy in Prostate Cancer Detection

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Introduction:
Purpose of this study is to evaluate the detection rates of prostate cancer (PCa) for cognitive-targeted biopsy (CTB) in comparison with magnetic resonance imaging (MRI)-guided biopsy (MRGB) related to prostate imaging reporting and data system (PI-RADS) score, lesion location and lesion volume. Furthermore, the addition of systematic transrectal ultrasound-guided biopsy (TRUS-GB) to CTB is evaluated.

Materials and Methods: We included all patients with cancer-suspicious lesions on 3-Tesla multiparametric MRI who underwent either CTB and additional TRUS-GB or only MRGB (in-bore) in Haga Teaching Hospital between January 2013 and January 2015.

Results: In total 219 patients were included: 64 CTB + TRUS-GB and 155 MRGB. In 32 (50%) men with CTB was positive for PCa. PI-RADS 3-, 4- and 5-lesions were in 17, 69 and 95% positive, respectively. In 100 men (65%) with MRGB was positive for PCa. Detection rates for PI-RADS 3-, 4- and 5-lesions were 10, 77 and 89%, respectively. CTB missed 4 (11%) low-grade tumors detected by TRUS-GB. In lesions between 0–1.5 ml PCa were significantly more often detected with MRGB than with CTB (69 vs. 39%).

Conclusion: CTB has a high detection rate of PCa in men with cancer-suspicious lesions on MRI. Correction for lesion volume shows that in lesions < 1.5 ml MRGB is more accurate than CTB. The addition of TRUS-GB to CTB can safely be avoided without missing any high grade PCa.

Key Words
Detection rate • Prostate cancer • Targeted prostate biopsy • Multiparametric magnetic resonance imaging

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MRI-guided prostate biopsy [MRGB (in-bore)] improves the quality of a biopsy after a diagnostic MRI [3, 12–15]. However, MRGB is not available in every hospital and requires more time and resources in comparison with TRUS-GB. Besides, patients experience MRGB as less comfortable because of the required position. For these reasons there is a need for assessing the capabilities of other targeted biopsy techniques.

A clinically used method for targeted prostate biopsy is the targeted TRUS-guided biopsy of CSL on prostate MRI, also known as the cognitive-targeted biopsy (CTB) or visually-registered targeted biopsy. CTB is a fast and relatively simple technique: an existing TRUS facility, knowledge of the target location on MRI and familiarity with prostate anatomy on ultrasonography are sufficient. Recent studies show promising results for cognitive targeting of CSL [16–21].

In this study, we aim to assess the detection rates of PCa of CSL on 3-Tesla mp-MRI for CTB in comparison with MRGB (in-bore) related to PI-RADS score, lesion location and lesion volume in men analyzed for PCa diagnosis to identify those CSL in which CTB could replace MRGB. Furthermore, we compared biopsy outcomes of CTB and TRUS-GB with the aim to identify the percentage of men in whom TRUS-GB could have been safely avoided after CTB without missing any PCs.

Materials and Methods

Patient Selection

This retrospective study was approved by our institutional review board. It was determined that informed patient consent was not needed. For comparison of the CTB versus MRGB detection rates we used a MRGB patient cohort from a previous publication of our research group [15]. A copyright license was provided by Springer to reuse these data.

A diagnostic prostate mp-MRI in Haga Teaching Hospital [used as 1; primary diagnostic tool, 2; after previous negative (TRUS) biopsy or MRI and 3; for further staging in case of positive biopsy] was performed in patients with (persistent) suspected PCa based on elevated prostate specific antigen (PSA) level and/or abnormal digital rectal examination, for follow-up of (benign) PI-RADS 3-, 4- and 5-lesions and in patients with PCa on active surveillance and suspicion of (more) significant disease. The treating urologist decided to perform either MRGB or CTB with TRUS-GB in case of CSL (normally PI-RADS ≥ 3; some PI-RADS 2-lesions were also targeted because of the high clinical suspicion). In this study, we included all the patients analyzed for PCa with CSL on 3-Tesla prostate mp-MRI who underwent either CTB in addition to TRUS-GB or only MRGB (in-bore) in Haga Teaching Hospital in the Netherlands between January 2013 and January 2015.

CTB versus MRGB in Prostate Cancer Detection

Results

In total 664 patients analyzed for PCa diagnosis underwent a prostate mp-MRI between January 2013 and January 2015. Total 219 patients underwent a targeted biopsy procedure. CTB and TRUS-GB was performed in 64 patients, MRGB in 155 patients. Patient characteristics are presented in table 1. CTB was performed in significantly larger lesions than MRGB and more biopsy cores were taken on average during a CTB + TRUS-GB session. The other characteristics are similar.
In both CTB + TRUS-GB and MRGB patients, the majority of suspected lesions (52 and 65%) were located in the peripheral zone of the prostate. There was no difference in distribution of the 3 zones between both groups. In both groups PCa was not significantly more often anterior located than negative lesions (CTB + TRUS-GB: 53 vs. 39% and MRGB: 64 vs. 55%). Between CTB + TRUS-GB and MRGB group there was no difference in distribution of lesion location (table 2).

In 36 of 64 (56%) men PCa was detected with CTB and TRUS-GB together. PI-RADS 2-, 3- and 4-lesions were in 19, 17 and 69% PCa positive, respectively. Biopsies of PI-RADS 5-lesions were positive in 95% of the cases. PCa detection rate of CTB + TRUS-GB for PI-RADS 4- and 5-lesions together was 83%. In 100 of 155 (65%) men PCa was detected with MRGB. None of the biopsied PI-RADS 2-lesions were positive. PI-RADS 3- and 4-lesions were in 10 and 77% positive for PCa, respectively. Biopsies of PI-RADS 5-lesions were in 89% of the cases positive. MRGB of PI-RADS 4- and 5-lesions combined was positive in 81%. CTB + TRUS-GB and MRGB rates are statistically similar (table 2).

Cross tabulation of CTB outcomes versus TRUS-GB outcomes in men in the CTB + TRUS-GB group is shown in table 3. The percentage of missed PCa by CTB but detected with TRUS-GB is 11% (4/36). All these men

Table 1. Patient characteristics

| Characteristics | Patients CTB + TRUS-GB (n = 64) | Patients MRGB only (n = 155) | p |
|-----------------|---------------------------------|------------------------------|---|
| Age, year, mean (range) | 68 (48–83) | 68 (48–83) | 0.991 |
| PSA level, ng/ml, mean (range) | 14.3 (1.9–135) | 11.1 (2–56) | 0.957 |
| Prostate volume on MRI, ml, mean (range) | 55 (16–164) | 61 (19–260) | 0.795 |
| Lesion volume on MRI, ml, mean (range) | 3.9 (0–22) | 2.2 (0–22) | 0.001** |
| Biopsy cores, n, mean (range) | 8 (1–12)** | 3 (1–6) | 0.001** |

P-values were calculated using an unpaired t-test for numeric parametric data and a Mann-Whitney U test for non-parametric data. **p < 0.05 was considered statistically significant. ***number of targeted cores (= 1–5) and number of systematic cores (= 4–12).

Table 2. Distribution of lesion zone and lesion location; detection rates of CTB + TRUS-GB and MRGB related to PI-RADS score (lower part of table)

| Characteristics | Patients CTB + TRUS-GB, n (%) | PCa, n (%) | Negative biopsy n (%) | Patients MRGB, n (%) | PCa, n (%) | Negative biopsy n (%) | p |
|-----------------|-----------------------------|-----------|----------------------|---------------------|-----------|----------------------|---|
| Lesion zone     |                             |           |                      |                     |           |                      |   |
| Peripheral zone | 33 (52)                     | 25 (69)   | 8 (29)               | 101 (65)            | 76 (76)   | 25 (45)              | 0.06 |
| Transitional zone | 31 (48)                  | 11 (31)   | 20 (71)              | 52 (34)             | 23 (23)   | 29 (53)              | 0.039** |
| Central zone    | 0 (0)                       | –         | –                    | 2 (1)               | 1 (1)     | 1 (2)                | 1.0 |
| Lesion location |                             |           |                      |                     |           |                      |   |
| Anterior        | 30 (47)                     | 19 (53)   | 11 (39)              | 94 (61)             | 64 (64)   | 30 (55)              | 0.061 |
| Posterior       | 34 (53)                     | 17 (47)   | 17 (61)              | 61 (39)             | 36 (36)   | 25 (45)              | 0.061 |
| Total           | 64 (100)                    | 36 (100)  | 28 (100)             | 155 (100)           | 100 (100) | 55 (100)             |   |
| PI-RADS score   |                             |           |                      |                     |           |                      |   |
| 1               | 0 (0)                       | –         | 0 (0)                | 1 (1)               | 3 (10)    | 0.407                |   |
| 2               | 21                          | 4 (19)    | 6 (0)                | 0 (0)               | 3 (10)    | 0.407                |   |
| 3               | 6                           | 1 (17)    | 29 (10)              | 3 (10)              | 0.459     |                      |   |
| 4               | 16                          | 11 (69)   | 84 (57)              | 65 (77)             | 0.414     |                      |   |
| 5               | 21                          | 20 (95)   | 36 (19)              | 32 (89)             | 0.414     |                      |   |
| Total           | 64 (100)                    | 36 (56)   | 28 (44)              | 155 (100)           | 100 (65)  | 55 (35)              | 0.251 |

P-values were calculated using a Pearson chi-square test for differences in proportions; in case of small numbers the Fischer’s exact test was used. p < 0.05 was considered statistically significant.
had a PI-RADS 2-lesion on MRI and Gleason 6 PCa was detected in TRUS-GB. No high-grade PCa was missed by CTB. Excluding TRUS-GB results, in 32 of 64 (50%) men PCa was detected with CTB. The detection rates for PI-RADS 2-, 3-, 4- and 5-lesions were 0, 17, 69 and 95%, respectively. This remains statistically similar with the MRGB rates (p = 0.101). In both CTB- and MRGB-patients the majority of detected cancers (63 vs. 63%) were GS ≥ 7, this number increases to 85% (17 of 20) for CTB versus 75% (24 of 32) for MRGB in positive PI-RADS 5-lesions.

Patients, lesion characteristics (zone, location) and detection rates of PCa for both cohorts (with and without including TRUS-GB results) were in all but one aspect similar. CTB was performed in significantly larger lesions than MRGB (3.9 vs. 2.2 ml; p = 0.001). After correction for lesion volume, PCa was significantly more often detected with MRGB than with CTB in lesions between 0 and 1.5 ml. In lesions between 1.5 and 3 ml and lesions ≥ 3 ml the detection rates of CTB and MRGB were similar (table 4).

Follow-Up

CTB of PI-RADS 5-lesions was benign in 1 case (5%). Because of persistent clinical suspicion MRGB was performed, this resulted in a Gleason 7 tumor. Biopsies of PI-RADS 4-lesions were benign in 31% (n = 5) of the cases. Two men underwent MRGB after CTB and TRUS-GB, resulting in a Gleason 7 and Gleason 8 tumor. The others were followed-up including PSA measurements every 3–6 months, without PCa diagnosis after average follow-up of 2.5 years.

MRGB of PI-RADS 5-lesions was in 11% (n = 4) of the cases benign. Two patients were previously diagnosed with Gleason 6 PCa and treated accordingly. One patient was diagnosed with prostatitis and the remaining patient was followed-up. Men with negative PI-RADS 4-lesions (n = 19) after MRGB were also followed-up. In case of persistent PCa suspicion mp-MRI or TRUS-GB was repeated. In 2 cases this resulted in Gleason 6 PCa after average follow-up of 2.5 years.

Discussion

In the present study the detection rates of PCa for CTB (with and without concomitant TRUS-GB) related to PI-RADS score, lesion location and lesion volume in patients with suspected PCa on 3-Tesla prostate mp-MRI have been evaluated and compared with those of MRGB (in-bore). Excluding TRUS-GB results, CTB of CSL on mp-MRI resulted in 50% of the cases in PCa, predominantly clinically significant. The detection rate of PCa for CTB increases with the PI-RADS score, to 83% when only PI-RADS 4- and 5-lesions will be biopsied. The MRGB detection rates (65% overall rate; 81% in PI-RADS 4- and 5-lesions combined) are slightly better but statistically similar to CTB rates [15]. It is known that systematic TRUS-GB has a detection rate of PCa ranging from 27 to 40%, with a low detection of clinically significant cancers [5]. Compared to these rates targeted biopsy after mp-MRI, either CTB or MRGB, is a more accurate and efficient procedure for the detection of clinically significant PCa. Overall CTB (without TRUS-GB results) seems nearly as good as MRGB. But after stratification on lesion volume, PCa was significantly more often detected with MRGB than with CTB in lesions between 0 and 1.5 ml. From 1.5 ml and up the detection rates of CTB and MRGB were similar. In an era of increased need for targeted biopsies we prefer CTB in the larger

| Table 3. Cross tabulation of biopsy outcomes CTB versus TRUS-GB |
|------------------|------------------|------------------|------------------|------------------|
| MRI + CTB, PI-RADS ≥ 2 | No PCa | GS 3 + 3 PCa | GS ≥ 3 + 4 PCa | Total |
|------------------|-------|--------------|---------------|-------|
| TRUS-GB No PCa | 28 | 10 | 13 | 51 |
| GS 3 + 3 PCa | 4 | 2 | 0 | 6 |
| GS ≥ 3 + 4 PCa | 0 | 0 | 7 | 7 |
| Total | 32 | 12 | 20 | 64 |

| Table 4. Detection rates of CTB (without TRUS-GB) and MRGB related to lesion volume |
|------------------|------------------|------------------|------------------|------------------|
| Lesion volume (ml) | n | CTB PCa n (%) | n | MRGB PCa n (%) | p |
|------------------|---|------------------|---|------------------|---|
| 0–1.5 | 23 | 9 (39) | 92 | 63 (69) | 0.009** |
| 1.5–3 | 18 | 9 (50) | 27 | 15 (56) | 0.384 |
| ≥ 3 | 23 | 14 (61) | 36 | 22 (61) | 0.303 |
| Total | 64 | 32 (50) | 155 | 100 (65) | 0.101 |

P-values were calculated using a Pearson chi-square test for differences in proportions; in case of small numbers the Fischer’s exact test was used. *p < 0.05 was considered statistically significant.
lesions in context of time, resources and patient comfort. The present study shows that CTB missed 11% of all cancers in the CTB + TRUS-GB subgroup of our cohort without missing any high-grade PCa. Furthermore, three additional patients were diagnosed with significant PCa after a previous negative CTB + TRUS-GB session during follow-up because of high clinical suspicion. As we were used in the recent past after negative TRUS-GB, one should always repeat analysis in case of persistent clinical suspicion of PCa.

CTB allows the adaptation of targeted biopsy without costs for new equipment. Several publications analyzed the value of cognitively performed targeted biopsy [16, 17, 20, 21]. Our overall detection rate for CTB without concomitant TRUS-GB is 50% and with concomitant TRUS-GB is 56%. Peuch et al. [16] found that MRI prior to biopsy improved detection rate to 47% by CTB. Kasivisvanathan et al. [20] detected in 57% of the cases PCa. Labanaris et al. [21] evaluated 260 patients who had a prior negative biopsy. They show a PCa detection rate of 56%. Haffner et al. [17] compared results of CTB with those of 12 random biopsies in 555 patients. They detected in 67% PCa with CTB. Our result is in agreement with these publications and significant higher than the detection rate (≤ 18%) of repeated TRUS-GB sessions [23]. Using our definition for clinical significance (GS ≥ 7) 63% of all detected cancers (both CTB and MRGB) are clinically significant. The previous studies describe rates between 43 and 62%. Comparison of these rates should be done with caution due to the use of different definitions for clinically significant PCa. However, apart from the definition used the clinical significance rate for MRI based targeted biopsy (either CTB or MRGB) is high compared to TRUS-GB.

Several publications investigated the detection accuracy of targeted biopsy and standard biopsy alone or in combination [24–27]. Only a few studies have compared the detection rates of PCa between different targeting techniques. We compared CTB and MRGB in two statistical similar patient groups and found nearly similar detection rates of PCa for CTB and MRGB related to PI-RADS score and lesion location. However, correction shows that in lesions < 1.5 ml MRGB is more accurate. Other studies concern mainly a comparison of CTB with MRI/TRUS-fusion biopsy (MTFGB) and the results are controversial [16, 19, 28, 29]. Delongchamps et al. [19] and Wysock et al. [28] reported that MTFGB was slightly better than CTB (PCa detection rates ranging from 32 to 61% versus 27 to 42%). Peuch et al. [16] and Lee et al. [29] found no evidence of a significant difference in the detection of any grade PCa between CTB and MTFGB. A recent review shows superior overall PCa detection for MRGB (in-bore) and MTFGB compared to CTB [30]. In none of the just described studies the detection rates related to lesion volume has been mentioned.

In contrast to the literature, we showed no significant added value for a TRUS-GB procedure after a cognitively targeted biopsy procedure in men analyzed for PCa diagnosis, i.e. CTB missed 11% of all cancers detected by TRUS-GB but no high-grade PCa was missed by CTB in our cohort. One could question the benefit of concomitant TRUS-GB during a CTB session. In an era of active surveillance for insignificant PCa, we doubt this missed insignificant PCa would cause any harm to these patients. In this perspective, the addition of TRUS-GB to CTB could safely be avoided according to our results. Two studies evaluated the performance of MTFGB versus TRUS-GB using START recommendations [31, 32]. Both studies show that a targeted biopsy protocol improves clinically significant PCa detection rate compared to a systematic biopsy protocol, with an added value for targeted biopsies of 36–42%. However, limiting prostate biopsy to a targeted biopsy protocol without TRUS-GB missed 1–4% of high-grade tumors. Our finding of safely avoiding concomitant TRUS-GB during CTB is not reproduced in these MTFGB studies. Apart from the different technique of targeted biopsies, this difference with our findings could be due to variations in patient population, quality of MRI imaging, experience of the radiologist interpreting the MRI images and the experience of the urologist performing the biopsies.

This study represents the true clinical setting, but has some limitations due to its retrospective design. Although both patient groups were statistically similar in all relevant aspects, the groups differed in size. Population size of the CTB group may have been underpowered to show a statistically significant difference between CTB and MRGB techniques. Because of the retrospective character we could not exclude a selection bias. Furthermore no concomitant TRUS-GB has been performed in the MRGB group. Although concomitant TRUS-GB did not diagnose any significant PCa in the CTB group, data about missed PCa by MRGB detected with concomitant TRUS-GB are lacking. Finally, our follow-up is limited to median 2.5 years. Though significant tumors ought to be detected within this period, a longer follow-up period could stronger endorse these study conclusions. However, despite these limitations, due to the comparability of both groups we believe the results of this study are very useful in clinical practice.
Conclusion

This study shows that prostate mp-MRI followed by either CTB (with or without additional TRUS-GB) or MRGB of CSL in patients with suspected PCa results in a high detection rate and clinical significance of diagnosed tumors. These results confirm that MRI based diagnosis and subsequent targeted biopsies fulfill an important role in increasing detection rate and accuracy in the diagnosis of PCa. With different biopsy techniques available a strategy where the choice for a biopsy modality is based on lesion characteristics on MRI can provide an adequate, individual and more cost effective diagnostic algorithm. According to our results, we suggest to use MRGB for small lesions < 1.5 ml and the relatively simple and cost-effective technique of CTB for the majority of larger lesions ≥ 1.5 ml. Furthermore this study shows that in our cohort we could have safely avoided TRUS-GB in all men undergoing CTB without missing any significant PCa. These results suggest to perform CTB without additional TRUS-GB in men analyzed for PCa diagnosis. Prospective studies with longer oncologic follow-up and standardization of both MRI parameters, MRI interpretation and biopsy procedures will need to confirm these 2 strategies in the future.

Abbreviations

CSL = cancer-suspicious lesion(s)
CTB = cognitive-targeted biopsy
GS = Gleason score
mp-MRI = multiparametric magnetic resonance imaging
MRGB = magnetic resonance imaging-guided prostate biopsy
MRI = magnetic resonance imaging
MTFGB = MRI/TRUS-fusion biopsy
PCa = prostate cancer
PI-RADS = prostate imaging reporting and data system
PSA = prostate specific antigen
TRUS = transrectal ultrasonography
TRUS-GB = transrectal ultrasound-guided prostate biopsy

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