

Evaluation of the current status, significance, and availability of prostate MRI und MRI guided biopsy in Germany

Statuserhebung zum Stellenwert, zur Qualität und zur Verfügbarkeit der MRT und MRT-gestützten Biopsie der Prostata in Deutschland

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ABSTRACT

Purpose Evaluation of the current status, significance and availability of multiparametric prostate MRI and MRI-guided biopsy in Germany.

Materials and Methods A voluntary web-based questionnaire with 26 distinct items was emailed to members of the German Radiological Society (DRG) and the Professional Association of German Radiologists (BDR). The questions referred to personal qualification, acquisition, quality, and management of prostate MRI, and assessment of the importance of the method.

Results In total 182 questionnaires were captured from all 10 german postal regions (over 60% of the university hospitals, almost 50% of the maximum care hospitals and approx. 12% of the practices or medical service centers). 43% of the respondents had a Q1 or Q2 quality certificate from the DRG, 10% had a certificate from the BDR, respectively. The majority (90%) criticized inadequate reimbursement of the examination. In 47% MRI cases were discussed in an interdisciplinary tumor board, in 44% case discussions happened rarely, and 12% never had interdisciplinary discussions. On a scale from 0–100 (0%: low; 100%: high) the estimation of the clinical relevance of prostate MRIs received an average of 84% (±16%) and the estimated approval by urologists was 75% (±21%). Lacking clinical feedback (59%) and clinical information (42%) were perceived as the largest problems.

Conclusion In this representative survey the respondents estimated multiparametric MRI of the prostate as highly diagnostic and relevant with an increased approval by urologists. There is still a perceived need for continuous professional education of the method for urologists and for more widespread coverage of fusion biopsy. Prostate MRI is currently primarily offered by high volume centers. Current challenges are particularly insufficient interdisciplinary communication and inadequate reimbursement.

Key Points

- Prostate MRI is perceived as highly diagnostic and clinically relevant. The method is currently primarily offered by high volume centers.
- Bigger current problems are insufficient interdisciplinary communication (e.g., clinical information, biopsy results) and inadequate reimbursement.
- Continuous education for urologists and expanded coverage by fusion biopsy are desirable.

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ZUSAMMENFASSUNG

Ziel Evaluation des Stellenwerts der MRT der Prostata (auch MR-Prostatografie) in Deutschland im Jahr 2023 und Erfassung möglicher Optimierungsansätze.

Material und Methoden Mittels webbasierter Umfrage wurde ein freiwilliger Online-Fragebogen mit 26 distinkten Punkten per E-Mail an Mitglieder der Deutschen Röntgengesellschaft (DRG) und des Berufsverbands Deutscher Radiologen (BDR) versandt sowie ein Umfragelink auf der Website der Arbeitsgemeinschaft Uroradiologie und Urogenitaldiagnostik der DRG erstellt. Die Fragen betrafen allgemeine Angaben und Ausbildungsstatus, Akquise und Management der Prostata-MRT, Qualität der Untersuchung und Einschätzungen zum Stellenwert.

Ergebnisse Es wurden 182 Fragebögen aus allen 10 deutschen Postleitzonen erfasst (über 60% der Universitätskliniken, knapp 50% der Maximalversorger und ca. 12% der Praxen/MVZ), wobei 43% der Antwortenden ein Q1- bzw. Q2-

Status der DRG besaßen und 10% ein Qualitätstestat des BDR. 90% fanden es problematisch, dass die Prostata-MRT nicht adäquat abrechenbar ist. Bei 47% wurden Fälle in einem interdisziplinären Tumorboard besprochen, bei 44% erfolgte selten und bei 12% kein interdisziplinärer Austausch. Auf einer Skala bis 100 (0%: niedrig; 100%: hoch) wurde die klinische Relevanz der MRT der Prostata im Mittel mit 84% (±16%) und die Akzeptanz in der Urologie mit 75% (±21%) bewertet. Bei der Frage nach den größten Schwierigkeiten waren die meistgegebenen Antworten "Fehlendes klinisches Feedback" mit 59% und "Fehlende klinische Informationen" mit 42%.

Schlussfolgerung In dieser Umfrage wurde die Prostata-MRT unter anderem durch die zunehmende Standardisierung als klinisch relevant und sehr aussagekräftig eingeschätzt mit einer zunehmenden Akzeptanz durch die Urologie. Es wurde aber ein Fortbildungsbedarf der Methode in der Urologie und eine bisher unzureichende Abdeckung durch eine MR/US-Fusionsbiopsie gesehen. Die Methode wird aktuell primär in größeren Zentren angeboten. Große Herausforderungen der Prostata-MRT bestehen in einem noch ungenügenden interdisziplinären Austausch und insbesondere in der inadäquaten Abrechenbarkeit, die noch eine flächendeckendere Verfügbarkeit und Qualitätssteigerung außerhalb dezidierter Zentren erschwert.

Kernaussagen

- Die Prostata-MRT wird als sehr aussagekräftig und klinisch relevant eingeschätzt.
- Sie hat deutschlandweit eine gute Verfügbarkeit, wird aber primär in größeren Kliniken/Zentren angeboten.
- Größere aktuelle Herausforderungen sind ein ungenügender interdisziplinärer Austausch (z. B. klinische Angaben, Biopsieergebnisse) und eine inadäquate Abrechenbarkeit.
- Es werden ein urologischer Fortbildungsbedarf und eine unzureichende Abdeckung mittels Fusionsbiopsie angegeben.

Introduction

Multiparametric MRI of the prostate (mpMRI), also known as MR prostatography, is considered the most sensitive imaging procedure for detecting prostate cancer, and it is now a standard component of guideline-based diagnostics for prostate cancer [1, 2]. It has been sufficiently demonstrated that risk stratification using mpMRI significantly improves the detection and localization of relevant carcinomas and can prevent a high proportion of unnecessary biopsies [3, 4, 5]. The high diagnostic value is reflected in the successive upgrading of the examination for various questions in national and international urological guidelines over the past few years.

A 2015 Germany-wide survey conducted among radiologists criticized a pronounced heterogeneity in technical acquisition of prostate MRI and diagnostics [6]. In the meantime, further development of the internationally widely accepted Prostate Imaging Reporting and Data System (PI-RADS), currently in version V2.1, as well as the national joint recommendation of the German Radiological Society (DRG) and the Professional Association of Ger-

man Radiologists (BDR) for the preparation and performance of mpMRI, as well as the quality and certification campaign of the DRG's Working Group for Uroradiology and Urogenital Diagnostics with now over 1,000 certifications (Q-Level), have led to a significantly improved standardization of preparation and assessment [7, 8].

A regional German survey among urologists and general practitioners from 2018 showed that the traditional diagnosis of prostate cancer using digital rectal examination (DRE) and determination of the PSA value (prostate-specific antigen) was rated as very good and largely sufficient. mpMRI of the prostate was primarily used in secondary diagnostics after negative biopsy [9]. Meanwhile, mpMRI of the prostate is also recommended in the German S3 guideline and in the guideline of the European Society of Urology (EAU) for primary diagnostics before the first biopsy [1, 2]. Although the number of MRI prostatographies performed annually and the areas of application have increased significantly, other hurdles, including a lack of approval for the service in the Uniform Assessment Standard (EBM) and adequate billing, currently stand in the way of a further spread of mpMRI. Since reliable

mpMRI of the prostate requires a high level of expertise and experience [10], a limited availability, especially outside dedicated centers, could have a negative impact on the quality and thus also on the clinical significance.

The aim of this nationwide survey in radiological clinics and specialist practices is therefore to record the current importance and limitations of prostate MRI, taking into account the scientific findings and increasing standardization over the last few years, and to work out potential ways of optimizing the entire diagnostic chain.

Materials & Methods

Study design

Using the web-based, commercially available REDCap survey platform (Vanderbilt University, Nashville, Tennessee), an online questionnaire addressed to radiologists with 26 distinct items was created and finally agreed upon by two Q2-certified radiologists (T.U. and L.S.). The institutional ethics committee approved the study (Study ID: 2021–1411). The items included multiple-choice questions with single or multiple selection as well as scaled questions with the possibility of a continuous selection between two poles. Answering the questions in the survey is voluntary. In order to answer the questions in the survey, participants had to first read the attached and linked detailed study information (**Appendix 1**) and then consent to voluntary participation in the study by means of a decision question (Question 1). Refusal to participate ended the survey. This did not result in any negative consequences for the participant.

A link to the survey was sent by email to members of the DRG and BDR in April 2023. At the same time, the survey was linked to the website of the DRG's Working Group for Uroradiology and Urogenital Diagnostics. Responses and data were collected for 3 months. The survey was anonymous and no questions were asked that would identify the person or their origin, except for a query about the first 3 digits of the postal code, which was to capture the general distribution of the questionnaire (**Appendix 2**).

Questionnaire

The first section of the survey with questions 2 to 7 concerned general information, and included questions about specialist and training status, age group, special certifications in MR prostatography (Q1/Q2 certificate of the DRG's Working Group for Uroradiology, quality certificate of the BDR), as well as the current institution and region. The second section with questions 8 to 14 dealt with acquisition and management of prostate MRI, and included questions about the number of prostate MRIs performed per week, magnetic field strength and use of an endorectal coil, number of radiologists on site and referring urologists who performed prostate MRI, time availability, and assessment of the problems of billing for prostate MRI. The third section with questions 15 to 19 concerned the quality of the examination, and included questions about the use of contrast media, dealing with ambiguous results, interdisciplinary exchange, and training opportunities. The last section with questions 20 to 26 dealt with the importance of prostate MRI, and included the indication, handling of the PI-RADS v2.1 catalog, significance, clinical relevance, and acceptance of prostate MRI, number of biopsies among the abnormal findings, and finally questions about difficulties of prostate MRI.

Statistics

The data collected were transferred and further analyzed using MS Excel (Microsoft, Redmond, WA, USA), SPSS version 29 (IBM Corp., Armonk, NY, USA) and GraphPad Prism version 9 (GraphPad Boston, MA, USA). Continuous and categorical values were expressed as absolute numbers, percentages, means with standard deviation, or medians with interquartile range between upper (75%) and lower (25%) quartiles.

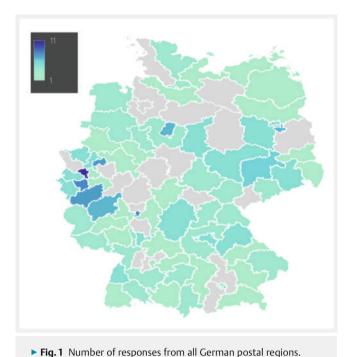
Results

Questionnaire participants

A total of 182 questionnaires were completed by radiologists. This includes 5% resident physicians, 47% specialists, 30% senior physicians, 14% chief physician and 4% other (9, 85, 54, 26, 8 of 182, respectively). The age distribution was 1% <31 Y (years), 26% 31-40 Y, 26% 41-50 Y, 39% 51-60 Y, 9% >61 Y (2, 46, 46, 69, 16 of 179, respectively; 3 not specified). Among respondents 43% had Q1 status (78/182), 43% (78/182) Q2 status, and 14% (26/182) had no Q-certificate. At the time of the survey, this represented about 18% of Q-certified radiologists in Germany. 10% (18/182) had a quality certificate from the Professional Association of German Radiologists (BDR). Among the respondents, 41% were employed in a practice, 20% in a medical care center, 8% in a primary/standard care hospital, 13% in a specialist/maximum care hospital, and 18% in a university hospital (74, 37, 15, 23, 33 of 182, respectively). The total response rate comprised approximately 14% of the radiological institutes in Germany. Responses came from all 10 of Germany's 10 postal zones (77 of 99 postal routing regions) (▶ Fig. 1).

Availability

8% of respondents completed ≤50 prostate MRIs per year, 23% 51-150, 32% 151-300, 22% 301-600 and 16% >600 (14, 41, 58, 40, 29 of 182, respectively). The majority of respondents used a magnetic field strength of 3 Tesla for prostate MRI (48%, 87/182; 1.5T: 35%, 64/182; 3T and 1,5T: 16% 30/182; other: 1%, 1/182). The vast majority did not use an endorectal coil (98% vs. 2%, 3/182). Of the respondents, 10% worked in institutions with a radiologist who interprets mpMRI of the prostate, 27% had 2 interpreters, 22% had 3, 20% had 4, and 20% had 5 interpreters (19, 49, 40, 37, 37 of 182, respectively). 7% reported 1–2 referring urologists, 26% 3–4, 21% 5–6, 12 7–8, and 34% >8 (13, 48, 38, 21, 62 of 182, respectively). For 38%, the time availability was <2 weeks, for 39% 3-6 weeks and for 23% >6 weeks (69, 71, 42 of 182, respectively). 90% of respondents considered it problematic that prostate MRI is not adequately billable (163 of 182).

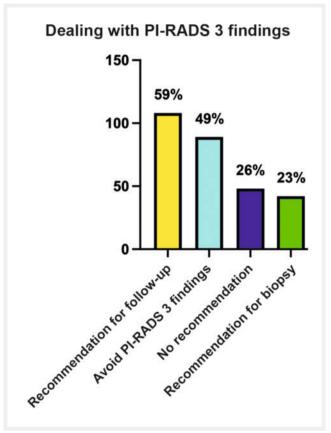


Quality

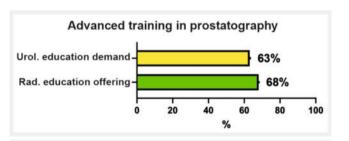
The majority generally used contrast media for prostate MRI (59%, 108/182; primarily with contrast media: 34%, 61/182; primarily without contrast enhancement: 7%, 13/182, general without contrast enhancement: 0%). The handling of PI-RADS-3 findings was recommended by 59% (108/182) for follow-up, 23% (42/182) for biopsy, 49% (89/182) tried to avoid PI-RADS 3 findings, 26% (48/182) gave no specific recommendation (▶ Fig. 2). In 47% (86/182) cases were discussed in an interdisciplinary tumor board, in 44% (80/182) interdisciplinary exchange occurred rarely, and in 12% (21/192) no interdisciplinary exchange occurred. On a scale of 0−100%, where 0% corresponds to insufficient/low and 100% to optimal/high, the radiological offer of continuing education on prostate MRI was given as an average of 68% (±20%). The need for further training in urology was rated at 63% (±19%) (▶ Fig. 3).

Importance

When asked about the indication for mpMRI of the prostate, the most common answer was "primary indication" with 98% (178/182), followed by "active surveillance monitoring" with 83% (151/182), "secondary indication" with 82% (150/182), "inclusion in active surveillance" with 71% (130/182), "recurrence diagnostics" with 71% (129/182), "patient/referrer request" with 69% (126/182), "local staging" with 55% (100/182), and "screening" with 19% (34/182) (▶ Fig. 4). On a scale of 0−100%, where 0 is easy and 100% is difficult, the ability to use the PI-RADS v2.1 system was rated on average with 31% (±19%). On a scale of 0−100%, where 0 corresponds to "not very clear" and 100% to "very clear," the significance of prostate MRI was rated on average at 71% (±15%). On a scale of 0−100%, where 0 corresponds to low and 100% to high, the clinical relevance was rated on average

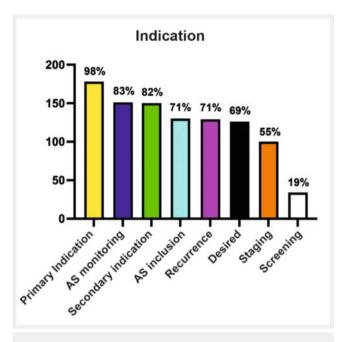


▶ Fig. 2 Number of responses regarding management of PI-RADS 3 cases. column 1: follow-up, column 2: biopsy, column 3, avoidance of PI-RADS 3 lesions, column 4: no recommendation.

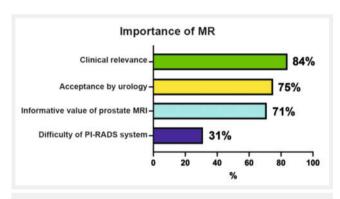


► Fig. 3 Estimated demand and offering of professional training in prostate MRI in percent.

at 84% (±16%) and the acceptance in urology at 75% (±21%) (▶ Fig. 5). In 4% of the respondents, conspicuous findings were knowingly biopsied using MR/US fusion biopsy in less than a quarter of the cases, in 6% in less than half of the cases, in 18% in more than half, in 48% in more than three quarters, and in 24% the biopsy rate was unknown (7, 11, 33, 88, 43). When asked about the biggest problems with mpMRI of the prostate, the most common answer was "lack of clinical feedback" with 59% (108/182), followed by "lack of clinical information" with 42% (77/182), "long examination time" with 35% (63/182), "insufficient diagnostic experience" with 22% (40/182), "insufficient image quality" with 12% (22/182), "poor MR-targeted biopsy" with 9% (16/



▶ Fig. 4 Number of responses regarding prostate MRI indication.



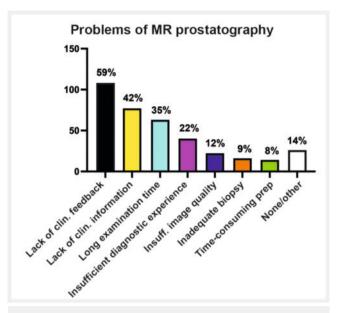
▶ Fig. 5 Estimated significance of prostate MRI in percent.

182), "complex patient preparation" with 8% (14/182), and "none of the answers" in 14% (26/182) (\triangleright Fig. 6).

Discussion

The broad distribution of questionnaire returns from all 10 post-code zones in Germany with a high total examination volume of approximately 50,000 MRIs per year with good nationwide availability demonstrated the representativeness of the survey (**> Fig. 1**). However, with an approximate incidence of 65,000 new cases per year, the assumed need for MRI examinations of the prostate still significantly exceeds this number.

Even though more than half of the respondents in the current survey were employed in a specialist practice or a medical care center, this was only approx. 14% of the practices/medical care centers in Germany (in 2023). In contrast, over 60% of university hospitals and almost 50% of maximum care providers were represented. It can be assumed that currently, larger clinics/centers



▶ Fig. 6 Number of responses regarding problems of prostate MRI.

perform the majority of prostate MRIs. In line with this result, participants from 10 university hospitals and maximum care clinics produce more than 600 mpMRIs per year. Since a high number of examinations and thus experience of the examiners is necessary for adequate quality, it seems sensible to provide care for complex cases and possibly borderline findings in active surveillance in larger centers.

According to current knowledge, primary diagnostics in routine cases can be performed well on an outpatient basis in smaller institutions. In the present survey, the absolute majority of respondents (86%) had a special certification from the DRG in MR prostatography (Q-certificate).

The majority of respondents consider the standard PI-RADS system (v2.1) to be relatively easy to use. The trend of increasing, broad adoption of the standardized system and the high level of quality certification indicate a significantly increased homogeneity of acquisition and reporting compared to previous surveys. In line with this, not only are the numbers of MRI scans of the prostate increasing, with at least 150–300 cases per year in more than 2/3 of the responses in this survey, but the clinical relevance of prostate MRI and its acceptance in urology are now also assessed as significantly better (**Fig. 5**). The biggest challenges of prostate MRI are seen in insufficient interdisciplinary exchange and, above all, insufficient billing.

The optimization of the PI-RADS in the first and second versions has led to a significantly improved congruence of the results between different radiologists in the current version (v2.1) [10, 11]. The introduction of an image quality rating scale (PI-QUAL) by Giganti et al., currently in version 2 [12, 13], has also led to an increasing homogeneity of image acquisition and optimization of mpMRI for the prostate by standardizing the evaluation criteria when the recommended technical parameters were met [14]. In line with this, in the current survey, a higher proportion of respondents (over 60% in total) used a magnetic field strength of 3 Tesla (T), while in a 2015 survey this figure was 28% [6]. Although ade-

quate diagnostic image quality can be achieved with 1.5 T and 3 T, the higher magnetic field strength often has qualitative advantages, especially in diffusion imaging and staging [15]. Only one participant indicated a lower (different) magnetic field strength, which, however, does not meet the quality requirements of PI-RADS v2.1.

The inherent diagnostic potential and the increasing improvement of mpMRI of the prostate has led to the examination being established not only in combination but also as an independent test procedure alongside PSA value and digital rectal examination, which finds a relevant proportion of clinically relevant carcinomas even with low PSA values [16]. Clinically relevant higher-grade carcinomas can almost always be visualized with appropriate MRI quality and experience [17]. Accordingly, in the current survey, the informative value of MRI of the prostate was now rated as high, whereas in the regional survey among urologists and general practitioners in 2018 it was only rated as moderate to low [9]. At that time, the physicians surveyed saw the main indication for prostate MRI as secondary diagnostics after a negative biopsy, and only less than a third of the patients surveyed at that time actually received an MRI after a negative biopsy. In the current survey, almost all radiologists stated that they use prostate MRI as the primary indication before biopsy, thus reflecting the now scientifically proven diagnostic capabilities of the examination and its increasing anchoring in the corresponding guidelines. Other widely used indications in the current survey were secondary indication, inclusion and monitoring in active surveillance and for recurrence diagnostics, which represents a significant expansion of the areas of application compared to the 2015 survey (> Fig. 4). The application for local staging was less represented, although valuable information for the selection of the appropriate treatment procedure can be acquired here [18, 19]. According to the survey results, prostate MRI is used less frequently in screening, which is in line with current recommendations in the guidelines [1, 2].

The survey shows that the procedure is primarily carried out in accordance with current recommendations using contrast media. The diagnostic added value of standard contrast media administration in prostate MRI has long been discussed. While on the one hand, for example, in the international, multicentric, prospective PRIME study, a comparable performance in native bi-parametric examination (bpMRI) with the advantages of shorter examination time and fewer adverse side effects is reported, other studies show an advantage in sensitivity and specificity with contrast media, especially when the examiners are less experienced [20, 21, 22]. Repeated administration of contrast media could probably be dispensed with, particularly in follow-up examinations, for example, as part of active surveillance or after a negative biopsy.

The respondents saw the greatest challenges of the study as being, on the one hand, a lack of clinical information, which is essential for adequate diagnosis and particularly for recommendations for action based on the MRI results [7]. On the other hand, a lack of clinical feedback prevents important, targeted self-control and optimization of findings. Accordingly, more than half of the radiologists stated that interdisciplinary exchange regarding prostate MRI rarely or never takes place. Direct (possibly personal) contact and exchange with the respective referring physicians

about possible feasibility and the advantages of feedback for quality improvement would be one possible solution. Mandatory feedback of histological results by urology, for example, as part of the reimbursement, could also represent an intrinsic control for success and quality improvement. In order to further optimize the diagnostic chain, it is also considered useful to expand the range of training courses on prostate MRI (MR prostatography) in urology, as well as to expand fusion biopsy, although this would result in significantly increased costs due to the complex hardware and software components.

Almost half of the respondents stated that they wanted to avoid unclear findings (PI-RADS 3). The tendency to achieve a clear discriminatory power in the MRI results is desirable and is proven with increasing experience [20, 23]. The PI-RADS distribution in one's own collective can also be used for quality control (e.g. less than 25% PI-RADS-3 findings). In addition, the avoidance of results in the "grey area" can be an expression of the lack of communication or option for detailed, individual interdisciplinary discussion of the findings. However, a forced avoidance of PI-RADS category 3 does not seem to be productive. In some cases, benign biological processes such as prostatitis or (atypical) stromal hyperplasia can complicate the assessment and mask carcinomas, but also incipient degeneration and smaller carcinomas can only be reliably diagnosed by imaging over a period of time, which a PI-RADS-3 assessment would or could cover [24, 25]. Here too, detailed, possibly mandatory clinical information is helpful. Information such as whether a recent negative biopsy, low PSA density or known prostatitis reduces the risk of the presence of a clinically relevant carcinoma. However, there are currently no uniform recommendations regarding the clinical relevance and precise management of these findings, e.g. taking into account other parameters such as PSA density or AI applications [26].

More than a quarter of the respondents stated that they would not give any recommendations for action to the treating urologist based on these findings. In general, radiological recommendations underline the clinical added value of the examination, but in some cases intervention in the therapeutic course may be undesirable for some referring physicians. Suspicious MRI findings should receive a targeted biopsy (S3LL). In the current survey, less than half of the radiologists stated that this is actually done in more than three-quarters of cases using the most advanced biopsy variant, fusion biopsy [27, 28]. An expansion of fusion biopsy and optimized interdisciplinary cooperation are also desirable here. While the current version of the S3 guideline on prostate cancer recommends a biopsy in cases of PI-RADS-3 findings, follow-up of such lesions in specialized centers also seems justified to avoid overtreatment [29].

Ninety percent of respondents considered it problematic that mpMRI of the prostate is not adequately billable. This circumstance prevents the examination from being available in a manner that is appropriate to its clinical value, which is also reflected in the fact that almost two-thirds of patients were able to offer a prostate MRI within at least 3 to 6 weeks and the majority were only able to offer it after more than 6 weeks. Various professional associations have long campaigned for admission to the health insurance catalog of services, and corresponding requests have

been submitted to the Federal Joint Committee. At the same time, there are now a large number of direct health insurance contracts that enable service providers to be directly remunerated by the majority of company health insurance providers. This approach accelerates the development of a broad range of options to meet the high demand for prostate MRI examinations (MR prostatographies), but is not subject to statutory health insurance regulation.

This study has limitations. The opinion given reflects radiological responses only. For a comprehensive description of the care conditions, the opinion of the treating urologists and, if relevant, the patients would be desirable. Although the questionnaire was sent to all members of the DRG and the BDR, a disproportionate number of radiologists who have already dealt extensively with prostate MRI per se and hold special DRG certification in MR prostatography (Q1/Q2 certificate) may have responded, which may result in a certain bias. Resident physicians and radiologists who are less involved with the topic are underrepresented in this survey. Nevertheless, the survey reflects very well the current Germany-wide importance and availability of the method, primarily from the perspective of those who deal with the methodology. The high level of new certifications over the last few years and the overall high level of satisfaction with the radiological training program show that the previous qualitative training initiatives on prostate MRI have proven their worth. A targeted training of resident physicians to enable them to deal with the topic at an early stage and possibly attain the first level of certification seems to make sense.

In summary, prostate MRI is considered in this survey to be significantly more clinically relevant and meaningful due in part to increasing standardization and optimization, with significantly improved acceptance by urology. In keeping with these results, it is being incorporated increasingly in national and international guidelines. The field of application areas has also expanded significantly. The present radiology survey shows a need for advanced training in MRI prostate diagnostics in urology. Furthermore, the coverage by MR/US fusion biopsy is still insufficient. The biggest problems with MRI of the prostate are lack of interdisciplinary exchange, which makes further quality improvement difficult, and inadequate billing, which prevents more widespread availability and potentially improved quality outside dedicated centers.

Conflict of Interest

The authors declare that they have no conflict of interest.

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