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Impact of Prostate Urethral Lift Device on Prostate MR Image Quality

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Abstract

Introduction: Prostatic urethral lift with UroLift® is a minimally invasive approach to treat symptomatic benign prostatic hypertrophy. This device causes artifacts on prostate MR images. Our aim was to evaluate the impact of artifact on prostate MR image quality.

Material and Methods: Single-center, retrospective review of patients with UroLift® who subsequently had prostate MRI. Two readers graded UroLift® artifact on each pulse sequence using a 5-point scale (1. Non-diagnostic; 5. No artifact). Prostate Imaging Quality scores were assigned for the whole dataset. The volume of gland obscured by artifact was measured. Linear and logistic regression models were used to identify predictors of poor image quality.

Results: 37 patients were included. Poor image quality occurs more in the transition zone than the peripheral zone (15% vs 3%), at base/mid regions vs the apex (13%, 9% and 5%, respectively) and on diffusion-weighted images (DWI) vs T2-weighted (T2WI) and dynamic contrast-enhanced (DCE) sequences (27%, 0.3%, 0%, respectively) ($p < 0.001$). Suboptimal image quality (i.e., PI-QUAL score < 2) was found in 16-24% of exams. The percentage of gland obscured by the UroLift® artifact was higher on DWI and DCE sequences than T2WI (32%, 9%, and 6%, respectively; $p < 0.001$).

Conclusion: UroLift® artifact negatively affects prostate MR image quality with greater impact in the mid-basal transition zone, obscuring a third of the gland on DWI. Patients considering this procedure should be counseled on the impact of this device on image quality and its potential implications for any image-guided prostate cancer workup.

Introduction

Lower urinary tract symptoms due to benign prostatic hyperplasia (BPH) are prevalent in the aging male(1). Among non-pharmacological options for managing symptomatic BPH, minimally invasive techniques offer the advantage of ambulatory, rapid recovery, and improved safety profiles when compared to transurethral resection of the prostate (TURP) (1). Specifically, the prostatic urethral lift (PUL) procedure using UroLift® (Neotract Inc, Pleasanton, Ca, USA) not only offers durable relief of symptoms but does so without compromising sexual function (2). When compared to standard TURP, PUL resulted in earlier recovery and higher rates of both ejaculatory and erectile function (3). Despite a higher 2-year retreatment rate than standard TURP, PUL's benefits in preserving sexual functions have made this technique a more favorable alternative for potent patients (3).

The UroLift® device consists of inner stainless-steel and outer nitinol (nickel titanium) tabs connected by a monofilament. Under cystoscopy, these tissue-retracting implants are placed along the anterolateral aspect of the prostatic urethra at the 2 and 10 o'clock positions (4). Once deployed, the device displaces the lateral lobes of the prostate (5). Generally, four to six tabs are placed depending on the degree and length of prostatic urethral obstruction (6).

UroLift® is labeled as magnetic resonance (MR) conditional, and according to the manufacturer, patients can be safely scanned immediately after placement up to 3 Tesla with a spatial field gradient of up to 1,500 Gauss/cm (15 T/m), and a maximum MR system-specific absorption rate of 4 W/kg for 15 minutes of continuous scanning (7). While the monofilament connecting both tabs is not visualized on MRI, both metal tabs create signal loss and geometrical distortion of the signal originating from adjacent structures (6). To the best of our knowledge, the impact of these susceptibility artifacts on prostate MR image quality and readability has not been investigated in a clinical setting. As patients are now increasingly undergoing prostate MRI for pre-biopsy triage and prostate cancer treatment planning, the impact of Urolift® on image quality remains an area that needs to be explored.

In this study, we aimed to qualitatively and quantitatively evaluate the impact of the artifact caused by Urolift on prostate MR image quality.

Material and Methods

2.1 Patient population

This single-center retrospective study was compliant with the Health Insurance Portability and Accountability Act. The local Institutional Review Board approved this study with a waiver for informed consent due to its retrospective nature.

Adult patients with UroLift® implants who underwent prostate MRI for prostate cancer workup were identified in our Institution's prostate MRI database. Patients were excluded from this study if they had concomitant brachytherapy seeds or fiducial markers for radiation treatment in the prostate.

2.2 Prostate MR imaging protocol and quality assessment

Prostate MRI exams were performed at 3T and 1.5T scanners without endorectal coil using acquisition parameters compliant with Prostate Imaging Reporting and Data System version 2.1 (PI-RADS v2.1) and included T2-weighted images (T2-WI), diffusion-weighted images (DWI) with apparent diffusion coefficient (ADC) maps, and dynamic contrast-enhanced (DCE) sequences (8).

Qualitative assessment of prostate MR images was performed by two radiologists with 9 and 3 years of experience in prostate MRI interpretation. The prostate was divided into twelve areas according to the zones (peripheral zone [PZ] and transition zone [TZ]), regions (apex, mid, and base), and laterality (right and left). Both readers independently graded the impact of the UroLift® artifacts on the ability to interpret T2-WI, DWI/ADC, and DCE images in each of those areas (i.e. thirty-six areas per prostate MR exam) using a 5-point scale: 1. Non-diagnostic impairment; 2. Severe impairment; 3. Moderate impairment; 4. Mild impairment; 5. No impairment. Areas that received an artifact score ≤ 2 were considered to have poor image quality. Subsequently, the readers rated the entire MR exams using the Prostate Image Quality (PI-QUAL) system, a standardized assessment method that permits readers to determine if the MR exam is of adequate diagnostic quality to rule in and rule out the presence of clinically significant cancer (**Table 1**) (9). Exams that received a PI-QUAL score ≤ 2 are considered to have insufficient diagnostic quality (i.e., it is not possible to rule in and rule out clinically significant cancer). One of the study members (F.G), who participated in the design of PI-QUAL, provided a training session to both readers prior to scoring the exams.

Quantitative assessment of the artifact on the MR images was performed by a third reader with 10 years of experience with prostate MRI interpretation. The volume of the artifact that obscured or severely distorted the prostate was measured by contouring the artifact on each image using 3-dimensional segmentation software (DynaCAD, Invivo, Philips, Gainsville, FL). These measurements were performed on axial T2-WI, ADC, and DCE images. The whole gland volume was measured by segmenting the gland on T2-WI using a semi-automated tool available in the same software. The percentage of the gland volume affected by the artifact was calculated as follows: (artifact volume / whole gland volume) x 100.

2.3 Statistical Analysis

For the qualitative assessment of images, logistic regression models were used to assess the impact of zone, side, region, MRI sequence, gland volume and number of UroLift® tabs on the probability of poor image quality. The results were pooled across readers. For the quantitative assessment of images, a linear regression model was used to assess the impact of MRI sequence and site on the proportion of the gland obscured by artifact. More detail on outcome variables for both qualitative and quantitative analysis are found in Supplementary Table 1. Generalized estimating equations were used to account for the clustered nature of the data in both analyses. A significance level of 0.05 was applied.

Interreader agreement on poor image quality for individual pulse sequences (i.e. artifact score 1-2 vs. 3-5) and on inadequate diagnostic quality for the entire exam (PI-QUAL scores 1-2 vs. 3-5) was measured using Cohen's Kappa and interpreted according to the following definition: 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41– 0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement (10). All analyses were performed in R version 4.1.1. (11) In all models, generalized estimating equations were used to account for the clustered nature of the data (multiple observations per patient). A significance level of 0.05 was applied to all hypothesis tests.

Results

Forty patients with UroLift® device placed between 6/2016 and 3/2021 had subsequent prostate MRI performed between 6/2018 and 7/2021. Of these, three patients were excluded due to brachytherapy seeds (n = 2) or fiducial markers for radiation therapy (n = 1). Of the 37 patients included in the study, three DWI/ADC maps were excluded from the analysis due to artifacts from hip implants. Table 2 has a summary of patient's characteristics. The median number of UroLift® tabs per patient was 4 (range 3-7).

3.1 Qualitative assessment

Artifacts caused by UroLift® were identified in all exams. Overall, the readers gave a score indicating at least moderate UroLift® artifact in 19% (493/2640) of the areas they graded, and poor image quality in 9% (243/2640) of the areas (**Fig.1**). The TZ was more likely to be affected by poor image quality compared to the PZ (15% vs 3%, $p < 0.001$). The base and mid regions were more affected than the apex (13% and 9% vs 5%, respectively; $p < 0.001$). DWI/ADC were more affected than T2-WI (27% vs 0.3%; $p < 0.001$) and DCE (27% vs 0%; $p < 0.001$). The left and right sides were affected similarly (9.4% vs 9%, $p = 0.516$). Assessment of imaging characteristics as predictors of poor image quality, including odds ratios is shown in **Table 3**. Both readers agreed on the presence of poor image quality secondary to the UroLift® artifact in 95% of the graded areas (1247/1320) (Cohen's kappa 0.67). Reader 1 indicated poor image quality more often than reader 2 (10% vs 8%).

At the exam level, the readers gave a score indicating poor diagnostic quality for 20.3% (15/74) of the exams. The number of UroLift® tabs was associated with a statistically significant increased risk of PI-QUAL ≤ 2 (odds ratio [OR] 2.5, 95% confidence interval [CI] 1.13-5.70, p 0.024), while the gland volume was not associated (OR 0.99, 95% CI 0.88-1.12, p 0.877). The readers agreed on PI-QUAL scores 1-2 vs. 3-5 in 81% (30/37) of the patients (Cohen's kappa 0.42). Reader 1 indicated insufficient diagnostic quality more than reader 2 (24% vs 16%)(**Fig. 2**). None of the MR exams were deemed to have all sequences with optimal diagnostic quality (i.e., PI-QUAL 5).

3.2 Quantitative assessment

A summary of the proportion of the gland obscured by the artifact on quantitative assessment stratified by sequence is shown in **Table 4**. On average, a higher percentage of the gland was obscured by UroLift® artifact on ADC maps (mean: 32%) and DCE images (mean: 9%) than on T2-WI (mean: 6%) ($p < 0.001$). On linear regression, sequence assessment was an independent predictor of the proportion of gland obscured by artifact (ADC vs T2-WI, mean difference 26%, 95 CI 22-31%; ADC vs DCE, mean difference 23%, 9% CI 18-28%, $p<0.001$ for both comparisons). Examples of UroLift® artifact on image quality are shown in **Fig. 3-5**.

Discussion

In this study, we found that artifacts caused by the Urolift® device negatively affected prostate MRI image quality, with a greater impact in the mid-basal TZ. The artifact caused by the device was more pronounced on DWI compared to T2-WI and DCE images, obscuring nearly a third of the prostate on ADC maps.

Image quality is one of the determinants of the diagnostic capability of MRI for prostate cancer detection (12). High-quality images are associated with lower rates of indeterminant MRI results (i.e., PI-RADS score 3) and higher confidence of readers to rule in and rule out the presence of clinically significant disease (13). The PI-RADS guidelines provided standards for imaging acquisition, but adherence to those standards is not enough to guarantee high-quality images (14). This is because MR images can be degraded by artifacts, such as the susceptibility artifacts caused by metallic hip implants (15). Techniques to reduce the artifacts from metallic implants placed outside of the prostate have been described (16), but they have not been shown to eliminate the artifacts from implants inside of the prostate (e.g., brachytherapy seeds and fiducial markers for radiation therapy), and therefore they are unlikely to be useful in patients with UroLift® (**Fig. 4**).

The artifacts caused by UrolLift® had a greater impact on the TZ, which harbors approximately 20-25% of prostate cancer (17). According to PI-RADS version 2.1, T2-WI remains the dominant sequence for the evaluation of nodules in the TZ, but a greater role was given to DWI/ADC for the characterization of TZ abnormalities in the revised scoring system (8,18). The percentage of the prostate volume obscured by the UroLift® artifact on T2-WI was

relatively small, 6% on average. However, the impact on DWI/ADC was much more substantial, 32% on average, raising concerns about the ability of readers to appropriately score the lesions in patients with UroLift®. In fact, readers in this study found that the images were of poor diagnostic quality (i.e., PI-QUAL ≤ 2) in 16-24% of the exams. For comparison, only 5% of the exams received similar scores in the PRECISION trial, the pivotal multicenter, randomized clinical trial that demonstrated the superiority of MRI–targeted biopsy over standard transrectal ultrasound-guided biopsy for clinically significant prostate cancer detection (19). It is likely that, UroLift® related susceptibility artifacts can hinder lesion detection, which is a critical step in the MRI-guided localized prostate cancer diagnosis quality cascade (20). Simply, the susceptibility artifacts can mask the lesion visibility and a clinically significant cancer can remain undiagnosed in the TZ, which is already documented to be undersampled using traditional ultrasound-guided systematic biopsy approach.

The inter-reader agreement on poor image quality using the artifact score was substantial (κ 0.67), but only moderate using PI-QUAL (κ 0.42), which likely reflects the more nuanced approach of the PI-QUAL system. Interestingly, more cases were found to have poor image quality by the more experienced reader, perhaps due to greater awareness of the implication of image quality in the diagnosis of prostate cancer by that reader.

Beyond the assessment with PI-RADS scores, the quantitative information obtained from ADC maps is also compromised by the susceptibility artifacts. ADC measurements have been shown to inversely correlate with prostate cancer grade groups and can be helpful in discriminating benign from malignant lesions (21,22). Additionally, UroLift® related artifacts can diminish the capability of tumor burden estimation for focal therapy planning, and its presence is a contraindication in many centers for focal therapy. As such, while Urolift is touted at preserving sexual function, it may in the long run, exclude patients from being considered for a treatment option for prostate cancer (focal therapy) that aims to optimize both sexual and functional outcomes. Another concern raised by our findings is the potential impact of UroLift® on staging. Specifically, poor image quality was more common at the base and mid portions of the prostate (19% and 14%), which are regions that interface with the bladder neck and seminal vesicles.

Based on the finding of our study, we recommend that patients with UroLift® should be offered a multiparametric rather than a biparametric MR exam with only T2-WI and DWI/ADC, since DCE MRI, which appears to be impacted least by UroLift®-associated susceptibility artifacts among other pulse sequences, can represent a safety net (**Fig. 5**). Additionally, it is important to highlight that studies with a PI-QUAL score < 3 may have insufficient diagnostic quality to rule out all significant cancers, and in this setting, a systematic biopsy may not be avoided in patients with negative MRI results. Lastly, for patients considering a prostatic urethral lift procedure with UroLift® who have risk factors for prostate cancer such as a positive cancer history in their families or elevated serum prostate-specific antigen levels, a baseline MRI should preferentially be obtained prior to the procedure, as previously suggested (23).

Our study had some limitations. It is a single-center, retrospective analysis of images, and the correlation between the severity of the artifacts and MRI accuracy for prostate cancer detection and staging was not evaluated due to the relatively small cohort size. Nevertheless, our results underline the need for future studies with a larger number of patients to determine the actual impact of UroLift® on the workup for prostate cancer using MRI-guided pathway. The impact of the UroLift® device on image quality of other modalities being considered alternatives to MRI for prostate cancer detection, including micro-ultrasound, multiparametric ultrasound, and prostate-specific membrane antigen positron emission tomography has not been reported and should also be explored in future research.

In conclusion, based on our single-center case series, the UroLift® device can cause significant artifacts on prostate MRI that can result in poor image quality and can limit diagnostic capabilities. Patients considering the prostatic urethral lift procedure for symptomatic BPH should be counseled by urologists about the possible impact of UroLift® device on prostate MR image quality and its potential implications on MRI-guided prostate cancer workup.

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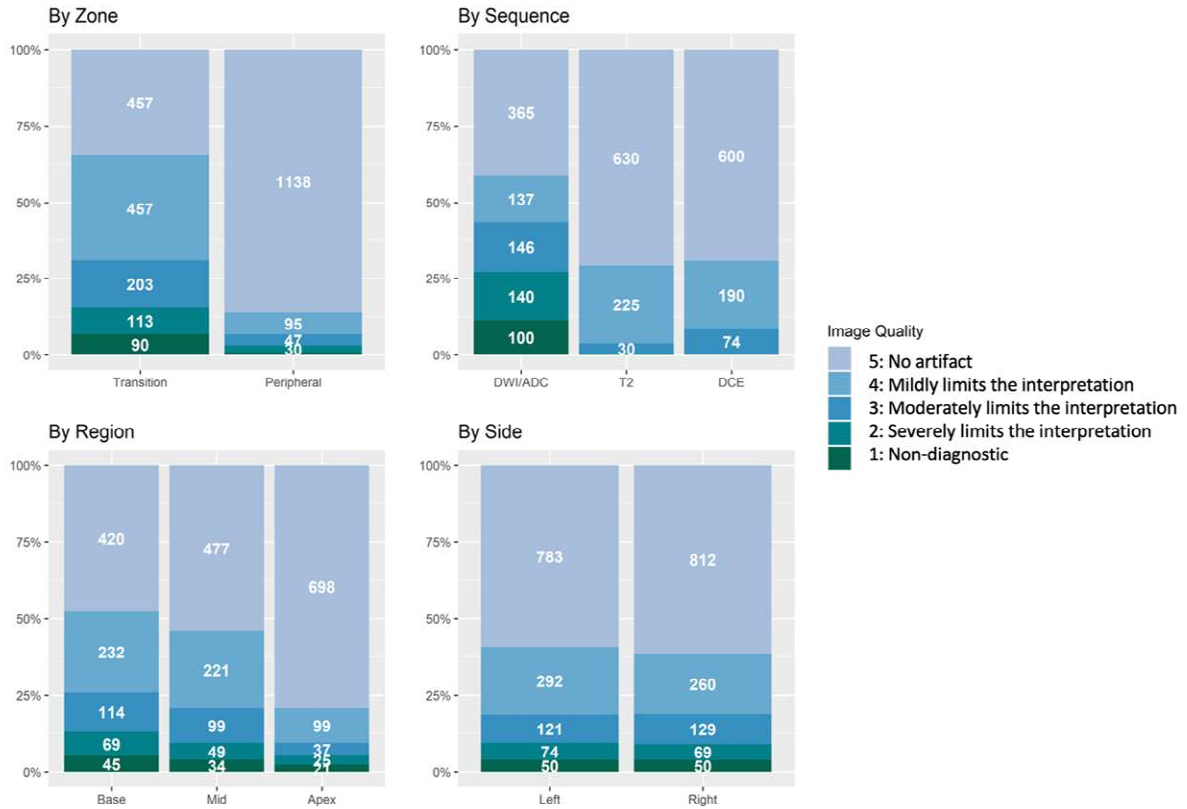
Fig. 1 – Distribution of image quality scores on qualitative assessment, stratified by zone, sequence, region, and side. Results pooled across readers.
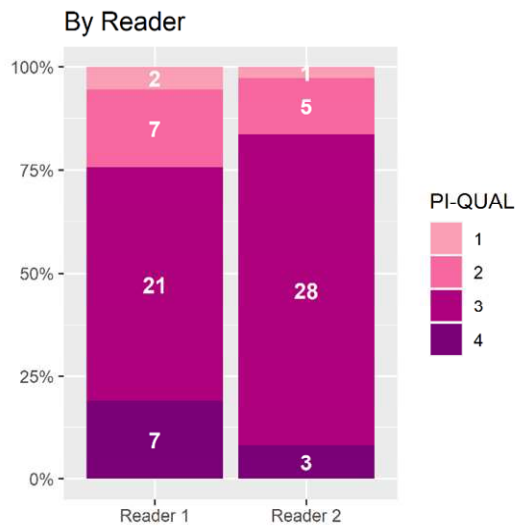
Fig. 2 – Distribution of PI-QUAL scores for overall image quality, stratified by the reader.
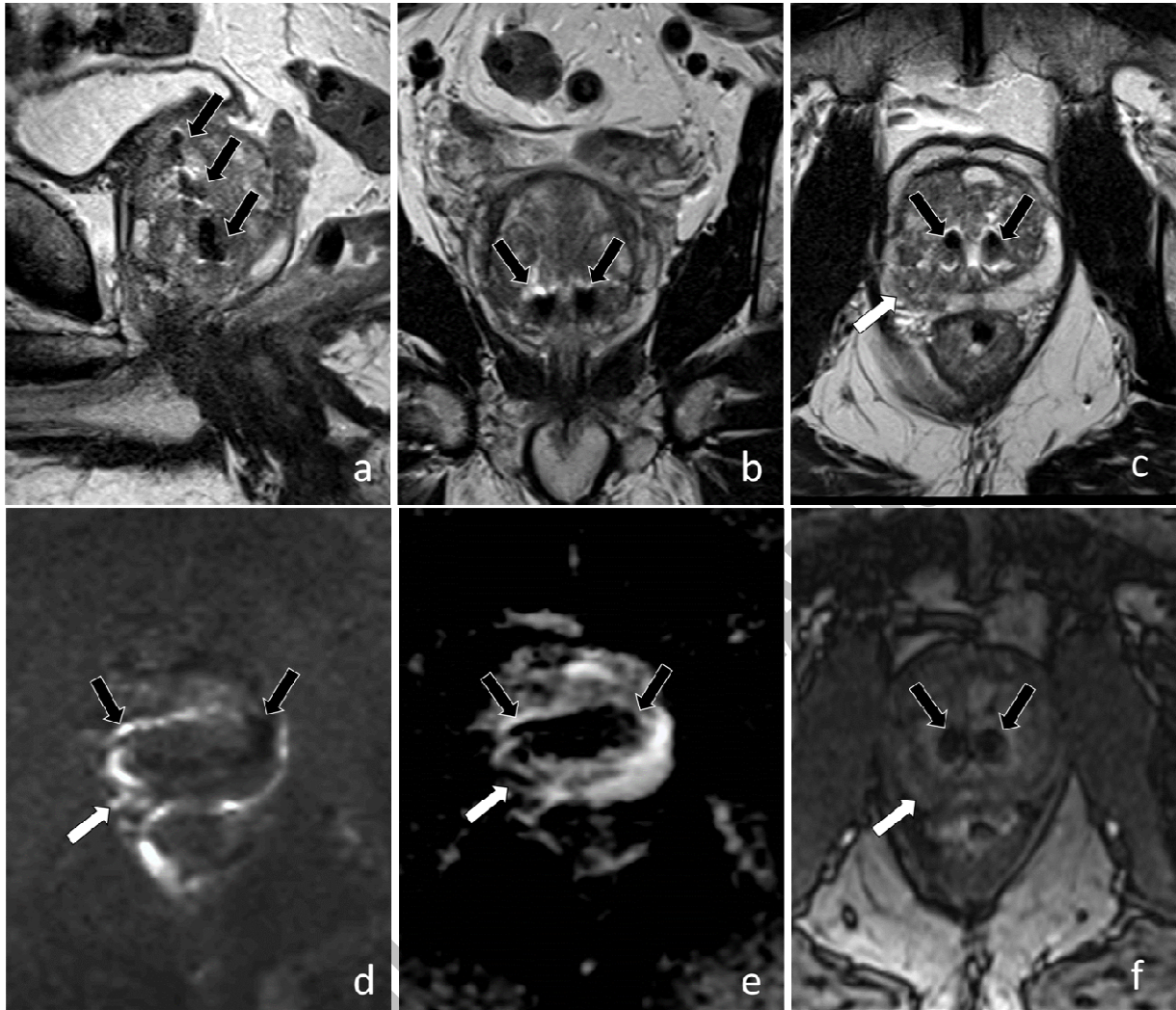
Fig. 3 – 68-year-old man with a history of prostatic urethral lift procedure and elevated PSA (PSA 6.39 ng/ml, PSA density 0.08), with no prior prostate biopsy. Sagittal, coronal and axial T2-weighted images show susceptibility artifacts from the UroLift® device (black arrows, a, b and c, respectively) obscuring 3% of the gland volume. The device caused a large area of signal void on the diffusion-weighted image and apparent diffusion coefficient map that obscures 38% of the gland (black arrows, d and e, respectively). On T1-weighted dynamic contrast-enhanced images, the artifact obscures 6% of the gland volume (black arrow, f). Both readers gave a PI-QUAL score of 3 for the exam. A 0.8 cm focal heterogeneous hypointense lesion was identified on T2-weighted images in the right mid posterolateral peripheral zone (white arrow, c). The signal in the corresponding location of the lesion on the axial diffusion-weighted image and apparent diffusion coefficient map is markedly distorted (white arrows, d and e). No corresponding lesion with early arterial enhancement was identified on the dynamic contrast-enhanced T1-weighted image (white arrow, f). The lesion was scored PI-RADS 3, and an MRI-guided biopsy of the lesion revealed benign prostatic tissue. Grade group 1 cancer was identified on systematic biopsy in the left mid gland (involving 55% of 1 core and measuring 8 mm).
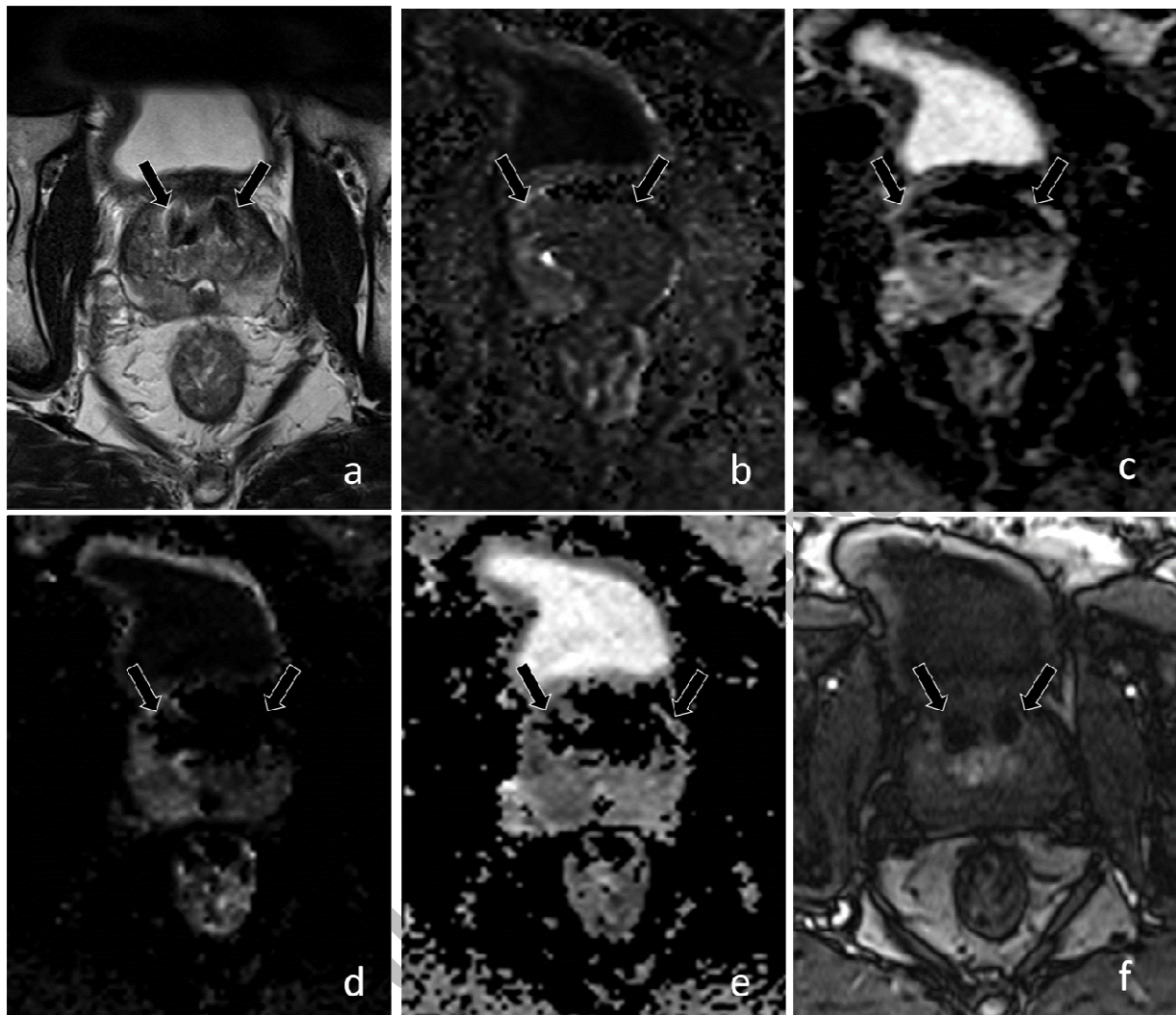
Fig. 4 – 65-year-old patient with a history of prostatic urethral lift procedure and elevated PSA (most recent PSA 4.86 ng/ml, PSA density 0.09), with prior negative prostate biopsy. Axial T2-weighted image shows susceptibility artifacts from the Urolift® device in the transition zone at the mid and base segments of the prostate (black arrow, a). The UroLift® artifact causes severe distortion of the signal in the anterior transition zone of the prostate on the axial diffusion-weighted image and apparent diffusion coefficient map using a conventional echo-planar technique (black arrows, b, and c, respectively). Axial diffusion-weighted image and apparent diffusion coefficient map obtained using a readout-segmented echo-planar diffusion method (RESOLVE, Siemens) that is used to reduce susceptibility artifact does not show a substantial improvement in the volume of the prostate obscured by the UroLift® artifact. The exam was scored as PI-RADS 2 and no biopsy was performed subsequently.
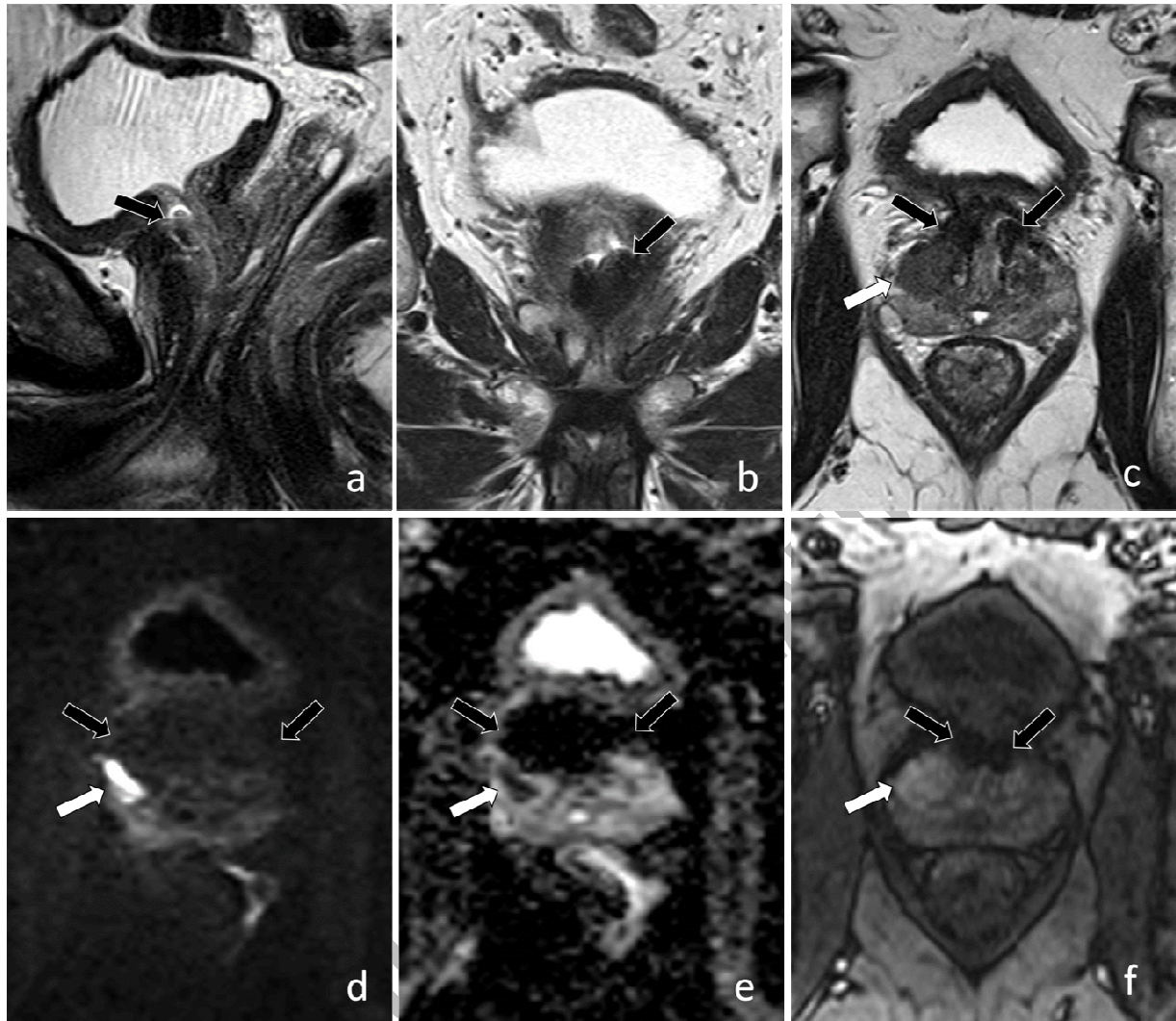
Fig. 5 – 73-year-old man with a history of prostatic urethral lift procedure and elevated PSA (most recent PSA 10.9 ng/ml, PSA density 0.32), with no prior prostate biopsy. Sagittal, coronal, and axial T2-weighted images show susceptibility artifacts from the UroLift® device (black arrows, a, b and c, respectively) obscuring 6% of the gland volume. The device causes a large area of signal void on the diffusion-weighted image and an apparent diffusion coefficient map that obscures 47% of the gland. On T1-weighted dynamic contrast-enhanced images, the artifact obscures 8% of the gland volume. Both readers gave a PI-QUAL score of 3. A 2 cm focal hypointense lesion was identified on T2-weighted images in the right mid anterior peripheral zone and transition zone (white arrow, c). In the same location of the abnormality seen on T2-weighted images, there is hyperintense signal on diffusion-weighted image and hypointense signal in the apparent diffusion coefficient map, but with marked distortion of the signal (white arrow, d and e). On T1-weighted dynamic contrast enhanced image, the lesion demonstrates early arterial enhancement (white arrow, f). The final PI-RADS score assigned was 5. An MRI-targeted biopsy of the area identified prostate adenocarcinoma grade group 3. Multiple cores were positive for grade group 1 cancer on systematic biopsy of all sextants.

PI-QUAL score	Criteria	Clinical implications
1	All mpMRI sequences are below the minimum standard for diagnostic quality	It is NOT possible to rule in or rule out all significant lesions
2	Only one mpMRI sequence is of acceptable diagnostic quality	
3	At least two mpMRI sequences taken together are of acceptable diagnostic quality	It is possible to rule in all significant lesions It is NOT possible to rule out all significant lesions
4	Two or more mpMRI sequences are independently of optimal diagnostic quality	It is possible to rule in and to rule out all significant lesions
5	All mpMRI sequences are of optimal diagnostic quality	

Table 1 – Assessment of the diagnostic quality of prostate MRI using the PI-QUAL score
Source: ref 9. Abbreviation: mpMRI: multiparametric magnetic resonance imaging

Total number of patients	37
Age at time of MRI (median (Q1, Q3))	68.0 [64.0, 73.0]
MRI indication (%)	
Active Surveillance	7 (18.9)
Staging	4 (10.8)
Suspected prostate cancer, biopsy naïve	7 (18.9)
Suspected prostate cancer, prior negative biopsy	19 (51.4)
Prior biopsy result (%)	
GG1	6 (16.2)
GG2	3 (8.1)
GG3	2 (5.4)
Negative	19 (51.4)
No prior biopsy	7 (18.9)
PSA at time of MRI (median [Q1, Q3))	6.7 [4.8, 11.7]
Urolift placement timing (%)	
Before prostate cancer diagnosis	12 (32.4)
After prostate cancer diagnosis	5 (13.5)
No prostate cancer diagnosis	20 (54.1)
Number of MRI lesions (%)	
0	21 (56.8)
1	13 (35.1)
2	2 (5.4)
3	1 (2.7)
Highest PI-RADS score (%)	
1	1 (2.7)
2	21 (56.8)
3	5 (13.5)
4	6 (16.2)
5	4 (10.8)
Lesion location (%)	
No lesion	22 (59.5)
Peripheral Zone	11 (29.7)
Peripheral and transition zone	2 (5.4)
Transition zone	2 (5.4)
Post-MRI biopsy result (%)	
ISUP-GG1	4 (10.8)
ISUP-GG2	4 (10.8)
ISUP-GG3	2 (5.4)
ISUP-GG5	1 (2.7)
Negative	8 (21.6)

No post MRI biopsy	16 (43.2)
Unknown	2 (5.4)
Biopsy method (%)	
MRI/ultrasound fusion guided biopsy combined with systematic sextant biopsy	10 (27)
Systematic sextant biopsy	10 (27)
Digital rectal exam at the time of MRI (%)	
Negative	30 (81.1)
Not available	5 (13.5)
Positive	2 (5.4)

Table 2 – Summary of patient characteristics.

*Information available for 29 of the 37 patients.
Abbreviations: ISU-GG: International Society of Uropathology Grade Group

Table 3 – Assessment of various image characteristics as predictors of poor image quality on qualitative assessment.* Results pooled across readers. Odds ratio (OR) > 1 indicates increased odds of poor image quality; OR < 1 indicates decreased odds of poor image quality. Results are from univariable analysis. N=37 patients.

Effect	OR	95% CI	p-value
Zone (Transition vs Peripheral)	5.8	3.1, 10.7	<0.001
Region (Base vs Mid)	1.4	1.1, 1.9	0.021
Region (Base vs Apex)	2.7	1.6, 4.4	<0.001
Side (Left vs Right)	1.1	0.9, 1.2	0.516
Sequence (DWI/ADC vs DCE)	Infinite**	-	<0.001
Sequence (DWI/ADC vs T2)	109	27, 447	<0.001

* Poor subjective image quality defined as scores of "severely limits interpretation" or "non-diagnostic".
** There were no instances of poor image quality on DCE.

Table 4 – Assessment of sequence as a predictor of the proportion of gland that is obscured by artifact on quantitative assessment. Results pooled across readers.

Effect	Mean difference	95% CI	p-value
Sequence (ADC vs T2)	26%	22%, 31%	<0.001
Sequence (ADC vs DCE)	23%	18%, 28%	<0.001