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Assessment of the Utility of Multiparametric Magnetic Resonance Imaging for Initial Detection of Prostate Cancer

Mladen Doykov[1,2]*, Lyubomir Chervenkov[3,4], Silvia Tsvetkova-Trichkova[3], Katya Doykova[3,4], Aleksandar Georgiev[3,5]

[1]Department of Urology and General Medicine, Medical Faculty, Medical University of Plovdiv, Plovdiv, Bulgaria; [2]Clinic of Urology, University Hospital "Kaspela", Plovdiv, Bulgaria; [3]Department of Diagnostic Imaging, Medical Faculty, Medical University of Plovdiv, Plovdiv, Bulgaria; [4]Department of Imaging Diagnostics, University Hospital "Kaspela", Plovdiv, Bulgaria; [5]Complex Oncology Center Plovdiv, Plovdiv, Bulgaria

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***Correspondence:** Mladen Doykov, Department of Urology and General Medicine, Medical Faculty, Medical University of Plovdiv, Plovdiv, Bulgaria. Clinic of Urology, University Hospital "Kaspela", Plovdiv, Bulgaria. E-mail: mladen.doykov@mu-plovdiv.bg
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Abstract

BACKGROUND: An accurate diagnosis is essential for the effective treatment of prostate cancer (PCa) and for the patients' well-being.

AIM: The main purpose of this study was to assess the utility of multiparametric magnetic resonance imaging (mp-MRI) for initial detection of PCa among the Bulgarian population of men with prostate diseases.

MATERIALS AND METHODS: Fifty-three patients, aged 44 to 82 years, were evaluated for clinically significant PCa. Assessment methods included prostate-specific antigen (PSA) serum levels, transrectal ultrasonography (TRUS), GE Discovery 3T MRI, and 12-core TRUS biopsy.

RESULTS: mp-MRI showed 83.20% concordance with TRUS biopsy: sensitivity of 91.43% (76.90–98.20), specificity of 75.00% (34.90–96.80), positive predictive values 94.10% (82.80–98.20) and negative predictive values 66.70% (38.70–86.40). Of the patients classified in prostate imaging–reporting and data system (PI-RADS) levels 4 and 5, 94.12% had positive TRUS biopsy, as well as 44.40% of PI-RADS had level 3. Irrespective of the patients' age and PSA, PI-RADS was found to be a significant predictor of a positive TRUS biopsy ($p = 0.009$). PSA serum levels showed a low concordance with TRUS biopsy (area under the curve = 0.539; 95% confidence interval [CI]: 0.363–0.712) and a low, although significant, correlation with PI-RADS (rs = 0.416; 95% CI: 0.164–0.617).

CONCLUSION: According to our findings, mp-MRI and TRUS biopsy have a high level of concordance for the initial detection of PCa. The incorporation of mp-MRI into the diagnostic pathway for PCa can significantly reduce the number of incorrect diagnoses based on PSA serum levels and/or suspicious physical and digital examinations.

Introduction

Prostate cancer (PCa) is the second most common cancer that affects men globally [1], [2]. Prostate-specific antigen (PSA) testing is a routine procedure in prostate screening [3]. Other popular diagnostic methods include digital rectal examination (DRE) and transrectal ultrasonography (TRUS) [4]. The European Association of Urology guidelines recommend performing a 12-core transrectal ultrasound-guided biopsy (TRUS-biopsy) in biopsy-naive men with elevated serum levels of PSA ≥4 ng/ml and/or an abnormal DRE [5].

The current diagnostic methods have their limitations in terms of sensitivity and specificity. In a meta-analysis, Song *et al*. (2005) reported pooled sensitivity of 91.3% and specificity of 35.9% for PSA levels >4 ng/mL; 68.4% and 71.5% for DRE; 73.6% and 61.3% for TRUS, respectively [4]. Screenings based on PSA often lead to overdiagnosis [6] and unnecessary biopsies that are associated with complications such as bleeding, infections, and increased health-care costs [7].

Multiparametric magnetic resonance imaging (mp-MRI) has opened up new opportunities for PCa detection and diagnosis. It is specifically recommended for patients with elevated PSA levels, but with negative biopsy results, as well as for biopsy naïve patients who are being monitored for PCa due to risk factors. Multiparametric MRI is considered to be a safer alternative to TRUS biopsy, reducing the rate of post-biopsy complications [8].

Three-dimensional images of the prostate gland, including high-resolution T2-weighted (T2WI), diffusion-weighted (DWI), and dynamic contrast-enhanced (DCEI) images, are obtained using mp-MRI. The results are combined to determine the level of risk for clinically significant cancer, following the prostate imaging-reporting and data system (PI-RADS), whose most recent version from 2019 is characterized by improved sensitivity and specificity [9].

Research has shown that the use of mp-MRI in the diagnosis of PCa contributes to an improved detection and identification of the stage

and aggressiveness of the tumor [10]. Ahmed *et al*. concluded that if mp-MRI was used as a triage test, 25% of unnecessary biopsies could be avoided by reducing the overdiagnosis of clinically insignificant PCa [11]. A reduction in the rate of unnecessary biopsies and improved cost-effectiveness after including mp-MRI as part of the diagnostic pathway for PCa screening was also observed by Brown *et al*. [12].

The present study aimed to fulfill the following goals: (1) to assess the utility of mp-MRI (PI-RADS version 2.1) for initial detection of PCa in a Bulgarian population of men with prostate diseases; (2) to investigate the relationship between PI-RADS, TRUS biopsy, and serum PSA.

Materials and Methods

The study included 53 patients, aged 44 to 82 years, who were examined for clinically significant PCa at the Urology Department of the University General Hospital "Kaspela" in Plovdiv, Bulgaria, from March to November, 2021. The data collection was conducted in adherence to the World Medical Association Declaration of Helsinki (1964) and its revised version (Edinburgh, 2000). The research protocol was approved by the Committee for Scientific Ethics at the University General Hospital "Kaspela," Plovdiv, Bulgaria (IRB document No 171, issued on April 14th, 2020).

Eligible for participation in the study were men who satisfied the following inclusion criteria: (1) never had a prostate biopsy or surgery; (2) PSA level >4ng/mL; (3) suspicious rectal examination; (4) aged ≥18 years; (5) fit for anesthesia; (6) signed a written consent for participation in the study. Patients were excluded if they: (1) had previous biopsy or surgery for PCa or other prostate disease; (2) had contraindications for MRI; (3) had urinary tract infection or prostatitis; (4) were <18 years; (5) refused to sign a written consent for participation in the study.

Procedures

The patients were scanned on GE Discovery 3T MRI, including sagittal, axial, coronal T2 FrFSE, Ax FOCUS, and Ax Lava and T1, with "Body 24 AA1" coil. The sagittal, axial, and coronal T2 sequences were performed with frequency field-of-view (FOV) 22.0 and slice thickness 3.0. The other characteristics were as follows: (1) Ax FOCUS 500 800 1400 2000 – scan plane: oblique, frequency FOV: 22.0, phase FOV: 1.00, slice thickness: 3.6.; (2) Ax LAVA dynamic (6 s) – scan plane: oblique, frequency FOV: 24.0, phase FOV: 1.00, slice thickness: 3.0.; (3) Ax T1 (HIGH RES – 3 MM) – scan plane: oblique, frequency FOV: 24.0, slice thickness 3.0.

The PI-RADS version 2.1 was used to classify the lesions on a scale of 1 to 5 for the probability of cancer [9]:

- PI-RADS 1: Very low (clinically significant cancer is highly unlikely to be present)
- PI-RADS 2: Low (clinically significant cancer is unlikely to be present)
- PI-RADS 3: Intermediate (the presence of clinically significant cancer is equivocal)
- PI-RADS 4: High (clinically significant cancer is likely to be present)
- PI-RADS 5: Very high (clinically significant cancer is highly likely to be present.)

A lesion was classified as PI-RADS 4 if it was lenticular or non-circumscribed, homogenous, and moderately hypointense on T2WI, showing focal, marked diffusion restriction on DWI and apparent diffusion coefficient (ADC), with size <1.5 cm (Figure 1).

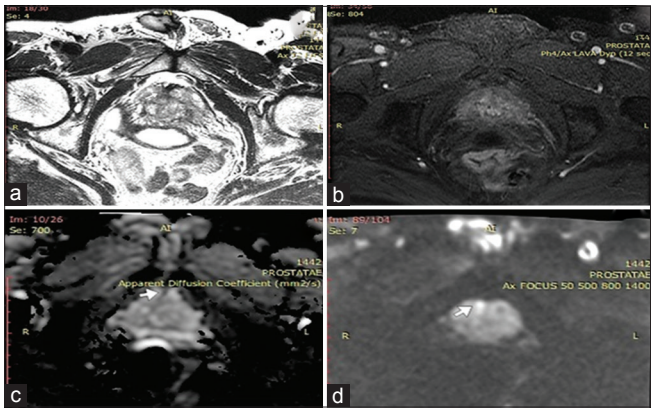

Figure 1: Carcinoma of the prostate imaging-reporting and data system 4 in a 65-year-old patient with prostate-specific antigen 9 mmol/L. Cor, Sag T2, Ax diffusion-weighted image + apparent diffusion coefficient and dynamic contrast sequences were performed. After biopsy, the lesion was classified Gleason 4 + 4 = 8. Shown on the panels are: (a) T2 sequence; (b) DCE sequence; (c) apparent diffusion coefficient map panel; (d) diffusion-weighted image sequence panel

A lesion was classified as PI-RADS 5 if it was lenticular or non-circumscribed, homogenous, and moderately hypointense on T2WI, showed a marked diffusion restriction on DWI and ADC, with size >1.5 cm, or with extraprostatic extension (Figure 2).

A 12-core TRUS (Hitachi Aloka F37 ultrasound) biopsy was performed in 43 cases with cancer suspicious lesions on mp-MRI. Moller Medical® DNG-1020 disposable needle (18 gauge), Moller Medical® RBG-1000 reusable biopsy gun, and end-firing transrectal ultrasonography probe (7.5 MHz) were used. All patients were given two tablets ciprofloxacin (500 mg) along with one tablet tamsulosin (0.4 mg) one night before biopsy. Post-biopsy, the two oral medicaments were continued for 4 days.

Statistical analysis

The statistical analyses were performed using the SPSS version 27.0 (SPSS Inc., Chicago, IL, USA)

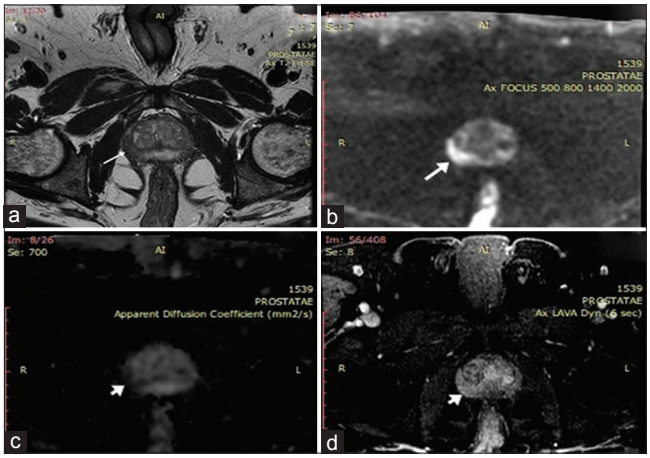

Figure 2: Carcinoma of the prostate imaging-reporting and data system 5 in a 62-year-old patient, with prostate-specific antigen 6 mmol/L. Cor, Sag T2, Ax diffusion weighted image + Apparent diffusion coefficient and dynamic contrast sequences were performed. Operation was performed which confirmed the carcinoma – classified Gleason 4 + 4 = 8. Shown on the panels are: (a) T2 sequence; (b) Diffusion-weighted image sequence; (c) Apparent diffusion coefficient map; (d) Dynamic contrast-enhanced sequence

and MedCalc version 20.104 (MedCalc Software Ltd, Ostend, Belgium). The continuously measured variables were screened for normality through the Shapiro–Wilk test and were described with the median values and the interquartile ranges. The categorical variables were presented as frequencies and percentages (%). The receiver operating characteristic (ROC) curve was used to assess the degree of concordance between the target methods, including values of area under the curve (AUC), sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV). Associations between target variables were examined through the Spearman rank-order correlation. Multivariate and univariate binary logistic regressions were carried out to establish the prognostic role of patients' age, PSA, and PI-RADs for a positive TRUS biopsy. The independent-samples Hodges–Lehmann test was used to compare median differences. All tests were two-tailed and the results were interpreted as significant at Type I error alpha = 0.05 ($p < 0.05$).

Results

Background information

The study included 53 men of median age of 66 years, with an age range between 44 and 82 years. The data from PSA testing, multiparametric MRI and TRUS biopsy are given in Table 1. The PSA values ranged from 2 ng/mL to 183ng/mL, with a median of 8.40 ng/mL. The patients with values of PSA < 4ng/mL comprised 9.4% (*n* = 5) of the total and those with PSA > 4ng/mL made up 90.60% (*n* = 48).

Table 1: Clinical characteristics of the patients

Variables	Statistics
Age (years)	
Median (IQR)	66 (10)
Minimum–maximum	44–82
PSA ng/mL	
Median (IQR)	8.40 (5.6)
Minimum–maximum	2.00–183.00
Zone, n (%)	
TZ	16 (30.20)
PZ	27 (50.90)
No lesions	10 (18.90)
Part, n (%)	
Apical	16 (30.20)
Basal	5 (9.40)
Middle	22 (41.50)
No lesions	10 (18.90)
T2, n (%)	
Positive	43 (100.00)
Negative	0
DWI, n (%)	
Positive	40 (93.00)
Negative	3 (6.00)
DCE, n (%)	
Positive	30 (69.70)
Negative	13 (30.30)
ADC, n (%)	
Positive	39 (90.60)
Negative	4 (9.40)
PI-RADS v. 2, n (%)	
1 – Very low	1 (2.10)
2 – Low	9 (16.90)
3 – Equivocal	9 (16.90)
4 – High	21 (39.60)
5 – Very high	13 (24.50)
TRUS biopsy	
Positive	35 (81.40)
Negative	8 (18.60)

PSA: Prostate-specific antigen, TZ: Transition, PZ: Peripheral, DWI: Diffusion-weighted image, DCE: Dynamic contras- enhanced, ADC: Apparent diffusion coefficient, PI-RADS version 2: Prostate imaging-reporting and data system version 2.1, TRUS: Transrectal ultrasound, IQR: Interquartile range.

Cancer suspicious lesions were found in 43 (81.10%) of the patients, and were most frequently located in the peripheral zone (PZ) and in the middle part of the prostate gland. Forty-three lesions were positive on the T2WI sequence, of which 27 (62.80%) in the PZ and 16 (37.20%) in the transition zone (TZ). Positive on the DWI sequence were 40 lesions, of which 26 (65.00%) were in PZ and 14 in TZ (35.00%). The DCEI sequence showed 30 positive lesions, 20 (66.70%) in PZ and 10 (33.30%) in TZ. Thirty-nine lesions were positive according to ADC, of which 25 (64.10%) in PZ and 14 (35.90%) in TZ.

The average number of lesions per patient was 2.62 (±0.61), minimum of 1 and maximum of 3. According to PI-RADS version 2.1, 34 (61.10%) patients were categorized as likely or very likely to have clinically significant cancer and 9 (16.90%) as equivocal. TRUS biopsy showed positive results for 35 out of the 43 patients with suspicious lesions (66.00%).

Concordance between prostate imaging-reporting and data system versus TRUS biopsy

We observed an 83.20% concordance between the PI-RADS classification of the lesions and the TRUS biopsy, with sensitivity of 91.43%, specificity of 75.00%, PPV 94.10%, and NPV 66.70% (Table 2). Of the nine equivocal cases (PI-RADS level 3), 5 (55.60%) had negative biopsy, and 4 (44.40%) were cancer positive. Of the 21 cases classified in PI-RADS level 4, 20 (95.20%) had positive biopsy and 1 (4.80%) had

Table 2: Results from the receiver operating characteristic curve analysis between multiparametric magnetic resonance imaging and transrectal ultrasound biopsy for the initial detection of prostate cancer

Parameter	AUC 95% CI	p	Sensitivity	Specificity	PPV 95% CI	NPV 95% CI
PI-RADS	0.832 0.670–0.999	< 0.001	91.43 76.90–98.20	75.00 34.90–96.80	94.10 82.80–98.20	66.70 38.70to86.40

PI-RADS: Prostate imaging-reporting and data system, AUC: Area under the curve, PPV: Positive predictive value, NPV: Negative predictive value, CI: Confidence interval.

negative. Of the 13 cases that were classified as very likely to have clinically significant cancer (PI-RADS level 5), 12 (92.30%) were cancer positive and 1 (7.70%) was negative on TRUS biopsy. As a whole, 2 out of 34 (5.90%) patients classified in PI-RADS levels 4 and 5 showed negative biopsy results (Figure 3).

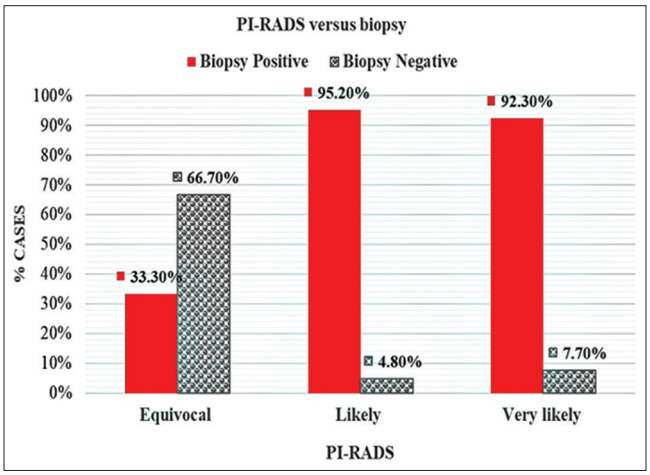

Figure 3: Cross-tabulation of prostate imaging-reporting and data system classification versus positive and negative cases on TRUS-biopsy

Concordance between prostate-specific antigen and TRUS biopsy

The PSA serum marker was not found to be a reliable indicator of a positive or negative TRUS biopsy. The ROC curve showed a low concordance between PSA and TRUS biopsy with AUC = 0.539 (95% CI: 0.363 to 0.712, p = 0.662). At a criterion value of PSA > 4.00 ng/mL, we observed sensitivity of 91.43% and specificity of 0.00%. Two other criterion values are given in Figure 4 to illustrate the change in sensitivity and specificity. The patients with negative biopsy had median PSA of 8.40 ng/mL versus median PSA of 9.00 ng/mL in the patients with positive biopsy. The independent-samples Hodges–Lehmann median difference was 0.60 ng/mL; 95% CI: 8.50 ng/mL to 2.40 ng/mL.

Correlation between prostate-specific antigen and prostate imaging-reporting and data system

Although significant, the correlation between PSA and PI-RADS was relatively low (rs = 0.416;

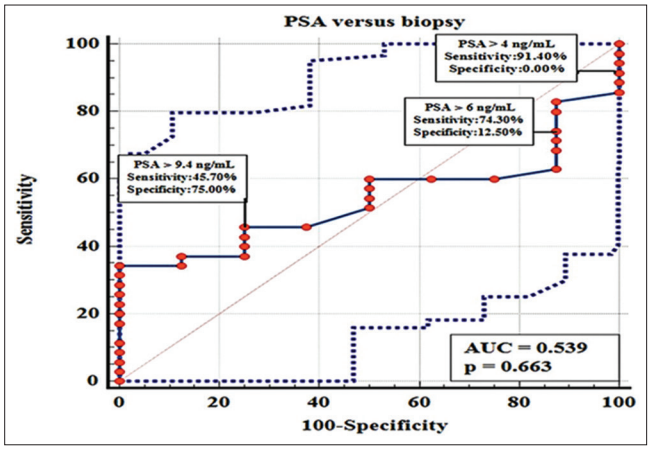

Figure 4: Receiver operating characteristic curve between prostate-specific antigen and biopsy

95% CI: 0.164 to 0.617, p = 0.002). At level 3 PI-RADS, the median PSA was 8.40 ng/mL, range from 4 to 183 ng/mL; at PI-RADS 4, the median PSA was 7.40 ng/mL, range from 2.3 to 80 ng/mL; at PI-RADS 5, the median PSA showed 11.00 ng/mL, range 6.00 ng/mL to 169 ng/mL (Figure 5). Of the five patients with PSA < 4 ng/mL, one was categorized in PI-RADs level 1, one in PI-RADS level 2, and three in PI-RADS level 4. The latter three had positive results on TRUS biopsy; among them was the patient with PSA of 2 ng/mL.

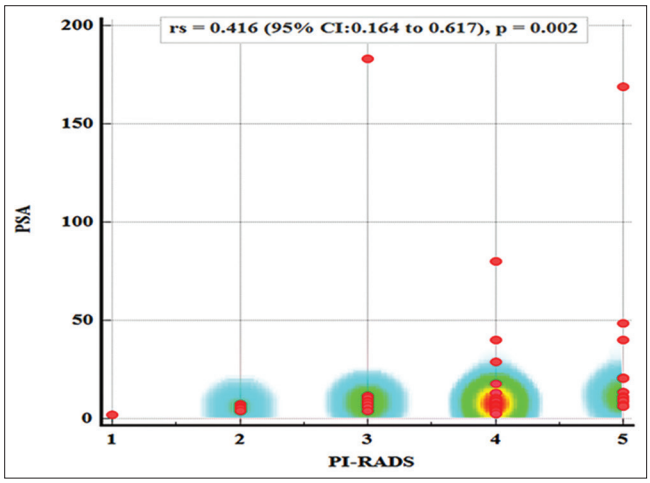

Figure 5: Dot plot showing the distribution of prostate-specific antigen values across prostate imaging-reporting and data system levels

Multivariate binary logistic regression

We performed a multivariate binary logistic regression (Backward method) with biopsy as the dependent variable (1 = positive; 0 = negative) and independent factors PI-RADS, PSA, and the age of the patients. PI-RADS was found to be the only significant prognostic indicator of a positive TRUS biopsy (p = 0.009) with the following regression equation: P(1) = exp(Y')/(1 + exp(Y')), where Y' = −0.223 + PI-RADS 3 or + 3.22 PI-RADS 4 or + 2.71 PI-RADS 5. The patients' age and PSA did not show a significant prognostic ability and were excluded from the regression model.

Discussion

An accurate diagnosis is essential for the effective treatment of PCa, as well as for the patients' physical and psychological well-being. It can prevent traumatic experiences, negative consequences, and unnecessary health costs [13], [14]. The purpose of our study was to find the level of concordance between mp-MRI and transrectal ultrasound-guided biopsy for initial detection of PCa among the Bulgarian population of men with prostate diseases.

Our findings support previous research indicating that mp-MRI is a reliable diagnostic method for PCa when used as a triage test [10], [11], [12], [15], [16], [17]. We found sensitivity of 91.43% which falls at the high end of the range of 58% to 96% reported in systematic reviews [15]. The observed specificity of 75% is at the upper limit of the established range of 23–87% [15]. The negative predictive value of 66.70% is contained in the reported range of 63–98%; however, we need to acknowledge that it is closer to the lower limit [15], [17].

In our data, the PI-RADS classification was shown as a significant predictor of positive or negative TRUS biopsy results irrespective of the patients' age and PSA. Our results are consistent with the findings of Thompson *et al*., who also found PI-RADS to be highly predictive of the presence of PCa [16].

We also analyzed the connection between PSA serum levels, mp-MRI, and TRUS biopsy.

PSA serum levels were found to have a weak relationship with both TRUS biopsy results and the PI-RADS classification. Previous research has warned against overdiagnosis if screenings are solely based on PSA levels [7]. We observed the same issue as 21% of the patients with PSA > 4 ng/mL had a negative biopsy (8/38); six of them were classified in PI-RADS level 2 (low risk) and two in level 3 (equivocal). There was also a risk for underdiagnosis as 60% of the men with PSA < 4 ng/mL were diagnosed with PCa on both TRUS biopsy and PI-RADS.

Conclusions

According to our findings, mp-MRI and TRUS biopsy have a high level of concordance for the initial detection of PCa. The incorporation of mp-MRI into the diagnostic pathway for PCa can significantly reduce the number of incorrect diagnoses based on PSA serum levels and/or suspicious physical and digital examinations. It is also important to work on improving the specificity and negative predictive value of mp-MRI.

Institutional review board statement

The study was conducted in accordance with the Declaration of Helsinki, and approved by the Committee for Scientific Ethics at the University General Hospital "Kaspela," Plovdiv, Bulgaria (IRB document No 171, issued on April 14th, 2020).

Informed consent statement

Written informed consent was obtained from all subjects involved in the study for voluntary participation and reporting the data in scientific publications.

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