



Impact of prostate imaging quality (PI-QUAL) score on the detection of clinically significant prostate cancer at biopsy

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ABSTRACT

Purpose: To investigate the impact of Prostate Imaging Quality (PI-QUAL) scores on the diagnostic performance of multiparametric MRI (mpMRI) in a targeted biopsy cohort.

Patients and methods: 300 patients who underwent both mpMRI and biopsy were included. PI-QUAL scores were retrospectively assigned by two radiologists in consensus and were correlated to pre-biopsy PI-RADS scores and biopsy outcomes. Clinically significant prostate cancer (csPCa) was defined as ISUP grade ≥ 2 .

Results: Image quality was optimal (PI-QUAL ≥ 4) in 249/300 (83%) and suboptimal (PI-QUAL < 4) in 51/300 (17%). The proportion of PI-RADS 3 scores referred for biopsy was higher in scans of suboptimal vs optimal quality (51% vs 33%). For PI-QUAL < 4 scans, the positive predictive value (PPV) was lower compared to PI-QUAL ≥ 4 (35% [95%CI: 22, 48] vs 48% [95%CI: 41, 55]; difference -13% [95%CI: -27, 2]; p 0.090), as was the detection rate of csPCa in both PI-RADS 3 and PI-RADS 4-5 (15% vs 23% and 56 vs 63%, respectively). The overall MRI quality increased over time.

Conclusions: Scan quality may affect the diagnostic performance of prostate mpMRI in patients undergoing MRI-guided biopsy. Scans of suboptimal quality (PI-QUAL < 4) were associated with lower PPV for csPCa.

1. Introduction

Multiparametric MRI (mpMRI) plays a pivotal role in the diagnostic pathway of prostate cancer (PCa) [1]. Given its widespread adoption, it has become of outmost importance to ensure consistent MRI scan quality in routine clinical practice [2,3]. In fact, the quality of MRI may have a relevant impact on the whole MRI-directed diagnostic pathway [4].

The Prostate Imaging Reporting and Data System (PI-RADS) guidelines represented the first step towards the definition of an optimal scan protocol, providing minimal technical requirements for mpMRI acquisition [5]. However, the adherence to these standards is variable and image quality can also be affected by patient-related factors (e.g. movement, rectal gas, hip prosthesis) [6,7]. Of note, PI-RADS does not

provide measures to evaluate prostate MRI quality. To address this issue, the Prostate Imaging Quality (PI-QUAL) scoring system was proposed, consisting in a 1–5 Likert scale based on a defined set of objective criteria to assess image quality [8]. The different scores determine the likelihood of being able to rule-in and rule-out clinically significant prostate cancer (csPCa). PI-QUAL represents a useful tool in both the research and clinical settings and provides clinicians with practical information that can influence patient care. Several studies have already investigated PI-QUAL reproducibility, reporting moderate to good interreader agreement [4,9–11], while evidence on its clinical impact is still limited [4,11].

Therefore, the aim of our study was to investigate the impact of image quality, as defined by PI-QUAL scores, on the diagnostic

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performance of mpMRI in a targeted biopsy cohort.

2. Materials and methods

This retrospective, single institution study was approved by our Institutional Review Board. Written informed consent was obtained for all patients. A prospective database was used to identify treatment-naïve patients who underwent both prostate mpMRI and subsequent biopsy at our institute (IRCCS San Raffaele Scientific Institute). Patients were included if all relevant information (clinical, radiological and histopathological) were available. The final cohort consisted in 300 consecutive men who underwent mpMRI between April 2017 and November 2021. Original MRI examinations were interpreted and scored using PI-RADS v2 or v2.1 by staff radiologists, as per standard of care.

MRI acquisition.

1.5-T MRI (Achieva and Achieva dStream, Philips Medical Systems) was performed with 32-channel phased-array body coil and endorectal coil (ERC; Prostate eCoilTM, Medrad®). Patients were asked to perform an enema just before the hospital visit, to reduce faecal content in the rectum. Gastrointestinal peristalsis was suppressed by intramuscular administration of 20 mg of scopolamine-butylbromide (Buscopan, Boehringer) immediately before MR scanning. All patients underwent full multiparametric MRI protocol, as follows: multiplanar turbo spin-echo T2-weighted images (T2WI); echo-planar DWI with b values of 50, 800, and 1600 s/mm² (ADC maps were calculated using b values of 50 and 800 s/mm²); 3-D fast field-echo dynamic contrast-enhanced (DCE) MRI; and delayed axial turbo spin-echo T1-weighted images with fat suppression. For DCE-MRI, an IV bolus of 0.1 mmol/kg of gadobutrol (Gadovist, Bayer Schering Pharma) was injected. Technical specifications for the mpMRI protocol are reported in Supplementary Table S1.

Image analysis

Images were reviewed for quality assessment by an expert urologist (8 years of experience in prostate MRI interpretation) and a trained junior radiologist (1 year of experience) in consensus, blinded to the original MRI reports and histopathology outcomes. Both radiologists underwent self-assessed training on the use of PI-QUAL scoring system using the PI-QUAL primer [12]. The readers assessed PI-QUAL scores for each scan based on a 1–5 scale that indicates the adequacy of the diagnostic quality: 1) all the sequences are below the minimum standard of diagnostic quality; 2) only one mpMRI sequence is of acceptable diagnostic quality; 3) at least two mpMRI sequences taken together are of acceptable diagnostic quality; 4) two or more mpMRI sequences are independently of optimal diagnostic quality; 5) all three sequences are of optimal diagnostic quality [8]. Scans with PI-QUAL score ≥ 4 were referred to as of “optimal quality”, while scans with PI-QUAL score < 4 were referred to as of “suboptimal quality”. PI-RADS scores were obtained from the clinical mpMRI reports: all scans were reported as per standard clinical care by a pool twelve radiologists, eight and four of which reported more than 300 and 100 prostate MRI scans per year, respectively.

Biopsy and histopathology.

All patients with at least one visible lesion at MRI (i.e. PI-RADS score ≥ 3) underwent targeted biopsies with concomitant standard 12-core random systematic biopsy (TRUS-Bx). Random sampling was performed avoiding the suspicious lesions identified by mpMRI, keeping a margin distance of 5 mm. Patients without visible lesions underwent standard 12-core TRUS-Bx. All prostate biopsy specimens were analysed by dedicated uropathologists. Clinically significant PCa (csPCa) was considered as Gleason $\geq 3 + 4$ (ISUP grade ≥ 2).

Statistics.

The primary aim was to evaluate the difference in PPV for the detection of csPCa in high versus low quality images. The threshold for csPCa on mp-MRI was PI-RADS ≥ 3 and on biopsy was ISUP ≥ 2 . The threshold for optimal quality image on mp-MRI was PI-QUAL ≥ 4 . The secondary aims were to describe: (1) the proportion of indeterminate mp-MRI findings (PI-RADS 3) in high versus low quality images; (2) the

detection rate of csPCa in high versus low quality images, stratified per original PI-RADS score; (3) the variation of image quality and PPV for the detection of csPCa according to the year of the scan.

The study was originally powered to detect a 20% difference in positive predictive value for the detection of csPCa in high versus low quality images, based on a previous study [11]. Based on a systematic review, we estimated that the PPV would be 40% for optimal quality images [13]. Since the expected rate of low-quality scans in our practice was unknown a priori, it was estimated based on the analysis of the first 100 scans where 15% were categorised as suboptimal quality. Therefore, to achieve 80% power, 300 scans were analysed.

Diagnostic accuracy measures (sensitivity, specificity, positive predictive value [PPV] and negative predictive value [NPV]) were calculated with 95% confidence intervals (95% CI). Statistical significance was based on Wilson's 95% CI [14]. Analyses were performed using Stata 17 (College Station, TX, USA).

3. Results

A summary of the baseline demographic, imaging and biopsy data of the 300 men included in the study is presented in Table 1. The median age was 66 years (IQR 59–72), the median PSA was 6 ng/ml (IQR 4.27–9), the median PSA density was 0.11 ng/ml/cc (IQR 0.07–0.2). The prevalence of any PCa at biopsy was 182/300 (61%), the prevalence of csPCa was 129/300 (43%). According to original MRI reports, 24/300 (8%) had a maximum score of PI-RADS 2, 109/300 (36%) had PI-RADS 3 and 167/300 (56%) had PI-RADS 4–5.

MRI was judged of optimal quality (PI-QUAL ≥ 4) in 249/300 (83%), of which 167/249 (67%) where PI-QUAL 5; of suboptimal quality (PI-QUAL < 4) in 51/300 (17%), of which 6/51 (12%) were PI-QUAL 2. Regarding the individual sequences: 292/300 (97%) of T2WI, 259/300 (86%) of DWI and 259/300 (86%) of DCE were judged of diagnostic quality, respectively. All patients with suboptimal scan quality and 225/249 (90%) of patients with optimal scan quality had at least one PI-RADS ≥ 3 lesion at MRI. Examples of PI-QUAL 5 and PI-QUAL 2 scans are shown in Fig. 1.

The proportions of PI-RADS scores and biopsy results stratified per image quality are reported in Table 1, Figs. 2a–b and Supplementary Table S2; the diagnostic accuracy estimates of MRI are reported in Supplementary Table S3–S4. The PPV of MRI in scans of suboptimal quality was 35% (95% CI: 22, 48), compared with 48% (95% CI: 41, 55) for scans of optimal quality, a non-statistically significant difference of 13% (95% CI: –27, 2; p 0.090). Although the study was not powered to detect differences beyond that outlined in the primary aim, the percentage of indeterminate mpMRI findings (PI-RADS 3) in scans of suboptimal quality was 51% (26/51), compared with 33% (83/249) for scans of optimal quality, a statistically significant difference of 18% (95% CI: 3, 33; p = 0.015). In addition, the detection rate of csPCa for PI-

Table 1
Summary of demographic, imaging and biopsy data. Data are n (%) or median (IQR).

	Total n = 300	PI-QUAL 4/5 n = 249 (83%)	PI-QUAL 2/3 n = 51 (17%)
Age (years)	66 (59, 72)	66 (60, 71)	67 (58, 73)
PSA (ng/ml)	6 (4.27, 9)	6 (4.37, 9.6)	5.91 (3.85, 8.45)
Prostate Volume (cc)	50 (35, 70)	50 (35, 70)	45 (29, 68)
PSA density (ng/ml/cc)	0.11 (0.07, 0.2)	0.11 (0.07, 0.2)	0.13 (0.07, 0.23)
MRI results, n (%)			
PI-RADS 1–2	24 (8)	24 (10)	0 (0)
PI-RADS 3	109 (36)	83 (33)	26 (51)
PI-RADS 4–5	167 (56)	142 (57)	25 (49)
Biopsy results, n (%)			
No cancer	118 (39)	95 (38)	23 (45)
ISUP 1	53 (18)	43 (17)	10 (20)
ISUP 2–3	92 (31)	79 (32)	13 (25)
ISUP 4–5	37 (12)	32 (13)	5 (10)

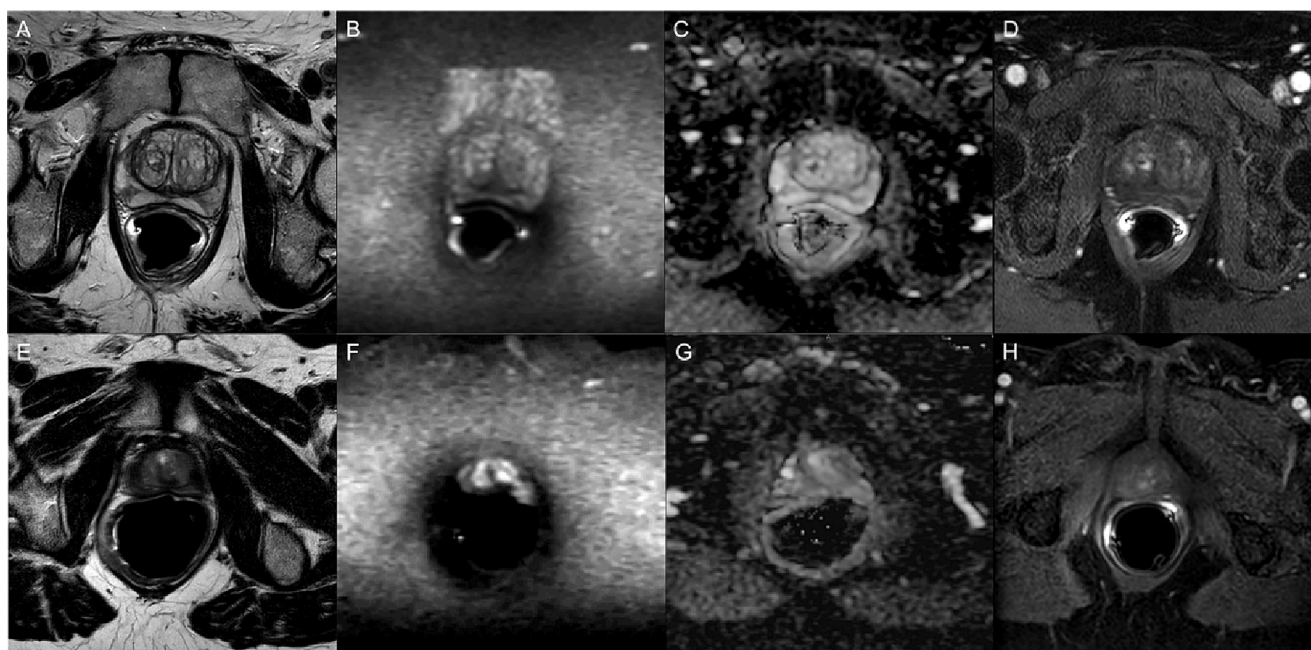


Fig. 1. Examples of mpMRI image quality. T2W (A,E), b1600 DWI (B,F), ADC map (C,G), DCE (D,H). Top row (A-D), PI-QUAL 5: all sequences are of optimal quality. Bottom row (E-H), PI-QUAL 2: motion artefacts on T2W (E); rectal gas artefacts on b1600 DWI and ADC map (F,G); motion and ERC-related artefacts on DCE (H).

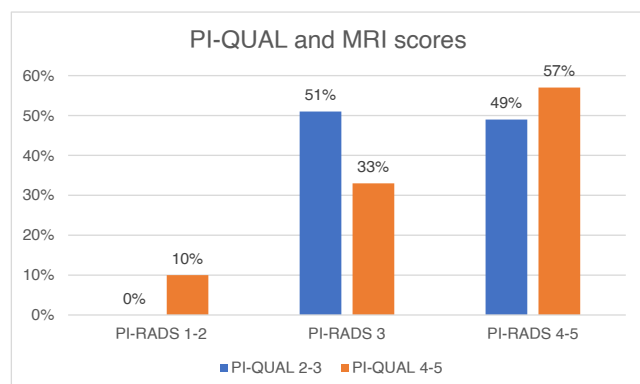


Fig. 2a. PI-QUAL and MRI scores.

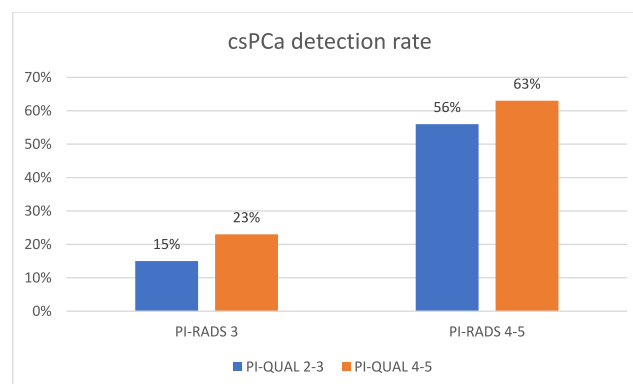


Fig. 2c. csPCa detection rate in PI-RADS 3 vs 4-5 scores.

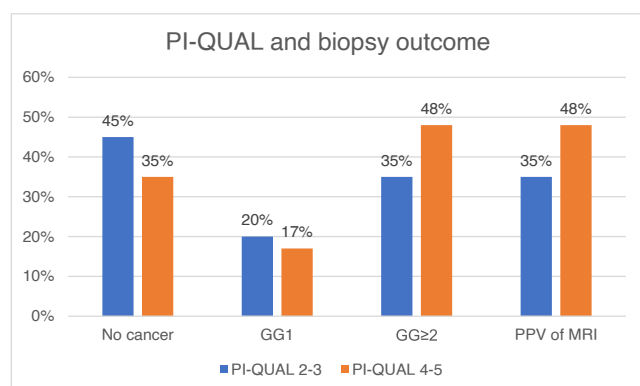


Fig. 2b. PI-QUAL and biopsy outcome in men with visible lesions at MRI.

RADS 3 and PI-RADS 4-5 lesions in scans of suboptimal quality was 15% (4/26) and 58% (14/25), compared with 23% (19/83) and 63% (89/142) for scans of optimal quality, a difference of -8% (95% CI: -24, 8; p 0.383) and -5% (95% CI: -26, 16; p 0.634), respectively.

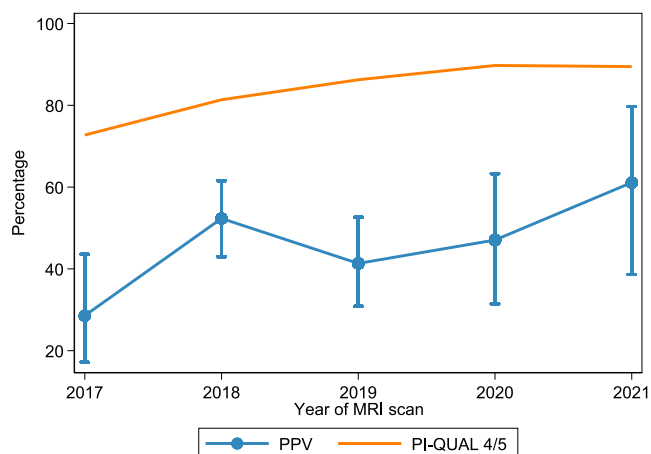


Fig. 3. Variation of scan quality and PPV of mpMRI according to the year of the scan.

In the period of the study (2017–2021) the overall MRI quality increased, with the proportion of PI-QUAL 4/5 increasing from 73% up to 90%; in the same period, the overall PPV of MRI increased from 29% (95% CI: 16, 44) to 61% (95% CI: 39, 80) (Fig. 3; Supplementary Table S6).

4. Discussion

In recent years, awareness has grown over the importance of scan quality for a successful delivery of the MRI-directed diagnostic pathway [15], also considering the potential advent of biparametric MRI in which the amount of information is limited [16,17]. Accordingly, an ESUR/ESUI expert panel stated that MRI quality should be routinely checked and reported in clinical practice [2]. In this context, the PI-QUAL scoring system represents a useful tool to standardize quality evaluation and reporting, with potential implications on patient care [18]. Consequently, it is of high clinical interest to understand the impact that scan quality has on the diagnostic performance of MRI in routine clinical practice.

Our study provided evidence that MRI scan quality may affect the performance of mpMRI relative to biopsy outcomes. Scans of suboptimal quality (PI-QUAL 2–3) were associated with a higher proportion of biopsy referrals for equivocal MRI findings (PI-RADS score 3) and with a lower PPV (detection rate of csPca), resulting in a higher number of false positive biopsy referrals. To our knowledge, this is the first study evaluating the per-patient impact of image quality on biopsy outcomes in a targeted biopsy cohort using PI-QUAL scores.

Our results are in line with other recently published studies. In the study of Karanasios et al. on 247 biopsy-naïve men with suspected Pca [4], the rate of equivocal findings (PI-RADS 3) were lower for higher quality studies (10.4% vs 31.8%) and more PI-QUAL 1–3 scans resulted in biopsy procedures for equivocal findings if compared to PI-QUAL 4–5 scans. Accordingly, we observed a 18% higher proportion of PI-RADS 3 MRIs referred for biopsy in scans of suboptimal quality (Table 1, Fig. 2a), with a concomitant 35% reduction of csPca detection rate (Fig. 2c). This finding may indicate that one of the major impacts of low scan quality could be that of reducing readers' confidence in MRI interpretation, increasing the number of equivocal calls and of unnecessary biopsy referrals.

In the study of Pötsch et al. [11], the impact of PI-QUAL scores on the performance of mpMRI was assessed in 274 diagnostic areas from 50 patients who underwent prostate biopsy. In PI-QUAL ≤ 3 areas, the observed prevalence of prostate cancer was significantly lower (16.7% vs 30.2%), as was the PPV of mpMRI (36.2% vs 56.1%) when compared to PI-QUAL greater than 3 areas. To a minor extent, we observed 13% higher prevalence of csPca and PPV in PI-QUAL 4–5 vs PI-QUAL 2–3 scans (Fig. 2b). Of note, we did not analyse multiple prostatic areas for each patient, rather we evaluated the impact of image quality on a per-patient level, an approach that might be more reproducible and has more obvious implications on patient selection for biopsy.

Another recent multicentre study investigated the impact of PI-QUAL scores on local staging with mpMRI [19]. Lower scan quality (PI-QUAL < 3) was associated with a higher rate of upstaging from organ-confined disease to locally advanced disease at pathology. Contrary to our findings, biopsy results did not differ significantly between the different PI-QUAL groups. However, it must be noted that the study was based on a radical prostatectomy cohort, and all the patients ($n = 351$) had a positive biopsy.

The overall quality of our scans performed at 1.5 T with an endorectal coil was high, with 83% judged of optimal quality (PI-QUAL score ≥ 4). While the original PI-QUAL study reported an overall lower quality of MRI scans from multiple centres [8], our results are comparable to those of the single-institution study of Karanasios et al [4]. Among the potential reason for the consistently high quality are the use of pre-scan enemas [20] and the on-scan monitoring of image quality, so that non-diagnostic sequences can be repeated to achieve a better quality.

Interestingly, we observed an increase in overall scan quality over time, with the proportion of PI-QUAL 4–5 scans increasing from 73% up to 90% in the study period. Several factors may explain this finding: software/hardware upgrades over time, constant revision and optimization of scan protocols, increased experience of radiologists and radiographer and increased awareness of MRI quality issues (e.g. recognition of major image artefacts on different sequences). Paralleling an increase in image quality, we observed an overall increase of PPV of MRI in the same study period. Nevertheless, we cannot infer any direct causality related to this finding, that is likely multifactorial (e.g.: increase in radiologists/urolologists experience, better patient selection, variable disease prevalence).

In all, the findings of our study support the concept that lower image quality may impair the radiologist's reliability in ruling-in csPca, resulting in more equivocal findings and a lower yield for csPca. Conversely, we were not able to evaluate the impact on ruling-out csPca, given that all negative MRIs referred for biopsy in our cohort were scored as PI-QUAL 4–5.

Among the main strengths of our study is the homogeneous cohort of patients included in the study, who underwent the same protocols for mpMRI and biopsy at a single institution. Moreover, the per-patient evaluation allowed a more straightforward estimation of the impact of image quality on patient care, relative to false positive biopsy referrals and csPca detection rates.

Several limitations should also be taken into account when interpreting the results of our study. First, the generalizability of our findings may be limited considering the single-institutional nature of the study and the routine use of an endorectal coil in our cohort. Second, the assessment of PI-QUAL scores was made by 2 radiologists in consensus: we acknowledge that, in the light of the moderate-to-good inter-reader agreement of the PI-QUAL scores [9,10], the results may be variable if PI-QUAL is assessed by different readers. Third, the differences reported in the outcome of interests between the optimal/suboptimal quality groups did not reach statistical significance, apart from the proportion of PI-RADS 3 scans. One of the reasons is the limited size of the suboptimal quality group (PI-QUAL < 4) over the total number of scans reviewed ($n = 51/300$, 17%); also, the study was not powered to detect the differences that we actually observed in our cohort (e.g. in PPV). Larger, multireader and multi-institutional studies are needed to confirm our results. Finally, since all the PI-QUAL < 4 scans had at least one visible lesion, we could not assess the effect of MRI quality on the ability to rule out csPca in negative MRIs.

In conclusion, prostate MRI scan quality as defined by PI-QUAL scores may have an impact on the diagnostic accuracy of the MRI-biopsy diagnostic pathway, with a higher number of false positive biopsy referrals observed for mpMRI scans of suboptimal quality and a lower PPV for csPca. These findings support the importance of an adequate quality control on MRI scan acquisition following PI-RADS guidelines, as well as standardized image quality evaluation and reporting in routine clinical practice using PI-QUAL scores, to guide a more thorough and informed clinical decision.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.ejrad.2023.110849>.

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