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Assessment of the performance of the SarQoL[®] questionnaire in screening for sarcopenia in older people

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Aging Clinical and Experimental Research Assessment of the performance of the SarQoL® questionnaire in screening for sarcopenia in older people. --Manuscript Draft--

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Abstract:	Background: Because of its low prevalence and the need for expensive instruments to measure body composition, recruiting sarcopenic people for clinical studies can be a resource-intensive process. Aims: We investigated whether the SarQoL®, a 55-item questionnaire designed to measure quality of life in sarcopenia, could be used to identify older people with a high likelihood of being sarcopenic, and compare its performance to the SARC-F tool. Methods: We performed a secondary analysis of data from older, community-dwelling participants of the SarcoPhAge study, evaluated for sarcopenia according to the EWGSOP2 criteria, and who completed the SarQoL® and SARC-F questionnaires. We determined the optimal threshold to distinguish between sarcopenic and nonsarcopenic people with the Youden index. Diagnostic performance was evaluated with the area under the curve (AUC) and by calculating sensitivity and specificity. Results: The analysis of 309 participants provided an optimal threshold value of \leq 52.4 points for identifying people with sarcopenia with the SarQoL® questionnaire, which resulted in a sensitivity of 64.7% (41.1-84.2%), a specificity of 80.5% (75.7-84.7%) and an AUC of 0.771 (0.652-0.889). Compared to the SARC-F, the SarQoL® has greater sensitivity (64.7% vs 52.39%), but slightly lower specificity (80.5% vs. 86.6%). Discussion: The SarQoL® questionnaire showed acceptable diagnostic accuracy, on par with the SARC-F. The optimal threshold of \leq 52.4 points should be confirmed in other cohorts of older people. Conclusions: This exploratory study showed that the SarQoL® could potentially be applied in a screening strategy, with the added benefit of providing a measure of QoL at the same time.			
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Author Comments:	Dear Editor,
	I am pleased to submit an original manuscript on the performance of a sarcopenia- specific QoL questionnaire as a screening instrument for sarcopenia as diagnosed with the EWGSOP2 criteria. We hope you consider the results of this study worthy of publication in your journal.
	Thank you in advance for your consideration,
	Anton Geerinck

±

Title:

Assessment of the performance of the SarQoL[®] questionnaire in screening for sarcopenia in older people.

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Abstract

Background: Because of its low prevalence and the need for expensive instruments to measure body composition, recruiting sarcopenic people for clinical studies can be a resource-intensive process.

Aims: We investigated whether the SarQoL[®], a 55-item questionnaire designed to measure quality of life in sarcopenia, could be used to identify older people with a high likelihood of being sarcopenic, and compare its performance to the SARC-F tool.

Methods: We performed a secondary analysis of data from older, community-dwelling participants of the SarcoPhAge study, evaluated for sarcopenia according to the EWGSOP2 criteria, and who completed the SarQoL[®] and SARC-F questionnaires. We determined the optimal threshold to distinguish between sarcopenic and non-sarcopenic people with the Youden index. Diagnostic performance was evaluated with the area under the curve (AUC) and by calculating sensitivity and specificity.

Results: The analysis of 309 participants provided an optimal threshold value of \leq 52.4 points for identifying people with sarcopenia with the SarQoL[®] questionnaire, which resulted in a sensitivity of 64.7% (41.1-84.2%), a specificity of 80.5% (75.7-84.7%) and an AUC of 0.771 (0.652-0.889). Compared to the SARC-F, the SarQoL[®] has greater sensitivity (64.7% vs 52.39%), but slightly lower specificity (80.5% vs. 86.6%).

Discussion: The SarQoL[®] questionnaire showed acceptable diagnostic accuracy, on par with the SARC-F. The optimal threshold of \leq 52.4 points should be confirmed in other cohorts of older people.

Conclusions: This exploratory study showed that the SarQoL[®] could potentially be applied in a screening strategy, with the added benefit of providing a measure of QoL at the same time.

Keywords: Sarcopenia, screening, SarQoL, sensitivity, specificity

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Conflicts of interest/Competing interests: CB, J-YR and OB are shareholders of SarQoL sprl. AG, BD-H and ML report no conflicts of interest related to this work.

Availability of data and material: Data is available as a supplementary file.

Code availability: No specific code was written for this study.

Authors' contributions: AG, CB, OB and J-YR designed the study. ML and CB collected the data. AG performed the analysis and wrote the manuscript. All authors provided feedback on the manuscript and analyses and approved the final manuscript.

Ethics approval: The SarcoPhAge study was approved by the Ethics Committee of the University Teaching Hospital of Liège (n° 2012-277). Because this is a secondary analysis of previously collected data, no additional approval was sought for this specific analysis.

Consent to participate: All participants provided written informed consent.

Consent for publication: Not applicable.

<u>1.</u> Introduction

Sarcopenia has been described by the 2nd European Working Group on Sarcopenia in Older People (EWGSOP2) as a *"progressive and generalised skeletal muscle disorder that is associated with increased likelihood of adverse outcomes including falls, fractures, physical disability and mortality"*. In the same article, the EWGSOP2 also presented a revision of its diagnostic criteria for sarcopenia, presenting a new diagnostic algorithm and changing the threshold values for low muscle strength and low muscle mass [1]. This revision has increased the consistency between studies in the evaluation of sarcopenia, but some studies have observed that it lowers the prevalence of sarcopenia compared to the EWGSOP1 criteria [2, 3]. For clinical research and epidemiological studies this means that more candidates need to be evaluated to achieve a sufficient number of sarcopenic participants to obtain the desired statistical power.

To help researchers recruit sarcopenic individuals in an efficient and cost-effective manner, multiple screening tools have been developed to identify those candidates with the highest probability of having sarcopenia. These come in different forms: there are questionnaires such as the Mini Sarcopenia Risk Assessment (MSRA – both a 7 and 5-item version available) and the SARC-F questionnaire (a 5 and 3-item version exist, as well as a version with calf circumference and a version which takes into account age and body mass) [4]. Other screening instruments rely solely on physical characteristics, such as the score developed by Ishii et al (age, grip strength and calf circumference), muscle mass prediction formulas or the chair stand test [4, 5].

Clinical studies in sarcopenia require a substantial amount of time and effort, because of the need to include and evaluate a large number of candidates in order to find sufficient sarcopenic subjects to achieve the required level of statistical power. A full diagnostic evaluation where muscle mass is evaluated by DXA and muscle strength by dynamometer, as recommended, necessitates the use of qualified personnel and expensive instruments. Given the cost per patient for these evaluations, screening instruments that can significantly increase the proportion of sarcopenic persons within the pool of candidates invited for a full body composition assessment, could greatly help the financial feasibility of large-scale clinical studies in sarcopenia. With this in mind, the hypothesis was raised that an existing instrument, developed to measure quality of life in sarcopenia, could potentially be of use in screening candidates for referral to full body composition evaluation and/or physical function assessment.

The instrument investigated in this study is the Sarcopenia Quality of Life (SarQoL[®]) questionnaire. It evaluates quality of life in sarcopenia through 55 items categorized into 7 domains of health-related dysfunction [6]. It is an auto-administered instrument and takes about 15 minutes to complete. Its clinimetric properties as a QoL questionnaire have been demonstrated in multiple validation studies

conducted in multiple languages [7–18]. Of particular interest in this context is the repeated observation that the SarQoL[®] questionnaire is able to discriminate between sarcopenic and non-sarcopenic groups, with the former scoring significantly lower on the overall QoL score of the questionnaire than the latter. Its focus on the impact of musculoskeletal health on quality of life contributes to our expectation that the overall QoL score produced by the SarQoL[®] questionnaire could be used to screen older people and identify those with a higher likelihood of sarcopenia.

The objective of this study is therefore to evaluate the diagnostic performance of the Overall QoL score of the SarQoL[®] questionnaire to detect individuals with sarcopenia according to the revised EWGSOP2 consensus criteria. The hypothesis linked to this objective is that the Overall QoL score of the SarQoL[®] questionnaire has an area under the ROC curve (AUC) greater than 0.7, indicating the test is useful in distinguishing between sarcopenia and non-sarcopenic people [19].

The secondary objective of this study is to compare the diagnostic performance of the Overall QoL score of the SarQoL[®] questionnaire with the performance of the 5-item SARC-F questionnaire, the screening tool recommended by the EWGSOP2 [1]. The hypothesis linked to this objective is that the Overall QoL score is at least as performant as the SARC-F, judged by AUC, sensitivity and specificity.

2. Material and methods

This study is a cross-sectional secondary evaluation of data collected at the third year of follow-up of the Sarcopenia and Physical Impairment with advancing Age (SarcoPhAge) prospective cohort study, carried out in the Liège province of Belgium [20]. The SarcoPhAge study was conducted in compliance with the principles outlined in the Declaration of Helsinki. The study protocol and its amendments received approval from the Ethics Committee of the University Teaching Hospital of Liège (n° 2012-277), and all participants provided written informed consent. This article was written to comply, as much as feasible, with the most recent version of the Standards for Reporting Diagnostic Accuracy (STARD) checklist [21].

2.1 Participants

The SarcoPhAge study enrolled a convenience sample of people who visited an outpatient clinic in Liège (Belgium) as well as people who responded to a press advertisement between June 2013 and July 2014. Participants in this study were 65 years of age or older, and, because of the limitations of the dualenergy x-ray absorptiometry (DXA) instrument, people with a BMI above 50 kg/m² or with amputated limbs were not eligible. There were no additional criteria beyond these [20]. The third year of followup (July 2015 to July 2016) was selected for inclusion because this was the first year that both the SarQoL[®] questionnaire and the SARC-F questionnaire were administered to all participants.

2.2 Measurements

For each participant, muscle mass was measured with a dual-energy X-ray absorptiometry instrument (Hologic Discovery A, USA) and grip strength with the Saehan hydraulic hand dynamometer (Saehan Corp., Masan, South Korea). Both instruments were calibrated according to the respective manufacturer's instructions at the recommended intervals. Appendicular skeletal muscle mass was calculated as the sum of all 4 limbs, and divided by the squared height of the participant in question to obtain a skeletal muscle mass index (SMI= ASM/Ht²). The grip strength of a person was defined as the highest value out of 6 measurements (3 for the dominant hand and 3 for the non-dominant hand). Detailed descriptions of both measurements are available in the article on the baseline results of the SarcoPhAge study [20]. These data allowed us to diagnose sarcopenia according to the EWGSOP2 criteria in participants with low muscle mass (ASM/Ht² < 7.0 kg/m² for men and <5.5 kg/m² for women) and low muscle strength (grip strength <27 kg for men and <16 kg for women) [1]. Sarcopenia diagnosed with the EWGSOP2 criteria constitutes the reference standard in this study because of its status as the current consensus criteria and its applicability to samples recruited in Europe [1].

The index test in this study, the paper-based French-language SarQoL[®] questionnaire, was completed by the participants without assistance. An Overall QoL score (0-100 points) is calculated where lower scores indicate lower QoL and thus also greater sarcopenia-related disability [6, 22]. The questionnaire is available in multiple languages from the website <u>www.sarqol.org</u>, and the Overall QoL score was calculated with an Access database developed for this purpose. Given the exploratory nature of this investigation, we did not pre-specify a test-positivity cut-off point.

We included a second index test in this analysis, so as to be able to compare the performance of the SarQoL[®] questionnaire against the current most-widely used screening instrument in sarcopenia, the SARC-F [23]. It is composed of 5 questions on strength, locomotion, rising from a chair, climbing stairs and history of falls. A total score is calculated and ranges from 0 to 10 points, where higher scores are linked with a higher probability of being diagnosed with sarcopenia. A score of \geq 4 points is used as a cut-off to identify individuals who require a full examination for sarcopenia in clinical practice [23]. The SARC-F was developed to be able to detect sarcopenia as diagnosed with the EWGSOP criteria, and a meta-analysis found a pooled sensitivity of 0.21 (0.13-0.31) combined with a specificity of 0.90 (0.83-0.94) [24]. With the publication of the revised EWGSOP2 criteria, several authors have looked again at the performance of the SARC-F, and a meta-analysis that pooled the results from 4 studies found an AUC of 0.75 (95% CI: 0.71-0.78) with a sensitivity of 0.77 (95% CI: 0.49-0.92) and a specificity of 0.63 (95% CI: 0.43-0.79) [25].

The reference test and the two index tests were performed by the same investigator or completed by the participant during a single study visit. The study investigator who also recorded clinical and demographic information. The results from the reference test and one of the index tests, the SARC-F, was directly available to the investigator. The second index test, the SarQoL[®] Overall score, was calculated some time after the end of the study visit.

2.3 Statistical measurements

Statistical analyses were carried out with the Statistical Package for the Social Sciences version 27.0.0.0 (SPSS Statistics; IBM, Armonk, NY) . The distribution of variables in this analysis was examined by looking at the distance between median and mean, histogram, QQ-plot and the Shapiro-Wilk test. Continuous variables are presented as mean \pm standard deviation if normally distributed and as median (25th percentile – 75th percentile) if not normally distributed. The evaluation of the screening performance of both the Overall QoL score of the SarQoL[®] questionnaire and the SARC-F was based on their sensitivity (Se), specificity (Sp), positive likelihood ratio (LR+), negative likelihood ratio (LR-), positive predictive value (PPV), negative predictive value (NPV),) in relation to sarcopenia as diagnosed with the EWGSOP2 criteria. These values and the associated 95% confidence intervals were

 obtained through the GENLIN procedure, as outlined in document 422875 from IBM support [26]. Receiver Operating Characteristic (ROC) curves and the Area Under the Curve (AUC) provided the overall accuracy of both screening instruments. An AUC value above 0.9 indicates high accuracy of the screening instrument, between 0.8 and 0.9 excellent accuracy and between 0.7 and 0.8 acceptable accuracy [19]. The Youden J statistic (sensitivity + specificity -1) was used to find the optimal cut-point for the Overall SarQoL score [27]. The analyses presented in this article have been performed in all participants who were assessed for sarcopenia using the EWGSOP2 criteria, screened with the SARC-F questionnaire and who completed the SarQoL[®] questionnaire at the third follow-up of the SarcoPhAge study. A p-value of 0.05 was considered statistically significant.

<u>3. Results</u>

A total of 309 people were included in this analysis. All participants were assessed for sarcopenia with the EWGSOP2 criteria in the third yearly evaluation of the SarcoPhAge study, and 17 (5.5%) of them were effectively diagnosed with sarcopenia. The sarcopenic participants were older than those not diagnosed as sarcopenic [80.07 (71.98 – 86.36) years versus 73.55 (69.68 – 78.58) years; p=0.011] and had a lower body mass index [23.91 (19.01 – 26.58) kg/m² versus 26.74 (23.97 – 29.57) kg/m²; p=0.001]. They also took more medication and had a lower gait speed than those not diagnosed with sarcopenia. The complete clinical characteristics for the sample are detailed in table 1.

Table 1: Clinical characteristics				
	Sarcopenic (n=17)	arcopenic (n=17) Not sarcopenic (n=292)		
Age (years)	80.07 (71.98 - 86.36)	73.55 (69.68 - 78.58)	0.011	
Gender (women)	10 (58.8%)	170 (58.2%)	0.961	
BMI (kg/m²)	23.91 (19.01 - 26.58)	26.74 (23.97 – 29.57)	0.001	
N° of drugs	9.00 (3.50 - 12.50)	6.00 (4.00 - 8.00)	0.035	
N° of comorbidities	4.00 (3.00 - 7.00)	4.00 (2.00 - 5.00)	0.462	
Gait speed (m/s)	0.70 ± 0.27	1.14 ± 0.28	< 0.001	
^a P-values from Mann-Whitney U-test, Pearson Chi-square or Student t-test, depending on variable				
characteristics.				

The SARC-F questionnaire identified 48 (15.5%) participants with a score \geq 4 points and thus suspected of having sarcopenia. A ROC curve of both the SarQoL[®] Overall score and the SARC-F score is presented in figure 1. The AUC for the SarQoL[®] Overall score is 0.771 (95% CI: 0.652-0.889) and for the SARC-F 0.802 (95% CI: 0.696-0.909). The two AUC are not significantly different (p=0.606).

The Youden index was maximised at \leq 52.4 points for the SarQoL[®] Overall score (J_c = 0.452; Se=0.647; Sp=0.805) and \geq 4 points for the SARC-F questionnaire (J_c = 0.396; Se=0.529; Sp=0.866). These threshold values were used for the construction of table 2, detailing the diagnostic accuracy of the two instruments.

The SarQoL[®] Overall score, dichotomized at \leq 52.4 points, was slightly more sensitive than the SARC-F score (64.7% vs. 52.9%), because it correctly identified 11 out of the 17 sarcopenic participants, whereas the SARC-F correctly identified 9 out of 17. The opposite is true for the specificity of the two instruments, where the SARC-F was slightly more specific than the SarQoL[®] Overall score (80.5% vs. 86.6%), with 253 healthy subjects correctly identified compared to the 235 found by the SarQoL[®] questionnaire. Therefore, the SarQoL[®] questionnaire was slightly better at correctly identifying people who have sarcopenia, and the SARC-F is slightly better at correctly identifying participants who do not have sarcopenia in this sample.

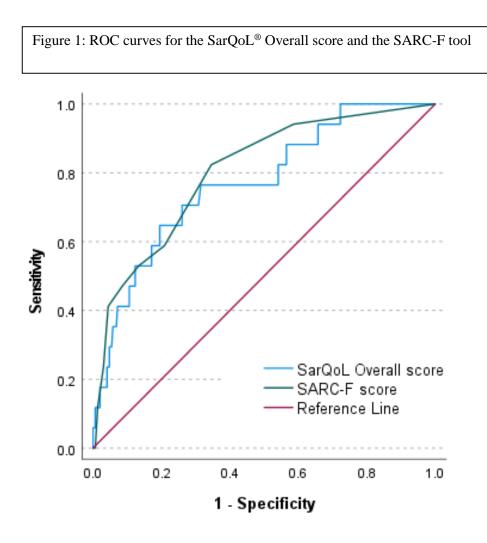


Table 2: Diagnostic accuracy of the SarQoL [®] Overall score and the SARC-F instrument				
	SarQoL	SARC-F		
True positives	11	9		
False positives	57	39		
True negatives	235	253		
False negatives	6	8		
Sensitivity	0.647 (0.411 – 0.842)	0.529 (0.301 – 0.750)		
Specificity	0.805 (0.757 – 0.847)	0.866 (0.824 - 0.902)		
Positive predictive value	0.162 (0.088 - 0.261)	0.188 (0.095 – 0.313)		

Negative predictive value	0.975 (0.950 - 0.990)	0.969 (0.944 - 0.986)	
Positive likelihood ratio	3.315 (2.175 - 5.051)	3.964 (2.322 - 6.768)	
Negative likelihood ratio	0.439 (0.230 – 0.837)	0.543 (0.327 – 0.901)	
AUC	0.771 (0.652-0.889)	0.802 (0.696-0.909)	
AUC= area under the ROC curve			

We also looked at the sensitivity and specificity of a range of threshold values for the SarQoL[®] Overall score, which are displayed in table 3.

Table 3: Sensitivity and specificity for a range of threshold values for the SarQoL® Overall score				
Threshold value	Se	Sp	PPV	NPV
\leq 30 points	5.9%	100%	100%	94.8%
≤40 points	17.6%	95.9%	20.0%	95.2%
\leq 50 points	52.9%	85.6%	17.6%	96.9%
≤52.4 points (optimal threshold)	64.7%	80.5%	16.2%	97.5%
≤60 points	76.5%	65.8%	11.5%	98.0%
≤70 points	88.2%	40.1%	7.9%	98.3%
≤80 points	100%	21.2%	6.9%	100%
≤90 points	100%	7.9%	5.9%	100%
≤100 points	100%	NA	5.5%	NA
Se= sensitivity; Sp= specificity; PPV= positive predictive value; NPV= negative predictive value				

4. Discussion

This exploratory study showed that the SarQoL[®] questionnaire may be useful in screening potential candidates who are suspected of having sarcopenia. The AUC of 0.771 (95% CI: (0.652-0.889) places it into the category of screening instruments with acceptable accuracy and confirms the primary study hypothesis. There might thus be a role for the SarQoL[®] questionnaire in a screening strategy, certainly if it is already being considered to measure quality of life. We also found that the screening accuracy of the SarQoL[®] questionnaire in this sample was comparable to the SARC-F questionnaire, confirming the secondary study hypothesis. The SarQoL[®] questionnaire was able to correctly identify more sarcopenic participants than the SARC-F (64.7% vs. 52.9%), but at the cost of a slightly lower specificity (80.5% vs 86.6%).

The screening efficacy of the SARC-F, one of the most widely used tools and recommend by several organizations, has been investigated for multiple diagnostic criteria, and summarized in a meta-analysis published in 2021. The authors found that the screening accuracy of the SARC-F was characterized by relatively low sensitivity (27-39%) combined with relatively high specificity (86-91%) when used in conjunction with the EWGSOP, Asian Working Group on Sarcopenia, International Working Group on Sarcopenia, and the Foundation for the National Institutes of Health Sarcopenia Project criteria. Interestingly, when they calculated the pooled sensitivity and specificity of the SARC-F based on the EWGSOP2 criteria, they found inverse results: moderate sensitivity (77%) and lower specificity (63%), although these results were only based on 4 studies. It is also important to mention that 3 of the 4 included studies focused on hospitalized patients, and that the pooled prevalence of sarcopenia was higher than in the general population at 21.56% [25]. We are aware of two other studies that are not included in this meta-analysis, namely Piotrowicz et al who reported a sensitivity of 35.3% and a specificity of 85.7%, and Nguyen et al, with a sensitivity of 46.9% and a specificity of 86.5%, both of which recruited community-dwelling older people [28, 29]. It has been argued that the SARC-F is better suited to ruling out sarcopenia rather than case-finding, which seems to be the case for the last two articles mentioned, but not so for the 4 included in the meta-analysis of Lu et al [30, 31].

In our study, the SarQoL[®] questionnaire performed similarly to the SARC-F questionnaire, with slightly higher sensitivity but slightly lower specificity. The SarQoL[®] questionnaire was able to correctly identify more sarcopenic patients in the sample, but the PPV of 16.2% was lower than the PPV of 18.8% of the SARC-F instrument. This means that 68 people would have been singled out for further investigation by the SarQoL[®] questionnaire, and 48 for the SARC-F, for two additional sarcopenic subjects to be found. Therefore, in our example, the SarQoL[®] questionnaire would have been preferable if the recruitment strategy called for finding the greatest number of sarcopenic participants in the shortest amount of time, accepting the extra cost in performing complete body composition and/or physical performance assessments on more people. The SarQoL[®] questionnaire also has the advantage

that it is self-administered and therefore requires fewer hours of study personnel time than the SARC-F, which is interviewer-administered.

There are some limitations to take into account when interpreting the results of this study. First off, this study was a secondary analysis of data collected previously, and not specifically designed to answer the research question. This has led to certain issues around the reduction of risk of bias, such as the fact that the research assistant was not blinded to the results of the body composition analysis, grip strength measurement and SARC-F score. A second issue is the fact that, because no pre-specified cut-off exists, we determined the optimal threshold with the Youden index. This reflects the best balance between sensitivity and specificity, but may not necessarily be generalizable. The various studies performed with the SarQoL[®] questionnaire have already shown that absolute quality of life scores can significantly differ between countries. Normative population data or pilot studies will be needed to inform the appropriate threshold value in different situations. Lastly, because of the design of this study, we did not perform sample size calculations, but provide confidence intervals around the main outcome values to provide a measure of precision. For both the SarQoL[®] and the SARC-F questionnaire, relatively large confidence intervals are observed around the point estimates, owing to the small number of people diagnosed with sarcopenia according to the EWGSOP2 criteria in this sample.

This study shows the feasibility of using the SarQoL[®] questionnaire as a tool to select those people who may benefit from a complete sarcopenia evaluation. While this study presents an interesting new use for the SarQoL[®] questionnaire, caution should be used in copying the threshold value used in this study (\leq 52.4 points) to other populations.

5. Conclusion

In the population presented in this study, the SarQoL[®] Overall score, dichotomized at \leq 52.4 points, performed roughly equal in terms of sensitivity and specificity to the SARC-F tool in identifying people considered sarcopenic with the EWGSOP2 criteria.

6. <u>References</u>

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Dataset

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