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Сравнение измерения линейного размера и объёма лёгочных очагов по данным скрининга рака лёгких с помощью низкодозной компьютерной томографии

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АННОТАЦИЯ

Обоснование. Согласно результатам голландско-бельгийского исследования скрининга рака лёгких NELSON, измерение объёма (волюметрия) очагов позволяет снизить распространённость ложноположительных результатов до 2,1%.

Цель — сравнение диагностической точности и согласованности результатов ручного измерения линейного размера с полуавтоматическим измерением объёма очагов по данным пилотного проекта «Московский скрининг рака лёгкого» с использованием низкодозной компьютерной томографии.

Материалы и методы. В программу скрининга были включены 293 пациента без верифицированного до 2020 года диагноза рака лёгкого, у которых на первичной низкодозной компьютерной томографии, выполненной в период с февраля 2017 по февраль 2018 года, был выявлен очаг в лёгком размером не менее 4 мм. Лучевая нагрузка подбиралась индивидуально и не превышала 1 мЗв. Все изображения низкодозной компьютерной томографии независимо оценивались тремя экспертами для измерения длинной оси очага, а также экстраполированного объёма. В качестве референсного значения размера и объёма брали среднее, полученное по итогам измерений экспертов. Очаг $<6 \text{ мм}/<100 \text{ мм}^3$ признавали ложноположительным результатом, очаг $\geq 6 \text{ мм}/\geq 100 \text{ мм}^3$ — ложноотрицательным.

Результаты. В исследование были включены 293 пациента (166 мужчин; 56%; средний возраст $64,6 \pm 5,3$ года). Лёгочных очагов $<6 \text{ мм}/<100 \text{ мм}^3$ было 199. Экспертами 1, 2 и 3 при измерении объёма зафиксированы отличия от референсного стандарта по 32 [10,9%; 4 ложноположительных, 28 ложноотрицательных], 29 [9,9%; 17 ложноположительных, 12 ложноотрицательных] и 30 [10,2%; 6 ложноположительных, 24 ложноотрицательных] очагам, а также расхождения при измерении линейного размера по 92 [65,5%; 107 ложноположительных, 85 ложноотрицательных], 146 [49,8%; 58 ложноположительных, 88 ложноотрицательных] и 102 [34,8%; 23 ложноположительных, 79 ложноотрицательных] очагам соответственно.

Заключение. Использование волюметрии лёгочных очагов значительно снижает количество ложноположительных и ложноотрицательных результатов в сравнении с измерением линейного размера очагов в программе скрининга рака лёгких методом низкодозной компьютерной томографии.

Ключевые слова: компьютерная томография; скрининг рака лёгкого; лёгочные узлы.

Как цитировать

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Volumetry versus linear diameter lung nodule measurement: an ultra-low-dose computed tomography lung cancer screening study

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ABSTRACT

BACKGROUND: The Dutch–Belgian Randomized Lung Cancer Screening Trial (NELSON) used a volume-based protocol and significantly reduced the prevalence of false-positive results (2.1%).

AIM: To compare the performance of manual linear diameter and semi-automated volumetric nodule measurement in the pilot project “Moscow Lung Cancer Screening” ultra-low-dose computed tomography pilot study.

MATERIALS AND METHODS: The study included individuals with a lung nodule of at least 4 mm on baseline-computed tomography of the Moscow lung cancer screening between February 2017 and February 2018, without verified lung cancer diagnosis until 2020. The radiation dose was selected individually and did not exceed 1 mSv. All scans were assessed by three blinded readers to measure the maximum and minimum transversal nodule diameter and extrapolated volume. As a reference value of size and volume, the average value from the results of expert measurements was obtained. A false-positive nodule was defined as a nodule <6 mm/ <100 mm³ and a false-negative nodule as a nodule ≥ 6 mm/ ≥ 100 mm³.

RESULTS: Overall, 293 patients were included (166 men; mean age, 64.6 ± 5.3 years); 199 lung nodules were <6 mm/ <100 mm³ and 94 were ≥ 6 mm/ ≥ 100 mm³. Regarding volumetric measurements, 32 [10.9%; 4 false-positive, 28 false-negative], 29 [9.9%; 17 false-positive, 12 false-negative], and 30 [10.2%; 6 false-positive, 24 false-negative] nodule discrepancies were reported by readers 1, 2, and 3 respectively. For linear diameter measurement, 92 [65.5%; 107 false-positive, 85 false-negative], 146 [49.8%; 58 false-positive, 88 false-negative], and 102 [34.8%; 23 false-positive, 79 false-negative] nodule discrepancies were reported by readers 1, 2, and 3 respectively.

CONCLUSIONS: The use of lung nodule volumetry strongly reduces the number of false-positive and false-negative nodules compared with nodule diameter measurements, in an ultra-low-dose computed tomography lung cancer screening program.

Keywords: tomography X-Ray compute, early detection of cancer, lung neoplasms.

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根据通过低剂量计算机断层扫描的肺癌筛查数据对肺部病灶线性尺寸和体积进行的测量比较

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简评

论证。根据荷兰-比利时NELSON肺癌筛查研究，病灶的体积测量（容量分析法）可以将假阳性结果的发生率降低到2.1%。

目的是根据莫斯科肺癌筛查试点项目的数据通过低剂量计算机断层扫描对人工病灶线性尺寸测量与半自动病灶体积测量的诊断准确性和一致性进行比较。

材料和方法。293名在2020年前没有被核实诊断为肺癌的患者被纳入筛查计划，他们在2017年2月至2018年2月时间内接受了一次低剂量计算机断层扫描，显示肺部结节的大小至少为4毫米。辐射负载是个性化的，不超过1毫西弗。所有低剂量计算机断层扫描图像都由三位专家独立评估，以测量病灶的长轴以及外推体积。从专家测量得到的尺寸和体积的平均值作为参考值。<6毫米/<100毫米³的病灶视为假阳性，≥6毫米/≥100毫米³的病灶视为假阴性。

结果。293名患者（166名男性；56%；平均年龄为64.6±5.3岁）被纳入研究。共有199个<6毫米/<100毫米³的肺部病灶。专家1、2和3分别记录了32个[10.9%；4个假阳性，28个假阴性]、29个[9.9%；17个假阳性，12个假阴性]和30个[10.2%；6个假阳性，24个假阴性]的病灶的体积测量与参考标准的差异，以及分别记录了92个[65.5%；107个假阳性，85个假阴性]、146个[49.8%；58个假阳性，88个假阴性]和102个[34.8%；23个假阳性，79个假阴性]病灶的线性尺寸测量与参考标准的差异。

结论。在低剂量计算机断层扫描肺癌筛查项目中，与病灶的线性大小的测量相比，使用肺部病灶的容积测定法可显著减少假阳性和假阴性结果的数量。

关键词：计算机断层扫描；肺癌筛查；肺部结节。

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BACKGROUND

Lung cancer remains one of the top 10 causes of death worldwide, owing largely to late diagnosis.¹ Low-dose computed tomography (LDCT) screening was found to significantly reduce lung cancer mortality in a high-risk population [1]. LDCT screening is intended to detect lung cancer at an early stage and primarily involves the detection, classification, and subsequent management of lung nodules. Numerous guidelines on pulmonary nodules have been developed to assist with the aforementioned tasks, including the International Early Lung Cancer Action Program [2] and Lung CT Screening Reporting And Data System (Lung-RADS) [4], as well as recommendations of the British Thoracic Society (BTS), [5] European Position Statement on Lung Cancer Screening (EUPS), [6] and National Comprehensive Cancer Network [7].²

According to the results of the Dutch-Belgian NELSON lung cancer screening, the volumetry of nodules can reduce the incidence of false-positive results to 2.1% [1]. Volumetry using semiautomatic volume estimation was thus approved and recommended in the EUPS protocols [6] and later in the NELSON-plus protocols [8]. According to the BTS guidelines for the management of pulmonary nodules identified by LDCT, volumetry should be used instead of measuring linear dimensions whenever possible.

The NELSON study found that lung cancer screening with LDCT was effective [9], although an effective radiation dose of 0.4–1.6 mSv was used for screening, depending on the patient's body weight [10]. Moreover, according to SanPin 2.6.1.2523-09 sanitary standards,³ the annual effective dose during preventive X-ray examinations should not exceed 1 mSv. As a result, the radiation dose in the Moscow Lung Cancer Screening pilot project was limited to 0.7 mSv [12]. To the best of our knowledge, no validation study has compared volumetric data with estimated maximum linear dimensions based on computed tomography with a radiation dose of <1 mSv (ultra-LDCT) performed as part of lung cancer screening. The findings of the Moscow Lung Cancer Screening project provide an invaluable opportunity to conduct such a study [13].

This study aimed to compare the diagnostic accuracy and consistency of the results of manual linear dimension measurement with semiautomatic volumetry in the Moscow Lung Cancer Screening pilot project using LDCT.

MATERIALS AND METHODS

Study design

A cross-sectional retrospective study was performed.

Eligibility criteria

The *inclusion criteria* were as follows: age from 50 to 80 years, smoking index ≥ 30 pack-years, current smoking or quitting <15 years ago, an ultra-LDCT study during the specified time period, and no history of lung cancer.

The *exclusion criteria* were as follows: no pulmonary nodules on LDCT; a history of lung cancer; a history of lung surgeries (except for lung biopsy); severe cardiovascular, immunological, respiratory, or endocrine diseases with a life expectancy of <5 years; acute respiratory diseases; taking antibiotics for at least 12 weeks before LDCT; hemoptysis or weight loss >10 kg in the year before screening.

Study conditions

The study included 293 participants of the Moscow Lung Cancer Screening pilot project. The subject selection flowchart is presented in Fig. 1. The study was conducted in accordance with Order No. 49 dated February 1, 2017, of the Moscow Healthcare Department.

Study duration

The dataset contains the findings of LDCT studies performed between February 2017 and February 2018.

Description of the intervention

Scanning was performed in 10 outpatient clinics, each with one CT scanner. Toshiba Aquilion 64 (Canon Medical Systems, Japan) CT scanners were used with the following scanning parameters: 64-slice CT scanners, tube voltage of 135 kV, intensity of 15–25 mA (depending on the patient's body weight: <69 kg = 15 mA; 70–90 kg = 20 mA; >90 kg = 25 mA), rotation time of 0.50 s, spacing of 1.484, slice thickness of 1 mm, and slice spacing of 1 mm. The matrix size was 512, and the reconstruction filter FC07 was used. Two scanners used a vendor-specific iterative reconstruction algorithm (AIDR 3D), whereas the remaining eight scanners used filtered back projection with quantum noise reduction software (FBP/QDS+) [13]. Only axial slices were retained. After scanning, maximum intensity projections and multiplanar reconstructions were used to analyze the data.

The breath-hold scanning time at maximal inspiration was ≤ 10 s. The field of view was determined on the CT scan from the lung apices to the costophrenic sinuses. The distance from the ribs to the edge of the image reconstruction area was <1 cm. The computed tomography dose index CTDI_{vol} depended on the patient's body weight: <69 kg = 0.8 mGy,

¹ WHO [Internet]. The top 10 causes of death cited 2020 Dec 9]. Available at: <https://www.who.int/news-room/fact-sheets/detail/the-top-10-causes-of-death>.

² American College of Radiology. Lung CT Screening Reporting & Data System (Lung-RADS®), Version 1.1 cited 2021 March 30]. Available at: <https://www.acr.org/Clinical-Resources/Reporting-and-Data-Systems/Lung-Rads>.

³ Resolution of the Russia's Chief Public Health Officer dated July 7, 2009, No. 47 on the approval of SanPiN 2.6.1.2523-09 "Radiation Safety Standards (NRB-99/2009)." Available at: <https://docs.cntd.ru/document/902170553>.

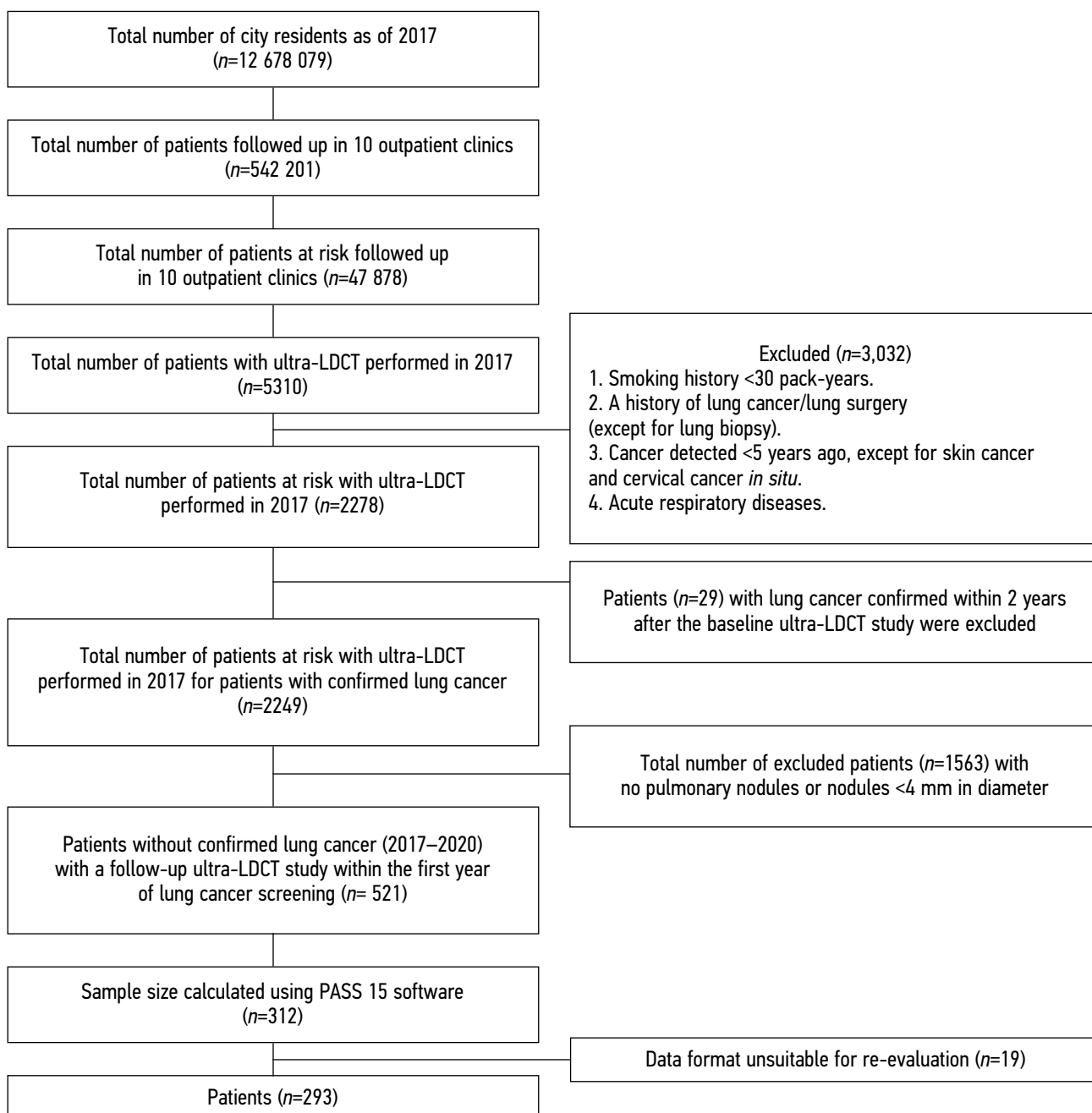


Figure 1. Subject selection flowchart.

70–90 kg = 1.0 mGy, and >90 kg = 1.2 mGy. The radiation dose was selected individually based on the patient's body weight.

Primary study outcome

A total of 1,450 pulmonary nodules were measured, 878 (61%) solid and 572 (39%) subsolid nodules, and the largest nodule was selected for each patient. After selecting the largest nodule, the final analysis included 293 nodules. Table 1 shows the distribution of nodules for each expert based on linear dimensions and volume. Following a consensus decision, 199 pulmonary nodules were classified as benign (<6 mm/<100 mm³) and 94 as requiring further evaluation (≥6 mm/≥100 mm³).

Ethics review

The study was approved by the independent ethics committee of the Central Clinical Hospital and Outpatient Clinic of the Administrative Directorate of the President of the Russian Federation (Moscow) on May 20, 2017. All participants signed an informed consent form.

Statistical analysis

The linear dimensions of pulmonary nodules were rounded to the nearest whole number. Pearson's chi-square test was used to examine differences in discrepancies and false-positive and false-negative results between the pulmonary nodule volume and linear dimensions. Fleiss' kappa was used to determine agreement among three

independent experts. To interpret the magnitude of this parameter, the Landis and Koch (1977) criteria were used: poor agreement, <0; slight agreement, 0.00–0.20; fair agreement, 0.21–0.40; moderate agreement, 0.41–0.60; substantial agreement, 0.61–0.80; and almost perfect agreement, >0.81 [14]. IBM SPSS Statistics version 26 was used for all statistical calculations, and $P < 0.05$ was considered significant.

RESULTS

Study subjects

The study included 293 participants, 166 (57%) of whom were men aged 50–80 (mean age 64.6 ± 5.3) years, with an average smoking history of 34.5 ± 10.7 years.

Main study outcomes

For volumetry, discrepancies with the reference standard were distributed as follows: 32 (10.9%; 4 false-positive results, 28 false-negative results), 29 (9.9%; 17 false-positive results, 12 false-negative results), and 30 (10.2%; 6 false-positive results, 24 false-negative results) nodules for experts 1, 2, and 3, respectively. For linear dimensions, incorrect nodule measurements were identified as 192 (65.5%; 107 false-positive results, 85 false-negative results), 146 (49.8%; 58 false-positive results, 88 false-negative results), and 102 (34.8%; 23 false-positive results, 79 false-negative results) for experts 1, 2, and 3, respectively (Table 2). When the BTS-recommended threshold value of 80 mm^3 was used, the number of incorrect measurements

increased: 35 errors were registered for expert 1, 50 for expert 2, and 41 for expert 3.

When three experts' averages were used, a total of 30 (10.2%) errors were detected for volumetry, compared with 147 (50.2%) for linear dimensions ($P < 0.001$). Volumetry demonstrated significantly fewer false-positive results ($n = 9$; 3.1%) than linear dimensions ($n = 63$; 21.5%; $P < 0.001$) and significantly fewer false-negative results (21; 7.2% vs. 84; 28.7%, respectively; $P < 0.001$).

The expert agreement analysis revealed that measuring volume had higher agreement than measuring linear dimensions. For volumetry, Fleiss' kappa was 0.672 (substantial agreement, 95% confidence interval 0.670–0.674), whereas for linear dimensions, Fleiss' kappa was 0.027 (slight agreement, 95% confidence interval 0.025–0.029).

DISCUSSION

Summary of the main study outcome

According to our findings, the use of volumetry instead of linear dimensions significantly reduced the number of incorrect interpretations while also lowering the number of false-positive and false-negative results. Expert agreement was significantly higher when volumetry was used instead of linear dimensions.

Discussion of the main study outcome

Our findings are consistent with those of the NELSON study and support the use of pulmonary nodule volumetry for

Table 1. Distribution of nodules per expert for linear dimensions and NELSON-plus/EUPS category

Parameters	Expert 1	Expert 2	Expert 3
<i>Linear dimensions</i>			
Nodule $\geq 6 \text{ mm}$	101	147	191
Nodule $< 6 \text{ mm}$	192	146	102
<i>Volume</i>			
$\geq 100 \text{ mm}^3$	223	194	217
$< 100 \text{ mm}^3$	70	99	76

Table 2. Results and discrepancies per expert for volumetry and linear dimensions

Parameters	Expert 1	Expert 2	Expert 3
<i>Volume</i>			
False-positive results	4 (1,4)	17 (5,8)	6 (2,0)
False-negative results	28 (9,6)	12 (4,1)	24 (8,2)
Discrepancies for each expert	32 (10,9)	29 (9,9)	30 (10,2)
<i>Linear dimensions</i>			
False-positive results	107 (36,5)	58 (19,8)	23 (7,8)
False-negative results	85 (29,0)	88 (30,0)	79 (27,0)
Discrepancies for each expert	192 (65,5)	146 (49,8)	102 (34,8)

Note. The percentage of the total number of nodules is shown in parentheses ($n = 293$).

ultra-LDCT results. Oudkerk et al. demonstrated that when using LDCT, the nodule size cannot be accurately interpreted solely by measuring its linear dimensions, especially in contentious cases. When extrapolating the volume from the linear dimensions, nodules measuring 8–10 mm fell into groups with volumes ranging from 50 to 500 mm³, and compared with semiautomatic volumetry, the use of linear dimensions resulted in a significant overestimation of the nodule volume. Previously, Revel et al. [14] also reported a problem in the analysis of small- and medium-sized nodules: the assessment of intra- and inter-expert agreement revealed that the measurement error reached 1.73 mm when assessed by two radiologists. Furthermore, Xie et al. [15] discovered that semiautomated volumetry yielded higher accuracy than manual measurements. Moreover, volumetry, including the use of artificial intelligence algorithms, is recommended by the European Society of Radiology and the European Respiratory Society [16]. In another study with pulmonary nodule marking, several radiologists found that the number of experts affected the correctness and consistency of estimates when measuring the nodule diameter. With an increase in the number of experts performing an independent interpretation of CT findings, the correctness of their assessments increases, whereas consistency decreases [17].

Study limitations

This study has several limitations. Owing to its retrospective design, a sampling bias is possible. Furthermore, this study used a relatively small sample. A larger number of cases may be more representative of a lung cancer screening population. According to Lung-RADS recommendations, the linear dimensions of the nodule along the long and short axes must be measured and the average

value calculated; however, the purpose of this work was to test the findings of the NELSON study.

CONCLUSION

This study shows that the use of semiautomatic volumetry of pulmonary nodules in the interpretation of LDCT findings can significantly reduce the number of false-positive and false-negative results when compared with measuring linear dimensions. This discovery is accompanied by increased agreement among experts and may reduce the unavoidable harms associated with lung cancer screening.

ADDITIONAL INFORMATION

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Authors' contribution. All authors made a substantial contribution to the conception of the work, acquisition, analysis, interpretation of data for the work, drafting and revising the work, final approval of the version to be published and agree to be accountable for all aspects of the work. M.M. Suchilova, I.A. Blokhin, V.Yu. Bosin — writing the original draft; O.O. Aleshina — data curation, investigation; V.A. Gombolevskiy, O.V. Omelyanskaya — conceptualization, study design; R.V. Reshetnikov, A.V. Vladzimirskyy — data curation.

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