journal of clinical practice 2025 Vol 16 №1

THE DETECTION OF EROSIVE CHANGES IN THE JOINTS OF HANDS AND FEET IN RHEUMATOID ARTHRITIS: A COMPARISON OF ULTRASOUND AND RADIOLOGY METHODS

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ABSTRACT

BACKGROUND: *The detection of bone tissue erosions in cases of rheumatoid arthritis has a fundamental importance for the purpose of defining the treatment strategy and it indicates the unfavorable outcomes. It is recognized that the sensitivity of X-ray in detecting the bone tissue erosions is lower comparing to the ultrasound examination, especially at the early stages of the disease. The application of non-invasive and safe methods for the diagnostics of rheumatoid arthritis opens new possibilities for successful treatment.* ***AIM:*** *to compare and to evaluate the results of ultrasound and radiological detection of destructive changes in the joints of the hands and feet in rheumatoid arthritis patients.* ***METHODS:*** *The research included 76 patients with an established diagnosis of rheumatoid arthritis. Radiography and ultrasound examination of the joints in the hands and feet were carried out at the moment of enrollment into the research and later on in 1 and 4 years.* ***RESULTS:*** *The findings included a slight degree of correlation between the two absolute values — the number of joints with erosions according to the data from the ultrasound examination and according to the radiology examination findings. The rate of progression of the erosive changes was more pronounced in the data from ultrasound examination comparing to the radiology findings: from 0.5 [0; 1] to 2.5 [0; 6.0] (p=0.001) and from 0 [0; 1] to 0 [0; 3] (p=0.001), respectively. When evaluating the comparability of the two methods used for detecting the erosive changes in the joints of the hands and feet at each observation point by means of using the Bland–Altman method, it was shown that the results from both methods partially reach the outside of the margins of two standard deviations, which indicates the low degree of agreement between them. The mean difference between the measurements was -0.38 (95% CI -0.63…-0.13) before treatment, -1.15 (95% CI -1.5…-0.79) at the follow-up point of 12 months and -1.52 (95% CI -2.32…-0.73) in 4 years, which indicates the presence of systematic deviations. No correlation was detected between the difference in the number of joints with erosions and the mean number of joints with erosions according to the ultrasound examination and according to the radiography findings.* ***CONCLUSION:*** *Ultrasound examination and radiography are not equivalent methods of detecting erosions in rheumatoid arthritis, however, ultrasound examination helps detecting early progression of the process, which is a key to successful therapy of rheumatoid arthritis.*

Keywords: *rheumatoid arthritis; erosions; ultrasound examination; radiography.*

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BACKGROUND

Currently, the visualization is reaching its new stage, not only in the diagnostics of rheumatic diseases, but also in the evaluation of its course and prognosis. High-precision methods, used in modern medical equipment, allow for evaluating not only the structure of the object, but also to arrange the dynamic imaging, which may give additional information for detecting the diseases at the early and pre-clinical stages [1–3].

Detecting the bone tissue erosions in rheumatoid arthritis has a fundamental importance for the purpose of defining the treatment strategy, for the structural lesions play an important role in the diagnostics,

ВЫЯВЛЕНИЯ ЭРОЗИВНЫХ ИЗМЕНЕНИЙ СУСТАВОВ КИСТЕЙ И СТОП ПРИ РЕВМАТОИДНОМ АРТРИТЕ: СРАВНЕНИЕ УЛЬТРАЗВУКОВОГО И РЕНТГЕНОГРАФИЧЕСКОГО МЕТОДОВ

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АННОТАЦИЯ

Обоснование. *Обнаружение костных эрозий при ревматоидном артрите имеет решающее значение для определения стратегии лечения и указывает на неблагоприятные исходы. Считается, что чувствительность рентгенографии в выявлении эрозий костей ниже, чем при ультразвуковом исследовании, особенно на ранних стадиях заболевания. Применение неинвазивных и безопасных методов диагностики ревматоидного артрита открывает новые возможности для успешного лечения.* ***Цель исследования*** *— сравнить и оценить результаты ультразвукового и рентгенографического выявления деструктивных изменений суставов кистей и стоп у больных ревматоидным артритом.* ***Методы.*** *В исследование включены 76 пациентов с установленным диагнозом ревматоидного артрита. Рентгенография и ультразвуковое исследование суставов кистей и стоп проводились на момент включения в исследование, далее через 1 и 4 года.* ***Результаты.*** *Наблюдалась слабая степень корреляции между двумя абсолютными значениями количества суставов с эрозиями по данным ультразвукового исследования и рентгенографии. Темп нарастания эрозивных изменений в большей степени отмечался по данным ультразвукового исследования, чем при рентгенографии: от 0,5 [0; 1] до 2,5 [0; 6,0] (p=0,001) и от 0 [0; 1] до 0 [0; 3] (p=0,001) соответственно. При оценке сопоставимости двух методов определения эрозивных изменений суставов кистей и стоп в каждой точке наблюдения с помощью анализа Блэнда–Альтмана показано, что результаты обоих методов частично выходят за пределы двух стандартных отклонений, что свидетельствует о низкой степени согласия между ними. Средняя разница между измерениями показателей составила -0,38 (95% ДИ -0,63…-0,13) до лечения, -1,15 (95% ДИ -1,5…-0,79) при наблюдении через 12 месяцев и -1,52 (95% ДИ -2,32…-0,73) при наблюдении через 4 года, что указывает на систематические отклонения. Корреляции между разницей количества суставов с эрозиями и средним количеством суставов с эрозиями по ультразвуковому исследованию и рентгенографии не выявлено.* ***Заключение.*** *Ультразвуковое исследование и рентгенография не являются эквивалентными методами обнаружения эрозий при ревматоидном артрите, однако ультразвуковое исследование помогает выявить раннее прогрессирование процесса, что является ключом к успешной терапии ревматоидного артрита.*

Ключевые слова: *ревматоидный артрит; эрозии; ультразвуковое исследование; рентгенография.*

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indicating the unfavorable outcomes [4]. Currently, the gold standard for the visualization and quantitative evaluation of bone tissue lesions in patients with rheumatoid arthritis is radiography [5], while the standard method of evaluating the structural lesions in cases of rheumatoid arthritis is the modified Van der Heijde Sharp score (SHS) [6].

According to the recommendations from the European Alliance of Associations for Rheumatology (EULAR) on using the visualization of joints in the

journal of clinical practice 2025 Vol 16 №1

clinical therapy of rheumatoid arthritis, radiography must be used as a first choice visualization instrument for detecting the lesions in the joints (bone tissue erosions and narrowing of the articular fissures) [7].

As it is known, the sensitivity of radiography in detecting the bone tissue erosions is lower comparing to other visualization methods, such as Magnetic resonance imaging (MRI), ultrasound examination (USE) and computed tomography, especially at the early stages of the disease [8–12], opening new possibilities for the non-invasive and safe diagnostics.

High labour-intensity and cost of MRI, being a significant downside of the technology, determines the preference of ultrasound examination [9] — an accessible and relatively inexpensive examination method not related to the exposure of ionizing radiation, which is used for the evaluation of the status practically in all the joints during a single examination. Ultrasound examination of the joints allows for evaluating not only the synovitis and the lesions in the peri-articular tissues, but also the structural lesions of the articular surface, for example, detecting the erosive changes. According to the results from a number of research works, ultrasound examination allows for detecting more erosions than radiography, also having a higher sensitivity and specificity [13]. There are several qualitative and semiquantitative systems of ultrasonographic evaluation [14–19], but, up to the present moment, there is no commonly used standardization method. Ultrasound examination is an attractive method for the evaluation of bone tissue erosions in cases of early rheumatoid arthritis, when the possibilities of radiography are limited by low sensitivity. Based on the large publication base, it can be concluded that ultrasound examination is a reliable tool for the evaluation of erosions in cases of rheumatoid arthritis [9, 20, 21].

The detection of bone tissue erosions by means of ultrasound examination has not only a diagnostic value, but it also predicts the development of rheumatoid arthritis in cases of non-differentiated arthritis in patients with antibodies to cyclic citrullinated peptide, also precedes the development of structural changes in the radiography images in rheumatoid arthritis patients [22], with the bone tissue erosions in the radiography images being rarely detectable in the group of individuals positive for antibodies to the cyclic citrullinated peptide, not predicting the development of rheumatoid arthritis.

At the present moment, the literature worldwide contains an insufficient number of trials comparing the visualization methods for assessing the destructive changes in the joints, while the published sources contain controversial data on the comparison of these two methods. Thus, the research by J. Grosse et al. [22] has shown that, when using the ultrasound to evaluate the joints in patients with rheumatoid arthritis, 2 times more erosions of the joints were found comparing to radiography (SHS scores). The conclusions from the authors of one of the recent researches, stating that ultrasound examination and radiography of the erosions are well in agreement and that ultrasound examination plays an auxiliary role in assessing the destructive process [23], was the basis for the conduction of our research.

Research aim — an assessment of the possibilities of ultrasound examination in the visualization of destructive changes in cases of rheumatoid arthritis comparing to the gold standard — the radiography.

METHODS

Research design

A prospective observational single-center research was carried out in patients with rheumatoid arthritis with the aim of comparing the two methods (radiography and ultrasound) in detecting the erosions of articular surfaces.

Conformity Criteria

Inclusion criteria:

- validated presence of RA in accordance with the classification criteria for RA (ACR/EULAR 2010);
- age over 18 years;
- high or moderate activity of the disease at the moment of inclusion (SDAI ≥ 11, swollen and painful joints ≥ 3 + ESR (Westergren) ≥ 28 mm/h or CRP ≥ 10 mg/l).

Exclusion criteria:

- active tuberculosis, positive Mantoux test (papula ≥ 5 mm) and/or the presence of suspiciousness in terms of an active tuberculosis process based on the radiological changes in the lungs combined with positive Diaskintest or QuantiFERON test;
- the presence of viral hepatitis B, infection of hepatitis B virus;
- the presence of oncological diseases within the last 10 years;
- demyelinating diseases of the nervous system;
- severe cardiac insufficiency;
- active bacterial or viral infection;
- allergic reaction to proteinic medicines in the past medical history;
- pregnancy or breast-feeding.

Research facilities

The research was conducted with the participation of patients with rheumatoid arthritis, which were under long-term supervision and were receiving therapy at the Federal State Budgetary Scientific Institution "Scientific Research Institute of Rheumatology named after V.A. Nasonova" (FSBSI V.A. Nasonova SRIR) [24].

Research Duration

The research was conducted during the period from 2015 until 2022.

Medical procedure description

The ultrasound examination was carried out using the Logiq 9 (GE, USA) and MyLabTwice (ESAOTE, Italy) devices and using the multi-frequency linear probe (10–18 MHz) with the technique of Power Doppler, the parameters of which were adapted for the registration of low-speed flows (PRF 300–600 Hz, low filter, dynamic range 20–40 dB). During the process of examination, 7 articular zones were evaluated in the palms and feet on the clinically dominating side (wrists, II and III metacarpophalangeal, II and III proximal interphalangeal, II and V metatarsophalangeal joints).

The ultrasonography sings of destructive changes (erosions), according to the criteria from the international network on the improvement of the evaluation of results in rheumatology (Outcome Measures in Rheumatology Clinical Trials, OMERACT), was the deepening of the bone tissue contour, visualized in two perpendicular sections, with a width of more than 2 mm and with a depth of more than 1 mm [25]. The estimation of destruction was performed using the binary accounting system (present/absent) for each examined joint (a number of joints with erosions) in three points: at the moment of enrollment into the trial, in 12 months of therapy and after 4 years of follow-up. The dynamic (quantitative and qualitative) parameter of the increase in the number of joints with erosions was also used. For the quantitative evaluation of radiological changes, the Sharp's method was used (modified by van der Heijde) before treatment, in 12 months and 4 years after the treatment initiation [6].

For the comparison of the two methods for evaluating the destructive changes, we have used the evaluation of the identical articular zones with counting the number of joints with erosions according to the data from radiography and ultrasound examination for the purpose of alleviating the specific features of ultrasonic visualization and the radiographic evaluation (the primarily benefits of the ultrasonic method in the evaluation of joints, where the ultrasonography access is possible from three sides, for example, metacarpophalangeal joints II and V, and the benefit of radiography is the intra-articular evaluation).

To estimate the possibilities of using ultrasound examination for the diagnostics of erosive changes in cases of rheumatoid arthritis, both methods were used simultaneously and compared at all the stages of follow-up.

Statistical analysis

The statistical processing of the results was carried out using the Statistica software package ver. 8.0 (StatSoft, USA), including the commonly used methods of parametric and non-parametric analysis. For the parameters, the distribution of which differed from the normal one, when comparing the two groups, the Mann-Whitney test was used, the results were presented as the median (Me) [25th; 75th percentile]. For the graphic comparison of the results obtained using various methods, the Bland–Altman method was applied. The differences were considered statistically significant at the $p < 0.05$.

RESULTS

Research sample (participants)

The general characteristics of the patients with rheumatoid arthritis, included into the research (n=76), is presented with dynamic follow-up data in table 1.

Primary findings

According to the data from radiography of the palms and feet, erosions were found in 30% of the patients before treatment initiation, in 39% of the patients one year after the treatment initiation and in 66% at the end of the research, according to the data from ultrasound examination — in 50, 75 and 71%, respectively. The median of the number of joints with erosions detected by USE was higher than for radiography, with gradual progression of changes during the process of follow-up (see table 1).

The estimation of the relation between the two methods at three stages of the trial has shown a weak degree of relation between the absolute values — the number of joints with erosions, evaluated using the ultrasound examination and radiography (r=0.36; p=0.001) before treatment: in 15 patients with ultrasonographic signs of erosions, they were not revealed according to the data obtained when using the radiography (a total of 38 patients with detected erosions according to the data from ultrasound

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journal of clinical practice 2025 Vol 16 №1

Table 1

General characteristics of the patients with rheumatoid arthritis (*n*=76), Me [25; 75]

Parameters	On enrollment	In 1 year	In 4 years
Age, years	53.5 [44.0; 61.5]	-	-
Duration of disease, months	6.0 [4.0; 16.5]	-	-
Number of swollen joints	7 [5; 11.5]	0 [0.0; 2.0]	0.5 [0.0; 3.0]
Number of painful joints	9.5 [5.0; 14.5]	1.0 [0.0; 3.5]	3.5 [0.0; 6.5]
DAS28	5.53 [4.54; 6.15]	2.64 [1.98; 3.92]	3.61 [2.64; 4.79]
SDAI	28.5 [19.38; 40.14]	4.52 [1.7; 11.63]	9.68 [3.59; 18.29]
CDAI	26.25 [17.25; 36.5]	4.0 [1.5; 11.0]	9.0 [3.35; 17.95]
ESR, mm/h	34.5 [8.5; 50]	10.0 [4.0; 24.0]	20.0 [12.0; 34.0]
CRP, mg/l	11.4 [1.1; 35.4]	2.5 [0.2; 6.1]	2.8 [1.15; 7.35]
RF (+), *n*	66 (87%)	-	-
A/B to CCP(+), *n*	63 (83%)	-	-
Percentage of patients with Rg-erosions, Sharp's method, %	47	53	66
Percentage of patients with Rg-erosions in the examined joints, %	30	39	58
Ultrasonographically determined number of joints with erosions	0.5 [0.0; 1.0]	2.0 [0.5; 3.0]	2.5 [0.0; 6.0]
Radiologically determined number of joints with erosions	0.0 [0.0; 1.0]	0.0 [0.0; 1.0]	1.0 [0.0; 3.0]

Note. DAS-28 (Disease Activity Score-28) — index of inflammatory activity of rheumatoid arthritis; SDAI — Simplified Disease Activity Index of rheumatoid arthritis; ESR — erythrocyte sedimentation rate; CRP — C-reactive protein; RF (+) — positive test for Rheumatoid factor; A/B to CCP(+) — positive test for antibodies to cyclic citrullinated peptide; X-ray/US — radiological/ultrasound examination.

examination and 23 patients with erosions according to the data from radiography). One year after treatment initiation, the correlation was also weak (r=0.29; *p*=0.01), while after 4 years of follow-up is has become more clear (r=0.502; *p*=0.001).

We have analyzed the consistency of measurement results obtained using different methods. The method of Bland–Altman has demonstrated a dependence of the difference between the ultrasonography and the radiography results on the mean number of joints with erosions, obtained using two methods (Fig. 1). All the graphs were compiled within a standardized range of ±1.96 standard deviations, showing the expected scattering of differences between two measurements.

The lower and the upper limits of agreement at the first point were -2.55 and 1.79 respectively, with the dislocation to -0.38 for radiography. Upon the correlation analysis, the findings showed a dependence of the

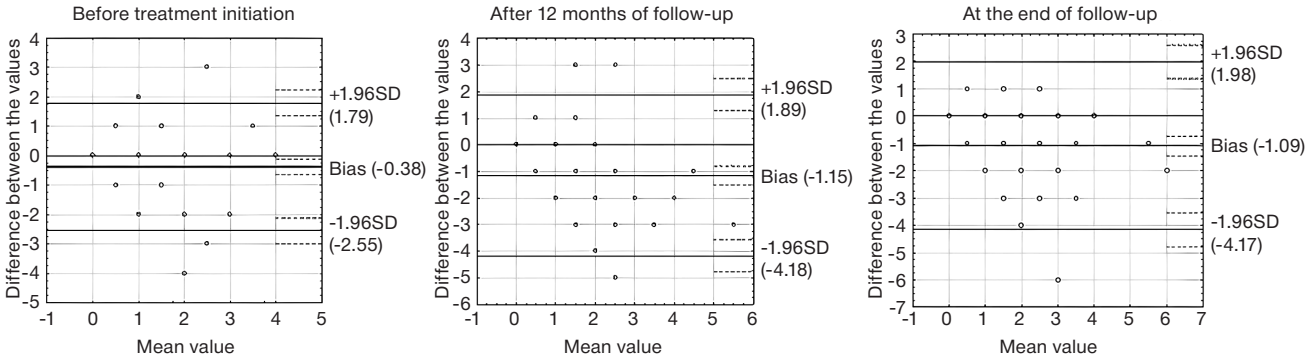

Fig. 1. The dependence of the difference in the number of joints with erosions, measured ultrasonographically and radiologically, on the mean value. Bland–Altman plot: upon enrollment (before treatment initiation), in 1 year from the moment of treatment initiation and at the end of the research.

difference in the values on its means when using the two methods (Fig. 2). After a year of follow-up (the second point), the limits of agreement have expanded (-4.18 for the lower and 1.89 for the upper), the dislocation has also become more significant (-1.15). The dependence of the difference between the values on its mean value was also statistically significant (see Fig. 2). After 4 years of follow-up (the third point), the abovementioned tendencies persisted: the lower and the upper limits of agreement were -4.17 and 1.98, respectively, the dislocation was significant (-1.09), there was also a statistically significant relation of the difference between the values and their means (see Fig. 2).

Thus, despite the presence of a mild to moderate correlational relationship between the ultrasonography and the radiology methods, the Bland–Altman analysis shows a systematic discrepancy due to the significant deviation of the absolute values, the results are partially out of the ranges of two standard deviations, with a demonstrated statistically significant relation of the difference in the values and their mean values.

Taking into consideration the absence of agreement between the two methods in a single point and a more frequent detection of erosions when using the ultrasonography, a conformity was analyzed between the ultrasound examination and the radiography in various follow-up time points. Due to the fact that ultrasonography detects erosions earlier and more frequent than radiography, the ultrasonographic method at the beginning of follow-up and after a year of treatment (the first and the second points) was compared to the radiography results after 4 years of follow-up (the third point). Upon the comparison of the results from the ultrasound examination at the first point and from radiography — at the third one, a moderate correlation was found in the relationship between the number of joints with erosions, evaluated using two methods (r=0.46; *p*=0.001). The average deviation of the radiography results comparing to the data obtained using the ultrasound examination was -0.13, the lower range was -2.49, the upper was 2.23 (Fig. 3, *a*). The correlation coefficient was 0.014 (*p*=0.9),

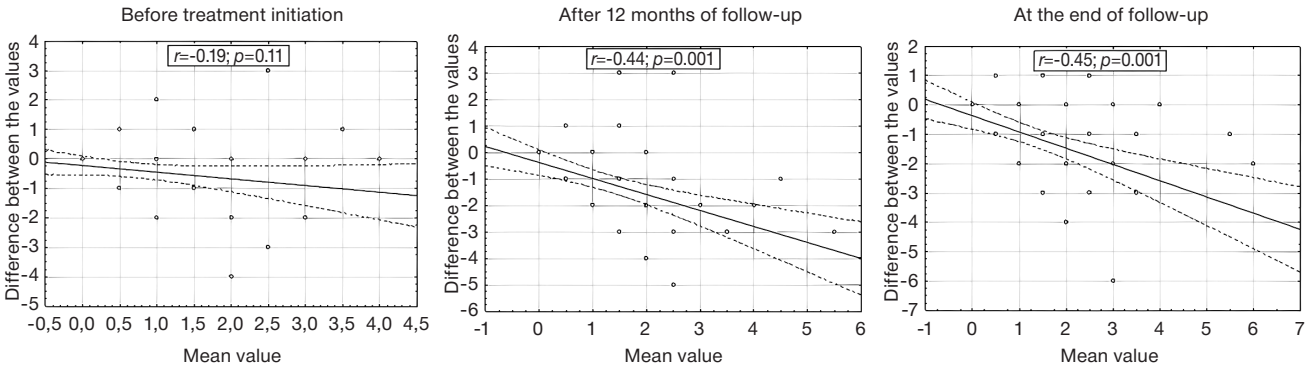

Fig. 2. The dependence of the difference in the number of joints with erosions, measured ultrasonographically and radiologically, on the mean value for the two methods of detecting erosions: upon enrollment (before treatment initiation), in 1 year from the moment of treatment initiation and at the end of the research.

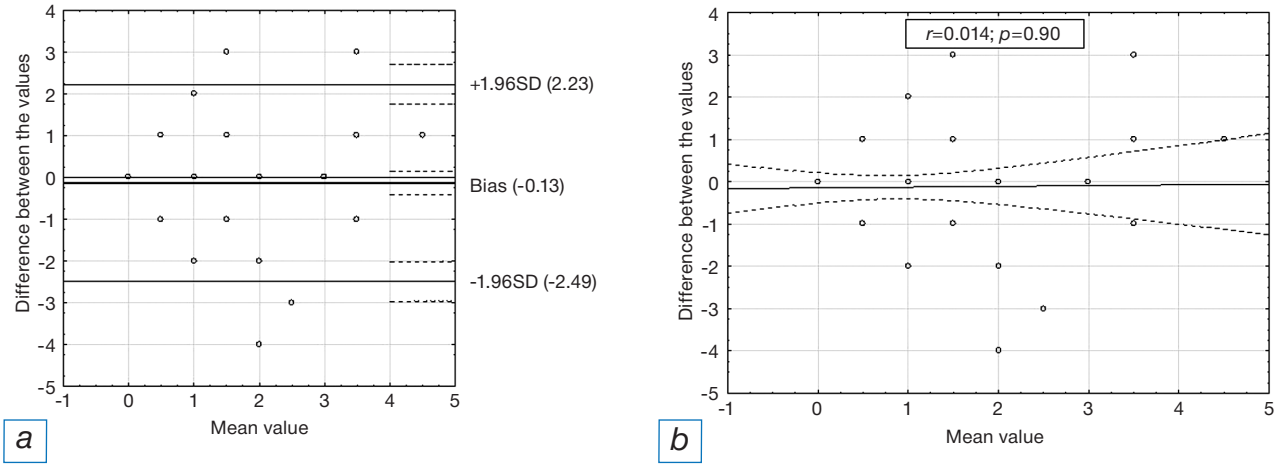

Fig. 3. The dependence of the difference in the number of joints with erosions, measured using ultrasound method upon enrollment and radiologically at the end of follow-up, on the mean values: *a* — Bland–Altman plot; *b* — correlations.

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journal of clinical practice 2025 Vol 16 №1

5% of the values were outside the interval of two standard deviations (see Fig. 3, *b*).

The similar analysis was carried out when comparing the ultrasonography results after one year of follow-up and the radiography results at the end of the follow-up period. There was a moderate statistically significant dependence between the two changes (r=0.31; *p*=0.006). The Bland–Altman analysis has shown a deviation of the results being -1.07, with the lower range of -3.94 and the upper being 1.8. The correlation coefficient was -0.35 (*p*=0.0015; r^2=0.13); 4% of the values did not fit into the ranges of two standard deviations.

The Bland–Altman analysis has shown minimal discrepancy of the results upon the comparison of ultrasonography at the first point and of the radiography at the third one. The mean difference between both measurements is -0.13, only 5% of the values do not fit into the range of two standard deviations and there was no detected dependence of the measured difference on the mean parameter value — the number of joints with erosions. Only the high ranges of the agreement do not allow for concluding on the 100% equivalence of two methods, which is probably related to the available limitations.

The comparison of the results for the second and the third point has shown a significant systematic discrepancy.

Thus, the ultrasound examination is not an equivalent for the radiological method of detecting erosive changes in the joints of the palms and feet, but it is comparable to the radiological detection of erosions after 4 years of follow-up.

DISCUSSION

We have conducted a comparative evaluation of the results of measuring the destructive changes in the joints of the palms and feet using the ultrasound examination and the radiography in patients with a slight (median — 6 months) duration of the disease. A total of 1/3 of the patients at the moment of their inclusion into the research had erosions detectable by radiography, which allowed for adequately tracing the progression of destructive changes within 4 years of follow-up. The gold standard of detecting destructive changes is the radiography, despite its exclusion from the classification criteria for rheumatoid arthritis issued in 2010 [26]. This is due to delayed (as it was also shown by our research) development of erosions, absence of which at early stages shall not provide the possibility of early diagnostics of rheumatoid arthritis. The exclusion are the patients, in which a long-term inactive disease is suspected, which can be classified as non-rheumatoid arthritis, while the presence of typical erosions could allow for setting the correct diagnosis [27]. It is also necessary to point out that the detection of erosive changes at early stages is a prognostically unfavorable factor [4, 8, 11, 19], due to which, the search of the methods of early and accessible detection of erosions in cases of rheumatoid arthritis is still in progress [28–30].

The data obtained by us allow for stating the significance of ultrasound examination as a predictive method in the evaluation of destructive changes, meaning the most agreement of the methods in cases of 4 years interval between them. The absence of agreement in the simultaneous use of the methods can be explained by the presence of limitations (for example, partial accessibility of the ultrasonographic evaluation of the bone tissue contour with an intra-articular location, the subjectiveness of the method, the examination of the limited number of joints). We have found that the ultrasound detection of erosions occurs significantly earlier comparing to the radiological examination and, hypothetically, the time difference is not less than 4 years.

The early detection of erosions using the ultrasound examination is described in a number of research articles comparing the visualization methods with simultaneous evaluation in each joint. In one of the recent reviews, an analysis was undertaken to estimate the sensitivity and specificity of ultrasound examination of the locomotor system for the purpose of identifying the synovitis and early erosive changes in small joints for cases of rheumatoid arthritis. In the sample provided, the sensitivity and specificity of ultrasound examination for detecting early erosions of the bones was 58% and 94%, respectively, including the described earlier detection of erosive changes by the data from ultrasound examination comparing to radiography [9].

The comparison of two methods for detecting erosive changes was carried out using the correlation analysis (kappa-test) in several research works from foreign authors, where it was shown that the estimated degree of agreement was not high (from 0.59 to 0.74) [11, 13]. Our research showed similar findings and it led to the conclusion that ultrasound examination is an effective and earlier method of detecting erosions, with the statistical discrepancy of two methods being minimal at the moment of enrollment into the trial and increasing during the follow-up (from -0.38 on enrollment to -1.15), which indicates the more often

ultrasonographic detection of destructive changes with the increase in the duration of the disease.

Similar results were demonstrated by U.M. Dohn et al. [31]: based on their results, in accessible areas, ultrasound examination also has high precision in terms of detecting and evaluating the erosions in rheumatoid arthritis patients. Also interesting is the research by R.H. Mohammed et al. [32] on comparing the capabilities of ultrasound examination and radiography in the diagnostics of early rheumatoid arthritis: of the 720 palm joints examined using the ultrasound, erosions were detected in 23 (3%) joints of 7 (18%) patients comparing to radiography, where the erosions were detected in 7 (1%) palm joints in 3 (8%) patients. Thus, the number of palm joints with erosions detected by ultrasound examination was 3.28 times more than the number detected using radiography images. Similarly, the number of patients with erosions in palm joints based on the data from ultrasound examination was 2.33 times higher than the number detected in the radiography images. These differences were statistically significant.

CONCLUSION

We have not found any proof of equivalence for the ultrasound examination and the radiography in detecting erosions in the joints of the palms and feet. With an increase in the follow-up time, the relation of changes detectable using the ultrasound examination and the radiography becomes more significant, but the clinical value of such a late detection of erosions in cases of rheumatoid arthritis is doubtful.

The detected delayed agreement of radiological and ultrasonographic detection has a great importance in further validation and clinical implementation of ultrasound examination for detecting the destructive arthritis in patients with early stages of rheumatoid arthritis.

ADDITIONAL INFORMATION

Author contribution. *A.V. Smirnov* — general concept, search and analytical work, processing and discussion of research results, writing the text of the article, X-ray evaluation; *O.G. Alekseeva* — search and analytical work, processing and discussion of research results, participation in recruitment and management of patients, ultrasound examination; *S.I. Glukhova* — statistical processing and discussion of the results of the study; *M.V. Severinova* — participation in ultrasound examination and filling out thematic maps; *E.L. Nasonov* — general concept and search and analytical work; *A.V. Volkov* — search and analytical work and processing and discussion of research results and writing the text of the article and editing. The 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.

Ethics approval. The study was approved by the Local Ethics Committee of V.A. Nasonova Scientific Research Institute of Rheumatology, in accordance with the protocols No. 25 of 12/03/2015 and No. 11 of 06/18/2020. All participants in the study provided voluntary informed consent in order to participate in the research.

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