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ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Diagnostic performances and clinical usefulness of comprehensive non-commercial software for renogram analysis – values of renal output efficiency and normalized residual activity in suspected kidney outflow obstruction

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SUMMARY

Introduction/Objective Nuclear Medicine Section of IAEA has developed the software for dynamic renal scintigraphy, which allows calculation of advanced parameters of drainage: renal output efficiency (OE) and normalized residual activity (NORA).

The aim of this study was to validate IAEA software by comparing results of parameters of renal drainage in normal subjects against their established reference values and to assess diagnostic accuracy of OE and NORA in distinguishing between obstruction/unobstruction.

Methods Fifty-five patients with suspected obstruction and 36 kidney donors were investigated. Group A consisted of 24 obstructed kidneys, Group B of 37 kidneys with dilated urinary tract, and Group C of 72 normal kidneys. Forty-minute acquisition was applied. Furosemide was administered after 20 minutes. Post-micturition image was acquired at 50 minutes. The analyzed parameters were as follows: OE at 20 minutes (OE_{20}) and at the end of the furosemide test (OE_{40}), NORA at 20 minutes ($NORA_{20}$) and after micturition ($NORA_{PM}$). One-way ANOVA was used for evaluating the differences between the groups. Ability of OE_{40} and $NORA_{PM}$ to distinguish between obstruction/unobstruction was determined by ROC curve analysis. The sensitivity, specificity, area under the curve, and cut-off values were analyzed.

Results Excellent agreement of our results with established OE and NORA values was found. The difference between the groups was significant for OE_{20}, OE_{40}, $NORA_{20}$, and $NORA_{PM}$ ($p < 0.001$). Cut-off values for obstruction were 82% and 0.11 for OE_{40} and $NORA_{PM}$, respectively.

Conclusion IAEA software gives reliable analysis of diuretic renography and helps to better diagnose obstruction. IAEA should be encouraged to produce final version of the software and to release it online.

Keywords: radionuclide renography; uroobstruction; output efficiency; normalized residual activity

INTRODUCTION

Diuretic renography is an old nuclear medicine technique, which is still widely used in the diagnosis of upper urinary tract obstruction. The differentiation between obstruction and non obstructive dilatation is assessed by the analysis of the down-slope of renogram curve after injection of furosemide [1]. The advanced quantitative parameters of kidney drainage, i.e., renal output efficiency (OE) and normalized residual activity (NORA) were proposed some time ago. They were shown to be the least dependent of the underlying single kidney function in comparison with other parameters [2, 3].

Nonetheless, these parameters have not been routinely used, since the majority of software for the analysis of diuretic renography did not incorporate the tools for their calculation. In the meanwhile, the Nuclear Medicine and Diagnostic Imaging Section of the International Atomic Energy Agency (IAEA) has developed non-commercial software for renogram processing on a simple p-computer, which gave the opportunity of calculating OE and NORA [4]. However, neither was this software fully completed, nor was the quality of its quantitative indices validated in comparison with any commercial software package.

In this study we used MAG-3 and a specific time for injecting furosemide and studied the performances and clinical reliability of the use of IAEA Software Package in detecting urine flow obstruction. The aims were as follows: a) to validate the numerical outputs of this software by comparing the results of parameters of renal drainage in normal subjects against their established reference values, and b) to assess the diagnostic accuracy of OE and NORA in distinguishing between obstructed and patent upper urinary tract.

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METHODS

Patients enrolled in this study were referred from the Urology Department between November 2011 and July 2014 with the diagnosis of unilateral or bilateral urological disorder which caused the dilatation of the collecting system and suspected upper urinary tract obstruction. They had undergone ^{99m}Tc-MAG-3 dynamic scintigraphy with furosemide stimulation. The criteria for inclusion in the patients' groups were age over 18 years, renal function tests (serum creatinine level – sCr, creatinine clearance – cCr) and at least two imaging tests whose findings suggested obstruction. The exclusion criteria were recent renal or ureteral surgery and high grade of vesicoureteric reflux. There were 55 patients, 23 males and 32 females, aged 21–73 years (mean: 44.4 ± 16.0 years). For the control group, we selected 36 healthy subjects who were candidates for kidney donation. They had no structural abnormality of kidneys on ultrasound examination nor any history of kidney, urinary, or cardiovascular disorder, autoimmune disease, or diabetes. There were 16 males and 20 females (age range: 35–73 years; mean: 51.7 ± 10.6 years) in the control group.

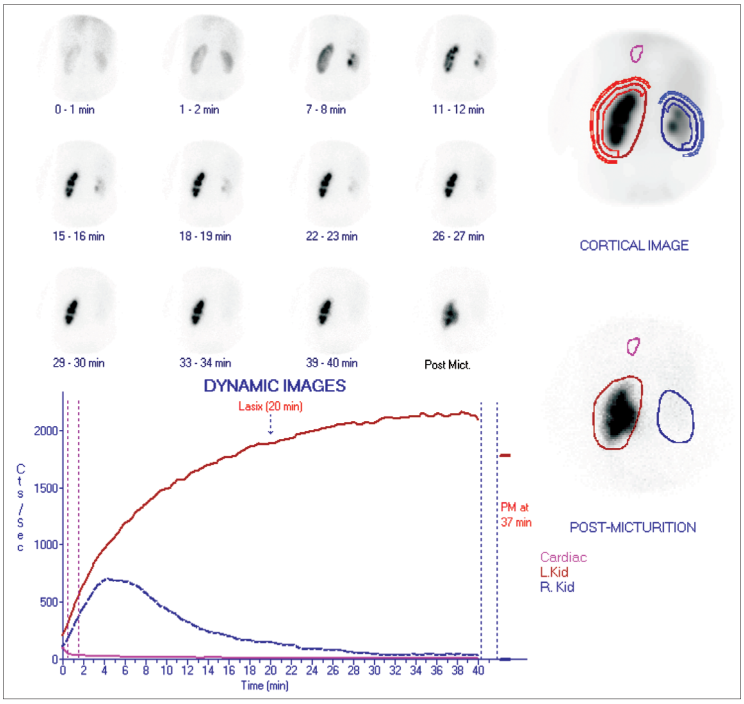

Figure 1. A structured display of IAEA Software Package review screen; serial 1-minute images of kidneys enable the estimation of tracer kinetics; composite parametric image with regions of interest over kidneys, left ventricle, and background; postmicturition image; renogram curves

Ethical approval for this study was obtained from the Ethics Committee of the University Clinical Center of Serbia (approval number: 668/6/2018), and the written informed consent from the patients was obtained.

Each subject received 500 ml of water 60 minutes before the study and emptied the bladder just before the acquisition. A large field of view γ camera (Siemens Orbiter 7500, Siemens, Erlangen, Germany) was set up with low-energy all-purpose collimator. The subject was in the supine position above the camera, which was positioned to include the left ventricle and both kidneys. A 40-minute acquisition protocol with 240 10-second images in 128 × 128 matrix size was applied. The dose of ^{99m}Tc-MAG-3 was adjusted for body weight, with a minimum of 74 MBq (2 mCi) and a maximum of 200 MBq (5.5 mCi), according to the respective guidelines [5, 6]. Furosemide was administered 20 minutes after the acquisition. Post-void static image of one minute duration was acquired 50 minutes after tracer injection.

Regions of interest were drawn over the left ventricle and both kidneys. The renal regions of interest included the kidney cortex and pelvis. From the generated renograms, the time to maximum activity (T_{max}) and to half maximum ($T_{1/2}$) were calculated. Differential renal function (DRF) was determined using the Rutland–Patlak plot method [7].

Three experienced physicians (two nuclear medicine specialists and one urologist) analyzed each patient and classified the kidneys into two categories. The division was based on the analysis of the pattern of excretion on diuretic renography after furosemide (by visual assessment of dynamic images and curves, T_{max} and $T_{1/2}$ values) and imaging tests other than renography (ultrasound, IVU, CT, MRU). Kidneys with poor drainage after furosemide and clinical/radiological signs of obstruction were classified into Group A. They were characterized by progressive accumulation of the radiopharmaceutical in the collecting system on dynamic scintigraphy and retention of the tracer on post-micturition images. Other imaging tests showed significant dilatation of pelvi-calyceal system and lack of appearance of radiology contrast media in the lower urinary tract. Group B consisted of hypotonic unobstructed kidneys with good drainage of the pelviureteric system after furosemide on dynamic scintigraphy images, followed by significant further drainage on post-micturition images. Radiology imaging tests revealed moderate pelvic dilatation and signs of patent urinary tract.

For the OE and NORA, the IAEA software package was used (Figure 1). These parameters were determined at two time points: OE at 20 minutes (OE_{20}) and at 40 minutes (20 minutes after furosemide injection, OE_{40}), NORA at 20 minutes ($NORA_{20}$) and on the post-micturition acquisition ($NORA_{PM}$).

Statistical analysis

For assessing the results of the research, descriptive and analytical statistics (IBM SPSS Statistics, Version 20.0; IBM Corp., Armonk, NY, USA) were used. The default level of significance was put below 0.05 level. We used the one-way ANOVA for evaluating the differences between the groups. The unpaired t-test was used to compare the values

Table 1. Parameters of ^{99m}Tc-MAG-3 renogram in normal kidneys

Values	T_{max} (min)	$T_{1/2}$ (min)	OE_{20} (%)	OE_{40} (%)	$NORA_{20}$	$NORA_{PM}$	DRF (%)
N	72	72	72	72	72	72	72
Mean	3.57	6.61	91.29	97.06	0.38	0.02	50.23
SD	0.66	1.75	2.77	1.25	0.11	0.01	3.43
Min	0.7	2.5	84	92	0.16	0.01	43
Max	5.2	11	97	98	0.69	0.06	57

DRF – differential renal function; T_{max} – time to maximum activity; $T_{1/2}$ time to half maximum activity; OE_{20} – output efficiency at 20 minutes; OE_{40} – output efficiency at the end of the furosemide test; $NORA_{20}$ – normalized residual activity at 20 minutes; $NORA_{PM}$ – normalized residual activity after micturition

Table 2. Output efficiency and normalized residual activity in kidneys with obstructed or dilated urinary tract.

Groups	OE_{20} (%)	OE_{40} (%)	$NORA_{20}$	$NORA_{PM}$
Group A (obstructed)				
n	24	24	24	24
Mean	49.61	66.18	2.4	0.32
SD	12.2	10.64	0.54	0.11
Min	31	47	1.73	0.17
Max	71	82	3.46	0.65
Group B (dilated)				
n	37	37	37	37
Mean	66.92	93.31	1.57	0.03
SD	12.75	3.70	0.66	0.01
Min	38	84	0.42	0.01
Max	91	98	3.51	0.06
p*	< 0.001	< 0.001	< 0.001	< 0.001

OE_{20} – output efficiency at 20 minutes; OE_{40} – output efficiency at the end of the furosemide test; $NORA_{20}$ – normalized residual activity at 20 minutes; $NORA_{PM}$ – normalized residual activity after micturition;
*significance level from comparison of kidneys with good and poor drainage

between groups A and B. The relationship between OE_{20} and $NORA_{20}$ was assessed by Pearson correlation coefficient and linear regression analysis. The ability of the OE_{40} and $NORA_{PM}$ to distinguish between obstruction/unobstruction was determined by receiver operating characteristics (ROC) curve analysis. Sensitivity, specificity, the area under the curve (AUC) with 95% confidence interval, and cut-off values were analyzed.

Table 3. Receiver operating characteristics analysis for output efficiency at the end of the furosemide test and normalized residual activity after micturition

Predictor variables	n	AUC	95% CI	p	Optimal cut-off value	Sensitivity (%)	Specificity (%)
OE40 (%)	61	0.992	0.934–1.000	< 0.001	≤ 82	98	91
NORAPM	61	1.00	0.852–1.000	< 0.001	> 0.10	97	95

OE_{40} – output efficiency at the end of the furosemide test; $NORA_{PM}$ – normalized residual activity after micturition; AUC – area under the receiver operating characteristics curve

RESULTS

Subjects

Fifty-five patients presented with 61 hydronephrotic kidneys (49 patients with unilateral, six with bilateral HN). The underlying clinical diagnosis were pelviureteric junction narrowing (51%), renal calculus (38%), ureteral stenosis (4%), and other (7%). Twenty-four kidneys had the signs of obstruction and were classified into Group A, while Group B consisted of 37 kidneys with dilated but unobstructed upper urinary tracts. The control Group C consisted of 36 subjects with 72 renal units. In total, 91 subjects and 133 renal units were analyzed.

Parameters of renal washout in control subjects

There were 72 kidneys in Group C (36 on the left and 36 on the right side). In all kidneys, the DRF was normal, 43–57%. Table 1 shows the mean and standard deviation, the minimum and maximum values for T_{max}, $T_{1/2}$, OE_{20}, OE_{40}, $NORA_{20}$, $NORA_{PM}$, and DRF. As expected, the values for NORA were low, whereas OE was high.

Parameters of kidney washout in patients

Group A consisted of 23 kidneys, and Group B of 36 kidneys. The results of $NORA_{20}$, OE_{20}, OE_{40}, and $NORA_{PM}$ are shown in Table 2.

The one-way ANOVA comparison between the groups, taking normal Group C as the reference, showed significant difference for the OE_{20}, OE_{40}, $NORA_{20}$, and $NORA_{PM}$ ($p < 0.001$, Figure 2). Comparing the values between groups A and B, the significant difference was obtained for the values of OE_{40} and $NORA_{PM}$ ($p < 0.001$).

Significant inverse linear correlation between $NORA_{20}$ and OE_{20} was obtained by linear regression analysis ($r = -0.982$; $y = 99.1 – 20.2x$) at 0.001 level. The dispersion of the values along the line of regression slightly increased when the quality of drainage decreased (Figure 3).

The ability of the OE_{40} and $NORA_{PM}$ to distinguish between obstructed and unobstructed kidneys were analyzed by the ROC curve analysis. The AUC with 95% confidence interval, optimal cut-off values, sensitivity, and specificity are summarized in Table 3.

DISCUSSION

In adult patients with suspected upper urinary tract obstruction, we studied the performances of the IAEA software for the comprehensive analysis of radionuclide renography and validated the reliability of its numerical outputs for characterizing kidney drainage, by comparing with reference values for ^{99m}Tc-MAG-3. The obtained results revealed excellent agreement with established normal ranges of OE and NORA. Normal kidneys presented with OE_{20} values higher than 83%, OE_{40} higher than 91%, $NORA_{20}$ lower than 0.70 and $NORA_{PM}$ lower than 0.07. In kidneys with obstruction, OE_{40} was lower than 83% and $NORA_{PM}$ was higher than 0.17. Furthermore, OE_{40} showed high sensibility and specificity in verifying insufficient drainage. The calculated cut-off values for predicting

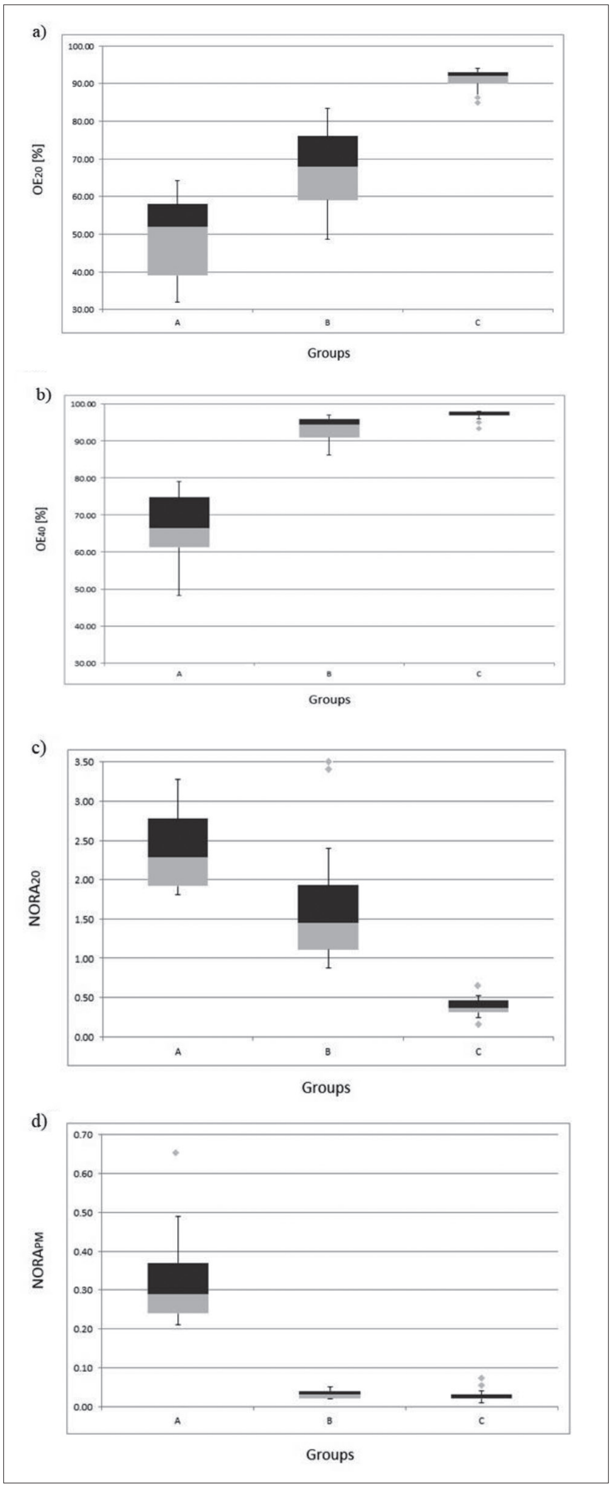

Figure 2. In a–d, the values of output efficiency OE_{20}, OE_{40}, normalized residual activity $NORA_{20}$ and $NORA_{PM}$ (postmicturition) are, respectively, represented for the groups of patients A, B, and C; OE is given in percentage and NORA in units

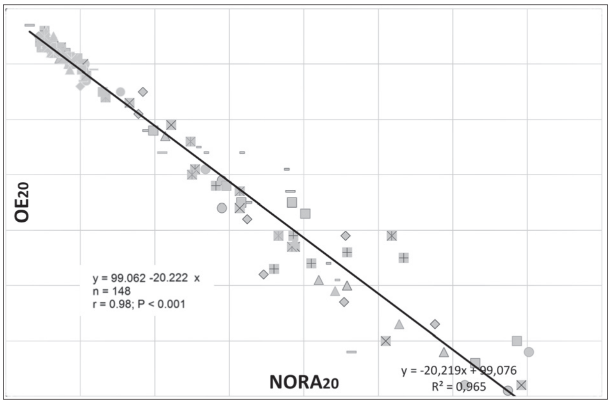

Figure 3. Correlation between output efficiency OE_{20} and normalized residual activity $NORA_{20}$; the Pearson's correlation coefficient was high (r = - 0.982, p < 0.001)

poor drainage were shown to be ≤ 82% and > 0.10 for OE_{40} and $NORA_{PM}$, respectively.

The traditional way to analyze the diuretic renogram consisted of visual interpretation of dynamic images and time/activity curves, as well as the calculation of T_{max} and $T_{1/2}$ values [8]. The problem appears in cases of reduced renal function or grossly dilated renal pelvis when $T_{1/2}$ is prolonged, even in the absence of obstruction, which leads to equivocal findings of diuresis renography [9]. The output efficiency index and the normalized residual activity are two measurements that have been proposed by the International Scientific Committee of Radionuclides in Nephro-urology to compensate for slower rates of clearance due to reduced renal function [5]. Some commercial software packages incorporated the tools for calculating these two parameters, but users in developing countries could not afford them due to their high price. IAEA released the non-commercial Software Package for the Analysis of Scintigraphic Renal Dynamic Studies as a draft version in 2010 [4]. However, to date, the software has not been completed, probably due to the lack of interest in nuclear medicine centers in developed countries to apply the software, since their departments are equipped with high-quality commercial software packages. In our department, there has been considerable interest to apply the advanced analysis of diuretic renography. To the best of our knowledge, this is the first study on the validation of numerical indices of the IAEA software in patients with impaired drainage.

In the previously published studies about OE and NORA, various protocols were used, with the differences in duration of acquisition and in the time of diuretic challenge. This invalidates the comparison between studies and avoids the determination of the cut-off values of these parameters for differentiation between obstruction/unobstruction. In the newest guidelines for diuresis renography, three time points were specified for the calculation of renogram parameters: 20 minutes after the start of the acquisition, 20 minutes after the diuretic challenge, and on the post-micturition scan. The current version of the IAEA offers the calculation of OE_{20} and OE_{40}, $NORA_{20}$, and $NORA_{PM}$ [5, 10]. According to these time points, we calculated the present results.

The normal ranges for parameters of ^{99m}Tc-MAG-3 renogram were reported in several studies, mainly for T_{max} and $T_{1/2}$ [11–15]. The results calculated in our study with the use of IAEA software showed substantial agreement with these values (Table 4).

Table 4. Comparison with related studies for T_{max} and $T_{1/2}$

Study (year)	Tmax (minutes)			T1/2 (minutes)		
	n	Mean	SD	n	Mean	SD
[11] (1994)	36	3.6	2.2	36	6	2.5
[12] (2002)	82	3.2	0.6	-	-	-
Jung and coworkers (2005) [13]	22	3.8	1.2	22	6.2	2.5
[14] (2006)	106	3.8	1.9	106	6.5	4.1
[15] (2015)	48	3.1	0.5	-	-	-
Present study	72	3.6	0.7	72	6.6	1.7

T_{max} – time to maximum activity; $T_{1/2}$ time to half maximum activity

For the OE, in the study that validated this index as an objective quantitative parameter of kidney drainage, Chaiwatanarat et al. [2] reported the normal values in 22 kidneys of healthy control subjects to be 91.6 ± 4.6%, which is in complete agreement with our results. In obstructed kidneys, they obtained somewhat lower values in comparison with the present study, probably due to shorter time for diuretic challenge (30 minutes acquisition instead of 40 minutes in our protocol). In the study of output efficiency as a method for clarifying equivocal renograms, the 30-minute acquisition protocol was also applied and the reported cut-off value for excluding obstruction was lower than that in our study [16].

The NORA index was proposed as a robust parameter of renal drainage and simpler for calculation than OE. This parameter has not been widely assessed in the literature. More frequently used was the residual activity index expressed as a percentage of the maximal activity, but it does not take into account the value of renal clearance [17]. The reported normal threshold for $NORA_{20}$ was 0.70, which is identical with the result of the present study [18].

We correlated the values of NORA and OE at calculated at 20 minutes and obtained high values of Pearson correlation coefficient, since a significant correspondence was reported between these two parameters in the literature [19]. This correlation confirmed the statement of the possibility to replace the OE with NORA, when deconvolution method for calculation of OE could not be applied or is not available [20].

We have determined the optimal cut-off values for OE_{40} and $NORA_{PM}$ to distinguish between hypotonic unobstructed kidneys and kidneys with obstruction. They were similar with the previously reported cut-off values for obstruction and yielded a sensitivity and specificity of almost 100%, thus affirming the use of these parameters in evaluation of kidney drainage [18].

CONCLUSION

This study demonstrates that the implementation of the new algorithm for quantification of renal drainage, incorporated in the IAEA software package, provides comprehensive, high-quality quantitative analysis of diuretic renography. Renal output efficiency and normalized residual activity are accurate parameters of renal drainage, which contribute to the diagnosis of kidney outflow obstruction. The calculation of these quantitative indices should become a part of routine analysis of dynamic renal scintigraphy. They would facilitate the comparison between studies during follow-up and monitoring the response to surgical treatment. In addition, the use of this software can help to standardize the protocols for acquisition and processing of the diuretic renography and to avoid the measurement of excretory parameters at various times after diuretic challenge, which hampers the comparison of studies between centers. The harmonization of the scintigraphy reports could enable the exchange of quantitative data between physicians and departments. We would appeal to the Nuclear Medicine and Diagnostic Imaging section of the IAEA to complete the work on the software and to release it through the IAEA website.

Conflict of interest: None declared.

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Клиничка евалуација новог софтвера за анализу динамске сцинтиграфије бубрега – значај ефикасности бубрежне елиминације и нормализоване резидуалне активности у дијагностици опструкције уринарног тракта

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САЖЕТАК

Увод/Циљ У Одсеку за нуклеарну медицину Међународне агенције за атомску енергију (МААЕ) направљен је софтвер за анализу динамске сцинтиграфије бубрега, који омогућава израчунавање нових, прецизнијих показатеља бубрежног излучивања – ефикасности елиминације (ЕЕ) и нормализоване резидуалне активности (НОРА).

Циљ нашег рада је валидирање софтвера МААЕ поређењем вредности параметара ренограма код здравих испитаника са њиховим референтним вредностима и процена значаја ЕЕ и НОРА у диференцијалној дијагностици уроопструкције.

Методе Анализиран је 91 испитаник – 55 болесника са суспектном опструкцијом уринарног тракта и 36 давалаца бубрега. У Групи *А* су била 24 опструктивна бубрега, у Групи *B* 37 бубрега са неопструктивном дилатацијом, у Контролној групи *C* 72 нормална бубрега. Сцинтиграфија је рађена током 40. минута после *i.v.* убризгавања *^{99m}Tc-MAG*-3, фуросемид је убризган у 20. минуту, а постмикциона сцинтиграфија снимљена у 50. минуту. За обраду је коришћен софтвер МААЕ. Анализирани су ЕЕ у 20. минуту ($ЕЕ_{20}$) и 20 минута после фуросемида ($ЕЕ_{40}$), НОРА у 20. минуту ($НОРА_{20}$) и после микције ($НОРА_{ПМ}$). У процени резултата истраживања коришћене су методе дескриптивне и аналитичке статистике.

Резултати Поређење наших резултата са референтним вредностима ЕЕ и НОРА показало је висок степен сагласности. Разлика између група је била статистички значајна за $ЕЕ_{20}$, $ЕЕ_{40}$, $НОРА_{20}$ и $НОРА_{ПМ}$ ($p < 0,001$). *Cut-off* вредности за дијагнозу опструкције су биле 82% за $ЕЕ_{40}$ и 0,11 за $НОРА_{ПМ}$.

Закључак Примена софтвера МААЕ повећава дијагностичку тачност диурезне ренографије и доприноси прецизнијој дијагностици уроопструкције. С обзиром на то да одељења нуклеарне медицине у многим земљама не поседују савремене софтвере за сцинтиграфију бубрега, било би значајно да МААЕ омогући преузимање софтвера преко електронског сајта.

Кључне речи: радиоизотопна ренографија; уроопструкција; ефикасност елиминације; нормализована резидуална активност