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The evaluation of agreement between the measurement methods used in the diagnosis of prostate cancer with the statistical methods

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Abstract

The aim of this study is to evaluate the compatibility of the "Computed Tomography (CT)" and "Magnetic Resonance (MR)" methods which are imaging techniques used to describe prostate cancer with the pathology accepted as the reference method. In this study, the concordance between CT and MR results and pathology results of 37 prostate cancer patients was evaluated using the Bland-Altman, Interclass Correlation Coefficient, Concordance Correlation Coefficient, Deming Regression and Passing-Bablok method comparison methods. Inter-class correlation coefficient and Concordance Correlation Coefficient values for CT-Pathology results were 0.62 and 0.62, respectively. Inter-class correlation coefficient and Concordance Correlation Coefficient values for MR-Pathology results were 0.74 and 0.75, respectively. The regression equation for the Deming regression method is y=-6.21+1.03x for CT-Pathology, whereas for the MR-Pathology y=-6.86+1.11x. When the CT-Pathology measurement values are evaluated by the Bland-Altman statistical method, the mean values of the measurement differences are -2.42 and the standard deviation is 33.50. When the agreement between MR-Pathology measurement values is examined by the Bland-Altman method, the mean values for the difference between the measurement values are 4.14 and the standard deviation is 26.78. Among the applied methods, the Bland-Altman method is the most suitable method for data structure. According to the results of the Bland-Altman method, the tumor size obtained by the pathology method can be found to be 2.4 smaller than the mean values obtained from the CT results and an average of 4.1 cc from the measurement values obtained by the MR imaging technique.

Keywords: Bland-altman, deming regression, passing-bablok regression, interclass correlation coefficient, concordance correlation coefficient, prostate cancer

Introduction

Prostate cancer is the most common male malignant tumor in developed and developing countries. Although it is a type of cancer that progresses slowly, when considered together with the cancer groups it is included in, it is the second most common type of cancer that results in death [1]. Today, in the diagnosis of prostate cancer, the decision is made as a result of the pathological evaluation with needle biopsy taken from the prostate [2]. The Computed Tomography (CT) and Magnetic Resonance (MR) imaging methods that are frequently used in the cancer staging process in cases with a definitive diagnosis of tumor are. Thanks to technological developments, besides isotropic imaging with CT devices, it is also possible to examine with multi-phase contrast. However, it is not a successful imaging technique in providing detailed information about the prostate gland structure due to insufficient soft tissue and contrast in resolution. On the other hand, it can detect tumor or recurrence areas with a significant blood supply difference. It is also very successful in identifying lymph nodes. MR imaging device, on the other hand, is the most successful radiological method in examining the inner structure of the prostate gland due to its high contrast resolution. In addition to showing detailed anatomical information, it also reveals pathological indicators, making it more prominent than other imaging methods [3].

In the technologically developing world of science, methods that are thought to perform better than previous methods are

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recommended every day. Newly developed methods can replace the old methods used to measure clinical values such as heart rate and HbA1c level. However, for this, clinicians are not able to determine the true value of the subject or subject that has been removed due to the influence of other factors. It is inevitable that the measurements made will contain some error. More simply, an accurate and reliable measurement value is that the value of the new measurement made is the same as the actual value or has a certain agreement with the actual value. However, the new measurement may not exactly match the actual value. The new measurement can only be accepted with some negligible error. Therefore, when testing the new method found, it is compared with a reference method, not with actual values. When clinicians discover a new method for parameter measurement that is cheaper and faster than the previous one, they compare the new method with the currently used method (reference) to find out how compatible the two measurements are. Harmony means that the values obtained as a result of the two methods are equal. Measurements of the same parameter obtained by different methods often do not show complete agreement. However, it is possible to say how much is the difference between the reference method and the new method. The usability of the new method instead of the old method depends on the fact that this difference is not at a level that would cause problems in clinical interpretation [4].

Different statistical methods are used to examine the agreement between the two measurement methods. Classical methods were generally used in the studies of comparing the compatibility between the methods previously made. However, the wrong results of these known methods have led to the recommendation of alternative methods. A few of the existing approaches that can be used to evaluate the fit between methods can be listed as Bland-Altman method, Intra-Class Correlation Coefficient, Concordance Correlation Coefficient, Deming Regression and Passing-Bablok Regression. The aim of this study is to explain some of the method comparison methods used to determine the consistency between measurements and to examine the relationship between them through an example.

Material and Methods

Dataset

In this study, a data set consisting of the results obtained by CT MR imaging techniques applied to 37 patients who applied to the Urology Department of İnönü University Turgut Özal Medical Center and diagnosed with prostate cancer, and the pathology results of the same patients were used. In the power analysis, when $\alpha=0.05$, $1-\beta$ (power)=0.80, it was calculated that at least 36 subjects should be taken in order for the mean measurement difference of tumor diameter measurements to be 4.02 cc compared to the pathology results of MR and CT for the analyzes to be applied to compare the method [5,6]. This study was approved with the protocol number 2017/41 of Malatya Clinical Research Ethics Committee. The research was conducted in accordance with the principles set of the Helsinki Declaration 2008.

Bland-Altman analysis

In studies investigating compatibility between methods, the main purpose is to determine whether two or more methods are compatible enough to be used interchangeably. Correlation and least squares (LS) regression analysis, in which fit is determined and also called calibration statistics, may cause researchers to make mistakes. There are many reasons for this situation [7].

Due to all the disadvantages existed, a different method was proposed by Bland and Altman for the studies in which the compatibility between the methods was evaluated [8]. The first step of the method is to calculate the difference between the measurement values obtained from the two methods. In the second step, the average of the measurement values obtained through the two methods is calculated. Then, the scatter plot of the mean values against the differences is drawn [9]. As mentioned before, this graph gives information about the existence of a relationship between measurement errors and actual values. It is also possible to comment on your bias and error from this graph. The average of the differences of the values obtained as a result of the measurement through the two methods is the estimated bias. If there is no relationship between the difference and mean values, the agreement between the two methods can be calculated with the help of the mean value of the differences ($\bar{d}$) and standard deviation values (S_d) [8].

If there is a relationship between the difference values and the mean values, it is not possible to calculate the limits of agreement with these formulas. The reason why it is desirable to have a difference between the two measurements is to generalize the research results to another population. There are two important problems that may arise in method comparison studies. The first of these is the existence of a relationship between the difference values and the mean values, and the other is the varying variance. These problems can be solved with logarithmic transformation and regression approaches [9].

Intraclass correlation coefficient (ICC)

Reliability can be defined as the absence of random error in a measurement or the consistency of measurements taken repeatedly from a subject. Intraclass correlation coefficient (ICC) is the rate of variance depending on the measurements taken from the patients included in the study, and it emerged to reveal the extent of the relationship between the measurements of the same class [10,11]. In studies investigating the compatibility between methods, ICC values are interpreted as “Perfect Agreement” if 1.00-0.95, “Strong Agreement” if 0.94-0.85, “Moderate Agreement” if 0.84-0.70 and finally 0.69-0.00 “Unacceptable Agreement”.

ICC estimates differ depending on whether the relationship between methods is evaluated as "consistency" or "absolute agreement". What sets these two concepts apart is how the

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systematic variability arising from measurements or methods is taken into account. For ICC, which is calculated as an absolute fit criterion, the systematic variability between the methods is taken into account and the method variance, that is, the main effect of the method, is added to the denominator in the formula. If the methods are not assumed to be the source of the variance, the method variance is not included in the denominator of the formula. As a result, this calculated ICC value is considered as the "consistency" criterion [12].

Concordance correlation coefficient (CCC)

Let the values measured by each method be Y_{i1} and Y_{i2} (i=1,2,…,n), the mean vector of the methods $\mu=(\mu_1,\mu_2)$ and finally the covariance matrix A,

$$\begin{pmatrix} \sigma_1^2 & \sigma_{12}^2 \\ \sigma_{12}^2 & \sigma_2^2 \end{pmatrix}$$

the selected sample measurement pairs are selected regardless of the normal distribution. Lin [13] characterized the degree of agreement between the two measurements with the following equation.

$$E[(Y_1 - Y_2)^2] = (\mu_1 - \mu_1)^2 + (\sigma_1^2 + \sigma_2^2 - 2\sigma_{12}^2)$$

$$= (\mu_1 - \mu_1)^2 + (\sigma_1^2 - \sigma_2^2) + 2(1-\rho)\sigma_1\sigma_2$$

In this equation, ρ is the Pearson correlation coefficient. In this case, the CCC coefficient is obtained by equation.

$$\rho_c = \frac{2cov(Y_1, Y_2)}{E[(Y_1 - Y_2)^2] + 2cov(Y_1, Y_2)} = \frac{2\sigma_{12}}{\sigma_1^2 + \sigma_2^2 + (\mu_1 + \mu_2)^2}$$

The values for the interpretation of the obtained concordance correlation coefficient (CCC) values are: perfect agreement for >0.99, strong agreement for 0.95-0.98, moderate agreement for 0.90-0.94, <0.89 for unacceptable agreement.

Deming regression

The Deming Regression (DR) method, which is used in cases where the inadequacy of the least squares (LS) method is discussed and it is not clear which method to choose as the dependent variable, takes into account the errors of both methods [14]. By minimizing the error value of only the y dependent variable, b_0 (intercept point) and b_1 (slope) values are found in order to obtain the most accurate regression equation with the LS analysis. On the other hand, errors arising from both methods in the DR equation are tried to be minimized at the same time. The "Error Sum of Squares (ESS)", which is tried to be minimized, is calculated with the following formula.

$$ESS = \sum[(X_i - \hat{X}_i)^2 + \lambda(Y_i - \hat{Y}_i)^2]$$

To obtain the regression equation for the DR method, the value of λ must be known. This value is obtained by dividing the variances of the two methods to be compared. This calculated λ value minimizes the sum of the squares of the deviations along a straight line, allowing the required angle to be determined [15].

Passing-Bablok regression

The Passing-Bablok (PB) method, a new regression method based on a powerful non-parametric model, works just as the Deming regression method works on the assumption that the results from both methods investigated may have a certain error. Unlike LS linear regression, Passing and Bablok regression are not sensitive to outliers, both methods have the condition that the measurement errors do not necessarily fit the normal distribution. PB regression assumptions; is that the measurements are continuous and the linear relationship between the two methods. The calculations to be made in this method, which does not require the parametric structure requirement, are made according to the sequence numbers of the measurements obtained from the methods, and it is assumed that the tested method and the reference method are independent of each other [16,17].

Statistical analysis

Data were summarized as mean±standard deviation and min-max values. According to the assumption of the Bland-Altman method, which is one of the methods used to evaluate the compatibility between methods, the conformity of the difference values between CT and Pathology measurements, and the difference values between MR and Pathology measurements, to normal distribution, were tested with the Shapiro-Wilk normality test. The existence of the relationship between these obtained difference values and the pathology measurement values, which is the reference method, was examined with the Pearson Correlation coefficient. ICC values used to evaluate the agreement between CT and Pathology measurement values and between MR and pathology measurement values were calculate. Similarly, the CCC coefficient and the 95% confidence interval of this coefficient were calculated when examining the agreement between CT and Pathology and MR and Pathology measurement values with the correlation coefficient of agreement. Values that allow interpretation of the concepts of "Accuracy" and "Precision" regarding the methods were also obtained with CCC. The constant coefficient and slope coefficient of the DR method equation, which is used to evaluate the compatibility between methods and explained in the previous sections, were calculated, and the 95% confidence intervals for these coefficients were calculated. The constant coefficient and slope coefficient of the PB regression method equation, which is another regression method, were calculated. A PB regression graph was drawn to evaluate the agreement between these values and MR measurement values and Pathology measurement values, and to evaluate the agreement between CT measurement values and Pathology measurement values. p<0.05 was considered statistically significant. IBM SPSS Statistics 25.0 [18] and MedCalc version 10.1.6.6.0 [19] package programs were used for statistical analysis.

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Results

The mean±standard deviation values for CT, MR and Pathology of the subjects included in the study were 99.62±38.03, 93.05±34.95, 97.20±39.10, respectively. In this study, the actual values of the postoperative mass obtained from patients with prostate cancer are available. Therefore, the measurements obtained through imaging techniques can be compared with the pathology results, which is the reference method. First of all, the distribution of the measurements of the differences between the CT measurement values and the values obtained by pathology was normal (p=0.259). There is no statistically significant relationship between the mean and difference values of the values of these two methods (r=-0.035, p=0.837). On the other hand, the distribution of the measurements of the differences between the MR measurement values and the values obtained by pathology is normal (p=0.648). There is no statistically significant relationship between the difference values of the values of these two methods and the values related to pathology measurements (r=-0.165, p=0.328). Therefore, since BA analysis assumptions are provided for both methods, the BA graph of the agreement between Pathology-CT and Pathology-MR measurement values, respectively, is given in Figure 1 and Table 1.

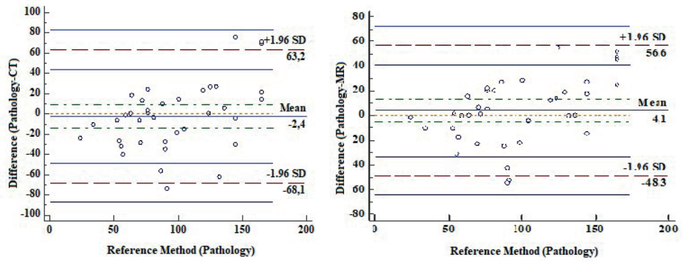

Figure 1. BA analysis graph of the Pathology-CT and Pathology-MR methods of tumor measurement values

Table 1. Results of the BA method, respectively CT-pathology and MR-pathology

	Descriptives	Differences	95% CI
CT-pathology	Mean±SD	-2.42±33.50	-13.59–8.74
	Lower limit	-68.09	-87.35–-48.82
	Upper limit	63.24	-43.98–82.51
MR-pathology	Mean±SD	4.14±26.78	-4.78–13.07
	Lower limit	-48.34	-63.74–-32.94
	Upper limit	56.63	41.29–72.03

CI: confidence interval, CT: computed tomography, MR: magnetic resonance, SD: standard deviation

In the analyzes to be performed to examine the compatibility of each of the CT and MR imaging techniques with the pathology result, the interaction between the method and the subject was ignored, and ICC values were calculated, which calculate the absolute agreement and consistency of tumor size obtained from the same patient by CT, MR and Pathology methods. The results of ICC values of the measurements obtained from Pathology and CT and Pathology and MR imaging techniques, respectively, are given in Table 2.

Table 2. ICC estimation between the measurement values obtained by the pathology method and the measurement values obtained by the CT, MR imaging method

		ICC*	Lower limit (95% CI)	Upper limit (95% CI)	F value	p
Pat/CT	**ICC (Absolute agreement)**	0.623	0.378	0.786	4.300	<0.001
	ICC (Consistency)	0.767	0.548	0.880	4.300	<0.001
Pat/MR	**ICC (Absolute agreement)**	0.739	0.549	0.857	6.669	<0.001
	ICC (Consistency)	0.850	0.709	0.923	6.669	<0.001

CI: confidence interval; CT: computed tomography, MR: magnetic resonance, Pat: pathology, ICC: intraclass correlation coefficient, *: Two way mixed model

The concepts of "accuracy" and "precision" were also taken into consideration with the CCC estimation, which is another coefficient in which the agreement of the measurement values obtained from CT and MR imaging techniques with the Pathology values is examined. The results of the CCC values of the measurements obtained from the Pathology and CT and MR imaging techniques, respectively, of the same patient are given in Table 3.

Table 3. CCC estimation between the measurement values obtained by the pathology method and the measurement values obtained by the CT, MR imaging method

Tumor Size	**CCC**	**95% CI**		**ρ***	**C_b****
	($\rho_c=\rho C_b$)	**Lower limit**	**Upper limit**	**(Accuracy)**	**(Precision)**
CT/Pat	0.62	0.38	0.78	0.62	0.99
MR/Pat	0.75	0.55	0.85	0.74	0.99

CCC: concordance correlation coefficient, CI: confidence interval; CT: computed tomography; MR: magnetic resonance, Pat: pathology, * Pearson correlation coefficient, ** Bias correction factor

The findings of the Deming regression method, in which the agreement between the measurement values obtained from CT, MR and pathology is examined, are given in Table 4. In the application phase of this method, it was assumed that the distribution of error values related to the methods was normal.

Table 4. DR analysis results of CT and pathology and MR pathology measurement value

	Reference/test	Bias	95% CI	SE
Pat/CT	Intercept (Constant)	-6.21	-46.22-33.80	19.73
	Slope (Proportional)	1.03	-0.57-1.50	0.23
Pat/MR	Intercept (Constant)	-6.86	-30.54-16.81	11.67
	Slope (Proportional)	1.11	0.82-1.41	0.14

CI: confidence interval, CT: computed tomography, MR: magnetic resonance, Pat: pathology, SE: standard error

According to the results of the analysis, the cut-off point of the regression line is -6.21 and the confidence interval for this value includes the “zero” value. The slope point was found to be 1.03 and the confidence interval for this slope point includes the value of "one". For this reason, it is concluded that there is no systematic and proportional bias between the measurement values obtained by CT and Pathology methods. The DR equation for Pat/CT is expressed as y=-6.21+1.03x. Similarly, according to the analysis results, the cut-off point of the regression line is -6.86, and the confidence interval for this value includes the "zero" value. The slope point was found to be 1.11 and the confidence interval for this slope point includes the value of "one". For this reason, it is concluded that there is no systematic and proportional bias between the measurement values obtained by MR and Pathology methods. The equation for DR for Pat/MR is expressed as y=-6.86+1.11x. In Figure 2, DR graphs of CT and Pathology and MR and pathology results are given, respectively.

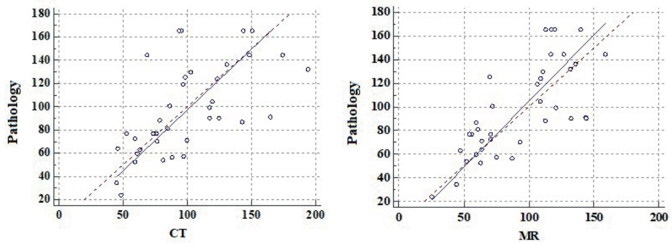

Figure 2. DR graphs of CT and Pathology and MR and pathology results

The results of pathology with CT and pathology with MR are given in Table 5.

Table 5. PB analysis results of CT and pathology and MR pathology measurement values

	Reference/test	Bias	95% CI
Pat/CT	Intercept (Constant)	-7.34	-51.02-17.96
	Slope (Proportional)	1.06	0.74-1.56
Pat/MR	Intercept (Constant)	-8.58	-35.03-12.18
	Slope (Proportional)	1.19	0.90-1.51

CI: confidence interval, CT: computed tomography, MR: magnetic resonance, Pat: pathology

According to the results of the analysis, the cut-off point of the regression line is -7.34 and the confidence interval for this value is “zero”. Similarly, the confidence interval for the slope point of 1.06 includes the value of “one”. Due to all these reasons, no systematic and proportional error is observed between the measurement values. The PB regression equation for pathology and CT measurement values is obtained as y=-7.34+1.06x. Similarly, according to the results obtained for MR / Pat, the cut-off point of the regression equation is -8.58 and the 95% confidence interval for this value includes the “zero” value. Similarly, the confidence interval for the slope point of 1.19 includes the value of “one”. Due to all these reasons, no systematic and proportional error is observed between the measurement values. The PB regression equation for pathology and MR measurement values is obtained as y=-8.58+1.19x. The Passing-Bablok regression line for pathology with CT and pathology results with MR is given in Figure 3.

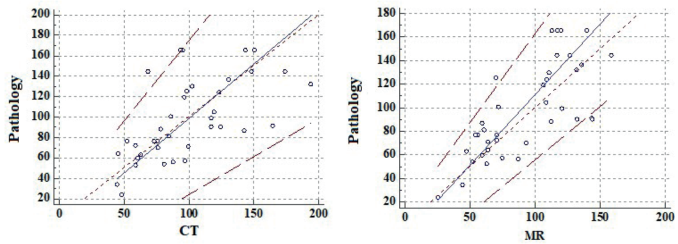

Figure 3. PB graphs of CT and Pathology and MR and pathology results

Discussion

Prostate cancer, the most common cancer in men, is a public problem accompanied by many difficulties. The incidence of prostate cancer increases with increasing age. It is a serious threat to the health of men over 50 years of age. Today, the mortality of the disease has decreased with the developments in diagnosis and treatment programmes. Imaging plays an important role in the diagnosis of prostate cancer. CT and MR are the most commonly used imaging methods in the diagnosis of prostate cancer [20,21].

In this study, the statistical methods used to compare the compatibility of the methods with each other are explained practically on a data set obtained as a result of a single measurement. The data used consists of the measurement values obtained from the imaging techniques CT and MR on patients with prostate cancer and the measurement values obtained as a result of the pathology. The consistency between the measurement results obtained from these two imaging techniques, which is accepted as the reference method, was evaluated by comparison methods, and it was decided which method was more compatible with the reference method.

These statistical approaches applied are used in the literature to examine the compatibility between many methods. Sahoo et al. in a study involving 953 tribal adolescents from boarding schools of Odisha from January to July 2019, methods such as Bland Altman analysis, Deming regression, ICC and CCC were used to validate a new point-of-care (POC) device developed for anemia screening against the gold standard method, spectrophotometry [22]. In a study published by Tinsley et al., 171 participants were evaluated using methods such as Deming regression, Bland–Altman analysis, and CCC to evaluate the agreement between four commercially available 3D optical scanning devices to measure body composition [23]. Finally, in a study published in 2013, weighted deming regression, CCC and ICC statistical methods were used to compare Luminex (LX) and MesoScale Discovery (MSD) technologies used for multiplex immunoassay platforms, which are indispensable in biomarker discovery, with ELISA, which is the golden test [24]. In the literature review, no study was found in which the compatibility of imaging methods used in the diagnosis and follow-up of prostate cancer with pathology, which is the gold standard method, was examined. Therefore, it is thought that our study will contribute to the literature in this respect.

It was determined that the pathology results, which are the actual tumor size, and the difference measurement values of the tumor sizes obtained from both CT and MR methods (CT-Pathology, MR-Pathology) provided the assumptions of normal distribution, and there was no statistically significant relationship between the difference measurement values and the mean measurement values. Since all the assumptions regarding the BA method were met, the agreement between the measurement values of the actual tumor size and the measurement values of the imaging methods was evaluated with this method. Since the difference between the upper and lower limits of agreement for the measurements obtained with the CT imaging method is wider than the difference between the upper and lower limits of agreement for the measurements obtained with the MR imaging method, it can be said that the MR imaging method is more compatible with the pathology, which is the reference method.

The compatibility of the measurement values obtained from CT and MR imaging techniques with the measurement values obtained from the pathology result, which is the reference method, was also evaluated with ICC and CCC. Comparison between these two methods gave almost the same results when compared with both ICC (absolute agreement) and CCC. Considering the coefficients obtained in question, it was observed that the values obtained with the MR imaging device were more compatible with the pathology results. When the 95% confidence interval obtained with the ICC value, which is an absolute fit measurement, is examined, it is observed that it does not have a very wide interval. Similarly, it can be said that the confidence interval for the ICC value, which is a measure of consistency, does not narrow too much. Therefore, there is no mathematical relationship between the values obtained through the methods. However, if the confidence interval of 95% for ICC values, which is an absolute fit measure, was compared with the confidence interval for ICC, which is a measure of consistency, if there was a significant narrowing in the confidence interval, it would be possible to mention the existence of a mathematical relationship between the measurements obtained through the methods. Therefore, due to this situation, it is not appropriate to evaluate inter-method agreement with ICC and CCC. In this case, the equation obtained by the DR method could be used for the estimations to be made.

DR and PB regression methods were used to analyse the correspondence of the measurement values obtained by CT and MR methods with pathology. No systematic or proportional error was observed between CT and pathology measurement values and between MR and pathology measurement values. If a systematic or proportional error was detected between any of the two methods and the pathology method, the agreement between the methods can be examined with the help of regression equations obtained by DR or PB regression methods. Therefore, it can be said that it is more appropriate to use the BA statistical method to examine the agreement of these two methods with pathology.

Limitation and future works

In the clinic where this study was conducted, the most important criterion for the inclusion of prostate cancer patients in the study was the measurement of three parameters (CT, MRI and Pathology) related to the patient. In the clinic, some of the patients are followed up with CT and undergo prostatectomy, while some are followed up with MR and undergo prostatectomy. Obtaining both CT and MR images from the same patient causes a financial burden for the centre and a loss of time for the patient for prostatectomy. Therefore, the study was terminated and analyses were performed after the calculated sample size was obtained. This is a limitation of the study. Therefore, repeating the study by increasing the sample size will support the findings of this study.

Conclusion

Statistical methods in which absolute agreement among the methods are evaluated are BA method and CCC, statistical methods in which relational fit is evaluated are DR and PB regression method, and statistical methods in which both relational and absolute agreement are evaluated are ICC. Considering all these analysis results, it is seen that the size of the mass obtained by the pathology method is 2.4 cc less on average than the measurement values obtained by the CT imaging method. Similarly, it can be said that tumor sizes obtained by MR imaging method and pathology method are on average 4.1 cc more than the measurement values obtained by MR imaging technique.

Conflict of Interests
The authors declare that there is no conflict of interest in the study.

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Ethical Approval
This study was approved with the protocol number 2017/41 of Malatya Clinical Research Ethics Committee.

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