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Comparative Study of Ultrasonographic Accuracy at 8-16 Weeks of Gestational Age With the Naegele's Revised Rule for Delivery History

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ABSTRACT

Background & Objective: Determining the correct date of pregnancy and fetal age has a very important role in the management of pregnancy from the first trimester to delivery, which makes it necessary to know the exact method in this field. Therefore, this study aimed to compare the accuracy of ultrasound at 8-16 weeks with Naegele's Revised Rule of the delivery date.

Materials & Methods: This study was performed on 50 pregnant women. After recording demographic information and age of delivery, sonography of weeks 8-16 and Naegel's Revised Rule were also recorded. A Paired t-test was used to compare data.

Results: The results of our study showed that the average difference between the Naegele's Revised Rule and real age was 3.52 days, which is a significant difference. However, the average difference between the estimated date by ultrasound and real age is 0.58 days, which is not a significant difference. Ultrasound is more accurate than the Naegele's Revised Rule, which still did not differ significantly from the actual date of delivery by grouping by age, sex of the fetus, number of pregnancies, and deliveries.

Conclusion: Ultrasound has more accuracy in accurately estimating the date of delivery, and therefore using this method and relying on it has more reliability than the Naegele's Revised Rule.

Keywords: Ultrasound, Gestational age, Naegele's Revised Rule, Women

Introduction

Accurate determination of gestational age to plan for prenatal and postnatal care and maternal care is a necessity, used to identify the fetal status and growth limitations **(1-5)**. In developed countries, ultrasound is used to determine the age of the fetus in the first trimester, but in countries with limited medical facilities, other methods such as Naegele's Revised Rule are also used to determine gestational age **(6-8)**. There may be complications in pregnancy which their treatment depends on gestational age, and incorrect determination of gestational age could lead to the lack of proper age-dependent gestational care **(9)**. With the advancement of technology, more scientific evidence to show which of the methods of estimating gestational age is clinically appropriate and cost-effective is becoming more important. Currently, the two main methods for predicting birth weight are clinical methods and ultrasound **(10, 11)**. One of the formulas for estimating the gestational age is Naegele's Revised Rule, which is the oldest method of estimating the date of delivery that begins on the first day of the last menstrual period and describes the development of the fetus in terms of weeks since the LMP. The average interval from the LMP to the birth of the fetus is about 280 days or 40 weeks **(12)**. For the past 40 years, fetal ultrasound evaluation and weight estimation have been part of the routine practice in obstetrics and gynecology **(5, 13, 14)**, but there is still evidence that routine ultrasound screening has significant effects on pregnancy outcomes. Unsuccessful prediction of

delivery date by other methods have been introduced as benefits of routine ultrasound screening **(14, 15)**. On the other hand, it has not yet been proven that ultrasound is more accurate than Naegele's Revised Rule. Normally, a pregnant woman becomes severely anxious after the date of delivery is estimated. In these cases, if the gestational age has not been estimated by ultrasound in early pregnancy, the pregnant woman may be subject to various unnecessary interventions such as ultrasound, a non-stress test (NST), and a contraction stress test (CST). In addition to being stressful, each of the above tests is often erroneous, and these women are often induced to give birth. Also, it will have a high rate of failure, is very painful when induction is performed in women with an unprepared cervix, and due to lack of labor progress, it often leads to cesarean section **(9)**. Therefore, considering the importance of estimating the date of delivery and deciding on induction of labor and cesarean section in pregnancy complications, we decided to investigate the value and accuracy of Naegele's Revised Rule in predicting the time of delivery and comparing it with sonographic estimation.

Methods

This study was a cross-sectional observational study (descriptive and analytical) that has been registered in the ethics committee of Zahedan University of Medical Sciences with code IR.ZAUMS.REC.1399.211. Based on reference (9), considering these values and the formula below, a sample size of 10 people was estimated, but to increase the study power, 50 people were examined.

$$N=\left(\frac{\left(z_{1-\alpha/2}+z_{1-\beta}\right)^2\left(s_1^2+s_2^2\right)}{(\mu_1-\mu_2)^2}\right)$$

$\alpha = 0.05$, $\beta=0.2$, $S_1=1.2$, $S_2=2.59$, $\mu_1=2.42$, $\mu_2=5.51$

Inclusion criteria were having a singleton pregnancy, live fetus without anomaly with ultrasound report, no previous history of cesarean section, having regular menstrual cycles with intervals of 31-35 days, accurate information about the date of the last menstruation period, having regular menstruation, and not taking contraception pills. Exclusion criteria contains pregnancies following discontinuation of contraception pills, pregnancy complications (complications including placental abruption, preeclampsia, placenta previa, gestational diabetes, preterm labor or post-term labor), anomalous fetuses, molar pregnancy, and ectopic pregnancy. Data were entered into statistical software and analyzed. In describing the data, appropriate statistical tables and indicators such as mean and standard deviation for quantitative and frequency variables (number-percent) for qualitative variables were used. Pearson correlation coefficient was used to analyze the correlation between quantitative variables. The software used in this study was SPSS v.20 (IBM Company, USA), and the significance level of the tests was less than 5%.

Results

This study aimed to compare the accuracy of the 8–16 week ultrasound and the Naegele's Revised Rule for the delivery date in patients who were referred to the Ali Ebn-e Abi Taleb Hospital in Zahedan, Iran. This study was performed on 50 pregnant women. The mean age of the subjects was 28.58 ± 5.23 years. According to Table 1, based on Naegele'sRevised Rule, the mean estimated duration of pregnancy was 279.02 days; also, based on ultrasound, it was 276.08 days, and the real-time was 275.5 days.

Table 1. Estimated gestational age based on ultrasound and Naegele's Revised Rule

Method	Number	Mean (days)	Standard deviation
Naegele's Revised Rule	50	279.02	11.774
Ultrasound	50	276.08	10.900
Real-time	50	275.50	10.160

According to Table 2, the difference between the Naegele's Revised Rule and the real-time is -3.5200 ± 7.71757, and the difference between the ultrasound and the real-time is -0.5800 ± 2.92135.

Table 2. The mean and standard deviation of the difference between different methods and real-time

	Number	Mean	Standard deviation
Difference between the Naegele's Revised Rule and the real-time	50	-3.5200	7.71757
Difference between the ultrasound and the real-time	50	-0.5800	2.92135

According to Table 3, the Pearson correlation test showed a significant relationship between determining the time of the delivery based on the method of the Naegele'sRevised Rule with the real-time of the delivery (days) in the referred patients to the Ali Ebn-e Abi Taleb Hospital in Zahedan (p <0.001). There is a significant relationship between the estimated delivery time based on 8–16week ultrasound with delivery time (days) and real delivery time (days) in the referred patients to the Ali Ebn-e Abi Taleb Hospital in Zahedan (p <0.001).

Table 3. Pearson correlation between different estimation methods with real-time

		Naegele's Revised Rule	Ultrasound	Real-time
Naegele's Revised Rule	Correlation coefficient	1		
	Significance			
	Number	50		
Ultrasound	Correlation coefficient	0.679**	1	
	Significance	0.000		
	Number	50	50	
Real-time	Correlation coefficient	0.762**	0.964**	1
	Significance	0.000	0.000	
	Number	50	50	50

**. P< 0.01 level (2-tailed).

Discussion

This study showed mean duration of pregnancy estimation was 279.02 days; also, based on ultrasound, it was 276.08 days, and real-time was 275.5 days. In other words, the frequency of deliveries earlier than the date set according to the Naegele's Revised Rule was 60%, but according to ultrasound, it was 56%. Also, the frequency of deliveries after the date determined according to the Naegele's Revised Rule was 30%, but according to ultrasound, it was 36%. Finally, the frequency of deliveries on the date set according to the Naegele's Revised Rule was 10%, but according to ultrasound, it was 8%. Eventually, it was found that the average difference between the Naegele's Revised Rule and the real-time was 3.52 days, which is a significant difference. However, the average difference between the time estimated by ultrasound and real-time is 0.58 days, which is not a significant difference. Therefore, ultrasound is more accurate than the Naegele's Revised Rule, which by grouping according to age, sex of the fetus, number of pregnancies, and deliveries, still did not differ significantly from the actual delivery time. Firoozabadi et al. in 2007 compared the two methods of ultrasound and Naegele's Rule in determining gestational age. The results of their studies showed that Naegele's Rule in Iranian society is more accurate than ultrasound **(12)**. Our study found that ultrasound was more accurate in estimating delivery time than Naegele's Rule. The reason for this difference may be due to differences in the sample size, demographic indicators of the subjects, differences in sampling, and differences in factors affecting the increase in the incidence of errors in estimates.

In a study, Butt K et al. reviewed the gestational age by the ultrasound and Naegele's Revised Rule and compared the two methods. According to the results, ultrasound at each gestational age determined the delivery time to be 1.7 days more accurate than the time of the last menstrual period (LMP); finally, it was concluded that the Naegele's Revised Rule has a lower accuracy than the ultrasound **(9)**. The findings of the study are in line with the findings of our study. In our study, it was found that ultrasound is more accurate in estimating the time of delivery. In a study examining the accuracy of three methods of estimating the date of delivery in 2009, Bisahnyui P et al. compared the three methods of Naegele's Rule, Naegele's Revised Rule, and ultrasound. This study is a descriptive cross-sectional study on 540 pregnant women who were referred to Mobini Hospital in Sabzevar from 22/09/2008 until 21/12/2008 with symptoms of labor onset. The delivery date was determined using three methods, and the difference with the actual date was calculated. Data were analyzed using the SPSS (version 15) with descriptive statistics, the Pearson correlation coefficient, and t-test. The results showed that 6.3%, 36%, and 6.7% of women gave birth on the date set by Naegele's Rule, Naegele's Revised Rule, and ultrasound, respectively, and 45.6, 60.9, and 54% of women gave birth by the date determined by three methods, respectively. The difference between the actual date of delivery and the date set by the Naegele's Rule and ultrasound showed a significant correlation with the infant's weight and uterine height. The rate of postpartum deliveries was 39.3%, 48.2%, and 32.8% based on ultrasound estimates, Naegele's Rule,

Naegele's Revised Rule **(16)**. The findings of the study regarding the rate of postpartum deliveries were similar to those of our study; additionally, similarly to our study, it was discovered that 6% more in the Naegele's Revised Rule method, the delivery time was estimated to be more than the ultrasound method; additionally, similarly to our study's findings, the revised delivery time was estimated to be 6% higher than the ultrasound method.. In a critical review, Olsen showed that in women with regular cycles and knowing the date of the LMP, Naegele's Rule predicts the time of delivery to be 3.3 days earlier and ultrasound 2 days later, and ultrasound was found to be more accurate **(17)**. The findings of the study are in line with the findings of our study. We found that ultrasound is more accurate in estimating the time of delivery. However, there was a difference between the two studies. In our study, both methods estimated the duration of labor more, but in Olsen's study, Naegele's Rule estimated it less. In 2007, Dehghani et al. conducted a study aimed to determine the accuracy of ultrasound and Naegele's Rule in estimating the delivery time **(18)**. In their study, the evaluation of the diagnostic test of the 260 pregnant women who were referred to the Shahid Sadoughi and Yazd hospitals for pregnancy care was performed with an equal distribution in the second and third trimesters, and their EDC was estimated according to the Naegele's Rule and the ultrasound by the BPD and FL methods and compared with the real-time of delivery. The difference between EDC according to Naegele's Rule and the real-time delivery was 5- to +8 days. This difference was changed to -1 to +18 days when EDC was based on ultrasound. In the second trimester, the mean for Nigel's law was 2.21 days, and for ultrasound, it was 4.32 days. In the trimester, the numbers obtained through Naegele's Rule were 2.42 days; also, with the ultrasound method, 9.20 days was different from the real-time delivery. The results indicated that Naegele's Rule for estimating the time of delivery was more accurate than ultrasound and the accuracy of both methods, especially ultrasound, decreases with increasing gestational age **(18)**. The findings of their study contradict the findings of our study.

Conclusion

The findings of our study showed that the average difference between the Naegele's Revised Rule and the real-time was 3.52 days, which is a significant difference. However, the average difference between the time estimated by ultrasound and real-time is 0.58 days, which is not a significant difference. Therefore, ultrasound is more accurate than the Naegele's Revised Rule, which did not differ significantly from the real-time of the delivery by grouping according to the age, sex of the fetus, number of pregnancies, and deliveries. So, based on the findings of our study, it can be seen that ultrasound is more accurate in estimating the exact time of delivery and thus using this method and relying on it is more reliable than the Naegele's Revised Rule, although the Naegele's Revised Rule is dependent on the LMP. Therefore, knowing the exact LMP depends on the culture and knowledge of the subjects and may be more accurate in some communities, so a more detailed study is needed in other studies.

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Availability of Data and Material

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflict of interest

I (as the corresponding author) declare that the authors: Farahnaz Farzaneh, Shahla Mirgaloybayat, Marziyeh Ajdary, and Neda Eslahi are faculty members of Iran University of Medical Sciences, and Sharareh Saneei, Saeedeh Sarhadi, and Foroogh Sadat Mousavi are faculty members of Obstetrics and Gynecology, Zahedan University of Medical Sciences.

Ethical Approval

Research Ethics Board of the Department of Obstetrics and Gynecology, Zahedan University of Medical Sciences, Iran No. IR.ZAUMS.REC.1399.211.

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