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Research Article

The Efficacy of Mean Gestation Sac Diameter Measurement By Ultrasound In Estimating The Gestational Age

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ABSTRACT

This research aimed to determine the efficacy of Mean Gestation Sac Diameter (MGSD) by ultrasound in estimating the Gestational Age (GA) compared to GA by Naegele's rule using Last menstrual period (LMP) date. This was a prospective observational study of women with a normal spontaneously conceived viable singleton pregnancy, a regular menstrual cycles, and spontaneous onset of labor at term. The LMP was considered certain in all cases. We used ultrasound to scan 2067 fetuses (894 healthy women) and we had 515 MGSD measurements. Data were collected prospectively and used for statistical analysis. We used Descriptive Statistics to calculate the Mean, Standard Deviation (SD), Median and Percentiles values (3rd, 5th, 10th, 50th, 90th, 95th, and 97th) for MGSD measurements on gestational age. We found a regression equation to estimate the GA using MGSD measurements. The results of the current study were compared with different studies using the Paired Differences (t-test analysis). The Mean Sum of Squares of regression deviations of the GA regression model using (MGSD) was 897.9 and this value is significant at $P < 0.001$. The standard error of the Estimate (Standard Error) and the standard deviation (SD) for the GA regression model (using MGSD measurements) was 0.74 and 0.73 when the GA is <12 weeks to 0.82 when the GA is between 12-18, respectively.

INTRODUCTION

Monitoring fetal growth and assessing the growth predictors has an important role in the care of pregnant women. Accurate estimation of GA gestational age and Fetal Weight (FW) are clinically important. Ultrasound is useful as an accurate method for estimating Gestational Age (GA). Different embryonic measurements can be used to date pregnancy. Accurate estimation of GA is important in for normal and pathological pregnancies management.(1,2,3) We used MGSD (mean gestational sac diameter) to predict the GA in pregnant women reviewing ALZAHRAWI Hospital. Up to our Knowledge, this study is the first of its kind in Syria.

MATERIALS AND METHODS

1- Study design: This study is a prospective descriptive longitudinal population study.

2- Setting: AlTawlid University Hospital

3- Description of populations and variables: All the participants were pregnant women representing a specific geographic region from Damascus and its suburbs, who reviewed the hospital either to confirm pregnancy or for following up. 51% (455/894) of all participants were between 22-30 years old and most of them were housewives of a low socioeconomic status.

4- Inclusion criteria:

- Voluntary participation with informed consent.
- A correct, accurate and reliable patient's knowledge of the first day of the LMP.
- Regular menstrual cycles (at least three previous regular menses).
- Singular alive normal fetus with a gestational age between 13-41 weeks. [3].
- Spontaneous labor by full term pregnancy (259-293 days/37-41 weeks).

5- Exclusion criteria: Women who have one of the following:

- Uncertainty of the LMP date.
- Irregular menstrual cycles.
- Multi-gestation or fetal demise.
- Oral contraceptive use (OCP) or any recent hormonal treatment (3-4 months) before current pregnancy.
- Pregnancy during lactation.
- History of previous abortion or recent delivery preceding the current pregnancy.
- Diagnosis of fetal malformations during examination or after birth.
- Presence of any medical or obstetric complication with known effect on fetal growth.
- Smoking or drug addiction.
- MGSD measures taken after week 41 of pregnancy.
- Pregnancies that ended in abortion preterm or postterm deliveries.
- Date of delivery (vaginal or cesarean section) is inaccurate.
- Malpositioned deliveries.

6- Ultrasound examination: An ultrasound examination was made for 894 pregnant women (2067 fetuses) who were selected according to the previously explained inclusion and exclusion criteria and reviewed the hospital between March 2017 and November 2017 to determine gestational age by measuring different fetal parameters (in this study MGSD). We had 515 MGSD measurements.

Statistical Analysis Methods

The regression model of the MGSD was used to determine the GA and in order to choose the best regression model we used the: 1- Coefficient of Determination (r^2) and the adjusted Coefficient of Determination ($\overline{r^2}$) and chose the one with the higher value. 2- The standard error (Std.Error) of both methods and chose the one least value. 3- Durbin–Watson Test and chose the one that gives a value close to the Std.Error. 4- The significance of regression model by doing an analysis of variance. 5- The significance of the regression model constants' (parameters) using T test. 6- Estimating the SD of the GA using the MGSD regression model. Paired – Samples T-TEST were done to test each method accuracy.

RESULTS AND DISCUSSION

Growth chart of the MGSD measurements (mm) showing the Percentile Values and Standard deviation (SD) between 5-15 weeks of pregnancy, Table 1.

The Embryonic Parameters have several applications in clinical practice such as estimating the gestational age, fetal weight, and fetal growth. In this study, we presented Growth Charts & Tables with the (3rd, 5th, 10th, 50th, 90th, 95th, and 97th) Percentile Values and the standard deviation of MGSD during the concordant pregnancy periods. We set a regression model equation that can be used to estimate the expected GA using MGSD measurements (mm).This equation was statistically significant (P <0.001). A strong correlation was found between the dependent variable (GA) and the independent variable (MGSD). We found a third degree valuable regression equation (p<0.001) that we can use to get the expected GA from MGSD measures (mm).

GA from MGSD measures (mm):

$$\hat{Y}_i = 5.155 + 0.05(MGSD)_i + 0.0024(MGSD)_i^2 - 1.83{*}10^{5-} (MGSD)_i^3$$

$\bar{r}^2$ =0.91 Std. Err =0.74 **Sig**=0.000

The Adjusted Coefficient of Determination ($\bar{r}$)^{2} of the regression model of GA (weeks) using MGSD measurements (mm) was 0.91.). The coefficient of determination is greater than 0.75 (75%), therefore, the correlation between the dependent variable Y line (GA) and the independent variable X line (MGSD) is very strong (Figure 2).

The Mean Sum of Squares of regression deviations of the GA regression model using (MGSD) was 897.9 and this value is significant at P <0.001. The standard error of the Estimate (Std.Error) for the GA regression model (using MGSD measurements) was 0.74 (Figure 2). This value represents the effect of many factors that were not included in the regression model which affect the dependent variable Y line (GA). (Figure 2).

Figure 2 shows the expected GA (weeks) using MGSD measurements (mm). Based on the regression model, we also demonstrated the expected GA, the lower and upper limits of the confidence interval (Table 2). The standard deviation (SD) of estimated the GA (weeks) from the actual GA using MGSD measurements (mm) was 0.73 weeks when the GA is <12 weeks and 0.82 weeks when the GA is between 12-18 years. (Table 3)

We compared this study to two similar studies, one was done in Japan and the other was Hellman LF and colleagues (1969) [34]. We compared the correlation coefficient , the mean, standard deviation, standard Error, lower and upper limits of the confidence interval (95% Confidence Interval of the Difference), the T value, the degree of freedom df, P value and Statistical Significance.

The comparison results were: the correlation coefficients values were strong (0.998 and 0.997) and significant (0.000 and 0.000) between this study and the compared studies (The Japanese study and the Hellman LF study and colleague's studies), respectively (P <0.001) (Table 4). The mean difference in the MGSD measurements (mm) using the Paired-Samples T-TEST between this study and the (Japanese study and Hellman LF study and colleagues) was -5.85 and -3.08 mm, respectively according to GA (weeks). The negative values indicates that the values of the compared studies were higher. There is statistical significance (P <0.001) between the current study and the compared studies. (Table 5, Figure 3).

CONCLUSION

Many women do not recall their LMP and most pregnant women review the clinic in the first three months of pregnancy and the estimation of GA is important for the follow up and determing the Expected delivery date (EDD) for assessing growth during the rest of pregnancy and predicting the expected date of delivery (EDD). We presented diagrams and tables for the estimation of GA using MGSD measurements in a group of pregnant Syrian women reviewing ALZAHRAWI Hospital according to the inclusion and exclusion criteria stated before. These results can be useful in women who cannot recall their last menstrual period (LMP). Our criteria will provide useful references for estimating gestational age and fetal care. A larger study might be needed to include a larger sample of the population. We also compared our results with similar studies abroad, and we found that our results were lower than their counterparts were. These results could help in estimating the gestational age, diagnosing fetuses who are younger than their GA, and IUGR embryos. Thus, ultrasound may be more accurate and could replace LMP method.

RECOMMENDATIONS

1. Emphasize the importance of doing a bigger more inclusive study to determine the accuracy of the fetal measurements in predicting the delivery date

2. Using the MGSD by ultrasound to determine the GA especially in women who cannot recall their LMP accurately.

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TABLE AND FIGURE

Table 1: Growth chart of the MGSD measurements (mm) showing the Percentile Values and Standard deviation (SD) between 5-15 weeks of pregnancy.

GA (weeks)	Standard deviation (SD)	MGSD (mm) Percentiles						
		%3	**%5**	**%10**	**%50**	**%90**	**%95**	**%97**
5	3.4	2.3	3.1	4.3	8.7	13.1	14.3	15.1
6	4.6	4.6	5.7	7.4	13.3	19.2	20.9	22.0
7	6.7	7.2	8.8	11.2	19.8	28.5	30.9	32.5
8	5.5	17.6	18.9	20.9	28.0	35.0	37.0	38.3
9	6.0	23.8	25.2	27.4	35.1	42.7	44.9	46.3
10	6.0	30.4	31.8	34.0	41.6	49.3	51.5	52.9
11	5.1	35.8	37.0	38.9	45.4	52.0	53.8	55.0
12	5.3	41.4	42.7	44.6	51.3	58.1	60.0	61.2
13	6.4	48.4	50.0	52.3	60.4	68.6	70.9	72.4
14	4.5	54.0	55.1	56.7	62.5	68.3	69.9	71.0
15	5.9	66.1	67.5	69.6	77.2	84.8	87.0	88.4

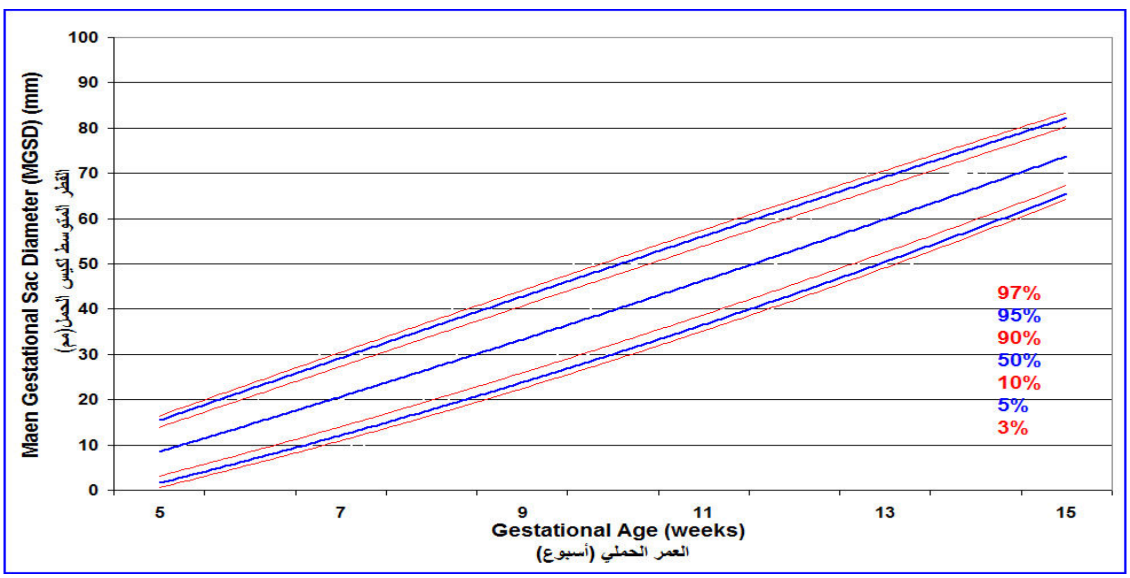

Figure 1: MGSD growth chart showing the fitted Percentile Values (3rd ،5th ،10th ،50th ،90th ،95th ،97th(of the MGSD and GA

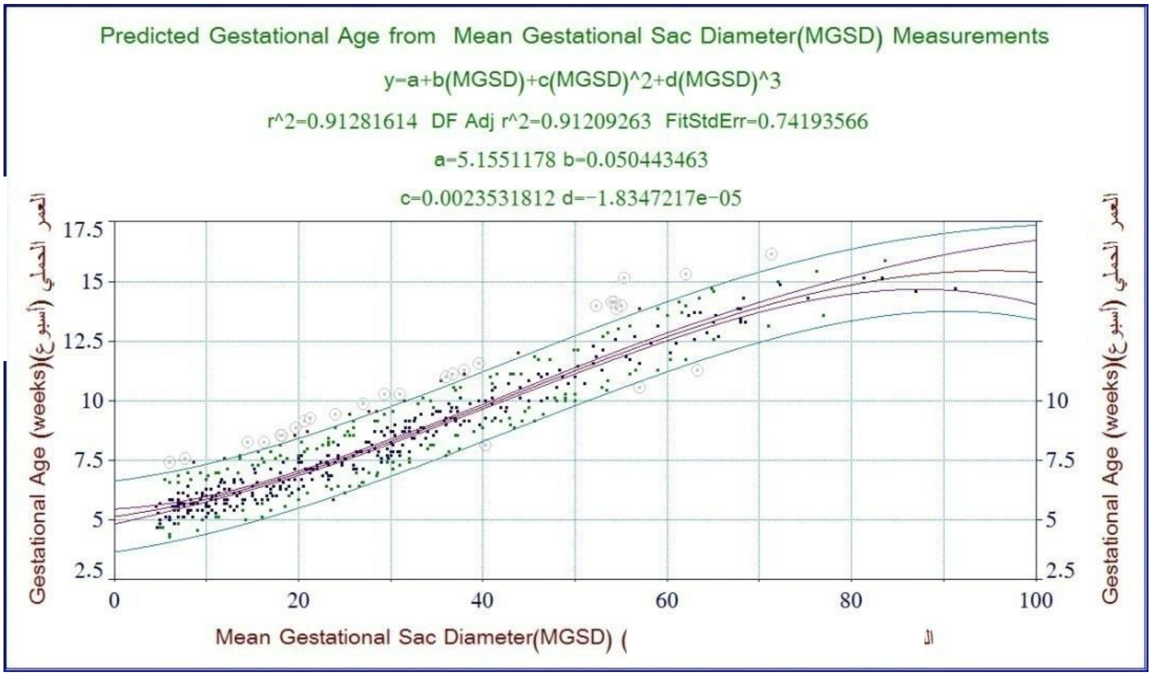

Figure 2: Predicted GA (weeks) using MGSD measurements (mm). Each point represents one fetus result.

Table 2: Expected GA (weeks) using the MGSD measurements (mm) and the lower and upper limits of both the 95% Prediction Limits and the 95% Confidence Limits based on the regression model.

95% Confidence Limits		**95%** Prediction **Limits**		$\hat{Y}_i$	**Xi**
Upper limit	**Lower limit**	**Upper limit**	**Lower limit**	**GA (weeks)**	**MGSD (mm)**
5.7	5.3	6.9	4.0	5.5	5
5.7	5.4	7.0	4.1	5.5	6
5.8	5.5	7.1	4.2	5.6	7
5.8	5.6	7.2	4.2	5.7	8
5.9	5.7	7.2	4.3	5.8	9
6.0	5.8	7.3	4.4	5.9	10
6.1	5.9	7.4	4.5	6.0	11
6.2	6.0	7.5	4.6	6.1	12
6.3	6.1	7.6	4.7	6.2	13
6.4	6.2	7.7	4.8	6.3	14

95% Confidence Limits		**95%** Prediction **Limits**		$\hat{Y}_i$	**Xi**
Upper limit	**Lower limit**	**Upper limit**	**Lower limit**	**GA (weeks)**	**MGSD (mm)**
6.5	6.3	7.8	4.9	6.4	15
6.6	6.4	8.0	5.0	6.5	16
6.7	6.5	8.1	5.1	6.6	17
6.8	6.6	8.2	5.3	6.7	18
6.9	6.7	8.3	5.4	6.8	19
7.1	6.9	8.4	5.5	7.0	20
7.2	7.0	8.5	5.6	7.1	21
7.3	7.1	8.7	5.7	7.2	22
7.4	7.2	8.8	5.9	7.3	23
7.6	7.4	8.9	6.0	7.5	24
7.7	7.5	9.1	6.1	7.6	25
7.8	7.6	9.2	6.3	7.7	26
8.0	7.8	9.3	6.4	7.9	27
8.1	7.9	9.5	6.5	8.0	28
8.2	8.1	9.6	6.7	8.1	29
8.4	8.2	9.8	6.8	8.3	30
8.5	8.3	9.9	7.0	8.4	31
8.7	8.5	10.0	7.1	8.6	32
8.8	8.6	10.2	7.3	8.7	33
9.0	8.8	10.3	7.4	8.9	34
9.1	8.9	10.5	7.6	9.0	35
9.3	9.1	10.6	7.7	9.2	36
9.4	9.2	10.8	7.9	9.3	37
9.6	9.4	10.9	8.0	9.5	38
9.7	9.5	11.1	8.2	9.6	39
9.9	9.7	11.2	8.3	9.8	40

95% Confidence Limits		95% Prediction Limits		$\hat{Y}_i$	Xi
Upper limit	**Lower limit**	**Upper limit**	**Lower limit**	**GA (weeks)**	**MGSD (mm)**
10.0	9.8	11.4	8.5	9.9	41
10.2	10.0	11.5	8.6	10.1	42
10.3	10.1	11.7	8.8	10.2	43
10.5	10.3	11.8	8.9	10.4	44
10.6	10.4	12.0	9.1	10.5	45
10.8	10.6	12.1	9.2	10.7	46
10.9	10.7	12.3	9.4	10.8	47
11.1	10.8	12.4	9.5	11.0	48
11.2	11.0	12.6	9.7	11.1	49
11.4	11.1	12.7	9.8	11.3	50
11.5	11.3	12.9	10.0	11.4	51
11.7	11.4	13.0	10.1	11.6	52
11.8	11.6	13.2	10.2	11.7	53
12.0	11.7	13.3	10.4	11.9	54
12.1	11.8	13.5	10.5	12.0	55
12.3	12.0	13.6	10.7	12.1	56
12.4	12.1	13.7	10.8	12.3	57
12.6	12.3	13.9	11.0	12.4	58
12.7	12.4	14.0	11.1	12.6	59
12.9	12.5	14.2	11.2	12.7	60
13.0	12.7	14.3	11.4	12.8	61
13.1	12.8	14.4	11.5	13.0	62
13.3	12.9	14.6	11.6	13.1	63
13.4	13.0	14.7	11.7	13.2	64
13.5	13.2	14.8	11.9	13.3	65
13.6	13.3	14.9	12.0	13.5	66

95% Confidence Limits		95% Prediction Limits		$\hat{Y}_i$	Xi
Upper limit	Lower limit	Upper limit	Lower limit	GA (weeks)	MGSD (mm)
13.8	13.4	15.1	12.1	13.6	67
13.9	13.5	15.2	12.2	13.7	68
14.0	13.6	15.3	12.3	13.8	69
14.1	13.7	15.4	12.5	13.9	70
14.3	13.8	15.5	12.6	14.0	71
14.4	13.9	15.6	12.7	14.1	72
14.5	14.0	15.7	12.8	14.2	73
14.6	14.1	15.8	12.9	14.3	74
14.7	14.2	15.9	13.0	14.4	75
14.8	14.2	16.0	13.0	14.5	76
14.9	14.3	16.1	13.1	14.6	77
15.0	14.4	16.2	13.2	14.7	78
15.1	14.4	16.3	13.3	14.8	79
15.2	14.5	16.4	13.4	14.9	80
15.3	14.5	16.4	13.4	14.9	81
15.4	14.6	16.5	13.5	15.0	82
15.5	14.6	16.6	13.5	15.1	83
15.6	14.6	16.7	13.6	15.1	84
15.7	14.7	16.7	13.6	15.2	85
15.8	14.7	16.8	13.7	15.2	86
15.9	14.7	16.9	13.7	15.3	87
16.0	14.7	16.9	13.7	15.3	88
16.0	14.7	17.0	13.7	15.3	89
16.1	14.6	17.0	13.7	15.4	90

Table 3: Standard Deviation (SD) of estimated the GA (weeks)

Standard Deviation	**GA (weeks)**
0.73	12 ≥
0.82	18 – 12

Table 4: Comparison between our study and reference studies:

	N	Correlation (r)	Sig.
Present Study & Tokyo*	9	0.998	0.000
Present Study & Hellman LF, Kobayashi M, Fillisti L et al [4]	6	0.997	0.000

Table 5: Comparison of Paired Differences between our study and reference studies about predicting the GA (weeks) using MGSD (mm)

Statistical significance	Sig	df	T value	Paired Differences					Comparison
				95% Confidence Interval of the Difference		Std. Error/ Mean	Std. Deviation	Mean	
				Upper	Lower				
Yes	0.000	8	7.34-	4.01-	7.69-	0.80	2.39	5.85-	Present Study & Tokyo*
Yes	0.001	5	7.59-	2.04-	4.13-	0.41	0.99	3.08-	Present Study & Hellman LF, Kobayashi M,and Fillisti L [4]

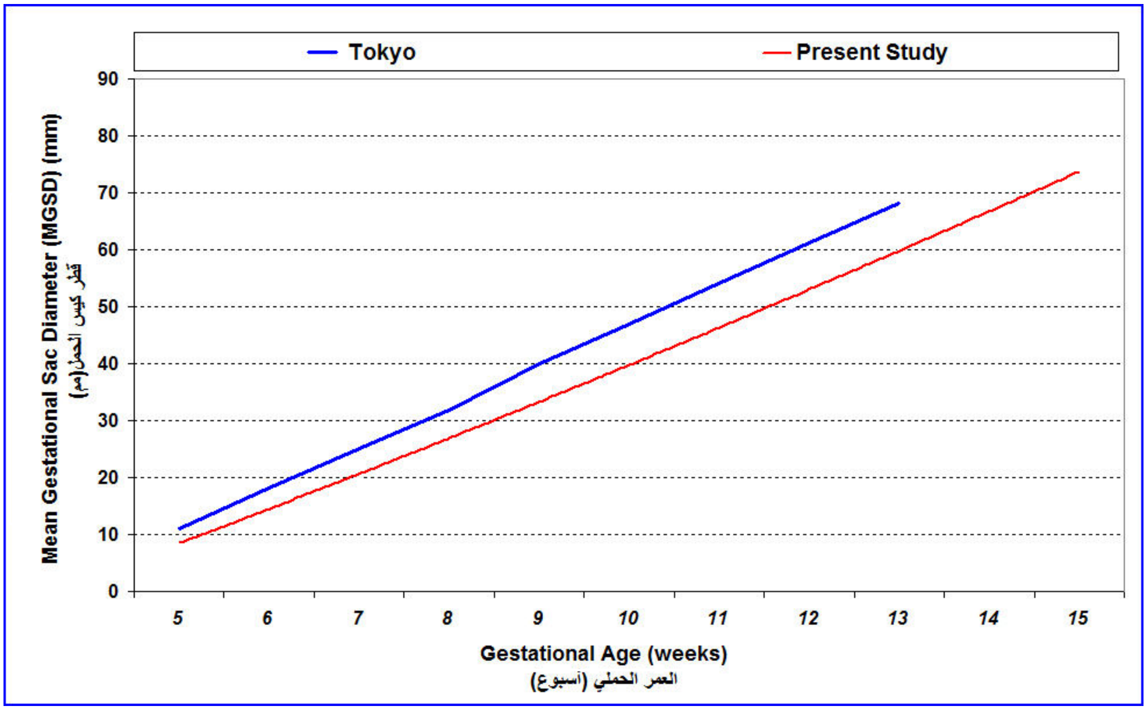

Figure 3: Comparison between GA using MGSD in our study (red line) and the GA using MGSD in reference studies (blue line)