

Implication of negative urine pregnancy testing in subjects with unknown last menstrual period

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Summary

Background: In laboratory medicine, a urine pregnancy test is an easily available diagnostic test today. Urine pregnancy is a monitoring of human chorionic gonadotropin (hCG), which is secreted by the trophoblastic cells of the placenta. The most common indication for a urine pregnancy test is secondary amenorrhea. However, there are other conditions that can lead to secondary amenorrhea. Only a few recent studies have estimated population pregnancy rates using objective, laboratory-based criteria.

Methods: A study on laboratory-measured pregnancy rates and the correlation to age in a tertiary hospital in Thailand was carried out. This study not only provides good information from a medical aspect but also from a social aspect. The data from the medical records of female patients who underwent a diagnostic urine pregnancy test at the Division of Laboratory Medicine, King Chulalongkorn Memorial Hospital, Bangkok Thailand from August 2004 to December 2004 were reviewed. The definitive last menstrual period was not known for all subjects.

Results: There were 1,005 medical records reviewed in this study. From the total medical records, there was no subject younger than ten years or older than 50 years of age. The diagnostic test results were positive in 121 cases (12.0%) and negative in 884 cases (88.0%). Classified by age group, we found that most subjects were under 35 years of age. The laboratory-measured pregnancy rates in the subjects aged less or equal to, or more than 35 years old were 11.3% and 14.8%, respectively. There was no significant difference in positive rate in either group.

Conclusion: In our setting, a negative pregnancy test in the presence of amenorrhea can imply more than a pregnancy. Close follow-up and checking for other possible pathological conditions should be considered.

Key word: Urine pregnancy test; Secondary amenorrhea; Last menstrual period.

Introduction

A urine pregnancy test is an easily available diagnostic test today. Because of the basic simplicity of the immunological principle [1-3], many urine pregnancy diagnostic tests have been produced [4]. Moreover due to the easiness of use and low cost, it is widely used at present. Only a few recent studies have estimated population pregnancy rates using objective, laboratory-based criteria [5]. Studies on the demographic data of laboratory screenees, especially for marital status, can provide a good predictive pregnancy factor [5].

Generally, urine pregnancy testing monitors human chorionic gonadotropin (hCG), which is secreted by the trophoblastic cells of the placenta soon after implantation of the fertilized egg into the uterine wall [6]. According to a recent study by Wiwanitkit, the most common indication for a urine pregnancy test is secondary amenorrhea [7]. However, there are other conditions that can lead to secondary amenorrhea. Recently, Subhan *et al.* noted that the health awareness of women in developing countries on pregnancy was low and that these populations usually do not get evaluations for pregnancy [8]. They stated that this could lead to serious complications if the secondary amenorrhea was not truly due to pregnancy [8].

A study on laboratory-measured pregnancy rates and the correlations to subject ages was performed in a tertiary hospital in Thailand.

Materials and Methods

The data from the medical records of female patients who had a diagnostic urine pregnancy test at the Division of Laboratory Medicine, King Chulalongkorn Memorial Hospital, Bangkok, Thailand from August 2004 to December 2004 were reviewed. The last definitive menstrual period was not known for all subjects. Data were processed at the largest laboratory of the Thai Red Cross Society with accredited ISO 15189 standards. Demographic data on age noted in the medical records were collected.

The urine pregnancy test mentioned in this study was a one-step pregnancy test, a rapid one-step membrane test, for the detection of hCG in urine. The accuracy of the test is about 99%. Results of each test noted in the medical records were also reviewed and collected.

The subjects were classified into two groups, aged less or equal to, or more than 35 years old. This classification is set according to the cut-off point of elderly gravida, which was used in a previous study [9]. Records that did not have complete data were excluded. Descriptive statistics were carried out on the data where appropriate.

Results

There were 1,005 medical records reviewed in this study. From the total medical records, there was no subject younger than ten years old or older than 50 years old. The diagnostic test results were positive in 121 cases (12.0%) and negative in 884 cases (88.0%). Classified by age group, we found that most were less than 35 of age. The laboratory-measured pregnancy rates in the subjects aged less or equal to, or more than 35 years old were 11.3% and 14.8%, respectively (Table 1).

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Table 1. — Demographic data of the subjects.

Group	Urine pregnancy test	
	negative	positive
≤ 35 years old	694	88
> 35 years old	190	33

There was no significant difference in positive rate in either group. A detailed age breakdown of data, by half decades, is reported in Table 2.

Table 2. — Detailed age breakdown of data by half decades.

Age group	Urine pregnancy test		Positive rate (%)
	negative	positive	
10-14 years old	21	1	4.8
15-19 years old	224	26	11.6
20-24 years old	238	22	9.2
25-29 years old	110	21	19.1
30-34 years old	101	18	17.8
35-39 years old	103	22	21.4
40-44 years old	60	8	13.3
45-49 years old	27	3	11.1

*No subject was younger than ten years or older than 50 years of age.

Discussion

Urine pregnancy testing in medical laboratory practice is frequently used due to the convenience and effectiveness. The most common indication for a laboratory request was missed menstruation [2]. In this study, most of the results of the urine pregnancy tests were negative, thus a high rate of negative urine pregnancy tests in subjects with secondary amenorrhea was observed. This result is concordant with a recent study in Pakistan by Subhan *et al.* [8]. However, this result is discordant with a report from a developed country, which revealed a pregnancy rate up to 79% [10].

Concerning subject age, most were aged less than 35 years old. Indeed, there was a previous report that the average age of subjects with negative urine pregnancy tests was significantly higher than that of subjects with positive urine pregnancy tests [8]. However, a non significant difference in laboratory-measured pregnancy rate between elderly and non-elderly gravida was detected in this study. It means that there were several conditions leading to secondary amenorrhea in both elderly and non-elderly gravidae. The urine pregnancy positive rate in this study was about 12% with a peak positive rate in the age group between 25 and 40 years old. This rate is concordant with a previous Thai report (about 10%) [7] as well as a report from the Middle East (about 10%) [8]. This rate is also concordant with a recent report on urine pregnancy testing from the USA (about 11%) [11]. Concerning the pregnancy rate in different age groups, the urine pregnancy rate among subjects aged 15-44 years old in this study (14.0%) was 1.5 times more than the rate described in the USA 2000 report (10.4%) [12]. In addition, the rate of teenage pregnancy in this study (11.0%) was also higher than the USA 2000 report (8.5%) [12] as well as reports from other countries [13] (Table 3). In addition, a positive rate in the subjects aged more than 45 years old can also be seen.

Table 3. — Teenage pregnancy rate in this study compared to other countries.

Countries	Rate (%)
Thailand (this study)	11
USA [12]	8.5
UK [13]	5.5
Canada [13]	5.5
Sweden [13]	3.0
France [13]	2.5
Japan [13]	1.5

In conclusion, in our setting, a negative pregnancy test in the presence of amenorrhea can imply more than pregnancy. Close follow-up and looking for other possible pathological conditions should be considered. However, this study was done in a rather specific area so the results and conclusion of the study may not be applicable in all communities. However this study can provide basic data for continuing studies. Further studies such as multi-center studies are recommended.

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