

Salivary Human Chorionic Gonadotropin as a Novel Biomarker for Early Detection of Pregnancy: A Pilot Study

Madhura Mahajan¹, Uzma Iqbal Belgaumi^{2*}, Rajendra Baad², Nupura Vibhute², Vidya Kadashetti², Sushma Bommanavar², Wasim Kamate²

¹Intern, School of Dental Sciences, KIMSDU, ²Department of Oral Pathology and Microbiology, School of Dental Sciences, KIMSDU, Karad, Maharashtra, India

Abstract

Context: The role of saliva in detection of pregnancy has not received the due importance it deserves.

Aims: The present paper aims at determining the role of saliva in detection of pregnancy using home-based pregnancy detection kits to provide an alternative biofluid that is more user friendly, acceptable, noninvasive, rapid, and easy for home use.

Settings and Design: The study was conducted among 35 women visiting a gynecology clinic for confirmation of pregnancy, who gave a history of a missed menstrual cycle not more than 4 weeks.

Subjects and Methods: A home-based pregnancy detection kit meant for urinary human chorionic gonadotropin (hCG) detection with 20 mIU specification was used in the study for estimation of salivary hCG. Routine test that was prescribed to the patient such as laboratory-based urine hCG and/or ultrasound examination was used for confirmation of pregnancy status and correlation with the saliva-based result.

Results: A positive test was obtained in 74% participants, with a dark band in 43% participants and a light band in 31% participants. A negative result was noted in 26% participants. We observed that salivary hCG estimation showed a 77% accuracy and 23% false-negative results.

Conclusions: An astounding 74% of participants showed a positive result with an existing pregnancy kit which indicates a strong plausibility of using salivary hCG as a biomarker for detection of pregnancy. With the findings obtained from our study, we could positively affirm that salivary hCG can be used as a potential, user friendly, and more acceptable biomarker for early detection of pregnancy.

Keywords: Human chorionic gonadotropin, pregnancy, saliva, salivary diagnostics

INTRODUCTION

Saliva is a clinically important biologic fluid that can be utilized for novel approaches in prognosis, diagnosis, monitoring, and management of patients with oral and systemic diseases. Saliva can be easily collected and stored and is ideal for early detection of disease. It is known to contain specific soluble biologic markers commonly referred to as biomarkers. The presence of multiple biomarkers makes it useful for multiplexed assays that can be developed as point-of-care devices, rapid tests, and for centralized clinical laboratory operations.^[1]

Article History:

Received 18 May 2018

Received in revised form 6 November 2018

Accepted 15 November 2018

Available online 29 April 2019

Access this article online

Quick Response Code:



Website:
www.e-gmit.com

DOI:
10.4103/GMIT.GMIT_47_18

The measurement beta-human chorionic gonadotropin (β -hCG) in plasma and urine are currently used in the detection of pregnancy. β -hCG levels in saliva are usually detectable at about 3–4 weeks of pregnancy and continue to increase throughout the pregnancy. However, only a few studies have been carried out to evaluate the role of saliva as a noninvasive, rapid, and more acceptable biofluid for pregnancy detection. With this objective, the present study was carried out to determine the role of saliva in the detection of pregnancy using home-based pregnancy detection kits.

Address for correspondence:

Dr. Uzma Iqbal Belgaumi,
Department of Oral Pathology and Microbiology, School of Dental Sciences,
KIMSDU, Karad, Maharashtra, India.
E-mail: uibelgaumi@gmail.com

This is an open access journal, and articles are distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 4.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as appropriate credit is given and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

How to cite this article: Mahajan M, Belgaumi UI, Baad R, Vibhute N, Kadashetti V, Bommanavar S, *et al.* Salivary human chorionic gonadotropin as a novel biomarker for early detection of pregnancy: A pilot study. *Gynecol Minim Invasive Ther* 2019;8:59-61.

SUBJECTS AND METHODS

After taking informed consent, the study was conducted among 35 women visiting a gynecology clinic for confirmation of pregnancy with a history of a missed menstrual cycle not more than 4 weeks. A home-based pregnancy detection kit meant for urinary hCG detection with 20 mIU specification was used in the study for estimation of salivary hCG. Routine test that was prescribed for the patient such as laboratory-based urine hCG and/or ultrasound examination was used for confirmation of pregnancy and for correlation with the saliva-based result.

RESULTS

All the participants evaluated were in the age group 21–27 years of age, with 77% patients in the age group of 23–26 years. About 43% participants had a history of missed period of less than or equal to 10 days, 49% between 11 and 15 days, and 9% more than 15 and 30 days [Table 1].

The confirmation (presence of pregnancy) was obtained in 23% participants by an ultrasound examination and in 77% participants by a laboratory-based urine hCG level. About 74% participants with a confirmed pregnancy showed a positive result, of which 43% showed a dark band [Figure 1] and a light band was noted in 31% participants [Figure 2]. A negative result was noted in 26% participants [Chart 1]. Of the 9 subjects who showed a negative result, 8 showed a positive confirmation with a urine test and 1 was confirmed negative on further evaluation.

Hence, in the present study, we observed that salivary hCG estimation showed a 77% accuracy and 23% false-negative results.

DISCUSSION

Saliva is an exceptional biological fluid that is useful for noninvasive diagnosis and monitoring of the diseases and physiological phenomenon.^[2]

In addition, it offers an edge over the other body fluids that it is a more patiently acceptable method and it may be retrieved many times a day, making repetition possible along with a very high durability. Although it mainly contains water, the other

constituents include cellular elements, organic and inorganic substances, and biological markers that are also known to be present blood and urine. All these may be used in the early detection and monitoring of many diseases.^[3]

Some other advantages of saliva include the characteristic that hormonal analysis of saliva is not influenced by changes in concentrations of binding globulins as free concentration of the hormones in saliva is measured.^[4]

Liu *et al.* in their study on quantification of steroid hormones in human saliva, stated that steroid hormones follow the same metabolic pathway and therefore have an unequivocal degree of correlation with respect to their concentrations.^[5]

Saibaba *et al.* in 2016 in their study on proteomic analysis of human saliva, an approach to find the marker protein for ovulation, reported that theirs was the first study on salivary proteins as biomarkers of ovulation in the human. They observed that of all the ovulation-specific proteins that have been found, cystatin-S was the highly expressed protein.^[6]

Detection of pregnancy is based on the measurement of hCG and its variants. In a normal menstrual cycle, ovulation occurs on an average of 14 days before the next anticipated menses, and the corpus luteum then starts to develop. If the oocyte is fertilized, implantation takes place approximately during the next 7 days, resulting in an increase in the concentrations of



Figure 1: Test kit showing a dark band (positive)



Figure 2: Test kit showing a light band (positive)

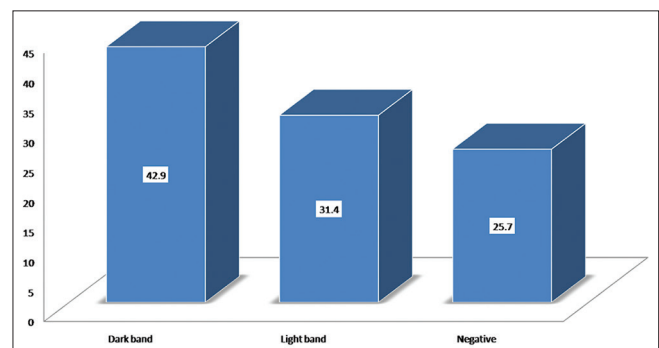


Chart 1: Gestational age when the salivary hCG test was performed

Saliva results	Days after missed periods			Total
	≤10 days	11-15 days	>15 days	
Dark Band	7	8	0	15
Light Band	4	4	3	11
Negative	4	5	0	9
Total	15	17	3	35

hCG and its variants. Pregnancy tests utilizing urine or serum can detect hCG from the time of the missed menses. Hence, pregnancy tests for hCG are widespread in hospital and home settings. A urinary hCG level of 25 U/l is generally considered positive urine pregnancy test result.^[7]

Based on the results of the previous studies, we intended at evaluating if saliva could be used as a potential biomarker for detection of pregnancy. In the present study, a home-based pregnancy detection kit meant for urinary hCG detection with 20 mIU specification was used in the study for estimation of salivary hCG.

Saliva is considered as an alternative matrix for monitoring of biochemical parameters. A graphene-based chemiluminescence resonance energy transfer immunoassay for the detection of hCG in the serum and saliva samples had been utilized. The results of their study indicated that hCG level could be detected in the saliva samples in the concentrations ranging from 0.3 mIU/mL to 0.8 mIU/mL. The authors hence stated that it was necessary to develop simple and sensitive analytical method for detection of hCG in saliva samples that would have widespread clinical applications.^[8]

In the present study, although we used home-based pregnancy detection kit meant for urinary hCG detection, we still noted that salivary hCG estimation using these kits showed a 77% accuracy and 23% false-negative results.

It was interesting to find that 43% subjects had a history of missed period of ≤ 10 days, 49% between 11 and 15 days, and 8% more than 15–30 days [Table 1], and hence, the test was able to detect pregnancy status in most women at a gestational age of 2–3 weeks or lesser.

Although this is a pilot study, the results from the study are encouraging. Some of the limitations of the study were a small sample size and since the study setting was a rural one, many pregnant women were not willing for an ultrasound due to educational and financial barriers though the ultrasonography examination would have provided a more confirmatory result. With a larger sample size and more sensitive kits meant for salivary hCG, saliva has a promising potential as an early, user-friendly biomarker of pregnancy.

In the dearth of literature, it was not possible to compare the results of our study with other studies. Second, the initiative was taken by an undergraduate student, and with limited resources, the study design was a simple one. However, the idea holds promise in that a user-friendly home-based salivary

hCG-based pregnancy detection kit may be developed with further research.

CONCLUSION

The results from this study, though preliminary, can go a long way in replacing the traditionally used bio fluids with more user friendly and acceptable bio fluid i.e. saliva as a biomarker for detection of pregnancy.

Though this was a pilot study and the kit used was a commercially available kit meant for urinary hCG, strong positive data obtained is encouraging and opens new avenues towards development of new saliva based diagnostic kits using salivary hCG as a diagnostic bio fluid for early detection of pregnancy. With the findings obtained from our study we could positively affirm that Salivary hCG can be used as a potential, user friendly, more acceptable home based biomarker for early detection of pregnancy

Acknowledgment

This research was supported by the Department of Oral Pathology, School of Dental Sciences, Krishna Institute of Medical Sciences “Deemed to be University,” Karad.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

REFERENCES

1. Malamud D. Saliva as a diagnostic fluid. *Dent Clin North Am* 2011;55:159-78.
2. Wong DT. Towards a simple, saliva-based test for the detection of oral cancer ‘oral fluid (saliva), which is the mirror of the body, is a perfect medium to be explored for health and disease surveillance’. *Expert Rev Mol Diagn* 2006;6:267-72.
3. Chojnowska S, Baran T, Wilińska I, Sienicka P, Cabaj-Wiater I, Knaś M. Human saliva as a diagnostic material. *Adv Med Sci* 2018;63:185-91.
4. Langelaa ML, Kisters JM, Oosterwerff MM, Boer AK. Salivary cortisol in the diagnosis of adrenal insufficiency: Cost efficient and patient friendly. *Endocr Connect* 2018;7:560-6.
5. Liu J, Qiu X, Wang D, Li Y, Zong Y, Liu Y, *et al.* Quantification of 10 steroid hormones in human saliva from Chinese adult volunteers. *J Int Med Res* 2018;46:1414-27.
6. Saibaba G, Rajesh D, Muthukumar S, Sathiyarayanan G, Padmanabhan P, Akbarsha MA, *et al.* Proteomic analysis of human saliva: An approach to find the marker protein for ovulation. *Reprod Biol* 2016;16:287-94.
7. Berger P, Sturgeon C. Pregnancy testing with hCG – Future prospects. *Trends Endocrinol Metab* 2014;25:637-48.
8. Lei J, Jing T, Zhou T, Zhou Y, Wu W, Mei S, *et al.* A simple and sensitive immunoassay for the determination of human chorionic gonadotropin by graphene-based chemiluminescence resonance energy transfer. *Biosens Bioelectron* 2014;54:72-7.