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Original Research Article

Overlaps of CA-125 Bio Marker As a kind of Medical Error in Women's Complications: A Cross Sectional Study in Korramabad (west of Iran)

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ABSTRACT

Introduction: Medical errors secondary to false positive and false negative of immunoassay have not ever been as considerable as therapeutic and surgical errors so. Of the overlapping bio markers, Cancerous Antigen 125 (CA-125) can be noted as a factor which its level is high in a wide spectrum of disease that mainly leads to medical error between endometriosis and ovarian cancer. So we intend to represent a way to distinguish endometriosis from the other CA-125 related complications.

Materials and Methods: Present paper is a cross sectional study on the medical records of Noor pathobiology laboratory in Khorramabad (west of Iran) during 2014-2015.

Results: There were totally 693 records for CA-125. In 90 patients (about 12.9%) the level of CA-125 was high that 7 individuals were male. Totally, CA-125 level was high in about 10% and 13% of respectively male and female required to the test patients. Among the female patients having high level of CA-125, only 20 of them were required to test Carcino-embryonic Antigen (CEA). No one of these 20 individuals has abnormal CEA.

Conclusion: It can be concluded that dual assaying CA-125 and CEA might be a helpful method to distinguish endometriosis from ovarian cancer. Also it is suggested to use combined method including immunoassay and imaging. Further research is necessary to identify a more specific bio marker for endometriosis and other complications.

KEY WORDS: medical errors, CA-125, CEA, endometriosis, ovarian cancer.

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INTRODUCTION

Medical errors secondary to false positive and false negative of immunoassays have not ever been as considerable as therapeutic and surgical errors so. The editorial of Kricka (2000) has it that in spite of numerous progressions in laboratory assays, a lot of the cases are still false positive and false negative [1]. Of the overlapping bio markers, Cancerous Antigen 125 (CA-125) can be noted as a factor which its level is high in a wide spectrum of disease that mainly leads to medical error between endometriosis [2-4] and ovary cancer [5]. Thus we intend to remind the importance of such errors as invasive errors so. Why fail to diagnosis of high risk conditions like cancers could result in more progression of disease and on the other

hand diagnosis of cancer instead of endometriosis could result in loss of morale in patients.

Based on the literatures, use of CA-125 in diagnosis of disease has burgeoned since 1980s. According to nowadays' science, endometriosis is a kind of inflammation of pelvis related to immunologic processes [3]. Other than endometriosis, other cases such as septicemia secondary to *E. coli* also can result in up-regulation of CA-125 [1]. Also in endometrial carcinoma which is one of the most commonplace malignancies in women we have up-regulation of CA-125 [6].

CA-125 is an antigen which is found normally in a lot of tissues such as endometrium, endocervix and pretoneum [3]. According to the founding of Sutcu (2015), in grades 3 and 4 of endometriosis, bio markers such as CA-125, CA-19-9, Interleukin-6 (IL6) and C reactive protein (CRP) are higher and this assessment is performed in secreting phase [3]. In its author's estimation CA-19-9 is of the biomarkers of colorectal carcinomas that is up-regulated in malignancies of endometrium too; but its sensitivity and specificity for endometriosis is lesser than CA-125. The above founding made us to think that as a solution, simultaneous assay of the present 4 factors can be effective in distinguishing endometriosis from other complications; but we should know that CA-19-9 is also of the tumor bio markers of ovary [7] and also IL6 and CRP are up-regulated in ovarian cancers [8]. So the mentioned overlaps are still with no answer. Serum level of CA-125 in grade 1 and 2 of endometriosis shows no significant difference [2].

In relapse of endometriosis, assayed serum sensitivity of CA-125 was about 15% and the specificity was 100%. Thereby CA-125 is not a sufficient index for diagnosis of endometriosis relapse and the high specificity was secondary to this point that the samples of Fedele et al had been screened from the other up-regulating CA-125 factors such as menstruation, pregnancy, pelvic infectious disease, uterine fibroma and genetic neoplasms [2].

As we see, ovarian tumors and endometrial carcinomas are also resulted in increase of CA-125. The main morbidity and mortality cause of ovarian tumors is because of its late and difficult diagnosis that more than 80% of cases are diagnosed in progressed stages and on-time identification is related with more than 5 year surviving after removing the tumors [5]. Another study showed that 82% of patients with ovarian cancer has a high level of CA-125 that this increasing is observed in 44% of the patients with grade 3 and 4 of endometriosis, 13% of the patients with grade 2 of endometriosis and 5% of the patients with pelvic infections [4].

Finally we intend to represent a way to distinguish endometriosis from the other CA-125 related complications.

MATERIALS AND METHODS

Present paper is a cross sectional study on the medical records of CA-125 in Noor pathobiology laboratory- Khorramabad (west of Iran) during 2014-2015. Then we investigated the level of carcino-embryonic antigen (CEA) in the records of the women data with high level of CA-125 as another bio marker. The maximum normal level of CA-125 and CEA were respectively considered as 35 u/ml and 5.5 ng/ml.

The sampling method was convenient and not randomized; convenient, because we had our best access to Noor laboratory among the pathobiology laboratories in Khorramabad and not randomized for this reason that we used all the records during the mentioned time period. The excluding steps of the documents from 693 records to finally 20 records is discussed in the results.

RESULTS AND DISCUSSION

There were totally 693 records for CA-125 that 69 of them (about 9%) were for male patients (table 1). In 90 patients (about 12.9%) the level of CA-125 was high (more than 35 u/ml) that 7 individuals were male (table 2). Totally, CA-125 level was high in about 10% and 13% of respectively male and female required to the test patients (table 3). It can be concluded that in general female patients both are more required to test CA-125 and have more positive results rather than male.

Among these 83 female patients having high level of CA-125, only 20 of them were required to test CEA (table 4). It was notable that no one

Table 1: Frequency distribution of patients requested for CA-125 assay.

Gender	frequency (N)	Frequency (%)
Female	624	90.1
Male	69	9.9
Overall	693	100

Table 2: CA-125 condition.

Gender	CA-125 >35	CA-125 <35	Overall
Female	83 (11.9%)	541 (78%)	624 (90.1%)
Male	7 (1.01%)	62 (8.9%)	69 (9.9%)
Overall	90 (12.9%)	603(87.1%)	693 (100%)

Table 3: Total patients with CA-125 > 35 u/ml.

CA-125	Female	Male	Overall
>- 35	83 (92.3%)	7 (7.7%)	90 (100%)

Table 4: Gender distribution of CA-125 level.

Female	CA-125	Male
83 (13.8%)	>- 35	7 (10.1%)
520 (86.2%)	< 35	62 (89.9%)
603 (100%)	Overall	69 (100%)

Table 5: Condition of CEA in female with CA-125 >35.

CA-125 level	Total frequency (n)	Requested for CEA	CEA > 5.5
Female >-35	83	20	0

of these 20 individuals has abnormal (more than 5.5 ng/ml) CEA. It can be concluded that dual assaying CA-125 and CEA might be a helpful method to distinguish endometriosis from ovarian cancer.

About the level of CEA in endometriosis also Cirkel et al (1991) found 0% specificity [9] as we hypothesized so. They are also of the conviction that CA-125, CA-19, and CEA are not sufficient bio makers to replace surgical and imaging procedures of monitoring endometriosis and the significant reduction of CA-125 represents loss of ovarian function rather than regression of the disease.

CONCLUSION

By improving information system reporting and keeping all the medical records we can improve our diagnosis and reduce the medical errors [10, 11]. As a conclusion, in order to prevent from the noted medical errors it is suggested to use combined method including immunoassay, Doppler colorful ultrasonography [5] and trans-vaginal ultrasonography [6]. Immunoassay method in turn should be consisted of dual assaying CA-125 and CEA, because it might be helpful to distinguish endometriosis (stage 3 and 4) from ovarian cancer. A specific bio marker for stage 1 and 2 endometriosis is still unknown. Further research is necessary to identify a more specific bio marker for endometriosis and other complications.

ABBREVIATION

CA-125 - Cancerous Antigen 125

CRP- C Reactive Protein

IL6- Interleukin-6

CEA- Carcino-embryonic Antigen

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