

**A STUDY ON BIOCHEMICAL CHANGES AND CYTOGENETIC
ANALYSIS IN THE PROGNOSIS AND SCREENING OF CERVICAL
CANCER PATIENTS FROM ERODE DISTRICT, TAMILNADU**

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**FIRST YEAR REPORT OF MINOR RESEARCH PROJECT
FOR COLLEGE TEACHERS
SUBMITTED TO**



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ENCLOSURE I

Brief Objective of the Project

ENCLOSURE I

Brief Objective of the Study

The main objective of the present study

The aim of this study is to provide an integrated action plan, for early detection of Cervical Cancer in high risk individuals, its prevention and control as well as health promotion in relation to the disease by fixing the following objectives:-

- **Screening and Awareness (Phase I)**
To quantitatively and qualitatively assess the levels of awareness, perceived susceptibility and attitude towards screening before and after a health literacy session, among a sample of Urban Women in Erode District of Tamil Nadu.
- **Biochemical Analysis (Phase II)**
To assess the biochemical changes in the serum levels of Antioxidants (Vitamin A,C,E) Minerals (Ca, P, Mg) and Trace elements (Zn and Cu) in Cervical Cancer patients.
- **Cytogenetic Analysis (Phase III)**
To evaluate genetic damage and heterogeneity in the cervical nuclei and lymphocytes from patients with different levels of dysplasia and to determine the risk factors associated with the development of Cervical cancer for early detection, prevention and treatment.

The proposed study will be highly useful for efficient management of Cervical Cancer in high risk individuals.

ENCLOSURE II

ENCLOSURE II

Summary of the findings of the study: (Phase I & Phase II)

Ethical approval

Ethical approval for the study was obtained from the Institutional Ethical Committee, Erode Cancer Centre, prior to the commencement of the study and the ethical principles according to the declaration were considered during the course of the research.

I. Screening and Awareness (Phase I)

The qualitative and quantitative portion of this study based on the objectives was carried out through a questionnaire survey taken before and after a health literacy session, among a sample of Urban Women in Erode District of Tamil Nadu. This survey is mainly done to examine the relationship between awareness and knowledge of Cervical Cancer besides attitude towards participation in Cervical Cancer screening among women in order to explore the potential impact of increased awareness and knowledge on screening attitude after Cervical Cancer health literacy session.

For this 500 women living in and around Erode District were subjected to study through a convenience sampling strategy. Data for the Cervical Cancer portion of the Erode District Health Behaviour Survey were collected using a lengthy 60-question cross-sectional social survey. The English and Tamil versions of the questionnaire survey are attached as Appendices to this report.

All surveys were administered during one of five sessions held in the campus of Kongu Arts and Science College, Erode Cancer Centre and Field visits in and around Erode district. At each session participants were asked to provide informed consent, respond to a two-part survey, and to participate in a Cervical Cancer health literacy session presented by a trained health care professional.

The guidelines for informed consent were in accordance with human subjects research guidelines established by the appropriate governing institutions in India. Women were informed of their right to discontinue participation at any point during the survey or health literacy session.

Through these qualitative and quantitative observations it was realized that many women were either unaware of Cervical Cancer or, in the case of those who were aware of Cervical Cancer, had very limited knowledge of Cervical Cancer and/or screening.

The results of our study indicated that lack of awareness is one of the major barriers to women seeking cervical cancer screening services. Some other barriers include:

- Fear of the procedure
- Women feel embarrassed about gynaecological examinations, especially older women
- Socio-cultural barriers (it is considered to be “a woman’s disease” that is not discussed openly so women are not “free” to request the service even when they know about it)
- Myths and stigmas (e.g. according to health care workers, communities associate Pap smears with HIV testing, though recent surveys have failed to demonstrate this)
- Poor communication between health providers and women attending health services – services not accessible to women

However, It appeared that despite initially being unaware of Cervical Cancer, during the survey process, most women were eager to learn more about Cervical Cancer and their individual risk, as well as steps necessary for protecting themselves.

It was also noted through observation that after receiving information about Cervical Cancer in the health literacy session, most women had a positive attitude toward participating in screening. Therefore, it was clear from our study that lack of awareness and/or knowledge were significant barriers to Cervical Cancer screening among Tamil women; and further, that with increased awareness and knowledge of cervical cancer, the majority of women would be receptive to Cervical Cancer screening.

In considering the development of a Cervical Cancer awareness campaign, participant feedback suggest that women do not necessarily need or desire in-depth levels of information about Cervical Cancer, but they do want to know about symptoms, methods for prevention, the lack of hereditary factors, and the availability and cost of treatment.

To bridge the information gaps and address these barriers requires a comprehensive and sustained Health literacy programme with extensive community. The purpose of this extensive Health literacy programme should be to raise awareness about cancer of the cervix and the importance of screening as a preventive measure, to publicise the availability of screening services in the public sector at clinic level, and to encourage women to attend health services for screening according to the screening policy. Taking into account the gender and socio-cultural barriers, it is imperative that both women and men in the community are involved.

II. Biochemical Analysis (Phase II)

Although recent scientific advances have led to improved prevention, earlier diagnoses, and innovative treatments for many cancers, there is still tremendous unmet medical need.

The present study was therefore planned to understand the biochemical changes in blood of CaCx patients in order to evaluate the correlation between oxidative stress and status of Antioxidants (Vitamin A,C,E) , Minerals (Ca, P, Mg) and Trace elements (Zn and Cu) in Cervix cancer and thereby assist in the early detection of premalignant lesions, identify individuals at high risk of developing cancer, predict response to therapy and clinical course of the disease.

For this purpose, 60 recently diagnosed patients with squamous cells carcinoma of the cervix and 60 control subjects who had no malignancy were taken up for study. The control subjects were those who were not suffering from any cancerous lesions.

After obtaining prior consent, venous blood was collected from the subjects under aseptic condition by vein puncture using 10ml sterile disposable syringe and needle. About 5ml of blood was collected in clot activator tube and was allowed to clot. The serum samples were stored at 4°C before analysis and all the samples were analyzed on the same day of collection by the following methods.

- (i) Antioxidants (Vitamin A,C,E)– by HPLC and LC-MS**
- (ii) Minerals(Ca,P,Mg) and Trace elements(Zn and Cu)–by Spectrophotometer**

1. Antioxidant (Vitamins)

The results of the present study revealed a reduction in all serum antioxidant nutrients levels, Vitamin A, Vitamin C and Vitamin E in women with cervical cancer. This study therefore clearly suggest the scavenging activity of antioxidants against the free radicals in the pathogenesis of cervical cancer and provides some evidence for the protective role of the serum concentration of antioxidant Vitamins (Vitamin A, Vitamin E, and Vitamin C) in the etiology of cervical cancer. Also Coexisting deficiency of antioxidants may potentially increase the risk for cervical cancer and the implication in terms of prevention is to encourage intake of fresh vegetables and fruits rich in antioxidant Vitamins. Replication of this study in different populations may give further credence to its findings.

From the results of our present study, it is observed that the Zinc and Copper levels are found to be significantly lower in Cervical Cancer patients compared to control. Similarly Serum Magnesium level is also decreased in Cervical Cancer patients. However mean Serum Phosphorus level is found to be higher than the Control and Calcium level was well within the normal range.

2. Trace Element and Minerals

From the results of our present study, it is observed that the Zinc and Copper levels are found to be significantly lower in Cervical Cancer patients compared to control. Similarly Serum Magnesium level is also decreased in Cervical Cancer patients. However mean Serum Phosphorus level is found to be higher than the Control and Calcium level was well within the normal range.

In summary, the outcome of the present study clearly hint that patients with Cervical Cancer are at risk for electrolyte imbalances from a myriad of causes, and continuous assessment of their status is often necessary.

The biochemical analysis of the present study supports the fact that oxidative stress in Cervical cancer patients may result in depletion of the antioxidant vitamins and vital micro and macro minerals in the body and suggest that Zinc, Copper, Magnesium and Phosphorus can be used a biomarker for the early diagnosis and possible preventive measures in the management of Cervical Cancer.

However, future robust prospective studies are needed to determine if these trace element concentrations will impact clinical outcomes and to establish whether routine provision of these trace elements as supplements will result in improved Cervical Cancer treatment outcomes in Cervical Cancer affected women.