

## Abstract

**Background:** Ovarian cancer is the fourth commonest cancer among females in Sri Lanka. Despite new treatment modalities, mortality rates have remained high, and the incidence has been rising over the past two decades. There is no established screening programme for ovarian cancer at present, and often these cancers are detected late. Therefore, introducing a low-cost tool with good psychometric properties for high-risk women, while appreciating the economic burden incurred by the epithelial ovarian cancers is vital.

**Objectives:** To assess the prevalence of abnormal ovarian masses, risk factors and the economic burden on the state health sector attributed to epithelial ovarian cancer in women over the age of 40 years in the district of Colombo, Sri Lanka.

**Methods:** The study comprised of four components: Component I was a community based, descriptive cross-sectional study conducted in the district of Colombo, to assess the prevalence of abnormal ovarian masses, based on ultrasound scan findings among 931 females aged over 40 years, who were selected by probability proportionate to cluster sampling technique, with 41 clusters having 25 women in each. All the study participants underwent trans-abdominal ultrasound scanning in a field clinic conducted by a consultant Gynaecologist. Married subjects were offered a subsequent trans-vaginal scan if indicated. Abnormal ovarian mass on USS was diagnosed based on explicit criteria. In the Component II, a case control study was conducted among 91 consecutively selected newly diagnosed patients with epithelial ovarian cancer residing in Colombo district, from tertiary care hospitals, versus systematically selected 377 community controls with no abnormal ovarian masses detected at component I. A pre-tested interviewer administered risk assessment questionnaire, was introduced by three trained data collectors to assess reproductive, exogenous hormonal, and genetic factors, alcohol and smoking habits/exposure, which was supplemented by a questionnaire on food frequency patterns and lifestyle physical activity levels that had been validated for Sri Lanka. Univariate analysis and Unconditional Multiple Logistic Regression were performed.

The component III was a case control study validate the translated Sinhala version of Goff Symptom Index (GSI) among a consecutive sample of 55 cases of ovarian cancer, irrespective of the histology type, selected from National Cancer Institute, Maharagama, and consecutive sample of 56 controls who were found free of abnormal ovarian masses during the component I.

Interviews were carried out by a trained data collector prior to surgery or chemotherapy in cases and prior to ultrasound scanning in controls. Receiver Operative Curve was applied. Component IV was conducted to assess the cost incurred for the management of epithelial ovarian cancers at each stage by the state health sector at NCIM using scenario building approach.

**Results:** The prevalence of abnormal ovarian masses based on ultrasound assessment in females aged over 40 years in the district of Colombo was 2.9% (95% C.I: 1.8-4.0). The risk factors associated with epithelial ovarian cancer were: age >50years (AOR= 2.6, 95% C.I:1.2-5.3), been educated beyond O/Ls ( AOR=4.2, 95% C.I: 2.0-9.0), ever been employed (AOR=2.3, 95% C.I: 1.1-4.8), income <Rs:30,000 (AOR=1.4, 95% C.I:0.54.0), being menopausal (AOR=5.1, 95% C.I:2.4-10.8), positive family history of breast/ovary/colon cancer in a first-degree relative (AOR=10.2, 95% C.I:3.7-28.6), passive smoking (AOR=3.2, 95% C.I:1.01-10.1), exposure to abdominal X-rays (AOR=3.4, 95% C.I:1.2-9.8), sub optimal consumption of red meat (AOR=3.9, 95% C.I: 1.4-11.2), sub-optimal consumption of vegetables (AOR=2.2, 95% C.I:1.0-4.6), and sub optimal consumption of dairy products (AOR=2.0, 95% C.I:1.03-4.0). Having irregular menstrual cycles ( AOR=0.4, 95% C.I:0.2-0.9), breast feeding $\geq$ 24months (AOR=0.1, 95% C.I:0.06-0.4), using OCP for $\geq$ 2years (AOR=0.1, 95% C.I: 0.03-0.3), history of LRT (AOR=0.2, 95% C.I:0.04-0.9) and optimal consumption of fruits (AOR=0.2, 95% C.I:0.1-0.5) were noted as statistically significant protective factors against epithelial ovarian cancer. The optimal cut-off level for the Sinhala version of modified ovarian cancer symptom index was 3 positive symptoms, indicating sensitivity of 72.7% (95% CI 60.9% -84.5%) and specificity of 76.8% (95% CI: 65.7% – 87.8%). Sensitivity of the tool to detect stage I ovarian cancer was 62.5%, whereas the sensitivity of the tool at stage IV was 85.7%. The direct costs for managing a patient with epithelial ovarian cancer increased with the stage of the disease (Stage IA or IB; Rs. 43,632.83, Stage IC; Rs 81,931.06, stage II or III or IV Rs. 114,013.10).

**Conclusions and recommendations:** Both modifiable and non-modifiable risk factors related to reproductive and genetics domains contribute to the epithelial ovarian cancers. Application of valid, reliable, low-cost tools to high-risk groups in order to detect ovarian cancers at early stages, in the primary care setting, is recommended until better biomarkers become available.