

# Can artificial intelligence, applied on ultrasound images, discriminate benign and malignant ovarian tumours, and thus be used in the triage of women with these lesions? An external international multicentre validation study by the Ovarian Tumour Machine Learning Collaboration (OMLC)

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<b>Registration date</b> 24/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 02/09/2024	<b>Condition category</b> Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Expert ultrasound examination has become the main imaging technique for assessing ovarian lesions. While the diagnostic accuracy is higher in experts than in less experienced doctors, there is a shortage of expert examiners. Every year approximately 10,000 ovarian surgical procedures are performed in Sweden. We believe that up to a quarter of these are unnecessary procedures that could be avoided if expert ultrasound assessment would be available. AI approaches have gained interest in several medical fields where experts visually assess images. Automated imaging AI tools have matched or even surpassed experts. Our own recent data show that artificial intelligence (AI), using deep neural networks (DNN), can discriminate between benign and malignant ovarian tumors with performance on par with ultrasound experts.

**Aim:** To externally validate our DNN models, and to compare the results to the assessment made by expert ultrasound examiners, in a large international multicentre setting.

### Who can participate?

Any secondary/tertiary gynecological/gyneoncological ultrasound referral centre using high-end ultrasound systems (GE Voluson E8, GE Voluson E10, Philips IU22, Philips EPIQ, or similar), that can provide at least 100 consecutive cases (50 benign and 50 malignant) with at least 3 good quality, representative ultrasound images per case.

### What does the study involve?

This study involves the validation and the comparison of machine learning models to human experts with regard to assessing ovarian tumours as benign or malignant.

What are the possible benefits and risks of participating?

None

Where is the study run from?

Karolinska Institutet (Sweden)

When is the study starting and how long is it expected to run for?

July 2020 to December 2020

Who is funding the study?

SLL: Innovations fonden, ALF-medicin (Sweden)

Who is the main contact?

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## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

## Study information

Scientific Title

External validation of the deep learning models Ovry-Dx1 and Ovry-Dx2, applied on ultrasound images, to discriminate benign and malignant ovarian tumours. An external international multicentre validation study by the Ovarian Tumour Machine Learning Collaboration (OMLC)

## **Acronym**

OMLC validation study

## **Study objectives**

Based on our preliminary findings we hypothesize that DNN models can discriminate between benign and malignant ovarian tumors with performance similar to ultrasound experts, and this performance generalizes to a large scale multicenter setting including images of varying quality. We anticipate that DNN models can be used in the triage of women with ovarian tumours, aiding and improving clinical decision making. Especially in the case of non-expert examiners, an autonomous AI clinical decision support tool is expected to result in higher detection of ovarian cancer, at a lower rate of false positives, and thus a more cost-effective utilization of healthcare resources and reduced morbidity among patients.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

Approved 10/11/2020, Swedish Ethical Review Authority (Etikprövningsmyndigheten, Box 2110, 750 02, Uppsala, Sweden; +46 10-475 08 00; [registrator@etikprovning.se](mailto:registrator@etikprovning.se)), ref: DNR 2020-04090

## **Study design**

Observational retrospective study

## **Primary study design**

Observational

## **Study type(s)**

Diagnostic

## **Health condition(s) or problem(s) studied**

Ovarian tumours

## **Interventions**

Observational study: Multi-centre (n=22) study, including at least 6,000 images from at least 2,000 cases (1,000 benign and 1,000 malignant) of adnexal lesions, with known histological outcome from surgery. Subjective classification of tumours prior to surgery; benign or malignant and the certainty in the assessment will be used for comparative analysis.

All cases will also undergo external review by 3 experts from other centres, evaluating tumours as benign or malignant based on the available images from each case. Images and questionnaires will be made available on a web-based platform.

## **Intervention Type**

Other

## **Primary outcome(s)**

Diagnostic performance of the previously developed deep learning models (Ovry-Dx1 and Ovry-Dx2) in discriminating benign and malignant lesions. These models were created by transfer learning on three pre-trained DNNs: VGG16, ResNet50 and MobileNet. Each model was trained, and the outputs calibrated using temperature scaling. An ensemble of the three models was then used to estimate the probability of malignancy based on all images from a given case. Using DNNs, tumours were classified as benign or malignant (Ovry-Dx1); or benign, inconclusive or malignant (Ovry-Dx2).

### **Key secondary outcome(s)**

Data collected from patient records:

1. Case ID
2. Subjective expert assessment prior to surgery
3. Classification of tumours (benign, borderline or malignant)
4. The certainty in the assessment (uncertain vs. certain)
5. Histological outcome (benign/malignant)
6. Specific histological diagnosis from surgery
7. Date of examination
8. Ultrasound system used

### **Completion date**

31/12/2022

## **Eligibility**

### **Key inclusion criteria**

1. Women with adnexal lesions undergoing structured ultrasound examination prior to surgery
2. At least 3 good quality, representative ultrasound images per case
3. Histological outcome from surgery available

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

All

### **Sex**

Female

### **Total final enrolment**

3657

### **Key exclusion criteria**

Does not meet inclusion criteria

### **Date of first enrolment**

31/07/2020

**Date of final enrolment**

30/04/2021

**Locations****Countries of recruitment**

Belgium

Czech Republic

Greece

Italy

Lithuania

Philippines

Poland

Spain

Sweden

**Study participating centre****Södersjukhuset**

Department of Obstetrics and Gynecology

Stockholm

Sweden

11883

**Study participating centre****European Institute of Oncology IRCCS**

Preventive Gynaecology Unit

Division of Gynaecology

Milan

Italy

20141

**Study participating centre****Charles University and General University Hospital**

Gynaecological Oncology Centre

Department of Obstetrics and Gynecology

First Faculty of Medicine

Prague

Czech Republic  
50005

**Study participating centre**

**Alexandra Hospital**

First Department of Obstetrics and Gynaecology

Athens

Greece

115 28

**Study participating centre**

**IRCCS "Burlo Garofolo"**

Institute for Maternal and Child Health

Trieste

Italy

34137

**Study participating centre**

**Biomedical and Clinical Sciences Institute L. Sacco**

Department of Obstetrics and Gynaecology

Milan

Italy

20157

**Study participating centre**

**Clinica Universidad de Navarra**

Department of Obstetrics and Gynaecology

Pamplona

Spain

31008

**Study participating centre**

**San Gerardo Hospital**

Clinic of Obstetrics and Gynaecology

Monza

Italy

20900

**Study participating centre**

**Policlinico Universitario Duilio Casula**  
Department of Obstetrics and Gynaecology  
Monserato  
Cagliari  
Italy  
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**Study participating centre**  
**S Orsola-Malpighi Hospital**  
Gynecology and Reproductive Medicine Unit  
Bologna  
Italy  
40138

**Study participating centre**  
**School of Health Sciences in Katowice**  
Department of Perinatology and Oncological Gynaecology  
Katowice  
Poland  
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**Study participating centre**  
**Skåne University Hospital Lund**  
Department of Obstetrics and Gynaecology  
Lund  
Sweden  
22185

**Study participating centre**  
**Kaunas Medical University Hospital**  
Department of Obstetrics and Gynecology  
Vilnius  
Lithuania  
44307

**Study participating centre**  
**Third Faculty of Medicine, Charles University**  
Institute for the Care of Mother and Child  
Prague  
Czech Republic  
100 00

**Study participating centre**  
**Hospital Universitario Dexeus**  
Department of Obstetrics, Gynecology, and Reproduction  
Barcelona  
Spain  
08028

**Study participating centre**  
**Medical University of Lublin**  
First Department of Gynaecological Oncology and Gynaecology  
Lublin  
Poland  
20-059

**Study participating centre**  
**St Luke's Medical Centre**  
Department of Obstetrics and Gynecology  
Manila  
Philippines  
1000

**Study participating centre**  
**Clinica Ostetrica e Ginecologica, Ospedale "G.Salesi"**  
Via F.Corridoni 11  
Ancona  
Italy  
60123

**Study participating centre**  
**Mater Olbia Hospital, Gynaecology and Breast care centre**  
Strada Statale 125 Orientale  
Olbia  
Italy  
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**Study participating centre**  
**Fondazione Poliambulanza**  
Via Bissolati 57

Brescia  
Italy  
25124

## Sponsor information

### Organisation

Stockholm County Council

### ROR

<https://ror.org/02zrae794>

### Organisation

Stockholm County Council, ALF medicine

## Funder(s)

### Funder type

Government

### Funder Name

SLL: Innovations fonden, ALF-medicin

## Results and Publications

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.

### IPD sharing plan summary

Stored in repository

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Other publications</a>	development and testing ultrasound image analysis using deep neural networks	03/11/2020	02/09/2024	Yes	No
<a href="#">Protocol file</a>	version V4		11/12/2020	No	No