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)

Submission date	Recruitment status No longer recruiting	[X] Prospectively registered			
16/07/2020		[X] Protocol			
Registration date	Overall study status	Statistical analysis plan			
24/07/2020 Last Edited	Completed Condition category	Results			
		[] Individual participant data			
02/09/2024	Cancer	[] 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. Al 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 discriminating 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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Type(s)

Public

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

Nil known

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), 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 form 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 form surgery available

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

ΔII

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 Monserrato Cagliari Italy 09042

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 40-055

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 07026

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-publically available repository.

IPD sharing plan summary

Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient- facing?
Other publications	development and testing ultrasound image analysis using deep neural networks	03/11 /2020	02/09 /2024	Yes	No
Participant information sheet	Participant information sheet	11/11 /2025	11/11 /2025	No	Yes
Protocol file	version V4		11/12 /2020	No	No