

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 16/07/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/07/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/08/2024	Condition category Cancer	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English Summary

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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Type(s)

Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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 hypothesis

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

Secondary study design

Cross sectional study

Study setting(s)

Other

Study type(s)

Diagnostic

Participant information sheet

No participant information sheet available

Condition

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 measure

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).

Secondary outcome measures

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

Overall study start date

16/07/2020

Overall study end date

31/12/2022

Eligibility

Participant 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

Age group

All

Sex

Female

Target number of participants

at least 1,600

Total final enrolment

3657

Participant exclusion criteria

Does not meet inclusion criteria

Recruitment start date

31/07/2020

Recruitment end date

30/04/2021

Locations**Countries of recruitment**

Belgium

Czech Republic

Greece

Italy

Lithuania

Philippines

Poland

Spain

Sweden

Study participating centre**Södersjukhuset**

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Study participating centre
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Funder(s)

Funder type

Government

Funder Name

SLL: Innovations fonden, ALF-medicin

Results and Publications

Publication and dissemination plan

Planned publication in high-impact peer-reviewed journal within 1-1.5 years.
OMLC collaborators will be offered to use the image data set to validate their own AI-models.

Intention to publish date

31/12/2023

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?
Protocol file	version V4		11/12/2020	No	No