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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

Registration date
24/07/2020

Last Edited
02/09/2024

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Cancer

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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 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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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 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

Secondary study design
Cross sectional study

Study setting(s)
Other

Study type(s)
Diagnostic

Participant information sheet
No participant information sheet available

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 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 form surgery
7. Date of examination
8. Ultrasound system used

Overall study start date
16/07/2020

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

Age group
All

Sex
Female

Target number of participants
at least 1,600

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
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor type
Government

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https://forskningsstod.vmi.se/Ansokan/start.asp

ROR
https://ror.org/02zrae794

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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-revewed 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-publically 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

Other publications	development and testing ultrasound image analysis using deep neural networks	03/11/2020	02/09/2024	Yes	No