Application of Artificial Intelligence for Automatic Evaluation of Routine Whole Slide H&E Images for Presence of Malignancy

Anthony Magliocco MD\textsuperscript{1,3}, Eliron Amir\textsuperscript{2}, Lotan Chorev\textsuperscript{2},

\textsuperscript{1}Protean BioDiagnostics Inc, \textsuperscript{2}Nucleai Ltd

Pathology Informatics Symposium 7 May 2019
Disclosures – A. Magliocco

- Protean BioDiagnostics - Founder and CEO, Shares, Board of Directors

Other: Merck, BMS, Genentech, Roche, Ventana, Proscia, Leica, Illumina
Protean Biodiagnostics

Re-imagining the Future of Pathology
AI Powered Revolution in Medical Diagnostics
Introduction - Opportunity for AI in Pathology

- Routine screening pathology in colon, breast and prostate is common and not normally challenging to pathologists

- However, it can be tedious and errors can be made due to pathologist inattention or missing areas of slides

- Errors in screening pathology can have significant consequences for patients

- There is prediction of increasing shortages of pathologists due to changing demographics of patients, pathologist retirements, and global shortages of pathologists

- Digital pathology with artificial intelligence could potentially assist practicing pathologists with efficiency and quality of routine tissue screening analysis
Targeted Tissues for Analysis

- Colon polyps and screening colonoscopic biopsy
- Breast biopsy of mammographic lesions
- Prostate needle core biopsies

Initially use whole slide images of H and E stained slides scanned at 20x
Convolutional Neural Network Architecture
Classification Algorithm – High Level Design

The algorithm is based on 3 main sub-components:

1. Tissue Segmentation Algorithm
2. Tile Classification Algorithm
3. Slide Level Decision Algorithm

This was performed for several hundred slides
These slides were annotated by pathologists, and the results compared
Method

- Nucleai Ltd. The framework was trained to distinguish between benign and malignant/dysplastic cases

- Whole slide images (WSI) of routine H&E samples slides from 3 indications:
  - 2512 Colonic polyps
  - 2038 Breast core biopsies
  - 3007 Prostate core biopsies

- A retrospective analysis of a test sample sets taken from a laboratory clinical archive containing 200 WSI from each indication

- All cases were evaluated by multiple (n=2) pathologists
## Results

<table>
<thead>
<tr>
<th></th>
<th>Overall Concordance</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Colon Polyps</td>
<td>98.5% (197/200)</td>
<td>98.8% (87/88)</td>
<td>98.2% (110/112)</td>
</tr>
<tr>
<td>Breast Core Biopsies</td>
<td>97% (194/200)</td>
<td>98.03% (100/102)</td>
<td>95.9% (94/98)</td>
</tr>
<tr>
<td>Prostate Core Biopsies</td>
<td>97% (194/200)</td>
<td>97.01% (98/101)</td>
<td>96.9 (95/98)</td>
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Breast Core Biopsy

[Image: A histological section showing the classification of areas as Benign or Malignant.]
Prostate Core Biopsy

- Benign
- Malignant
Conclusions

- The findings demonstrate the capability of the investigated GPHAI to successfully detect malignancy in various tissue types and indications.
- This shows the potential of a novel artificial intelligence system in assisting in clinical diagnostic workflows including triaging cases or quality control.
Future Directions

- Development of a product to assist pathology departments with rapid review of tissues to support quality assurance and quality improvement programs
- Current algorithm is designed to be supervised by human pathologist
- Future algorithm may operate independently of human pathologist
- Future applications may focus on development grading tools, prognostic and predictive marker development
Nucleai Products

Digital Resident
Increase efficiency by creating initial reports

Digital Quality Assurance
Reduce misdiagnosis by comparing manual and automated reports
Data Sources
- 25 Million Slides

Multidisciplinary Team
- Leading pathologists
- Expert AI researchers
- Experienced medical product team

Add support for a new indication every 3 months