Initial Canadian experience using a telerobotic ultrasound system to perform adult abdominal examinations

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Disclosure

- In this exhibit we discuss the investigational use of the MELODY System.

- The MELODY System is not currently an approved medical device by Health Canada or the U.S. Food and Drug Administration.

- The authors have no conflict of interest.
Introduction

- Sonography offers many advantages for medical imaging; however, a lack of trained sonographers in remote communities limits access to sonography for many patients.
- In this study, we trial a telerobotic ultrasound system consisting of a robotic arm (MELODY System, Société AdEchoTech, Naveil, France), an ultrasound system (SonixTablet, BK Ultrasound, Richmond, Canada), and a videoconferencing system (TE30 All-in-One, HD Videoconferencing Endpoint, Huawei Technologies, Shenzhen, China).
- By manipulating a mock probe at a distant site, a sonographer can control fine movements (rotating, rocking and tilting) of the transducer in real-time via movement of a robotic arm, as well control all ultrasound settings.
- We assess the feasibility of this telerobotic ultrasound system to perform complete abdominal examinations, ability of the system to generate images of diagnostic quality, and acceptability of the system to patients and sonographers.
Methods

Patient-site

- A sonography room at an imaging clinic (“patient-site”) was equipped with the ultrasound system and robotic arm.

Sonographer-site

- At our academic health sciences centre 2.75 km away (“sonographer-site”), a mock probe and touchscreen monitor which displayed the ultrasound system interface enabled the sonographer to control all settings and fine-movements of the transducer.
- The videoconferencing system allowed for communication between the sonographer and the patient and patient-site assistant, enabling the patient-site assistant to adjust pressure and gross placement of the robotic arm based on instructions from the sonographer.
- A non-dedicated internet connection connected the two sites.
Methods

Study Cohort

- Our institutional research ethics board approved this study.
- Written consent was obtained from all participants.
- 19 patients, scheduled for routine abdominal sonography examinations at an imaging clinic (Saskatoon Medical Imaging), were prospectively recruited in December 2015.
- One participant was excluded from data analysis as the telerobotic abdominal imaging protocol was not correctly followed.
Methods

Sonographer Training and Scanning Protocol

- Four sonographers received a 90 minute training session on use of the SonixTablet and MELODY System prior to commencement of the study.
- All patients included in the study were initially scanned using a conventional ultrasound system (EPIQ 5, Philips or LOGIQ E9, GE Healthcare) according to a standardized abdominal imaging protocol.
- Patients were then scanned by a sonographer with similar experience and qualifications using the telerobotic system and the same abdominal imaging protocol, blinded to the findings of the conventional examination.
- Each of the sonographers performed two to six telerobotic examinations.

Patient, Sonographer and Patient-Site Assistant Assessment

- Following each telerobotic examination, sonographers, patient-site assistants, and patients were presented with a series of Likert items to assess acceptability of the system.
Methods

Image Assessment

- Images from the conventional and telerobotic examinations were read independently from each other using a standardized form broadly based on Stenman et al. [1] and Stenman et al. [2].
- The reader also assessed whether each organ was sufficiently visualized based on the acquired images.
- Hepatorenal indices using telerobotic and conventional images were calculated as previously described [3].

Statistical Analysis

- Descriptive statistics were determined. Measurements of structures and hepatorenal indices from conventional and telerobotic exams were compared using a paired sample t-test and Wilcoxon signed rank test. A significance threshold of p<0.05 was used. Analysis was performed using SPSS, version 23 (IBM, Chicago, Ill).

### Results

*Number of organs/structures sufficiently visualized using robotic vs. conventional sonography*

<table>
<thead>
<tr>
<th>Organ / structure</th>
<th>Robotic sonography</th>
<th>Conventional sonography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Liver</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Gall bladder</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>Bile duct</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Pancreas</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>Spleen</td>
<td>15</td>
<td>17</td>
</tr>
<tr>
<td>Pancreas</td>
<td>14</td>
<td>16</td>
</tr>
<tr>
<td>Right kidney</td>
<td>17</td>
<td>17</td>
</tr>
<tr>
<td>Left kidney</td>
<td>15</td>
<td>17</td>
</tr>
</tbody>
</table>
Results

**Imaging Findings**

- Five pathological findings were identified on both examinations (two renal cysts, enlarged common bile duct, hepatic cyst, and hyperechoic focus in the spleen)
- Three findings were identified only using conventional sonography (a hepatic cyst, focal fatty sparing of the liver, and renal cyst)
- Two findings were identified only using telerobotic sonography (a renal cyst and gallbladder wall polyp).

Transverse view of a 1.8 cm left renal cyst in a 45-year-old female using the (a) EPIQ 5 (conventional) ultrasound system and (b) SonixTablet/MELODY (telerobotic) system.
### Results

#### Image Measurements

<table>
<thead>
<tr>
<th>Measurement</th>
<th>Telerobotic measurement, (sd)</th>
<th>Conventional measurement, (sd)</th>
<th>n*</th>
<th>Mean difference (sd)†</th>
<th>p-value‡</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aorta diameter, proximal, mm</td>
<td>16.61 (2.94)</td>
<td>15.40 (3.31)</td>
<td>15</td>
<td>1.48 (4.12)</td>
<td>0.19 (0.05)</td>
</tr>
<tr>
<td>Aorta diameter, distal, mm</td>
<td>15.64 (3.54)</td>
<td>12.02 (2.22)</td>
<td>13</td>
<td>3.45 (2.93)</td>
<td>0.001 (0.005)</td>
</tr>
<tr>
<td>Common bile duct, mm</td>
<td>4.85 (3.23)</td>
<td>3.90 (2.92)</td>
<td>16</td>
<td>1.15 (1.12)</td>
<td>0.001 (0.004)</td>
</tr>
<tr>
<td>Spleen, cm</td>
<td>9.50 (1.45)</td>
<td>9.84 (1.62)</td>
<td>17</td>
<td>-0.32 (0.97)</td>
<td>0.19 (0.08)</td>
</tr>
<tr>
<td>Liver, cm</td>
<td>13.2 (2.30)</td>
<td>12.37 (2.04)</td>
<td>16</td>
<td>0.51 (2.14)</td>
<td>0.36 (0.44)</td>
</tr>
<tr>
<td>Right kidney, sagittal length, cm</td>
<td>10.4 (0.97)</td>
<td>10.95 (0.84)</td>
<td>18</td>
<td>-0.51 (0.83)</td>
<td>0.02 (0.02)</td>
</tr>
<tr>
<td>Left kidney, sagittal length, cm</td>
<td>10.3 (1.02)</td>
<td>10.91 (0.71)</td>
<td>16</td>
<td>-0.58 (0.82)</td>
<td>0.01 (0.02)</td>
</tr>
<tr>
<td>Hepatorenal index</td>
<td>1.18 (0.24)</td>
<td>1.69 (0.52)</td>
<td>15</td>
<td>-0.50 (0.57)</td>
<td>0.004 (0.006)</td>
</tr>
</tbody>
</table>

sd, standard deviation; *number of paired robotic-conventional assessments; †Robotic measurement minus conventional measurement; ‡paired t-test (Wilcoxon signed rank test)
Results

*Image Measurements – Hepatorenal indices*

- There was significant discrepancy between hepatorenal indices calculated from images obtained using the telerobotic system as compared to the conventional system (see Table on previous slide).
- Overall, images obtained using the SonixTablet appeared more hyperechoic as compared to those obtained using the EPIQ5 and LOGIQ E9 ultrasound systems.

Regions of interest used to calculate the hepatorenal index for a 41-year-old female based on images obtained using the (a) EPIQ 5 ultrasound system (conventional) and (b) SonixTablet/MELODY system (telerobotic).
Results

Duration of Scanning

- The mean duration of telerobotic examinations was 39.9 minutes (range 27 to 58 minutes), compared to 15.7 minutes (range 7 to 25 minutes) for conventional examinations.
- The duration of each telerobotic examination decreased an average of 21% from each sonographer’s first examination to last examination as they gained additional experience operating the telerobotic system.
## Results

### Patient Assessment

<table>
<thead>
<tr>
<th>Statement</th>
<th>Strongly agree, n (%)</th>
<th>Somewhat agree, n (%)</th>
<th>Neither agree nor disagree, n (%)</th>
<th>Somewhat disagree, n (%)</th>
<th>Strongly disagree, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) If in the future I required another ultrasound study and sonography was not available in my community, I would be willing to have a robotic telesonography scan</td>
<td>16 (89)</td>
<td>2 (11)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(2) I felt comfortable communicating with the remote sonographer using the video conferencing system</td>
<td>14 (78)</td>
<td>4 (22)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(3) I felt comfortable knowing that a person in a different room was controlling the ultrasound probe</td>
<td>14 (78)</td>
<td>2 (11)</td>
<td>2 (11)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(4) I felt less pressure on my abdomen during the robotic telesonography study than I did during the conventional study</td>
<td>7 (39)</td>
<td>6 (33)</td>
<td>2 (11)</td>
<td>3 (17)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
# Results

## Sonographer and Patient-Site Assistant Assessment

<table>
<thead>
<tr>
<th></th>
<th>Strongly agree, n (%)</th>
<th>Somewhat agree, n (%)</th>
<th>Neither agree nor disagree, n (%)</th>
<th>Somewhat disagree, n (%)</th>
<th>Strongly disagree, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sonographers</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) The audio was of sufficient quality to allow me to adequately communicate with the patient-site assistant</td>
<td>17 (94)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(2) The patient-site assistant and I were able to effectively communicate regarding probe or patient positioning</td>
<td>14 (78)</td>
<td>3 (17)</td>
<td>0 (0)</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(3) Manipulating the remote ultrasound probe resulted in less physical strain than scanning a similar patient using conventional sonography</td>
<td>4 (22)</td>
<td>7 (39)</td>
<td>3 (17)</td>
<td>3 (17)</td>
<td>1 (6)</td>
</tr>
<tr>
<td><strong>Patient-site assistant</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(1) The audio was of sufficient quality to allow me to adequately communicate with the remote sonographer</td>
<td>17 (94)</td>
<td>1 (6)</td>
<td>0 (0)</td>
<td>0 (0)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(2) The sonographer and I were able to effectively communicate regarding probe or patient positioning</td>
<td>16 (89)</td>
<td>0 (0)</td>
<td>1 (6)</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>(3) Holding the MELODY system caused moderate or severe physical strain (i.e. I felt tired or sore as a result of holding the MELODY system)</td>
<td>1 (6)</td>
<td>14 (78)</td>
<td>2 (11)</td>
<td>1 (6)</td>
<td>0 (0)</td>
</tr>
</tbody>
</table>
Discussion

- Visualization of abdominal organs was generally sufficient, though due to either limited range of motion of the probe or the quality of the ultrasound processing system, some small findings were not identified using the telerobotic system.
  - However, there were also lesions unequivocally identified using the telerobotic system which were not identified on the conventional examination, emphasizing the user-dependency of sonography.

- Measurements of structures using conventional and telerobotic sonography were generally comparable; however, significant differences in measurements of the distal aorta, common bile duct, kidney, and hepatorenal indices were noted.

- Duration of examinations was longer for telerobotic examinations, though the duration of exams continued to decrease throughout the study period.

- Patients generally accepted the technology and would be willing to undergo another telerobotic examination.

- Sonographers and the patient-site assistant readily developed communication strategies with each other and for almost all examinations reported they were able to effectively communicate regarding probe or patient positioning.
Strengths and Limitations

**Strengths**
- Patients were recruited prospectively
- Sonographers were blinded to findings from the corresponding examination
- Standardized imaging protocol was used for all examinations
- All examinations were reported using a standardized reporting form

**Limitations**
- Differences in diagnostic performance cannot solely be attributed to the method of scanning (telerobotic versus conventional) since ultrasound systems of differing quality (SonixTablet for telerobotic examinations and EPIQ 5 or LOGIQ E9 for conventional examinations) were used for each type of examination
- Variation in scanning technique and thus diagnostic findings may have been introduced as telerobotic and conventional scanning was conducted by different sonographers
- A user-dependent modality—sonography—was used as the control for telerobotic examinations
Future Directions

- We plan on developing a remote sonography clinic utilizing a telerobotic ultrasound system placed in a remote community, enabling patients to access sonography in their home community and bridging the differential in care for remote populations.
- We envision a network of telerobotic ultrasound systems located in remote, low-volume centres to be serviced by sonographers at central telerobotic sonography clinics.
- Remote ultrasound clinics have the potential to provide:
  a) Routine examinations for patients in low-volume or underserviced communities;
  b) After-hours sonography for emergent cases, possibly avoiding transport to a larger centre for imaging or calling in a sonographer for a single study; and/or
  c) Access to subspecialized sonography which would otherwise be unfeasible to offer in small to mid-sized centres with low patient volume.
Conclusions

- The telerobotic ultrasound system assessed is feasible for performing abdominal ultrasound examinations at a distant location with minimal training and set-up requirements and a moderate learning curve.

- Telerobotic sonography may open up the possibility of remote ultrasound clinics for communities which lack skilled sonographers and radiologists, thereby improving access to care.
Acknowledgements

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