Sensitivity of Radiofrequency Devices for Detection of Retained Surgical Sponges in Morbidly Obese Subjects

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Significance

• Retained surgical items (e.g. sponges, needles, and instruments)
  – Were the most frequently reported sentinel events in 2011\textsuperscript{1}
  – Occur in an estimated 1:5500 surgeries.\textsuperscript{2}
  – Result in negative patient outcomes
    • reoperation (69-83\%)\textsuperscript{3, 4}
    • readmission/prolonged hospital stay (30-59\%)\textsuperscript{3, 4}
    • infection/sepsis (43\%)\textsuperscript{3}
    • fistulas/ bowel obstructions (15\%)\textsuperscript{3}
    • visceral perforation (7\%)\textsuperscript{3}
    • death (2\%).\textsuperscript{3}
Surgical Counts

• The sensitivity of surgical counts is 77%\(^5\)
• Healthcare Failure Mode & Effect Analysis\(^6\)
  – 43 high risk failures during management of surgical sponges that require control
  – Causes are difficult to control
    • Distraction
    • Multitasking
    • Not following procedure
    • Time pressure
Intraoperative Radiographs

- Often used with the surgical count is reported as being incorrect
- Expose the patient & personnel to radiation
- Difficult to read in obese patients
- 67% sensitive\(^2\)
- Add time to surgical procedure
- Cost $600-$1000
RF Technology

• In a previous study using the RF wand\textsuperscript{7}
  – 210 subjects
    • 101 morbidly obese
  – Results:
    • Sensitivity 100%
    • Specificity 100%
    • Positive predictive value 100%
    • Negative predictive value 100%
Purpose

• To evaluate the sensitivity and specificity of the detection of surgical sponges through the torso of non-morbidly obese and morbidly obese subjects using a radiofrequency mattress
Design & Sample

• A prospective, crossover, and observer blinded study design was used.
• Subjects served as their own controls.
• Sample
  – N = 203
  – Adult patients and visitors in the bariatric clinic
  – Able to read & write English & give consent
  – Exclusion criteria: infection isolation, pregnant, unable to lie in a supine position, electronic medical device
Methods: Phase I

- Evaluated mattress scan
- N = 203
- Subject supine
- 4 surgical sponges were sequentially placed on top of the subject’s torso approximating abdominal quadrants.
- Mattress scanned torso
Methods: Phase 2

- Evaluated scanning with mattress vs. wand
- Subset of 118 subjects
- Mattress scanned
- Scanned with wand
  - Sponge behind torso, wand over torso
<table>
<thead>
<tr>
<th>Demographics of Sample (N=203)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
</tr>
<tr>
<td><strong>Race</strong></td>
</tr>
</tbody>
</table>
## Body Habitus of Subjects (N=203)

<table>
<thead>
<tr>
<th></th>
<th>Median</th>
<th>Range</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>167.5 cm</td>
<td>145.0 – 200.5 cm</td>
<td>9.12 cm</td>
</tr>
<tr>
<td>Abdominal Height</td>
<td>30.5 cm</td>
<td>16.5 – 50.0 cm</td>
<td>5.34 cm</td>
</tr>
<tr>
<td>Weight</td>
<td>121.9 kg</td>
<td>57.0 – 251.1 kg</td>
<td>37.3 kg</td>
</tr>
</tbody>
</table>
Body Mass Index of Subjects

N=203

BMI

# of subjects

20.0 - 29.9  | 30.0 - 39.9  | 40.0 - 49.9  | 50.0 - 59.9  | 60.0 - 69.9  | 70.0 - 79.9

20  | 54  | 74  | 36  | 14  | 5
## Detection of Sponges with RF Mattress

<table>
<thead>
<tr>
<th></th>
<th>Non-morbidly Obese Subjects (n=74)</th>
<th>Morbidly Obese Subjects (n=129)</th>
<th>All Subjects (N=203)</th>
</tr>
</thead>
<tbody>
<tr>
<td># readings</td>
<td>296</td>
<td>516</td>
<td>812</td>
</tr>
<tr>
<td>True positive readings</td>
<td>228</td>
<td>378</td>
<td>606</td>
</tr>
<tr>
<td>False positive readings</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>True negative readings</td>
<td>68</td>
<td>126</td>
<td>194</td>
</tr>
<tr>
<td>False negative readings</td>
<td>0</td>
<td>12</td>
<td>12</td>
</tr>
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</table>
## Detection of Sponges with RF Mattress

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</thead>
<tbody>
<tr>
<td><strong>Sensitivity</strong></td>
<td>100% (98.3-100%)**</td>
<td>96.9% (94.7-98.2%)</td>
<td>98.1% (96.6-98.9%)</td>
</tr>
<tr>
<td><strong>Specificity</strong></td>
<td>100% (94.7-100%)</td>
<td>100% (97.0-100%)</td>
<td>100% (98.1-100%)</td>
</tr>
<tr>
<td>Positive</td>
<td>100% (98.3-100%)</td>
<td>100% (CI=99.0-100%)</td>
<td>100% (99.4-100%)</td>
</tr>
<tr>
<td>Negative</td>
<td>100% (94.7-100%)</td>
<td>91.3% (85.4-95%)</td>
<td>94.2% (90.1-96.6%)</td>
</tr>
</tbody>
</table>

*95% CI
Comparison of Readings of the RF Mat & Wand in the Same Subjects (N=117)

<table>
<thead>
<tr>
<th></th>
<th>Non-morbidly Obese Subjects (n=32)</th>
<th>Morbidly Obese Subjects (n=85)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mat</td>
<td>Wand</td>
</tr>
<tr>
<td># readings</td>
<td>128</td>
<td>128</td>
</tr>
<tr>
<td>Sensitivity*</td>
<td>100% (96.0-100%)</td>
<td>100% (96.0-100%)</td>
</tr>
<tr>
<td>Specificity*</td>
<td>100% (93.1-100%)</td>
<td>100% (93.1-100%)</td>
</tr>
<tr>
<td>Positive predictive value*</td>
<td>100% (96.0-100%)</td>
<td>100% (96.0-100%)</td>
</tr>
<tr>
<td>Negative predictive value*</td>
<td>100% (90.1-100%)</td>
<td>100% (90.1-100%)</td>
</tr>
</tbody>
</table>

*95% CI
Conclusions

• Both the RF wand and mattress are more sensitive than the surgical count or intraoperative radiographs

• When using RF technology, the wand should be used for morbidly obese patients
References


