Comparing MammaPrint and BluePrint results between core needle biopsy and surgical resection breast cancer specimens

Joseph McKelley1, Jennifer Wei2, Brian Hoxeng3, Andrea Menicucci4, Erin Yoder3, Shiyu Wang1, William Audeh1

1. Medical and Clinical Affairs, Agenda, Inc., Irvine, CA; 2. Agenda Laboratory Services, Agenda, Inc., Irvine, CA

San Antonio Breast Cancer Symposium™ - December 8-11, 2020

Background

Pre-operative/neoadjuvant treatment utilization in early-stage breast cancer has been increasing, particularly during the COVID-19 pandemic. With goals of minimizing potential exposure to SARS-COV-2, as well as resource rationing, physicians are urged to triage breast cancer patients by identifying those who require urgent surgical care vs. those who may delay surgical treatment.1 Accurate risk assessment is an integral component of this triaging process, and recent guidelines have recommended that genomic testing on diagnostic core needle biopsy (CNB) samples be used to assist with the identification of patients with low risk tumor biology who may be candidates for surgical delay.1

Methods

Routine diagnostic samples submitted to Agenda, Inc. (Irvine, CA) between February 2017 and May 2020 for MP and BP testing were processed according to standard FFPE microarray procedures. MP was used to stratify samples into Low (LR) and High Risk (HR). An additional subset analysis of the LR group was performed to identify patients with an Ultralow Risk (UL) result (MPI > +0.355). Of the 39,287 samples included in this analysis, 35% were CNB and 65% were SR. BluePrint Basal, Luminal, and HER2-Type distributions were 10%, 86%, and 4%, respectively for CNB samples and 5%, 94%, and 1%, respectively for SR samples.

Of the 39,287 samples included in this analysis, 35% were CNB and 65% were SR. BluePrint Basal, Luminal, and HER2-Type distributions were 10%, 86%, and 4%, respectively for CNB samples and 5%, 94%, and 1%, respectively for SR samples. Overall, MammaPrint risk category distributions were similar between samples tested from CNB vs. SR (Table 1). When including all BluePrint Subtypes, the distribution of MP High Risk in CNB is marginally higher compared to SR (49% vs 43%), attributed to the higher frequency of more biologically aggressive tumors (HER2 & basal) also observed with CNB. Pre-operative testing on CNB is typically indicative of more clinically high-risk tumors from patients who are candidates for neoadjuvant therapy.

Within BluePrint defined Luminal-Type tumors (Table 2), the frequency of UL, LR, and HR results were 18%, 58%, and 42% for CNB, and 16%, 60%, and 40% for SR, respectively. MammaPrint Index distributions were highly comparable between specimen types (Figure 1). Average turn-around time between CNB and SR were 4.52 and 4.55 days, respectively. For specimens that met the minimum 30% invasive tumor threshold, successful testing rates for CNB and SR were 97.5% and 98.4%, respectively (Table 3).

Conclusion

MammaPrint and BluePrint testing were successfully performed on both CNB and SR samples in approximately 98% of all eligible specimens with rapid TAT allowing for timely pre-operative decision-making. Among Luminal-Type tumors, the frequency of each MP risk group as well as the distribution pattern of MP Index were essentially identical between CNB and SR, indicating comparable performance regardless of specimen type. Increased utilization of genomic testing on CNB to guide pre-operative management (accelerated by recent COVID-19 pandemic guidelines), highlight the importance of reliable assay performance across specimen types. With no observed differences in MPI distribution, TAT or success rate between CNB and SR specimens, use of MammaPrint and BluePrint on CNB is reliable and could be a useful tool to pre-operatively triage BC patients.

Comparing MammaPrint and BluePrint results between core needle biopsy and surgical resection breast cancer specimens

Joseph McKelley1, Jennifer Wei2, Brian Hoxeng3, Andrea Menicucci4, Erin Yoder3, Shiyu Wang1, William Audeh1

1. Medical and Clinical Affairs, Agenda, Inc., Irvine, CA; 2. Agenda Laboratory Services, Agenda, Inc., Irvine, CA

San Antonio Breast Cancer Symposium™ - December 8-11, 2020

Background

Pre-operative/neoadjuvant treatment utilization in early-stage breast cancer has been increasing, particularly during the COVID-19 pandemic. With goals of minimizing potential exposure to SARS-COV-2, as well as resource rationing, physicians are urged to triage breast cancer patients by identifying those who require urgent surgical care vs. those who may delay surgical treatment.1 Accurate risk assessment is an integral component of this triaging process, and recent guidelines have recommended that genomic testing on diagnostic core needle biopsy (CNB) samples be used to assist with the identification of patients with low risk tumor biology who may be candidates for surgical delay.1

Methods

Routine diagnostic samples submitted to Agenda, Inc. (Irvine, CA) between February 2017 and May 2020 for MP and BP testing were processed according to standard FFPE microarray procedures. MP was used to stratify samples into Low (LR) and High Risk (HR). An additional subset analysis of the LR group was performed to identify patients with an Ultralow Risk (UL) result (MPI > +0.355). Of the 39,287 samples included in this analysis, 35% were CNB and 65% were SR. BluePrint Basal, Luminal, and HER2-Type distributions were 10%, 86%, and 4%, respectively for CNB samples and 5%, 94%, and 1%, respectively for SR samples.

Most of the 39,287 samples included in this analysis, 35% were CNB and 65% were SR. BluePrint Basal, Luminal, and HER2-Type distributions were 10%, 86%, and 4%, respectively for CNB samples and 5%, 94%, and 1%, respectively for SR samples.

Overall, MammaPrint risk category distributions were similar between samples tested from CNB vs. SR (Table 1). When including all BluePrint Subtypes, the distribution of MP High Risk in CNB is marginally higher compared to SR (49% vs 43%), attributed to the higher frequency of more biologically aggressive tumors (HER2 & basal) also observed with CNB. Pre-operative testing on CNB is typically indicative of more clinically high-risk tumors from patients who are candidates for neoadjuvant therapy.

Within BluePrint defined Luminal-Type tumors (Table 2), the frequency of UL, LR, and HR results were 18%, 58%, and 42% for CNB, and 16%, 60%, and 40% for SR, respectively. MammaPrint Index distributions were highly comparable between specimen types (Figure 1). Average turn-around time between CNB and SR were 4.52 and 4.55 days, respectively. For specimens that met the minimum 30% invasive tumor threshold, successful testing rates for CNB and SR were 97.5% and 98.4%, respectively (Table 3).

Conclusion

MammaPrint and BluePrint testing were successfully performed on both CNB and SR samples in approximately 98% of all eligible specimens with rapid TAT allowing for timely pre-operative decision-making. Among Luminal-Type tumors, the frequency of each MP risk group as well as the distribution pattern of MP Index were essentially identical between CNB and SR, indicating comparable performance regardless of specimen type. Increased utilization of genomic testing on CNB to guide pre-operative management (accelerated by recent COVID-19 pandemic guidelines), highlight the importance of reliable assay performance across specimen types. With no observed differences in MPI distribution, TAT or success rate between CNB and SR specimens, use of MammaPrint and BluePrint on CNB is reliable and could be a useful tool to pre-operatively triage BC patients.

Results

Table 1: All BluePrint Subtypes

<table>
<thead>
<tr>
<th>Subtype</th>
<th>CNB (n) (%)</th>
<th>SR (n) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total CNB</td>
<td>13,603 35%</td>
<td>25,684 65%</td>
</tr>
<tr>
<td>CNB UltraLow*</td>
<td>2,175 16%</td>
<td>3,898 15%</td>
</tr>
<tr>
<td>CNB Low Risk</td>
<td>6,900 51%</td>
<td>14,656 57%</td>
</tr>
<tr>
<td>CNB High Risk</td>
<td>6,703 49%</td>
<td>11,028 43%</td>
</tr>
</tbody>
</table>

*Ultralow results are a subset of Low Risk

Table 2: BluePrint Luminal-Type

<table>
<thead>
<tr>
<th>Subtype</th>
<th>CNB (n) (%)</th>
<th>SR (n) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Luminal-type CNB</td>
<td>10,057 38%</td>
<td>16,311 62%</td>
</tr>
<tr>
<td>CNB UltraLow*</td>
<td>1,824 18%</td>
<td>2,588 16%</td>
</tr>
<tr>
<td>CNB Low Risk</td>
<td>5,785 58%</td>
<td>9,771 60%</td>
</tr>
<tr>
<td>CNB High Risk</td>
<td>4,272 42%</td>
<td>6,540 40%</td>
</tr>
</tbody>
</table>

*Ultralow results are a subset of Low Risk

Table 3: Logistics Metrics

<table>
<thead>
<tr>
<th>Subtype</th>
<th>CNB (n) (%)</th>
<th>SR (n) (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Success %</td>
<td>97.5%</td>
<td>98.4%</td>
</tr>
<tr>
<td>Avg TAT</td>
<td>4.52 days</td>
<td>4.55 days</td>
</tr>
</tbody>
</table>

*Definitions: Turnaround Time (TAT) is calculated from the time a specimen is received at the laboratory until the result is available. Success Excludes test failures due to insufficient RNA yield and/or suboptimal RNA quality, and evaluates the total number of specimens that have met the prerequisite 30% minimum invasive tumor requirement that have a valid result.

Figure 1: CNB vs SR: MammaPrint Index (MPI) Result Distribution

MPI distribution between CNB and SR samples were highly comparable amongst BluePrint Luminal-Type classified samples.

References

3. ClinicalTrials.gov ID: NCT01042379
4. ClinicalTrials.gov ID: NCT01479101
5. ClinicalTrials.gov ID: NCT01479101
6. ClinicalTrials.gov ID: NCT01479101

This presentation is the intellectual property of the authors/presenter. Please contact them at joe.mckelley@agendia.com for permission to reprint and/or distribute.

Poster #PS6-19