PRIMARY TREATMENT OF EARLY BREAST CANCER
ST. GALLEN 2017

ESCALATING AND DE-ESCALATING TREATMENT IN EARLY BREAST CANCER ACROSS SUBTYPES AND TREATMENT MODALITIES

Consensus and Controversy

15th St.Gallen International Breast Cancer Conference 2017 Consensus
**International Consensus Panel 2017**

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Expert Opinion on Areas of Controversy

- Escalation and de-escalation of treatment are major issues for management of early breast cancer.
- Evidence from randomized clinical trials does not cover all controversies that arise in treating individuals.
- The opinion of the panel members is used to implement guidance for controversial issues.
- When data are lacking, expert opinion can be used.
- This is the unique feature of the St. Gallen International Consensus.
Panelists’ Answers

- Questions have been prospectively reviewed by the panelists and revised to be as clear as possible.
- Panelists are asked to answer either
  
  1 Yes or 2 No

  for most questions
  or in certain cases

  select from mutually exclusive choices, 1, 2, 3, 4, etc.

- Option for Abstain if Panelist has insufficient data, lack of specific expertise on the issue, or conflict of interest. Do not hesitate to abstain, if appropriate.
Practice Question

T1. The venue of the 2017 St. Gallen International Breast Cancer Conference is in Vienna/Austria?

(1) Yes 93.1%
(2) No 0%
(3) Abstain 6.9%
Practice Question

T2. The population of Vienna is (select one):

(1) More than 1,500,000 - 55.6%
(2) From 1,000,000 to 1,500,000 - 25%
(3) From 500,000 to 1,000,000 - 11.1%
(4) <500,000 - 2.8%
(5) Abstain - 5.6%
LET’S START
Escalating and De-escalating

APPROPRIATE MARGINS IN PRIMARY SURGERY AND IN SURGERY FOLLOWING NEO-ADJUVANT SYSTEMIC THERAPY

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Breast Conserving Surgery of the Primary (DCIS)

1. In women undergoing breast conserving surgery for DCIS and planned whole breast radiation treatment which minimum margin width is sufficient to avoid re-excision?

(1) No ink on DCIS? 34.6%
(2) 2 mm clearance? 61.5%
(3) 5 mm clearance? 0%
(4) Margin is irrelevant? 0%
(5) Abstain 3.8%

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Primary Surgery of Multi-focal/ Multicentric Disease

2. >2 tumor foci contained in one ‘quadrant’ of the breast (multifocal) can be treated with breast conservation, provided margins are clear and adequate RT is planned.

- **(1) Yes**  
  97.1%

- **(2) No**  
  2.9%

- **(3) Abstain**  
  0%
Primary Surgery of Multi-focal/Multicentric Disease

3. Tumor foci in more than one ‘quadrant’ of the breast (multicentric) can be treated with breast conservation, provided margins are clear and adequate RT is planned.

(1) Yes 60.6%
(2) No 33.3%
(3) Abstain 6.1%
Surgery of the Primary Tumor

4. Should the margin required be dependent on tumor biology?

(1) Yes 6.5%
(2) No 93.5%
(3) Abstain 0%
Surgery of the Primary (IBC) after Neo-Adjuvant Systemic Therapy

9. In women undergoing breast conserving surgery after neo-adjuvant chemotherapy and proceeding to standard radiation with or without additional adjuvant systemic therapy. Should the entire area of the original primary be resected after downstaging?

(1) Yes 14.3%

(2) No 82.1%

(3) Abstain 3.6%
Surgery of the Primary (IBC) after Neo-Adjuvant Systemic Therapy

10. In women undergoing breast conserving surgery after neo-adjuvant chemotherapy and proceeding to standard radiation with or without additional adjuvant systemic therapy. Which is the **minimum** acceptable surgical margin to avoid re-excision (with multifocal residual disease in the pathological specimen)?

(1) No ink on invasive tumor or DCIS?  
   - 55.2%

(2) 2 mm clearance?  
   - 27.6%

(3) > 2 – 5 mm clearance?  
   - 6.9%

(4) > 5mm clearance?  
   - 3.4%

(5) Margin is irrelevant?  
   - 0%

(6) Abstain  
   - 6.9%

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Surgery of the Primary (IBC) after Neo-Adjuvant Systemic Therapy

11. In women undergoing breast conserving surgery after neo-adjuvant chemotherapy and proceeding to standard radiation with or without additional adjuvant systemic therapy. Which is the minimum acceptable surgical margin to avoid re-excision (without multifocal residual disease in their pathological specimen)?

(1) No ink on invasive tumor or DCIS? 95.8%
(2) 2 mm clearance? 4.2%
(3) > 2 – 5 mm clearance? 0%
(4) > 5mm clearance? 0%
(5) Margin is irrelevant? 0%
(6) Abstain 0%

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Surgery of the Primary (IBC) after Neo-Adjuvant Systemic Therapy

12. In women undergoing breast conserving surgery after neo-adjuvant chemotherapy and proceeding to standard radiation with or without additional adjuvant systemic therapy. Is nipple-sparing mastectomy safe after neo-adjuvant treatment?

(1) Yes 80%
(2) No 4%
(3) Abstain 16%
Escalating and De-escalating

WHEN CAN AXILLARY SURGERY BE REDUCED?
Surgery of the Axilla

13. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following:
Mastectomy (no radiotherapy to lymph nodes planned)

(1) Yes 14.3%
(2) No 85.7%
(3) Abstain 0%
Surgery of the Axilla

14. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following:
Mastectomy (radiotherapy to lymph nodes planned)

(1) Yes
   84.6%
(2) No
   15.4%
(3) Abstain
   0%

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Surgery of the Axilla

15. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following:
Conservative resection with radiotherapy using standard tangents

(1) Yes 78.1%
(2) No 18.8%
(3) Abstain 3.1%
Surgery of the Axilla

16. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following:

Conservative resection with radiotherapy using high tangents

(1) Yes 77.5%
(2) No 10%
(3) Abstain 12.5%

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Surgery of the Axilla

17. In patients with macro-metastases in 1-2 sentinel nodes, completion of axillary dissection can safely be omitted following:
Irrespective of tumor biology (LVI, ER-, grade 3 etc.)

(1) Yes 76.9%
(2) No 23.1%
(3) Abstain 0%
Surgery of the Axilla following Neo-Adjuvant Chemotherapy

18. In a patient who is clinically (at palpation and US) node-negative at diagnosis:
Is SN biopsy appropriate?

(1) Yes 95.7%
(2) No 4.3%
(3) Abstain 0%
Surgery of the Axilla in the context of Neo-Adjuvant Chemotherapy

19. In a patient who is clinically (at palpation and US) node-negative at diagnosis:
   When is the best time point for SN biopsy?

(1) Before the start of neo-adjuvant chemo 20%
(2) After neo-adjuvant chemo 60%
(3) Either before or after chemo are valid options 16.7%
(4) Abstain 3.3%
Surgery of the Axilla following Neo-Adjuvant Chemotherapy

20. In a patient who is clinically node-positive at diagnosis and who downstages after chemotherapy: Is SN biopsy appropriate with 1-2 LN detected?

(1) Yes 42.9%
(2) No 53.6%
(3) Abstain 3.6%
Surgery of the Axilla following Neo-Adjuvant Chemotherapy

21. In a patient who is clinically node-positive at diagnosis and who downstages after chemotherapy:
   Is SN biopsy appropriate only in selected cases such as:
   More than 2 SN detected?

(1) Yes 52.2%
(2) No 30.4%
(3) Abstain 17.4%
Surgery of the Axilla following Neo-Adjuvant Chemotherapy

23. In a patient who is clinically node-positive at diagnosis and who downstages after chemotherapy: Is SN biopsy appropriate only in selected cases such as: Clipping/seeding of involved nodes at diagnosis and targeted removal?

(1) Yes 50%
(2) No 28.6%
(3) Abstain 21.4%

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Surgery of the Axilla following Neo-Adjuvant Chemotherapy

25. In a patient who is clinically node-positive at diagnosis and who downstages after chemotherapy: Can ALND be avoided if micrometastasis is present in the SN?

(1) Yes 48.5%
(2) No 45.5%
(3) Abstain 6.1%
Surgery of the Axilla following Neo-Adjuvant Chemotherapy

26. In a patient who is clinically node-positive at diagnosis and who downstages after chemotherapy: Can ALND be avoided if a single SN is positive (macrometastasis)?

(1) Yes 20%
(2) No 80%
(3) Abstain 0%
Escalating and De-escalating

IN WHICH CLINICAL SCENARIO MAY RADIOTHERAPY COURSES BE SHORTENED?
Hypofractionated Breast Irradiation

27. Following breast conserving surgery, hypofractionated whole breast irradiation is a standard of care in:

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Hypofractionated Breast Irradiation

28. Following breast conserving surgery, hypofractionated whole breast irradiation is a standard of care in:
- Patients over 50 years

(1) Yes 70%
(2) No 15%
(3) Abstain 15%
Partial Breast Irradiation

32. Following breast conserving surgery, partial breast irradiation may be used:
As the definitive irradiation, without whole breast irradiation in ASTRO/ESTRO “suitable” patients?

(1) Yes 64.7%
(2) No 23.5%
(3) Abstain 11.8%
Partial Breast Irradiation

33. Following breast conserving surgery, partial breast irradiation may be used:
As the definitive irradiation, without whole breast irradiation in ASTRO “cautionary” / ESTRO “intermediate” patients?

(1) Yes 20%
(2) No 46.7%
(3) Abstain 33.3%
"Boost" Radiotherapy to Primary Tumor Bed

40. "Boost" Radiotherapy to Primary Tumor Bed after Breast Conservative Surgery can be omitted

1. Never
   - 9.1%

2. Always
   - 9.1%

3. In patients > 60 years old, low grade, or favourable
   - 54.5%

4. In case of negative margins
   - 9.1%

5. Abstain
   - 18.2%

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Escalating and De-escalating

WHEN SHOULD RADIOTHERAPY VOLUMES BE EXPANDED?
Regional Node Irradiation

41. Following breast conserving surgery, radiation should include regional nodes:
If number of positive nodes is 1-3

(1) No  
11.8%

(2) Only if adverse biological features  
52.9%

(3) At all cases  
35.3%

(4) Abstain  
0%
Regional Node Irradiation

42. Following breast conserving surgery, radiation should include regional nodes:
If number of positive nodes is 4 or more

(1) No
   0 %

(2) Only if adverse biological features
   0 %

(3) At all cases
   100 %

(4) Abstain
   0 %
Radiation Therapy: After Mastectomy

44. Should post mastectomy RT (chest wall and regional nodes) be standard for patients with:
T size >= 5 cm and N0?

(1) Yes 53.8%
(2) No 23.1%
(3) Abstain 23.1%
Radiation Therapy: After Mastectomy

45. Should post mastectomy RT (chest wall and regional nodes) be standard for patients with:
N+ 1 to 3 all patients?

(1) Yes 54.5%
(2) No 36.4%
(3) Abstain 9.1%
Radiation Therapy: After Mastectomy

46. Should post mastectomy RT (chest wall and regional nodes) be standard for patients with:
N+ 1 to 3 with adverse pathology?

(1) Yes 88.2%
(2) No 5.9%
(3) Abstain 5.9%

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Radiation Therapy: After Mastectomy

47. Should post mastectomy RT (chest wall and regional nodes) be standard for patients with:
N+ 1 to 3 at young age (< 40 years)?

(1) Yes  
69.2%

(2) No  
23.1%

(3) Abstain  
7.7%
48. Should post mastectomy RT (chest wall and regional nodes) be standard for patients with:
Positive sentinel node biopsy but no axillary dissection?

(1) Yes 57.1%
(2) No 14.3%
(3) Abstain 28.6%
Radiation to Breast Following Neo-Adjuvant Systemic Therapy

50. Should follow the stage

(1) **Before** neo-adjuvant therapy?
   - 11.1%

(2) **After** neo-adjuvant therapy?
   - 0%

(3) Should take into account the stage **before and after**
   - 77.8%

(4) Can be omitted in women with pCR after NAC?
   - 11.1%

(5) Abstain
   - 0%
Escalating and De-escalating

WHEN IS TRADITIONAL PATHOLOGY (STAGE, GRADE, LVI, ER/PR/HER2) NOT INFORMATIVE ENOUGH?
Pathology: Subtypes

51. If derived using IHC, distinction between ‘Luminal A-like’ and ‘Luminal B-like’ (HER2 neg.):
Describes important categories in the biology of luminal breast cancer

(1) Yes 100%
(2) No 0%
(3) Abstain 0%
Pathology: Subtypes

52. If derived using IHC, distinction between ‘Luminal A-like’ and ‘Luminal B-like’ (HER2 neg.):
Should be used for therapy decisions

(1) Yes: 80%
(2) No: 20%
(3) Abstain: 0%
Pathology: Subtypes

53. If derived using IHC, distinction between ‘Luminal A-like’ and ‘Luminal B-like’ (HER2 neg.):
Generates working categories but should not be used for clinical decisions due to low analytical validity

(1) Yes 33,3 %
(2) No 53,3 %
(3) Abstain 13,3 %
Pathology: Subtypes

54. Distinction between ‘Luminal A-like’ and ‘Luminal B-like’ (HER2 neg.) can be derived:
Using IHC (ER, PR and grading) to approximate multigene testing

(1) Yes  66.7%
(2) No   29.2%
(3) Abstain 4.2%
55. Distinction between ‘Luminal A-like’ and ‘Luminal B-like’ (HER2 neg.) can be derived:
Using ER, PR and ‘high’ Ki67

(1) Yes 78.6%
(2) No 21.4%
(3) Abstain 0%
Pathology: Subtypes

57. Distinction between ‘Luminal A-like’ and ‘Luminal B-like’ (HER2 neg.) can be derived:

*Subtype can be more* appropriately determined by multi-gene tests (when available)?

1. Yes: 63.6%
2. No: 18.2%
3. Abstain: 18.2%

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Pathology: TILs

58. Should the evaluation of tumor-infiltrating lymphocytes (TILs) be reported in the pathology report of Triple-Negative and HER2 positive EBC?

(1) Yes - 29.4%
(2) No - 64.7%
(3) Abstain - 5.9%
Multi-Gene Signatures and Chemotherapy: Node-Negative Patients

59. Is there a role for multi-gene testing in node-negative, pT1a, pT1b, ER positive, PgR positive, HER2 negative, low grade, low Ki67 breast cancer?

(1) Yes 14.3%
(2) No 85.7%
(3) Abstain 0%
Multi-Gene Signatures and Chemotherapy: Node-Negative Patients

60. In a patient with ER + /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by: **Oncotype DX® RS**

Prognosis: Years 1-5?

1. Yes
   - 93.8%

2. No
   - 6.3%

3. Abstain
   - 0%
Multi-Gene Signatures and Chemotherapy: Node-Negative Patients

62. In a patient with ER + /HER2 negative clinically valuable information on prognosis and risk helping us to decide to omit chemotherapy may be provided by:

MammaPrint 70®

Prognosis: Years 1-5?

(1) Yes 81.3%
(2) No 6.3%
(3) Abstain 12.5%
Multi-Gene Signatures and Chemotherapy: Node-Negative Patients

64. In a patient with ER+/HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by: **PAM-50 ROR Score**

Prognosis: Years 1-5?

(1) Yes  
   80 %

(2) No  
   0 %

(3) Abstain  
   20 %
Multi-Gene Signatures and Chemotherapy: Node-Negative Patients

66. In a patient with ER+ /HER2 negative clinically valuable information on prognosis and risk helping us to decide to omit chemotherapy may be provided by:

EndoPredict® (EpClin)

Prognosis: Years 1-5?

(1) Yes 70%
(2) No 20%
(3) Abstain 10%

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Multi-Gene Signatures and Chemotherapy: Node-Negative Patients

68. In a patient with ER+ /HER2 negative clinically valuable information on *prognosis* and risk helping us to decide to omit chemotherapy may be provided by:

**Breast Cancer Index**

Prognosis: Years 1-5?

1. Yes [60%]
2. No [20%]
3. Abstain [20%]
Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

70. In a patient with ER+ /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by:

**Oncotype DX® RS**

Prognosis: Years 1-5?

1. Yes  
   - Yes  
   - 60%

2. No  
   - No  
   - 30%

3. Abstain  
   - Abstain  
   - 10%

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Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

71. In a patient with ER+/HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by:

**Oncotype DX® RS**

Chemotherapy?

(1) Yes  58.6%

(2) No   31%

(3) Abstain 10.3%

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Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

72. In a patient with ER + /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by: **MammaPrint 70®**

**Prognosis: Years 1-5?**

1. Yes
   - 42.9%
2. No
   - 35.7%
3. Abstain
   - 21.4%

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Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

73. In a patient with ER+/HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by:

**MammaPrint 70®**

Chemotherapy?

1. Yes 40%
2. No 50%
3. Abstain 10%

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Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

74. In a patient with ER+ /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by:

**PAM-50 ROR Score**

Prognosis: Years 1-5?

1. Yes 75%
2. No 12.5%
3. Abstain 12.5%

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Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

75. In a patient with ER+ /HER2 negative clinically valuable information on prognosis and risk helping us to decide to omit chemotherapy may be provided by:

PAM-50 ROR Score

Chemotherapy?

(1) Yes 46.7%
(2) No 53.3%
(3) Abstain 0%
Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

76. In a patient with ER+ /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by: **EndoPredict® (EpClin)**

Prognosis: Years 1-5?

1. Yes 55.6%
2. No 16.7%
3. Abstain 27.8%
Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

77. In a patient with ER + /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by:

**EndoPredict**® (**EpClin**)

Chemotherapy?

1. Yes
   - 15.8%
2. No
   - 52.6%
3. Abstain
   - 31.6%

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78. In a patient with ER + /HER2 negative clinically valuable information on **prognosis** and risk helping us to decide to omit chemotherapy may be provided by:

**Breast Cancer Index**

Prognosis: years 1-5?

(1) Yes 43.3%
(2) No 33.3%
(3) Abstain 23.3%
Multi-Gene Signatures and Chemotherapy: Node-Positive Patients

79. In a patient with ER+ /HER2 negative clinically valuable information on prognosis and risk helping us to decide to omit chemotherapy may be provided by:

Breast Cancer Index

Chemotherapy?

(1) Yes
   8.1%

(2) No
   64.9%

(3) Abstain
   27%
Multi-Gene Signatures and Extended Endocrine Therapy:

80. In a patient with ER+/HER2 negative, clinically valuable information on prognosis and risk helping us to decide for an extended endocrine therapy (beyond five years) may be provided by one or more multigene signatures.

(1) Yes 46.2%
(2) No 50%
(3) Abstain 3.8%

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Escalating and De-escalating

WHICH WOMEN SHOULD RECEIVE OVARIAN SUPPRESSION AS PART OF ADJUVANT ENDOCRINE THERAPY?
Endocrine Therapy
Premenopausal: Selection Factors

81. Does each of the following clinico-pathological features by itself argue for inclusion of ovarian function suppression (OFS)?
Age < 35 years

(1) Yes 77.4%
(2) No 18.9%
(3) Abstain 3.8%
Endocrine Therapy
Premenopausal: Selection Factors

82. Does each of the following clinico-pathological features by itself argue for inclusion of ovarian function suppression (OFS)?
Premenopausal oestrogen level after adjuvant chemotherapy

(1) Yes 60%
(2) No 34%
(3) Abstain 6%

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Endocrine Therapy
Premenopausal: Selection Factors

85. Does each of the following clinico-pathological features by itself argue for inclusion of ovarian function suppression (OFS)?
Involvement of 4 or more nodes

(1) Yes
   - 83.7%

(2) No
   - 12.2%

(3) Abstain
   - 4.1%

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Endocrine Therapy Premenopausal Patients: (assessed by Estradiol, FSH and LH): Selection Factors

87. Should some patients receive OFS + AI?

(1) Yes 92.3%
(2) No 5.8%
(3) Abstain 1.9%

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Endocrine Therapy
Postmenopausal Patients

93. Is Tamoxifen alone still appropriate for some patients?

(1) Yes 92.3%
(2) No 5.8%
(3) Abstain 1.9%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Endocrine Therapy
Postmenopausal Patients

94. Parameters for inclusion of an AI at some point are:
All postmenopausal patients

(1) Yes 51.1%
(2) No 44.7%
(3) Abstain 4.3%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Endocrine Therapy
Postmenopausal Patients

95. Parameters for inclusion of an AI at some point are:
Node-positive

(1) Yes 86%
(2) No 14%
(3) Abstain 0%
Endocrine Therapy
Postmenopausal Patients

96. Parameters for inclusion of an AI at some point are:
Grade 3 or high Ki67

(1) Yes 80.8%
(2) No 17.3%
(3) Abstain 1.9%
Endocrine Therapy
Postmenopausal Patients

97. Parameters for inclusion of an AI at some point are:
HER2 positivity

(1) Yes   62 %
(2) No    34 %
(3) Abstain 4 %
Endocrine Therapy
Postmenopausal Patients

98. If an AI is used, should it be started upfront: In any patients?

(1) Yes  98.1%
(2) No  1.9%
(3) Abstain  0%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Endocrine Therapy
Postmenopausal Patients

99. If an AI is used, should it be started upfront:
In patients at higher risk?

(1) Yes 94.4%
(2) No 5.6%
(3) Abstain 0%
Endocrine Therapy
Postmenopausal Patients

100. If an AI is used, should it be started upfront:
In lobular cancer (letrozole or other AI)?

(1) Yes  78.4%
(2) No   13.7%
(3) Abstain  7.8%
Endocrine Therapy
Postmenopausal Patients

101. Can upfront AI be switched to TAM after 2 years in all?

(1) Yes 19.1%
(2) No 72.3%
(3) Abstain 8.5%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Escalating and De-escalating

WHICH WOMEN SHOULD RECEIVE LONGER DURATION OF ADJUVANT ENDOCRINE THERAPY?
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

103. Provided an indication exists for therapy beyond the first 5 years:

After 5 years of adjuvant therapy involving *switch from TAM to an AI* (therefore assuming postmenopausal status at the 5 year time point and reasonable tolerance to endocrine therapy), patients at moderate or high risk of recurrence should be recommended to receive:

A further 5 years of Tamoxifen

<table>
<thead>
<tr>
<th>Option</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Yes</td>
<td>30.6%</td>
</tr>
<tr>
<td>No</td>
<td>61.2%</td>
</tr>
<tr>
<td>Abstain</td>
<td>8.2%</td>
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</tbody>
</table>
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

104. Provided an indication exists for therapy beyond the first 5 years:

After 5 years of adjuvant therapy involving switch from TAM to an AI (therefore assuming postmenopausal status at the 5 year time point and reasonable tolerance to endocrine therapy), patients at moderate or high risk of recurrence should be recommended to receive:

Continue AI to a cumulative total of 5 years AI

(1) Yes 88.5%
(2) No 5.8%
(3) Abstain 5.8%
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

105. Provided an indication exists for therapy beyond the first 5 years:

After 5 years of adjuvant therapy involving **switch from TAM to an AI** (therefore assuming postmenopausal status at the 5 year time point and reasonable tolerance to endocrine therapy), patients at moderate or high risk of recurrence should be recommended to receive:

- A further 5 years AI

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<tr>
<th>Option</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Yes</td>
<td>66%</td>
</tr>
<tr>
<td>No</td>
<td>23.4%</td>
</tr>
<tr>
<td>Abstain</td>
<td>10.6%</td>
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</tbody>
</table>

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

106. Provided an indication exists for therapy beyond the first 5 years:

After 5 years of adjuvant therapy involving **switch from TAM to an AI** (therefore assuming postmenopausal status at the 5 year time point and reasonable tolerance to endocrine therapy), patients at moderate or high risk of recurrence should be recommended to receive:

No further endocrine therapy

(1) Yes
   - 7.7%

(2) No
   - 82.7%

(3) Abstain
   - 9.6%
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

107. Provided an indication exists for therapy beyond the first 5 years:
After 5 years of **straight AI** adjuvant therapy, patients should be recommended to receive:
A further 3 to 5 years of Tamoxifen

(1) Yes 25.5%
(2) No 58.8%
(3) Abstain 15.7%
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

108. Provided an indication exists for therapy beyond the first 5 years:
After 5 years of **straight AI** adjuvant therapy, patients should be recommended to receive:
A further 3 to 5 years of AI

(1) Yes  
64.7%

(2) No  
27.5%

(3) Abstain  
7.8%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

109. Provided an indication exists for therapy beyond the first 5 years:

After 5 years of **straight AI** adjuvant therapy, patients should be recommended to receive:

Duration of AI depend upon tolerance and absolute risk

(1) Yes
   - 97.9%

(2) No
   - 2.1%

(3) Abstain
   - 0%
Adjuvant Endocrine Therapy Duration (Postmenopausal Patients)

110. Provided an indication exists for therapy beyond the first 5 years:
After 5 years of **straight AI** adjuvant therapy, patients should be recommended to receive:
No further endocrine therapy

1. Yes 25.5%
2. No 66%
3. Abstain 8.5%
Adjuvant Endocrine Therapy Duration (Premenopausal Patients)

111. For premenopausal women (who remain premenopausal) TAM to 10 years should be recommended to:
Premenopausal patients at high risk at presentation?

(1) Yes - 86.3%
(2) No - 9.8%
(3) Abstain - 3.9%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Endocrine Therapy Duration (Premenopausal Patients)

112. For premenopausal women (who remain premenopausal) TAM to 10 years should be recommended to:
Premenopausal patients with any risk at presentation?

(1) Yes  13.7 %
(2) No  86.3 %
(3) Abstain  0 %
Escalating and De-escalating

WHICH WOMEN SHOULD RECEIVE ADJUVANT CHEMOTHERAPY?
Adjuvant Chemotherapy

115. Treatment decision about both prognosis and the potential benefits of chemotherapy in N0 disease can be aided by which of the following:
Biology defined by IHC features

(1) Yes 96.1%
(2) No 3.9%
(3) Abstain 0%
Adjuvant Chemotherapy

116. Treatment decision about both prognosis and the potential benefits of chemotherapy in N0 disease can be aided by which of the following:

- Multigene risk predictor

(1) Yes: 96.1%
(2) No: 3.9%
(3) Abstain: 0%
117. If IHC is used, factors which are relative indications for the inclusion of adjuvant cytotoxic chemotherapy include:

Histological grade 3 tumor

(1) Yes
   - 90.6%

(2) No
   - 5.7%

(3) Abstain
   - 3.8%
Adjuvant Chemotherapy

118. If IHC is used, factors which are *relative* indications for the inclusion of adjuvant cytotoxic chemotherapy include:

Any positive node

1. Yes  68.5%
2. No  31.5%
3. Abstain  0%
If IHC is used, factors which are relative indications for the inclusion of adjuvant cytotoxic chemotherapy include:

Ki67 high

- **Yes**: 84.9%
- **No**: 11.3%
- **Abstain**: 3.8%
121. If IHC is used, factors which are *relative* indications for the inclusion of adjuvant cytotoxic chemotherapy include:

Age < 35

(1) Yes

55.8%

(2) No

44.2%

(3) Abstain

0%
122. If IHC is used, factors which are relative indications for the inclusion of adjuvant cytotoxic chemotherapy include:

- Extensive lympho-vascular invasion

(1) Yes 67.9%
(2) No 30.2%
(3) Abstain 1.9%
123. If IHC is used, factors which are **relative** indications for the inclusion of adjuvant cytotoxic chemotherapy include:
Low hormone receptor staining

- **Yes**: 91.1%
- **No**: 8.9%
- **Abstain**: 0%
Adjuvant Chemotherapy
Luminal B-like Patients

127. In patients with poor prognosis biology by IHC, chemotherapy should be recommended in:
All patients N0 and N+

(1) Yes 57.1%
(2) No 34.7%
(3) Abstain 8.2%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
Luminal B-like Patients

128. Chemotherapy may be safely omitted for N+ patients with:
Low risk Oncotype Dx® score

(1) Yes 87.8%
(2) No 10.2%
(3) Abstain 2%
Adjuvant Chemotherapy
Luminal B-like Patients

129. Chemotherapy may be safely omitted for N+ patients with:
Intermediate Oncotype Dx® score

(1) Yes: 22.4%
(2) No: 67.3%
(3) Abstain: 10.2%
Adjuvant Chemotherapy
Luminal B-like Patients

130. Chemotherapy may be safely omitted for N+ patients with:
MammaPrint® Low Risk

(1) Yes 55.1%
(2) No 34.7%
(3) Abstain 10.2%
Adjuvant Chemotherapy
Luminal B-like Patients

131. Chemotherapy may be safely **omitted** for N+ patients with:
Low PAM50 ROR score

1. Yes  30.8%
2. No   50%
3. Abstain 19.2%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
Luminal B-like Patients

132. Chemotherapy may be safely omitted for N+ patients with:
   EndoPredict® Low Risk

(1) Yes 20 %
(2) No 66 %
(3) Abstain 14 %
Adjuvant Chemotherapy
Patients with Luminal B-like tumors (HER2 negative)

135. If given, should the regimen contain anthracyclines and taxanes?

1. Yes 52.1%
2. No 39.6%
3. Abstain 8.3%
Adjuvant Chemotherapy
Patients with Luminal B-like tumors (HER2 negative)

136. Should chemotherapy ever comprise 6 cycles of the same therapy (e.g. 6 courses of EC or AC or TC)?

(1) Yes 23.1%
(2) No 63.5%
(3) Abstain 13.5%
Adjuvant Chemotherapy in patients with Ductal Triple-Negative BC

138. In stage I should the regimen for all TNBC phenotype contain anthracyclines and taxanes?

(1) Yes 55.8%
(2) No 40.4%
(3) Abstain 3.8%
Adjuvant Chemotherapy in patients with Ductal Triple-Negative BC

139. In stage II-III should the regimen for all TNBC phenotype contain anthracyclines and taxanes?

(1) Yes 94%
(2) No 4%
(3) Abstain 2%
Adjuvant Chemotherapy in patients with Ductal Triple-Negative BC

140. Should a platinum based regimen be considered? In all patients with TNBC?

(1) Yes 9.8%
(2) No 86.3%
(3) Abstain 3.9%
Adjuvant Chemotherapy in patients with Ductal Triple-Negative BC

141. Should a platinum based regimen be considered? **Only** with known germline mutation?

- **Yes** 47.1%
- **No** 43.1%
- **Abstain** 9.8%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy in patients with Ductal Triple-Negative BC

142. Can we avoid chemotherapy in pT1a pN0 stage?

(1) Yes 78%
(2) No 20%
(3) Abstain 2%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy in patients with Ductal Triple-Negative BC

143. Should dose-dense chemotherapy be a preferred regimen?

(1) Yes 37.3%
(2) No 54.9%
(3) Abstain 7.8%
Adjuvant Chemotherapy
HER2-positive (node-positive disease) patients

144. Should chemotherapy always be given to patients with N+ disease who require anti-HER2 therapy?

1. Yes 88.2%
2. No 2%
3. Abstain 9.8%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy

HER2-positive (node-positive disease) patients

145. Should the chemotherapy regimen for these patients include anthracyclines?

(1) Yes 62%
(2) No 32%
(3) Abstain 6%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-positive disease) patients

146. Should the chemotherapy regimen for these patients include taxanes?

(1) Yes
87.8%

(2) No
6.1%

(3) Abstain
6.1%
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

148. With HER2 positivity determined according to ASCO/CAP guidelines:
Do the large majority of patients with HER2 positive node-negative disease require anti-HER2 therapy:
With pT1a disease?

(1) Yes 33,3%
(2) No 62,5%
(3) Abstain 4,2%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

149. With HER2 positivity determined according to ASCO/CAP guidelines:
Do the large majority of patients with HER2 positive node-negative disease require anti-HER2 therapy:
With pT1a disease?

(1) Yes 85.7%
(2) No 10.2%
(3) Abstain 4.1%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

150. With HER2 positivity determined according to ASCO/CAP guidelines:
Do the large majority of patients with HER2 positive node-negative disease require anti-HER2 therapy:
With pT1c disease?

(1) Yes 94.1%
(2) No 0%
(3) Abstain 5.9%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

151. With HER2 positivity determined according to ASCO/CAP guidelines:
If given, is the combination of Paclitaxel and Trastuzumab a reasonable option?

(1) Yes 92%
(2) No 4%
(3) Abstain 4%
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

152. With HER2 positivity determined according to ASCO/CAP guidelines:
If given, is the combination of Paclitaxel and Trastuzumab a reasonable option?
With primary less than 1 cm?

(1) Yes 88.5%
(2) No 9.6%
(3) Abstain 1.9%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

153. With HER2 positivity determined according to ASCO/CAP guidelines:
If given, is the combination of Paclitaxel and Trastuzumab a reasonable option?
With primary of 1-2 cm?

(1) Yes
(2) No
(3) Abstain

---

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

154. With HER2 positivity determined according to ASCO/CAP guidelines:
If given, is the combination of Paclitaxel and Trastuzumab a reasonable option?
With primary of 2-3 cm?

(1) Yes  50 %
(2) No   44 %
(3) Abstain  6 %

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Chemotherapy
HER2-positive (node-negative disease) Patients

155. With HER2 positivity determined according to ASCO/CAP guidelines:
If given, is the combination of Docetaxel and cyclophosphamide x 4 and Trastuzumab a reasonable option?

(1) Yes 66%
(2) No 21.3%
(3) Abstain 12.8%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Anti-HER2 Therapy

159. In a patient who received neo-adjuvant chemotherapy with Trastuzumab and Pertuzumab, adjuvant therapy should include:
Trastuzumab alone at completion of one year

(1) Yes 88%
(2) No 2%
(3) Abstain 10%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
160. In a patient who received neo-adjuvant chemotherapy with Trastuzumab and Pertuzumab, adjuvant therapy should include:
Trastuzumab + Pertuzumab at completion of one year

(1) Yes 6.1%
(2) No 69.4%
(3) Abstain 24.5%
Biosimilars in HER2-Positive Disease

161. If approved, are biosimilars of Trastuzumab acceptable in the neo-adjuvant and/or adjuvant treatment of HER2+ disease, based on current evidence?

(1) Yes: 53.8%
(2) No: 17.3%
(3) Abstain: 28.8%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Neo-Adjuvant Systemic Therapy
(possibly followed by additional adjuvant chemo)

162. In a woman eligible to breast conservative surgery should neo-adjuvant chemotherapy and anti-HER2 therapy be the preferred option for HER2-positive EBC patients in stage II-III?

(1) Yes 94.1%
(2) No 3.9%
(3) Abstain 2%
Neo-Adjuvant Systemic Therapy
(possibly followed by additional adjuvant chemo)
Stage II-III HER2-positive Disease

163. If given, in patients with HER2-positive tumors, acceptable regimen include:
Taxane + Trastuzumab only

(1) Yes 34.8%
(2) No 56.5%
(3) Abstain 8.7%
Neo-Adjuvant Systemic Therapy
(possibly followed by additional adjuvant chemo)
Stage II-III HER2-positive Disease

164. If given, in patients with HER2-positive tumors, acceptable regimen include:
Taxane, Trastuzumab and Pertuzumab

(1) Yes 84.3%
(2) No 7.8%
(3) Abstain 7.8%
Neo-Adjuvant Systemic Therapy
Stage II-III Triple-Negative Disease

168. In a woman eligible to breast conservative surgery should neo-adjuvant chemotherapy be a preferred option for TN EBC patients?

(1) Yes 92.5%
(2) No 5.7%
(3) Abstain 1.9%
Neo-Adjuvant Systemic Therapy
Stage II Triple-Negative Disease

169. If given, in patients with ductal triple-negative tumors (irrespective of BRCA status), the preferred regimen should include:
Platinum or alkylating agents containing regimen

(1) Yes 70.8%
(2) No 14.6%
(3) Abstain 14.6%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Neo-Adjuvant Systemic Therapy
Stage II Triple-Negative Disease

170. If given, in patients with ductal triple-negative tumors (irrespective of BRCA status), the preferred regimen should include:

- Anthracycline → taxane non-dose dense

<table>
<thead>
<tr>
<th>(1) Yes</th>
<th>74.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>(2) No</td>
<td>11.8%</td>
</tr>
<tr>
<td>(3) Abstain</td>
<td>13.7%</td>
</tr>
</tbody>
</table>
Neo-Adjuvant Systemic Therapy
Stage II Triple-Negative Disease

172. If given, in patients with ductal **triple-negative** tumors (irrespective of BRCA status), the preferred regimen should include:

Nab-Paclitaxel -> EC

(1) Yes  
56.3%

(2) No  
22.9%

(3) Abstain  
20.8%
Escalating and De-escalating

WHICH WOMEN SHOULD RECEIVE ADDITIONAL THERAPY AFTER NEO-ADJUVANT TREATMENT?
Additional Adjuvant Chemotherapy in the Post-Neo-Adjuvant Setting

174. In case of clinical response and residual disease of greater than 1 cm and/or a positive node at surgery following neo-adjuvant (anthracycline-, taxane- and alkylator-based) chemotherapy for TNBC, we should propose:

(1) No further chemotherapy 31.1%
(2) Capecitabine 48.9%
(3) Platinum 6.7%
(4) Platinum if BRCA+ 8.9%
(5) Metronomic chemotherapy 4.4%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Additional Adjuvant Chemotherapy in the Post-Neo-Adjuvant Setting

175. In case of clinical response and residual disease of greater than 1 cm and/or a positive node at surgery following neo-adjuvant (anthracycline-, taxane- and alkylator-based) chemotherapy for TNBC, we should propose:

A clinical trial when available

(1) Yes
   - 90.2%

(2) No
   - 7.8%

(3) Abstain
   - 2%
176. Is a scalp cooling device an option to prevent hair loss during (neo-)adjuvant chemotherapy?

(1) Yes  
83%

(2) No  
10.6%

(3) Abstain  
6.4%

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Escalating and De-escalating

SHOULD WE ROUTINELY ADD BONE-MODIFYING THERAPY AS ADJUVANT TREATMENT?
Adjuvant Bisphosphonates

177. Is bisphosphonate treatment, such as zoledronic acid q 6 months or oral clodronate, during adjuvant endocrine therapy, indicated to improve DFS irrespective of BMD?

In premenopausal patients receiving LHRH plus TAM or plus AI?

(1) Yes 53.1 %
(2) No 36.7 %
(3) Abstain 10.2 %

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Bisphosphonates

178. Is bisphosphonate treatment, such as zoledronic acid q 6 months or oral clodronate, during adjuvant endocrine therapy, indicated to improve DFS irrespective of BMD?
In premenopausal patients not receiving LHRH?

(1) Yes
   - 2%

(2) No
   - 90%

(3) Abstain
   - 8%
179. Is bisphosphonate treatment, such as zoledronic acid q 6 months or oral clodronate, during adjuvant endocrine therapy, indicated to improve DFS irrespective of BMD? In postmenopausal patients?

(1) Yes 75.6%
(2) No 17.8%
(3) Abstain 6.7%
Adjuvant Bisphosphonates

180. Should adjuvant denosumab (60 mg twice a year) substitute for bisphosphonate?

(1) Yes  30%
(2) No   44%
(3) Abstain  26%

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Escalating and De-escalating

SPECIAL POPULATIONS
Age and Adjuvant Chemotherapy

181. In the absence of significant co-morbidity, the maximum age at which a standard adjuvant chemotherapy regimen should be advised is:

1. 65 years 0 %
2. 70 years 2 %
3. 75 years 0 %
4. 80 years 2 %
5. There is no absolute age limit. Rather, it depends on the disease, the 94.1 %
6. Abstain 2 %

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Elderly Patients: Adjuvant Radiation

182. In postmenopausal patients with ER-positive tumors, who have a low-risk genomic score, node-negative, receiving endocrine therapy, radiation after breast conserving surgery may be **omitted** in patients:

1. 65 years - 12.2%
2. 70 years - 26.5%
3. 75 years - 2%
4. 80 years - 4.1%
5. When multiple co-morbidities are diagnosed - 53.1%
6. Abstain - 2%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Pregnancy After Breast Cancer

183. For patients planning pregnancy in the 5 years following surgery, is it reasonable to discuss to interrupt endocrine therapy to allow attempted pregnancy:
At any time during endocrine therapy?

(1) Yes 38%
(2) No 52%
(3) Abstain 10%
Male Breast Cancer

187. In male patients with ER positive breast cancer, post-operative adjuvant Tamoxifen is currently advised. Adjuvant therapy options beyond Tamoxifen (if TAM is contraindicated in the adjuvant setting) include:

Aromatase inhibitors alone

(1) Yes 15.7%
(2) No 68.6%
(3) Abstain 15.7%
Male Breast Cancer

188. In male patients with ER positive breast cancer, post-operative adjuvant Tamoxifen is currently advised. Adjuvant therapy options beyond Tamoxifen (if TAM is contraindicated in the adjuvant setting) include:
Aromatase inhibitors + LHRH a

(1) Yes 55.3%
(2) No 23.4%
(3) Abstain 21.3%
Escalating and De-escalating

SHOULD WE EXPAND THE USE OF GENETIC TESTING IN BREAST CANCER PATIENTS?
High Risk Mutations

192. Genetic testing for high risk mutations should be considered, after counselling, in:
Patients with a strong family history

(1) Yes 96.2%
(2) No 1.9%
(3) Abstain 1.9%
High Risk Mutations

193. Genetic testing for high risk mutations should be considered, after counselling, in:
Patients under 40 at breast cancer diagnosis

(1) Yes 75%
(2) No 21.2%
(3) Abstain 3.8%
194. Genetic testing for high risk mutations should be considered, after counselling, in:
Patients under 50 at breast cancer diagnosis

(1) Yes  18.9%
(2) No  77.4%
(3) Abstain  3.8%
High Risk Mutations

195. Genetic testing for high risk mutations should be considered, after counselling, in:
Patients under 60 with TNBC only

(1) Yes 68.6%
(2) No 29.4%
(3) Abstain 2%
High Risk Mutations

196. BRCA 1 or 2 mutations may impact treatment decisions on Breast surgery

(1) Yes 88,5 %

(2) No 7,7 %

(3) Abstain 3,8 %
High Risk Mutations

197. BRCA 1 or 2 mutations may impact treatment decisions on Systemic therapies

(1) Yes 73.1%
(2) No 23.1%
(3) Abstain 3.8%
High Risk Mutations

198. BRCA 1 or 2 mutations may impact treatment decisions on
Other prophylactic interventions

(1) Yes 94.1%
(2) No 3.9%
(3) Abstain 2%
ESCALATING AND DE-ESCALATING

SHOULD BREAST CANCER PATIENTS RECEIVE SPECIFIC DIET AND LIFESTYLE INTERVENTIONS BEYOND ‘ORDINARY’ ADVICE ON MAINTAINING HEALTHY LIFESTYLES?

15th St.Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Diet and Exercise

199. Independent of any lifestyle recommendations that may be offered for rehabilitation, symptom control and/or general health, would you ALSO recommend the following with the goal of reducing risk of recurrence and/or death from breast cancer?

That patients should receive dietary advice in keeping with national guidelines?

(1) Yes 56%
(2) No 34%
(3) Abstain 10%

15th St. Gallen International Breast Cancer Conference 2017 Consensus
Adjuvant Diet and Exercise

200. Independent of any lifestyle recommendations that may be offered for rehabilitation, symptom control and/or general health, would you ALSO recommend the following with the goal of reducing risk of recurrence and/or death from breast cancer?

That physical activity (at least 150 minutes per week) be recommended as part of standard care?

(1) Yes 65,4 %
(2) No 30,8 %
(3) Abstain 3,8 %
Adjuvant Diet and Exercise

201. Independent of any lifestyle recommendations that may be offered for rehabilitation, symptom control and/or general health, would you ALSO recommend the following with the goal of reducing risk of recurrence and/or death from breast cancer?

That weight loss to a normal BMI (20-25) and avoidance of weight gain (providing BMI at least 20) be recommended?

(1) Yes 67.3%
(2) No 26.9%
(3) Abstain 5.8%

15th St.Gallen International Breast Cancer Conference 2017 Consensus
THANK YOU

Would you please *remain in your seats* for some minutes to allow the closing message of the conference.

15th St.Gallen International Breast Cancer Conference 2017 Consensus
174 B

1) Yes

2) No

3) Abstain

1 - 55.8%

2 - 36.5%

3 - 7.7%