台灣乳房醫學會
TAIWAN BREAST CANCER SOCIETY

2024 HER2-low Breast Cancer Consensus

主編 台灣乳房醫學會

Preface

乳癌是台灣女性中最常見的癌症之一，其發病率呈現逐年上升的趨勢。隨著乳癌治療領域的發展，對特定亞型乳癌的治療策略日益受到關注。本會於 2024 年 01 月 07 日舉辦「2024 HER2–low Breast Cancer Consensus」，匯聚眾多專家學者共同討論，並經台灣乳房醫學會第九屆理監事審議通過，我們完成了針對 HER2 弱陽性乳癌 (以下簡稱 HER2–low) 治療的共識手冊。

為了提供一份全面且系統化的臨床參考資料，以協助臨床醫師為 HER2–low 病人制定合適的治療方針。因此，在 2023 年 10 月學會邀請多位專家組成共識會議工作小組，並擬定在 HER2–low 臨床治療上的重要議題，本人衷心感謝工作小組的辛勤付出。

透過這份共識的制定和實施，我們期望能促進臨床實踐和研究的結合，推動乳癌治療領域的不斷創新和進步。同時，讓國內的臨床醫生能更準確地評估病人的治療風險和預後，從而制定出最適合的治療決策。

最後，我想對所有參與本次共識手冊編撰工作的專家學者和同仁們表達深深的感謝。正是由於您們的專業知識和支持，我們才得以完成這份重要的共識。期待能夠為台灣的乳癌治療帶來更大的福祉，為病人提供更多的希望與援助。

台灣乳房醫學會 理事長

陳守棟 于 2024 年 3 月

特別感謝以下專家提供寶貴建議（依姓氏筆畫排列、職稱省略概以醫師稱謂）

于承平、王明暘、李國鼎、沈士哲、沈陳石銘、周旭桓、林金瑤、俞志誠、施昇良、洪志杰、洪志強、洪朝明、洪進昇、張金堅、張振祥、張源清、張獻崑、張端瑩、張耀仁、許志怡、郭文宏、郭玟伶、陳守棟、陳芳銘、陳訓徹、陳達人、曾令民、馮安捷、黃其晟、黃俊升、黃柏翔、葉顯堂、廖國秀、趙大中、趙祖怡、劉良智、劉峻宇、歐陽賦、蔡宜芳、鄭翠芬、盧彥伸、蕭君平、賴峻毅、賴鴻文、戴明燊、鍾為邦、饒坤銘等諸位醫師。

Contents

Strength of the Recommendation and Quality of Evidence

Strength	Recommendation
A	Strong recommendation for use
B	Moderate recommendation for use
C	Marginal recommendation for use
D	Recommendation against use

Quality	Evidence
I	Evidence from at least 1 properly designed randomized, controlled trial
II	Evidence from at least 1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from > 1 center); from multiple time series; or from dramatic results of uncontrolled experiments
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive case studies

1. AGREE Next Steps Consortium. AGREE II: advancing guideline development, reporting and evaluation in health care. CMAJ 2012; 182: E839–E842
2. Grading quality of evidence and strength of recommendations in clinical practice guidelines part 3 of 3. The GRADE approach to developing recommendations. Allergy 2011; 66:8
3. Annals of Hematology (2018) 97:1271–1282

The Principle of Voting for Strength of Recommendation

Strength	Recommendation
A	Strong recommendation for use
B	Moderate recommendation for use
C	Marginal recommendation for use
D	Recommendation against use

For the “Strength of Recommendation A and B”, a majority panel vote of at least 85% is required.

For the “Strength of Recommendation C”, a panel vote of at least 50% (but less than 85%) is required.

For recommendations where there is strong panel disagreement regardless of the quality of the evidence, “Strength of Recommendation D” requires a panel vote of at least 25%.

1. NCCN giudelines. Development and Update of Guidelines.

Re-classification of breast cancer based on clinical trial results

—— 臺北榮民總醫院 / 趙大中 主任・成大醫院 / 鍾為邦 醫師

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
The HER2–low classification encompasses HER2 testing results that exhibit with IHC 1+ or IHC 2+/ISH– as determined by validated methods.	I	A	1
The HER2–low classification is specifically designated for but not limited to usage of the HER2–directed antibody–drug conjugate such as trastuzumab deruxtecan.*	I	A	2–7

* TROP2–directed antibody–drug conjugates are suitable for patients with metastatic breast cancer that are negative for HER2, under the specified circumstances.

The HER2–low classification now falls inside the specified criteria for the HER2–negative classification.

Reference

1. Wolff, A. C., Hammond, M. E. H., Allison, K. H., Harvey, B. E., Mangu, P. B., Bartlett, J. M., ... & Dowsett, M. (2018). Human epidermal growth factor receptor 2 testing in breast cancer: American Society of Clinical Oncology/College of American Pathologists clinical practice guideline focused update. Archives of pathology & laboratory medicine, 142(11), 1364–1382.
2. Mass, R. D., Press, M. F., Anderson, S., Cobleigh, M. A., Vogel, C. L., Dybdal, N., ... & Slamon, D. J. (2005). Evaluation of clinical outcomes according to HER2 detection by fluorescence in situ hybridization in women with metastatic breast cancer treated with trastuzumab. Clinical breast cancer, 6(3), 240–246.
3. Fehrenbacher, L., Cecchini, R. S., Geyer Jr, C. E., Rastogi, P., Costantino, J. P., Atkins, J. N., ... & Wolmark, N. (2020). NSABP B–47/NRG Oncology Phase III Randomized Trial Comparing Adjuvant Chemotherapy With or Without Trastuzumab in High–Risk Invasive Breast Cancer Negative for HER2 by FISH and With IHC 1+ or 2+. Journal of Clinical Oncology, 38(5), 444–453.
4. Burris, H. A., Rugo, H. S., Vukelja, S. J., Vogel, C. L., Borson, R. A., Limentani, S., ... & O'Shaughnessy, J. A. (2011). Phase II study of the antibody drug conjugate trastuzumab–DM1 for the treatment of human epidermal growth factor receptor 2 (HER2)—positive breast cancer after prior HER2–directed therapy. Journal of Clinical Oncology, 29(4), 398–405.
5. Krop, I. E., LoRusso, P., Miller, K. D., Modi, S., Yardley, D., Rodriguez, G., ... & Rugo, H. S. (2012). A phase II study of trastuzumab emtansine in patients with human epidermal growth factor receptor 2—positive metastatic breast cancer who were previously treated with trastuzumab, lapatinib, an anthracycline, a taxane, and capecitabine. Journal of clinical oncology, 30(26), 3234–3241.
6. Modi, S., Park, H., Murthy, R. K., Iwata, H., Tamura, K., Tsurutani, J., ... & Takahashi, S. (2020). Antitumor activity and safety of trastuzumab deruxtecan in patients with HER2–low—expressing advanced breast cancer: Results from a phase Ib study. Journal of Clinical Oncology, 38(17), 1887–1896.
7. Modi, S., Jacot, W., Yamashita, T., Sohn, J., Vidal, M., Tokunaga, E., ... & Cameron, D. A. (2022). Trastuzumab deruxtecan in previously treated HER2–low advanced breast cancer. New England Journal of Medicine, 387(1), 9–20.

How to identify HER2-low breast cancer consistently and reproducibly

—— 臺北榮民總醫院 / 許志怡 主任・三軍總醫院 / 于承平 主任

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
Follow 2023 ASCO/CAP guidelines to control pre-analytic factors, validate staining, follow scoring criteria, and report with HER2 IHC scores (3+ / 2+ / 1+ / 0).	II	A	1–2
Due to notable inter-assay variabilities in the HER2 test, one may consider using the 4B5 kit with its validated staining protocol as a companion test.*	II	B	3–4
HER2-low status may be heterogeneous and subject to dynamic changes. Recommend re-biopsy in case of recurrence or metastasis.	II	B	5–6

* The suggested 4B5 kit with standard protocol was employed in the DB-04 trial; nevertheless, other validated assays are also acceptable for assessing HER2 status.

Reference

1. Human epidermal growth factor receptor 2 testing in breast cancer: ASCO–College of American Pathologists guideline update. J Clin Oncol. 2023;41(22):3867–72.
2. Standardized pathology report for HER2 testing in compliance with 2023 ASCO/CAP updates and 2023 ESMO consensus statements on HER2–low breast cancer. Virchows Arch. 2023 Sep 28. doi: 10.1007/s00428–023–03656–w.
3. Trastuzumab Deruxtecan in previously treated HER2–low advanced breast cancer. N Engl J Med. 2022;387(1):9–20.
4. Comparison of HercepTest ™ mAb pharmDx (Dako Omnis, GE001) with Ventana PATHWAY anti–HER–2/neu (4B5) in breast cancer. Virchows Arch. 2022;481:685—94.
5. Intra–patient and inter–metastasis heterogeneity of HER2–low status in metastatic breast cancer. Eur J Cancer 2023;188:152—60.
6. Evolution of low HER2 expression between early and advanced–stage breast cancer. Eur J Cancer. 2022;163:35–43.

Comparison of transcriptomic profiles between HER2-low and HER2-zero BC

—— 長庚醫院 / 郭玟伶 主任・臺大醫院 / 黃柏翔 醫師

Comparison of mutational landscapes between HER2-low and HER2-zero BC

—— 臺大醫院 / 張端瑩 醫師・臺北榮民總醫院 / 蔡宜芳 醫師

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
According to currently available genomic and transcriptomic studies, HER2–low breast cancer is not considered as a biologically distinct entity.	II	B	1–6

Reference

1. Dai LJ, et al. Molecular features and clinical implications of the heterogeneity in Chinese patients with HER2–low breast cancer. Nat Commun. 2023;14:5112.
2. Berrino E, et al. Integrative genomic and transcriptomic analyses illuminate the ontology of HER2–low breast carcinomas. Genome Med. 2022;14:98.
3. Atallah NM, et al. Characterisation of luminal and triple–negative breast cancer with HER2 Low protein expression. Eur J Cancer. 2023;195:113371.
4. Jin J, et al. Analysis of clinical features, genomic landscapes and survival outcomes in HER2–low breast cancer. J Transl Med 2023;21:360.
5. Tarantino P, et al. Comprehensive genomic characterization of HER2–low and HER2–0 breast cancer. Nat Commun 2023;14:7496.
6. Marra A, et al. Genomic characterization of primary and metastatic HER2–low breast cancers. San Antonio Breast Cancer Symposium 2022 Abstract HER2–07.

Clinical presentations and prognostication of HER2-low BC from RWD

—— 長庚醫院 / 周旭桓 醫師・高醫附醫 / 蕭君平 醫師

- About 50% of all breast cancers are HER2-low disease. The percentage of HER2-low cases in HER2 non-amplification disease was higher in hormone receptor-positive breast cancer (around 60%-65%) compared to hormone receptor-negative breast cancer (around 35%-40%)[1-3].

- In pooled analysis, there was a trend of higher pathological complete response (pCR) rate in HER2-zero disease (around 22%-24%) versus HER2-low disease (around 15%-18%). The difference of pCR rate was mainly attributed to hormone receptor status[3-6].

- In current real-world data with or without novel agents, it is still difficult to compare survival benefit in HER2-zero disease versus HER2-low disease directly even though there was slightly improved overall survival rate in HER2-low breast cancer compared to HER2-zero population regardless of hormone receptor expression in meta-analysis, but high heterogenicity in different setting of real-world clinical data was observed[3-7].

Reference

1. Francesco Schettini, Nuria Chic, Fara Brasó-Maristany, et al. Clinicopathologic Characteristics and Prognosis of ERBB2-Low Breast Cancer Among Patients in the National Cancer Database. Npj Breast Cancer 2021; 7(1):1. doi: 10.1038/s41523-020-00208-2.
2. Paolo Tarantino, Erika Hamilton, Sara M Tolaney, Javier Cortes, Stefania Morganti, Emanuela Ferraro, Antonio Marra, Giulia Viale, Dario Trapani, Fatima Cardoso, Frédérique Penault-Llorca, Giuseppe Viale, Fabrice Andrè, Giuseppe Curigliano. HER2-Low Breast Cancer: Pathological and Clinical Landscape. J Clin Oncol. 2020 Jun 10;38(17):1951-1962. doi: 10.1200/JCO.19.02488.
3. Daniel S. Peiffer, Fangyuan Zhao, Nan Chen, et al. Prognostic value of HER2-low status in breast cancer: a systematic review and meta-analysis. ESMO OPEN 2023.
4. Paolo Tarantino, Qingchun Jin, Nabihah Tayob, et al. Prognostic and Biologic Significance of ERBB2-Low Expression in Early-Stage Breast Cancer. JAMA Oncol 2022.
5. Carsten Denkert, Fenja Seither, Andreas Schneeweiss, et al. Clinical and molecular characteristics of HER2-low-positive breast cancer: pooled analysis of individual patient data from four prospective, neoadjuvant clinical trials. Lancet oncol 2021.
6. Petrelli F, Rea C, Parati MC, Borgonovo K, et al. Prognostic Value of HER2-low Status in ER+ Early Breast Cancer: A Systematic Review and Meta-Analysis. Anticancer Res. 2023 Oct;43(10):4303-4313.
7. Ergun Y, Ucar G, Akagunduz B: Comparison of HER2-zero and HER2-low in terms of clinicopathological factors and survival in early-stage breast cancer: A systematic review and metaanalysis. Cancer Treat Rev 115: 102538, 2023. DOI:10.1016/j.ctrv.2023.102538.

Biomarkers for HER2-low BC

—— 成大醫院 / 李國鼎 主任・台中慈濟醫院 / 林金瑤 主任

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
HER2–low expression is currently the only biomarker capable of predicting the therapeutic efficacy of Trastuzumab Deruxtecan (T–DXd) in patients with HER2–low metastatic breast cancer.	I	A	1–2

Reference

1. Modi S, Jacot W, Yamashita T, et al. Trastuzumab deruxtecan in previously treated HER2– low advanced breast cancer. N Engl J Med 2022;387:9—20.
2. Modi S, Niikura N, Yamashita T, et al. Trastuzumab deruxtecan (T–DXd) vs treatment of physician's choice (TPC) in patients (pts) with HER2–low, hormone receptor–positive (HR+) unresectable and/or metastatic breast cancer (mBC): Exploratory biomarker analysis of DESTINY–Breast04. JCO.2023.41.16_suppl.1020.

Anti-TROP2 ADC in HER2-low BC

—— 臺大醫院 / 王明暘 醫師・三軍總醫院 / 馮安捷 醫師

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
Anti-TROP2 ADC may be used as later line of treatment for patients with HR-negative, HER2-low (IHC 1+ or 2+/ ISH negative) recurrent unresectable or metastatic disease, received at least 2 prior therapies.	I	A	1-3
Anti-TROP2 ADC may be used as later line of treatment for patients with HR-positive, HER2-low (IHC 1+ or 2+/ ISH negative) metastatic/locally advanced unresectable breast cancer after prior systemic treatment including endocrine therapy, a CDK4/6 inhibitor and at least 2 lines of chemotherapy.	I	A	4-5

* The endorsement of Anti-TROP2 ADC for treating HER2-low diseases is not grounded in clinical trials specifically designed to elucidate the efficacy of the anti-TROP2 ADC in various HER2 positivity scenarios.

Reference

1. Carey LA, Loirat D, Punie K, Bardia A, Diéras V, Dalenc F, Diamond JR, Fontaine C, Wang G, Rugo HS, Hurvitz SA, Kalinsky K, O'Shaughnessy J, Loibl S, Gianni L, Piccart M, Zhu Y, Delaney R, Phan S, Cortés J. Sacituzumab govitecan as second-line treatment for metastatic triple-negative breast cancer-phase 3 ASCENT study subanalysis. NPJ Breast Cancer. 2022 Jun 9;8(1):72. doi: 10.1038/s41523-022-00439-5. PMID: 35680967; PMCID: PMC9184615.
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3. Aditya Bardia, Sara M. Tolaney, Delphine Loirat, Kevin Punie, Mafalda Oliveira, Hope S. Rugo, Adam Brufsky, Kevin Kalinsky, Javier Cortes, Joyce O'Shaughnessy, Veronique C Dieras, Lisa A. Carey, Luca Gianni, Martine J. Piccart-Gebhart, Sibylle Loibl, Yanni Zhu, See-Chun Phan, and Sara A. Hurvitz. Sacituzumab govitecan (SG) versus treatment of physician's choice (TPC) in patients (pts) with previously treated, metastatic triple-negative breast cancer (mTNBC): Final results from the phase 3 ASCENT study. Journal of Clinical Oncology 2022 40:16_suppl, 1071.
4. Rugo HS, Bardia A, Tolaney SM, Arteaga C, Cortes J, Sohn J, Marmé F, Hong Q, Delaney RJ, Hafeez A, André F, Schmid P. TROPiCS-02: A Phase III study investigating sacituzumab govitecan in the treatment of HR+/HER2- metastatic breast cancer. Future Oncol. 2020 Apr;16(12):705-715. doi: 10.2217/fon-2020-0163. Epub 2020 Mar 30. PMID: 32223649.
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Treatment sequence of novel ADCs for HER2-low BC for initial HR+ BC

—— 中國附醫 / 劉良智 教授・臺北榮民總醫院 / 賴峻毅 醫師

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
In HER2–low, HR+ metastatic breast cancer, current evidence support the use of Trastuzumab Deruxtecan (T–DXd) for patients who have progressed upon ≥ 1 lines of chemotherapy in the metastatic setting.	I	A	1
In HER2–low, HR+ metastatic breast cancer, current evidence support the use of Sacituzumab Govitecan (SG) for patients who have progressed upon ≥ 2 lines of chemotherapy in the metastatic setting.	I	A	2
There is currently insufficient evidence to support using an antibody drug conjugate (ADC) after progression on prior ADC in HER2–low, HR+ metastatic breast cancer.	II	B	3
There is currently no evidence to support using an antibody drug conjugate (ADC) in chemotherapy naïve setting in HER2–low, HR+ metastatic breast cancer.	III	A	1
Both ADCs (T–DXd and SG) proved activity in patients with metastatic HER2–low, HR+ BC. T–DXd could be considered before SG as the first ADC in this setting.	II	B	4

* HER2 low: defined as HER2 IHC 1+ or 2+ and HER2–FISH negative

Reference

1. Modi S, Jacot W, Yamashita T, Sohn J, Vidal M, Tokunaga E, et al. Trastuzumab Deruxtecan in Previously Treated HER2–Low Advanced Breast Cancer. The New England journal of medicine. 2022;387(1):9–20.
2. Rugo HS, Bardia A, Marme F, Cortes J, Schmid P, Loirat D, et al. Overall survival with sacituzumab govitecan in hormone receptor–positive and human epidermal growth factor receptor 2–negative metastatic breast cancer (TROPiCS–02): a randomised, open–label, multicentre, phase 3 trial. Lancet. 2023;402(10411):1423–33.
3. Rachel Occhiogrosso Abelman LS, Geoffrey G. Fell, Phoebe Ryan, Neelima Vidula, Arielle J Medford, Jennifer Shin, Elizabeth Abraham, Seth Andrew Wander, Steven J. Isakoff, Beverly Moy, Leif W. Ellisen, Aditya Bardia. Sequential use of antibody–drug conjugate after antibody–drug conjugate for patients with metastatic breast cancer: ADC after ADC (A3) study. ASCO2023.
4. ESMO Metastatic Breast Cancer Living Guidelines, v1.1 May 2023. Ann Oncol 2021;32(12): 1475–1495.

Treatment sequence of novel ADCs for HER2-low BC for initial TNBC

—— 馬偕醫院 / 張源清 主任・三軍總醫院 / 廖國秀 主任

Consensus Statement	Quality of Evidence	Strength of Recommendation	Key Reference
In HER2–low, HR– metastatic breast cancer, current evidence support the use of Sacituzumab Govitecan (SG) for patients who have progressed after receiving ≥ 2 prior therapies (with at least 1 line in the metastatic setting).	I	A	1
In HER2–low, HR– metastatic breast cancer, current evidence support the use of Trastuzumab Deruxtecan (T–DXd) for patients who have progressed upon ≥ 1 lines of chemotherapy in the metastatic setting.	I	A	2
There is currently insufficient evidence to support using an antibody drug conjugate (ADC) after progression on prior ADC in HER2–low, HR– metastatic breast cancer.	II	B	3
Both ADCs (T–DXd and SG) proved activity in patients with metastatic HER2–low, HR– BC. SG could be considered before T–DXd as the first ADC in this setting.	II	B	4

* HER2–low: defined as HER2 IHC 1+ or 2+ and HER2–FISH negative

Reference

1. Bardia A, Hurvitz SA, Tolaney SM, Loirat D, Punie K, Oliveira M, Brufsky A, Sardesai SD, Kalinsky K, Zelnak AB, Weaver R, Traina T, Dalenc F, Aftimos P, Lynce F, Diab S, Cortés J, O'Shaughnessy J, Diéras V, Ferrario C, Schmid P, Carey LA, Gianni L, Piccart MJ, Loibl S, Goldenberg DM, Hong Q, Olivo MS, Itri LM, Rugo HS; ASCENT Clinical Trial Investigators. Sacituzumab Govitecan in Metastatic Triple–Negative Breast Cancer. N Engl J Med. 2021 Apr 22;384(16):1529–1541.
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4. ESMO Metastatic Breast Cancer Living Guidelines, v1.1 May 2023. Ann Oncol 2021;32(12): 1475–1495.

Note

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