Tips and Talking Points for Healthcare Providers

COMET
A Study for Low-Risk DCIS
Expanding Knowledge & Options

TIP 1: DCIS is not an emergency.

- → DCIS is not the same as invasive breast cancer. It does not spread to other parts of the body and therefore is generally not life-threatening.
- → There is no medical reason for patients to feel rushed. Patients have time to make decisions.
- → Some fear is natural, but DCIS can be managed safely and with excellent long-term results.

TIP 2: Not all DCIS is the same.

- → There are three grades of DCIS — low, intermediate, and high.
- → Some investigators consider low or intermediate grade, and estrogen receptor (ER) positive DCIS to be "low-risk,"[1] with the lowest chance of recurrence.[2]

TIP 3: Most DCIS carries a very low risk for breast cancer, and some risk factors are known.

- → Death from breast cancer is rare after a diagnosis of DCIS.[3]
- → About 80% of women treated for DCIS will not have a future DCIS or invasive breast cancer.[4]
- → Less than 10% of women treated for DCIS get invasive breast cancer in the long term.[5]
- → Risk factors include: under 35 years of age; African-American; high-grade; positive margins; palpable lump.[5]

TIP 4: Aggressive Treatment for low-risk DCIS is now being questioned and studied.

- → Currently, women with any grade of DCIS are treated with the same surgery and radiation as if they had invasive breast cancer.
- → Treatment for DCIS does not appear to improve overall survival or to substantially lower the risk of breast cancer-specific mortality.[6]

TIP 5: Randomized clinical trials are designed to compare treatments.

- → There are three large randomized clinical trials for women with low-risk DCIS.
- → The COMET study is in the United States. Two others, called LORIS & LORD, are in Europe.
- → The COMET study will randomize 900 women diagnosed with low-risk DCIS to one of two groups:
  1. The **Active Surveillance** group is monitored with 6-month mammograms and physical exam.
  2. The **Surgery** group is treated by surgery (with or without radiation) and annual mammogram.
- → Women in either group can choose to have endocrine therapy.
- → If there is evidence of disease progression or recurrence in follow-up, procedures are in place to safely manage the patient.
- → Women must agree to be randomized to participate in the study. If, after randomization, the patient declines the group they are randomized to, they will be asked whether they still agree to be followed and complete the scheduled surveys.

Thank you for helping us to try and improve future treatment options for women with DCIS.

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TIP 6: Why should your patient consider joining the COMET Study?

- → Waiting to remove DCIS upon progression (if that ever occurs), may have the same survival benefit as immediate surgery.
- → Active Surveillance is not yet standard of care: the COMET study may help determine its role.
- → Women in the Surgery group are treated according to standard of care.
- → Women in the Active Surveillance group may be spared the physical and emotional side effects, and personal and financial burdens that can occur with surgery and radiation.
- → Women in the COMET study will make an invaluable contribution to the understanding of DCIS and its management for those who are diagnosed with low-risk DCIS in the future.

TIP 7: If your patient enrolls in the COMET study, they will be:

- → asked to complete surveys at baseline, 6 months, and then every year for 5 years.
- → closely monitored during the 5 years of the study, and if diagnosed with invasive cancer, will receive appropriate treatment for their diagnosis.
- → able to drop out of the study at any time for any reason.

TIP 8: The COMET Study brochure and website (www.dcisoptions.org) may be a helpful resource for you and your patients.

- → Please encourage your patients to check out the COMET study brochure and associated website, which includes supportive resources, information and videos on various topics for women with all types of DCIS, and includes further information on the COMET Study.

[1] Maxwell AJ, Clements K, Hilton B, Dodwell DJ, Evans A, Kearins O, Pinder SE, Thomas J, Wallis MG, Thompson AM, Sloane Project Steering Group. Risk factors for the development of invasive cancer in unresected ductal carcinoma in situ. *Eur J Surg Oncol* 2018. Apr;44(4):429-435.

[2] Grimm LJ, Ryser MD, Partridge AH, Thompson AM, Thomas JS, Wesseling J, Hwang ES. Surgical Upstaging Rates for Vacuum Assisted Biopsy Proven DCIS: Implications for Active Surveillance Trials. *Ann Surg Oncol.* 2017 Nov;24(12):3534-3540. doi: 10.1245/s10434-017-6018-9. Epub 2017 Aug 9.

[3] Worni M, Akushevich I, Greenup R, Sarma D, Ryser MD, Myers ER, Hwang ES. Trends in Treatment Patterns and Outcomes for Ductal Carcinoma In Situ. *J Natl Cancer Inst.* 2015 Sep 30;107(12):djv263. doi: 10.1093/jnci/djv263. Print 2015 Dec.

[4] Sagara Y, Mallory MA, Wong S, Aydogan F, DeSantis S, Barry WT, Golshan M. Survival Benefit of Breast Surgery for Low-Grade Ductal Carcinoma In Situ: A Population-Based Cohort Study. *JAMA Surg.* 2015 Aug;150(8):739-45. doi: 10.1001/jamasurg.2015.0876.

[5] Rudloff U, Jacks LM, Goldberg JI, Wynveen CA, Brogi E, Patil S, Van Zee KJ. Nomogram for predicting the risk of local recurrence after breast-conserving surgery for ductal carcinoma in situ. *J Clin Oncol.* 2010 Aug 10;28(23):3762-9. doi: 10.1200/JCO.2009.26.8847.

[6] Narod SA, Iqbal J, Giannakeas V, Sopik V, Sun P. Breast Cancer Mortality After a Diagnosis of Ductal Carcinoma In Situ. *JAMA Oncol.* 2015 Oct;1(7):888-96. doi: 10.1001/jamaoncol.2015.2510.

A more comprehensive set of references is available at www.dcisoptions.org/resources/researchers

Please share these* Tips and Talking Points *with referring primary care physicians, radiologists, surgeons, pathologists, oncologists, and other healthcare providers.